REVIEW #1

Title: Vaginal Hysterectomy for Enlarged Uteri, With or Without Laparoscopic Assistance: Randomized Study

Authors: E. Daraï, D. Soriano, P. Kimata, C. Laplace, F. Lecuru

Site: Paris, France

Published : Obstet. Gynecol. 2001; 97: 712-6

Objective: To evaluate the feasibility and complication rate of vaginal hysterectomy in women with enlarged uteri and other traditional contraindications of vaginal hysterectomy, and to compare short-term results for vaginal hysterectomy and LAVH.

Methods: 80 women undergoing hysterectomy for benign disease were randomized to either vaginal hysterectomy or LAVH Type IV (laparoscopic division of uterine vessels and uterosacral ligaments). Inclusion criteria were: uterine size > 280g (12 weeks) and one or more of the following traditional contraindications to vaginal surgery: previous pelvic surgery, history of P.I.D., moderate or severe endometriosis, concomitant adnexal masses, or indication for adnexectomy. LAVH was performed using bipolar cautery. Exclusion criteria were: anesthesia contraindications for laparoscopic surgery, suspicious adnexal masses, vagina narrower than two fingers wide or uterus with no descent or lateral mobility.

Results: There were no significant differences between groups in age, parity, weight, previous pelvic surgery or indications for surgery. The most common indications were myoma and abnormal bleeding. Uteri ranged in size from 280 to 1560 g, averaging 424 g in the VH group and 513 g in the LAVH group; this was not significantly different; vaginal morcellation of uteri was done in all women in both groups. Indicated adnexectomy was successful in all women in both groups (21/40 in the VH and 15/40 in the LAVH). Average operating time was 108 min in the VH group compared to 160 min in the LAVH group; this was highly significant. Conversion to laparotomy was required in three of 40 women in the LAVH group, compared with none in the VH group. Bladder injury occurred in one woman in the LAVH group and was repaired laparoscopically. Overall, there were significantly more minor and major complications in the LAVH group (16/40 vs. 6/40).

Conclusions: Vaginal hysterectomy can be successful in most women with enlarged uteri who have traditional relative contraindications to vaginal hysterectomy. Laparoscopic assistance increases both operating time and complication rates. There is no doubt that the vaginal route is preferable if possible.

Commentary: In an ideal world, all gynecologists would be able to perform any type of hysterectomy with equal facility, and would choose the route most appropriate for a specific patient. The wide variation in published vaginal hysterectomy rates suggests that the choice of operation for benign disease is determined mainly by surgeon preference. The latter, in turn, reflects the operator's training and experience. While the virtuosos of the laparoscopic and vaginal routes compete to report the largest uterus removed without laparotomy, the average gynecologist eschews gymnastics and sticks to what (s)he knows best—abdominal hysterectomy.

Despite the small sample size, this paper lends further support to the proposition that hysterectomy for benign disease can be performed safely and quickly by the vaginal route. This is

hardly novel. Before 1900, gynecologists routinely removed large fibroid uteri through the vagina, and were in agreement that this was much safer than laparotomy. Improvements in asepsis and anesthesia led surgeons –especially in the USA-- into the abdomen, where they expanded the scope of their work to include non-gynecologic indications, and largely abandoned the vaginal approach. By 1928, Howard Kelly could state that *vaginal hysterectomy, at one time in great vogue both for cancer of the cervix and for fibroid tumors of any and all sizes, is but exceptionally resorted to in these latter years.* [1]

Heaney, of Chicago, revived vaginal hysterectomy for benign disease in the U.S.A. In 1940, having reported an ever-expanding series, he wrote: *Since the vaginal approach to pelvic disease is associated with less mortality, a smaller morbidity rate and a much more rapid convalescence, it is high time that present day gynecologists learned to appreciate the value of vaginal hysterectomy, acquire its technique, and extended its use*.[2] His views attracted a small but zealous group of disciples, especially in the Midwest; however, the major Gynecology textbooks in the USA---- descended from Kelly and his successors at Johns Hopkins --- continued to emphasize the contra-indications to vaginal hysterectomy. As a result, most hysterectomies in the U.S.A. are still performed abdominally.

The development of operative laparoscopy encouraged the notion that many abdominal hysterectomies could be converted to the vaginal route, thereby reducing length-of-stay and convalescence. Spurred-on by equipment manufacturers and the opportunity to make their mark in a new field, the more adventurous surgeons soon began performing virtually every gynecologic procedure using minimally invasive techniques. The surgically-timid struggled with a steep learning curve, discovering that laparoscopic assistance did little to facilitate the vaginal part of the operation unless most of it was done from above. This, however, required greater skill, more time, and was associated with more complications.

Vaginal hysterectomy is easier to master than LAVH, and is much quicker to perform. It uses familiar instruments and suturing techniques. Traditional cane stirrups offer better exposure, especially for the assistants, than any laparoscopic stirrup. The equipment never breaks down, never becomes obsolete, and the circulating nurse rarely has to leave the room. Since success breeds confidence, it is best to start with small, mobile uteri in multipara with a gynecoid pelvis—typically women with refractory dysfunctional bleeding and/or small fibroids. Having mastered the art of incising the vagina at the correct level and depth to enter the vesico-uterine and recto-vaginal spaces elegantly, the surgeon will soon feel comfortable removing larger uteri. Once the peritoneum has been entered anteriorly and posteriorly, and the uterine vessels ligated, the uterus can be bivalved or morcellated with surprisingly little bleeding.

Kovac, from Ohio, wrote in 1998: *The evidence-based data…strongly suggests that 80% of hysterectomies currently performed can be completed vaginally, taking full advantage of the medical and surgical benefits of this surgical route.*[3]

1. Kelly, H.A. In: GYNECOLOGY. D. Appleton and Company, 1928:444
2. Heaney, N.S. Vaginal Hysterectomy – Its Indications and Technique. Am. J. Surg.1940;40:284
3. Kovac, S.R. Guidelines to Determine the Role of Laparoscopically Assisted Vaginal Hysterectomy. Am. J. Obst. Gyn. 1998;178: 1262

REVIEW #2

Title: Low-Dosage Esterified Estrogens Opposed by Progestin at 6-Month Intervals

Authors: B. Ettinger, A. Pressman, A. Van Gessel

Site: Oakland, California

Published: Obstet. Gynecol. 2001;98:205-211

Objective: To estimate the incidence of endometrial hyperplasia, vaginal bleeding, and menopausal symptoms in women who changed from standard monthly cyclic hormone replacement therapy (HRT) to half-strength estrogen opposed by medroxyprogesterone acetate (MPA) at 6-month intervals.

Methods: 138 women aged 55-75 who had regularly used cyclic HRT (0.625 mg/day conjugated estrogen with monthly MPA 5-10 mg) and no hyperplasia on endometrial biopsy were switched to 0.3 mg/day conjugated estrogen with 14-day courses of MPA, 10 mg/day, every 6 months. Endometrial biopsy was repeated after 1 year. Patients kept a daily diary of vaginal bleeding, using a 5-point scale. Menopausal symptoms were evaluated at baseline, 3, 6, and 12 months, using the Greene Menopausal Symptom Index.

Results: 13 women withdrew from the study, mostly because of increased menopausal symptoms. Of the 125 women who completed the 1-year trial, 2 developed endometrial hyperplasia –neither with atypia. 38.4% of the women had atrophic endometrium on the lower estrogen regimen, compared with 5.0% prior to the study. Whereas nearly all women reported withdrawal bleeding on the standard HRT regimen, 44% had no bleeding following MPA at either 6 month or 12 months. The overall incidence of unscheduled bleeding was 9.4% during the trial, but no prior data was available for comparison. On average, the vasomotor, somatic, and psychologic domains of the Greene Menopause Symptom Index were low at baseline, and remained low throughout the study. However, 15-20% of women reported a worsening of vasomotor symptoms. In contrast, the authors observed statistically significant improvements in somatic and psychologic scores at each assessment time points during the study.

Conclusions: Most women over 55 can switch from standard dosage, cyclic monthly HRT to low-dosage, long-cycle HRT without compromising safety or control of menopausal symptoms.

Commentary: While there may be considerable debate about the role of HRT in the prevention of coronary artery or Alzheimer's disease, there is no doubt that standard dose estrogen (equivalent to 0.625 mg/d conjugated estrogen) reduces bone loss and relieves vasomotor and atrophic symptoms.

Despite the favorable benefit/risk ratio of HRT compared to many widely-prescribed medications for hypertension and hyperlipidemia, doctors know that HRT is a "hard sell" in the U.S.A.. In this country, "hormone" conjures up a host of negative associations ---from Olympic doping scandals to blood clots and cancers of the breast or uterus. It does not help that the best-known estrogen is extracted from pregnant mare's urine. These perceptions, and the frequent nuisance side-effects, lead to poor compliance except in women with troublesome hot-flashes.

The authors of this study neatly bypassed the compliance issue by recruiting only women who were already using a cyclic HRT regimen. In this cohort, a lower dose of estrogen with semi-annual MPA controlled most menopausal symptoms without increasing the risk of endometrial

hyperplasia. The incidence of unscheduled bleeding was 9.4% ---about a third of that associated with combined E/P regimens.

A generation ago, case-control studies first revealed an association between estrogen supplementation and endometrial cancer. While the oncogenic potential of estrogen has never been demonstrated in prospective trials, the causal relationship between estrogen use and endometrial hyperplasia has been repeatedly documented. The latter is believed to be a precursor of endometrial cancer, but it is uncertain just how often simple hyperplasia progresses to cancer; nor is it known how long it takes, nor which women are at increased risk in this context. This reviewer is aware of several women who have taken unopposed conjugated estrogens for 20-30 years without developing either abnormal bleeding, hyperplasia, or endometrial cancer. Fortunately, the addition of a progesterone analog ---either cyclically or continuously--- prevents the development of endometrial hyperplasia, and can reverse it in many cases.

However, the authors comment, "*Using less progestin is a worthwhile goal. Progestin use may cause troublesome, premenstrual-like symptoms, doubles the incidence of breast tenderness, lowers HDL, increases mammographic density, and appears to increase the risk of breast cancer. The regimen…used in our study exposes a woman to 280 mg of MPA annually ---much less than the 913 mg required when using 2.5 mg daily.*"

It is sensible to use the lowest dose of medication that will achieve therapeutic goals. Treatment should always be individualized. This low-dose regimen will appeal to women with vasomotor symptoms and significant progestin side-effects. In the absence of data documenting fracture reduction or other non-gynecological benefits, low-dose (equivalent to 0.3 mg/day conjugated estrogen) HRT cannot be recommended to asymptomatic post-menopausal women.

REVIEW #3

Title: Recurrence of Dysplasia after Loop Electrosurgical Excision Procedure with long-term follow-up

Authors: D.I. Gonzalez, C.M. Zahn, M.G. Retzloff, W.F. Moore, E.R. Kost, R.S. Snyder

Site: San Antonio, Texas

Published: Am. J. Obstet. Gynecol. 2001; 184:315-21

Objective: To evaluate recurrence of dysplasia after LEEP in women with biopsy-confirmed dysplasia and to determine whether margin status was associated with recurrence.

Methods: A retrospective chart review of 199 women who had LEEP between January 1993 and December 1994. Fifteen were excluded because of inadequate follow-up, significant glandular atypia, or uninterpretable margins. All procedures were performed under local anesthesia; hemostasis was achieved with epinephrine, cautery and Monsel solution or silver nitrate. All women were examined at 4-6 weeks; follow-up visits at 4-6 month intervals included a PAP smear, colposcopy/biopsy as indicated. After one year without abnormality, patients were sent back to their primary care providers for yearly PAP smears. Cases of residual or recurrent abnormality were treated with repeated LEEP, laser ablation, or cold-knife cone biopsy as indicated.

Results: The mean duration of follow-up for all women (average age 28) was 24 months. Margins were positive in 28%, with 73% of these being endocervical. The overall recurrent dysplasia rate was 31%, with a mean time to recurrence of 11.9 months. The presence of positive margins was associated with a higher recurrence rate (47% vs 26%, P<.009) of dysplasia; this was highest with high-grade lesions (56%). With negative margins, the recurrence rate was independent of the histologic diagnosis of the LEEP specimen.

Conclusions: The recurrence rate of dysplasia following LEEP is considerable, even with negative margins. Patients should be counseled about this risk, and the importance of follow-up emphasized.

Commentary: This study documents the high recurrence rate of dysplasia following LEEP. Similar failure rates have been observed following all treatment modalities: cryotherapy, LASER ablation, LASER conization, and cold-knife conization.

This should come as no surprise, given the relationship between Human Papilloma Virus (HPV) and dysplasia. No known therapy will eliminate these viruses from the body.

Regular follow-up of women with dysplasia is prudent, but the clinician must guard against over-zealous treatment of low-grade lesions, especially in young nullipara. The ease with which LEEP can be performed in the office setting has encouraged its use for all types of cervical abnormality. In this study, 56% of LEEP procedures were done for CIN1 and CIN2; the average age was 28, 42% were nulliparous, and the average time-to-recurrence was only 11.9 months. It is surely not appropriate to repeat a LEEP every year; this can remove a large part of the vaginal cervix, making subsequent screening more difficult, and possibly interfering with fertility or cervical competence.

HPV-DNA typing may help guide the choice of therapy. Suitable indications for LEEP would include: CIN3 with high-grade HPV; inadequate colposcopy in a patient with HGSIL cytology and high-grade HPV.

In the absence of high-grade HPV, progression of CIN1 and CIN2 to malignancy is very improbable. Regression of low-grade lesions has been observed in many untreated patients lost to follow-up for several years after such diagnosis. In reliable patients, semi-annual follow-up without treatment may be adequate. This would give gynecologists a chance to observe the natural history of such lesions with minimal risk to the patient.

If treatment is judged necessary, any technique that destroys the cervical epithelium probably works just as well. Although currently unfashionable, cryotherapy is easy, inexpensive, and destroys less cervix than LEEP. Cryotherapy is definitely much better than LEEP or LASER for the large, multiparous cervix with extensive cervicitis. Anecdotally, 5-fluorouracil cream or topical application of trichloroacetic acid have been used to treat low-grade lesions successfully.

In the woman who has completed her family, the persistence of dysplasia is an appropriate indication for vaginal hysterectomy. This will definitely prevent cancer of the cervix. The presence of high-grade HPV may predispose to future vaginal or vulvar malignancy, but these are very rare.

REVIEW #4

Title: Preoperative assessment of unilocular adnexal cysts by transvaginal ultrasonography: A comparison between ultrasonographic morphologic imaging and histopathologic diagnosis.

Authors: E. Ekerhovd, H. Wienerroith, A. Staudach, S. Granberg

Site: Göteborg, Sweden and Salzburg, Austria

Published: Am. J. Obstet. Gynecol. 2001; 184:48-54

Objective: To evaluate the risk of malignancy in surgically removed ovarian cysts that were characterized as unilocular according to transvaginal ultrasonography.

Methods: This prospective analysis included 927 premenopausal and 377 postmenopausal women operated at two European hospitals between January 1992 and December 1997. On the basis of ultrasonographic findings, the cysts were classified either as echo-free (Group 1) or as having solid parts or papillary formations (Group 2). The U.S. and macroscopic appearances of the cysts were compared with histopathologic diagnosis.

Results: In Group 1, 3 of 413 cysts in premenopausal women (0.73%) proved to be borderline or malignant, and in postmenopausal women, 4 of 247 cysts (1.6%) were borderline or malignant; all measured > 75 mm in diameter. Comparative figures in Group 2 were 11 of 514 (2.1%) and 13 of 130 (10.0%); when papillary formations were present, the smallest borderline tumor measured 26 mm, the smallest malignant tumor 45 mm. It was not possible to differentiate by U.S. between benign, borderline, and malignant cysts when solid parts or papillary formations were visualized.

Conclusions: The risk of malignancy associated with unilocular echo-free cysts was low. Serial ultrasonographic follow-up should be the standard procedure with unilocular cysts < 50mm. In cysts with a mean diameter > 50 mm, papillary formations or solid parts may be missed by transvaginal ultrasonography.

Commentary: This study provides re-assurance that small unilocular, echo-free, cysts are unlikely to be malignant, even in post-menopausal women. This is good news, because several articles have documented a 10-15% prevalence of such cysts in older women. The authors report previously unpublished autopsy data showing an 8.2% incidence of 20-50 mm unilocular cysts in women who died of non-gynecologic disease. This means that at least 3.2 million asymptomatic postmenopausal women in the U.S.A. have unilocular adnexal cysts > 20 mm in diameter. Most will escape diagnosis.

An estimated (*American Cancer Society data*) 23,300 American women will develop ovarian cancer this year; 13,900 will die from this disease ---more than all other genital cancers combined. Nonetheless, the 1.6% incidence of borderline or malignant tumors found in postmenopausal Group 1 overestimates the observed prevalence of ovarian malignancy by a factor of 2.5. Because all the bad tumors in Group 1 measured > 75mm, the recommended 50 mm cut-off for conservative management of unilocular cysts should provide a considerable margin of safety. In the age-group 50-54, the incidence of ovarian cancer was 30.5/100,000; the peak incidence was 60.6/100,000 at ages 75-79. [*Center for Disease Control data*]

The authors either did not measure, or chose not to report, **CA-125** levels in their patients. There is little evidenced-based data to support routine screening for early ovarian cancer by ultrasound, the measurement of serum tumor markers, or pelvic examination ---although such measures are frequently advocated in popular books, WEB sites, and by many doctors. The **A.C.O.G.** Committee Opinion (Dec 2000): "*Measuring **CA-125** levels in serum and ultrasonography have not been shown to be effective in population-based screening for ovarian cancer*."

REVIEW #5

Title: Postoperative Fatigue Negatively Impacts the Daily Lives of Patients Recovering from Hysterectomy.

Authors: A.H. DeCherney, G. Bachmann, K. Isaacson, S. Gall

Sites: Los Angeles, CA ; New Brunswick, NJ ; Boston, MA; Louisville, KY

Published: Obstet. Gynecol. 2002;99:51-57

Objective: To assess, from the patient's perspective, the prevalence and impact of postoperative fatigue after hysterectomy and to increase understanding of physician-patient communications before and after surgery regarding recovery and diminished postoperative energy level.

Methods: A telephone survey of 300 women aged 25-50 who had undergone a hysterectomy or myomectomy within the past two years. Patients were questioned about their postoperative fatigue.

Results: Overall, 74% of patients experienced moderate-to-severe fatigue within the first few weeks after surgery. Fatigue occurred more frequently and persisted twice as long as pain. By week 8 post-op, 12% still complained of severe fatigue, and 29% of moderate fatigue. Patients employed at the time of surgery missed an average of 5..8 weeks of work.

Conclusions: Fatigue is a highly prevalent posthysterectomy and myomectomy symptom and has substantial negative physical, psychosocial, and economic effects on patients during recovery.

Commentary: Kudos for documenting what many of us have suspected for years: that post-operative fatigue is often out of proportion to the difficulty of the operation, the degree of anemia, or the level of pain. What sometimes appears to be malingering, or a desire to use up the maximum allowable disability leave, may have deeper roots. Similar symptoms are sometimes seen in women with prolonged periods, despite normal hemoglobin levels.

The 300 patients in this study represented 32% of the 945 women in a national database who had undergone abdominal hysterectomy or myomectomy within the previous two years. Since no data is available for the others, it cannot be concluded that this sample is representative. The reliability of retrospective interviews, dealing with subjective symptoms up to two years earlier, is also open to question.

Ten percent of the women had a radical hysterectomy, presumably for cancer. Eighty-two women underwent TAHBSO, yet did not appear to be on any hormone replacement therapy. No attempt was made to analyze the relationship between the indications for surgery and subsequent symptoms, although they may be germane.

The authors have opened the door for further research. A prospective comparison of pre-op and post-op symptoms for different types of operation would answer some interesting questions; among them: Have minimally invasive techniques realized their promise of faster recovery?

Howard Kelly[1],in 1898, wrote: " *It is surprising to find in the great body of gynecological literature so little reference to the remoter results of the various operations, either moral or physical*."

Thirty years later[2], his advice to patients was: "…*complete recovery to health often takes a year or a year and a half. Fresh air, change of scene, rest, freedom from cares, regulated bowel*

function, and cheerful companions are invaluable aids in convalescence….I often insist…on an hour's rest recumbent in a darkened room, after the midday meal."

1. Kelly, Howard A. In: OPERATIVE GYNECOLOGY. D. Appleton and Company, 1898:519
2. Kelly, H.A. In: GYNECOLOGY. D. Appleton and Company, 1928:414

REVIEW #6

Title: Clinical and Patient Estimation of Fetal Weight vs. Ultrasound Estimation

Authors: J.D. Baum, D. Gussman, J.C. Wirth III

Site: New York University. New York

Published: Journal Reproductive Medicine 2002;47:194-198

Objective: To compare clinical and patient estimation of fetal weight to ultrasound estimation.

Methods: 200 women with singleton pregnancies admitted in labor at term were enrolled in this study. An obstetric resident estimated fetal weight (EFW) using clinical methods; a different resident obtained ultrasonographic measurements of biparietal diameter, abdominal circumference, and femur length and calculated the fetal weight using Hadlock's formula. Patients were also asked to guess the weight of their baby. These estimates were compared prospectively with actual birth weights. Accuracy was assessed by calculating the percentage of estimates within 10% of the actual weight for each method.

Results: Overall, 64.0% of clinical estimates were within 10% of the actual weight, compared with 62.5% of the ultrasound estimates. This was not significant. Senior resident clinical and sonographic estimates of fetal weight were significantly more accurate than junior resident estimates: clinical 75.2% vs. 59.2% (P< .03); Ultrasound 73.1% vs. 58.3% (P< .05). Multiparous patients were slightly better at guessing the size of their baby than nullipara, 57.4% vs. 48.1%, but this difference was not statistically significant.

Conclusions: Sonographic estimation of fetal weight offers no advantage over clinical or patient estimation of fetal weight. Senior resident clinical and sonographic estimates are superior to those of junior residents.

Commentary: The authors did not specify what clinical method(s) were used to estimate fetal weight. Not that it matters, since their conclusions re-affirm our inability to estimate fetal size with any degree of accuracy, either clinically, or by ultrasound.

In this age of "evidence-based medicine", why do we keep ordering ultrasounds for EFW when the best published algorithms have a 10-15% error? Why do we attach greater significance to a printed report than to our best guesstimate?

These are more than rhetorical questions. Numerous protocols, including ACOG Bulletins, use EFW as a basis for clinical decision-making. Such recommendations become "standards of care" that are difficult to ignore in the American medico-legal climate.

A case-in-point is shoulder dystocia: fear of birth trauma has prompted an increasing number of elective Cesarean sections for presumed fetal macrosomia. Yet, in a detailed analysis of the subject, Rouse[1] calculated that 3695 Cesareans would have to be performed in order to prevent each case of permanent brachial palsy in fetuses estimated to weigh > 4500 by ultrasound measurement.

Even if fetal weight could be determined with great precision, labor and delivery would continue to be dynamic processes --- complex, unpredictable interactions between the uterine contractions (*powers*), the size and position of the fetus (*passenger*) and the size and conformation of the pelvis (*passage*). Since obstetricians have largely abandoned attempts at pelvimetry, and EFW is inaccurate, the only way to gauge the possibility of a vaginal birth is a trial of labor.

In 1903, Munro Kerr wrote:[2]

With sorrow then we must admit that by the present method at our disposal we can obtain measurements of the maternal pelvis and fetal head only approximately correct…The fetal head is the best pelvimeter.

We have come full-circle.

1. Rouse, D.J., Owen, J., Goldenberg, R.L., and Cliver, S.P.; JAMA 1996; 276 : 1480-1486

2. Munro Kerr, J.M.; J. Obstet. Gynec. Brit. Empire 1903; 3 : 341-43

REVIEW #7

Title: The effect of the increasing prevalence of maternal obesity on perinatal morbidity.

Authors: G. C. Lu, D. J. Rouse, M. DuBard, S. Clivers, D. Kimberlin, J.C. Hauth

Site: University of Alabama, Birmingham

Published: Am. J. Obstet. Gynecol. 2001;185: 845-9

Objective: To study the temporal trends, and assess the relative and attributable perinatal risks of maternal obesity over a 20-year period.

Methods: This is a retrospective cohort study of all women who received prenatal care and delivered their infants within a regional health care system between 1980 and 1999. The main outcome measures extracted from the computerized perinatal database were: (1) annual mean body weight (2) the percentage of women classified as obese at the first prenatal visit [primary definition ≥200 lb; secondary definitions ≥250 lb, ≥300 lb, and body mass index ≥29 kg/m^2] and (3) relative and attributable risks of obesity for selected maternal and perinatal morbidities in successive 5-year periods.

Results: Data from 53,080 women were available for analysis. All the patients were on social assistance; approximately 70% were African-American. The most significant demographic change during the 20-year study period was a decline in the rate of smoking from 29.6% to 15.5%.

From 1980 to 1999, the mean maternal weight of women at the first prenatal visit increased 20% (144 to 172 lb), as did the percentage of women ≥200 lb (7.3 to 24.4), ≥250 lb (1.9 to 10.7), ≥300 lb (0.5 to 4.9) and body mass index ≥29 kg/m^2 (16.3 to 36.4). These changes were all significant at the $P < .01$ level.

Controlling for maternal age, race, and smoking status, obese women were at increased risk for cesarean delivery (adjusted RR 1.5 - 1.8), gestational diabetes (RR 1.8 - 2.9), and large (> 90^{th} centile) for-gestational-age infants (RR 1.8 – 2.2).

Conclusions: Over a 20-year period within a well-characterized obstetric delivery system, the increasing prevalence of maternal obesity and its associated complications is a countervailing force to the general improvements in pregnancy outcome achieved over the same period.

Commentary: Popular magazines have documented the increasing obesity of Americans in the past generation. These data reflect that trend, one that we have all observed in our own practices – although not to the same degree as in the study population.

The authors used a statistical technique called *the population etiologic fraction*[1] to calculate the proportion of adverse events that can be attributed to obesity. Their results confirm what is already known about obesity, gestational diabetes and LGA infants: they are not independent variables.

This study provides no information about the indications for C/S, the incidence of instrumental vaginal delivery, the characteristics of labor, or neonatal outcomes other than size. There is no attempt to analyze the reasons for the increased rate of Cesarean delivery in obese women. *A priori*, one would think that an obstetrician would shy away from what is likely to be a more challenging operation, with greater maternal morbidity.

Others have shown that a diagnosis of gestational diabetes lowers the threshold for intervention and doubles the Cesarean rate for babies of comparable size. Clearly, Obstetricians are spooked by the fear of shoulder dystocia.

It is noteworthy that the rate of smoking decreased by half from 1980 to 1999. This seems a remarkable achievement in this population, and one can only speculate about the reasons for this change. Smoking cessation is often associated with weight gain, and may have contributed to the overall increased rate of obesity prior to pregnancy. In their analysis, the authors controlled for smoking-status, but it would have been interesting to examine smoking-status as the study variable rather than obesity.

1. Miettinen, O. S.; Am J Epidemiol 1974; 99 : 325-32

REVIEW #8

Title: Active pushing versus Passive fetal descent in the second stage of labor: A randomized controlled trial.

Authors: S. L. Hansen, S. L. Clark, J. C. Foster

Site: LDS Hospital, Salt Lake City, Utah

Published: Obstet. Gynecol 2002;99:29-34

Objective: To compare perinatal outcomes among women with epidural anesthesia who were encouraged to push at complete dilatation with those who had a period of rest before pushing began.

Methods: This is a prospective, randomized trial involving 252 women with epidural anesthesia. At complete dilatation, patients were randomized to a rest period or immediate pushing. In the rest group, patients were encouraged NOT to push until the head was visible at the introitus, or after 120 minutes in primigravidas or 60 minutes in multigravidas.

Variables measured include: rate of fetal descent, length of time pushing, the number and type of fetal heart rate decelerations, Apgar scores, arterial cord pH, perineal injuries, type of delivery, length of second stage, maternal fatigue, and endometritis.

Results: When a period of rest was used before pushing, the authors observed a longer second stage, decreased pushing time, fewer decelerations, and, in primiparous women, less fatigue compared with control patients. Apgar scores, arterial cord pH, rates of perineal injury, instrumental delivery, and endometritis were similar in both groups.

Conclusions: Delayed pushing was not associated with demonstrable adverse outcome, despite second-stage length of up to 4.9 hours. In select patients, such delay may be of benefit.

Commentary: In his classic 1920 paper on "The Prophylactic Forceps Operation", De Lee justified early interference in the second stage on the grounds that:

> *It saves the babies' brains from injury and from the immediate and remote effects of prolonged compression. Incision in the soft parts not alone allows us to shorten the second stage; it also relieves the pressure on the brain and will reduce the amount of idiocy, epilepsy, etc. The easy and speedy delivery also prevents asphyxia, both its immediate effects and its remote influence on the early life of the infant.*[1]

This opinion, offered with no supporting data, had a profound influence on Obstetric practice in the U.S.A. which persists to this day. During the past decade, the concept of an arbitrary "safe" duration of the second stage has been eroded by numerous reports to the contrary.[2] In this study, second stages as long as 4.9 hours were associated with good immediate maternal and fetal outcomes

Epidural anesthesia undoubtedly contributes to longer second stages,[3] and the ideal management of labor in this context remains a work in progress. One option –surprisingly prevalent – is to turn down the epidural pump when the patient reaches complete dilatation. This is usually counterproductive since (1) patients prefer no pain, (2) the analgesic effect wears off from top to bottom, and painful contractions return long before normal sensation to the pelvic floor is restored, (3) if progress is slow, the absence of analgesia prompts premature operative intervention and (4)

should operative delivery or repair be needed, there is a delay restoring analgesia. Although not explicitly stated, it is assumed that in this study both groups had effective epidurals throughout the second stage.

The important conclusions from this research, favoring delayed pushing were: (1) although the 2nd stage was longer, actual pushing time was shorter (2) there were fewer FHR decelerations (3) there were no adverse fetal or maternal results.

One puzzling aspect of this article was the high rate of instrumental delivery, and the lack of information on the indications for intervention. Although the average length of the 2nd stage in the immediate-pushing primiparous group was only 76 min, 29.7% of the women had a forceps or vacuum delivery; in the delayed-pushing group, 22.6%. These numbers, and the 60% episiotomy rate, seem somewhat high for a tertiary care teaching center. It would have been better to analyze the spontaneous delivery groups separately.

1. DeLee, J. B.; **Am. J. Obstet. Gynec.1920; 1: 34-**
2. Menticoglou, S., et al.; Am. J. Obstet. Gynec. 1995; 173: 906-912
3. Paterson, C.M. et al.; Br. J. Obstet. Gynaecol.1992; 99 : 377-80

REVIEW #9

Title: Is the Formation of a Bladder Flap at Cesarean Necessary? A Randomized Trial

Authors: M. Hohlagschwandtner, E. Ruecklinger, P. Husslein, E.A. Joura

Site: University of Vienna, Austria

Published: Obstetrics and Gynecology

Objective: To evaluate the effects of not forming a bladder flap at lower-segment cesarean delivery.

Methods: 102 women undergoing primary cesarean were prospectively randomized to one of two groups. In the study group (N=53), a cesarean was performed without formation of a bladder flap. In the control group (N= 49) a bladder flap was performed before incising the uterus.

Results: There were differences of median skin incision-delivery interval (5 vs. 7 minutes, $P < .001$), median total operating time (35 vs. 40 minutes, $P = .004$), and median blood loss (Δ hemoglobin 0.5 vs. 1 g/dL, $P = .009$) in favor of the study group. Postoperative microhematuria was reduced in the study group (21% vs. 47%, $P < .01$). The median need for analgesics was reduced in the study group (75 mg diclofenac vs. 150 mg, $P < .001$), and there was a lower percentage of patients receiving analgesics 2 or more days after cesarean in the study group (26.4% vs. 55.1%, $P = .006$). There was no difference in bowel function.

Conclusions: Omission of the bladder flap provides short-term advantages such as reduction of operating time and incision-delivery interval, reduced blood loss, and need for analgesics. Long-term effects remain to be evaluated.

Commentary: The transverse, low-segment cesarean section was popularized in America by DeLee, who published a report of 40 cases in 1919. This procedure largely replaced the “classical” operation and persists, virtually unchanged, to this day.

In the pre-antibiotic era, the bladder flap served to reduce the risk of post-operative peritonitis by confining any infected hematoma to the retroperitoneal space above the bladder.

Until about twenty years ago, most surgeons developed a bladder flap, sutured the uterus in two layers, closed both visceral and parietal peritoneum, fascia, subcutaneous layer and skin. In recent years, an increasing number of obstetricians choose to close the uterus in a single-layer, and omit suturing peritoneum or subcutaneous tissue. None of these variations appear to increase short-term complications; however, a recent retrospective study from Montreal linked single-layer uterine closure with a 4-fold increase in uterine rupture during a subsequent trial of labor.

In this study, the uterus was closed in a single-layer, peritoneum was not sutured, and subcutaneous sutures were placed only if the fat layer was > 2 cm. Omission of the bladder flap reduced operating time and was associated with less blood loss and post-operative pain.

This modification would appear to be most practical in primary C/S, where the bladder reflection can be seen clearly.

REVIEW #10

Title: Antepartum, Intrapartum, and Neonatal significance of exercise on healthy Low-Risk pregnant working women.

Authors: E. F. Magann, S. F. Evans, B. Weitz, J. Newnham

Site: U. Mississippi Medical Center, Jackson; U. Western Australia, Perth

Published: Obstet Gynec 2002;99:466-72

Objective: To evaluate the influence of exercise on maternal and perinatal outcome in a low-risk healthy obstetric population.

Methods: This was a prospective observational study of low-risk healthy women exercising during their pregnancy. An extensive questionnaire collected antepartum, intrapartum, and postpartum patient information on 750 women. The women were divided into four groups based on exercise level during pregnancy.

Results: There were no differences among groups for maternal demographic characteristics, antenatal illnesses, stress, social support, or smoking. Heavily-exercising women were older (P = .042), had higher incomes (P = .001), and were exercising more at conception (P = .001). Women who did more exercise were more likely to need an induction of labor (P = .033, RR 1.84, 95% confidence interval 1.05, 3.20), induction or augmentation with oxytocin (P = .015, RR 1.53, 95% C.I. 1.19, 1.97), and had longer first-stage labors (P = .032) resulting in longer total labors (P = .011). The difference in the length of first-stage labor was even greater if the no-exercise group was compared with the strongly exercising group (P = .009, RR 1.38, 95% C.I. 0.16, 2.60). Fewer umbilical cord abnormalities (P = .034) were observed with exercise, but exercising women had more colds and flu (P =.008). Heavily exercising women had smaller infants (mean difference 86.5 g) compared with sedentary women.

Conclusions: Exercise in working women is associated with smaller babies, increased number of inductions and augmentations of labor, and longer labors. Colds and flu are more frequent in exercising women.

Commentary: Medical recommendations concerning exercise during pregnancy have been largely empirical, based on common-sense considerations such as risk of injury to mother or baby. There is no evidence that ordinary athletic activity is harmful to the fetus. In particular, there is no data to support the belief that exercise increases the risk of first-trimester pregnancy loss.

It has long been believed that the babies of athletic mothers are smaller than average, in the "lean-and-mean" sense. It has also been believed that the good physical condition associated with regular exercised conferred benefits during labor.

This study throws cold water on such assumptions. It does not, however, shed much light on why regular exercise adversely affects labor. All the women in this study were active-duty Navy personnel, and it would be premature to generalize the results to other populations. More study and analysis is required.

This latest research would not have surprised our professional ancestors:

I fear infinitely more the strong buxom athletic woman who has led an active physical life from early girlhood than the woman who is poorly nurtured. In my experience the former has a long drawn out labor, in a considerable frequency, terminated by a difficult instrumental operation, while the latter will have an easy, comfortable, and often rapid termination of labor. In the one, uterine action is inadequate to overcome the overdevelopment of the pelvic soft parts, while in the other these same structures are so poorly developed they offer slight interference with the progress of labor.[1]

1. Holmes, Rudolph W.; Comments; Trans. Am.Gyn.Soc. 1919; 44 : 249-263

REVIEW #11

Title: Persistence of Placenta previa according to gestational age at Ultrasound Detection

Authors: J.S. Dashe, D.D. McIntire, R.M. Ramus, R. Santos-Ramos, D.M. Twickler

Site: U. of Texas, Southwestern Medical Center, Dallas, Texas

Published : Obstet Gynecol 2002; 99:692-7

Objective: To correlate the gestational age at ultrasound detection of placenta previa with the persistence of previa until delivery. To assess the effects of previa type, parity, and prior cesarean delivery on previa persistence.

Methods: This was a retrospective cohort study of 714 pregnancies with placenta previa detected during transabdominal or endovaginal ultrasound examination. Previa was categorized as "complete" if the placenta completely covered the internal cervical os. Gestational age was grouped into 4-week intervals from 15 to 36 weeks. The outcome was cesarean delivery for persistent previa.

Results: Of those with placenta previa at 15-19 weeks, 20-23 weeks, 24-27 weeks, 28-31 weeks, and 32-35 weeks, previa persisted until delivery in 12%, 34%, 49%, 62%, and 73%, respectively. At each interval, complete previa was more likely to persist than incomplete previa, all $P < .001$. Prior cesarean delivery was an independent risk factor for persistent previa among women diagnosed with previa in the second trimester, $P < .05$. However, parity was not an independent risk factor for persistence at any gestational age after adjusting for prior cesarean delivery.

Conclusions: Gestational age at ultrasound detection of placenta previa may be used to predict likelihood of previa persistence. After midpregnancy, risk of persistence appears to be higher than previously reported.

Commentary: This study re-enforces the view that a high percentage of "placenta previas" diagnosed at second trimester ultrasound do "migrate" as pregnancy advances. The most important conclusion is that, while parity is a risk factor for previa *prevalence* at screening U.S., it does not appear to be a risk factor for previa *persistence* at time of delivery unless there was a prior cesarean section.

There are many flaws in this report, based largely on its retrospective nature and incomplete data. No information is presented about the total number of deliveries during the 10-year study period, nor about the percentage of patients who had "routine" ultrasound. How many "previas" were diagnosed by abdominal *versus* transvaginal ultrasound?

It is likely that those picked-up between 15 and 24 weeks were incidental findings at abdominal screening sonograms. Only 940 U.S. were performed in the 714 patients: this implies that only one U.S. was done in most of these pregnancies, and begs the question " how was the persistence of previa diagnosed? " We know that 215 of these women (30%) underwent cesarean for "persistent previa", but there are no data on whether the patients presented with bleeding, or were sectioned on the basis of a single earlier U.S. Except in cases of central previa, accreta or percreta, it is not easy to tell at cesarean whether the placenta completely covers the cervical os.

It would have been interesting to read about the clinical course and management of these patients, since the diagnosis of "placenta previa" inspires anxiety in both patients and physicians. Yet, in twenty years of busy obstetric practice, this reviewer can recall only one case of previa

requiring hysterectomy: she had undergone previous cesarean delivery, and had a placenta accreta involving the lower segment behind the bladder. This low incidence is in keeping with data presented in 1994 by Zelop et al.[1]: "placenta previa" was diagnosed at 2nd trimester U.S. in 925 patients; 267 had cesarean delivery, but in only 43 (4.6%) was the diagnosis of "previa" obvious at the time of surgery; of these, only 21 had antepartum bleeding.

An ultrasound report of "placenta previa" cannot be ignored, but neither should it prompt overreaction. In the asymptomatic patient, a transvaginal scan performed late in the 2nd trimester will help sort-out the real previas from the "low-lying" placentas.

Two recent articles, from Canada[2] and Germany[3], showed that placental "migration" can continue through the 3rd trimester. However, all patients where the placental edge overlapped the cervical os by more than $20mm^2$ or $25mm^3$, required cesarean delivery.

When complete placenta previa persists in the 3rd trimester, it appears sensible to counsel the patient about avoiding intercourse or excessive activity, and to go to the hospital promptly in the event of bleeding or contractions. The possibility of blood transfusions or hysterectomy should also be discussed.

Symptomatic placenta previa has traditionally been managed by hospitalization until delivery. Wing et al.[4] showed that outpatient expectant management was safe in selected patients, and much more cost-effective.

1. Zelop CC, Bromley B, Frigoletto FD Jr., Benacerraf BR "Second trimester sonographically diagnosed placenta previa: prediction of persistent previa at birth." International Journal of Gynaecology and Obstetrics 1994; 44: 207-10

2. Oppenheimer L, Holmes P, Simpson N, Dabrowski A "Diagnosis of low-lying placenta: can migration in the third trimester predict outcome?" Ultrasound in Obstetrics and Gynecology 2001; 18: 100-2

3. Becker RH, Vonk R, Mende BC, Ragosch V, Entezami M " The relevance of placental location at 20-23 gestational weeks for prediction of placenta previa at delivery: evaluation of 8650 cases." Ultrasound in Obstetrics and Gynecology 2001; 17: 496-501

4. Wing DA, Paul RH, Millar LK " Management of the symptomatic placenta previa: A randomized controlled trial of inpatient versus outpatient expectant management." American Journal of Obstetrics and Gynecology 1996; 175: 806-811

REVIEW #12

Title: A Comparison of two dosage regimens of oral misoprostol for labor induction at term.

Authors: A. Shetty, R. Martin, P. Danielian, A. Templeton

Site: Aberdeen Maternity Hospital, Aberdeen, UK

Published: Acta Obstet Gynecol Scand 2001; 81: 337-342

Objective: To compare the efficacy and safety of 50µg vs 100µg oral doses of misoprostol for the induction of labor at term

Methods: 251 women with indications for induction of labor at term were randomized to receive either 50µg or 100µg of oral misoprostol, repeated every 4h to a maximum of 5 doses. Parous women in the higher dose group received an initial dose of 50µg, followed by 100µg doses. Women who failed to respond to the 5 doses of misoprostol had the option of having vaginal PGE_2 gel. The primary outcome measure was the induction to delivery interval in those who delivered vaginally. Patient satisfaction was assessed by postpartum questionnaire.

Results: The induction to vaginal delivery interval was shorter in the 100µg group (26.8 vs 33.7h), but this difference was not statistically significant. There were more failed inductions with misoprostol in the 50µg group (12.7% vs 4.8%).There were no significant differences in the methods of delivery, number of cesarean sections for fetal distress or neonatal outcomes. Most patients, 83% and 92% in the 50µg and 100µg groups, repectively, were satisfied with their inductions.

Conclusions: Oral misoprostol is effective in inducing labor and seems acceptable to patients. Both the 50µg and 100µg dose regimens have a reasonable safety profile, but in view of the higher incidence of failed inductions with the lower dosage, the 100µg dose regimen may be preferable.

Commentary: Induction of labor in the primigravida with an unfavorable cervix remains a major Obstetric challenge. Achieving vaginal delivery in this circumstance is an uncertain process that requires patience and more than a little luck. Despite our best efforts, all this work often ends in cesarean after several frustrating days for both staff and family.

Over the years countless mechanical and chemical methods of induction have been proposed. Few have withstood the test of time and, today, only intravenous oxytocin and vaginal or intra-cervical PGE_2 are universally employed. Mechanical methods such as the intracervical Foley catheter have remained popular in some centers, and the recent literature suggests that this is a safe and inexpensive technique that deserves to be more widely practiced. However, mechanical dilatation does not invariably translate into effective labor. The perfect method of induction must await a better understanding of human parturition.

There is some consensus in the literature that, other things being equal, prostaglandins lead to shorter induction-to-delivery intervals than oxytocin. PGE_2 was the first prostaglandin used to induce labor in term pregnancy. While vaginal PGE_2 was widely employed in Europe, the first FDA-approved PGE_2 in the U.S.A. was oral PROSTIN©. Unfortunately, prolonged oral use was associated with significant GI side-effects such as nausea, vomiting and diarrhea. Clinicians soon

began inserting the tablets directly into the vagina; many hospital pharmacies compounded their own PGE2 gels by grinding the oral tablets or 20 mg vaginal suppositories (intended for 2nd trimester termination of pregnancy) with K-Y jelly. It may be imagined that there were considerable variations in the bio-availability of these home-made medications.

There are currently only two PGE_2 products specifically approved for the induction of labor: PREPIDIL© and CERVIDIL©. PREPIDIL© gel is intended for intracervical use; this is cumbersome, and it has been used mostly for outpatient "ripening" of the cervix over a few days. Its repeated use is very expensive, and most Obstetricians are not impressed with this product. CERVIDIL© is a vaginal insert designed to release a constant amount of PGE_2 over a 12-hour period. Anecdotally, it appears superior to the home-made PGE2 gel previously (and still) used. However, again anecdotally, several problems have arisen connected to the use of CERVIDIL©.

The first is the cost! Second, because constant monitoring is required, CERVIDIL© cannot be administered to outpatients; this increases utilization costs significantly. Third, despite placement in the vaginal vault, the CERVIDIL© insert frequently falls out of the ambulatory patient and needs to be re-inserted; this also raises the question of whether its presence in the lower vaginal canal impairs its absorption and efficacy.

The search for a safe, inexpensive labor-inducing agent led to a flurry of reports advocating the use of either oral or vaginal misoprostol (CYTOTEC©) for this purpose. This drug, a PGE_1 analog, has long been prescribed for the prevention of NSAID-associated gastritis; its oxytocic properties were soon recognized as side-effects, and it was contra-indicated in pregnancy. In combination with methotrexate, it was first used as a 1st-trimester abortifacient. Because of its low cost and wide availability, it was soon adopted in 3rd-world countries for labor induction.

Most published studies agree that misoprostol is at least as effective, at least as safe, and much less expensive than any PGE_2 preparation available. It is well-absorbed orally and has few of the G.I. side-effects associated with oral PGE_2. There remains uncertainty about the optimal route of administration (vaginal or oral), dose and frequency of administration. This study supports the efficacy and safety of oral misoprostol and proposes that this route is more acceptable to patients. In premature rupture of the membranes, the vaginal tablets may be washed out; oral dosing may result in more predictable absorption, and fewer vaginal examinations.

Given the solid body of published and anecdotal experience with this drug, it is not surprising that it has been adopted enthusiastically around the world. Not unexpectedly, there have been problems. Compared to other prostaglandins, misoprostol in therapeutic doses frequently causes polysystole: frequent, mild, painless contractions. These are usually not associated with FHR abnormalities, but have prompted the use of tocolytics and premature operative delivery. As with other PGs, the use of misoprostol in patients with previous cesarean has been associated with an increased risk of uterine rupture.

In response to adverse case reports and to protect itself against litigation, SEARLE, the manufacturer of CYTOTEC©, issued a warning in August 2000 advising against the use of its product for off-label indications such as the induction of labor. This had a predictable effect: many hospitals restricted the drug to formal research protocols.

Pressure from obstetricians prompted ACOG to issue a statement supporting the off-label use of misoprostol for the induction of labor. In May 2002, the FDA approved major changes to

CYTOTEC© labeling, that acknowledges the off-label use in obstetrics and gynecology, and provides safety information relating to those uses.

Physicians frequently prescribe drugs for indications other than those on the product label. Reasons for such off-label use during pregnancy include: prevention of repetitive abortion, inhibition of premature labor, reduction of fetal or neonatal infection, reduction in development of pre-eclampsia and its complications, and ripening of the cervix or induction of labor. A physician has a legal right to prescribe for off-label indications despite regulatory, manufacturer, and cost constraints. Such prescribing habits would not be considered experimental if based on sound scientific evidence. Adequate and well-controlled studies are difficult to perform during pregnancy. Evidence of widespread use and support from another qualified clinician are methods of justifying off-label prescribing. Each patient is entitled to know why she and her fetus would benefit from the treatment and whether any unnecessary risk is anticipated. Legible documentation of these discussions in the medical record is important.[1]

1. Rayburn WF Obstet Gynecol 1993; 81: 1052-5

REVIEW #13

Title: The Effects of Cigarette smoking on fetal heart rate characteristics

Authors: C. Oncken, H. Kranzler, P. O'Malley, P. Gendreau, W.A. Campbell

Site: U. of Connecticut School of Medicine, Farmington, Connecticut

Published: Obstet Gynecol 2002; 99: 751-5

Objective: To evaluate the effect of repeated cigarette smoking on fetal heart rate (FHR) characteristics

Methods: Fifteen chronic smokers between 28 and 36 weeks' gestation were evaluated during an 8-hour smoking session. Baseline FHR and reactivity were evaluated after overnight abstinence from smoking, and 4 hours later (after the fourth cigarette), when the effects of smoking on FHR were expected to be maximal. Plasma nicotine was measured at baseline and repeated at times of fetal monitoring.

Results: Subjects smoked a mean 22 (S.D.6) cigarettes per day. They abstained from smoking for 9.2 (S.D. 3.2) hours before evaluation. The initial baseline FHR was unchanged after the fourth cigarette. Plasma nicotine increased from 2.6 to 24 ng/mL ($P < .001$). The initial non-stress test (NST) was reactive in 12 of 15 fetuses. After the fourth cigarette, only 4 of the 15 NSTs were reactive. 8 of 15 tracings were initially reactive and became non-reactive after smoking. 3 of 15 NSTs remained non-reactive, while 4 of 15 were reactive throughout. None of the tracings that were initially non-reactive became reactive.

Conclusions: Acute, repeated smoking decreases FHR reactivity.

Commentary: This small study will sensitize the clinician to the effects of cigarette smoking on FHR reactivity. In the absence of other risk factors, decreased fetal movement and non-reactive NST in a heavy smoker may be normal. More prolonged observation may avoid unnecessary interventions in such patients.

REVIEW #14

Title: Pfannenstiel versus Maylard Incision for Cesarean Delivery: A Randomized controlled trial

Authors: P.L. Giacalone, J.P. Daures, J. Vignal, C. Herisson, B. Hedon, F. Laffargue

Site: Hôpital Arnaud de Villeneuve, U. de Montpellier, Montpellier, France

Published: Obstet Gynecol 2002; 99: 745-50

Objective: To compare the Pfannenstiel incision with the Maylard (transverse, muscle-cutting) incision for Cesarean delivery.

Methods: Women undergoing primary, non-urgent, cesarean at term were randomized to a Pfannenstiel or Maylard incision. Surgical characteristics, complications, post-operative pain (visual analog scale, analgesic use), and quality of life (1- and 3-month questionnaires) were analyzed. Abdominal wall muscle recovery was compared objectively by dynamometry.

Results: Fifty-four women had a Pfannenstiel incision and 43 had the Maylard incision. There were no differences in intraoperative characteristics, postoperative morbidity, or pain. Women's responses to the Nottingham Health Profile questionnaire at 1 and 3 months postoperatively, and clinical and isokinetic testing for abdominal strength were similar in both groups.

Conclusions: The Maylard incision was no more deleterious than the Pfannenstiel incision, and should be considered when good exposure of the pelvis is necessary.

Commentary: The conclusions appear somewhat surprising to this reviewer. Having used the Maylard incision for gynecologic surgery, there is no doubt that it provides great exposure of the pelvic organs. It is often used in preference to a vertical midline incision in patients at high risk of dehiscence, or for cosmetic reasons. Because it involves cutting the rectus muscles, it has always taken longer than a Pfannenstiel; it should also cause more pain, and have a greater risk of hematoma.

That said, my prejudice is showing, since I have never used a Maylard incision for cesarean section—nor, for that matter, do I know anybody who has. When I trained, in the late 70s, older attendings operated through vertical midline incisions, and used to deride the junior staff who often struggled to deliver babies through a five-inch Pfannenstiel. The young persisted, partly for macho reasons, partly because patients sought-out doctors who performed the "bikini cut". Nowadays, the residents would rather struggle with a Pfannenstiel than do a midline. They believe (wrongly) that, in an emergency, they can deliver a baby "just as fast" through a Pfannenstiel.

This study offers evidence that the Maylard can provide better exposure for cesarean without increasing operative time or morbidity. Unless there was a typographical error, the discrepancy (54 vs 43) in the number of women undergoing each procedure suggests that randomization was not perfect. Furthermore, all these patients were undergoing a primary cesarean. It remains to be seen whether the operative time would be longer in the presence of scarring sometimes found after a few previous operations.

In 1987, Ayers and Morley[1], at the University of Michigan, reported a similar series of 97

patients, with comparable results. There may be some truth to this!

A vertical incision remains the best choice for “STAT” delivery, classical cesarean, or women with impaired coagulation status. The Pfannenstiel gives adequate exposure for most primary cesareans, provided it is 3 cm above the pubis and at least 6 inches long. Potential indications for the Maylard would include suspected macrosomia, or patients with multiple prior Pfannenstiels.

1. Ayers JW, Morley GW Surgical Incision for cesarean section Obstetrics and Gynecology 1987; 70: 706-708

REVIEW #15

Title: Weight gain in women of normal weight before pregnancy: Complications in pregnancy or delivery and birth outcome

Authors: I. Thorsdottir, J.E. Torfadottir, B.E. Birgisdottir, R.T. Geirsson

Sites: U. of Iceland, Reykjavik, Iceland

Published: Obstet Gynecol 2002; 99: 799-806

Objective: To investigate the relation between gestational weight gain in women of normal non-pregnant weight and complications during pregnancy and delivery in a population with high gestational weight gain and birth weight.

Methods: 615 women of normal weight before pregnancy (BMI 19.5 –25.5 kg/m^2) were randomly selected. The sample size (14.7% of all deliveries in Iceland in 1998) was calculated to detect an effect of 1 kg weight pain in pregancy, with a power of at least 90 and $P< 0.05$.

Maternity records gave information on age, height, prepregnant weight, gestational weight gain, parity, smoking, gestational diabetes, preeclampsia, delivery complications, and infants' birth size and health.

Results: The mean weight gain in pregnancy was 16.8 ± 4.9 kg. The mean birth weight was 3778 ± 496 g. Women gaining weight according to the Iceland Institute of Medicine (11.5 – 16.0 kg) had lower frequency of pregnancy-delivery complications than women gaining more than 20.0 kg ($P = .017$). A low weight gain in pregnancy (less than 11.5 kg) was associated with an increased frequency of infants weighing less than 3500 g at birth ($P < .01$).

Conclusions: A gestational weight gain of 11.5 – 16.0 kg for women of normal prepregnancy weight is related to the lowest risk of pregnancy-related complications.

Commentary: The subject of weight gain in pregnancy has long been controversial. How much is too much, how little is too little? Is weight gain beyond that needed for the physiologic changes of pregnancy (baby, placenta, uterus, amniotic fluid, plasma volume and RBC expansion etc) dangerous or beneficial?

In his 1905 textbook, Hirst[1] reported an average 7.7% increase in body weight during pregnancy. In this population, the average weight gain, was 27% of the pre-pregnancy weight. Since physiologic weight gain is proportional to lean body mass, the authors adjusted for height in calculating the relative risk of pregnancy or delivery complications.

In a teleological sense, fat storage during pregnancy provides calorie reserves needed for survival and lactation in the event of famine. On the other hand, excessive weight gain leads to bigger babies and more difficult births. For many years, deliberate dietary restrictions were employed to restrict fetal size in patients with contracted pelves.

This study measured total weight gain, based on a review of prenatal records. It did not distinguish between weight attributable to water retention (edema) and excessive calorie consumption (fat). This distinction is important in correlating weight gain with pregnancy complications. Women with P.I.H. often have severe edema and would thus have more weight gain; one might conclude that there was a causal relationship between weight gain and P.I.H., whereas the converse is probably true.

Recommendations by “authorities” concerning nutrition and weight gain in pregnancy have changed considerably in the last 100 years. During WW1, it was observed that the incidence of pre-eclampsia decreased markedly in Germany, only to rise again after the Armistice. Without detailed analysis, the Journal of the American Medical Association editorialized that restriction of fat and meat during pregnancy reduced the incidence of toxemia. For many years, the pregnant kidney was believed to be particularly vulnerable to excessive protein intake. Goodlin[2] presented an interesting historical review of this subject.

In women who eat a “balanced diet” from all the major food groups, it is likely that weight gain within a wide range is compatible with good pregnancy outcomes.

1. Hirst BC “A Textbook of Obstetrics” 1905 p. 186 W.B. Saunders and Co.
2. Goodlin RC “Care of the Fetus” 1979 p. 14-25 Masson Publishing USA, Inc

REVIEW #16

Title: Body Weight and Risk of Oral Contraceptive Failure

Authors: VL Holt, KL Cushing-Haugen, JR Daling

Site: U. of Washington, Seattle, Washington

Published : Obstet Gynecol 2002; 99: 820-27

Objective: To examine the hypothesis that higher body weight increases the risk of oral contraceptive (OC) failure.

Methods: A retrospective cohort analysis of data from 755 randomly selected female enrollees of Group Health Cooperative of Puget Sound who completed an in-person interview and dietary questionnaire between 1990 and 1994 as control subjects for a case-control study of ovarian cysts. Among the 618 women who were OC ever-users, the authors used Cox proportional hazards regression models to estimate the relative risk (RR) of pregnancy while using OCs associated with body weight quartile.

Results: During 2822 person-years of OC use, 106 confirmed pregnancies occurred (3.8 per 100 person-years of exposure). After controlling for parity, women in the highest body-weight quartile (70.5 kg or more) had a significantly increased risk of OC failure (RR 1.6, 95% C.I. 1.4-2.4) compared with women of lower weight. In the highest weight quartile, the pregnancy risk was greater for very low-dose (< 35µg EE) users (RR 4.5, 95% C.I. 1.4-14.4) and low-dose (≤50µg EE) users (RR 2.6, 95% C.I. 1.2-5.9).

Conclusions: These findings suggest that increased body weight may decrease the effectiveness of oral contraceptive pills. Consideration of a woman's weight may be an important element of OC prescription.

Commentary: These results, if confirmed, have important implications for gynecologic practice.

It was not clear if the authors only reviewed data that were collected a decade ago for another study, or if they re-interviewed all these women more recently. If the latter, body weight estimates by patient "self-report" may be unreliable. This reviewer is not familiar with the statistical techniques employed in this study, but is willing to give the authors the benefit of the doubt that they were applied correctly to the data herein.

While the dosage of medications with a narrow therapeutic-toxic range is adjusted according to BMI, the OC, from its introduction, has been prescribed as a "one size fits all" pill. A few years ago, following grand rounds, a world-famous expert in contraception opined that even the lowest-dose OC on the market had sufficient hormone to achieve minimum "threshold levels" in all women. This opinion is consistent with the observed high efficacy of the OC, but there is surprisingly little literature on the subject. OC failure rates of up to 6% have been attributed to lapses in compliance; yet, all of us have reliable pregnant patients who cannot remember missing any pills.

Combination oral contraceptives act by suppression of gonadotropins. Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus, which increase the difficulty of sperm entry into the uterus, and changes in the endometrium

which reduce the likelihood of implantation, as well as inhibition of tubal motility. The progestin component is undoubtedly the most important: progestin-only pills containing as little as 0.35 mg of norethindrone are almost as effective as combination OCs.

Lowering hormone levels has decreased the incidence of serious side-effects, but may have compromised efficacy. It is known that lower-dose combination pills do not consistently inhibit ovulation. Advertising for the new transdermal contraceptive patch EVRA© acknowledges a higher failure rate in women >90kg.

The authors speculate that the reduced efficacy of OCs in heavier women is the result of their increased metabolism. Since OC hormones are largely metabolized by microsomal liver enzymes, it is possible that a heavier person has a larger liver, which in turn may accelerate metabolism; however, no evidence is presented that increased caloric metabolism decreases the half-life of active serum hormones. Moreover, total weight does not distinguish between more metabolically-active muscle mass and fat. A more likely explanation is that larger patients have a greater volume of distribution, hence lower effective serum levels. Clinicians have known for years that "petite" women experience less nausea and mastalgia on 20µg EE OCs.

The concept that OCs are less effective in heavier women appeals to common-sense and should be confirmed by larger, prospective studies. In the meantime, it may be wise to avoid prescribing the lowest-dose pills to heavier women.

REVIEW #17

Title: A randomized controlled trial of early versus "traditional" postoperative oral intake after major abdominal gynecologic surgery.

Authors: HL Steed, V Capstick, C. Flood, A. Schepansky, J Schulz, DC Mayes

Site: U. of Alberta, Edmonton, Alberta, Canada

Published: Am J Obstet Gynecol 2002; 186: 861-5

Objective: To compare early oral intake with traditional timing of feeding after major gynecologic surgery and its effects on length of stay.

Methods: Gynecologic oncology and urogynecology patients who underwent laparotomy were prospectively randomized to one of two groups. The traditional feeding group (Group A, n=49) received nothing by mouth until bowel sounds, passage of stool or flatus, and subjective sensations of hunger were present. They were then advanced slowly to solid diet. The patients in the early feeding group (Group B, n=47) began clear fluids on the first post-operative day. Once 500 mL of clear fluid was tolerated, they received a regular diet. The groups were compared with regard to length-of-stay, postoperative day that solids were tolerated, and the incidence of adverse effects.

Results: The demographic characteristics of the two groups were similar. The median length-of-stay for Group A was 6.0 days and for Group B was 4.0 days ($P < .0001$). There was no difference in the incidence of emesis, ileus, or other post-operative complications.

Conclusions: Early dietary advancement following major abdominal gynecologic surgery decreases the length of hospital stay and appears to be safe.

Commentary: Twenty-five years ago, hospital length-of-stay following even simple abdominal hysterectomy was 7-10 days. Gas pains and ileus were common, nasogastric and rectal tubes frequently employed. Except for ice chips, the patient was kept NPO until bowel sounds were active; the diet was then advanced over several days and discharge delayed until after a bowel movement.

It is ironic that the utilization/insurance issues which prompted shorter hospital stays have been beneficial for patients. Better, "lighter", anesthesia, early ambulation, decreased narcotic use have all contributed to the earlier resumption of normal bowel function. Caffeine and nicotine-users appear to have fewer headaches and less ileus if their habitual drugs are resumed promptly; in a hospital setting, nicotine patches have been helpful, but it has not escaped our attention that the need for a cigarette has been a powerful stimulus to early ambulation and discharge.

The study adds support to the experience of most surgeons that the earlier introduction of solid food is rarely detrimental. Fanning[1] reviewed the literature from 1996-2000 and provided Class 1 evidence that early feeding after major gynecologic surgery resulted in more emesis but no serious complications.

1. Fanning J, Andrews S. Early postoperative feeding after major gynecologic surgery: Evidence-based scientific medicine. Am J Obstet Gynecol 2001; 185: 1-4

REVIEW #18

Title: Do women prefer female obstetricians?

Authors: EA Howell, B Gardiner, J Concato

Site: Mount Sinai Medical Center, New York and Yale University School of Medicine, New Haven Cnnecticut

Published: Obstet Gynecol 2002: 99: 1031-5

Objective: To investigate gender preferences for obstetricians in a hospital setting and to examine its relationship to patient satisfaction.

Methods: The authors interviewed 67 obstetric patients during their postpartum hospital stay. They asked open-ended questions about gender preference in the choice of a health-care provider and satisfaction with health care.

Results: 58% of patients expressed no preference for physician gender, 34% preferred female physicians, while only 7% preferred male physicians. Interpersonal style, communication style, and technical expertise were considered important characteristics by patients. The majority of patients preferred a female nurse. Patient satisfaction scores were not associated with physician gender.

Conclusions: Physician gender is less important to patients than other physician characteristics.

Commentary: This is one of two similar articles[1] published recently, using similar methodologies and arriving at similar conclusions.

It is difficult to attach much practical significance to the results. Interviewing a captive audience of recently-delivered patients and asking rhetorical questions about gender preference is unlikely to reflect true preference. It stands to reason that patients would opt for a competent or empathic physician, regardless of gender.

The real question is: “other things being equal, sight-unseen, and given the choice, would you select a male or female gynecologist”? A more realistic study would be to sit with the receptionist at a large clinic, and tabulate the unprompted gender-preference requests of new patients, as well as their willingness to see a male if no female practitioner is available.

Established male physicians will definitely attract new patients by reputation, and keep the ones they have. However, any recruiter will tell you that there are far more job opportunities for female gynecologists.

Patient preference may be a moot point since perception is fast becoming reality: in the past twenty years, the ratio of men to women in most residency programs has reversed itself. The “man-midwife” may soon be as rare and reviled as he was in the eighteenth century.

1. BA Plunkett, P Kohli, MP Milad; The Importance of physician gender in the selection of an obstetrician or a gynecologist. Am J Obstet Gynecol 2002; 186:926-8

REVIEW #19

Title: What is the correct primary diagnostic tool in the "one-stop" clinic for the investigation of abnormal menstrual bleeding?

Authors: KD Jones, K Jermy, TH Bourne

Site: Royal Surrey County Hospital, Surrey, UK and St. George's Hospital, London, UK

Published: Gynecological Endoscopy 2002; 11: 27-32

Objective: To review the efficacy of techniques used to evaluate abnormal menstrual bleeding in a "one-stop" clinic setting.

Methods: This was a critical review of 31 published articles on the investigation of abnormal menstrual bleeding.

Results: The combination of transvaginal ultrasound (TVS) with saline hydrosonography (s-HS) has made ultrasound without hysteroscopy a potential primary diagnostic tool in the one-stop abnormal menstrual bleeding clinic. This is particularly true if outpatient hysteroscopy is carried out with blind endometrial sampling, rather than a directed biopsy. In the detection of focal endometrial pathology, compared with TVS alone, TVS plus s-HG increases the sensitivity from 67% to 87%, the specificity from 89% to 91%, the positive predictive value from 88% to 92% and the negative predictive value from 71% to 86%. Furthermore, TVS facilitates the diagnosis of adnexal and intramural pathology.

Conclusions: The authors believe that a critical appraisal of the evidence supports TVS plus s-HG and endometrial biopsy as the correct primary diagnostic tool in the evaluation of abnormal menstrual bleeding in the outpatient setting.

Commentary: The "one-stop" clinic is popular in the United Kingdom, offering patients more personal service and more efficient diagnosis of various medical conditions than National Health Service hospital clinics. In the USA most insured patients receive their gynecologic care in private offices; the closest we have come to the "one-stop" clinic is the colposcopic "LOOK and LEEP" approach to the investigation of abnormal PAP tests.

The "gold-standard" for diagnosing abnormal uterine bleeding remains hysteroscopy with directed biopsy. However, most such procedures are performed in a hospital setting, increasing both cost and patient inconvenience.

Transvaginal sonography (TVS) has been a boon to gynecologists, offering a good look at the endometrium, as well as diagnosing adnexal pathology. In post-menopausal women, an endometrial stripe < 5mm in thickness usually excludes significant pathology. Intrauterine saline infusion at the time of TVS (hysterosonography, sonohystogram, s-HG) has made it possible to outline submucous fibroids and endometrial polyps with great accuracy.

Mihm et al.[1] recently reported a sensitivity (few patients with disease were missed) of 97.0% (95% C.I. 88.6 – 99.5) and a negative predictive value (a negative test indicated a very low likelihood of disease) of 94.3% (95% C.I. 79.6 – 99.0) for TVS + s-HG + endometrial biopsy.

Office hysteroscopy without directed biopsy or the facility to carry out operative procedures offers no advantage over TVS + s-HG + endometrial sampling. Furthermore, patients prefer TVS to office hysteroscopy.

1. Mihm LM, Quick VA, Brumfield JA, Connors AF and Finnerty JJ. The accuracy of endometrial biopsy and saline sonohysterography in the determination of the cause of abnormal uterine bleeding. Am J Obstet Gynecol 2002; 186: 858-60.

REVIEW #20

Title: Prognostic factors for the success of thermal balloon ablation in the treatment of menorrhagia

Authors: MY Bongers, BWJ Mol, HAM Brölmann

Sites: Veldhoven and Utrecht, Netherlands

Published: Obstet Gynecol 2002; 99: 1060-66

Objective: To identify factors that will predict the success of thermal balloon endometrial ablation for the treatment of menorrhagia.

Methods: This is a prospective study on patients referred for menorrhagia and treated with hot fluid thermal balloon ablation. Potential prognostic factors for assessing the success of treatment were recorded. Success was defined by patient satisfaction and no subsequent hysterectomy a 2-year follow-up.

Results: 130 women were included in the final analysis. The cumulative rate of patients undergoing hysterectomy after 2 years was 12%. After 2 years, 81% of the remaining patients were satisfied with the results of the treatment. Predictive factors for adverse outcome were a retroverted uterus (RR 3.3, 95% C.I. 1.2-8.6), pre-treatment endometrial thickness of at least 4mm (RR 3.6, 95% C.I. 1.3 – 11), and the duration of menstruation (RR 1.2, 95% C.I. 1.0 – 1.3, per day in excess of 9 days). The risk of an adverse outcome declined steadily with increasing age (RR .86, 95% C.I. 0.77 – 0.96 per year over 42). Uterine depth and dysmenorrhea were not correlated with outcome.

Conclusions: Young age, retroverted uterus, endometrial thickness ≥ 4mm, and prolonged duration of menstruation were associated with an increased risk of treatment failure.

Commentary: In the past 10-20 years there has been increased criticism of hysterectomy as the first-line treatment for abnormal uterine bleeding. Total abdominal hysterectomy, in particular, has come under attack from academic gynecologists, health insurers, and consumer groups---for reasons ranging from complication rates, hospital costs, to negative changes in sexuality or body image.

The past decade has witnessed a proliferation of "hysterectomy alternatives" for benign abnormal uterine bleeding. Submucous fibroids are resected hysteroscopically; intramural fibroids are excised laparoscopically, infarcted by angiographic embolization, cold or heat. The endometrium has been ablated with lasers, electrocautery, cryotherapy, thermal balloons, hot water and microwaves. None of these techniques reliably produces amenorrhea, and all have complications.

Thermal balloon ablation has become popular because it is less operator-dependent than hysteroscopic laser or rollerball ablation: the risk of uterine perforation is minimal, there are no fluid-balance issues, and anyone who can do a D&C can perform the procedure after minimal training. Anecdotally, there are frequent equipment problems; the most-used device in this country often cannot be used for uterine cavities sounding more than 9 cm because the machine will not cycle if the minimum balloon pressure is not attained with 30 ml of fluid.

All these procedures have been promoted as "cost-saving" compared to hysterectomy. This remains to be proved. Hysterectomies will continue to be performed in large numbers because they stop the bleeding once and for all. There has been a trend, however, toward less invasive approaches such as LAVH and vaginal hysterectomy.

REVIEW #21

Title: U.S. Trends in Obstetric Procedures 1990-2000

Authors: L.J. Kozak, PhD and J. D. Weeks, PhD

Site: National Center for Health Statistics, Hyattsville, Maryland

Published : Birth 29:3 September 2002 157-161

Objective: During the 1980s, the rate of obstetric procedures during delivery increased dramatically. This paper examines the trends in obstetric procedures during the period 1990 to 2000 and compares them with data from the previous decade.

Methods: Data on total obstetric procedures and eight specific procedures (cesarean section, medical and surgical induction of labor, artificial rupture of membranes, episiotomy, repair of obstetric laceration, vacuum extraction, forceps delivery) were obtained from the National Hospital Discharge Survey (NHDS). The NHDS has been conducted by the National Center for Health Statistics annually since 1965. The ICD-9-CM discharge codes were collected from a sample of 32,000 inpatient records in 505 hospitals

Results: In 1980, 93.7 procedures were performed per 100 deliveries. By 1990, that rate had increased to 165.5 per 100 deliveries. During the following 10-year period, the *overall* rate of intervention remained stable, but the frequency of specific procedures underwent significant change.
Cesarean Section: After peaking at 24.7% in 1988, the C/S rate dropped to 20.8% by 1995; by 2000, the incidence had crept back up to 22.9%. The VBAC rate has mirrored the C/S rate: it increased dramatically from 20.4% in 1990, to 35.5% in 1995, and declined to 27.6% by 2000.
Induction of Labor: Medical induction of labor was reported in only 1% of deliveries in 1980. By 1990, this had increased to 5.6% and reached 11.7% by 2000. Surgical induction (ARM), rarely reported in 1980, was employed in 3.7% of deliveries in 2000.
Vacuum Extraction: Increased from 0.7% of vaginal births in 1980, to 6.1% in 1990; the rate peaked at 9.6% in 1996, and dropped to 8.4% by 2000.
Forceps Delivery: In 1980, 17.7% of deliveries were accomplished using forceps. By 1990, the rate had dropped to 8.6%, and there has been a steady decline to 4.0% by 2000.
Episiotomy: In 1980, episiotomy was performed in 64% of vaginal births. This decreased to 55.6% by 1990, and the rate has dropped steadily to 32.7% by 2000.
Repair of Obstetric lacerations: This has increased as the number of episiotomies has decreased, from 11.1% in 1980, to 25.5% in 1990, up to 39.2% by 2000. In 2000, 23% of the repairs were for 3rd or 4th degree lacerations, versus 45% in 1990. This represents a 22.4% drop in the actual number of major lacerations during the decade.

Conclusions: Unlike the 1980s, the overall rate of obstetric procedures did not increase from 1990 to 2000, but the mix of procedures performed continued to change during this period.

Commentary: This compilation of obstetric data might serve as a starting point for further research. The numbers document what obstetricians already know: operative vaginal deliveries and episiotomies are less common than they used to be. The authors ---neither of them clinicians--- wisely make no attempt to interpret the results. Because ICD-9-CM codes were designed for billing,

not clinical research, it is likely that non-billable services and procedures will be underestimated in this type of study. This is particularly true in Obstetrics where a global fee is paid for delivery.

The reported frequency of induction does not correspond to my experience. Even in 1980, many patients were being induced for elective reasons, especially in community hospitals; the induction and cesarean rate has always been higher on the "private" service of teaching hospitals. In the past few years, virtually everyone who has not delivered by 41 weeks is admitted for induction: that's about a quarter of all patients. That doesn't include women induced for "textbook" maternal and fetal indications, nor those delivered for either physician or parental convenience. The latter are rarely coded as inductions, particularly if the patient undergoes artificial rupture of membranes and does not require prostaglandins.

First and second degree obstetric tears are so common, and their repair so routine, that they are often not coded separately.

The devil is in the details and this report does not provide enough details relevant to the Obstetrician. Of more interest than the decrease in forceps delivery would be the changing indications for intervention, as well as the difficulty of the operation itself. That sort of information can only be found by delving into actual patient charts.

REVIEW #22

Title: Has the use of episiotomy decreased? Examination of episiotomy rates from 1983 to 2000

Authors: J. Goldberg, D. Holtz, T. Hyslop, J.E. Tolosa

Site: Jefferson medical College, Philadelphia, PA

Published: Obstet Gynecol 2002;99: 395-400

Objective: To determine if practice patterns have been altered by the large body of literature strongly advocating the selective use of episiotomy.

Methods: Data from the medical procedures database at Thomas Jefferson University Hospital was retrieved electronically for the 34,048 vaginal births from 1983 to 2000. The cumulative percentage of patients classified as white, black, Asian, Hispanic, or other, were 40.5%, 49%, 2.5%, 1.2%, and 6.8%, respectively. Univariate and multivariate models were computed using logistic regression models.

Results: The episiotomy rate dropped from 69.6% in 1983 to 19.4% in 2000. In white women, the rate decreased from 79% to 32.1%, whereas in Black women, the rate decreased from 60.5% to 11.2% during the study period. Cumulatively, episiotomy was performed in 43.3% of spontaneous births, 71.7% of vacuum-assisted deliveries, and 90% of forceps deliveries. The incidence of forceps declined from 19.8% in 1983 to a nadir of 6.5% in 1991, rising again to 11.7% in 2000. Vacuum use increased from 2.5% in 1983, peaked to 12.6% in 1991, and had dropped to 1.2% in 2000.

Decreased episiotomy rates were significantly ($P < .001$) associated with non-white race [63.8% for whites, 39.4% for blacks], MEDICAID status [28.4% versus 47.4%], SVDs [43.3% versus 82.8%]. Women having a 3rd or 4th degree perineal laceration were significantly more likely to have received an episiotomy [85.4% versus 46.5%, $P < .001$].

Conclusions: There was a statistically significant reduction in the overall episiotomy rate between 1983 and 2000. White women consistently had more episiotomies than black women, even when controlling for age, parity, insurance status, and operative vaginal delivery.

Commentary: The authors present convincing data that the frequency of episiotomy has decreased in their institution, and they have identified interesting racial differences. Their results don't address the reasons for this changed practice. That would have required an opinion survey of the obstetricians in their hospital. It would be interesting to know if the episiotomy rate of individual doctors has changed over the years, and why.

The type of episiotomy was not reported, but it is likely that the incidence of medio-lateral episiotomy has decreased significantly, in proportion to the falling number of mid-forceps deliveries. Although not the focus of their paper, the data on operative vaginal delivery was perplexing: it seems odd that the incidence of vacuum extraction in 2000 is lower than in 1983.

As someone who trained in hospitals where a high proportion of births were accomplished with forceps, I remember the "controlled elegance" of an outlet forceps. In hindsight, most of these were easy because they were unnecessary: spontaneous birth would have occurred eventually.

Convinced that prolonged pounding of the fetal head against a rigid perineum caused brain injury, DeLee proposed his “prophylactic forceps” operation in 1922; medio-lateral “perineotomy” was an integral part of the technique. DeLee himself said: “I myself would consider this meddlesome midwifery, were it not for the gratifying results I have obtained”. Despite criticism from Williams and other “conservatives”, the concept of an arbitrary second-stage duration took root, and influenced generations of American obstetricians until very recently. There is no doubt that, in the absence of fetal monitoring during the second stage, many babies were saved by this pro-active approach. A generous episiotomy undoubtedly facilitated delivery, and was easier to repair than a jagged laceration. The push toward fewer episiotomies certainly did not come from American obstetricians. Doctors usually emulate the practice style of their mentors during training, and are slow to change their habits.

DeLee commented that less scrupulous doctors might use forceps to hasten delivery for their own convenience; many of the unfortunate outcomes linked to forceps in the public mind have resulted from such nonchalance. Consumer resistance to the use of forceps—and the associated fear of litigation—reduced their frequency and, concomitantly, the number of large episiotomies. Median episiotomies have largely replaced mediolaterals, but at least 10% extend through the anal sphincter. This used to be considered trivial –indeed I have known doctors who deliberately performed procto-episiotomy—but the urogynecologic literature supports the notion that sphincter injury causes long-term functional impairment despite anatomical repair.

REVIEW #23

Title: Outcome after elective labor induction in nulliparous women: a matched cohort study

Authors: H. Cammu, G. Martens, G. Ruyssinck, J.J. Amy

Site: Academic Hospital-Free University Brussels, and University Hospital, Ghent, Belgium

Published: Am J Obstet Gynecol 2002;186:240-4

Objective: To determine whether elective induction of labor in nulliparous women is associated with changes in fetomaternal outcome when compared with spontaneous labor.

Methods: All 80 labor wards in Northern Belgium comprised a matched cohort study. From 1996 through 1997, 7683 women with elective induced labor and 7683 women with spontaneous labor were selected according to the following criteria: nulliparity, singleton pregnancy, cephalic presentation, gestational age at the time of delivery of 266 to 287 days, and birth weight between 3000 and 4000g. Both groups were compared with respect to the incidence of cesarean delivery, instrumental delivery, and transfer to the neonatal ward.

Results: Cesarean delivery [9.9% vs 6.5%], instrumental delivery [31.6% vs 29.1%], epidural anesthesia [80% vs 58%], and transfer to the neonatal ward [10.7% vs 9.4%] were significantly more common [$P < .01$] when labor was induced electively. The difference in cesarean delivery was due to significantly more 1st-stage arrest in the induced group. The difference in neonatal admission could be attributed to a higher admission rate for maternal convenience when the woman had a cesarean.

Conclusions: Elective labor induction in nulliparous women is associated with significantly more operative deliveries.

Commentary: Unlike the U.S., where elective induction is widely employed but not acknowledged, there seems to be no stigma attached to the practice in Northern Belgium. Indeed, 21% of primiparous labors were induced electively between 1996 and 1997. Elective induction is more frequent in university hospitals, again unlike the U.S., giving it the *imprimatur* of academic authority.

Delivery occurred at an average 39.8 weeks' gestation. It should not surprise anyone that elective induction of primigravidas leads to more epidurals and cesareans. However, the Belgian population must be very different from ours: the cesarean rate in the induced group was only 9.9%; in the U.S., that number would be 3-4 times greater. The C/S rate in the spontaneous labor group was only 6.5%--again much lower than in the U.S. Interestingly, approximately 30% of patients in both groups were delivered instrumentally, a rate much higher than in the U.S. No information is provided about the type of operative vaginal delivery, but it may be that in this country cesarean section would have been performed instead.

REVIEW #24

Title: The Impact of a single-layer or double-layer closure on uterine rupture

Authors: E. Bujold, C. Bujold, E.F. Hamilton, F. Harel, R.J. Gauthier

Site: Hôpital Ste-Justine(Université de Montréal) and McGill University, Montréal, Québec

Published: Obstet Gynecol 2002;186:1326-30

Objective: To measure the impact of a single-layer or double-layer closure of the lower segment incision at Cesarean on uterine rupture during subsequent delivery.

Methods: This is an observational cohort study of all women undergoing a trial of labor from 1988 to 2000 in a tertiary care center, after a single low transverse cesarean delivery. Factors most highly associated with uterine rupture were identified using univariate regression analysis. Multivariate logistic regression analysis was used to adjust for selected confounding variables. 2142 women met the study criteria; maternal records and operative reports were reviewed in 1980 (92.4%).

Results: 23 cases of uterine rupture were reviewed. After adjusting for confounding variables, the odds ratio for uterine rupture in women with a single-layer closure was 3.95 [95% C.I., 1.35 – 11.49].

Conclusions: A single-layer closure of the previous lower segment incision was associated with a 4-fold increase in the risk of uterine rupture compared with a double-layer closure.

Commentary: The good news is that significant uterine rupture occurred only 23 times in 1980 VBACs: in 15 (3.1%) of the 489 women with a previous single-layer closure and in 8 of the 1491 women with a double-layer closure. Chromic catgut was the suture material in 97.9% of the 1980 women; the rest were sutured with polyglactin 910. All patients with uterine rupture had their first uterine incision sutured with chromic catgut. None of the ruptures occurred before labor. The authors provide no information about maternal or fetal outcome.

The last twenty years have witnessed a sea change in American obstetric and surgical practice. Many surgeons now rarely close peritoneum or perform a bladder flap, and many suture the lower segment in a single layer. This reduces operating time and does not appear to be associated with any significant short-term complications.

The uterine ruptures may be related to the use of chromic catgut. This material frays badly when tied, loses its tensile strength rapidly, and causes a more intense inflammatory response that the newer absorbable sutures. In our institution, only one doctor still uses chromic for cesarean section, and he trained over 30 years ago, when VBACs were not planned.

The concerns raised in this paper can only be answered by a prospective trial using different suture materials. Because of the low incidence of uterine rupture, and the decreasing VBAC rate, it will take a very large number of subjects to reach statistical significance.

REVIEW #25

Title: Association between the use of antenatal magnesium sulfate in preterm labor and adverse outcomes in infants

Authors: R. Mittendorf, J. Dambrosia, P.G. Pryde, K-S Lee, J.G. Gianopoulos, R.E. Besinger, P.G. Tomich

Sites: Loyola University Medical Center, Maywood, IL

Published: Am J Obstet Gynecol 2002; 186: 1111-8

Objective: To determine whether the use of antenatal magnesium sulfate prevents adverse neonatal outcomes (intraventricular hemorrhage, periventricular leucomalacia, death, and cerebral palsy).

Methods: 149 women admitted in labor before 34 weeks were classified into two groups: Group A: 92 eligible for "aggressive tocolysis" [cervix < 4 cm dilatation] and Group B: 57 with cervix > 4 cm.

Women in Group A were randomized to receive either magnesium sulfate tocolysis or "other" tocolysis. Women in Group B were randomized to receive either "neuroprotective" magnesium sulfate or saline control.

At delivery, umbilical blood was collected for later measurement of ionized magnesium. IVH and periventricular leukomalacia was diagnosed by serial cranial ultrasound. Among survivors, the diagnosis of cerebral palsy was made at 18 months.

Results: Children with adverse outcomes had higher umbilical cord magnesium levels at delivery. In regression models that controlled for confounders, which included very low birth weight, magnesium remained a significant risk factor [O.R., 3.7; 95% C.I., 1.1 –11.9, P = .03]

Conclusions: Contrary to original hypotheses, this randomized trial found that the use of antenatal magnesium sulfate was associated with worse perinatal outcome, in a dose-related fashion. These findings, combined with the tenuous scientific support for the efficacy of magnesium sulfate as a tocolytic agent, prompt the authors to recommend abandoning magnesium sulfate for tocolysis except in controlled clinical trials.

Commentary: This article summarizes the findings of the Magnesium and Neurologic Endpoints Trial, the so-called *Mag*NET *Trial*. Multivariate analyses revealed that clinical evidence of chorioamnionitis and cord blood ionized magnesium were independently strongly associated with adverse outcomes, whereas vaginal bleeding before delivery and very low birth weight were insignificant.

Two other large randomized controlled trials, one in the U.S., the other in Australia, are currently studying the putative neuroprotective benefits of magnesium sulfate in the setting of premature labor. These studies should provide definitive data that may sound the death knell of magnesium sulfate as a tocolytic agent.

The authors offer no theories on how magnesium sulfate causes neurologic injury. Magnesium is naturally found in the human body. It has been used for eclamptic seizure prevention,

although its mechanism of action is unknown; there is no evidence that it crosses the blood-brain barrier or stops EEG seizure activity, but it does cause hypotonia and seems to work. It is not a great tocolytic, but has a better safety profile than alcohol, beta-mimetics, calcium-channel blockers or NSAIDs. At increasing serum levels, magnesium first causes respiratory arrest then, much like potassium, cardiac asystole which can be reversed with ionized calcium. Since magnesium is excreted by the kidneys, serum levels should be checked frequently in patient with impaired renal function.

REVIEW #26

Title: Spontaneous abortion: expectant management, medical treatment or surgical evacuation

Authors: L Gronlund, AL Gronlund, L Clevin, B Andersen, N Palmgren

Site: Herlev University Hospital, Denmark

Published : Acta Obstet Gynecol Scand 2002; 81: 781-782

Objective: The aim of this study was to compare expectant management, vaginal misoprostol and surgical evacuation in women with incomplete spontaneous first-trimester abortion.

Methods: Three gynecologic departments in Copenhagen county participated in this prospective crossover study with alternating treatments every 4 months during 1 year.

Entry criteria were: fresh bleeding, +UCG or HCG > 30 IU/L, transvaginal US demonstrating retained products of conception (A-P diameter 15 – 50 mm) or CRL < 50mm with no cardiac activity if a fetus was visible. Exclusion criteria included suspicion of ectopic pregnancy, heavy bleeding or signs of infection.

The three treatment regimens were: expectant management (EM), medical treatment with 400mcg vaginal misoprostol (MT) and surgical evacuation under general anesthesia (SE).

HCG was measured on days 1, 8 and 14. US was done on day 8. If products > 15 mm or a gestational sac was present, US was repeated at day 14. Persistence of products on day 14 led to surgical evacuation. The patients were asked to return a questionnaire after 21 days.

Results: Of 224 women presenting with spontaneous abortion during the 1-yr study period, 124 were eligible and agreed to participate.

EM was successful in 82%, MT in 90% and SE in 97% of women. Two women in the EM + MT groups were treated with antibiotics for presumed endometritis.

83% of the women returned the questionnaire. The reported length of bleeding in the three groups was: EM 6.5 days, MT 7.6 days, and SE 0.4 days. Number of days with analgesic need: EM 1.8 days, MT 2.1 days and SE 0.4 days. The proportion of women recommending the specific regimens were: EM 62%, MT 67% and SE 84%.

Conclusions: Expectant management is successful in most patients with early incomplete spontaneous abortion, but implies a few days more bleeding than surgical intervention. Misoprostol, preferably given vaginally, may increase the rate of complete expulsion.

Commentary: The ready availability of quantitative HCG and endovaginal U.S. has facilitated the early diagnosis of failed pregnancy. This has created new management problems.

In the past (and , surprisingly, still today) women presenting with mild bleeding or cramping in the first trimester were told to rest, avoid sex and heavy lifting, with the knowledge that roughly 50% of them would go on to have a normal pregnancy. Some of our more “scientific” ancestors, misinterpreting the low hormone levels associated with failed pregnancy, prescribed DES. A whole generation of women was saddled with the burden of this misguided intervention. One still hears of patients with recurrent early pregnancy loss empirically receiving vaginal progesterone during the first trimester. Heavy bleeding and spontaneous abortion were followed by D&C, and patients counseled to wait at least three months before trying to get pregnant again.

Women presenting for their first prenatal visit often undergo office U.S. in the absence of any indication other than to confirm dates and provide a joyous “photo opportunity” for the new parents. Every few weeks, this excellent bit of P.R. is spoiled by failure to show the expected active fetus. There follow concern, tears, and numerous questions about “why?”; the more pragmatic ask “what now?”.

Even in the presence of reliable dates and documented early pregnancy tests some women, feeling all the symptoms of pregnancy, and having had no bleeding, refuse to accept the diagnosis, preferring to wait and repeat U.S. and HCG levels.

The majority, once they realize theirs is not a viable pregnancy, want it over as soon as possible and are not amenable to “expectant” management—particularly when nobody can give them a straight answer about how long they will have to wait for a miscarriage. Indeed, missed abortion diagnosed at 10-12 weeks’ gestation often shows fetal demise that occurred at least a month earlier without any clinical symptoms or signs of failed pregnancy.

There is no question that surgical evacuation of the uterus is the most efficient way to deal with failed pregnancy. As this study ---and most clinicians’ experience--- demonstrates, D&C is associated with the shortest duration of bleeding, pain, and greater patient satisfaction compared with expectant or medical management strategies.

However, no matter how emotionally taxing this diagnosis may be for the patient, missed abortion hardly qualifies as a medical emergency, and it is often difficult for the clinician to arrange a D&C on short notice. While manual vacuum aspiration in an office or clinic setting would be the most cost-effective approach, many patients experiencing pregnancy loss are not as highly-motivated as women undergoing termination and refuse procedures under local anesthesia—preferring “not to feel anything”. As a result, there may be a few days’ delay before elective O.R. time becomes available. In the meantime they are instructed to go to the E.R. if they have heavy bleeding or cramping, and many will get their D&C on an emergency basis.

Some women definitely want to avoid an operation and are willing to wait, hoping that they will have a complete abortion. Long before there were doctors to do D&Cs, women has miscarriages and most survived the experience without surgical intervention. Life-threatening hemorrhage and D.I.C. are very rare in first trimester abortions. Experience with medical abortion led to the idea that administration of a prostaglandin could accelerate spontaneous evacuation of a failed pregnancy. The low-cost and availability of misoprostol made it a natural choice for this purpose. Misoprostol (CYTOTEC©) is FDA-approved for the prevention of gastric ulcers in patients taking long-term NSAIDs, and prolonged use of 800µg/day has been shown to be safe, with few serious side-effects. In this study shows a single 400µg vaginal dose of misoprostol led to a greater percentage of complete abortion than expectant management, but was associated with more days of bleeding and cramping. Even though vaginal use may be more effective than oral –and this is not really proved--, repeated oral doses can be administered without office visits and I think this will turn out to be the most practical and cost-effective medical approach.

REVIEW #27

Title: Laparoscopic management of ovarian dermoid cysts. A series of 83 cases.

Authors: C Berg, U Berndorff, K Diedrich, E Malik

Site: Medical University of Lübeck, Germany

Published: Arch Gynecol Obstet 2002; 266: 126-129

Objective: To review the outcome of laparoscopic surgery for suspected ovarian dermoid cysts.

Methods: This was a retrospective survey of 83 patients who underwent laparoscopic removal of a benign dermoid cyst between 1994 and 2001.

Results: Pre-operative transvaginal sonography correctly identified a dermoid in 57 cases (68.7%). Mean tumor size was 4.7 ± 1.9 cm. 24 patients, mostly peri- or post menopausal, had salpingo-oophorectomy, while the other 59 had cystectomy. An endobag was used to remove the specimen in 62 of 83 cases (74.7%). Operating time was similar in both groups (83 minutes v 86 minutes). Spillage of cyst contents occurred in 8/24 (33.3%) of salpingo-oophorectomies, and 39/59 (66.2%) of cystectomies; cyst rupture with spillage happened only during mobilization, never during removal of the specimen from the abdomen. In cases of spillage, the abdominal cavity was rinsed with a minimum 3L of saline solution. No intra- or post-operative complications or chemical peritonitis occurred. The authors compare their results with those in 17 published reports on this subject.

Conclusions: Laparoscopic removal of small dermoids can be accomplished safely using laparoscopic techniques.

Commentary: This review will re-assure gynecologists that intraperitoneal spillage of dermoid-cyst contents is not as serious as they were led to believe in residency. Although spillage was reported in a majority of cases, copious irrigation of the abdominal cavity seemed to prevent any clinical peritonitis. Long-term follow-up would be needed to confirm that fertility was unaffected by this approach.

Few operations are as satisfying for the GYN surgeon as the intact removal of a paper-thin cyst; at laparotomy, the ovary can usually be mobilized through the incision, surrounded by sponges in the event of spillage, the capsule delicately incised with a scalpel and the cyst “peeled out” in just a few minutes. By contrast, laparoscopic ovarian cystectomy lacks elegance, even in expert hands; in 17 published studies reviewed by the authors, spillage occurred in a high percentage of cases. Despite longer operating times ---particularly in a teaching hospital--- successful minimally invasive removal undoubtedly reduces hospital length-of-stay and may reduce the convalescence time. Esthetics aside, the surgeon should always select the operation that is safest for the patient; this will usually be the procedure s/he is most familiar with.

The possibility of malignancy must be entertained whenever surgery is performed for a complex adnexal mass. In this study, only 68% of dermoid cysts were correctly diagnosed by Ultrasound. The risk of spillage in a case of unexpected malignancy is controversial, but it would seem prudent to remove the entire ovary rather than attempt cystectomy in a woman who has completed her family.

REVIEW #28

Title: Acceptance of altering the standard 21-day/7-day oral contraceptive regimen to delay menses and reduce hormone withdrawal symptoms

Authors: PJ Sulak, TJ Kuehl, M Ortiz, BL Schull

Site: Scott & White Clinic, Texas A & M University, Temple, Texas

Published: Am J Obstet Gynecol 2002; 186: 1142-9

Objective: Measure acceptance and use of shortening the hormone-free interval in combination oral contraceptive pills to reduce the frequency and severity of hormone withdrawal symptoms.

Methods: This was a retrospective review of patients on OCs with unwanted hormone withdrawal symptoms who were counseled by one gynecologist (PJS) about altering their standard 21/7 regimen. All patients used a monophasic 30 to 35 µg pill and underwent an initial counseling visit between 1993 and 2000. Patients were free to choose how long to stay on active pills; they were given a simple menstrual calendar to record spotting or bleeding. They were also instructed to record hormone-free days, and asked to rate their quality of life on a scale of 0 to 10.

Results: Of 318 women counseled on extending the number of active pills, 292 (92%) had documented follow-up. The primary reason for extending the number of active pills was to decrease symptoms of headache (35%), dysmenorrhea (21%), hypermenorrhea (19%), and premenstrual symptoms (13%). The remaining 12% cited convenience, endometriosis, or peri-menstrual acne.

25 patients (9%), chose not to change their regimen after counseling, mostly because they preferred to have regular periods. Of 267 patients who initiated an extended regimen, 57 discontinued OCs, 38 returned to a standard regimen, and 172 were extending use at the last follow-up. 46% of the women continued extended use for at least 5 years,

There were multiple reasons for discontinuing the OC: worsening of side-effects (42%), desire for pregnancy (23%).

Most of the 38 women who returned to the usual 21/7 OC regimen did so because of unscheduled bleeding or spotting.

In the 172 women who continued an extended OC regimen, the pattern of active pill use showed remarkable variation: a mean of 12 ± 12 weeks of active pills, with a median of 9 weeks, and a range of 104 weeks. The typical pill-free interval was 6 ± 2 days.

Not surprisingly, the quality-of-life measure was significantly better ($P < .00001$) in the women who continued an extended OC regimen, compared to those who stopped the pill or returned to the standard regimen.

No unintended pregnancies or serious complications were observed in these women.

Conclusions: A majority of women with hormone withdrawal symptoms on OCs will initiate a regimen of extended active pills, often with a shortened hormone-free interval, to reduce the frequency and severity of associated symptoms.

Commentary: The principal investigator (PJS) admits to a potential bias: “the counseling of all patients by a single physician who has a strong belief that monthly menses are unnecessary and, in fact, create a multitude of problems for many women”. Although the women were apparently informed of this bias, it is unclear whether the author’s admitted “clinical practice pattern since

1993” was intended as a research project from the beginning. In any case, Institutional Review Board approval was obtained for a retrospective review of her database.

When combination OCs were first introduced, the placebo pills were added to provide a withdrawal bleed that would mimic menstruation. This was reassuring to sexually-active women worried about pregnancy, and made it seem more “natural”. However, many women continued to have dysmenorrhea and a variety of symptoms most marked during the placebo week.

Gynecologists have known for years that menses could be delayed by omitting the sugar pills, and many a new bride has taken advantage of this possibility. Of course, continuous OC therapy ---pseudo-pregnancy--- has long been employed in the treatment of endometriosis.

64% of women with unwanted hormone withdrawal symptoms felt much better when skipping the placebo pills; this offers hope to many women who have problems with the pill. However each woman in this study was free to adjust the number of active pill days and pill-free intervals to suit herself; this does not permit any general recommendation about an “ideal regimen”. Indeed, it is possible that the sense of “control” associated with fine-tuning the regimen might in itself be therapeutic. This hypothesis could be tested in a prospective trial.

No significant short-term adverse effects were reported. However, recent reports showing increased breast cancer, MIs and CVAs in patients taking continuous estrogen-progestin HRT for more than 4 years should raise concerns about the long-term use of this type of regimen, particularly since OCs contain 4-6 times the amount of E/P as HRT. The low incidence of these adverse events in young women will make it difficult to show an association, but it is not unreasonable to discourage patients with significant risk factors from this therapy.

REVIEW #29

Title: Impact of early postpartum administration of progestin-only hormonal contraceptives compared with non-hormonal contraceptives on short-term breast-feeding patterns

Authors: LD Halderman, AL Nelson

Site: UCLA, Torrance, California

Published: Am J Obstet Gynecol 2002; 186: 1250-8

Objective: To identify the impact on breast-feeding patterns of early postpartum initiation of progestin-only contraception compared with non-hormonal methods.

Methods: A prospective, non-randomized trial was performed comparing progestin-only contraceptive methods administered before hospital discharge with non-hormonal methods on breast-feeding continuation rates, exclusive breast-feeding, and supplementation at 2, 4, and 6 weeks after delivery. Of 319 patients who were breast-feeding at the time of discharge from the hospital, 181 used progestin-only methods (102 DMPA, 77 pills, 2 NORPLANT) and 138 planned to use nonhormonal methods.

Results: By week six, 270 patients were available for study. 201 were still breast-feeding, although two-thirds were supplementing. There was no significant difference in breast-feeding continuation rates, or discontinuation because of insufficient milk, between the women receiving progestin-only contraception and those not on hormones.

Conclusions: This study demonstrates no detectable adverse impact on breast-feeding attributable to progestin-only contraceptive methods initiated within the first three days postpartum.

Commentary: Breast-feeding without supplementation is associated with prolonged amenorrhea and provides effective contraception. The short maternity leaves available to working US women discourage this approach to birth-control, and most American women need something more predictable.

This study, although small and not randomized, supports the widely-held notion that progestin-only contraceptives do not inhibit milk production. Combination OCs have traditionally not been prescribed to lactating mother on the theoretical grounds that estrogen inhibits prolactin binding to receptors in breast tissue and would dry up the milk. Whether this is true remains conjectural, particularly if the milk supply is already well-established.

Standard postpartum discharge instructions typically tell patients to avoid intercourse until the lochia have stopped, and few women in a middle-class practice admit to having had intercourse before their 6-week check-up. Besides, they and their partners are usually too tired to be interested in anything except sleep. In public clinics, patients (or their partners) are deemed less reliable and a pre-emptive approach to contraception is widely employed: the administration of long-acting progestins before discharge from the hospital. It is unfortunate that NORPLANT is no longer available, since that provided 5 years of contraception and its removal required a conscious decision on the part of the patient.

REVIEW #30

Title: Premenstrual Daily Fluoxetine for premenstrual dysphoric disorder: A placebo-controlled, clinical trial using computerized diaries.

Authors: LS Cohen, C Miner, E Brown, EW Freeman, U Halbreich, K Sundell, S McCray

Sites: Multicenter: Harvard Medical School (Boston), U of Pennsylvania (Philadelphia), State U of New York (Buffalo), Lilly Research Laboratories (Indianapolis)

Published: Obstet Gynecol 2002; 100: 435-44

Objective: To evaluate premenstrual daily dosing with fluoxetine for treatment of premenstrual dysphoric disorder.

Methods: After a two-cycle screening and one-cycle single-blind placebo period, 260 women were randomized to fluoxetine 10 mg, fluoxetine 20 mg, or placebo (dosed daily from 14 days before the next expected period through the first full day of bleeding) for three cycles. Women recorded premenstrual dysphoric disorder symptoms daily using a computerized version of the Daily Record of Severity of Problems (DRSP).

Results: Premenstrual daily fluoxetine 20 mg demonstrated significant improvement in mean DRSP luteal scores compared with placebo (P= .005); premenstrual daily fluoxetine 10 mg did not (P= .100). DRSP total scores were statistically significantly improved by the first treatment cycle for both active treatment groups. However, only fluoxetine 20 mg remained significantly superior to placebo throughout the active treatment phase of the trial. Both fluoxetine groups showed significant treatment advantage over placebo for mood-related symptoms ($P < .05$). Only fluoxetine 20 mg showed significant treatment advantage over placebo for physical symptoms of breast tenderness ($P < .001$), bloating ($P < .001$), and joint/muscle pain ($P = .037$). Treatment was well-tolerated; discontinuation due to adverse events did not differ among the three groups (P= .316).

Conclusions: Luteal phase fluoxetine effectively treats mood, physical, and social functioning symptoms associated with premenstrual dysphoric disorder. Fluoxetine 20 mg appears to be more effective than fluoxetine 10 mg, and was tolerated just as well.

Commentary: Daily fluoxetine throughout the menstrual cycle is FDA-approved for the treatment of PDD. This study confirms that fluoxetine dosing during the luteal phase is equally effective in relieving symptoms. The advantages of this approach include lower cost and possibly fewer side effects.

When used for the treatment of depression, SSRIs typically take several weeks to achieve therapeutic results, so it seems surprising that the effect of fluoxetine on pre-menstrual symptoms should be so rapid. More startling, were the beneficial effect on mastalgia and bloating. Elucidating the pharmacology of fluoxetine in PDD will have to await a better understanding of why PDD (formerly-known as PMS) occurs in some women but not in others. Anecdotally, other SSRIs are also effective for PDD.

Experience has shown “PMS” to be a stubborn condition, and it is unlikely that fluoxetine will be effective in all cases. Over the years, many treatments have been proposed for this condition. RCTs have found the following classes of drugs to be of significant benefit[1] (versus placebo) in the management of premenstrual symptoms: NSAIDs, SSRIs, spironolactone/diuretics, danazol, GNRH

analogs. Some RCTs have shown limited benefits of cognitive behavioral treatment, exercise, estrogens, bromocriptine (mastalgia only).

Treatments of unknown effectiveness include chiropractic treatment, dietary supplements, endometrial ablation, evening primrose oil, laparoscopic bilateral oophorectomy, reflexology, oral contraceptives, progestogens, tibolone and vitamin B6.

Observational studies have found that hysterectomy plus bilateral oophorectomy is curative. In 1872 Robert Battey of Augusta, Georgia described the removal of normal ovaries from " a young lady who was suffering serious detriment to her health and peril to her life by reason of an excessive menstrual molimen which was wholly unrelieved by the usual menstrual flux."

1. Clinical Evidence, BMJ Publishing Group, June 2002 p.338-339

REVIEW #31

Title: Work Loss Associated with Increased Menstrual Loss in the United States

Authors: I. Côté, P. Jacobs, D. Cumming

Site: Institute of Health Economics; Departments of Public Health Sciences, and Obstetrics and Gynecology, University of Alberta, Canada

Published : Obstet Gynecol 2002; 100: 683-87

Objective: To estimate the effect of increased menstrual flow on the loss of employment among working women in the United States.

Methods: Data from the 1999 National Health Interview Survey (NHIS) were analyzed. The NHIS is an annual, personal interview household survey, using a nationwide representative sample of the civilian noninstitutionalized population of the United States. In 1999, questions about female health issues such as menstrual cycles were added to the questionnaire. Analysis was performed using data from 2805 women aged between 18 and 64 who reported having a natural menstrual period in the last 12 months and in the last 3 months and were not taking hormones or diagnosed with reproductive tract cancer. Of these women, 373 had self-described "heavy flow", while the other 2432 had "normal flow".

The menstrual flow characteristics were correlated to employment status reported in the NHIS.

Results: Using binary logistic regression, age, marital status, education, family size, perception of health, and menstrual flow are associated with work losses ($P < .05$). Women who have a heavier menstrual flow are 72% as likely to be working as are women who have normal flow.

Conclusions: Menstrual bleeding has significant economic implications for women in the workplace: work loss from increased blood flow is estimated to be $1692 annually per woman.

Commentary: The authors are to be commended for choosing to examine this important topic. Gynecologists hear first-hand how debilitating long and heavy periods can be. The embarrassment and nuisance of flooding through the thickest pads keeps many women close to home for a day or two each month. Even in the absence of demonstrable anemia, prolonged bleeding is commonly associated with profound fatigue. Add doctors' appointments for diagnosis or treatment, and there is no question that menstrual problems contribute to absenteeism from work —and likely affect productivity as well.

The conclusions of this study appear so plausible that is would be easy to ignore the shaky foundation on which they rest. This reviewer is not familiar with the methodology of the NHIS, but the notion that the 17,599 adult women interviewed in 1999 were a truly random sampling of the U.S. population strains credulity. The authors themselves question the reliability of the sampling: "there are segments of the population which may be under-represented…, such as the homeless. Such persons are less likely to work…". One could equally have said: " such as working women" since, unless interviewers do their work around the clock, working women are less likely to be at home. Also, people who consent to answer a long and detailed questionnaire may not be representative of the population. As an aside, this type of selection bias may help explain the seemingly contradictory results of various published randomized clinical trials.

Assuming the validity of the NHIS sampling, it is not clear why the authors chose to exclude from their analysis 5509 women who had taken medication containing estrogen. Most of them were likely on OCPs, either for contraception, cycle-control, or both; they would also most likely have had light to normal periods. So instead of 373/2805 (13.3%) women with heavy periods, we would have a much smaller percentage [possibly as few as 373/8669 (4.3%)] with menstrual problems — hence a much smaller possible impact on the work force.

In their analysis, the main outcome measure was "work loss associated with the degree of menstrual flow". The interview question used to determine if a woman was in the labor force was: "What were you doing last week? 1) Working at a job or business; 2) With a job or business but not at work; 3) Looking for a job; 4) Not working at a job or business; 5) Refused; 6) Don't know." The authors considered women who answered (1) to be working, and lumped all the others as "not working". In my view, the important category here would have been (2), since women in that group may have been absent from work because of their periods. However, there is nothing in the database to support either that theory, or the authors' assumption that women didn't work because of their heavy periods.

Notwithstanding this vague definition of "work loss", the authors processed their data through SPSS and showed an association ($P < .05$) between age, marital status, education, family size, perception of health, as well as menstrual flow, and "work losses". In Table 1, the authors report "…women having heavy flow were…**less** likely to be white…". In Table 2 (the results of their multivariate analysis), "all factors but race were significantly associated with working". In fact, although not statistically significant at the .05 level, non-whites were MORE likely to be working than whites. This apparent contradiction did not stop the authors from declaring that women with heavier flow are 72% as likely to be working as women with a normal flow—implying that a statistical association is proof of causality! This is the sort of stuff that gave rise to the saying: "There's lies, damned lies, and statistics".

Theories are created to explain observations. When they don't, they need to be revised. Gynecologists know that Black-Americans are at least 2-3 times as likely to have uterine fibroids as Whites. Since fibroids are often associated with menorrhagia unresponsive to hormonal treatment, one would expect more heavy bleeders in non-whites, which is consistent with the data presented here.

As an experienced gynecologist, this reviewer has known many women with heavy/painful/troublesome periods. Some do miss work because of their periods, but I'm not aware of any who don't work at all because of them. When menstrual loss becomes unmanageable by conservative methods, most women seek a surgical solution to their problem. This leads to a short-term absence from the workforce, and the economic impact postulated by the authors will be reduced.

Fishing expeditions in a large database such as the NHIS are an excellent way to identify trends and possible research projects, but they are no substitute for real research. The authors are encouraged to pursue this topic, using a questionnaire that inquires specifically about the impact of menstrual problems on work.

REVIEW #32

Title: A state-wide assessment of the obstetric, anesthesia, and operative team personnel who are available to manage the labors an deliveries and to treat the complications of women who attempt vaginal birth after cesarean delivery.

Authors: J.P. Lavin, L. DiPasquale, S. Crane, and J. Stewart, Jr

Site: Summa Health System and Northeastern Ohio Universities College of Medicine, Akron, Ohio

Published: Am J Obstet Gynecol 2002; 187: 611-4

Objective: To determine on a state-wide basis the range of obstetric, anesthesia, and surgical team personnel who are immediately available to manage the labors and deliveries of women who attempt vaginal birth after a previous cesarean. Additionally, to determine whether any hospitals had stopped performing VBACs or made changes in their VBAC policies as a result of recent American College of Obstetricians and Gynecologists recommendations.

Methods: *Available immediately* was defined as " being present in the hospital". All hospitals that provide obstetric care in the State of Ohio were surveyed to determine whether a full surgical and anesthesia team was available immediately when women attempted VBAC. The hospitals were also asked whether they had stopped allowing VBACs or had made changes in their VBAC policies in response to recent ACOG recommendations. Data were computerized and analyzed by the χ^2 test.

Results: One hundred and thirty (100%) of OHIO hospitals providing Obstetric care responded. Seventy-seven (93.9%) Level I, thirty-five (100%) Level II , and thirteen (100%) Level III hospitals performed VBACs. An Obstetrician was immediately available in 27.3%, 62.9%, and 100% of Level I, II, and III institutions, respectively (P <.001). Anesthesia availability was 39%, 100%, and 100% of Level I, II, and III institutions, respectively (P <.001). A surgical team was available in 35.1%, 97.1%, and 100% of Level I, II, and III institutions, respectively (P <.001). A complete complement was available in 15.6%, 62.9%, and 100% of Level I, II, and III institutions, respectively (P <.001). Two hospitals had stopped performing VBACs, and 10 other hospitals were considering stopping VBACs. Policy changes had been adopted in 15 institutions, and 4 others were considering changes.

Conclusions: Most Level I, and many Level II hospitals provide less than optimum staffing when women are attempting VBAC. Because VBACs are equally distributed among Level I, II and III institutions in OHIO, many women may be attempting VBAC under less than optimal conditions. The data suggest the need for changes in staffing or referral patterns to safely meet the Healthy People 2010 goal of increasing the VBAC rate nationally.

Commentary: Medical practice is more similar to fashion than we like to believe. When I trained, over twenty years ago, VBAC was considered dangerous by my preceptors. I can recall rushing to section someone at 8 cm., lest they rupture their uterus.

The VBAC controversy goes back almost a century. When Newell[1] wrote his monograph on Cesarean Section in 1922, the dictum "Once a Cesarean, always a Cesarean" was already part of folklore, and its origins uncertain. At that time, classical incisions were the norm, and neither antibiotics nor blood transfusions existed; anesthesia was usually ether by drip-mask. In reviewing the mostly anecdotal evidence, Newell reported J.W. Williams' opinion that VBAC was safe if the first cesarean incision had been closed primarily, and the convalescence afebrile. While

acknowledging that uterine rupture occurred in only 2-3% of cases, Newell expressed a firm conviction that elective repeat Cesarean was safer for both mother and baby. This opinion prevailed in the U.S. and, except in a few New York hospitals, VBAC was a rare –and usually unplanned— event until the 1980s.

The tripling of the cesarean rate in the USA during the 1970s raised concerns in some circles that abdominal delivery was being over-utilized. To assess the research-based evidence on the risks and benefits of C/S, the National Institute of Child Health and Human Development (NICHD) created a Task Force on Cesarean Childbirth in 1979. A year later, NICHD sponsored a Consensus Development Conference on Cesarean Childbirth which published its final report[2] in October 1981. Among the many recommendations was a cautious endorsement of vaginal birth after a previous Cesarean. The actual wording is worth repeating:

1. *In hospitals with appropriate facilities, services, and staff for prompt emergency cesarean birth, a proper selection of cases should permit a safe trial of labor and vaginal delivery for women who have had a previous low segment transverse cesarean birth. Informed consent should be obtained before a trial of labor is attempted…*
2. *In hospitals without appropriate facilities…the risk of a trial of labor...may exceed the risk for both mother and infant from a properly timed, elective repeat cesarean.* ***Patients should be informed in advance of the limits of a particular institution's capabilities*** *and of the availability of other institutions capable of offering this service, so that they can make a choice.*

With this *imprimatur*, VBAC protocols were implemented in many hospitals. By later standards, they were quite timid: await spontaneous labor, IV, NPO, no epidurals, no oxytocics, continuous FHR monitoring staff-in-house etc. The rarity of serious complications led to a predictable flurry of enthusiastic case reports, mostly from large academic centers where obstetricians were on-call once a week and had residents to do the work. Within a decade, VBAC had gone mainstream, and the Trial of Labor had become *de rigueur.* C/S and VBAC rates became quality-of-care markers for both doctors and hospitals. Anecdotally, some insurance carriers would not pay for elective repeat cesarean. Obstetricians in smaller communities were dragged kicking into offering VBAC, under pressure from hospital administrators worried about losing market share to larger facilities and "looking good" for JHACO (Joint Commission on Accreditation of Healthcare Organizations).

After a while, it became apparent that patients who had undergone a primary Cesarean after a failed post-dates induction didn't usually go into spontaneous labor the second time either, and that the VBAC rate could be increased by using oxytocin. As familiarity bred contempt, VBAC patients were treated *de facto* in the same manner as other obstetric patients: they were induced with prostaglandin analogs, stimulated with oxytocin, endured long second-stages, and a significant number underwent repeat cesarean after a heroic trial of labor.

The incidence of symptomatic uterine rupture during a trial of labor is widely quoted as less than 1%. Like other obstetric disasters, it is an uncommon experience for the individual obstetrician, but only a matter of time before it happens somewhere. A few well-publicized lawsuits in recent years have focused the profession's attention on these untoward events, and prompted ACOG to recommend that VBACs be carried out only in hospitals equipped to provide prompt emergency cesarean. It took less than a generation for history to repeat itself.

As the OHIO data demonstrate, only 16% of Level I and 63% of Level II hospitals have in-house staff 24 hours a day. In the face of the ACOG guidelines, it would appear medico-legally risky

to offer VBAC in these hospitals. However, a crude cost-analysis explains the reality: assume 1000 deliveries/year, a 25% total C/S rate (65% primary, 35% repeat), and a 35% trial-of-labor rate. This yields approximately 31 VBAC attempts per year. Assuming a 1% rate of uterine rupture, there would be one such event every 3+ years, with perhaps one every 6 years resulting in a catastrophic outcome. If the hospital has to pay $50/h (this is conservative) for each in-house obstetrician and anesthesiologist (if it can find such people), it would cost $880,000/yr, not including additional nursing salaries. From an actuarial point-of-view, it is cheaper to pay higher insurance premiums. However, since most emergency cesareans are NOT performed for suspected uterine rupture, the broader question is raised: "Should all hospitals that provide obstetric care be required to have immediate Cesarean capability around the clock?"

What is the prudent obstetrician to do? Truly informed patient choice is the obvious starting point. Since most reported instances of uterine rupture have happened in the context of induction with prostaglandins (or analogs, such as misoprostol) or prolonged stimulation with oxytocin in the face of slow progress, it would seem wise to avoid these situations. Early intervention in the presence of a non-reassuring FHR tracing or meconium may be golden.

In this day of guidelines and protocols, it is useful to heed a voice from the past, Newell again: "…it is…impossible to lay down any definite rule which can be applied to all cases, but each case must be considered on its merits…".

1. Newell, Franklin S.; Cesarean Section; D. Appleton and Company, 1922 p. 62-66

2. U.S. Department of Health and Human Services; Cesarean Childbirth; NIH Publication No. 82-2067; October 1981

REVIEW #33

Title: Sexually Transmitted Disease Screening by United States Obstetricians and Gynecologists

Authors: M. Hogben, J.S. St. Lawrence, D. Kasprzyk, D.E. Montano, G.W. Counts, D.H. McCree, W. Phillips, and M. Scharbo-DeHaan

Site: CDC, Atlanta, Georgia and University of Washington, Seattle, WA

Published: Obstet Gynecol 2002; 100: 801-7

Objective: To assess compliance with practice guidelines and to determine the extent of missed opportunities for STD prevention by describing screening practices of a national sample of obstetricians and gynecologists and comparing them to the practices of other specialists.

Methods: 7300 physicians in five specialties that diagnose 85% of STDs in the United States were surveyed. Obstetrics and Gynecology (n=647) was one of the five specialties. Besides providing demographic and practice characteristics, respondents answered questions about who they screen (nonpregnant females, pregnant females) and for which bacterial STDs (syphilis, gonorrhea, chlamydia).

Results: Responding Ob/Gyns were most likely to be non-Hispanic white (75%), male (66%), and in their 40s (mode 43 years old). They saw an average 90 patients per week during 47 hours of direct patient care. Approximately 95% were in private practice. 96% screened some patients for at least one STD. Ob/Gyns screened women more frequently than other specialties, but no specialty screened all women or all pregnant women.

Conclusions: Consistent with published guidelines, most Ob/Gyns in this survey screened pregnant women for chlamydia, gonorrhea, and syphilis. Nonetheless, only half of the ObGyns screened non-pregnant women for gonorrhea or chlamydia, and fewer screen nonpregnant women for syphilis.

Commentary: It comes as no surprise that Obstetrician/Gynecologists are more likely to screen for sexually transmitted disease in women than other doctors: they are often a woman's only physician during her reproductive years; their patients expect questions about their sex lives, as well as a pelvic exam.

This survey asked doctors to report their own STD screening practices. Actual screening behavior may be quite different, since people answering a non-anonymous questionnaire may want to appear more "compliant with guidelines" than they really are. Another reason for questioning the accuracy of the responses is the assertion that these physicians saw 90 patients a week in 47 hours of direct patient care. I don't know anyone in private practice (95%! of the respondents) who can make a living seeing only two patients an hour.

Since most screening strategies rely on targeting at-risk populations, it would have been helpful to report patient demographic data; the respondent information, however, makes it likely that we are dealing with insured, middle-class women.

The point of this article is that, by not screening ALL women for STDs, doctors are missing an opportunity to do some good. Yet in their zeal to eliminate STDs, the authors misquote actual U.S. Preventative Task Force recommendations. In fact, the USPTF[1] recommends routine STD screening in pregnancy **only** for syphilis; the rationale is that, despite its low prevalence in most communities, testing is inexpensive, the disease treatable, and the burden of preventable congenital

syphilis heavy. Chlamydia screening is recommended for women under age 26, or at high-risk; gonorrhea and HIV screening are recommended in women at high-risk. In nonpregnant women, STD screening is recommended only in women at high-risk of disease; in the case of chlamydia, sexually-active women under age 26 are considered at higher risk.

Thus, screening guidelines are subject to interpretation, and their implementation falls into the realm of clinical judgment.

> *" The ultimate objective of screening is to reduce mortality and morbidity. Conditions screened for should therefore include important causes of mortality or morbidity, in terms of prevalence, severity, or both. Moreover, such conditions should be amenable to either treatment or prevention when detected early. The screening procedure itself should be safe and easy to perform in order to maximize compliance. The ideal screening test should be capable of identifying a large group of subjects with disease and should also be capable of excluding the majority of those without disease. Harm should be avoided and adverse psychological effects kept to a minimum…Appropriate action should be taken based on explicit criteria when an abnormal result is obtained…adequate health care services should be available for the diagnosis and treatment of confirmed disease…There is widespread ethical, legal, and even medical agreement that screening should be preceded—and followed—by* ***counseling****…Screening should always be offered as an option, which may be accepted or rejected"*[2]

It is unfortunate that many screening tests have been implemented into clinical practice — particularly obstetrics--- without taking into consideration all the factors discussed above. Fear of litigation is often cited as a reason for performing screening tests. It is often easier to screen for "everything" than to spend time counseling patients about whether they really want to have a Triple Test, or cystic fibrosis testing etc. When a result comes back abnormal, this failure to involve the patient in their care can be costly in time for the doctor, and emotional stress for the patient. The second trimester "Fetal Survey", now routine, often identifies minor fetal abnormalities (choroid plexus cysts, echogenic foci in the left ventricle etc) that create a follow-up dilemma for the obstetrician. Payment by third parties has shielded doctors and patients from having to discuss the financial cost of screening. This, in turn, perpetuates screening modalities of limited cost-effectiveness and drives up the cost of health care.

Advances in technology now make it possible to screen for thousands of genetic disorders. It behooves experts in the field to define carefully which groups or individuals would benefit from such screening.

1. Guide to clinical preventive services, 2nd Ed 1996 Williams & Wilkins; 3rd Ed update on the USPTF WEB site.
2. TJ Peters, HIJ Wildschut, and CP Weiner, in When to Screen in Obstetrics and Gynecology, WB Saunders Company Limited 1996, p.11

REVIEW #34

Title: Leukorrhea and bacterial Vaginosis as In-Office Predictors of Cervical Infection in High-Risk Women

Authors: M.M. Hakakha, J. Davis, L.M. Korst, and N.S. Silverman

Site: Cedars-Sinai Medical Center, Los Angeles, CA

Published: Obstet Gynecol 2002; 100: 808-12

Objective: To evaluate 1) whether microscopic detection of leukorrhea or bacterial vaginosis identifies patients at high risk for cervical infection with *Chlamydia trachomatis* or *Neisseria gonorrhoeæ*, and 2) if pregnancy alters the predictive value of these findings.

Methods: Wet-mount screening examination of vaginal discharge was performed on all new patients seen at two resident-staffed clinics serving primarily indigent women. Leukorrhea was defined as > 10 WBCs per high power field (400X) on microscopic examination; Amsel criteria were used to determine the presence of bacterial vaginosis, with a positive clue cell test result defined as > 20% of epithelial cells. The diagnoses of C Trachomatis and N Gonorrhoeae infection were established by DNA amplification tests.

Results: The study population consisted of 194 women, 118 of whom were pregnant. Overall, 11% of women had cultures positive for chlamydia or gonorrhea. Although both leukorrhea and clue cells were independently associated with positive cervical cultures, multivariate analysis found that clue cells did not contribute to the predictive value of leukorrhea alone among both pregnant [RR=15.7] and nonpregnant [RR=58.7] women. Negative predictive values for the screening test were comparably high (98-100%), independent of pregnancy.

Conclusions: Leukorrhea, with or without bacterial vaginosis, was strongly associated with C Trachomatis and N Gonorrheoae in both pregnant and nonpregnant patients. In settings where patient follow-up is uncertain, on-site screening tests identify women for whom empiric antibiotic therapy may be appropriate.

Commentary: The results of this study are of practical value to the clinician. In a high-risk population, leukorrhea was observed in 20/27 (74.1%) of women with positive (DNA-amplification) chlamydia and/or gonorrhea cultures; only 1/167 (0.6%) of women with negative cultures had leukorrhea. Where the cost of testing is a factor, or patient compliance in question, this simple office test may allow empirical treatment of patients without culture; certainly the **absence** of leukorrhea could avoid unnecessary investigation and treatment.

Another recent study from Seattle[1] performed a Gram stain smear of endocervical secretions and used 30 leukocytes/hpf (1000x) as their standard for diagnosing infection. They found a weaker association between leukorrhea and STD than did Hakakha et al. but did not report the negative predictive value of their test. However, they used cultures rather than DNA-hybridization to diagnose chlamydia and gonorrhea, and probably underestimated the prevalence of disease in their population. They reported the interesting observation that mucopurulent cervicitis (MPC) and leukorrhea are more common in younger infected women; indeed, 41% of infected women < 20y had MPC, compared to 20% aged 25-29, and 9.5% of those over 45. There is no doubt an immulological explanation for this finding; perhaps older women are more likely to have antibodies

against chlamydia that mitigate the clinical symptoms of repeat infection. This may be analogous to the observation that Trichomonas infection is often asymptomatic in mature women. Further research is indicated.

1. JM Mazzarro, HH Handsfield, and WLH Whittington; Predicting Chlamydial and Gonococcal Cervical Infection: Implications for management of cervicitis; Obstet Gynecol 2002; 100: 579-84

REVIEW #35

Title: Factors that are associated with clinically overt postpartum urinary retention after vaginal delivery

Authors: M.E. Carley, J.M. Carley, G. Vasdev, T.G. Lesnick, M.J. Webb, K.D. Ramin, and R.A. Lee

Sites: Mayo Clinic, Rochester, MN

Published: Am J Obstet Gynecol 2002; 187: 430-3

Objective: To determine the incidence of clinically overt postpartum urinary retention after vaginal delivery and to examine what maternal, fetal, and obstetric factors are associated with the problem.

Methods: Retrospective case-controlled study of women with overt postpartum urinary retention after vaginal delivery from August 1992 through April 2000.

Results: Fifty-one of 11,332 (0.45%) vaginal deliveries were complicated by clinically-overt postpartum urinary retention. In most cases (80.4%), the problem had resolved before hospital dismissal. Persons with urinary retention were more likely than control subjects to be primiparous (66.7% vs 40.0%; $P < .001$), to have had an instrument-assisted delivery (47.1% vs 12.4%; $P < .001$), to have received epidural analgesia (98.0% vs 68.8%; $P < .001$), and to have had a mediolateral episiotomy (39.2% vs 12.5%; $P < .001$). On multivariate logistic regression analysis, only instrument-assisted delivery and regional analgesia were significant independent risk factors.

Conclusions: Clinically overt urinary retention complicates approximately 1 in 200 vaginal deliveries, with most resolving before discharge from hospital. Instrument-assisted delivery and regional analgesia were significant independent risk factors.

Commentary: The frequency of postpartum urinary retention depends on the definition. In this study, inability to void spontaneously (and presumably require catheterization) within 12 hours following vaginal delivery was observed in 51 of 11,332 women (0.45%). Using an ultrasound-measured post-void residual ≥150 ml, Yip et al[1], from Hong Kong, identified 101 cases of urinary retention in 691women (14.6%).

It is not clear why either definition was chosen. A residual between 150 and 300 ml indicates some bladder dysfunction, but does not constitute an inability to void; in most cases, such a residual would be asymptomatic anyway. Most patients receive liters of I.V. fluid during their labor and urine outputs greater than 100 ml/h are common. Since the average bladder cannot comfortably hold more than 500 ml of urine, women would normally experience a strong urge to void within 4-5 hours of delivery. This urge is often masked by the residual effect of epidural anesthesia, fatigue, pain medication, uterine cramps and perineal pain. By 12 hours, one would expect most bladders to be distended beyond their physiologic limit and require prolonged catheterization; this is far too long to wait.

Overdistension of the bladder after birth is a preventable condition. Its occurrence reflects poorly on postpartum care— a responsibility that falls mostly on the "recovery" nurse, but must be shared by physicians. Consistent with clinical experience, this study found urinary retention to be highly-associated with instrumental vaginal delivery and epidural analgesia. Postpartum orders in such cases, should err on the side of early catheterization. Knowing that urinary retention is most

likely to occur overnight, when staffing is lightest, I leave a Foley catheter until morning in patients who undergo a forceps or vacuum delivery after 9 pm—particularly if there is much vulvar edema.

If a patient is unable to void and catheterization yields more than 1000 ml, I prefer to leave a Foley for at least 24 hours; post-obstructive diuresis can produce hundreds of ml per hour, and intermittent catheterization might need to be done q 1-2h, more often than is practicable on most postpartum floors. The authors of this study did not report the amount of urine drained after initial catheterization, but 13 of the 51 women could not void spontaneously after 72 hours, and one needed 45 days before she could urinate on her own.

Postpartum urinary retention is more common than indicated in this study and associated with significant short-term, and possibly long-term disability. The best cure is prevention.

1. SK Yip, D Sahota, AMZ Chang and TKH Chung Four year follow-up of women who were diagnosed to have postpartum urinary retention. Am J Obstet Gynecol 2002; 187: 648-52

REVIEW #36

Title: Reassessing the labor curve in nulliparous women

Authors: J. Zhang, JF Troendle, and MK Yancey

Site: National Institute of Health, Bethesda, MD

Published : Am J Obstet Gynecol 2002; 187: 824--8

Objective: To examine the pattern of labor progression in nulliparous parturients in contemporary obstetric practice.

Methods: The authors analyzed data from an earlier study in which detailed labor and delivery information was collected. The study group was 1162 women who delivered vaginally between 1992 and 1996 and met the following criteria: nulliparity, term pregnancy, singleton vertex presentation, spontaneous onset of labor, birth weight between 2500-4000 g, cervical dilatation <7 cm at admission, and duration of labor from admission to delivery > 3h.

Results: The authors' average labor curve differed markedly from the Friedman curve. The cervix dilated more slowly during the active phase. It took approximately 5.5 h from 4 cm to 10 cm, compared to 2.5 h under the Friedman curve. No deceleration phase was observed. The 5th percentiles of rate of cervical dilatation were all below 1 cm/h. The 95th percentile of time interval for fetal descent from station +1/3 to + 2/3 was 3 hours during the second stage.

Conclusions: The pattern of labor progression in contemporary practice differs significantly from the Friedman curve. The diagnostic criteria for protraction and arrest disorders of labor may be too stringent in nulliparous women.

Commentary: The vocabulary and practice of clinical obstetrics owe much to the work of Emanuel Friedman. His eponymous labor curve has guided obstetric management in the United States since it was first described in 1954[1]. The concepts of *latent phase*, *active phase*, *protraction* and *arrest disorders* are Friedman's. His lifetime of research and practice, promulgated in over eighty publications, are most clearly expounded in his book —*LABOR: Clinical Evaluation and Management*[2].

This seminal work features an historical review of studies on human parturition from 1861 to 1976. Friedman acknowledges his debt to the pioneering research performed by Leroy A. Calkins (from Kansas) between 1930 and 1944. Calkins kept detailed records on over 16,000 patients and — he had a Ph.D.— was probably the first obstetrician to analyze his data using modern statistical techniques. In 1955, he published a very readable book summarizing his life's work.[3] Calkins considered the first and second stages of labor to be independent of each other. On physiological grounds, he believed the length of the first stage to be determined solely by the strength of uterine contractions and the resistance of the cervix; neither maternal age, size, nor fetal size influenced the first stage. Using criteria similar to what is now called the Bishop Score (engagement of the head, effacement, firmness of the cervix) and rating the contractions as poor, fair, or good, he drew up a table to estimate the length of the first stage at the time of admission.

PREDICTING THE LENGTH OF FIRST STAGE

		Primiparas	*Multiparas*
Effaced Engaged "2" cervix	Good pains 63%	3 hr.	2 hr.
	Fair pains 25%	6 hr.	4 hr.
	Poor pains 12%	12 hr.	8 hr.
Effaced Engaged "3" Cervix	Good pains 45%	6 hr.	4 hr.
	Fair pains 33+	9 hr.	6 hr.
	Poor pains 22%	15 hr.	10 hr.
If not effaced add		3 hr.	2 hr.
If not engaged add		1 hr.	1 hr.

The subjectivity of these parameters limited the application of Calkin's method to clinical practice.

Friedman's contribution was to recognize that, of all the clinical features of the woman in labor, only cervical dilatation and fetal descent were useful in assessing the progress of labor. By plotting these parameters graphically as a function of time, Friedman observed an S-shaped curve. Although the rate of change is specific to each patient, Friedman combined measurements from many women undergoing labor in an attempt to define normality in statistical terms.

There are in fact several "Friedman curves". His purpose was at first academic: to provide baseline data that could be employed for experimental comparisons between groups of patients. By analyzing a select group of women at term, all with adequate pelvis, vertex presentation, well-flexed occiput anterior position, whose labors progressed "normally" without interference, conduction anesthesia or heavy sedation, and who delivered spontaneously or by outlet forceps, Friedman defined a composite "ideal" labor course. The "ideal" nulligravida had an average latent phase of 6.1 hours, an active phase of 3.4 hours, and a second stage of 0.76 hours. What was more notable, however, was the large standard deviation of all these measurements.

Between 1969 and 1971, Friedman and Kroll[4,5] published composite data on the course of labor, based on observations from 10,293 women representing a cross-sectional sampling of the gravid population at large. This last iteration of the Friedman data" is THE "Friedman Curve" that has been used in clinical practice. The average nullipara has a latent phase lasting 6.4 hours, an active phase of 4.6 hours, a maximum dilatation of 3.0 cm/hr, and a second stage of 1.1 hours. Once again, the wide range of normal was emphasized. More importantly, from a clinical perspective, Friedman explicitly defined the limits of normality and used these limits in his classification of protraction and arrest disorders. These numbers represent the 5^{th} or 95^{th} percentile of the measured variable. In the nullipara, a latent phase > 20.1 hours, an active phase > 11.7 hours, maximum dilatation < 1.2 cm/hr, a deceleration phase > 2.7 hours, maximum descent < 0.96 cm/hr or a second stage > 2.9 hours were considered abnormal enough to warrant investigation and intervention of some sort.

Friedman's data and definitions have proved useful in standardizing the management of patients in labor, but were never intended to be applied without thought. The concept of normalcy is population-based, and it should come as no surprise that other authors, from different counties, or using different management styles, have observed different characteristics in their patients.

In Texas, the use of epidural analgesia lengthened the average active phase of labor from 5.0 to 6.0 hours in nullipara.[6] In Ireland, using an active management protocol in place since the 1960s, the mean duration of the first stage was only 4.9 hours, and 97.2% of nulliparas delivered within 12 hours of admission, despite an epidural rate of 76%.[7] In New Mexico, Rogers et al., using the Dublin active-management protocol, were able to shorten the length of nulliparous labor from 11.4 hours to 9.7 hours, and deliver 75% of their patients within 12 hours of admission.[8]

The old adage that the poor workman always blames his tools is apt in this context: Friedman's Curve is just a tool. Whatever one's approach to the management of labor, whether we believe in the existence of a deceleration phase or not, partograms inspired by Friedman's work serve as a reminder not to neglect the patient. "Expectant" management is not the same as "doing nothing unless there is a problem, or until after office hours"; it means making a conscious decision to stay the course, and this can only be done by regular and thoughtful assessments of every woman in labor.

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2. Friedman, Emanuel A.; LABOR: Clinical Evaluation and Management. 2nd Ed. New York, Appleton-Century-Crofts, 1978
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4. Friedman EA, Kroll BH: Computer analysis of labor progression. J Obstet Gynaecol Br Commonw 1969; 76:1075
5. Friedman EA, Kroll BH: Computer analysis of labor progression: II. Distribution of data and limits of normal. J Reprod Med 1971; 6: 20
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REVIEW #37

Title: Male gender predisposes to prolongation of pregnancy

Authors: MY Divon, A Ferber, H Nisell, and M Westgren

Site: Lenox Hill Hospital, New York and Karolinska Institute, Stockholm, Sweden

Published: Am J Obstet Gynecol 2002; 187: 1081-1083

Objective: To evaluate the association between fetal gender and prolonged pregnancy.

Methods: All deliveries in Sweden between 1987 and 1996 were evaluated for participation in this study. Inclusion criteria: (1) singleton pregnancy (2) absence of apparent congenital or chromosomal abnormalities (3) accurate dating established by early 2nd trimester ultrasound (4) gestational age at delivery ≥37 weeks.

Initially, the mean gestational age at delivery was used to calculate the percentage of prolonged pregnancies by fetal gender. Subsequently, the Mantel-Haenszel chi-square analysis was used to calculate the weekly odds ratios and their corresponding 95% confidence intervals for the delivery of a male fetus beyond 37 weeks of gestation.

Results: The study population comprised 656,423 deliveries: 333,192 were male, 323,231 were female (ratio 1.03). The mean gestational age at delivery was significantly higher in male fetuses (280.6 ± 8.9 days vs 279.8 ± 8.6 days, respectively [P < .0001]). The percentage of pregnancies that delivered beyond term was significantly higher for male relative to female fetuses (26.5% vs 22.5%) [P < .000001] at ≥ 41 weeks of gestation and 7.6% vs 5.5% [P < .000001] at ≥ 42 weeks of gestation respectively. The weekly odds ratios for a delivery of a male fetus beyond term were 1.14, 1.39, and 1.50 at 41, 42, and 43 weeks, respectively.

Conclusions: Male gender significantly predisposes to the prolongation of pregnancy to the extent that, by 43 weeks, there are 3 male deliveries for every 2 female deliveries. This raises the possibility that gender-specific mechanisms are involved in the initiation of labor in humans.

Commentary: Male fetuses are heavier than females of the same gestational age. In the absence of placental insufficiency, growth continues past 40 weeks, and the weight difference between the sexes increases with gestational age. It is not surprising that the ratio of males to females is 2:1 in macrosomic neonates. Now comes the startling observation that, by 43 weeks, the odds ratio of delivering a male is 1.5. Should this be confirmed in other countries, the authors' hypothesis about a gender-specific mechanism of labor is bound to inspire more research by physiologists.

The mean gestational age at delivery was 0.8 days longer for males. Although this is a small absolute difference, it is statistically highly significant because of the huge study population. The authors have considered the possibility that over-estimation of gestational age by second trimester ultrasound might account for this difference, since males are larger at all ages, and sonometric estimates are based on population curves. However, the likelihood of delivering a male increases in a linear fashion beyond 40 weeks, and this militates against the possibility of a male-related fixed error in dating.

The authors did not specifically exclude births following induction or elective cesarean since the indications for these interventions were believed to be gender-neutral.

If fetal sex is indeed implicated in the onset of labor, this effect should be independent of parity, and the authors are invited to further analyze their data.

REVIEW #38

Title: Maternal and Perinatal Morbidity Associated with classic and inverted T Cesarean Incisions

Authors: LS Patterson, CFM O'Connell, and TF Baskett

Site: Dalhousie University, Halifax, Canada

Published: Obstet Gynecol 2002; 100: 633-637

Objective: To estimate the maternal and perinatal morbidity associated with cesarean delivery involving the upper uterine segment compared with that of low transverse cesarean section.

Methods: A 19-year review of a perinatal database and the relevant charts was used to determine the maternal and perinatal morbidity associated with low transverse cesarean, classic cesarean, and inverted "T" cesarean deliveries.

Results: From 1980-1999, there were 19,726 cesarean deliveries: low-transverse 19,422 [98.5%]; classic 221 [1.1%]; inverted T 83 [0.4%]. As a proportion of all cesareans, the rate of LTCS and classic have remained stable, while the rate of inverted T has risen from 0.2% to 0.9%.

Maternal morbidity (puerperal infection, blood transfusion, hysterectomy, ICU admission, death) and perinatal morbidity (5-min Apgar < 7, intensive care) were also significantly higher for inverted T cesarean compared to low transverse cesarean.

Conclusions: Classic cesarean has a higher maternal and perinatal morbidity than inverted T cesarean and much higher than low transverse cesarean. There is no increased maternal or perinatal morbidity if an attempted low transverse incision has to be converted to an inverted T incision compared to performing a classic cesarean section.

Commentary: Randomized controlled trials are the "gold standard" in clinical research. The rarity or life-threatening nature of some Obstetrical events makes them unamenable to such rigorous study. Cord prolapse, shoulder dystocia, and the indications for classical cesarean section come to mind in this context. In such situations, the only recourse is to rely on *sang-froid*, personal experience, and the collective wisdom of the profession as gleaned from textbooks, case reports and retrospective reviews. Since established teaching hospitals have developed distinctive "styles" for managing certain conditions, comparing published results from different institutions provides "quality assurance" feedback that can improve patient care.

A comprehensive, searchable, database is an invaluable research tool. Unfortunately, such a resource is difficult to set up and maintain. In the United Stares, tightened privacy rules under HIPAA (Health Insurance Portability and Accountability Act) require IRB (Institutional Review Board) approval and specific patient consent just to create a database; if it contains any individually identifiable protected health information, IRB approval is needed for each new research project. The administrative burden of these regulations will have a negative impact on clinical research.

Baskett *et al.* are fortunate, then, to have access to the Nova Scotia Atlee Provincial Database. Created in 1988, it contains information on every birth in this small Canadian province. Because the Grace Hospital in Halifax is the only tertiary care center, and accounts for about half the births in the province, most of the complicated cases come under the care of the teaching faculty. This is the latest retrospective clinical report from Halifax.

The most interesting fact was the greater than four-fold increase in the number of "T" incisions from 1980-1984 to 1995-1998. Let us be candid: a "T" incision is not a planned incision. It is a desperation measure when the surgeon realizes the transverse lower segment incision is too small to deliver the fetus without trauma. It is not elegant, and it is difficult to suture. It reflects poor judgment in the initial choice of incision—both skin and uterine. This typically occurs when attempting to deliver a fetus less than 30 weeks, usually breech, after prolonged rupture of membranes. After the fact, everyone (including this reviewer) vows to do a classical the next time this happens. There is no information on the type of skin incision employed, but it is likely that all the "T" incisions were associated with Pfannenstiel skin incisions.

Until a generation ago, Cesarean sections were mostly performed through vertical midline incisions; this offered speed, exposure and —most importantly— the flexibility to choose the most appropriate uterine incision AFTER evaluating the lower segment. The cosmetic appeal of the "bikini cut" and its perceived lower incidence of dehiscence relegated the midline incision to "emeritus" status. Younger Obstetricians, unfamiliar with the benefits of the midline approach, would rather struggle through a Pfannenstiel.

It is unfair to compare the morbidity of the classical incision with that of the lower segment, since we are dealing with two extremely different populations. There are only a few indications for the classic incision (post-mortem, lower segment fibroids, anterior placenta previa/accreta/percreta, transverse lie with back down, immature breech with oligohydramnios) and either mother or baby would be ill-served by any other type of incision in these circumstances. If abdominal delivery is chosen for fetal indications, it behooves the surgeon to use an incision that will minimize fetal trauma and asphyxia; most mothers willingly accept increased risk for the sake of their children.

REVIEW #39

Title: Influence of Persistent occiput posterior position on delivery outcome.

Authors: M Fitzpatrick, K McQuillan, and C O'Herlihy

Site: University College and National Maternity Hospitals, Dublin, Ireland

Published: Obstet Gynecol 2001; 98: 1027-1031

Objective: To evaluate the influence of intrapartum persistent occiput posterior position on delivery outcome and anal sphincter injury, with reference to the association with epidural analgesia.

Methods: In this prospective observational study over a 2-year period, 246 women with persistent occiput posterior position in labor were compared with 13,543 women with occiput anterior positions who delivered vaginally during the same time period.

Results: The incidence of persistent occiput posterior position was significantly greater among primiparas (2.4%) than multiparas (1.3%) [P < .001] and was associated with significantly higher incidences of prolonged pregnancy, induction of labor, oxytocin augmentation of labor, epidural use, and prolonged labor. Only 29% of primiparas and 55% of multiparas with persistent occiput posterior position achieved spontaneous vaginal delivery, and the malposition was associated with 12% of all cesarean deliveries performed because of dystocia. Persistent occiput posterior position was also associated with a 7-fold higher incidence of anal sphincter disruption. Despite a high overall incidence of epidural analgesia (47% vs 3%), the institutional incidence of persistent occiput posterior position was lower than that reported 25 years ago.

Conclusions: Persistent occiput posterior position contributes disproportionately to cesarean and instrumental delivery. Persistent occiput posterior position leads to a 7-fold increase in the incidence of anal sphincter injury. Use of epidural anesthesia was not related to the malposition.

Commentary: In years past, the persistent occiput posterior position was looked upon as the *bête noire* of obstetric practice. At a time when cesarean was rarely performed, the attendant could only await Nature's pleasure with trepidation, hoping to avoid a difficult forceps extraction that would prove traumatic to mother and child. Myerscough thought this was a somewhat exaggerated view to take of this very common complication.

> *Nonetheless, the difficulties which develop may occasionally be serious, particularly in the primipara, and they always demand judicious handling…The mechanism of labor is more complicated; the real problems are the timing of intervention and the avoidance of operative vaginal delivery in the unrecognized presence of cephalopelvic disproportion.*[1]

The reported incidence of the occiput posterior position varies widely in the literature. This may be due to the uncertainty of diagnosis early in labor or, because many OPs undergo spontaneous rotation during labor, on the time of diagnosis. In this study, a number of cases were not diagnosed until cesarean for dystocia. There are undoubtedly population differences as well. In the homogeneous Irish population it has always been very low. Data from the Rotunda Hospital

(Dublin) for the year 1898-99[2] showed 24/1,591cases (1.5%), which is similar to the current 1.8%. In 1903, Williams[3] observed 233/1,687 cases (16.8%) at the Johns Hopkins Hospital; 85% were ROP, 15% LOP. Donald[4], in Scotland, reported a 10% incidence in early labor.

The OP position is typically associated with lower back pain, and an earlier need for analgesia. This limits patient mobility, makes contractions less efficient, and prolongs the latent phase. Deflexion of the head is common and the occipitofrontal diameter (11.7 cm) presents instead of the suboccipitobregmatic (9.5 cm); this keeps the head high and poorly applied to the cervix. Dilatation and descent take longer. Not uncommonly, a thick anterior lip of cervix persists for a long time, and there is considerable molding. In the absence of significant disproportion, given adequate contractions and sufficient time, many OPs will rotate to OA when the vertex reaches the pelvic floor. If labor proceeds face-to-pubis, a larger diameter will distend the outlet, causing more damage to the pelvic floor; this is especially true where the subpubic angle is narrow, as in the anthropoid-type pelvis often seen with OP positions.

Ian Donald[4] reported that 63% of OPs will deliver spontaneously with the occiput anterior, 14% have spontaneous face-to-pubis deliveries, and the remaining 23% require operative interference. In the present study, only 29% of nulliparas delivered spontaneously; low forceps (position not stated) was utilized in 29%, vacuum in 16%, and cesarean in 26%. The National Maternity Hospital protocol allows only 1 hour of active pushing; since 86% of the nulliparas had epidurals, it is not surprising that the rate of operative interference was so high.

There is no standard management plan for OP positions. Many are in fact diagnosed late in labor, usually in the course of assessing slow progress. The extensive molding and deflexion can be confusing even to experts, and quite a few are first diagnosed at delivery; we have all witnessed a "sunny-side–up" delivery after a Scanzoni rotation by a senior obstetrician. Excessive resistance during an outlet forceps or vacuum procedure is often caused by an unsuspected OP.

If the intention is to deliver vaginally, much patience is required by both parents and doctor. Good hydration, good analgesia, good contractions, and time. With epidural analgesia, pushing is delayed until the head reaches the pelvic floor or the patient experiences an urge to push. This prevents maternal exhaustion. Oxytocin is used liberally to ensure adequate contractions. In the presence of a re-assuring fetal heart rate pattern, there is no arbitrary limit to the second stage; however, there should be some observable descent.

In the case of mid-pelvic arrest (+2 station), most clinicians would opt to do a cesarean. An experienced attending may consider a forceps rotation if: the position is known, the ischial spines are not prominent, and the intertuberous distance at least 8 cm (a fist wide). In the current medico-legal climate, all midforceps should be conducted in the operating room, ready to proceed to cesarean if difficulty is encountered. This reviewer prefers to use the Kielland forceps, applied in a correct cephalic fashion (buttons facing the occiput); the head is flexed, elevated and slowly rotated in one smooth motion. Successful rotation requires minimal force, and is one of the most gratifying procedures in obstetrics. Following rotation, the Kiellands may be replaced with a Simpson-type forceps for traction; Kiellands can be used for this purpose, but the absence of a pelvic curve requires pulling almost toward the floor from a midpelvic station and the perineum gets in the way. When using Kiellands for traction, the handles should never be elevated above the horizontal in order to minimize vaginal lacerations.

When the vertex reaches the pelvic floor face-up, spontaneous delivery can sometimes be

accomplished by cutting a generous medio-lateral episiotomy. Avoid a midline unless you would rather repair the anal sphincter. There is something inelegant about using forceps to deliver a baby face-to-pubis; for one thing, the application is pelvic, not cephalic. Also, downward traction extends the head, increasing the diameter and pelvic floor trauma. I have had better results using a posterior vacuum cup or, more recently, the KIWI OMNICUP. This disposable device has a thin rigid plastic cup (Malmstrom-type) with a short flexible handle and built-in hand pump. Unlike other vacuum cups, it can be applied along the sagittal suture close to the occiput; traction then causes flexion, and the reduced diameter often allows spontaneous rotation to OA as the head crowns.

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2. Dublin J Med Sc 1900; cix: 192
3. Williams JW. Obstetrics, p.238, New York, D.Appleton and Company 1903
4. Donald I. Practical Obstetric Problems, 5th Ed, p.612, London, Lloyd-Luke Ltd., 1979

REVIEW #40

Title: Is rectal misoprostol really effective in the treatment of third stage of labor? A randomized controlled trial.

Authors: E Caliskan, MM Meydanli, B Aykan, M Sönmezer, and A Haberal

Sites: Maternity and Women's Health Hospital, Ankara, Turkey

Published: Am J Obstet Gynecol 2002; 187: 1038-1045

Objective: To compare misoprostol, 600µg intrarectally, with conventional oxytocics in the management of the 3rd stage.

Methods: Following vaginal delivery, immediately after cord clamping, 1606 women were assigned randomly to one of four groups: (1) oxytocin + rectal misoprostol + placebo IM (2) rectal misoprostol + placebo IM and placebo IV (3) oxytocin + placebo IM + placebo rectal tablets (4) oxytocin + methylergometrine + placebo rectal tablets. All medications were applied by midwives, but the doctors involved in the study were blinded to the actual treatment.

Oxytocin was administered as 10U/500 ml saline IV over 30 minutes. Two 200µg Misoprostol tablets were inserted rectally, followed by 100µg 4- and 8-h postpartum. 1 ml of methylergometrine was given IM.

The placenta was removed manually after 30 minutes. IM methylergometrine was given for persistent atony and bleeding after placental delivery. Blood was transfused in women with hemorrhage and hemoglobin < 8 g/dL. Blood loss at delivery was estimated by weighing pads after the 1st hour. Postpartum hemorrhage was defined as ≥ 500 mL; severe PPH as ≥ 1000 mL.

The main outcomes were the incidence of PPH and the dro p in hemoglobin concentration.

Results: The incidence of PPH was 9.8% in the misoprostol-only group, compared with 3.5% in the oxytocin-methylergonovine group [P = .001]. Significantly more women needed additional oxytocin in the misoprostol-only group compared with the oxytocin-ergot group (8.3% vs 2.2%) [P < .001]. The primary outcome measures were similar in the misoprostol-only and oxytocin-only groups. Side-effects such as shivering and hyperthermia (T ≥ 38°C) were significantly increased [P < .05] in both misoprostol groups compared with the oxytocin-alone or oxytocin-ergot groups.

Conclusions: Rectal misoprostol is significantly less effective than oxytocin plus methylergometrine for the prevention of PPH.

Commentary: Misoprostol has been the "My Big Fat Greek Wedding" of the pharmaceutical world: a low-budget drug that becomes a surprise hit —except that its producer is not making any money. Given the enthusiasm for all things misoprostol in the last few years, the quest for new off-label indications goes on.

It was only a matter of time before someone thought of using it for the prevention and treatment of post-partum hemorrhage. Given the availability of effective parenteral oxytocics (oxytocin, various ergot preparations and the $F_{2\alpha}$ prostaglandin, HEMABATE©) there is no great demand for a new product in this country. However, its low cost, stability, and ease of administration would be a boon in third-world countries—where hemorrhage remains a major cause of maternal mortality. It is not surprising, therefore, that this study comes from Turkey.

This is a well-conceived and executed RCT that could serve as a model in the United States. Rectal misoprostol was comparable in efficacy to I.V. oxytocin, but less effective than oxytocin + methylergometrine. Compared to oxytocin alone, misoprostol was associated with increased shivering and hyperthermia.

Gerstenfeld and Wing[1] found that rectal misoprostol was comparable to oxytocin in the short term, but patients were more likely to need additional oxytocics.

1. Gerstenfeld TS, Wing DA. Rectal misoprostol versus intravenous oxytocin for the prevention of postpartum hemorrhage after vaginal delivery. Am J Obstet Gynecol 2001; 185: 878-82

Special Review- January 2003

Title: Perspectives on the Women's Health Initiative Trial of Hormone Replacement Therapy

Authors: DA Grimes and RA Lobo

Site: Family Health International, N.C. and Columbia University, New York

Published : Obstet Gynecol 2002; 100: 1344-53

Objective: Analysis and Commentary on the WHI HRT Trial

Methods: The authors attempt to reconcile the results of the WHI Trial with those of earlier observational studies. They describe several biases inherent to observational studies, review the methods and results of the WHI trial, summarize recent systematic reviews of HRT, and suggest options for women and clinicians in light of the WHI Trial findings.

Conclusions: There is strong basic science, epidemiological, and clinical data to support the beneficial effects of estrogen on the cardiovascular system in older women. Several observational studies concluded that the reduction in all-cause mortality in estrogen users (25-50%) was largely attributable to a reduction in cardiovascular deaths. This highly protective effect of estrogen, seen in the Nurses' Study cohort (1991), occurred predominantly in younger healthy women who began hormone therapy at the onset of menopause, primarily for the relief of vasomotor symptoms. Trials carried out in monkeys have shown a 50-70% protective effect against coronary atherosclerosis when ERT or HRT is begun at the time of oophorectomy; delaying hormone therapy for even 2 years negates this protective effect.

In contrast, several randomized controlled trials [HERS 1998; Herrington 2000, 2001] concluded that HRT was ineffective at preventing the progression of coronary artery disease in women with established cardiovascular disease. Why aging and progressive atherosclerosis impede the apparent ability of estrogen to protect is unclear.

For logistic reasons, investigators often study surrogate markers (e.g. lipid levels, bone density) instead of primary clinical outcomes. This can lead to erroneous conclusions: the PEPI (1995) trial found that HRT improved serum lipids, but did not report clinical outcomes. Both the HERS and WHI trials noted significant elevations of HDL and lowering of LDL, yet the cardiovascular outcomes in the HRT group were significantly worse. The primary outcome should ALWAYS be the focus of clinical research.

Because of inherent biases (selection, adherence, surveillance, survivor) that are difficult to eliminate, observational research often reaches favorable (but incorrect) conclusions. In the case of hormone therapy, women who choose to use HRT are usually healthier, more affluent, better-educated, less likely to smoke, and more likely to exercise than non-users. They are also more likely to have regular contact with clinicians who may identify and treat other risk factors (e.g. hypertension). Selection biases can be eliminated by performing randomized controlled trials whenever possible.

Randomized controlled trials have two kinds of validity: internal and external. Internal validity implies that the trial answered the question it set out to answer: is the trial free of bias that might have distorted the results? In this respect, the WHI trial used excellent methods: large

sample size, good randomization, allocation concealment, double-blinding, only 3.5% loss to follow-up. All primary analyses used time-to-event methods and an intention-to-treat analysis.

External validity is the ability to extrapolate the trial's findings to other women. Are participants in the trial similar to one's practice? WHI participants were asymptomatic and older (mean age 63) than many women who take HRT. Because the trial results were uniform across age groups, it was felt that the findings could be extrapolated to asymptomatic women aged 50-79. Nevertheless, information is lacking about the age at menopause for these women, which has important implications regarding their inherent cardiovascular status. Whether the findings can be generalized to symptomatic women at the onset of menopause is unknown. Another concern is whether these HRT results can be extrapolated to other regimens than PREMPRO©. For statistical reasons, only one estrogen could be studied and conjugated equine estrogen 0.625mg is the most-widely prescribed estrogen in the USA. For reasons of convenience and bleeding pattern, a continuous daily progestin dose was selected over a cyclic regimen.

Primary prevention of cardiovascular disease was the focus of the WHI trial. However, 36% of women assigned to HRT had hypertension, 49% were past or current smokers, and 34% were obese (BMI > 30 kg/m^2). A perspective to be considered, therefore, is that not all women were healthy: for many, the HRT intervention was in the setting of a secondary prevention trial.

Women without a uterus in the ERT arm of the WHI trial showed no significant increase in the risk of breast cancer, whereas the HRT group showed a 26% increase over controls.

The WHI trial confirmed that HRT reduces both vertebral and hip fractures. Of note, women were excluded from the WHI trial if they had a history of fractures; an older population with severe osteoporosis might have enjoyed greater protection from fractures with HRT.

The WHI trial corroborates epidemiological studies suggesting that estrogen reduces the risk of colorectal cancer.

Estrogen may have important effects on the brain. Nine RCTs among symptomatic women have demonstrated a beneficial effect on verbal memory, vigilance, motor speed, and reasoning. The WHI trial did not examine this subject, and other randomized trials will be necessary.

The WHI study is the largest trial of HRT ever conducted. The data are valuable and will continue to be analyzed. However, the results need to be put into perspective. The results pertain only to this particular regimen (PREMPRO) in asymptomatic women with a mean age of 63 years, most of whom had never used hormones. Importantly, the results do not address symptom relief or quality-of-life issues, which were beyond the scope of the WHI trial.

Another large RCT (The Women's International Study of Long Duration Oestrogen After Menopause [WISDOM]) is ongoing in the U.K., Australia, and New Zealand. Both the steering committee and an independent safety panel for the WISDOM study reviewed the WHI trial results and unanimously recommended that the WISDOM trial should proceed. In July 2002, enrolment was paused to allow an international group of experts to consider the prudence of continuation.

Hormone replacement therapy remains the most effective treatment of menopausal symptoms. Other regimens than PREMPRO may be considered, and lower doses may be safer for long-term use.

HRT should not be used for primary or secondary prevention of cardiovascular disease. Each patient's risks, benefits, and preferences should be taken into account. Because cardiovascular disease is the leading cause of death, health care resources should be directed

toward lifestyle modification programs, supplemented by the medical treatment of hypertension and hyperlipidemia when indicated.

Commentary: This thoughtful review deserves to be read by everyone involved in the care of women. Perhaps because menopause eventually affects all women —and men indirectly— the subject of hormone therapy has engaged the attention of the public to a greater degree than almost any other medical topic. It is telling that the WHI trial administrators chose to announce their latest results at a nationally televised press conference, before their publication in a peer-reviewed journal. This type of grandstanding was justifiably criticized in academic circles; it also caused major headaches for clinicians —most of whom first heard of the study when their offices were deluged by calls from concerned patients.

Sad to say, hormone therapy has become like religion: there are true believers, atheists, and agnostics. The first two groups have already made up their minds and won't change it until the "definitive" study is published. In the meantime, they will find fault with any research that doesn't support their belief. The undecided lack faith: their opinions vacillate with every new recommendation from an "official" body. As clinicians, they want to do what's best for their patients while at the same time avoid medico-legal controversy. Yet, they know in their hearts that truth is elusive, that it is rarely found in the province of extremists. *In medio stat virtus!*

The controversy over hormone therapy is nothing new. In 1917 Cecil W. Vest wrote:

> *In view of the increasing interest and literature concerning the glands of internal secretion,…it is worthwhile to consider briefly how far practical gynecology has been advanced by these studies.*
>
> *The field affords abundant scope for the play of the imagination, and not a few practitioners have been led astray by the writings of enthusiastic, but not too well-balanced investigators, supplemented by the advertisements of the manufacturing druggists, so that they have accepted as dicta, based upon solid facts, what in reality were merely fantastic theories.* [1]

In 1928, Howard Kelly summarized his views on the subject:

> *Some virtue is here almost unanimously ascribed to ovarian therapy. Corpus luteum extract…appears to relieve the hot flashes, vertigo, and menopausal headache.*
>
> *…It must be emphasized that, rational as ovarian therapy appears to be in some ailments, the results, rarely striking, are often nil. It scarcely seems reasonable to expect that a commercial extract will replace the normal ovarian secretion developed and naturally administered in the living body, and there is, indeed, often doubt that such a product originally contains any active ovarian hormone. Herein lies the crux of the problem, the solution of which depends largely on the biochemist.*
>
> *The physician testing ovarian therapy must keep his feet on the ground and not be transported by the exaggerated claims of those who have something to market nor yet by ill-advised premature reports of honest but deluded colleagues. A wise man once said, " Ought we to assume, if the administration*

of cascara relieves constipation, that the constipated individual had been a victim of hypocascarism?"

There is little doubt as to the future import of ovarian therapy, but there is large room for discussion of its present value.[2]

It is now politically (and probably) correct to speak of "hormone therapy" rather than "hormone replacement therapy". This defuses the issue of whether or not menopause represents an organ "failure" that needs to be remedied (as in hypothyroidism e.g.), as opposed to a natural phenomenon associated with aging. It is also semantically more accurate, since no current hormone regimen precisely replicates the natural hormonal milieu.

A well-designed randomized controlled trial eliminates many of the biases typically associated with observational studies, and the conclusions of such a trial will be valid for the study group. Statistical methods, however, assume that the study group is a representative sample of the entire eligible population; they cannot magically turn bad or insufficient data into valid conclusions: "Garbage in, Garbage out" —to quote a computer software expression. Logistic considerations make it improbable that any clinical study will ever include more than a very small proportion of the eligible population. The WHI trial —the largest hormone therapy RCT so far— involved less than 5% of the eligible candidates at the forty study sites. The research process itself is not random: the methods used to recruit subjects (typically newspaper ads or flyers in a hospital clinic) introduce a selection bias, as does the language used in the recruitment brochure or informed-consent document. The word "hormone" itself is value-laden. Such considerations, and the self-selection inherent in continued participation in a long-term study, make it unlikely that research subjects as a class will ever be typical of the general population. Hence, it is prudent to maintain a healthy skepticism about the conclusions of any study — particularly when they appear to contradict either commonsense or widespread clinical experience.

Not all topics are suitable for RCTs [*has anybody ever done a RCT on the efficacy of parachutes?*]. Most women with significant vasomotor symptoms experience prompt relief following estrogen administration; randomizing such women to a placebo group would almost certainly "unblind" the study and lead to numerous drop-outs. It should, however, be possible to compare different hormone regimens. Institutional Review Boards struggle with the ethics of trial design: is it acceptable to compare a drug to placebo, as opposed to comparing the drug to the established "standard of care", if it may cause some patients more pain or discomfort?

Even if study results apply to the entire population, hormone therapy research has focused on serious clinical outcomes and largely ignored the quality-of-life issues that confront the individual patient and her physician. Women with significant vasomotor symptoms or genital atrophy will continue to request hormone therapy or turn to unproven —and possibly more risky— "natural" supplements. Intellectual honesty requires that "hormones" be treated like any other medication: neither panacea nor witch's potion. As clinicians, we have a fiduciary duty to interpret the literature for our patients, so they can make educated choices about their care.

What I think I know in early 2003

(with apologies to CNN's *Monday Morning Quarterback*)

1. In asymptomatic women (*mean age 63, about a third with obesity, treated hypertension or treated hyperlipidemia*) combination E/P (PREMPRO) increases the risk of MI, CVA, DVT compared to placebo.

2. Combination E/P reduces the risk of hip fracture and colon cancer compared to placebo.
3. Combination E/P increases the risk of breast cancer ~26% compared to placebo.
4. Combination E/P increases the risk of breast cancer significantly more than E alone (*in women with a previous hysterectomy*). The data on continuous progestins is not altogether surprising: except during pregnancy, progesterone is secreted only about 12 days per month. FDA-approval of Depo-Provera for contraception was delayed for 25 years because of reports of increased breast cancer in susceptible mice and in institutionalized patients; over a decade has passed, and it will be interesting to see if long-term progestin-users develop more breast cancer. The BCP delivers much higher doses of E/P than menopausal therapy for 3 weeks out of 4; the recent trend toward continuous dosing to relieve perimenstrual symptoms and periods raises theoretical concerns. It is re-assuring in this context that we have not observed (yet!) an epidemic of breast cancer in the cohort of high-dose oral contraceptive users from the 60s and 70s. If there is a risk, it may return to baseline following cessation of therapy.
5. It's probably a good idea to stop combination E/P in asymptomatic post-menopausal women, particularly if they are over 60 and have established coronary disease or hypertension.
6. Symptomatic women should be offered hormone therapy.
7. Continuous estrogen with scheduled Progestin withdrawal bleeding every two to three months may strike a balance between the risks of breast and cardiovascular disease, endometrial hyperplasia/cancer, and the nuisance of periods. The lowest estrogen dose that relieves symptoms should be used. There is no data to support the use of any particular estrogen over another.
8. Symptomatic women already on PREMPRO should be informed of the WHI trial results. After a review of their personal health risks and family history, they should make their own decision about continuing the medication. Optional regimens should be discussed. This conversation should be documented in the medical record.
9. New research will be published.
10. This list will be revised.
11. We need to do what we should have been doing all along: **treat the patient!** Protocol-based medicine that ignores individual characteristics may be "safe", but will never give the best results for the individual.

1. Cecil W. Vest; Relation of the glands of internal secretion to the female pelvic organs; Am J Obstet and Diseases of Women and Children; 1917; 75: 366-72
2. Howard A. Kelly; Gynecology 1928 p. 156-7; D. Appleton and Company, New York

REVIEW #41

Title: Guidelines for the selection of the route of hysterectomy: Application in a resident clinic population

Authors: SR Kovacs, S Barhan, M Lister, L Tucker, M Bishop, and A Das

Site: Emory University, Atlanta, Georgia and Wright State University, Dayton, Ohio

Published: Am J Obstet Gynecol 2002; 187: 1521-7

Objective: The purpose of this study was to evaluate the effectiveness of the Society of Pelvic Reconstructive Surgeons guidelines for the determination of the route of hysterectomy in a resident clinic population.

Methods: A total of 407 consecutive women (between October 1, 1994 and December 31, 1999) from the resident clinic population at Wright State University were assigned prospectively to abdominal or vaginal hysterectomy groups according to Society of Pelvic Reconstructive Surgeons guidelines. The women's age, race, preoperative uterine weight estimates were recorded. Outcome measures included operative time, length of stay, laparoscopic scores, and complications.

Results: Vaginal hysterectomy was completed in 91.8% of the women. As expected, vaginal hysterectomy required the shortest operative time and length of stay and was associated with fewer complications than the abdominal approach ($P < .01$). Laparoscopic assistance was necessary in 25.8% of patients to assess extrauterine disease.

Conclusions: Resident physicians who followed the practice guidelines reduced the ratio of abdominal-to-vaginal hysterectomy from 3:1 to 1:11. The application of practice guidelines for the selection of the route of hysterectomy can increase the ratio of vaginal hysterectomies that are performed in residency programs and can help eradicate inconsistencies in health care delivery that exist currently.

Commentary: My first MEDSCAPE review, in March 2002, dealt with the subject of vaginal hysterectomy for enlarged uteri. The gist of the commentary was that vaginal hysterectomy deserves to be more widely utilized in this country. In properly-selected cases, it is both faster and associated with fewer complications than either abdominal or laparoscopically-assisted hysterectomy. It is definitely easier to learn than LAVH — relying on techniques and instruments that have been around for over a century and are already familiar to all surgeons.

In 1995 S. Robert Kovac, now at Emory University in Atlanta, published guidelines to determine the route of hysterectomy.[1] These were developed by the Society of Pelvic Reconstructive Surgeons and adopted by the National Guideline Clearinghouse. By 1998, Kovac had concluded that:

> *The evidence-based data…strongly suggests that 80% of hysterectomies currently performed can be completed vaginally, taking full advantage of the medical and surgical benefits of this surgical route.*[2]

It would be foolish to pick an arbitrary "ideal" rate of vaginal hysterectomy. However, the wide variation in published rates suggests that the choice of operation for benign disease is determined

mainly by surgeon preference. The latter, in turn, reflects the operator's training and experience.

This latest publication by Kovac demonstrates that it is indeed possible to change the habits of surgeons —albeit those of still-impressionable residents. This augurs well for the future of the vaginal approach. By selecting the route of hysterectomy using the published guidelines, almost 92% of all hysterectomies for benign disease were completed vaginally, compared with only 25% between 1989 and 1993 at the same institution.

In 88 of 380 women deemed suitable for vaginal hysterectomy on the basis of vaginal accessibility and size <280 grams (~12-week size), some aspect of the history or physical examination raised the possibility of extrauterine disease. Diagnostic laparoscopy showed absent or mild pathology in 80 of these 88 women; in 2 cases, operative laparoscopy enabled the surgery to be done vaginally, while 6 were converted to the abdominal route because of severe adhesions or endometriosis obliterating the cul-de-sac. When used as a diagnostic tool prior to vaginal hysterectomy, laparoscopy added an average of 10.7 minutes to the duration of the procedure.

The mean operative time (including the diagnostic laparoscopy in 82 of 380 women) was significantly shorter in the vaginal hysterectomy group (94 min v. 118 min, P <.002), as was the mean length-of-stay (2.7 v. 4.9 days, P < .001). Overall, 55 of the 407 patients had complications; however, the complication rate in the abdominal hysterectomy group was 33.3% v, 11.8% in the vaginal group (P <.001).

LAVH was originally proposed as a way of reducing the rate of abdominal hysterectomy. It has become apparent that operative laparoscopy confers little benefit to the patient if hysterectomy can be done vaginally. Indeed, the less is done laparoscopically, the more efficient the operation. Having achieved a 92% rate of vaginal hysterectomy using laparoscopy as a diagnostic screening tool, there are diminishing returns to expanding the role of laparoscopy in the remaining 8%. Total laparoscopic hysterectomy in such challenging cases is risky, time-consuming, and should be attempted only by the virtuosos of the field — in patients highly-motivated to avoid a laparotomy.

1. Kovac SR Guidelines to determine the route of hysterectomy. Obstet Gynecol 1995; 85: 18-23
2. Kovac SR Guidelines to Determine the Role of Laparoscopically Assisted Vaginal Hysterectomy. Am. J. Obst. Gyn. 1998;178: 1262

REVIEW #42

Title: Urinary Incontinence Predictors and Life Impact in Ethnically Diverse Perimenopausal Women

Authors: CM Sampselle, SD Harlow, J Skurnick, L Brubaker and I Bondarenko

Site: U. of Michigan, Ann Arbor, Michigan; New Jersey Medical School, Newark, New Jersey; Loyola University Medical Center, Maywood, Illinois

Published: Obstet Gynecol 2002; 100: 1230-8

Objective: To document prevalence of mild, moderate, and severe urinary incontinence among ethnically diverse perimenopausal women, identify risk factors, and assess the effect of severity on women's daily lives using treatment seeking, bother, and nighttime voiding as indicators.

Methods: Baseline data from the longitudinal cohort of the Study of Women's Health Across the Nation, SWAN, a prospective, multiethnic, multisite study of menopausal transition was used (n= 3302). Interview and self-completed questionnaires assessed most variables of interest. Body mass index and diabetes mellitus were measured clinically. Incontinence severity was derived by multiplying frequency by volume leaked. Risk factors and effect on treatment seeking, bother, and nighttime voiding were assessed by the construction of multiple logistic regression models for each ethnic group and the total population.

Results: Mean age was 46.4 years. Incontinence prevalence was 57%, with nearly 15% categorized as moderate, and 10% as severe. Biologic factors constituted the most important risk for severity, specifically perimenopausal compared to premenopausal status [OR 1.35], body mass index [OR 1.04], diabetes mellitus [OR1.55], and current smoking [OR1.38]. Nonwhite groups had lower risk, but the relationship of ethnicity is complex. Severity was associated with likelihood of discussing with a health care provider, with bothersomeness, and with likelihood of nighttime voiding.

Conclusions: Large numbers of perimenopausal women experience urinary incontinence with 25% wearing protection or changing undergarments on several days per week. Mutable factors predicting severity included body mass index and current smoking.

Commentary: This very readable study summarizes the epidemiologic literature on urinary incontinence, and documents its high prevalence and severity in ethnically diverse perimenopausal women.

Since the conclusions are based on the answers to approximately eight questions about incontinence in the SWAN database, it come as no surprise that they are often self-evident, or of limited practical value to the clinician. Thus, women with severe symptoms and a greater "level of bother" were more likely to have discussed the issue with their health care provider. Gynecologists — most of whom routinely inquire about prolapse and incontinence symptoms— will not learn anything new from this article. It may sensitize the primary physician to ask about incontinence, since many women are reticent to bring up the subject —either from embarrassment or, more likely, because they think that a "weak bladder" is just a part of having children and growing older.

The application of statistical methods to a large database often yields "significant" associations between variables. This, of course, is a limitation of epidemiologic studies: the casual reader may assume —or some authors, imply— a cause-and effect relationship that cannot be

supported by the limited individual information available. Too often, the variables being studied are not really independent. For example, the correlation between diabetes and incontinence (Odds Ratio 1.55) cannot be interpreted clinically without considering the known link between BMI (also significantly associated with incontinence) and Type 2 diabetes. In this study, only 7.6% of women had diabetes of any severity; in practice, most women with urinary incontinence are NOT diabetic. In this publication, the authors are careful not to extrapolate too much from their conclusions, but I'm not so sure about headline writers (consider hormone therapy articles).

Clinicians try to distinguish between the stress and urge components of incontinence, since their etiologies and management are quite dissimilar. SWAN was never designed to study incontinence, so no attempt is made to refine the complaint of incontinence. This, in turn, complicates the interpretation of the data presented in this article. The reported relationship between incontinence and "nighttime voiding" is based on the question: "how often do you usually get up from bed at night to urinate?". Sixty percent of women answered "one or more times a week". One expects women with urgency symptoms to get up more often, so an analysis of women with BOTH nocturia and incontinence would have been helpful. Uterine fibroids near the bladder can cause urgency symptoms. Since Black women tend to have more — and bigger— fibroids than women of other races, it is not unexpected that they have more nighttime voiding (OR 1.42 v. White). However, Blacks were less likely than White women to suffer from moderate/severe incontinence (OR 0.88), suggesting that any reported increase in incontinence associated with fibroids is related to urgency symptoms. This interpretation is at variance with the authors' contention that fibroids cause stress incontinence. There are many reasons for nocturia, most having little to do with incontinence. It can be argued that the sleep disturbances associated with vasomotor symptoms heighten a woman's perception of her bladder and make it more likely that she will get up to void.

The greater incidence of incontinence in perimenopausal women is consistent with the known effects of ageing and loss of estrogen on pelvic support, as well as the urgency symptoms frequently associated with low estrogen levels.

Like most epidemiologic work, this study raises more questions than it can answer. More focused research is needed, and the authors are encouraged to continue their investigations in this field.

REVIEW #43

Title: Severity of mastalgia in relation to milk duct dilatation

Authors: F Peters, P Diemer, O Mecks, and LJ Behnken

Site: St. Hildegardis Hospital, Mainz, Germany and Bioscientia Institute of Laboratory chemistry, Ingelheim, Germany

Published: Obstet Gynecol 2003; 101: 54-60

Objective: To analyze the significance of milk-duct dilatation measured by ultrasound in patients with mastalgia.

Methods: A total of 335 premenopausal women participated in a genital and breast cancer screening program. Of these, 123 were asymptomatic, while 212 complained of breast pain: 136 had cyclical mastalgia; 76 reported the noncyclical type. The width of milk ducts was measured by ultrasonography and correlated with the intensity of breast pain. The site of the pain was correlated with duct dilatation. Statistical analysis was performed using the *t* test, the χ^2 test, analysis of variance, and Pearson correlation.

Results: In asymptomatic women, the maximum mean width of the milk ducts was 1.8 ± 0.84 mm, in cyclical mastalgia 2.34 ± 1.10 mm, and 3.89 ± 1.26 mm in noncyclical mastalgia ($P < .001$). The intensity of pain showed a significant, positive correlation with the width of the milk ducts ($r = .501$, $P < .001$). Noncyclical mastalgia patients located the pain at the site where dilated ducts were detected ultrasonographically ($P < .001$).

Conclusions: Duct ectasia is a major factor in mastalgia. The degree of duct dilatation correlates positively with the intensity of breast pain. In noncyclic pain, there is a positive correlation between the site of duct dilatation and the site of pain.

Commentary: To my knowledge, this is the first report linking mastalgia to dilatation of milk ducts. In one way this is not surprising, but it raises the question: “are the ducts dilated with milk?”. If so, wouldn’t these women have galactorrhea? Wouldn’t their prolactin be elevated? The authors did not record that information, but they address these issues in their discussion. They quote other work showing elevated prolactin response to Thyrotropin Releasing Hormone (TRH) in cyclic mastalgia, but normal basal and TRH prolactin response in women with noncyclic mastalgia. They believe that cyclic and noncyclic mastalgia are two different entities.

Gynecologists often see patients with breast pain, cyclic or not. In my experience, few women with severe mastalgia have either elevated prolactin levels or galactorhea. Conversely, most women with galactorhea don’t complain of pain.

Although dilated ducts may cause the pain, we are no closer to understanding why the ducts dilate in some women but not in others. It might be helpful to establish whether the duct fluid is in fact milk, or simply edema. There is clearly a relationship to estrogen or progesterone since mastalgia is rare in postmenopausal women not taking hormones. Caffeine intake has also been linked to mastalgia; anecdotally, many patients appear to improve when they cut back on coffee, tea, or caffeinated soda.

An evidence-based review of treatments for breast pain can be found at the *Clinical Evidence*

website: www.clinicalevidence.com . Therapies that have shown some benefit in randomized controlled trials include low fat/high carbohydrate diets, danazol (*gonadotrophin inhibitor*), tamoxifen (*anti-estrogen in breast*), gestrinone (*similar to danazol*), lisuride maleate (*dopamine agonist, also used in Parkinson's disease*), tibolone (*steroid with estrogenic, progestogenic and androgenic properties; has been used for menopausal symptoms and osteoporosis*), and bromocriptine (*dopamine agonist, reduces prolactin*). The latter has significant side-effects, including nausea, dizziness and postural hypotension.

Prior to the introduction of GnRH analogs, Danazol (DANACRINE©) was extensively used for suppressing endometriosis. Doses of 600-800 mg/d were required to produce amenorrhea and were often associated with unacceptable androgenic symptoms such as acne, hirsutism, and weight gain. Much lower doses (100-200 mg/d) have been shown to reduce breast pain; in my experience, this is well-accepted by patients. In cyclic mastalgia, as little as 100 mg/d during the luteal phase can be beneficial.

REVIEW #44

Title: Emergency contraception and fire extinguishers: A prevention paradox

Author: David A. Grimes

Site: Family Health International, Research Triangle Park, North Carolina

Published: Am J Obstet Gynecol 2002; 187: 1536-8

Methods: This is an opinion.

Abstract: Fire and unintended pregnancy are important causes of morbidity, mortality, and financial loss in the United States. Home fire extinguishers and emergency contraception are both effective preventive interventions. The disparity between access to fire extinguishers and emergency contraception is irrational and indirectly hurts women's health. Although fire extinguishers require the user to make a diagnosis, choose the appropriate treatment, and assume some risk of serious injury and death, these canisters of pressurized chemicals are widely available without restriction. In contrast, women face several unnecessary obstacles to overcome before using emergency contraception, which is both simpler and safer to use. Clearly, a double standard prevails in prevention strategies for women. The Food and Drug Administration should approve over-the-counter availability of emergency contraception without further study or delay.

Commentary: Dr. Grimes has a way with words. No doubt some will object to his choice of analogy, or consider this article too "political" for inclusion in a "scientific" journal. In my view, the message contained in this metaphor has the potential to improve women's health to a far greater degree than most of the "scientific" articles published in the same issue. As to "politics", fertility control has been politicized for centuries, and remains firmly in the grip of those who oppose a woman's right to choose. Physicians, by their nature, are not activists. Yet, there comes a time when silence is no longer golden, when speaking out on issues that affect our patients becomes a moral imperative.

Since Biblical times, the parable has been used to convey a moral in everyday words, and this one is very apt. Although most house-fires result from human carelessness (playing with matches, smoking in bed, forgetting to turn off the stove or iron) we, as a Society, usually forgive these lapses in judgment: we provide Fire Departments, encourage people to have fire extinguishers, and carry fire insurance. Why is our attitude toward sex so different?

Virtually every adult in this country has engaged in sexual activity, and very few believe that sex should only be used for procreation. In our media sex is always passionate, and we all understand how and why failure to use contraception occurs. The physical and psychological burdens of unwanted pregnancy fall disproportionately on women. Since —we wallow in similes— it takes two to Tango why, then, are we so hard on women? This is surely a double standard!

Although effective, safe (much safer than pregnancy), and relatively inexpensive post-coital contraception has been available for decades, the barriers to access described by Grimes are all too real. When pharmacies (WALMART, for example) can legally refuse to fill prescriptions for these products on "moral" grounds, when medical insurance plans pay for VIAGRA or pregnancy care but not for contraception, how can we pretend this is not "political"?

Keep up the good fight Dr. Grimes!

REVIEW #45

Title: The use of intraoperative cystoscopy in major vaginal and urogynecologic surgeries

Authors: CH Kwon, RP Goldberg, S Koduri, and PK Sand

Site: Evanston Continence Center, Northwestern University Medical School, Evanston, Illinois

Published: Am J Obstet Gynecol 2002; 187: 1466-72

Objective: To examine the frequency of significant intraoperative cystoscopic findings during major vaginal reconstructive and urogynecologic surgeries.

Methods: The records of 526 consecutive women who underwent routine cystoscopy with intravenous injection of indigo carmine at the time of their urogynecologic and major vaginal reconstructive procedures between January 1, 1997, and April 20, 2001, were reviewed. The authors determined the incidence of significant cystoscopic findings and their effect on operative management. Two-tailed *t* tests and logistic regression analyses were used to compare characteristics between the groups with and without significant cystoscopic findings.

Results: During the 526 operations, 26 significant findings (4.9%) were unsuspected before cystoscopy and 15 (2.9%) of these findings were operative injuries that required intervention. Of 79 women who underwent NO anti-incontinence operation, only 1 (1.3%) had a partial ureteral obstruction. Seven of the 184 Burch procedures (3.8%) resulted in injuries to the lower urinary tract requiring intervention, 3 of which (1.6%) were unrecognized before cystoscopy. Seven of the 15 complications requiring intervention were caused by anterior colporrhaphy sutures (2.0% of all anterior colporrhaphies). There were no unrecognized injuries that caused morbidity after surgery. There were no significant differences between patients with abnormal and normal cystoscopic findings in regard to mean age, parity, weight, estimated blood loss, previous surgery, or previous incontinence surgeries. No complications or morbidity occurred as a direct result of intraoperative cystoscopy.

Conclusions: Intraoperative cystoscopy with intravenous indigo carmine injection is a safe and effective way to detect injury of the lower urinary tract. Cystoscopy detected unsuspected operative injury in 2.9% overall, and in 1.3% of women who did NOT undergo an anti-incontinence operation. Anterior colporrhaphy was the most common cause of unrecognized ureteral compromise. Cystoscopy allows the immediate recognition and repair of lower urinary tract injury.

Commentary: Injury to the ureter has been the bugbear of gynecologic surgery since its inception, and postgraduate courses on “how to avoid injuries to the ureter” are fully subscribed year after year. Despite “due diligence” by experienced surgeons, ureters are still being kinked, sutured, clamped and stapled every day —most commonly at the level of the cervix. Except during radical hysterectomy for cancer, it is uncommon (and difficult) to dissect the ureter in the last few centimeters before it enters the bladder. In the absence of pathology (endometriosis, broad-ligament fibroids), surgeons usually avoid the ureter by using intrafascial techniques, or closely hugging the cervix with narrow clamps. Following abdominal procedures, observing normal peristalsis and diameter of the ureter is usually reassuring.

The potential for injuring the lower urinary tract is increased during complex vaginal repairs for genital prolapse and incontinence. The trend toward tension-free tape and other “blind”, minimally-invasive sling procedures for incontinence further threatens the ureter.

Since ureteral injuries are inevitable, identifying and treating these complications while the patient is still in the operating room will almost certainly reduce long-term morbidity. The technique described in this paper has been around for a long time. It is simple, safe, and should be used after every major anterior colporrhaphy or vaginal anti-incontinence operation.

REVIEW #46

Title: Post-Cesarean Delivery Fever and Uterine Rupture in a Subsequent Trial of Labor

Authors: TD Shipp, C Zelop, A Cohen, JT Repke, and E Lieberman

Site: Brigham & Women's Hospital, Boston, Massachusetts

Published : Obstet Gynecol 2003; 101: 136-9

Objective: To evaluate the impact of post-cesarean fever on the risk of uterine rupture during a subsequent trial of labor.

Methods: This is a case-controlled study in a cohort of 4393 women undergoing a trial of labor after cesarean over a 12-year period in a single tertiary care institution. The current study was limited to 21 women who experienced symptomatic uterine rupture and had undergone their prior cesarean at the same hospital. Four controls, who also had their prior cesarean at the same institution, were matched to each case by year of delivery, number of prior cesareans, prior vaginal delivery, and induction in the index pregnancy. Medical records were reviewed for maximum post-operative temperature during the previous cesarean. Fever was diagnosed as a temperature above 38°C. Symptomatic uterine rupture was defined as complete disruption of the prior cesarean scar with at least one of the following: hemorrhage, hysterectomy, damage to the bladder, extrusion of any portion of the feto-placental unit from the uterus, or cesarean delivery for non-reassuring fetal testing or suspected uterine rupture.

Results: The rate of fever following the prior cesarean was 38% (8/21) among the cases, and 15% (18/84) in the controls [P =0.03]. Multiple logistic regression analysis examining the association of uterine rupture and postpartum fever adjusting for confounders revealed an odds ratio of 4.0 [95% C.I. 1.0, 15.5].

Conclusions: Postpartum fever after cesarean delivery is associated with an increased risk of uterine rupture during a subsequent trial of labor.

Commentary: Henry C. Coe prefaced his 1892 paper on elective cesarean section with these words:

> *The literature of Cesarean section is already so voluminous…that it seems presumptuous to pretend to advance anything that is novel or interesting in connection with the subject.* [1]

Coe underestimated the presumptuousness of his professional descendents: a MEDLINE search identified 18,999 articles on Cesarean since 1964, 239 of them on VBAC. In the last year alone, there were 372 English-language reports on some aspect of Cesarean birth, 16 of them on VBAC. Uterine rupture has been the subject of 1480 articles printed since 1965.

It is in this context that we ask: *does this publication add to our knowledge of the subject, and will it change clinical practice?*

The last part of the question is more easily answered: any article from a well-known institution —and published in a widely-read Ob/Gyn journal— will influence practice. Busy clinicians who skim through the abstracts will find here one more reason to abandon VBAC.

It has been a recurring theme in this forum that "statistically significant" associations between clinical variables do not establish a clinically-relevant causal relationship between them. Most authors are careful to avoid such inferences within the "fine print" of their article. However, since few clinicians are familiar with clinical trial design or statistical methods, publication of "conclusions" in an authoritative journal induces the casual reader to attach greater significance to the results than is warranted by the study. Perception becomes reality as obstetricians change their practice-style in response to these articles. The rise and fall of VBAC in the past twenty years is a case-in-point that was analyzed in my November 2002 MEDSCAPE reviews.

The randomized controlled trial (RCT) remains the "gold standard" of clinical evidence, notwithstanding the fact that even the best-designed RCT may lack external validity. A case-control study stands lower in the hierarchy of evidence because it is subject to numerous biases.

Defining the clinical outcome that identifies a "case" is the first source of error in case-control trials. This study compared patients with *symptomatic uterine rupture while undergoing a trial of labor after a prior cesarean section at the same institution* ["cases"] with similar women who did not suffer a uterine rupture ["controls"]. Symptomatic uterine rupture was defined as complete disruption of the prior cesarean scar with at least one of the following: hemorrhage, hysterectomy, damage to the bladder, extrusion of any portion of the feto-placental unit from the uterus, or cesarean delivery for non-reassuring fetal testing or suspected uterine rupture. The authors did not report the number in each category; nor did they explain if "complete disruption" included peritoneal rupture. They also did not define "hemorrhage", "non-reassuring FHR testing", or "suspected uterine rupture". The only criterion not subject to interpretation is "extrusion from the uterus". This definition was used by Bujold et al. [2] in another paper on uterine rupture reviewed this month, and allows for comparisons between different reporting institutions. Using a narrower definition would reduce the number of "cases" and influence the conclusions of this study.

Other sources of bias involve the definition and selection method of "controls". Controls are used to reduce the number of confounding variables. This, in turn, requires a judgment on the part of the researcher as to what factors might influence the outcome being examined. In this study, each "case" was matched to 4 "controls" by year of delivery, number of prior cesarean sections, prior vaginal delivery, and induction in the index pregnancy. *Why just those factors?* Most obstetricians would consider the indication for the prior cesarean, as well as the surgical complications of that cesarean, to be important in assessing both the risk and VBAC success rate of subsequent labor. How can one compare an elective primary C/S for breech to abdominal delivery following prolonged second stage, with impacted head, and extensive cervical/vaginal lacerations? In my opinion, the indication for cesarean should have been a matching criterion. Since the progress notes or operative reports don't always document all the complications, the duration of the procedure might serve as an index of difficulty and be used for matching. The type of suture employed to repair the uterine incision may well have an effect on scar integrity and should be similar in both cases and controls.

When articles are published in a journal intended for clinicians, authors have a duty to explain their methodology in plain language. They might discuss how a *nested case-control* study differs from a garden-variety case-control study, since I don't think many doctors are familiar with this term. They might also rationalize their decision to match each case with 4 controls (rather than only one, or all the available controls). Although 4393 women underwent a trial of labor after prior cesarean at Brigham & Women's Hospital from July 1984 to June 1996, only those who had their prior cesarean at B&W were included in the present study. This is logical since it allowed a chart review of the prior C/S. However, the authors omitted to report the number of women included in the final cohort, so we cannot calculate the overall rate of rupture. How many of these women were "matches"? Were the 4 controls per case selected randomly from all the available ones, or the first 4 that came up? Does this mean that only 21 case and 84 control charts were reviewed, and the

properties of the control cohort extrapolated from this small sample? What is the uncertainty associated with this assumption?

The authors did not state if this investigation was prompted by the hypothesis that post-cesarean fever was associated with a higher incidence of subsequent uterine rupture, or if the temperature relationship was an incidental observation after analyzing a VBAC database in another context. In either case, if the goal was to demonstrate the effect of fever, they should have repeated the study with new controls when the data showed an even stronger relationship between rupture and maternal age ≥30y than with post-cesarean fever.

A link between post-cesarean infection and later uterine rupture during labor has been suspected for over 80 years. In 1916, Findlay analyzed 63 cases [*there are 21 cases reported in the present study*] of uterine rupture following a previous classical cesarean section and concluded:

> *When Cesarean section has been followed by a fever course, the uterine wound should be regarded as insecure in event of a subsequent pregnancy and should call for a repeated section at the onset of labor.* [3]

Other prominent obstetricians of that era, John W Williams (*THE* Williams), Edward P Davis, and Paul Titus, shared similar viewpoints. [4], [5], [6] Gamble, however, examined 20 hysterectomy specimens with a previous classical C/S scar and found no apparent correlation between the condition of the scar (either grossly or histologically) and the former convalescence. [7]

During that pre-antibiotic era, sepsis meant a prolonged, stormy post-operative course associated with a maternal mortality rate sometimes exceeding 30%. Cesarean section in the presence of infection, or after failed attempts at vaginal delivery, was so dangerous to the mother that it was rarely performed except where the diagonal conjugate was too narrow to practice craniotomy. Under such circumstances, cesarean followed by supracervical hysterectomy with exteriorization of the cervical stump (Porro operation) was usually life-saving and eliminated the problem of subsequent rupture.

One can easily imagine that such severe infection —likely associated with anemia— would impair healing; yet, even in 1920s, following classical cesarean, the rate of uterine rupture during subsequent pregnancy was only 4%, half of these before the onset of labor. [8]

Following creation of the Joint Committee on Maternal Welfare in 1919, puerperal morbidity was defined as follows:

> *Temperature 38.0°C (100.4°F) or higher, the temperature to occur on any 2 of the first 10 days postpartum, exclusive of the first 24 hours, and to be taken by mouth by a standard technique at least four times daily.*

This definition still appears in the 21st (2001) edition of Williams' Obstetrics, yet Shipp *et al* found it necessary to re-define "fever" as any temperature greater than 38°C persisting past the first postpartum hour. With 75% of their patients receiving antibiotic prophylaxis I suspect they would have found far fewer instances of fever using the standard definition. Transient temperature elevations during labor and the puerperium may have non-infectious etiologies, including epidural use, milk engorgement, and atelectasis following general anesthesia. The overall use of epidural was similar in cases and controls, but it was not stated how many Cesareans were performed under general anesthesia; the emergency nature of surgery for suspected uterine rupture makes it likely that G.A. was employed more often among the cases. This is yet another confounding factor that can be controlled for during the matching process.

If the authors' conclusions are valid, it will certainly knock one more nail into the VBAC coffin, since information about prior febrile morbidity is not readily available. As an experienced

obstetrician, I remain skeptical that "fever" as defined in this article has much impact on scar integrity. In light of my earlier comments, it will take a more rigorous prospective study to convince me otherwise.

In recent years, manuscript authors have been required to declare potential conflicts-of-interest, and document Institutional Review Board approval of their study before publication. The proliferation of articles containing extensive statistical analyses has made it tedious for clinical reviewers —and impossible for casual readers— to properly evaluate the CLINICAL significance of the results. It is time for journal editors to require an attestation from an independent professional statistician that the study design and statistical techniques employed were suitable to test the research hypotheses of the study.

1. Coe HC; The Elective Cesarean Section: The most favorable time for operation; Trans Am Gyn Soc 1892; 17: 87-97
2. Bujold E, Mehta SH, Bujold C, Gauthier RJ; Interdelivery Interval and Uterine Rupture;Am J Obstet Gynecol 2002; 187: 1199-1202
3. *quoted in* Getman WT; Indications and Contraindications for Cesarean Section; Am J Dis Women Child 1917; 75: 781-91
4. Williams JW; Delivery by the Natural Passages following Cesarean Section; Am J Obstet 1919; lxxx: 435
5. Davis EP; Elective Cesarean Section; Trans Am Gyn Soc 1919; 44: 249-63
6. Titus, P; Repeated Cesarean Section; Am J Obstet Gynecol 1920; 1: 835-48
7. Gamble TO; Johns Hopkins Hosp Bull 1922; xxxiii: 93; *reviewed in*: DeNormandie RL; Report on Obstetrics; Boston Med Surg J 1922; 187: 506-12
8. Williams JT; The Care of Pregnancy and Labor in patients previously delivered by Cesarean section; Boston Med Surg J 1922; 186: 599-602

REVIEW #47

Title: The Effect of Intra-abdominal Irrigation at Cesarean Delivery on Maternal Morbidity: A Randomized Trial

Authors: KM Harrigill, HS Miller, and DE Haynes

Site: University of Arizona Health Sciences Center, Tucson, Arizona

Published: Obstet Gynecol 2003; 101: 80-5

Objective: To determine if intra-abdominal irrigation with normal saline at cesarean delivery is associated with increased maternal morbidity.

Methods: 196 women undergoing routine cesarean delivery at term were randomized prospectively to receive either 500-1000 mL of normal saline intra-abdominal irrigation or no irrigation after closure of the uterine incision. The primary outcome measure was the incidence of maternal morbidity, defined as one or more of the following: postoperative fever, hemorrhage, severe anemia, and urinary retention.

Results: 97 patients received irrigation, and 99 served as the control group. The demographic characteristics of the two groups were similar. Fourteen patients (14.4%) in the irrigation group experienced maternal morbidity compared with 13 (13.1%) in the control group [P= 0.84].

Conclusions: Routine intra-abdominal irrigation at cesarean delivery in a low-risk population has no effect on post-operative maternal morbidity.

Commentary: There are probably as many rituals in surgery as there are surgeons. Rituals are procedures performed for no other reason than "that's what I learned as a resident" or because "something bad happened the last time we didn't do this". In this sense, surgery is no different from any human endeavor requiring a combination of skill and luck (golf ?): we stick with what works for us, and change only when our lucky streak comes to an end. If you still close the abdominal fascia with chromic, you haven't yet had a wound dehiscence or hernia.

To avoid being perceived as superstitious, surgeons rationalize their use of a particular ritual using any number of plausible explanations. Thus, intra-abdominal irrigation "confirms hemostasis", "dilutes the bug count", "prevents adhesions" etc. In the days when surgery was performed without the benefit of intravenous fluids, antibiotics, or blood transfusion, it was observed that leaving a liter or two of saline in the abdominal cavity reduced post-operative shock and improved urine output. Some surgeons added antiseptics to their irrigating fluid, prompting debates about whether or not it was possible to "sterilize" the peritoneal cavity. Antibiotics, Dextran, and heparin are among some of the more recent additives to irrigating fluid. Then again, many surgeons don't irrigate at all!

This randomized trial concluded that routine intra-abdominal irrigation at Cesarean section has no effect whatsoever on post-operative morbidity. In the absence of any measurable benefit, eliminating routine irrigation would reduce operating time by a few minutes, and save a buck or two in supplies.

Rituals are an endangered species. Changes in hospital practice and evidence-based clinical guidelines have conspired to eliminate many time-honored routines. Although there was evidence that night-before shave preps increased the incidence of wound infection, the practice was common

in Ob/Gyn until same-day surgical admissions made them impractical. For that matter, when was the last time anybody ordered a soap-suds enema prior to surgery?

REVIEW #48

Title: Interdelivery Interval and Uterine Rupture

Authors: E Bujold, SH Mehta, C Bujold, and RJ Gauthier

Site: Hôpital Ste-Justine, Montreal, Quebec, Canada

Published: Am J Obstet Gynecol 2002; 187: 1199-1202

Objective: To assess the impact of interdelivery interval on uterine rupture during subsequent delivery.

Methods: An observational cohort study was performed to assess the rate of symptomatic uterine rupture in women with a previous low transverse cesarean delivery and no previous vaginal delivery who underwent a trial of labor between 1998 and 2000 in a tertiary care center. The rate of uterine rupture was measured for each of the following interdelivery intervals: ≤ 12 months, 13-24 months, 25-36 months, and > 36 months. Multivariate logistic regression analysis was used to adjust for confounding variables.

Results: Of the 1527 women who met the study criteria, the rate of uterine rupture was 4.8% for patients with an interdelivery interval of ≤12 months, 2.7% with an interdelivery interval between 13 and 24 months, and 0.9% in each of the longer intervals [P= 0.04]. After adjusting for confounding variables, the odds ratio for uterine rupture in women with an interdelivery interval of ≤24 months was 2.65 (95% C.I.. 1.08-6.46). The O.R. for uterine rupture following single-layer (versus double-layer) closure of the previous uterine incision was 4.33 (95% C.I., 1.70-10.98). The combination of an interdelivery interval ≤24 months and a single-layer closure of the previous uterine incision were associated with a rate of uterine rupture of 5.6%.

Conclusions: An interdelivery interval of ≤24 months was associated with a 2-3 fold increase in the risk of uterine rupture compared with an interval > 24 months.

Commentary: In their first publication on uterine rupture [1] —reviewed in MEDSCAPE, August 2002— the authors concluded that single-layer closure of the uterine scar increased the risk of symptomatic uterine rupture during subsequent labor by a factor of 4.

They now report that the interval between prior cesarean and subsequent labor is inversely correlated with the risk of uterine rupture during the trial. The combination of short interdelivery interval and single-layer uterine closure was associated with a 5.6% rate of uterine rupture.

These are interesting observations that merit further study. Surgeons know that cosmetic maturation of an abdominal scar takes at least one year; it is thus plausible that complete healing of the uterine incision takes a similar amount of time. One could conjecture that pregnancy occurring within a few months would stretch out the uterus before healing was complete and lead to a weaker scar.

Nonetheless, this is an observational study involving very small numbers of patients, with no case-controls, and one should interpret the conclusions with caution. There were only 21 cases of uterine rupture over a 12 year period, and only 1 in the ≤12 month interdelivery interval group of 21 patients; no clinical details about that case were presented. Other writers [2] have shown an association between post-operative fever and subsequent uterine rupture, but there is no information about febrile morbidity in this paper.

If scar maturation is indeed a factor in uterine rupture, it is likely that the healing process is gradual rather than step-wise; the latter is an artifact of the limited dataset in this study. The cosmetic variations observed in skin incisions among different patients is evidence that individual characteristics play an important, but clinically ill-defined, role in healing. Finally, the type of suture material employed to close the uterine incision may influence the integrity of the scar; at this institution, chromic catgut was employed in almost all the operations.

1. Bujold E, Bujold C, Hamilton EF, Harel F, Gauthier RJ Am J Obstet Gynecol 2002; 186(6): 1326-1330
2. Shipp TD, Zelop C, Cohen A, Repke JT, Lieberman E Obstet Gynecol 2003; 101: 136-9

REVIEW #49

Title: Isolated Choroid Plexus Cyst in low-risk women less than 35 years old

Authors: K Demasio, J Canterino, C Ananth, C Fernandez, J Smulian, and A Vintzileos

Site: University of Medicine and Dentistry of New Jersey, New Brunswick, New Jersey

Published: Am J Obstet Gynecol 2002; 187: 1246-9

Objective: To determine the incidence of trisomy 18 in women < 35 years of age who have a sonographically-detected isolated choroids plexus cyst.

Methods: A meta-analysis of prospective trials that were published in the English language between 1990 and 2000 was performed. Each trial met the following inclusion criteria: (1) prospective trial, (2) total population screened during the study period reported, (3) maternal age reported, and (4) pregnancy/neonatal outcomes reported. An isolated choroid plexus cyst for the purpose of this study was defined as absence of sonographically-detected structural abnormalities and normal serum screens if reported.

Results: Eight trials met the criteria and were used for analysis. A total of 106,732 women were screened. 1235 (1.2%) choroids plexus cysts were identified during second-trimester ultrasound. The incidence of isolated choroids plexus cysts in women < 35 years of age was 1.0% (1017 women): there were no cases of trisomy 18 in this group. Four structural abnormalities were noted after birth; all four infants had normal karyotypes.

Conclusions: There is no evidence that detection of isolated choroids plexus cyst in women < 35 years of age increases the risk of Trisomy 18. Therefore, amniocentesis is not warranted.

Commentary: Improvements in the availability and technical quality of ultrasound have been a mixed blessing for obstetricians and their patients. In the October 2002 MEDSCAPE Journal Scan, I discussed some problems engendered by the earlier diagnosis of missed abortion.

Second trimester ultrasound now routinely identifies many fetal anatomical variants of uncertain clinical significance. These include choroids plexus cysts, echogenic foci in the cardiac ventricles, dilation of the upper urinary tract, short femurs, two-vessel umbilical cords etc…

Instead of just reporting their observations, many radiologists feel compelled to add boilerplate comments on the management of these findings. In my institution, a diagnosis of choroid plexus cyst is always accompanied by warnings about the possible association with Trisomy 18. This imposes a burden of counseling on the obstetrician, creates anxiety for the patient, and usually results in a referral to the High-Risk clinic for further testing.

This study provides much-needed re-assurance to patients and doctors alike, and will reduce the workload of genetic counselors.

REVIEW #50

Title: Clinical Significance of the Floating Head in Nulliparous Women in Labor

Authors: A Debby, S Rotmensch, O Girtler, O Sadan, A Golan, and M Glezerman

Sites: Edith Wolfson Medical Center, Tel Aviv, Israel

Published: J Reprod Med 2003; 48: 37-40

Objective: To examine the course of labor in nulliparous women in active labor with a floating fetal head.

Methods: A prospective cohort study of nulliparous women presenting in active labor at term with a floating fetal head (station above –3, N= 108), or engaged fetal head (N= 241). Assignment to groups was determined after examination by a senior physician. Active labor was defined as the presence of regular uterine contractions and cervical dilatation ≥4 cm. According to department protocol, all patients in active labor with intact membranes underwent artificial rupture of membranes. Subsequent management of labor was at the discretion of the labor ward team on duty.

Results: Cesarean section rates for failure to progress were significantly higher in the study group (17.1% versus 4.2%, $P < 0.0001$), and the second stage of labor was prolonged (65.3 ± 27.1 versus 54.9 ± 30.2 minutes, $P < 0.03$). None of the women who had a persistently floating fetal head at 7 cm of cervical dilatation delivered vaginally. Birth weights were larger ($P <0.03$) and Apgar scores lower ($P<0.0001$) in the study group. The lengths of the active phase, and the rates of instrumental delivery were similar in the two groups.

Conclusions: Nulliparous women presenting in active labor with a floating head are at substantially increased risk of cesarean section for abnormal progress of labor. However, the vast majority will still deliver vaginally. A persistently floating head at advanced cervical dilatation should prompt consideration of cesarean section since little is to be gained by waiting.

Commentary: In nulliparous women, the fetal head commonly engages before the onset of labor. This is sometimes called “lightening” when accompanied by a perceptible decrease in upper abdominal discomfort, and a parallel increase in pelvic pressure. A high head at term in a nullipara has long been considered a possible sign of cephalo-pelvic disproportion.

The good news from this study is that, although 31% of nullipara presented in active labor with a “floating head”, 82.9% of them delivered vaginally. This 17.1% C/S rate, however, was four times greater than in the control group.

American obstetricians will probably find all these numbers surprising. I doubt that any U.S. hospital has seen a C/S rate under 5% since the 1960s. The active-management protocol in Tel Aviv appears similar to the Dublin approach: early amniotomy, and liberal use of oxytocin. However, the exceedingly low cesarean rate probably reflects some characteristics unique to this population. The 16.2% rate of instrumental delivery in the study group suggests frequent elective intervention, given a mean 2nd stage duration of only 65.3 minutes.

According to Ian Donald.[1] the commonest cause of a high head at term is the occiput posterior position, usually associated with some degree of deflexion. This has also been my experience. In the absence of disproportion (which is rare in this country), oxytocin, good analgesia,

and time will usually correct malposition. Since estimates of fetal size are inaccurate, and pelvimetry methods unreliable, a trial of labor is almost always indicated when the head is high.

1. Donald I; Practical Obstetric Problems; 5th Ed 1979; Lloyd-Luke Ltd p. 523

REVIEW #51

Title: Mifepristone/ misoprostol and methotrexate/misoprostol in clinical practice for abortion

Authors: MD Creinin, C Potter, M Holovanisin, L Janczukiewicz, HC Pymar, JL Schwartz, L Meyn

Site: Department of Obstetrics, Gynecology, and Women's Health, University of Pittsburg, Pittsburgh, PA

Published : Am J Obstet Gynecol 2003; 188: 664-9

Objective: To evaluate the efficacy, side-effect profile, and follow-up rates in women who obtain a medical abortion in a nonresearch setting.

Methods: From December 1, 2000 to June 30, 2001 the authors followed 218 women who had been evaluated in their private office for medical abortion. Women received either mifepristone 200 mg orally followed 1 to 2 days later by self-administered misoprostol 800 μg vaginally, or methotrexate 50 mg/m^2 intramuscularly followed 3 to 7 days later by self-administered misoprostol 800 mg vaginally.

Results: Of the 174 women who had a medical abortion, 148 (85%) chose mifepristone/misoprostol and 26 women (15%) chose methotrexate/misoprostol. In women up to 49 days of gestation, complete abortion occurred by the first follow-up visit in 82 of 86 women (95.3%) and in 21 of 25 women (84.0%), respectively. In women who used mifepristone/misoprostol from 50 to 63 days of gestation, complete abortion occurred in 56 of 59 women (94.9%). 5 women in the mifeprostone group required a suction D&C for incomplete abortion, whereas 1 woman in the methotrexate group had a D&C because of failure to abort by the 3rd follow-up visit. Four women were lost to follow-up.

Conclusions: Medical abortion with either regimen can be provided in a nonresearch setting with efficacy similar to that reported in the medical literature for research protocols.

Commentary: Although abortion has been legal in the USA for 30 years, many States have enacted legislation that limits access to abortion. Paradoxically, these roadblocks have had the greatest impact on women who are the least-equipped —financially and socially— to raise a child. This is certainly not in the public interest.

Suction curettage in a specialized clinic is undoubtedly the most efficient way to provide abortion services. However, most such facilities have attracted a determined group of protesters who hope to prevent abortion by intimidating women and their providers. They have been successful enough that many physicians are unwilling to offer abortion services, for fear of attracting unwanted attention from anti-abortion groups.

Medical abortion evolved as a way of providing early pregnancy termination in a confidential office setting. This "low-profile" —to say nothing of the cost and the need for early and frequent office visits— makes medical abortion even less practicable for women of low socio-economic status.

The FDA-approved regimen for medical abortion at ≤49 days of gestation involves mifepristone 600 mg orally, followed 2 days later by misoprostol 400 μg orally. Many other regimens show comparable efficacy, at less cost; the authors of this study chose their particular protocols after reviewing the published literature.

This report documents the efficacy and safety of medical abortion in a private-practice setting. Although published as "research", with an "objective" and a "study-design", there is no evidence that this project was approved by an Institutional Review Board, or that patients signed a consent to participate in research. The authors state that the patients "chose" the protocol to be used, yet it is clear that methotrexate/ misoprostol was not offered after 49 days; the fact that 77% of women before 49 days chose the mifepristone regimen suggests some sort of information bias.

In brief, this appears to be a retrospective "series" and should have been published as such. Although it cannot be used to prove the superiority of one regimen over another, it does demonstrate that medical abortion can be provided in a cost-effective manner in a multi-provider private-practice setting.

REVIEW #52

Title: Metformin for the treatment of Polycystic Ovary Syndrome

Author: RL Barbieri

Site: Department of Obstetrics and Gynecology, Brigham and Women's Hospital, Boston, MA

Published: Obstet Gynecol 2003; 101: 785-93

Objective: To familiarize the obstetrician-gynecologist with the use of metformin for the treatment of polycystic ovary syndrome (PCOS).

Methods: This is a review of 94 English language articles published after 1966, indexed with the keywords "metformin" and "polycystic ovary syndrome". Studies were excluded if they did not have a control group, did not use the National Institute of Health definition of PCOS, did not have a clinical outcome as an end point. Reviews were also excluded, leaving 21 articles for inclusion in this study.

Results: Three clinical trials reported that for the induction of ovulation associated with PCOS, metformin plus clomiphene is more effective than clomiphene alone. For the treatment of irregular menses associated with PCOS, metformin therapy may restore ovulatory menses in the majority of women. However, most women will require 4-6 months of metformin therapy before they achieve ovulatory periods. In obese women, metformin plus a low-calorie diet may be associated with more weight loss than a low-calorie diet alone.

Conclusions: PCOS is a common gynecologic endocrine disorder. Obstetrician-gynecologists should be familiar with the indications and contra-indications for the use of metformion in their practice.

Commentary: This is an excellent summary of the recent clinical literature on the use of metformin in PCOS, by an author who has contributed to the field for over 20 years. Although endocrine/infertility specialists and internists have been aware of these applications, this information is only now reaching the non-academic gynecologist.

In 1935 Irving Stein and Michael Leventhal (from Chicago) described 7 women with amenorrhea associated with bilateral polycystic ovaries: [1]

> *…the ovaries were found to be from two to four times the normal size…The ovarian cortex was …hypertrophied in all of the cases and the tunica thickened, tough, and fibrotic. The cysts were follicle cysts, near the surface, and almost entirely confined to the cortex, and they contained clear fluid. There were from 20 to 100 cysts in each ovary, varying in size from 1 mm to about 1.5 cm, but rarely larger. The color of the ovary was oyster gray with bluish areas where the cysts were superficial.*
>
> Clinically, *…there was observed a distinct tendency toward masculinizing changes*.

The treatment of amenorrhea and sterility in the group of patients under consideration was at first conservative, using endocrine preparations; eventually the treatment became surgical. In some earlier cases … estrogenic hormone preparations were injected intramuscularly…in an effort to adjust the menstrual cycle…Uterine bleeding occurred…in some instances, but it is impossible to say whether this was true menstruation or anovular bleeding. At any rate, no lasting restoration of function followed these treatments and no pregnancies occurred.

…In the patients referred to in this series, we have resected from one-half to three-fourths of each ovary by wedge-resection, thereby removing the cortex containing the cysts, and have sutured the hilus with the finest catgut…All of the patients recovered uneventfully…Uterine bleeding occurred on the third to the fifth post-operative day and menstruation occurred monthly thereafter in every case, Our first patient, operated upon four years ago, has given birth to two children since operation.

Despite the difficulty of diagnosing polycystic ovaries without surgery, the Stein-Leventhal syndrome became a recognized entity in gynecology, and ovarian wedge-resection a standard surgical technique. Controversy about its mode of action continues to this day, but the simplicity of wedge-resection led to its indiscriminate use in women with amenorrhea and infertility. Although described in textbooks as recently as the 1990s, classic wedge-resection via laparotomy fell into disuse following the introduction of clomiphene citrate in the 1960s and the laparoscope in the 1970s. Clomiphene could induce ovulation in 80% of women with Stein-Leventhal syndrome, and laparoscopy revealed that wedge-resection often caused adhesions which interfered with fertility despite a resumption of ovulatory cycles.

By the 1960s, it was apparent to infertility/endocrine specialists that the diagnosis of Stein-Leventhal syndrome was not always simple: many women with infertility, amenorrhea and hirsutism did not have polycystic ovaries; conversely, many women with polycystic ovaries lacked the other stigmata of the syndrome. Nonetheless, clinical management became somewhat standardized: ovulation induction with clomiphene for the infertility patient, E/P BCP for cycle-control and reduction of androgen levels in the others.

Over the past twenty years, the Stein-Leventhal syndrome has become known as the Polycystic Ovary Syndrome (PCOS) in the world literature. The diagnosis remains controversial. In Europe, greater emphasis is placed on the presence of cysts, whereas in America recommended diagnostic criteria include biochemical evidence of hyperandrogenism and ovarian dysfunction. Whatever definition is applied, PCOS is extremely prevalent — affecting perhaps 10% of women— and more protean in its manifestations than was imagined by gynecologists.

In 1980, Burghen et al. [2] reported hyperinsulinemia in women with PCOS, compared with weight-matched controls, implying the presence of insulin resistance. They also found a positive linear relationship between insulin and androgen levels. Insulin resistance is important in the pathogenesis of Type 2 diabetes, and it has been confirmed that PCOS is a major risk factor for Type 2 diabetes in women, regardless of age. Because much of this research has been published in journals of endocrinology and internal medicine, it has been slow reaching the average gynecologist.

Agents that exacerbate insulin resistance should probably be avoided in obese women with PCOS. Oral contraceptives, widely-used in PCOS to control menstrual irregularity and

hyperandrogenism, are known to produce insulin resistance in normal women. It would seem prudent to test glucose tolerance in women with PCOS on the BCP, or consider the addition of metformin. Metformin (GLUCOPHAGE©) has been used for the management of Type 2 diabetes for many years. Its mechanism of action is not clearly understood, but it enhances insulin sensitivity and does not cause hypoglycemia.

In the treatment of hirsutism, as Barbieri points out in his review, agents that block androgen action (e.g. spironolactone) may be more effective than those that suppress androgen production (e.g. BCP or Metformin).

It remains to be seen whether metformin will prove to be a panacea for most women with PCOS, but it is a useful addition to our therapeutic armamentarium.

1. **Stein IF, Leventhal ML** Amenorrhea associated with bilateral polycystic ovaries. Am J Obstet Gynecol 1935; 29: 181-191
2. **Burghen GA, Givens JR, Kitabchi AE** Correlation of hyperandrogenism with hyperinsulinism in polycystic ovarian disease. J Clin Endocrinol Metab 1980; 50: 113-116

REVIEW #53

Title: A Study of non-closure of the peritoneum at vaginal hysterectomy

Authors: EC Janschek, M Hohlagschwandtner, A Nather, M Schindl, EA Joura

Site: Department of Obstetrics and Gynecology, General Hospital of Vienna, Vienna, Austria

Published: Arch Gynecol Obstet 2003; 267: 213-216

Objective: To determine whether non-closure of the peritoneum following vaginal hysterectomy is safe.

Methods: This was a retrospective case-controlled study of 233 patients who underwent either total vaginal hysterectomy (TVH) or laparoscopically-assisted vaginal hysterectomy (LAVH) at the General Hospital of Vienna. Surgeons were free to close the peritoneum or not. When the peritoneum was closed, the vault was left open; when the peritoneum was not closed, the vaginal cuff was sutured to the uterosacral ligaments and closed. Cohorts of patients were formed according to their peritonealization status (open, n=117; closed, n=116), and further stratifies according to the type of surgical procedure: simple TVH (n=115), TVH with concurrent vaginal repair and/or urinary incontinence surgery (n=91), and LAVH (n=27). Outcomes analyzed included: operative time, blood loss, analgesia, fever, infection, hemorrhage, or re-operation.

Results: No significant differences were observed in surgical outcomes or complications, based on peritonealization status. However, after simple TVH, resumption of bowel function took place earlier in patients with open peritoneum than in those where it has been sutured. (1.9 vs 2.4 days, P=0.001). No patients were re-admitted for prolapse of the vaginal vault in either group.

Conclusions: Non-closure of the peritoneum at vaginal hysterectomy appears to be safe. Omission of peritoneal closure reduces the potential risk of injury and has a beneficial effect on bowel function.

Commentary: In the March 2003 Ob/Gyn Journal Scan, I discussed the subject of surgical rituals in the context of peritoneal irrigation at the time of Cesarean section. Is closure of the peritoneum at gynecologic surgery a ritual i.e. a time-honored procedure unsupported by clinical evidence?

It would seem logical to suture all the layers we cut at surgery, including the peritoneum. This is indeed what surgeons have taught and practiced for most of the last hundred years. As recently as 20 years ago, most gynecologists spent almost as much time burying pedicles and re-peritonealizing as doing the actual hysterectomy. Contemporary atlases still describe closure of the parietal and visceral peritoneum as standard technique.

Perhaps it was reports that suturing peritoneum caused more adhesions, that peritoneum closed itself spontaneously within a few days and provided little additional strength to the incision…

As a junior attending in the mid eighties, I remember being told by residents —citing some recent reference— that it was *passé* to close peritoneum. So we gradually stopped closing

one layer after another without any obvious complications, and appreciated the decreased operating time.

Until recently, vaginal hysterectomy in most North American teaching hospitals was performed mostly for genital prolapse, with concomitant anterior and posterior colporrhaphy. Repair and prophylaxis of enterocele usually entailed McCall-type culdoplasties which closed the peritoneum. All pedicles were extra-peritonealized in order to permit early diagnosis of hemorrhage; the vault, of course, was whip-stitched and left open for drainage.

The trend to LAVH and simple vaginal hysterectomy for benign disease has decreased hospital stay and improved patient satisfaction. In the presence of good pelvic support, the vault is at a higher station, making it technically more difficult to close the peritoneum. In a younger woman, is it desirable to extra-peritonealize the utero-ovarian pedicles, thus anchoring the ovaries near the vaginal vault and possibly causing dyspareunia? A purse-string peritoneal suture bunches up the rectum at the level of the yellow-line, the bladder, and the ovaries just above the vault. Is that a good thing?

Having abandoned closing the visceral peritoneum at abdominal hysterectomy, and for the reasons outlined above, it seemed consistent to omit closure of the peritoneum at simple vaginal hysterectomy. For the last five years, I have left the peritoneum open, without any evident complications. I usually anchor the utero-sacral ligament pedicles to the vault and close the vault with interrupted figure-of-eight sutures, without drainage or packing.

Others have obviously had similar thoughts, and now comes a study vindicating this practice. Although no formal randomization took place, it is surprising that the number of patients in each group was so similar. It is not clear why the surgeons closing the peritoneum left the vault open and did not attach the utero-sacral ligament pedicles to the vault. It is not surprising that omitting peritoneal closure improved bowel function, since the rectal serosa is not sutured.

It is now time to do a prospective, randomized trial, using similar techniques except for peritoneal closure.

REVIEW #54

Title: Therapeutic Equivalence of Alendronate 35 milligrams once weekly and 5 milligrams daily in the prevention of postmenopausal osteoporosis

Authors: MM Luckey, N Gilchrist, HG Bone, MW Davie, TJ de Villiers, M Wu, AG Daifotis, AC Santora, JJ Orloff

Sites: Livingston, NJ; Christchurch, New Zealand; Detroit, MI; Shropshire, United Kingdom; Capetown, South Africa; Rahway, NJ

Published: Obstet Gynecol 2003; 101: 711-21

Objective: To evaluate the efficacy and safety of alendronate 35 mg once weekly compared to alendronate 5 mg daily in the prevention of osteoporosis.

Methods: The authors compared the efficacy and safety of treatment with alendronate 35 mg once weekly (n=362) and aldendronate 5 mg daily (n=361) in a 1-year, double-blind, multicenter study of post-menopausal women (6 months or greater), aged 40-70 years, with lumbar spine and femoral neck bone density T-scores between –2.5 and 1. The primary efficacy end point was the lumbar spine bone mineral density increases, defined by strict prespecified criteria.

Results: Mean increases in lumbar spine bone mineral density at 12 months were equivalent. Bone mineral density increases at other skeletal sites and effects on bone turnover were also virtually identical for the two dosing regimens. Both treatment regimens were well tolerated, and the larger weekly unit dose was not associated with an increased frequency of upper gastrointestinal events.

Conclusions: Aldendronate 35 mg once weekly is therapeutically equivalent to aldendronate 5 mg daily and provides patients with greater dosing convenience, in addition to the proven efficacy of alendronate and good tolerability.

Commentary: The negative publicity surrounding post-menopausal hormone therapy has led many women to stop what is also an excellent method of preventing bone loss. In women with documented osteopenia, or a strong family history of osteoporosis, aldendronate (FOSOMAX©) has been shown to improve bone density and reduce fractures. The need for daily administration and the frequent incidence of upper G.I. symptoms has limited the use of this otherwise excellent drug. Once a week administration, with no increase in side-effects, will undoubtedly improve compliance. The only question: will the cost be 7 times as much?

REVIEW #55

Title: Human Chorionic Gonadotrophin Follow-up in patients with molar pregnancy: A time for reevaluation

Authors: CM Feltmate, J Batorfi, V Fulop, DP Goldstein, J Doszpod, RS Berkowitz

Sites: multiple sites in Boston, MA; Budapest, Hungary

Published: Obstet Gynecol 2003; 101: 732-6

Objective: To determine the compliance of patients with molar pregnancy with follow-up protocols, and identify factors that may predict failure to complete the recommended HCG monitoring. The study also sought to determine the rate of relapse in non-compliant patients after attaining at least one undetectable HCG level.

Methods: 400 randomly selected patients with molar pregnancy were analyzed regarding the serum HCG levels after molar evacuation. The following demographic information was recorded: age, marital status, gravidity, parity, health insurance type, and distance from patient home to the trophoblastic center.

Results: Of the 333 uncomplicated cases, 211 (63%) completed the American College of Obstetrician and Gynecologists (ACOG)-recommended HCG follow-up. [HCG levels 48-hours post evacuation, and every 1-2 weeks until levels are undetectable. After that, HCG levels are measured every 1-2 months for an additional 6-12 months.] 320 patients achieved at least one undetectable HCG level; of these, 33% did not complete the recommended follow-up. However, none had any evidence of relapse. A distance greater than 20 miles from the patient's residence to the medical center was associated with failure to complete HCG follow-up (P=0.001)

Conclusions: Because none of the 320 patients who achieved at least one undetectable HCG level has been diagnosed with gestational trophoblastic tumor relapse, it may be appropriate to re-assess the duration of HCG monitoring in patients with molar pregnancy.

Commentary: In 1754, William Smellie described a classic hydatidiform mole:

> *…introducing my fore and middle fingers into the vagina, felt something which I mistook for clotted blood. It filled both my hands when I brought it away, and appeared to be a large bundle of Hydatides connected with one another by an infinite number of small, slender filaments. These bladders contained a clear lymph, and were of different sizes, some as large as my thumb, and others as small as a pin's head; and her pains continuing, she evacuated as many as filled a two quart basin: thus delivered, she was freed from her pains, her flooding ceased, and the womb contracted to the size of my fist.* [1]

J.W. Williams, in the first edition of his textbook, noted that Ætius had written about a mole in the early 6th century.[2] Velpeau and Madame Boivin in 1827, first recognized

hydatidiform moles as diseases of the chorion. In a small number of cases, the hypertrophic villi invade the uterine wall, sometimes reaching the peritoneal surface of the uterus, causing perforation and fatal intraperitoneal hemorrhage. This was referred to as *chorioadenoma destruens*. A hundred years ago, the immediate mortality associated with a mole was approximately 10%, (5% from infection, 3% from hemorrhage at the time of operation, 2% from perforation).

Sänger in 1889 first applied the term *deciduoma malignum* to a very malignant variety of uterine tumor which develops from the epithelial elements of the chorion after a full-term labor, abortion, or hydatidiform mole. The *deciduoma malignum* consisted of a small primary growth which gave rise to abundant metastases, particularly in the lungs, vagina, and brain. Unless diagnosed early and removed by surgical procedures, the tumor usually proved fatal within the first year. Williams described it as *the most rapidly fatal malignant growth with which we are acquainted*.

Recognizing both the inherent danger of moles, but especially the possible subsequent development of a *deciduoma malignum* (*aka* choriocarcinoma), Williams advocated emptying the uterus as soon as a positive diagnosis was made. He also advised:

> ***Every woman who has suffered from a hydatidiform mole should be carefully watched for the next few months**, and if hemorrhage makes its appearance the interior of the uterus should be palpated. Whenever a small nodular growth is present it should be removed and subjected to microscopic examination; and if the characteristic lesions of deciduoma are found to be present immediate hysterectomy is imperative, in the hope of avoiding metastases.* [2]

Treatment remained surgical (with over 50% mortality) until the introduction of methotrexate by Li, Hertz, and Spencer in 1956. [3] The rest, as they say, is history. Their classic paper is reprinted in Speert's "Obstetric and Gynecologic Milestones" [4]. As Speert observed, this was not a fortuitous discovery:

> *Hertz and Tullner showed that folic acid was indispensable to estrogen-induced growth of the uterus and that such growth could be inhibited by the addition of folic acid antagonists to the diet. In 1949 they predicted that "these phenomena may provide a basis for the development of chemical agents of therapeutic value in such clinical states as prostatic and breast cancer, in which the suppression of the biological effectiveness of endogenous steroid hormones has proven beneficial"*. [4]

Other scientists showed that methotrexate, a folic-acid antagonist, caused the death and resorption of fetal rats in doses well-tolerated by the mother. Because trophoblastic disease produced large amounts of gonadotrophins which could be assayed in the urine, it was a natural candidate for testing the effect of MTX in humans. GTN can now be cured in most cases, even in the presence of extensive metastases, with preservation of reproductive capacity following remission.

The risk of malignant sequelae following surgical evacuation of a hydatidiform mole is 15-20% for complete moles, and < 5% for partial moles. Most moles encountered by the average gynecologist are partial moles diagnosed after D&C for missed abortion. Follow-up

protocols typically reflect a “worst-case scenario” approach to surveillance. As these authors demonstrate, not one of 320 patients who achieved a single negative HCG following a diagnosis of molar pregnancy developed a recurrence. The ready availability of quantitative serum HCG and ultrasound permitting early diagnosis of a new pregnancy should permit a relaxation of surveillance without undue risk to the patient.

One *caveat* remains: there have been reports in the recent literature of false-positive HCG results. [5] Persistent low levels of HCG should be interpreted conservatively in order to avoid over-zealous or unwarranted treatment.

1. **Smellie W** A Collection of Cases and Observations in Midwifery 1754, Volume 2 p.98-101
2. **Williams JW** Obstetrics 1903: 489 D. Appleton and Company, New York
3. **Li MC, Hertz R, Spencer DB** Effect of Methotrexate Therapy upon Choriocarcinoma and chorioadenoma. Proc Soc Exp Biol & Med 1956; 93: 361-366
4. **Speert H** Obstetric and Gynecologic Milestones Illustrated 1996: 400-404 The Parthenon Publishing Group NY
5. **Rode L, Daugaard G, Fenger M, Hilsted L, Moller LK, Raaberg L, Ottesen B** Serum-hCG: still a problematic marker. Acta Obstet Gynecol Scand 2003; 82: 199-200

REVIEW #56

Title: Prophylactic administration of progesterone by vaginal suppository to reduce the incidence of spontaneous preterm birth in women at increased risk: A randomized placebo-controlled double-blind study

Authors: da Fonseca EB, Bittar RE, Carvalho MHB, Zugaib M

Site: University of Sao Paulo, Brazil

Published : Am J Obstet Gynecol 2003; 188: 419-24

Objective: To evaluate the effect of prophylactic vaginal progesterone in decreasing preterm birth rate in a high-risk population

Methods: Randomized double-blind, placebo-controlled study involving 142 high-risk singleton pregnancies. Progesterone (100 mg) or placebo was administered daily by vaginal suppository. All patients underwent 60 minutes of uterine contraction monitoring every week from 24 to 34 weeks of gestation. The two groups were compared for epidemiologic characteristics, uterine contraction frequency, and incidence of preterm birth, using χ^2 analysis and Fisher exact test.

Results: The overall preterm birth rate was 21.1% (30/142). Differences in uterine activity were found between the progesterone and placebo groups (23.6% vs 54.3%, respectively, $P < .05$) and in preterm birth (13.8% vs 28.5%, respectively, $P <.05$). More women were delivered before 34 weeks in the placebo group (18.5%) than in the progesterone group (2.7%) [$P <.05$].

Conclusions: Prophylactic vaginal progesterone reduced the frequency of uterine contractions and the rate of preterm delivery in women at high risk for prematurity.

Commentary: Despite the best efforts of care providers worldwide, the incidence of pre-term delivery has not changed appreciably in the last generation. By the time objective signs of labor are present, it is generally too late to prevent delivery. Tocolysis may provide a short window for the administration of antibiotics and steroids, but none of the agents utilized for this purpose has shown itself to be superior to any other —and all have significant maternal or fetal side-effects.

Professional attention has shifted to the earlier identification of patients at risk. It is now commonplace to measure cervical length by ultrasound. Salivary estriol and fetal fibronectin measurements have been used to discriminate between “true” and “false” labor in women presenting with contractions. The interpretation of these tests creates problems for clinicians: normal or negative tests are re-assuring, but abnormal results correlate poorly with outcome. Is a short cervix an anatomical variant, or a sign of impending labor? Do we put a woman on bed rest for weeks on end —and does that really make a difference? The surgically-inclined may recommend cervical cerclage, but do we have more than anecdotal evidence that such intervention is beneficial? If the process of labor is more complex than a bag with a drawstring around its neck, it is not at all intuitive that a suture alone will prevent the onset of labor. Since routine screening for cervical length is resource-intensive, it would be a mistake to advocate this measure until its benefits have been demonstrated in large prospective clinical trials.

Now comes this study suggesting that progesterone can PREVENT labor. In sheep, labor is preceded by a drop in progesterone levels. This effect has not been observed in humans, and the precise role of progesterone in human parturition remains unclear. However, the relaxing effect of

progesterone on smooth muscle tone has long been recognized, and it is surprising that nobody else has done this study before.

In this clinic, the rate of pre-term delivery prior to this study was 25%, and over 90% of the study subjects had a history of pre-term delivery. There is no question that progesterone reduced the frequency of uterine contractions; in addition the incidence of delivery before 34 weeks dropped from 18.6% in controls to only 2.8% in the progesterone group [P=.002].

Still, there are a few questions. Why did the authors choose 100 mg of progesterone, as opposed to any other dose? Were there measurable and sustained elevations in serum progesterone levels?

This seems a promising avenue for further study and I'm sure that many readers of the article are already planning their own study to confirm the findings and determine an optimal dosing regimen. We await their reports.

REVIEW #57

Title: Pregnancy-related mortality in the United States, 1991-1997

Authors: Berg CJ, Chang J, Callaghan WM, Whitehead SJ

Site: Center for Disease Control and Prevention, Atlanta, Georgia

Published: Obstet Gynecol 2003; 101: 289-96

Objective: To describe trends in pregnancy-related mortality and risk factors for pregnancy-related deaths in the United States for the years 1991 through 1997

Methods: The Pregnancy Mortality Surveillance System (Division of Reproductive Health, Center for Disease Control and Prevention), in collaboration with the American College of Obstetrics and Gynecology and State Health departments has collected information on all pregnancy-related deaths in the United States since 1979. Data are obtained from Death Certificates and, where available, matching birth or fetal death certificates. The mortality ratio is defined as pregnancy-related deaths per 100,000 live births.

Results: The pregnancy-related mortality ratio increased from 10.3 in 1991 to 12.9 in 1997. An increased risk of death was found for black women, older women, and women with no prenatal care. The leading causes of death were embolism, hemorrhage, and medical conditions, although the percentage of death from hemorrhage decreased from 28% in the early 1980s to 18% in the current study period.

Conclusions: The reported pregnancy-related mortality ratio has increased, probably because of improved identification of pregnancy-related deaths. Black women continue to have an almost four-fold increased risk of pregnancy-related death, the greatest disparity among the maternal and child health indicators. Although review of pregnancy-related deaths by States remains an important public health function, such work must be expanded to identify factors that influence the survival of women with serious pregnancy complications.

Commentary: This article contains substantially the same information as the CDC Morbidity and Mortality Weekly report for February 21, 2003, also co-authored by Berg and Chang. [1] It is for the editors of *Obstetrics & Gynecology* to decide whether this constitutes a breach of their publishing policies. There is no question, however, that the subject is of interest to obstetricians, and will achieve greater readership in the flagship publication of the American College of Obstetricians and Gynecologists. The MMWR is easier-to-read, and has nicer graphs.

Pregnancy-related maternal mortality decreased from 850 per 100,000 live births in 1900 to 7.5 in 1982. Since then, it has increased slightly, averaging 11.5 in the years 1991 to 1997. During this interval, racial disparity continued: black women had a mortality ratio of 29.6 compared to 7.9 for white women —a ratio of 3.7 to 1. This ratio increased with age, from 2.8 at ages 15-19 to 5.6 above age 39.

Embolism, hemorrhage and pregnancy-induced hypertension were the leading causes of death for both white and black women. However, the risk of death from cardiomyopathy and complications of anesthesia was 6 times higher for black women.

Concern about maternal mortality is not new, and reports on the subject have said much the same things for over 75 years. George C. Mosher, first chairman of the Committee on Maternal Welfare of the American Association of Obstetricians, Gynecologists and Abdominal Surgeons wrote, in 1924: [2]

> *The sins of omission and commission of all figures which could be presented relative to maternal morbidity and mortality, are included in the three sentences:*
>
> 1. *Maternal morbidity and mortality have not been reduced in the United States in the last twenty years.*
> 2. *In the loss of mothers, the United States stands fourteenth among the so-called civilized nations, only Spain and Belgium having a higher death rate.*
> 3. *Puerperal septicemia and eclampsia claim over one-half of all the patients who die. Oliver Wendell Holmes, in 1845, …showed that it is preventable. Joseph B. DeLee, in 1923, gives records of 40,000 cases of labor in the Chicago Lying-In Hospital without a death from eclampsia.*

In preparing his report, Mosher had sent a questionnaire to obstetricians all over the country, requesting their views on the causes and prevention of maternal mortality. He quotes some of the responses. Edward P. Davis, of Philadelphia,:

> *The population most in need of good obstetric care is the…middle class…Such cannot afford…the services of specialists…They are apt to consult general practitioners who undertake confinements in …private houses, without proper facilities, with more or less bad results as regards the health and strength of the mother and child.*
>
> *…the general practitioner is the greatest danger in obstetrics. A midwife, under strict control, does comparatively little harm, but the doctor who does obstetric work to get the medical practice of the family, giving as little time and attention as possible, because it pays but little, is the one responsible for many obstetric disasters.*
>
> *…obstetrics must be considered a specialty of equal importance with surgery.*

Franklin S. Newell, of Harvard:

> *Prenatal care is so comparatively recent that the general practitioner of over forty-five pays little or no attention to it.*

John E. Talbot, Massachusetts:

> *I believe the public needs education on the value of good obstetric care. At present it is the least appreciated branch of medicine, even among the educated classes…The public has been educated to require special postgraduate training of the surgical and medical men it employs, and is willing to pay fees commensurate with such special training. In obstetrics, however, the medical school graduate, with experience in only six to twenty cases is expected to handle all the*

complications and operative procedures in obstetrics. The fees which the public expects to pay are in keeping with the low grade service which is given then under these conditions…I do not believe that the importance of proper obstetrical training is appreciated by the profession itself.

Since a majority of births took place in the home until the late 1930s, statistics from that era probably underestimated actual maternal mortality. However, by 1940-41, maternal mortality in the U.S.A. was still 376 per 100,000 live births; in South Carolina, the rate was 678 per 100,000 — highest in the nation. The leading obstetric causes of maternal death were eclampsia (33.6%), hemorrhage (15.7%), sepsis (14.1%), and abortion (12.6%). [3] Little could be done in the home for hemorrhage or eclampsia, but infections were probably less common in that setting than in hospitals —where iatrogenic intervention was more likely.

The introduction of penicillin in the 1940s resulted in a dramatic decrease in deaths from puerperal sepsis. Notwithstanding the availability of antibiotics, 13.2% of the 3201 maternal deaths from 1991 to 1997 were attributed to infection.

By the 1960s, most births happened in hospitals, where intravenous fluids, oxytocics and blood transfusion were available to treat hemorrhage. This greatly reduced deaths from that cause, yet 582 women still died from hemorrhage between 1991 and 1997; 181 of these were from ruptured ectopic pregnancy —presumably from delays in diagnosis and treatment.

Widespread prenatal care, and standardization of the magnesium sulfate/hydralazine protocol during the 1950s and 60s (by Pritchard et al. in Dallas) greatly decreased deaths from pregnancy-induced hypertension. Nonetheless, 509 maternal deaths resulted from hypertensive disorders between 1991 and 1997.

How many of the 3201 maternal deaths from 1991 to 1997 were "preventable"? To quote Mosher again:

It is the individual who dies; there is no mass mortality in obstetrics until the records are filed. The re-iteration of statistics, in reference to facts which we are all familiar, is wearisome and time consuming. [2]

Only by reviewing the medical record in every single case can that question be answered. Since maternal deaths are few and far-between in most American hospitals — and likely litigated—it is certain that all such deaths are meticulously reviewed by local quality-improvement committees. The conclusions of such inquiries are protected under various peer-review statutes and not widely circulated. It is unlikely, however, that any sins of omission or commission alluded to by Mosher would surprise obstetricians.

Since we all know what causes maternal deaths, why do they still happen, and how can they be prevented? The answers lie less with the medical profession than in the public domain. The United States is a land of extremes: we spend more money on health care than any other country in the world, yet forty million Americans cannot afford medical insurance, and our health indices are among the worst of any industrialized society; sex permeates our media, yet sex education in schools is considered controversial. These "political" issues have a direct bearing on maternal morbidity and mortality. Earlier sex education and access to contraception lower the rate of STD and unplanned pregnancy; this, in turn reduces ectopic pregnancy, abortion and, paradoxically, infertility. The

treatment of infertility has engendered a dramatic increase in high-risk multiple births. Lack of medical insurance delays access to early pregnancy care; this leads to uncertain dates; it also prevents the timely diagnosis of failed/ectopic/multiple gestation and medical problems. Although pregnant women qualify for assistance in most States, most patients cannot find a doctor who will accept their Medicaid insurance. They are forced to seek care at a distant, understaffed, university hospital clinic or, more often, simply show up in the ED or labor room whenever they have a problem.

The Center for Disease Control has identified obesity and inactivity as the second leading cause of death after tobacco. In obstetrics, this translates into larger babies, more operative interference, and more deaths from thrombo-embolism and hemorrhage. The trend toward later marriage and childbirth will increase age-related medical complications of pregnancy. The racial dichotomy observed in pregnancy-related mortality goes beyond economic and educational status, and urgently need further study.

The maternal mortality ratio is a population statistic. It will decrease only when the health status of the nation improves. This will not happen until Society —through its elected representatives— achieves a more equitable distribution of resources in health and education. "Blaming the system" does not absolve the individual from responsibility for her own health; however, a just Society attempts to remedy inequities related to the circumstances of our birth.

1. Chang J, Elam-Evans LD, Berg CJ, Herndon J, Flowers L, Seed KA, Syverson CJ Pregnancy-Related Mortality Surveillance — United States, 1991-1999. CDCP MMWR 2003; 52: 1-8
2. Mosher GC Maternal Morbidity and Mortality in the United States. Am J Obstet Gynecol 1924; 7: 294-98
3. Report of the Committee on Maternal and Infant Welfare of the South Carolina Medical Association. J. South Carolina Med. Assoc. 1943; 39: 103-4. Abstracted in Quart Rev Obstet Gynecol 1943; 1: 249

REVIEW #58

Title: Shoulder dystocia and brachial plexus injury: a case-control study

Authors: Christoffersson M, Kannisto P, Rydhstroem H, Stale H, Walles B

Site: Departments of Obstetrics and Gynecology at Central Hospital, Kalmar, Hospital of Helsinborg, University Hospital, Malmö, and Central Hospital, Kristianstad, Sweden

Published: Acta Obstet Gynecol Scand 2003; 82: 147-151

Objective: To evaluate risk factors for shoulder dystocia and brachial plexus injury using a case-control study involving 102,271 deliveries at the four largest hospitals in southern Sweden for the 8-year period from 1987 to 1993.

Methods: For each case, two control infants with similar birthweight (±100 g) and identical year of birth were randomly selected. Original maternal records were reviewed and information regarding 10 potential risk factors was extracted. Odds ratios (OR) were calculated using the Mantel-Haenszel method. Stratification was made for year of delivery, parity, and maternal age (5-year class).

Results: Shoulder dystocia was reported in 107 infants (0.1%); 34 of these infants also suffered brachial plexus injury (32%). The OR was greater than 1 for all risk factors except gestational age, but only three of the risk factors (induction of labor, epidural anesthesia, and instrumental delivery) reached statistical significance. None of the nine risk factors for brachial plexus injury associated with shoulder dystocia achieved statistical significance.

Conclusions: In this case-control study based on over 100,000 births, induction of labor, epidural analgesia, and instrumental delivery were significant risk factors for shoulder dystocia. For brachial plexus injury following shoulder dystocia, no significant risk factor was identified.

Commentary: Every obstetrician is haunted by vivid memories of shoulder dystocia. Like so many war stories, the actual details matter less than the adrenaline rush that accompanied the event. Whether the outcome was good or bad, none of us want to re-live the experience.

As this study shows, shoulder dystocia is rare—roughly 1 per 1000 births; 25% of cases resulted in permanent injury to the brachial plexus. Thus, the average American obstetrician attending 10 deliveries a month would encounter major difficulty delivering the shoulders every 8 years, and severe Erb's Palsy perhaps once in a professional career.

One can quibble about the definition. There is no question that "dystocia" is subjective. In their haste to deliver the baby, many of our house officers struggle with the shoulder because they don't wait for external rotation to occur. This type of "dystocia" becomes less frequent with experience. Some have suggested an arbitrary time interval after delivery of the head. It can be argued that if delivery can be achieved without asphyxia or trauma, using simple maneuvers such as exaggerated hip flexion (McRobert's) and episiotomy, then it wasn't much of a "dystocia" and probably should not be classified as one.

Because the association between birth weight and shoulder dystocia is so well established, the authors of this paper used birth weight as a control variable —allowing them to assess the role of

other possible risk factors for shoulder dystocia. They concluded that induction of labor [O.R. 1.83; 95% C.I. 1.02-3.31], epidural anesthesia [O.R. 1.89; C.I. 1.07-3.34], and instrumental delivery [O.R. 3.44; C.I. 1.45-8.19] were significant risk factors for shoulder dystocia. No information was given about the indications for induction or instrumental delivery, nor any details about the type (forceps, vacuum, station) of operative delivery. Once shoulder dystocia was present, no antepartum or intrapartum risk factors was significantly associated with the development of brachial plexus injury. This study did not investigate brachial plexus injuries that occurred without shoulder dystocia.

It is wrong to equate statistical association —no matter how significant mathematically— with causality. Of the 107 cases of shoulder dystocia, 18 were induced, 20 had epidural analgesia, and only 14 were delivered with instruments. It is likely that most of the women with shoulder dystocia had more than one risk factor, and these are not independent variables. From a clinical perspective, knowing that shoulder dystocia is three times as likely with operative vaginal delivery is neither surprising, nor particularly useful in a prospective sense. The incidence of instrumental delivery in this population (102,271 deliveries) was 5.5%. Shoulder dystocia occurred in 14 (0.25%), and brachial plexus injury in 4 (0.07%), of the 5625 forceps or vacuum operations. Without a crystal ball, there is no way to predict which 4 of these 5625 procedures will lead to injury; and with a 99.75% or better chance of a good outcome for the child, what reasonable obstetrician would eschew all instrumental deliveries in favor of cesarean section? That approach would not prevent the other 93 shoulder dystocias and 30 brachial plexus injuries associated with spontaneous vaginal delivery.

There has evolved in recent years the notion that shoulder dystocia can be predicted, hence avoided by timely cesarean section. Taken one at a time, none of the risk factors for shoulder dystocia has much positive predictive value —as shown in the previous paragraph. O'Leary [1], among others, described an antepartum scoring system using five risk factors: estimated fetal weight, weight gain in pregnancy, maternal weight, glucose intolerance, and gestational age. Thus, a > 42-week diabetic weighing over 180 lbs, with a weight gain > 35 lbs, and an estimated fetal weight > 9.5 lb would be assigned a score of 0/10 and (retrospectively) shown to have a 17% risk of shoulder dystocia. However, only 3% of women are glucose-intolerant, and < 2% of newborns weigh more than 9.5 lb; furthermore, fetal weight cannot be predicted with better than a 10-15% error by any known technique. This type of scoring system is clearly of limited practical value.

The emphasis on fetal size in discussions of shoulder dystocia has overshadowed the (seemingly obvious) importance of pelvic capacity and shape in the causation of dystocia. At one time, no discussion of labor was complete without a consideration of the 3 Ps (Passenger, Passage, Powers). However, systematic clinical pelvimetry (using a variety of mechanical devices) has rarely been taught or practiced in the last 50 years, and X-Ray pelvimetry went out of fashion in the early 1980s. The contracted pelves described in older textbooks are rare in contemporary American practice, and ordinary pelvic examination is inadequate to identify minor bony abnormalities. The inescapable conclusion is that no obstetrician can reliably predict cephalo-pelvic disproportion. Every labor is a trial of labor and the head is the best pelvimeter.

The only way to eliminate shoulder dystocia would be to perform cesarean section in 100% of women, preferably before the onset of labor. Even that would not prevent some cases of brachial plexus injury. Since neither the public nor the profession would consider this a reasonable option, birth attendants are forced to evaluate each labor on its own merits. Clinical judgment is the art of drawing sufficient conclusions from insufficient premises (to paraphrase someone famous). It requires knowledge, experience, and a dash of intestinal/gonadal fortitude. The latter two are why computers (or biomedical engineers) will never replace obstetricians in the delivery room.

Until recently, most Obstetric textbooks did not even mention shoulder dystocia —much less discuss how to deal with it. The words "shoulder dystocia" do not appear once in Paul Titus' 1937 classic "The Management of Obstetric Difficulties" [2]; by the 6th edition, in 1961, there was a brief paragraph. The 9th edition of Williams' Obstetrics, 1945, devotes three lines to the subject. [3] It was either considered so rare as to not merit discussion, or else it was accepted that shoulder dystocia with its attendant morbidity was an unavoidable complication of delivery.

As maternal mortality and morbidity decreased dramatically in the 1950s and 60s, the welfare of the child assumed greater importance in the minds of parents and their doctors. As is often the case, the profession's interest in shoulder dystocia was heightened by the medico-legal implications of injury or death to the child. The proliferation of personal-injury law firms and their advertising has made it almost inevitable that every bad outcome will be equated to malpractice.

This phenomenon has spawned, in the last twenty years, a veritable cottage industry of "experts" on shoulder dystocia. Hardly a month goes by without some new article, book, or course on shoulder dystocia—how to predict it, how to manage it, how to cover your legal backside in the event of litigation… Bio-mechanical engineers — who have never delivered a baby in their life— elaborate computer models to simulate dystocia. No matter how unrealistic, such theoretical constructs have been used successfully to convince lay juries that the defendant must have used a negligent amount of force during delivery. The abstruse is made to seem plausible, and perception becomes reality.

The irony here is that there is no such creature as an "expert" on shoulder dystocia. I would question the veracity or skill of anyone who boasts of having personally experienced more than a handful of these cases. The rarity and unpredictability of shoulder dystocia are such that there will never be a randomized, controlled trial to prove the superiority of one delivery technique over another. In the heat of the moment, there is no time for reflection; it is essential to keep a cool head, and have a plan based on one's own experience and that of the profession.

That plan should include an acquaintance with the various positions and maneuvers that have been reported to be effective. Any traction on the child should be in the longitudinal axis and, if the usual amount of force does not deliver the shoulder, traction should be abandoned in favor of other techniques. The order of these techniques should logically proceed from those least injurious to mother or child. The McRoberts maneuver has been the most popular in recent years because it is simple and, anecdotally, seems to work in many cases. Firm suprapubic pressure may help, but is difficult to implement when the hips are hyperflexed, especially in an obese woman. A generous medio-lateral or procto-episiotomy will provide extra room to attempt rotation of the trunk/shoulders, or attempt to bring down the posterior arm. No single technique works all the time, and improvisation may be necessary. Our best efforts cannot always prevent permanent injury or death. To equate bad outcome in such situations with malpractice is untenable.

1. O'Leary James A Shoulder Dystocia and Birth Injury 1992 McGraw-Hill p.60
2. Titus P The Management of Obstetric Difficulties. C.V. Mosby Company 1937 879 pp
3. Stander HJ Textbook of Obstetrics, 9th Ed of Williams Obstetrics. Appleton-Century-Crofts, Inc. 1945 p. 383

REVIEW #59

Title: A double-blind, randomized, placebo-controlled trial of acyclovir in late pregnancy for the reduction of herpes simplex virus shedding and cesarean delivery

Authors: Watts HD, Brown ZA, Money D, Selke S, Huang ML, Sacks SL, Corey L

Site: University of Washington, Seattle and University of British Columbia, Vancouver, Canada

Published: Am J Obstet Gynecol 2003; 188: 836-43

Objective: To assess the efficacy of acyclovir in the reduction of herpes simplex virus culture and polymerase chain reaction positivity and cesarean delivery.

Methods: Women with recurrent genital herpes simplex were randomized to acyclovir 400 mg T.I.D. or placebo from 36 weeks of gestation until delivery. Daily specimens for herpes simplex virus culture and DNA polymerase chain reaction was self-collected. Analyses used χ^2, Fisher exact, and Mann-Whitney U tests.

Results: Lesions occurred at delivery among 11 of 78 women (14%) who received placebo and 4 of 84 women (5%) who received acyclovir (P = .08). Herpes simplex virus culture and polymerase chain reaction positivity near delivery occurred in 7% and 34% of women in the placebo groups, compared to 0% and 2% in the acyclovir group. [P = .03 and < .01 respectively]. Cesarean delivery for herpes simplex virus was performed in 8 women in the placebo group (10%) and in 3 women in the acyclovir group (4%) [P = .17]. Despite reductions in HSV detection, 6% of the women who received acyclovir had HSV detected by polymerase chain reaction on > 20% of days. Neonatal outcomes were similar between groups.

Conclusions: Acyclovir significantly reduced, but did not eliminate, HSV lesions and detection in late pregnancy.

Commentary: This study is the largest randomized, blinded trial to evaluate the impact of acyclovir on HSV detection among pregnant women.

Congenital Herpes Simplex Type 2 infection is believed to result from direct exposure of the neonate to active virus in the maternal genital tract. Because systemic neonatal herpes infection carries a 50% mortality rate —and severe morbidity in survivors— cesarean section has been recommended in women with active lesions or positive cultures within a short time of labor. Although this management strategy has never been evaluated in prospective trials, the rare incidence of fetal infection following cesarean section has been cited as evidence for the effectiveness of this approach. Since vaginal organisms are known to colonize the uterus within 4 hours of ruptured membranes, the putative benefits of cesarean section may well be negated if it is not performed promptly after rupture of the membranes.

Primary HSV2 infection in late pregnancy is rare, but is associated with a 30-50% rate of transmission to the newborn following vaginal delivery. In women with a history of recurrent HSV2 lesions antedating pregnancy, the risk of neonatal transmission is much lower, probably in the 2-5% range. [1] Some women reporting an HSV lesion for the first time in pregnancy are found to have antibodies consistent with earlier exposure. Many cannot recall ever having the classic stigmata of primary HSV2. On theoretical grounds, the presence of HSV2-IgG in maternal serum should convey

passive immunity to the fetus and protect it from developing significant HSV infection.

Outside pregnancy, anti-viral medications have been used to reduce the severity and duration of recurrent lesions. The daily use of anti-virals has effectively reduced the frequency of recurrence, with few side-effects.

Given the unpredictability of HSV lesions, and a desire to avoid cesarean section for this indication, it seemed logical to extend this strategy to pregnancy. Despite the lack of any "hard" data, many obstetricians have prescribe prophylactic ZOVIRAX or VALTREX during the last month of pregnancy.

In this study, 4 of the 84 women in the acyclovir group (5%) had lesions at delivery, compared with 11 of 78 (14%) in the control group; this was significant only at the 0.08 level. However, NO patient in the acyclovir group had either a positive culture or asymptomatic PCR positive within 2 days of delivery. Overall, 3/84 (4%) in the acyclovir group, and 8/78 (10%) in the placebo group had cesarean section for HSV. (P = .17) C/S was not performed for lesions on the thigh or buttock. Although clinicians were informed of HSV culture and PCR results, it is not clear if this influenced the choice of delivery method. Although not statistically significant, the placebo group had a total cesarean rate of 27% vs. 18% in the acyclovir group. No infants in either group developed neonatal herpes, and no adverse effect attributable to acyclovir were observed.

The study was closed to accrual after 170 patients, because of widespread use of antivirals in the community. This resulted in fewer referrals, and a lack of enrollment into a double-blind trial because women and their doctors preferred use of the antiviral.

Expect the use of anti-viral prophylaxis to increase, because it is perceived as low-risk and likely to benefit some women with HSV.

1. Guidelines for perinatal care 5th Ed 2002 American Academy of Pediatrics/Am Coll Ob Gyn p 293

REVIEW #60

Title: Screening for Gestational Diabetes Mellitus: A Summary of the evidence for the U.S. Preventive Services Task Force

Authors: Brody SC, Harris R, Lohr K

Sites: University of North Carolina, Chapel Hill, North Carolina

Published: Obstet Gynecol 2003; 101: 380-92

Objective: To review the evidence for gestational diabetes mellitus (GDM) screening.

Data Sources: A systematic search of MEDLINE and the Cochrane Collaboration Library for studies meeting pre-defined eligibility criteria. The search was supplemented by studies identified in the reference lists of reviews on gestational diabetes.

Methods: Two reviewers examined each article for eligibility. One reviewer abstracted relevant data from the included articles; the second reviewer checked the abstractions. The quality of the articles was graded according to criteria developed by the U.S. Preventive Services Task Force.

Results: No well-conducted, randomized, controlled trial provides direct evidence for the health benefits of screening for GDM. The evidence is unclear regarding the optimal screening and reference diagnostic test for GDM. The impact of hyperglycemia on adverse maternal and neonatal health outcomes is probably continuous. Although insulin therapy decreases the incidence of fetal macrosomia for women with more severe degrees of hyperglycemia, the magnitude of any effect on maternal and neonatal health outcomes is not clear. The evidence is insufficient to determine the magnitude of health benefit for any treatment among the large number of women with GDM at milder degrees of hyperglycemia. The authors found limited evidence regarding the potential adverse effects of screening for GDM.

Conclusions: There is no high-quality evidence to support routine screening for GDM. A randomized, controlled trial is necessary to assess the impact of screening on maternal and neonatal health outcomes.

Commentary: This article summarizes the evidence used by the U.S. Preventive Services Task Force to prepare its latest recommendations on screening for gestational diabetes. These are published in same issue (February 2003) of *Obstetrics & Gynecology*. [1] Here is the official summary:

> *The U.S. Preventive Services Task Force found fair to good evidence that screening combined with diet and insulin therapy can reduce the rate of fetal macrosomia in women with gestational diabetes mellitus (GDM). The USPSTF found insufficient evidence, however, that screening for GDM substantially reduces important adverse health outcomes for mothers or their infants (for example, cesarean delivery, birth injury, or neonatal morbidity or mortality). Screening produces frequent false-positive results, and the diagnosis of GDM may be associated with other harms, such as negatively affecting a woman's*

perception of her health, but data are limited. Therefore, the USPSTF could not determine the balance of benefits and harms of screening for GDM.

In academic circles, "evidence-based medicine" is all the rage. Professors everywhere preach the need for more "science" and less "opinion" in clinical practice. Yet, nowhere in Obstetrics is there such a discrepancy between evidence and practice as in the matter of gestational diabetes (well, maybe continuous fetal heart rate monitoring).

The rise of gestational diabetes from statistical out-lier to mainstream disease during the last 25 years has paralleled the growth of maternal-fetal medicine as a sub-specialty. So many academic careers have been founded on this subject, so many books and articles written, that it is almost heresy to ask: "Where's the beef?"

Evidence-based medicine is a comparatively recent concept that arose in the United Kingdom following Archie Cochrane's 1972 book *Effectiveness and Efficiency: Random reflections on Health Services.*[2] Cochrane's intention was to rationalize the allocation of scarce medical resources, and he singled-out Obstetrics and Gynecology as the specialty least influenced by evidence. Dr. Ian Chalmers, who worked with Cochrane in Wales, took up the challenge: between 1978 and 1984, his group systematically searched the published literature, and compiled a register of nearly 2800 trials in Perinatology. An editorial team was assembled to review the database, culminating in publication of the *Oxford Database of Perinatal Trials*, in 1989, and its companion two-volume text *Effective Care in Pregnancy and Childbirth*. [3] The latter was hailed by Cochrane:

It represents a real milestone in the history of randomized trials and in the evaluation of care, and I hope that it will be widely copied by other medical specialties. I have now, no hesitation whatsoever in withdrawing the slur of the wooden spoon [award] from obstetrics, and I feel honoured by being associated, even in an indirect way, with such an important publication. [3, foreword]

Ian Chalmers left the National Perinatal Epidemiology Unit in 1992 and established the UK Cochrane Center, from which arose the international "Cochrane Collaboration".

Effective Care… is the "granddaddy" of evidence-based perinatology texts, and it has not been superceded. Its chapter on GDM, written by Hunter and Keirse, concluded:

The diagnosis of GDM…is based on the abnormal glucose tolerance test. This test is not reproducible at least 50-70% of the time and the increased risk of perinatal mortality and morbidity said to be associated with this 'condition' has been considerably overemphasized. No clear improvement in perinatal mortality has been demonstrated with insulin treatment for Gestational diabetes, and screening of the pregnant population with glucose tolerance testing is unlikely to make a significant impact on perinatal mortality.

An abnormal GTT is associated with a two- to three-fold increase in the incidence of macrosomia, but the majority of macrosomic infants will be born to mothers with a normal GTT. Thus far, no improvement in neonatal outcome has been demonstrated from insulin treatment for gestational diabetes, nor has there been any demonstrated benefit to the mother or infant from reducing the incidence of macrosomia by insulin therapy.

> *There is, however, a great potential to do more harm than good. A positive test labels the woman as having some kind of diabetes. This is an unpleasant label to have under any circumstances, particularly when repeat testing will not confirm the diagnosis in up to 70% of cases. Pregnancy is likely to be transformed into a high-risk situation, invoking an extensive and expensive programme of tests and interventions of unproven benefit. Women who had a less than perfect outcome of pregnancy and who had not been screened for gestational diabetes, may unfairly accuse their physicians of negligence, while the large amounts of money and resources that are tied up in diagnosing and treating this 'condition' could be diverted to areas where they might be more effective…*
>
> *Except for research purposes, all forms of glucose tolerance testing should be stopped.*

As the article under review demonstrates, no convincing evidence has appeared in the last 15 years to change these recommendations. Yet, screening for GDM in the early 3rd-trimester is almost universally practiced in the United States. This is perhaps understandable in community settings— where busy obstetricians often practice "defensive" medicine— but more difficult to rationalize in academic institutions that preach "evidence-based medicine". In my own department, an abnormal 3-hour GTT triggers a referral to the "diabetic clinic", where patients receive extensive dietary counseling and begin QID blood-glucose testing. After a few weeks of dietary manipulation, women who fail to maintain arbitrary levels are placed on insulin therapy. Twice-weekly fetal testing is begun at 34 weeks and continues until term, when patients are induced if they go past their due date. In light of published evidence, there is little doubt that this resource-intensive approach is "overkill". Perhaps such protocols evolved to create enough "volume" to justify hiring the specialized staff needed to manage the few "real", Type 1, diabetics, and support the research efforts of academic clinicians.

Scientific and resource considerations aside, one cannot underestimate the effect of a "label" in medicine. A patient once diagnosed with "P.I.D."—no matter how inaccurately— is likely to be treated for this any time she shows up with pelvic pain. The same can be said for psychiatric diagnoses. Similarly, a diagnosis of GDM lowers the threshold for intervention in labor and leads to increased rates of cesarean delivery with no improvement in outcome.

If any subject in obstetrics is amenable to a large, multicenter randomized trial, this is the one.

1. U.S. Preventive Services Task Force. Screening for Gestational Diabetes Mellitus: Recommendations and Rationale. Obstet Gynecol 2003; 101: 393-95
2. Cochrane AL. Effectiveness and Efficiency: Random reflections on Health Services, Nuffield Provincial Hospitals Trust, London; 1972
3. Chalmers I, Enkin M, Keirse MJNC, eds. Effective Care in Pregnancy and Childbirth. Oxford University Press, Oxford: 1989
4. Hunter DJS, Keirse MJNC Gestational Diabetes in: Effective Care in Pregnancy and Childbirth. Oxford University Press, Oxford: 1989 p. 403-410

REVIEW #61

Title: A cost-effectiveness analysis of management strategies for cervical intraepithelial neoplasia grades 2 and 3

Authors: Kleinberg MJ, Straughn JM, Stringer SA, Partridge EE

Site: Department of Obstetrics and Gynecology, University of Alabama at Birmingham

Published : Am J Obstet gynecol 2003; 188: 1186-8

Objective: This study was performed to compare the cost-effectiveness of strategies for the management of cervical intraepithelial neoplasia, grades 2 and 3 (CIN2 and CIN3).

Methods: A decision analysis of six management strategies was applied to a hypothetical cohort of 100,000 women with CIN2 and CIN3. The treatment options were: observation (OBSERVE), cryotherapy (CRYO), carbon dioxide laser ablation (LASER), loop electrosurgical excision procedure (LEEP), cold-knife conization (CKC), and total vaginal hysterectomy (TVH). The options were selected for the sake of comparison, although some might be considered inadequate or excessive for CIN2 or CIN3.

Following initial "therapy", patients had a repeat PAP at 6 months; if normal, another PAP was performed 6 months later. Abnormal follow-up PAP smears were reevaluated with colposcopy and directed biopsies. If the biopsy result revealed CIN2 or greater, the patient was re-treated and the PAP repeated in 6 months. "See-and-treat" strategies were not considered in this analysis.

The probability of specific outcomes associated with each strategy was estimated from published data where available, or extrapolated from the authors' experience. The model estimated that 1.4% of patients with CIN2 and 2.2% of those with CIN3 would received no treatment would develop cancer within 1 year.

Two outcome measures, *Cure* and *Cancers Prevented*, were considered at 1 year. *Cure* was defined as normal cytologic or normal/CIN1 histologic results at 1 year. The number of invasive cancers that would develop over 1 year with observation as opposed to another strategy defined *Cancers Prevented* for that particular management option.

Cost estimates were based on local reimbursement schedules in year 2001 U.S. dollars, averaging the typical reimbursement by MEDICARE and the largest third-party payer in Alabama.

Results: In the analysis of CIN2, the cure rate ranged from 94.9% for CRYO, to 95.9% for LEEP, to 99.2% for TVH. Based on a cohort of 100,000 patients in each arm of the model, CRYO prevented 1,454 cancers compared to OBSERVE; LEEP prevented 1,473, and TVH 1,475 cancers. However, CRYO was by far the least expensive treatment modality ($112); by comparison, LEEP was $407, LASER $3,367, CKC $3,739, and TVH $11,898. The incremental cost-effectiveness per additional cure (compared to CRYO) was $31,437 for LEEP, and $351, 365 for TVH.

Similar trends were seen for CIN3. The cure rate was 91.3% for CRYO, 93.9% for LEEP and 99.2% for TVH. The incremental cost-effectiveness per additional cure (compared to CRYO) was $17,592 for LEEP and @210,340 for TVH.

Conclusions: CRYO is a cost-effective strategy that is appropriate in resource-poor settings. LEEP is also cost-effective, but the improved efficacy compared with CRYO comes at a significant cost. Total vaginal hysterectomy is very effective, but economically unsound.

Commentary: Decision analysis *is the logical and quantitative analysis of all the factors that influence a decision*. [1] For a given situation, the analyst develops a model that identifies all possible actions, and all outcomes whose occurrence may influence those decisions. From empirical data, personal experience, or even unscientific "hunches", the decision-maker assigns a probability of each outcome resulting from each action being considered. The correct decision is the one that maximizes the "pay-off".

Decision analysis was first employed in the business world, because the pay-off can usually be measured in dollars and cents. It is no surprise, then, that most such studies performed in the medical field have looked at cost-effectiveness. Since few outcomes are value-neutral, decision analysis becomes infinitely more complex when personal values are integrated into the decision framework. If outcomes are measured in "lives saved", how much is one life worth? It is facile to say that life is "priceless" —and it may be so to its owner— but actuaries earn their living assigning a monetary value to human lives. That's how insurance premiums are set.

The physician's fiduciary obligation toward his/her patient —*do no harm*— generally outweighs cost considerations in selecting a treatment option. However, as the article under review points out, more expensive treatments are often only marginally better than cheaper ones. In Alabama, the average payment for LEEP was 3.6 times greater than for cryotherapy; this ratio is out of proportion to either the relative cost of the equipment, or the time involved. In a "resource-rich" setting —a fee-for-service, 3rd-party payor system, for example— the physician's choice of therapy is not immune to economic self-interest.

Health care administrators who struggle with limited resources are guided by another ethical imperative, the principle of *justice* —the greatest good for the greatest number. In this larger context, individual lives become interchangeable, and resources should be allocated in a way that maximizes total lives saved.

This model is unrealistic because it compares treatment options that are not interchangeable. Although I question the authors' assumption that as many as 1.4% of patients with CIN2 would develop invasive disease within one year if untreated, few physicians would recommend expectant management of HGSIL. Similarly, not many would advise hysterectomy as the first-line treatment for CIN2 or 3. Among the other therapies considered, LASER vaporization and cold-knife cone biopsy are impractical in an office setting, hence *a priori* not cost-effective compared to either LEEP or cryotherapy. During the 1980s, LASER seemed like a high-tech solution to all sorts of GYN surgical problems; who uses LASER now? The high capital cost made it extravagant for small practices. The need for analgesia, and safety concerns — relating to both the beam itself and smoke evacuation— relegated it to the outpatient surgical center or hospital.

Since dysplasia is confined to the cervical epithelium, any technique that destroys the transformation zone to a sufficient depth should be effective; all the above, as well as thermal- and electro-cautery have been used successfully. Invasive cancers detected within a year of therapy more likely represent occult disease rather than progression of dysplasia. Biopsy-proven "recurrence" of CIN2/3 may represent either undertreated disease or neoplasia.

Gynecologists should have at their disposition both cryotherapy (nitrous oxide, with a large selection of tips) and LEEP equipment (with a large selection of electrodes). Although LEEP is generally believed to be more "effective" than cryotherapy, it is difficult to compare the two without knowing the technical details. Thus, LEEP can be done with small or large electrodes, single or

multiple pass, shallow or deep. Cryotherapy is less operator-dependent, but the best results will be obtained by matching the shape and size of the cryo-tip to the cervix, allowing the ice-ball to reach its maximum depth, and using a double-freeze technique. There is no question that LEEP has the greater potential to remove a large part of the cervix. For this reason, it should be employed with great care when treating young nulliparous women.

The authors specifically did not consider the cost-effectiveness of "see-and-treat" models. Colposcopy, initially used in Europe as a screening tool, was introduced into the U.S. during the 1970s as an aid to evaluating abnormal PAP tests. Four-quadrant and cone biopsies were replaced with directed biopsies based on colposcopic findings. However, the correlation between observation and actual pathology is rather poor, even in experienced hands. Szurkus and Harrison[1] recently reported that 54% of patients with histologically-proved high-grade dysplasia after LEEP had a normal or low-grade colposcopic examination. This begs the question, "why bother with colposcopy for HGSIL, when a LEEP —an office cone-biopsy— will be both diagnostic AND curative in most cases?"

This year marks the 60th anniversary of Papanicolaou and Trout's classic monograph *Diagnosis of Uterine Cancer by the Vaginal Smear*. [2] The eponymous "PAP" test is now such a routine part of most women's lives that it is difficult to imagine gynecological care without it. Yet, until the widespread use of cytological screening, cervical cancer was rarely diagnosed until symptomatic —and often incurable. Gilliam's almost poetic description of cervical cancer conveys some measure of its impact on women:

> *In cervical cancer woman finds the sovereign affliction of her sex. In the sum total of misery, loathsomeness, hopelessness, mental anguish, and fatality it exceeds all others.* [3]

More than a century ago, Howard Kelly observed that cervical malignancy was rare in unmarried and nulliparous women. [4] Although his approach was not widely applicable outside his carriage-trade practice, Kelly was an early advocate of prevention:

> *I have for a generation past insisted that every woman who has been through childbirth ought to have yearly or half-yearly examinations to detect early disease and any early changes in the cervix. If the cervix is lacerated, infiltrated, and everted, the condition should be destroyed by thorough cauterization, and the patient watched at intervals of four to six months for a couple of years. If this regime were carried out generally, thousands of lives would be saved*. [5]

As is often the case with important discoveries, Papanicolaou's was preceded by years of apparently-unrelated groundwork. In 1917, he discovered that vaginal smears taken from mammals showed cyclical cellular changes which could be used to detect the time of ovulation —a technique that he later applied to the human female. In 1928, he reported having observed cervical cancer cells in vaginal aspirates, but this finding elicited little interest, and he did not immediately follow-up on this. In fact, O'Dowd and Phillips [6] believe that Dr. Aurel Babes, of Romania, was the true pioneer in the cytological diagnosis of cervical cancer. Babes' 1927 work, however, was published in the Proceedings of the Bucharest Gynecological Society, and it is unlikely that Papanicolaou was aware of it. Papanicolaou's next communication on the subject did not appear until 1941 when, with gynecologist Herbert Traut, he published a paper on the diagnostic value of vaginal smears in

carcinoma of the uterus. [7] This was followed two years later by an illustrated monograph based on a study of over 3000 cases. [2]

The original "PAP" smears were made from vaginal aspirates. In 1946, Ayre showed that smears taken directly from the cervix were more accurate; a year later, he designed a wooden spatula shaped to collect cells from the squamo-columnar junction.[8] Ayre's spatula and technique for preparing slides are still used today.

Cytological screening of asymptomatic women was introduced on a limited basis in Massachusetts in 1945; the American Cancer Society endorsed screening in 1957. By 1960, over 3 million U.S. women were being screened each year. In 1962, David Boyes *et al.* reported on 146,833 British Columbia women screened between 1949 and 1960; from 1955 to 1960, the incidence of invasive carcinoma decreased 30.5%, from 28.4 to 19.7 per 1000 women. More importantly from a prevention point-of-view, 828 cases of carcinoma *in situ* were detected. [9] This study convinced many that the widespread application of screening cytology could lead to the eradication of cervical cancer .

Although the incidence of cervical cancer continues to decrease, over 12,000 new cases will be diagnosed this year in the United States, and more than 4,000 women will die from this disease. Few of these women will have had a PAP smear in the previous 5 years. Once again, this exemplifies the paradox of our Society: women at low-risk get screened annually, while those with multiple risk factors have limited access to health care.

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REVIEW #62

Title: Can ultrasound replace dilation and curettage? A longitudinal evaluation of postmenopausal bleeding and transvaginal sonographic measurement of the endometrium as predictors of endometrial cancer.

Authors: Gull B, Karlsson B, Milsom I, Granberg S

Site: Department of Obstetrics and Gynecology, University of Göteborg, Sahlgrenska University Hospital

Published: Am J Obstet Gynecol 2003; 188: 401-8

Objective: To evaluate post-menopausal bleeding and transvaginal sonographic measurement of endometrial thickness as predictors of endometrial cancer and atypical hyperplasia in women whose cases were followed for at least 10 years after referral for postmenopausal bleeding.

Methods: 394 women who had postmenopausal bleeding from November 1987 to October 1990 underwent transvaginal sonographic measurement of endometrial thickness and curettage. It was possible to assess the medical records (regarding recurrence of bleeding, development of endometrial cancer, and death) in 339 (86%) of the women ≥10 years after the initial referral.

Results: Thirty-nine of the 339 women (11.5%) had endometrial cancer, and 5 (1.5%) had atypical hyperplasia. The relative risk of endometrial cancer in women referred for postmenopausal bleeding was 63.9 [95%CI, 46.0-88.8] compared with women of the same age from the general population of the same region in Sweden.

No woman with an endometrial thickness ≤ 4 mm was diagnosed with endometrial cancer. The relative risk of developing endometrial cancer in women with an endometrial thickness > 4 mm was 44.5 [95% CI, 6.5-320.1]. The reliability of endometrial thickness ≤ 4 mm as a diagnostic test for endometrial cancer was assessed: sensitivity, 100%; specificity, 60%; positive predictive value, 25%; and negative predictive value, 100%.

The incidence of endometrial cancer or atypical hyperplasia in women with an intact uterus whose cases had been followed for ≥ 10 years was 5.8% (15/257) compared with 22.7% (15/66) in women who had ≥1 episode of recurrent bleeding. No endometrial cancer was diagnosed in women with recurrent postmenopausal bleeding who had an endometrial thickness ≤ 4 mm at the initial scan.

Conclusions: Postmenopausal bleeding incurs a 64-fold increase risk for endometrial cancer. There was no increased risk of endometrial cancer or atypical hyperplasia in women who did not have recurrent bleeding, whereas women with recurrent bleeding were a high-risk group. No endometrial cancer was missed when endometrial thickness was ≤ 4 mm, even if women were followed for 10 years.

Transvaginal sonographic scanning is an excellent screening tool for assessing the need for tissue diagnosis in women with postmenopausal bleeding.

Commentary: Short of hysterectomy, the gold standard for diagnosing intrauterine pathology remains hysteroscopy with biopsy or curettage. Some gynecologists perform hysteroscopy in the office without anesthesia, but most such procedures are done under some form of anesthesia in a surgical outpatient setting. Since most post-menopausal bleeding in contemporary practice occurs in

the context of hormone therapy, and is rarely associated with endometrial cancer, hysteroscopy in all such cases is neither cost-effective, nor patient-friendly.

Office endometrial biopsy is usually easy to do —albeit painful— but a negative biopsy does not rule-out carcinoma or atypical hyperplasia.

Vaginal probe ultrasound allows the measurement of endometrial thickness in a reproducible manner. More recently, the intra-uterine injection of saline during ultrasound (sonohysterography) has made it possible to distinguish focal lesions (polyps, carcinomas, and fibroids) from hyperplasia. However, such differentiation does not provide either tissue diagnosis or treatment.

Thus, abnormal endometrial thickening by ultrasound requires more definitive investigation and management. This paper offers re-assurance that endometrial thickness ≤4 mm is not associated with malignancy, even 10 years later. Other articles have used 5 mm as the cut-off.

A logical approach to post-menopausal bleeding would start by discontinuing hormone therapy, followed by a vaginal ultrasound. Women who stop bleeding and have ≤ 4-5 mm endometrial thickness need no further investigation. Persistent bleeding or > 5 mm thickness should prompt some form of tissue diagnosis.

REVIEW #63

Title: A comparison of two models of gynecology service consultation to the emergency department in an academic medical center.

Authors: LaCoursiere DY, Nager CW

Site: Department of Reproductive Medicine, University of California, San Diego, CA

Published: Am J Obstet Gynecol 2003; 188: 1166-8

Objective: This study was undertaken to determine the difference in resource use and outcomes when emergency department (ED) physicians consult the gynecology service routinely versus selectively.

Methods: In July 2000, an ED policy of "routine" gynecology consultation for pregnant women < 20 weeks' gestation with pain and/or bleeding changed to a policy of "selective" consultation. Resource use and outcomes were compared for 222 women who received care during the 9 months before the protocol change with 268 women who presented during the 9 months after the change in policy.

Results: With selective consultation, the percentage of patients receiving gynecologic evaluations decreased from 74 to 39. Return visits to the ED increased from 9% to 21%. Ultrasound studies performed by ED physicians and radiologists increased. Patients waited longer and received more unnecessary beta-HCG tests.

Conclusions: A policy of selective gynecology consultation in the ED increases diagnostic study resources use and patient length of stay compared with routine consultation.

Commentary: In most hospitals, patients with possible pregnancy-related problems are assessed in the labor & delivery suite if they are believed to be > 20 weeks. The rationale, of course, is that intervention for fetal indications might be necessary, and the 20-week threshold allows for possible date errors. The others —mostly 1st trimester bleeding, pain, or hyperemesis— are usually worked-up in the Emergency Department.

Prior to the development of emergency medicine as a specialty, EDs were typically staffed by family physicians whose knowledge—or, more likely, medico-legal comfort level— of obstetrics was limited. They were quick to consult Obstetricians. The Board-Certified urgentologist now has ready access to vaginal U.S. and quantitative HCG levels, and this has greatly simplified the diagnosis and management of early-pregnancy problems.

Whether or not to consult a specialist is usually a matter of local policy. Often, it reflects the amount of other activity in the ED, as well as the availability of a consultant. The stated motivation for changing the policy at this hospital was to decrease patient length-of-stay in the ED, increase the ED residents' exposure to gynecology, and to increase the availability of gynecology residents on other services. The 74% consultation rate prior to the change suggests that the policy was either impractical, or not strictly enforced. During the day, Ob/Gyn staff and residents are busy in the clinic or operating room, and will be slow to get to the ED unless the patient requires urgent surgery.

Paradoxically, the length of stay increased, and the return-to-ED rate doubled following the change in protocol. These observations can be interpreted in a number of ways. Patients in whom the HCG and U.S. results raised the possibility of ectopic pregnancy were likely referred to the Ob/Gyn service after going up the ED hierarchy. Direct referral would have bypassed the first chain-of-command and saved time. Furthermore, the routine work of the ED is often punctuated by life-threatening emergencies that delay the treatment of less seriously-ill patients. Having no office, ED residents have more difficulty scheduling outpatient follow-up visits or procedures, so patients are more apt to return to the ED if they experience more pain or bleeding.

REVIEW #64

Title: Don't ask, don't tell: A change in medical student attitudes after obstetrics/gynecology clerkships toward seeking consent for pelvic examinations on an anesthetized patient.

Authors: Ubel PA, Jepson C, Silver-Isenstadt A

Site: Veterans Affairs Ann Arbor Healthcare System and Division General Medicine, University of Michigan, Ann Arbor, MI; Division of General Internal Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA; Department of Pediatrics, University of Maryland, College Park, Md

Published: Am J Obstet Gynecol 2003; 188: 575-90

Objective: This study sought to determine whether completion of an obstetrics/gynecology clerkship was associated with a decline in the importance that students place on seeking permission from the patient before conducting a pelvic examination under anesthesia.

Methods: Students at five Philadelphia area medical schools (n=401) were asked how important it would be for a patient to be told that a medical student will perform a pelvic examination while she is anesthetized. The association between completion of an obstetrics/gynecology clerkship and attitudes toward consent was examined; linear regression was used to adjust for gender and the total amount of clerkship experience.

Results: After the data were controlled for gender and the total number of clerkships that had been completed, it was found that students who had completed an ob/gyn clerkship thought that consent was significantly less important than those who had not completed a clerkship [P = .01].

Conclusions: To avoid this decline in attitudes toward seeking consent, clerkship directors should ensure that students perform examinations only after patients have given consent explicitly.

Commentary: The results of this survey are not surprising. The authors' conclusions, however, need further discussion.

The teaching of obstetrics and gynecology (to men, at least) has always been hampered by the inherently private nature of the organs under study. Boasting of superior education and, more importantly, skill in the use of instruments and opioids, men insinuated themselves into the field of midwifery during the 17th and 18th centuries. The involvement of men in a domain hitherto exclusively the province of women and eunuchs was controversial, at least until the early 1900s. Given recent demographic trends in Ob/Gyn Residency training, it appears that within a generation or two, the man-midwife will become as rare as he was two centuries ago.

Elizabeth Nihell —one of the few literate midwives in England in 1760 — took up the pen to impute the motives of men-midwives, denounce their abuse of instruments, and extol the superiority of women in this field. She comments on vaginal examination, *touching*:

…that great and essential point of our profession, a skill in what we call the Touching, is not to be acquired without a frequent habit of recourse to the sexual parts whence the indications are taken. And in this nothing but personal experience can perfect the practitioner. But this admitted, only

proves the more clearly the utter impropriety of men addicting themselves to this occupation. For, once more, most certainly the season of acquiring the nicety of that faculty of Touching, besides other requisites of the art, is for obvious reasons that of youth…It may perhaps be granted , that men of a certain age, men past the slippery season of youth, may claim the benefit of exemption from impressions of sensuality, by objects to which custom has familiarized them. But, in good faith, can this be hoped or expected in the ungovernable fervor of youth? Can such a stoic insensibility be imagined in a boy or young man, as that he can direct such his researches by pawing and grabbling to the end of instruction only?…In short, even Dr. Smellie's doll is a more laudable method of instruction. [1]

The use of obstetric manikins for teaching thus goes back a few centuries. In discussing the use of manikins before the Obstetrical Society of Cincinnati in 1879, Dr. J. Trush commented:

> *Bedside instruction, of course, would be preferable to all artificial substitutes, but unfortunately neither the abundant obstetrical material in our public hospitals, nor private cases can be made available for such purposes. Even should the patients be perfectly willing to serve as means of instruction, public opinion would frown down all such attempts, and woe be unto the enterprising teacher who should venture to demonstrate the art of obstetrics upon the living in his lecture room! The entire army of able-bodied editors throughout the land would be sure to pounce upon the innovator, and, metaphorically speaking, tear him to pieces, totally forgetting, it would seem, that, some day possibly, a wife, sister, or daughter might require the assistance of a competent accoucheur.* [2]

The pre-eminence of European academic Ob/Gyn in the 19th century owes much to the existence of large lying-in hospitals for unwed and indigent mothers. These provided a wealth of "teaching material" for medical students —a resource not widely available in the U.S. until the 1900s. The stigmata of illegitimacy and poverty, as well as the class difference between patients and doctors, made short-shrift of any discussion on the propriety of this arrangement: the recipients of "Charity" effectively relinquished their modesty and body to the cause of medical education.

In America, the subject was more controversial. In 1848, Samuel Gregory, of Boston, published a 50-page pamphlet entitled Man-Midwifery Exposed and Corrected, in which alleged improprieties by men-midwives were recounted. He quotes the French naturalist Buffon: *In the submission of women to the unnecessary examinations of physicians, exposing the secrets of nature, it is forgotten that every indecency of this kind is a violent attack against chastity, that every situation which produces an internal blush is a real prostitution.*

When James P. White (1811-1882), a Professor of Obstetrics at the University of Buffalo, delivered an Irish girl before the twenty members of the graduating class in 1850, he received a mixed-bag of commendation and condemnation. A scathing editorial appeared in the *Buffalo Courier* , signed "L":

The patient was a woman in humble circumstances, whose poverty, perhaps, overruled her natural modesty. What mattered it then, if a score of scarcely adolescent youths satisfied their meretricious curiosity at her expense? The professor had enjoyed his "clinique" and his class their salacious stare, and, under the specious plea of scientific advancement, a precedent had been set for outrage indiscriminate. God forbid that it should be followed in our time.

17 out of the 40 doctors in Buffalo signed a letter condemning White:

The propriety of the exhibition with the living subject, before the graduating class of the College, does not…admit of a public discussion…the practice…merits a severe rebuke…because we deem it wholly unnecessary for the purpose of teaching, unprofessional in manner, and grossly offensive alike to morality and common decency.

The above letter was copied by the *Buffalo Courier* and the *Christian Advocate*, and was accompanied by such a vitriolic editorial in the latter, that Dr. White filed a suit for criminal libel against its editor, and Dr. Horatio N. Loomis, who was believed to have written the "L" editorial. After this, the entire question became a matter of national interest; within a short time, almost every medical journal in the country devoted an editorial to it, mostly commending the innovation.

The trial lasted four days, ending in the acquittal of Dr. Loomis. This did not end the discussion; the matter was referred to the A.M.A. Committee on Education, who reported in 1851 that the practice was neither immoral or wrong, but unnecessary for the purposes of instruction. In 1904, J. Withridge Williams wrote about this report:

> *…all the objections urged against this method of teaching were without avail, as the general sentiment of the profession was that it was advantageous to the student and without harm to the woman, and accordingly it came to be more and more extensively employed, so that in recent years it has come into general use in every Lying-In hospital in the country…*
>
> *…the widespread opposition of many otherwise well informed medical men, to the conduct of labor under the guidance of the eye would seem to offer a satisfactory explanation for the low grade of obstetrical technique which for so long a period characterized American medicine.*[3]

In spite of the controversy, the patients discussed above were for the most part conscious, and could presumably refuse to be examined by students. Examination under anesthesia poses a greater ethical dilemma, since the subjects are more vulnerable. Until the last generation, medical decision-making was guided by the ethical principles of non-malfeasance (*primum non nocere*), and beneficience. In this paternalistic model, the patient trusted the doctor (usually male) to act in her best interest. More recently, respect for patient autonomy has come to the forefront of ethical discussion. This emphasizes a competent patient's right to make informed decisions about her care. Kluge describes what he calls the *Fiduciary Model* of the physician-patient relationship:

> *It recognizes that the extent of duty for the physician cannot be measured in the precise wordings of a contract.…The right of autonomy of the patient is balanced against the knowledge and expertise of the physician and the rights of the physician both as an individual and as a professional. The patient has an ultimate and basic right to control the direction of the health care relationship, the physician has the right to determine what is appropriate under the values thus indicated…*[4]

In the context of informed consent for a surgical procedure, the physician has a duty to explain, in language the patient understands, the nature of the operation, its probable benefits, and all material risks that the "average prudent person" would consider in making a decision. Unless a

patient asks, it is not customary to describe the minutiæ of surgical ritual (IVs, catheters, vaginal preps, stirrups etc.), nor to obtain a specific consent for them. Pelvic/rectal examination under anesthesia is part of the routine of gynecological surgery. This is always done by the attending physician to confirm suspected diagnoses, and avoid surprises. In a teaching hospital, much of the actual surgery is performed by residents, and it is absolutely essential for them to also examine the patient. Medical students rotating on the GYN service often assist at surgery, and it is usual for them to examine the patient. This is definitely educational but, by helping the student better understand what the surgeon wants to accomplish, (s)he is more interested, provides better assistance, facilitating the operation and thereby benefiting the patient. This scenario is quite different from the shenanigans described in cynical/humorous "intern" books such as *The House of God* ; it has been over 25 years since I last witnessed half-a-dozen students line up to examine a patient purely for "education".

The authors state that "women feel almost universally that pelvic examinations…should occur only after the woman has given permission to the students' supervisor". How specific must a consent be? Can it be verbal, or must it be in writing? Women admitted to a teaching hospital sign an institutional consent acknowledging that they will receive care from students and residents under the supervision of an attending physician. The O.R. consent usually identifies the responsible surgeon, and authorizes "such assistants as are designated by the surgeon"; it also grants permission to videotape or photograph the operation. Patients are normally introduced to medical students and residents prior to surgery, and have an opportunity to ask questions before being medicated. I have never seen a written consent form specifically authorizing pelvic examinations by trainees, but I also cannot recall anyone ever asking about one. The actual survey questions were not stated, but I suspect that few women undergoing gynecological surgery would object to being examined in the context described above.

The observed change in student attitudes is easily explained — and not as negatively as the authors would believe. Prior to their Ob/Gyn clerkship, most medical students' non-sexual experience with the female genital tract has been limited to examining paid surrogate patients. Working on a gynecology service de-mystifies that part of the female anatomy, so that it can be treated like any other part of the body. Some might say that familiarity breeds contempt; in this case, it is the beginning of professionalism.

1. Nihell Elizabeth *A Treatise on the Art of Midwifery* LONDON 1760 p.85-86
2. Trush J *Obstetric Manikin of Drs. Budin and Pinard, of Paris* Am J Obstet Dis Women Child 1880; 13:170-174
3. Williams JW *The Introduction of Clinical Teaching of Obstetrics in the United States* Am J Obstet Dis Women Child 1904; 50: 302-321
4. Kluge EHW *Biomedical Ethics* 1992 p. 81 Prentice-Hall Canada, Scarborough

REVIEW #65

Title: The role of covering gowns in reducing rates of bacterial contamination of scrub suits.

Authors: Kaplan C, Mendiola R, Ndjatou V, Chapnick E, Minkoff H

Sites: Departments of Obstetrics and Gynecology and Internal Medicine, Maimonides Medical Center, Brooklyn, NY

Published: Am J Obstet Gynecol 2003; 188: 1154-5

Objective: This study was undertaken to determine whether covering gowns reduce the rate of contamination of surgical scrubs.

Methods: 75 clinicians had pieces of fabric from clean scrubs stapled to two areas of their scrub suits using a sterile technique — the chest pocket, and to the anterior waist area. Participants wore a covering garment (white coat or gown) when wearing scrub suits outside designated areas (n=25), did not wear a covering garment (n=25), or wore scrub suits outside the hospital. Subsequently, the fabric was assessed with culture in enhanced broth media and blood agar.

Results: Although there was a trend toward lower rates of contamination in the group that did not wear a covering garment, the difference was not significant. At no point, and at neither site of fabric attachment, did those who wore a covering garment demonstrate any advantage in regard to levels or frequency of contamination.

Conclusions: Wearing covering garments over scrub suits does not reduce rates of contamination.

Commentary: This is the latest chapter in our series on surgical rituals.

Long before the germ theory gained general acceptance, the infective nature of puerperal fever had been recognized by Alexander Gordon, of Aberdeen, (1795), Oliver Wendell Holmes, of Boston, (1843), and Ignaz Semmelweis, of Vienna (1847). Following exposure to a case of puerperal fever, Holmes advised:

> *…thorough ablution, change every article of dress, and allow twenty-four hours or more to elapse before attending any case of midwifery.*

By requiring doctors and students to wash their hands in a chloride of lime solution before attending women in labor, Semmelweis reduced maternal mortality from 11.4% in 1846 to 1.3% in 1848. After Pasteur demonstrated the link between bacteria and disease (1860), Lister (1865) markedly decreased his incidence of surgical infection by disinfecting instruments and skin with a carbolic acid (phenol) solution. In the pre-antibiotic era, *Listerism* greatly expanded the indications and scope of abdominal surgery.

Obstetricians and surgeons were slow to accept the principles of antisepsis but, when they did, it was with a vengeance that is still felt today. In 1876, William Priestley, in his Presidential address to the Obstetrical Society of London, could write:

> *Some doctors change their clothes and wash with a disinfectant whenever they have seen infectious cases. Whatever either will, or may, conduce to the well-*

being of patients, will, I am sure, not be regarded as either too irksome or troublesome by any member of our profession.

By the mid 1880s, antisepsis had become the standard of care in most European and American hospitals, although every institution —and every senior surgeon— had its own ritual. In his 1898 classic "Operative Gynecology", Howard A. Kelly advised:

Personal cleanliness must be observed by frequent bathing, changes of underclothing and of linen and by wearing clean, well-brushed clothes. A man who is dirty in his general habits is unfit to practice surgery…

Preparatory to operation, the coat, vest, shirt, and trousers must be removed and a sterilized linen suit put on; …A sterilized linen cap and white canvas shoes complete a costume fulfilling the requirements of an aseptic technique. Just before each operation the nurse takes a sterilized apron out of her stock of supplies and puts it on the operator, covering that part of his suit which necessarily becomes contaminated in moving about the room before and between operations…

The hands and forearms are first vigorously scrubbed for 10 minutes with a brush, using common brown kitchen soap or green soap and hot water…

The hands…are next immersed in a hot saturated solution of permanganate of potash until stained a deep mahogany color…

They are then immersed at once in a saturated solution of oxalic acid, which decolorizes and completely sterilizes them..

The oxalic acid may be removed by rinsing the hands in warm water…

Although the methods thus detailed are indispensable in the preparations for an operation, it is still more important that the surgeons, assistants, and nurses should live under such a keen realization of the vital relations of sepsis, antisepsis, and asepsis to their work that they shall always feel an instinctive repugnance to contact with any septic material…This instinctive shrinking from infection, keeping always on guard against sepsis, may well be termed "the antiseptic conscience".[1]

With hospital standardization in the 1920s, some areas in most American hospitals were designated as "sterile", and strict rules governed the type of clothing that could be worn in those rooms. For many years, it was forbidden to wear scrub suits outside the O.R. Nursing directors were usually better able to enforce these rules than their medical counterparts. Citing impracticality, doctors would wear a lab-coat over their O.R. clothes, but were on an honor system to change them before going back to the operating suite. As a medical student during the 1970s, I can remember observing that sterility increased with age and experience: students were yelled-at if they came within a few feet of anything blue or green, whereas the Chief could drop his glasses into the patient's wound without comment.

Despite the availability of antibiotics, potent antiseptics, positive-pressure ventilation, and better gloves, surgical infections continue to occur. Infection-control committees keep changing protocols, with uneven results. In one hospital, a report that just walking into the O.R. releases over 10,000 desquamating skin cells prompted a directive that O.R. and L&D nurses wear scrubs elasticized at the ankle "to prevent shedding". Although men are generally bigger and hairier, they were exempt from this requirement.

This simple study demonstrates that seemingly logical ideas don't always work as expected. The observation that wearing a lab-coat might even increase the bug count on scrubs should come as no surprise to anyone who has seen house-staff lab-coats. Considering that scrub suits are covered by sterile, impermeable operating gowns during surgery, does it really matter if those garments are "fresh" from the locker-room shelf or have been worn around the hospital? We need another study.

1. Kelly HA Operative Gynecology Volume 1, 1898 p. 21-22 D. Appleton and company, New York

REVIEW #66

Title: External cephalic version beginning at 34 weeks' gestation versus 37 weeks' gestation: A randomized multicenter trial.

Authors: E.K. Hutton et al., for the Early Cephalic Version Trial Group

Site: McMaster University, Hamilton, Ontario, Canada, and University of Toronto, Ontario, Canada

Published : Am J Obstet Gynecol 2003; 189: 245-54

Objective: To compare a policy of beginning external cephalic version (ECV) early, at between 34 and 36 weeks' gestation, and beginning ECV at 37 to 38 weeks' gestation.

Methods: At 25 centers in seven countries, 233 women with a singleton breech fetus were randomly assigned to having an ECV procedure done early (34-36 weeks), or delayed (37-38 weeks). An experienced practitioner undertook the ECV procedure, and repeat ECV were allowed. Tocolytics and use of epidural analgesia were included as part of the protocol. The primary outcome was the rate of non-cephalic presentation at birth. An intention-to-treat analysis was used.

Results: Data were received for 232 women, with 116 in each group. Of theses86.2% in the early ECV group and 67.2% in the delayed ECV group had at least one ECV performed. The rate of non-cephalic presentation at birth in the early ECV group was 56.9%, and 66.4% in the delayed ECV group (RR 0.86, 95% C.I. 0.70-1.05). The rate of serious fetal complications and the rate of preterm birth at < 37 weeks were not significantly increased in the early ECV group compared with the delayed ECV group (6.9% vs 7.8%, RR 0.89 CI [0.36-2.22], P = 0.69 and 8.6% vs 6.1%, RR 1.42 CI [0.56-3.59], P= 0.31, respectively. The rate of cesarean in the early ECV group was 64.7% compared with 71.6% in the delayed ECV group (RR 0.90, CI 0.76-1.08], P = 0.32). Neonatal outcomes were comparable in the two groups. The rate of reversion to non-cephalic was low in both groups.

Conclusions: Early ECV performed at 34-36 weeks compared to 37-38 weeks may reduce the risk of non-cephalic presentation at term. A large trial of early ECV is now required before recommending changes in clinical practice.

Commentary:

The incidence of breech presentation exceeds 20% until the third trimester. By 34 weeks, most have converted spontaneously to vertex, and 3-4% are still breech at term. A few of these are associated with congenital anomaly, placenta previa, cervical fibroids or uterine septa, but, in most cases, no obvious abnormality can be identified.

Midwifery and Obstetrics texts have always considered breech delivery to be more risky to the fetus than birth by the vertex. In the 1945 edition of Williams' *Obstetrics*, Stander wrote:

> *So far as the life of the mother is concerned, the prognosis differs but little in breech and vertex presentations, except that in the former labor is slower, the morbidity higher, and in operative cases is more likely to be complicated by perineal tears, which sometimes extend through the sphincter ani muscle. The prognosis for the child, on the other hand, is considerably worse, particularly so*

in the case of frank breech presentations in nulliparous women, than in vertex presentations…Goethals, in a careful review of 1242 breech deliveries in the Boston Lying-In hospital found… in full term uncomplicated pregnancies, in the absence of accidents of labor from abnormalities of the placenta or cord, a fetal mortality of 6.9%. [1]

These numbers —at a time when the Cesarean section rate was in the 2-3% range, with maternal mortalities under 1% when performed early in labor— were not considered by Stander to be an indication for Cesarean section:

…others have taken the extreme ground that it [Cesarean] may even be justifiable in breech…positions.

Given such an attitude, Stander recommended external cephalic version in all cases where the abdominal wall was sufficiently thin to permit accurate palpation, the presenting part not too deeply engaged, the uterine wall not too irritable, and sufficient amniotic fluid to permit easy movement of the child. Prior to ultrasound, this must have been an uncertain business. Nonetheless, he wrote:

We have employed it with great satisfaction in hundreds of patients and in no way share the apprehension of many writers that it give rise to twisting or to loops of the cord about the fetus or even lead to premature separation of the placenta. We believe that its only drawback consists in the fact, that after accomplishment of external version, the child tends to return to its original position, unless the head promptly becomes engaged.

The technique of external cephalic version used today was first described in 1807 by Wigand. Between the 1940s and 1970s, many authors were able to reduce the incidence of breech presentation at the onset of labor to as low as 1% by attempting version at every obstetric visit. [2]

The success of the procedure depends on many factors, the main ones being the parity of the patient, and the experience of the operator. Published series typically report 50% success in primiparous women, and 75% in multiparæ. Since the mid-1970s, higher success rates have been reported with the use of tocolytics; more recently, epidural anesthesia has been used to facilitate version.

Since the 1970s, increased concern for fetal welfare has led to a dramatic increase in the incidence of Cesarean section for breech presentation. Publication of the Term Breech Trial [3] in 2000 appears to have driven the final nail into the vaginal breech coffin. In this multicenter RCT, planned cesarean section was compared to planned vaginal birth for breech presentation at term. The incidence of serious fetal mortality/morbidity was approximately three times greater in the vaginal group, while serious maternal morbidity was comparable. Although experienced obstetricians (including this reviewer) have safely delivered many breeches at term, and numerous writers have found fault with the Term Breech Trial, Cesarean section is both efficient and almost guarantees a good baby. Given the medico-legal implications of bad outcome, this is a no-brainer for most obstetricians and mothers. In most U.S. hospitals, vaginal breech delivery will continue to occur when the patient presents with the breech on the perineum, for breech extraction of the second twin, and in the rare case where both mother and obstetrician agree to a trial of labor.

Parenthetically, since *every* labor is a trial of labor, and most serious fetal trauma and asphyxia leading to litigation is associated with labor and/or vaginal birth, it is only a matter of time before VBAC and operative vaginal birth also disappear. There will remain only "easy vaginal births", or "easy Cesareans", and I predict—conservatively— that the national rate of Cesarean will double in the twenty years.

Having convinced us that Cesarean section for breech is better than vaginal birth, why now are the authors writing about external version at 34 weeks? It seems that this research was undertaken before the findings of the Term Breech Trial were published. [3] Justification for continuing the work was that "any maneuver that lowers the rate of non-cephalic presentation at birth will have a direct impact on the rate of Cesarean section". Assuming that 50% of breeches can be converted to vertex, and that all of them deliver vaginally, the maximum reduction of the Cesarean rate would be 2% —hardly the most promising area to pursue in this regard.

In fact, of the 116 women in the early ECV group, only 41 (35.3%) achieved vaginal birth, 8 of them requiring operative intervention; comparable numbers in the late ECV group were 33 (28.5%) vaginal births, 24 of them spontaneous. If these numbers have any external validity, the maximum effect on the overall Cesarean rate would be 1.1%. Comparing the early and late ECV groups, there were 8 more vaginal births in the early group. This statistically insignificant result was achieved at considerable effort: 81 women had 1 ECV, 17 had 2 procedures, and 2 underwent ECV at least 3 times; only women anxious to avoid a Cesarean, or an investigator trying to publish a paper, would go to all that trouble for so little benefit. The authors speculate that a larger sample size might show a significant difference and thus suggest that a larger trial be pursued.

Why is this a bad idea? Despite the presence of 39 multiparæ, and a 48% use of tocolysis, the overall success of version in this study was only 34% in the early group —and only 23.1% in the late group. This is much lower than commonly reported in the literature, and suggests that the experience of the operators (at least 5 successful ECVs) in the 25 study centers was somewhat limited. This militates against the widespread adoption of ECV, since the occasional operator has no likelihood of doing better than this.

More important, however, is the fiduciary duty of researchers to avoid harming subjects. Pregnant patients and their fetuses are considered to be a "vulnerable" population by institutional review boards. Performing an ECV before term is in every sense an elective procedure, and it has the potential to cause "more than minimal" harm. Emergency Cesarean for fetal distress or abruption is uncommon, but certainly more hazardous than elective Cesarean at term for both mother and child. The authors did not list the 25 centers and 7 countries participating in this trial. However, I know that this particular study was NOT approved by the University of Michigan IRBMED, and I suspect it will meet with difficulties in other U.S. centers.

In my view, it is meddlesome midwifery to attempt version before 38 completed weeks, and I pay little attention to fetal presentation until then. If the breech presents at term, I offer patients one of three choices: (1) expectant management, with Cesarean at the onset of labor if still breech (2) elective Cesarean at 39-40 weeks if still breech, or (3) ECV, followed immediately by induction if successful, and either option (1) or (2) otherwise. I can't remember the last time a woman insisted on a trial of labor for breech and, in my experience, most women would rather have an elective Cesarean than ECV.

1. Stander, Henricus J *Textbook of Obstetrics* 3rd Ed 1945 Appleton-Century-Crofts, Inc. New York (9th Ed. of Williams' *Obstetrics*)

2. Quilligan, Edward J., Zuspan, Frederick *Douglas-Stromme Operative Obstetrics* 4th Ed 1982 Appleton-Century-Crofts, Inc. New York

3. Hannah, Mary E et al *Planned Cesarean section versus planned vaginal birth for breech presentation at term: a randomized multicenter trial* The Lancet 2000; 356: 1375-82

REVIEW #67

Title: Obstetric technologies: What determines clinical acceptance or rejection of results of randomized controlled trials?

Author: JT Parer

Site: University of California, San Francisco

Published: Am J Obstet Gynecol 2003; 188: 1622-8

Objective: The acceptance or rejection of obstetric technologies in clinical practice is not always based on the results of randomized controlled trials (RCTs). Possible reasons for this discordance are examined.

Methods: Eleven technologies introduced over the past 30 years were examined. RCT results were determined from the literature, with emphasis on meta-analyses and the Cochrane reviews. Results were graded for quality of evidence (I-III) and strngth of recommendations (A-E) on the basis of criteria adopted by the United States Preventive Services Task Force. Clinical use was based on data from the literature, or when this was lacking, on an estimate, and graded + to +++ or – to ---, based on degree of acceptance or rejection.

Results: There was concordance of results with midtrimester ultrasound imaging (US), home uterine activity monitoring (HUAM), Doppler velocimetry in high-risk pregnancy, short-term tocolysis, single-course antenatal corticosteroids (BMZ), thyroid-releasing hormone (TRH), and fetal fibronectin (fFN). There was discordance of results with fetal heart rate monitoring (FHRM), fetal blood sampling (FBS), US imaging in late pregnancy, Doppler velocimetry in low-risk pregnancy, and tocolysis beyond 7 days. In several cases there are published RCTs, but clinical acceptance is still evolving (multiple course BMZ, pulse oximetry, and electrocardiogram ST-segment analysis).

Conclusions: These observations suggest that technologies which are simple to apply, and have a single endpoint, show concordance between RCT results and clinical use (HUAM, short-term tocolysis, single-course BMZ, TRH, and fFN). Those that are complex to apply (FBS), or interpret (FHRM), and/or do not have a single clear end point (FHRM, Doppler), or have results that are of great personal interest to the patient (FHRM, US imaging, long-term tocolysis), are more likely to show discordance. These inconsistent relationships suggest that the decision-making processes of obstetric providers and patients would be a fruitful area of investigation.

Commentary: This article reflects on why clinicians adopt certain technologies, and discard others, and is followed by questions and commentaries from other obstetricians attending the 2002 Annual meeting of the Pacific Coast Obstetrical and Gynecological Society.

Dr. Parer observed relatively poor concordance between the use of technologies by clinicians, and the published RCT evidence about them. He postulates that the simpler it is to apply the technique, and the simpler the clinical endpoint, the more likely there will be acceptance of the trial results. The author cites single-dose betamethasone as an example of a therapy that is easily administered, effective, and widely-accepted by clinicians. This may be true in 2003 but, as Meadow et al. [1] point out, U.S obstetricians were slow to adopt this therapy (see Medscape review below). Liggins and Howie, [2] of New Zealand, reported the first RCT on BMZ in 1972; by the early 1980s,

at least six RCTs had been published, all reaching the same favorable conclusion. Yet, in 1985, BMZ was prescribed by only 8% of American obstetricians. The 1986 textbook *Obstetrics* [3] expressed surprise that there should remain any controversy about the use of antenatal steroids, but it was not until after publication of the 1994 NIH Consensus Statement [4] that a majority of U.S. obstetricians started to use BMZ routinely. HMOs also published practice guidelines that encouraged the use of BMZ. It is clear that acceptance of technology is often regional. When I was a resident in Montreal, in 1980, Robert Usher —one of the first full-time academic neonatologists in Canada— was an enthusiastic advocate of BMZ, and it was administered to every patient in pre-term labor between 26 and 34 weeks.

Home uterine activity monitoring never caught on because, (1) no RCT confirmed its efficacy, and (2) few insurance carriers would pay for it, and the private companies promoting it went out of business.

Fetal scalp pH sampling was not that difficult to do if the cervix was at least 4 cm dilated. A pH over 7.25 was re-assuring, but a persistent non-reassuring FHR tracing required serial sampling, and it was easier and less stressful to perform a Cesarean section instead. Fetal pulse oximetry is the latest attempt to replace serial scalp pH. It is too early to say whether this will be utilized widely outside large academic centers. Positioning the device to get a steady signal requires some fiddling, especially since these patients usually already have a fetal scalp electrode and an intra-uterine pressure catheter. Because few clinicians have much experience with pOX, it takes a large amount of *sang-froid* to sit there and watch a worrisome FHR tracing, no matter what the machine says. The average obstetrician will opt for early delivery by whatever means is practicable.

Fetal heart rate monitoring remains a universally-used technique despite the lack of RCT support for its continuous use in low-risk patients. As Parer points out, it is not intuitively obvious to either providers or parents (or lawyers) why the continuous collection of heart rate data would not be better than intermittent data collected by auscultation. The explanation, of course, is that severe intrapartum asphyxia or death is rare in the general population. One has to monitor hundreds or thousands of patients before seeing a FHR pattern that most clinicians would consider ominous. It is quite probable that with one-on-one nursing and systematic intermittent monitoring during labor most of these patterns would be detected. In real-life, continuous monitoring is used to compensate for a shortage of personnel; it allows anyone near a computer screen to monitor several rooms at a glance. And, yes, patients and their families are re-assured by hearing their baby's heartbeat.

The real problems with continuous FHR monitoring are that: (1) it should be continuously interpreted, but it often is not, and (2) its interpretation is very subjective. In the event of a bad outcome, continuous monitoring provides yards of "ammunition" for the plaintiff's expert.

Insofar as medicine remains as much art as it is science, there will be discordance between teaching and practice. RCTs draw conclusions about populations, and their external validity depends on how closely their sampling is representative of the population under study. When the results of RCTs are at odds with the experience of conscientious clinicians, it is natural to await further studies before changing individual practice patterns.

Every pregnancy and labor is unique, and birth attendants are called upon to make decisions based on incomplete information. This requires *clinical judgment*. Hard to define, easier to recognize, this commodity allows the clinician to integrate the exigencies of a situation with the wishes of the parents to achieve an outcome acceptable to all concerned. Although we don't like to

point fingers, we know that Board Certified Obstetricians are not all created equal, and that academic achievement does not always correlate with clinical excellence. In this age of statistics, it is well to remember that *clinical judgment* is normally-distributed among obstetric providers, and will ever be a confounding variable in any study.

1. Meadow WL, Bell A, Sunstein CR *Statistics, not memories: What was the standard of care for administering antenatal steroids to women in preterm labor between 1985 and 2000?* Obstet Gynecol 2003; 102: 356-62

2. Liggins GC, Howie RN A controlled trial of antepartum glucocorticoid treatment for prevention of the respiratory distress syndrome in premature infants. Pediatrics 1972; 50: 515-525

3. Main DM, Main EK in **Obstetrics** Ed. Gabbe SG, Niebyl JR, Simpson JL 1986, Chapter 23, Churchill Livingstone

4. National Institutes of Health Consensus Development Conference Statement. Effect of corticosteroids for fetal maturation on perinatal outcomes, February 28-March 2, 1994 Am J Obstet gynecol 1995; 173: 246-52

REVIEW #68

Title: Statistics, not memories: What was the standard of care for administering antenatal steroids to women in preterm labor between 1985 and 2000?

Authors: WL Meadow, A Bell, CR Sunstein

Site: University of Chicago, Chicago, IL

Published: Obstet Gynecol 2003; 102: 356-62

Authors' abstract: We determined the frequency of antenatal corticosteroid use for mothers with threatened premature delivery in 1985, 1990, 1995, and 2000. We next compared published data to the surveyed recollections of 302 obstetricians who were practicing during these years. Two points emerged. First, published reports reveal that the use of antenatal corticosteroids increased steadily, from 8% in 1985 to 20% in 1990, 52% in 1995, and 75% in 2000 ($P < .001$). Second, "expert" opinions derived from the recollections of practicing obstetricians consistently overestimated the actual use of steroids during the year in question —31% versus 8% for 1985, 56% versus 20% for 1990, 78% versus 52% for 1995, and 92% versus 72% for 2000 (all Ps <.001).

The use of antenatal corticosteroids by obstetricians in the past 15 years reveals a phenomenon that is widely recognized elsewhere —retrospective memories are often wrong, and when they are wrong they are not randomly wrong. Rather, recollections are systematically skewed toward an outcome that, in hindsight, is considered desirable (the "Monday Morning Quarterback" phenomenon). We offer a simple proposal. In determining the "standard of medical care", the legal system should rely on statistical data about doctors' performance rather than the recollection of experts about doctors' performance. The fallible memories of isolated experts are a crude second-best, far inferior to the data they approximate. Widespread adoption of this view by professional physician organizations would dramatically increase the rationality of expert testimony in medical malpractice tort law.

Commentary: This provocative article evolved from a malpractice case. In 1990, a woman delivered at 28 weeks; her 900 g infant survived, but suffered permanent morbidity from RDS. She sued the obstetrician for failing to administer antenatal corticosteroids. The plaintiff's expert stated that, in 1990, it was the "standard of care" to administer such medication, and that failure to do so in this case constituted medical negligence. This claim was based on the expert's experience and training in the field. The defendant's expert produced literature evidence that only 20% of women in the U.S.A. were receiving antenatal corticosteroids in 1990.

The authors did not report the jury's decision, but explored the question: " How much weight should be given to statistical descriptions of medical practice versus anecdotal recollection of an expert's individual experience?"

This raised the broader question of medical testimony. The adversarial system in our courts of law compels plaintiff and defense attorneys to produce "experts" whose opinion supports their claim. Although "professional" medical experts are viewed with contempt by many, the reluctance of physicians to testify against colleagues in their communities has fostered in the public mind the notion that doctors cover-up each others' mistakes. This misplaced solidarity —there but for the grace of God, go I— encourages lawyers to seek opinions from distant "experts" whose experience may be quite different from that of local practitioners.

Lest we think malpractice and expert testimony are contemporary issues, let me quote from Henry Campbell's Presidential address to the 1885 American Medical Association annual meeting: [1]

> *There are many conditions of professional life in which the medical man may become a defendant, either justly or falsely accused. It is, however, in suits for malpractice that the danger and the evil here have, in the course of years, grown so unpleasantly familiar to the medical profession…*
>
> *The light of scientific truth he [the medical expert] sheds is even sometimes suspected as coming with bent and refracted rays through the distorting lens of self-interest and a paid opinion…He is almost invariably presented as the medical witness or the medical expert in behalf of one side or other of the case upon trial…He is, as a witness and also, as an expert, subject in his deposition to the arbitrary and sometimes offensive and often irrelevant interrogation of the interested attorney whose duty it may become to misinterpret or to suppress the significance of his testimony…In this way can the profoundly scientific and strictly conscientious medical witness or expert, on account of the inherent difficulties of his deposition…be made to appear to the average jury and to all ordinary minds present in the light of a crafty charlatan—the tool of some hidden interest guiding and directing his testimony.*

Nothing has changed! In the U.S.A., bad outcome is equated to malpractice because there is no other recourse for victims to obtain compensation. Trial lawyers are the main beneficiaries of the present system, and meaningful tort reform — with a no-fault compensation fund— is not on the horizon. For its part, the medical profession must identify and deal in a transparent way with the bad actors within its ranks. The testimony of expert witnesses should be audited in a systematic way to ensure compliance with a professional code of ethics.

1. Campbell, Henry F *The past and the present—the physician as related to the tribunals of law* J. Am Med Assoc 1885; 4: 477-486

REVIEW #69

Title: A comparison of the effects of epidural and meperidine analgesia during labor on fetal heart rate.

Authors: JB Hill, JM Alexander, SK Sharma, DD McIntire, KJ Leveno

Site: University of Texas Southwestern Medical Center, Dallas TX

Published: Obstet Gynecol 2003; 102: 333-7

Objective: To study the effects of initiation of epidural analgesia on fetal heart rate (FHR) patterns compared with intravenous meperidine analgesia.

Methods: 469 nulliparous women requesting pain relief in labor for the first time were randomized to receive either epidural analgesia with 0.25% bupivicaine or intravenous meperidine 50 mg/promethazine 25 mg. FHR patterns occurring within 40 minutes of initiation of labor analgesia were reviewed retrospectively by three MFM specialists who were blind to clinical events, including type of analgesia.

Results: Meperidine, compared with epidural analgesia, was associated with statistically significantly less beat-to-beat variability (absent or less than 5 beats per minute) of the FHR (30% versus 7% of fetuses, P < .001) in the first 40 minutes after initiation of analgesia, as well as with fewer FHR accelerations (88% versus 62% of fetuses, P <.001). Neither the incidence of FHR decelerations nor the type of deceleration were significantly different between methods of labor analgesia. Specifically, 41% of women given meperidine exhibited FHR decelerations within 40 minutes, compared with 34% given epidural analgesia (P = .35).

Conclusions: Epidural analgesia does not have deleterious effects on FHR.

Commentary: This study concludes that epidural analgesia (bupivicaine and fentanyl) does not produce significant FHR anomalies compared with intravenous Meperidine (DEMEROL) + promethazine hydrochloride (PHENERGAN). Both methods of analgesia have been used for many years and have excellent safety profiles.

This is not to say that there are never any complications. The rapid intravenous administration of Demerol 50 mg can cause maternal respiratory arrest. Narcotics cross the placenta and sedate the fetus; it is not surprising, therefore, that variability is decreased for some time after narcotic injection, and that the occasional newborn requires naloxone to reverse respiratory depression. Cibils, in his 1981 textbook on Fetal-Maternal Monitoring, [1] quotes a 1967 study demonstrating a potent, although transient oxytocic effect following I.V. —but not I.M.— injection of meperidine. This hyperstimulation could explain the one case of prolonged bradycardia observed after meperidine in this study.

Although the authors observed only one case of prolonged bradycardia within 40 minutes of epidural analgesia, they quote three studies reporting 19/129 (14.7%), 9/128 (7.0%), and 11/366 (3.0%) instances of prolonged FHR deceleration. Some of these are associated with maternal hypotension, and respond to fluids, ephedrine, and position change. Every few months, I observe a prolonged bradycardia — to the 60s and 70s, within 30 minutes of epidural administration— NOT

associated with maternal hypotension as measured by a brachial cuff. This also respond to fluids, ephedrine, and position change, but it can take over 20 minutes for the FHR to return to baseline and show normal short-term variability. The appearance is worrisome, and I am aware of emergency Cesareans performed for such decelerations. Because I have seen these for many years, and the neonates do well, I am more conservative, but wary nonetheless.

There is little in the literature about this observation, and it appears idiosyncratic. The closest parallel is to the bradycardias associated with paracervical blocks during labor. First described in Europe in the late 1920s, this technique was introduced in the United States by Rosenfeld in 1954. The majority of observers reported bradycardias (2% to 56%) within 8 minutes after the anesthetic injection. According to Cibils [2], the effect is greater with higher concentrations of drug, more marked with bupivicaine than with either lidocaine or mepivicaine. The addition of epinephrine to the anesthetic solution markedly increases the likelihood of significant FHR alterations. Cibils, in 1976, proposed the *uterine artery spasm hypothesis* to explain this phenomenon. Exposure of the uterine arteries to high concentrations of local anesthetic causes a prolonged spasm impairing intervillous blood flow. Animal studies by Greiss demonstrated that local anesthetics infused into the uterine arteries markedly decreased uterine blood flow independent of the effects on uterine contractility. The wide range of "fetal reserve" would explain why FHR alterations are not seen more often while moderate arterial spasms may be frequently induced.

1. Cibils, Luis A Electronic Fetal-Maternal Monitoring 1981 p. 412 John Wright.PSG Inc, Boston
2. idid p. 448-467

REVIEW #70

Title: Impact of labor induction, gestational age, and maternal age on cesarean delivery rates.

Authors: LJ Heffner, E Elkins, RC Fretts

Sites: Departments of Obstetrics and Gynecology, Brigham and Women's Hospital; Center for risk analysis, Harvard school of Public Health; and Beth Israel Deaconess Medical center, Boston, Massachusetts

Published: Obstet Gynecol 2003; 102: 287-93

Objective: To quantify the impact of labor induction and maternal age on cesarean delivery rates in nulliparous and multiparous women between 36 and 42 weeks' gestation.

Methods: A retrospective cohort study on 14,409 women delivering at two teaching hospitals in metropolitan Boston during 1998 and 1999. Women with contraindications to vaginal birth, including prior cesarean delivery, were excluded. The Odds ratios for cesarean delivery by induction status, gestational age by completed week between 36 and 42 weeks, maternal age <35, 35-39, and ≥40 years, and stratified by parity, were calculated using regression analysis.

Results: In nullipara, labor induction was associated with an increase in C/S from 13.7% to 24.7% [adjusted O.R. 1.7; 95% C.I. 1.48-1.95]. In multipara, the corresponding increase in C/S was 2.4% to 4.5% [OR 1.49, 95% CI 1.10-2.00]. Other variables that placed a nulliparous woman at increased risk for cesarean delivery included maternal age of at least 35 and gestational ages over 40 weeks. For multipara, only maternal age ≥40 years and gestational age of 41 weeks were associated with an increase in cesarean delivery.

Conclusions: Induction of labor, older maternal age, and gestational age over 40 weeks each independently increase the risk of cesarean delivery in both nulliparous and multiparous women.

Commentary: This retrospective study provides an interesting snapshot of obstetric practice at two Boston teaching hospitals. From a computerized database, the authors identified 17,617 deliveries ≥ 36 completed weeks' gestation. Cases with contraindications to vaginal birth (including previous cesarean delivery) were excluded, leaving 14,409 deliveries for analysis. The practice patterns in the two hospitals were judged comparable enough to pool the data for final analysis.

The primary Cesarean section rate for the combined cohort was 10.8%. Roughly 80% of the women delivered spontaneously. Of the 7372 nulliparous women, 2227 (30%) had induced labor; induced nulliparas had a 24.7% cesarean delivery rate, versus 13.7% among spontaneously laboring nulliparas. Respective cesarean rates among the 7027 multiparas were 4.5% following induction, and 2.4% after spontaneous onset of labor. In both groups, the correlation between induction and the rate of Cesarean was significant [P <.001].

Multiparas did not demonstrate any substantive effects of gestational age on the rate of Cesarean delivery. In nullips, however, the Cesarean rate increased after 38 weeks in both induced and non-induced. Adjusted odds ratios (40 weeks = 1.00) for Cesarean delivery in nulliparas were 0.44 at 36 weeks, 0.65 at 38 weeks, 1.59 at 41 weeks, and 1.79 at 42+ weeks [P <.001].

Increasing maternal age was significantly associated with a higher risk of Cesarean. In nulliparas, the odds ratio (< 35 years = 1.00) was 1.97 between 35-39 years and 1.98 at 40+ years. In multiparas, similar odds ratios were 1.10 between 35-39, but 2.13 at 40+ years.

None of these data are surprising. However, the limitations of retrospective studies do not allow any clinically-useful conclusions to be drawn from them, since there are many ways to analyze the information. The doubling of the Cesarean rate in the presence of "diabetes" in both nullips and multips could be explained on the basis that the babies were bigger; however, other studies have shown that the mere diagnosis of "diabetes" leads to higher Cesarean rates for babies of similar size. Information bias may also explain the doubling of the Cesarean rate in nulliparas > 35, but not in multiparas until after age 40. If a pregnancy is considered "premium" because of age or infertility, the indications for intervention are broadened.

The authors are encouraged to continue their research, perhaps delving more deeply into actual patient charts, or setting up some RCTs.