

## CONTRACEPTION/FAMILY PLANNING

### SILCS Diaphragm

#### *Postcoital Testing of a New Single-Size Contraceptive Diaphragm\**

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**OBJECTIVE:** To compare the effectiveness of a new, single size silicone contraceptive diaphragm developed by PATH used with either spermicide (2% N-9) or petroleum jelly to prevent sperm from penetrating midcycle cervical mucus.

**METHODS:** A crossover postcoital testing in 33 healthy, sexually active women not at risk for pregnancy due to previous bilateral tubal ligation or salpingectomy was conducted at Eastern Virginia Medical School and University of Pittsburgh Medical Center. First, a baseline postcoital testing was performed without a device to verify normal measures. Qualified participants underwent up to 2 test cycles using the SILCS diaphragm (metal spring) with either N-9 or petroleum jelly (order randomized). Some participants underwent a third test cycle using the SILCS diaphragm (polymer spring) with N-9. Cycles were completed as follows: baseline (15), SILCS diaphragm (metal spring) with N-9 (13), SILCS diaphragm (metal spring) with petroleum jelly (12), and SILCS diaphragm (polymer spring) with N-9 (8).

**RESULTS:** The SILCS diaphragm (metal or polymer spring) with N-9 reduced the average number of progressively motile sperm per high power field from a baseline of 12.5 to 0. The SILCS diaphragm (metal spring) with petroleum jelly reduced the number of progressively motile sperm per high power field to 0.5.

**CONCLUSION:** Results from this most recent postcoital testing indicate that the current SILCS diaphragm design with the polymer spring and used with N-9 performed well and is acceptable for contraceptive effectiveness testing. The less expensive polymer spring, which is easier to manufacture, will replace the metal spring found in standard diaphragms.

### Comparative Trial of Continuous-Use and 21-Day Cyclic Levonorgestrel and Ethinyl Estradiol Oral Contraceptive

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**OBJECTIVE** To compare a new low-dose oral contraceptive containing levonorgestrel and ethinyl estradiol (E2) administered in a continuous, daily regimen with a 21-day cyclic oral contraceptive.

**METHODS:** A phase 3, randomized, open-label, multicenter study was conducted at 44 sites in Europe to evaluate the 2 oral contraceptives over 1 year (ie, 13 pill packs): continuous daily levonorgestrel 90  $\mu\text{g}$  and ethinyl E2 20  $\mu\text{g}$  (n = 323) and 21-day cyclic levonorgestrel 100  $\mu\text{g}$  and ethinyl E2 20  $\mu\text{g}$  (n = 318).

**RESULTS:** No pregnancies occurred with the continuous regimen, whereas 3 occurred with the cyclic regimen. With low-dose levonorgestrel and ethinyl E2 continuous use, the percentage of women who achieved amenorrhea (ie, no breakthrough bleeding or spotting) increased with each successive pill pack (40% at Pack 7 compared with 53% at Pack 13). The percentage of women who experienced breakthrough bleeding (ie, required sanitary protection) decreased with each subsequent pill pack (50% at Pack 3 compared with 21% at Pack 13). After Pack 4, the median number of days of breakthrough bleeding or spotting was lower with continuous use than with the cyclic regimen. The overall incidence of adverse effects was similar between the 2 regimens; nausea and breast pain were lower with continuous use during Packs 7 to 13. Bleeding-related adverse effects were not significantly different between regimens after Pack 6.

**CONCLUSION:** In this first large comparison of continuous and cyclic oral contraceptive regimens, continuous levonorgestrel 90  $\mu\text{g}$  and ethinyl E2 20  $\mu\text{g}$  was an effective oral contraceptive that also inhibited menses and had a similar safety profile to an established cyclic oral contraceptive.

\* This document includes a discussion of use of a product that is unapproved by the U.S. Food and Drug Administration.



## To B or Not B

### *A Survey of Access and Availability of Emergency Contraception in New Jersey Pharmacies*

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**OBJECTIVE:** To evaluate weekend availability or accessibility of Plan B emergency contraception in New Jersey.

**MATERIALS AND METHODS:** We carried out a telephone survey of all pharmacies in New Jersey between September 2004 and February 2005. We contacted or attempted to contact 1,222 pharmacies during weekends to enquire about the immediate availability of Plan B.

**RESULTS:** Of the 1,146 pharmacies that could be reached, 581 (47%) stated that Plan B was available immediately; 438 of the remaining 565 pharmacies would be able to obtain it within 120 hours; 11% were unable to fill the prescription within 5 days.

**CONCLUSION:** Emergency contraception is readily available in pharmacies in New Jersey. The results of this study ought to raise awareness of the importance of increasing the access and availability of this product to prevent unintended pregnancies.

## Fears About Not Being Able to Get Pregnant Among Pregnant Adolescents

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**OBJECTIVE:** To evaluate health history and contraceptive factors among pregnant adolescents who had fears that they would not be able to get pregnant.

**METHODS:** We interviewed 300 pregnant adolescents (aged 12–19 years) presenting for initial prenatal visits. The outcome for our analysis was a positive response to the question “Did you have any fears that you wouldn't be able to get pregnant.” Independent variables included demographic information, medical history, and reasons for contraceptive nonuse. The analysis included  $\chi^2$ , and Fisher exact test.

**RESULTS:** Remarkably, 42% (n = 126) of study participants stated they had fears about not being able to get pregnant. There were no statistically significant differences found in age or race or ethnicity between those with and without fears. There were also no differences in previous sexually transmitted disease rates, age at first intercourse, or number of partners between adolescents with and without fear about infertility. Birth control use among adolescents

who had fears was lower than the comparison group (17% compared with 26%,  $P = .09$ ). Among those who did not use birth control, those who had fears were more likely to report that they did not think they could get pregnant as a reason for not using birth control (61% compared with 19%  $P < .01$ ).

**CONCLUSION:** A large proportion of pregnant adolescents presenting for their first prenatal visit expressed fear that they would not be able to get pregnant and were not using any birth control method. Further investigation into the source of this fear is necessary to understand its association with adolescent pregnancy and contraceptive use.

## Satisfaction with Tubal Ligation in Rural El Salvador

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**OBJECTIVE:** To identify reasons for use and attitudes toward permanent sterilization in reproductive-age women in rural El Salvador and to assess their satisfaction and regret with this contraceptive choice.

**METHODS:** A Spanish-fluent moderator conducted 11 90-minute focus groups with 5–10 women each. A total of 87 women aged 15–45 years participated. Subjects were identified by El Salvadoran health promoters during a 2-week foreign medical delegation in San Pedro Perulapan, El Salvador. Sessions were tape-recorded, detailed notes were taken, and demographic information was obtained. Major themes were determined from these data.

**RESULTS:** Seventy-four women participated. Demographics included median age of 37 (range 24–45) years, median age at sterilization of 26 (20–45) years, and median number of offspring of 3 (1 to 12). Most of the women worked in the home, with a median of 4 years of education (0–9). Two major themes concerning the choice for sterilization were economic hardship of additional children and the counseling from health care providers. Women perceived the procedure as permanent, definitive, and irreversible. Many myths were held regarding sterilization, including: an increased risk of cancer, weakness, promiscuity, and abandonment by their husbands. The women studied chose sterilization because they believe it to be a free, more natural, and less harmful method than oral contraceptives, injections, or the intrauterine device. The majority of women would recommend the procedure to other women in their communities.

**CONCLUSION:** Overall, rural El Salvadoran women were satisfied with their choice of permanent sterilization. There was little regret despite negative beliefs toward sterilization.



## Noncomparative Contraceptive Effectiveness Trial of Cellulose Sulfate Gel

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**OBJECTIVE:** Cellulose sulfate is a noncytotoxic antifertility agent that exhibits antimicrobial activity in vitro. Cellulose sulfate has been shown to stimulate acrosomal loss, inhibit hyaluronidase, and impede sperm penetration into cervical mucus and is contraceptive in rabbits. Cellulose sulfate is active against cell-free and cell-associated human immunodeficiency virus (HIV)-1 by blocking gp120-CD4–coreceptor interaction and thus inhibiting HIV cell entry. Clinical studies have shown it to be safe for use up to 14 days in women and 7 days in men. The primary objectives of this trial were to estimate the cumulative pregnancy probability for 6 months of typical use of cellulose sulfate gel and 6 cycles of consistent use. Secondary objectives were to assess the acceptability, consistency of use, and frequency of abnormal cytology, candidiasis, urinary tract infections, bacterial vaginosis, and irritation.

**DESIGN:** This was a phase II noncomparative contraceptive effectiveness trial of 200 couples using cellulose sulfate as their primary contraceptive for 6 months. Visits occurred at enrollment and after 1 and 6 months. Participants kept a diary, reviewed by telephone at each menses, on which they recorded menses, coitus, product use, use of other contraceptives, and problems.

**RESULTS:** Enrollment was completed in January 2005, and the last participant exited by September 30, 2005. Preliminary results suggest that the final pregnancy probability will be within the range of other vaginal contraceptives. Complete results will be available at the American College of Obstetricians and Gynecologists meeting.

**CONCLUSION:** If effective, cellulose sulfate would be the first vaginal chemical contraceptive to enter the U.S. market in several decades. It is currently being tested in 2 phase III clinical trials for HIV prevention.

## Short-Term Contraceptive Use Patterns Among Kenyan Women With Recent Knowledge of Human Immunodeficiency Virus Diagnosis

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**OBJECTIVE:** To determine whether women change contraception method in the short term after the knowledge of human immunodeficiency virus (HIV) infection and determine whether there are associations between demographic, sexual history and behaviors, and change.

**METHODS:** In a prospective cohort study, 181 HIV-seropositive women were followed up for 4 years with scheduled health visits for contraception every 6 months and interval visits for healthcare concerns. Evaluation of short-term use patterns was completed at the first of the 6-month intervals.

**RESULTS:** In the month before HIV diagnosis, 85 (47%) of women used depot medroxyprogesterone acetate, 40 (22%) used oral contraceptives, 23 (13%) used condoms, and 9 (5%) used natural family planning. Significant reductions in use of depot medroxyprogesterone acetate ( $P = .001$ ) and oral contraceptives ( $P = .001$ ) occurred at 6 months after knowledge of HIV diagnosis when compared with the month before HIV diagnosis. After adjusting for age, education, socioeconomic status, husband's HIV status, breastfeeding at the time of study initiation, smoking, alcohol use, history of any method use, only history of illicit drug use remained positively correlated with an increased change in contraception ( $P = .023$ ).

**CONCLUSION:** Significant declines in the use of highly effective hormonal contraceptive methods correlated with the recent diagnosis of HIV-infection in this urban sub-Saharan African population. Human immunodeficiency virus care providers and centers need to make a concerted effort to discuss contraception with recently diagnosed HIV-seropositive clients.

## Rational Design of a Pregnancy Vaccine

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**OBJECTIVE:** An immunocontraceptive, or pregnancy vaccine, offers the hope of a fundamentally new form of birth control that is nonhormonal, simple to administer, without adverse effects, reversible, and easy to distribute, even in the developing world. Prototype vaccines have either gen-



erated a poor immune response that failed to prevent fertilization or resulted in an overly robust immune response that resulted in ovarian failure. Our studies using genomic analysis, exon-swapping, and chimeric proteins defined a portion (the sperm-binding glycopeptide) of an egg coat glycoprotein that was necessary and sufficient for sperm-egg binding. The goal of the study reported here was to advance this work so as to design a specific and effective vaccine that will prevent fertilization without causing ovarian failure.

**METHODS:** A fusion protein, immunoglobulin (Ig) G-sperm-binding glycopeptide, consisting of the Fc portion of human IgG followed by a tobacco etch virus (TEV) protease cleavage site, Flag tag, and sperm-binding glycopeptide was transfected into mammalian cells. Recombinant protein was purified by binding the IgG portion of the protein and cleaved with TEV protease to release the sperm-binding glycopeptide. Western immunoblotting was carried out and epitopes were identified using Kyte and Doolittle and Hopp and Woods algorithms.

**RESULTS:** Mammalian cells transfected with IgG-sperm-binding glycopeptide synthesized and secreted a fusion protein that we have shown to be necessary and sufficient for sperm-egg binding and that was readily purified. Digestion with TEV protease released a sperm-binding glycopeptide that contains 2 epitopes.

**CONCLUSION:** IgG-sperm-binding glycopeptide may allow for production of a purified pregnancy vaccine target that prevents fertilization without causing ovarian disease.

## Hysteroscopic Sterilization A Safe Choice for High-Risk Women

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**OBJECTIVE:** To assess the procedural and postprocedural outcome of women undergoing hysteroscopic sterilization who have high-risk medical and surgical conditions.

**METHODS:** Within a group of 972 women who underwent the Essure method of hysteroscopic sterilization, a cohort of 75 women were identified as having a significant surgical or medical condition that would normally place them in a high-risk group for a conventional laparoscopic sterilization procedure carried out under general anesthesia.

**RESULTS:** The nature and frequency of surgical risks were massive pelvic adhesions, 20; major complications from previous laparoscopic surgery such as bowel perforation and large vessel injury, 6; and previous failed laparoscopic entry, 3. The nature and frequency of medical risks were: morbid obesity (body mass index > 35), 13; severe diminished respiratory reserve, 5; cardiovascular, 6; thrombosis or pulmonary embolus, 9; neurovascular, renal, or hepatic failure, severe diabetes, Addisons disease, Sheehans syndrome, myasthenia gravis, and debilitating malignant disease, 12 of 972. The total number of major surgical and medical contraindications to a laparoscopic procedure was 75 of 972 or 7.7%. This high-risk group of women underwent a less invasive hysteroscopic sterilization procedure

without experiencing an intra-procedural or postprocedural adverse event.

**CONCLUSION:** Hysteroscopic sterilization can be performed on women experiencing serious illness with a high margin of safety and bypasses the risk of potential intra-abdominal laparoscopic complications. Cost savings from reduced morbidity and mortality, intensive care facilities, medical staff, equipment, drugs, rapid recovery, and return to normal activity are additional advantages.

## Determining Clinically Meaningful Benefit in the Treatment of Premenstrual Dysphoric Disorder

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**OBJECTIVE:** Previously published reports have demonstrated the efficacy of an oral contraceptive containing drospirenone 3 mg and ethinyl estradiol (E2) 20 µg in a 24/4 day regimen (drospirenone and ethinyl E2 24/4) for the treatment of premenstrual dysphoric disorder. We used these data to explore measures of clinical improvement in premenstrual dysphoric disorder.

**METHODS:** A total of 64 women (mean age 31.8 years) with premenstrual dysphoric disorder participating in a double-blind crossover study were randomly assigned to receive drospirenone and ethinyl E2-24/4 or placebo for 3 months followed by the alternative therapy for 3 months. We used the Daily Record of Severity of Problems symptom scores (items 1–21) and Clinical Global Impression-Improvement scale to compare different criteria for defining meaningful benefit. Effect size was calculated as the change in Daily Record of Severity of Problems symptom scores divided by the pooled baseline standard deviation.

**RESULTS:** The proportion of women experiencing a meaningful benefit, defined as “much” or “very much” improved on the Clinical Global Impression-Improvement instrument was greater after active treatment than after placebo (59.6% and 29.6%, respectively,  $P = .02$ ). The difference in the proportion of women experiencing a meaningful improvement in symptoms with active treatment compared with placebo was similar when benefit was defined as a Daily Record of Severity of Problems effect size of 0.5 or more (34.5%,  $P < .01$ ) and a 22% or more decrease in Daily Record of Severity of Problems symptom scores (29.9%,  $P < .03$ ). Daily Record of Severity of Problems impairment scores (items 22–24) improved among women experiencing a 22% or more decrease in Daily Record of Severity of Problems symptom scores ( $-5.4$ ,  $P < .01$ ) and worsened in women who did not ( $+1.1$ ,  $P < .01$ ).

**CONCLUSION:** Using Daily Record of Severity of Problems and Clinical Global Impression-Improvement scores to evaluate treatment response yielded similar results. A significant proportion of women with premenstrual dyspho-



ric disorder treated with drospirenone and ethinyl E2 24/4 should experience a meaningful clinical benefit.

## Providers' Perspectives on Minority Adolescent Contraceptive Behaviors

### *A Focus Group Approach*

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**OBJECTIVE:** To better understand factors related to contraceptive behaviors among African-American and Latino teens.

**METHODS:** We conducted 7 focus groups with physicians, midwives, medical assistants, case workers, and staff (N = 27) of clinics serving either low-income Latino or African-American populations.

**RESULTS:** Practitioners identified major issues contributing to poor contraceptive use in the communities. Practitioners lack educational materials and time to instruct youth about contraception. According to participants, lack of public assistance and immigrant status makes obtaining contraception difficult for Latinos. Fear of adverse effects and health risks limits use of hormonal contraception. Providers attribute low levels of effective condom use to lack of knowledge and access and an inability for girls to communicate with male partners. Latino males refuse to use condoms, viewing them as a sign of mistrust. African-American males were unlikely to use condoms if they knew their partner was using a hormonal contraceptive method. They state pregnancy may be desired due to hopelessness and lack of personal opportunity in financially depressed neighborhoods with gang violence and poor schools. Parents are characterized as over-worked, preoccupied, and unable to monitor their teen's behavior. Yet, whereas African American parents bring their children to a clinic to initiate a contraceptive method, Latino parents seem uninformed, unable to acknowledge their daughters' sexual activity, and may even condone their sons' sexual activity.

**CONCLUSION:** Community-based clinics provide ready access to practitioners, but financial barriers for contraceptive services still exist. Additional social and community forces may make adolescent child bearing particularly difficult to combat.

## Contraceptive Vaginal Ring Therapy Has Fewer Adverse Metabolic Effects Than an Oral Pill

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**OBJECTIVE:** To compare glucose-insulin metabolism and reproductive hormone function after contraceptive therapy with the vaginal ring compared with a low-dose oral contraceptive.

**METHODS:** Twenty-four women were randomly assigned to either the vaginal ring or oral contraceptive treatment for 6 cycles. Pretreatment (days 2–5 of menses) and during weeks 2–3 of the fifth treatment cycle, a 75-g oral glucose tolerance test was performed with insulin (I) and glucose (G) measured at 0, 30, 60 and 120 minutes after glucose load. Baseline samples were also used to evaluate hormone and lipid levels. Homeostasis model assessment of insulin resistance was calculated from fasting G and I levels. Indices of whole-body insulin sensitivity (composite insulin sensitivity index) and pancreatic B-cell function (corrected insulin response) were derived from the oral glucose tolerance test.

**RESULTS:** There were no baseline differences in age, body mass index or waist-hip ratio between treatment groups. No change in insulin sensitivity was measured by homeostasis model assessment of insulin resistance, whereas a significant reduction in the composite insulin sensitivity index was observed during oral contraceptive therapy ( $P < .005$ ), with only a slight reduction ( $P = .047$ ) in the vaginal ring group. B-cell function was not altered with either treatment. The free androgen index (T/sex hormone binding globulin) decreased with both oral contraceptive and vaginal ring therapy; a significant decrease in dehydroepiandrosterone sulfate concentrations was found with the vaginal ring.

**CONCLUSION:** These findings indicate that even low-dose oral contraceptives commonly prescribed in this population sample had measurable metabolic effects. The lower dose, steady state nonoral hormonal vaginal ring had a lesser effect on carbohydrate metabolism and greater reduction of free androgen levels than oral contraceptive treatment.



## EDUCATION

# Objective Measurement of Residents' Laparoscopic Competency Using a Training Model Protocol

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**OBJECTIVE:** Development of a laparoscopic training model to be used as an objective measurement of residents' laparoscopic competency.

**METHODS:** A laparoscopic trainer was created. Three laparoscopic training procedures were developed: 1) bead/pom-pom drop, 2) checkerboard drill, and 3) bead manipulation. Eight senior and 15 junior residents were timed performing the 3 procedures. Comparing the senior to junior residents, specific competency times were established.

**RESULTS:** The median time (in seconds) for completion of the laparoscopic training procedures is shown in Table 1. Competency time was calculated at 120% of senior residents' time.

**CONCLUSION:** The laparoscopic training model used in the study can provide objective measurement of resident laparoscopic competency.

Table 1.

	Seniors	Juniors	Competency
Bead/pom-pom	86	139*	95
Checkerboard	50	83*	60
Bead manipulation	95	268*	95

Values are median times in seconds.

\*  $P < .05$ .

Table 1. Rank Order Table

Resident (Code)	Nurses	Faculty	Medical Students	Ancillary Staff	Patients	Other Residents	Self
1	2	2	1	1	1	7	1
2	1	1	3	2	5	4	3
3	3	5	2	5	3	8	2
4	8	3	4	3	6	3	4
5	4	4	5	4	7	6	7
6	7	6	7	6	4	1	5
7	5	8	6	8	2	5	8
8	6	7	8	7	8	2	5

# Are Unique Skills Required for Communication and Interpersonal Relations Among Residents?

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**OBJECTIVE:** Evaluation of resident interpersonal and communication skills by various categories of evaluators, including self-assessment.

**METHODS:** A 10-item questionnaire, validated for content (question really assessed the behavior) and face validity (scoring scale really quantified the behavior), by a clinical psychologist and the hospital patient satisfaction department was distributed to 25 nurses, 16 faculty, 12 allied health professional staff, 12 medical students, 10 patients, all fellow residents (7), and each resident. Each behavior was graded on a scale of 1 (never) to 5 (always). The highest score was 50. Data were confidentially maintained, and each resident was assigned a code. Total and mean scores by each category of evaluator were calculated for each resident, creating a rank-order list.

**RESULTS:** The highest-ranked resident ranked high, and the lowest-ranked resident ranked low with most evaluators. The rank order among fellow residents was markedly different from other categories of evaluators and showed an opposite trend when compared with the rank order from other categories of evaluators. Self-assessment rank order was markedly different when compared with rank order among fellow residents (Table 1).

**CONCLUSION:** A unique set of interpersonal and communication skills, different from those required to interact with other individuals, may be required to interact well with one's fellow residents. This could become an interesting topic for further study.



# Forceps Delivery

## *A Disappearing Art?*

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**OBJECTIVE:** To evaluate chief residents' level of experience and feelings of competency in performing vacuum and forceps deliveries.

**METHODS:** An institutional review board–approved, Web-based survey concerning experience, comfort, and competency with vaginal, vacuum, and forceps deliveries was e-mailed to U.S. obstetrics and gynecology residents in April of their fourth year.

**RESULTS:** A total of 269 of 1,140 fourth-year residents responded (23%). Of these, 68.4% reported performing more than 300 total vaginal deliveries, 70% logged more than 20 vacuum deliveries, but 60% had less than 20 forceps deliveries. Vacuum deliveries occurred more frequently than forceps ( $z = -7.448$ ,  $P < .001$ ). University-based program residents comprised 68% of respondents. Those in community-based programs reported performing more total vaginal ( $z = -4.398$ ,  $P < .001$ ) and vacuum deliveries ( $z = -3.738$ ,  $P < .001$ ), but forceps rates were similar in both types of programs. Residents overall reported that attending faculty were willing to teach vacuum and forceps deliveries, and 98% wanted to learn how to perform them. Of all residents, 98.5% reported feeling competent to perform vacuum deliveries, but approximately 45% of residents in both types of programs, nationwide, reported not feeling competent to perform forceps deliveries. Of residents who reported not feeling competent using forceps, 84% said they would predominately use the vacuum for operative deliveries in their practice.

**CONCLUSION:** These results replicate and extend preliminary findings that many fourth-year obstetrics and gynecology residents have limited experience and feel inadequately trained in the use of forceps, despite their desire to learn and their attendings' willingness to teach. Moreover, this perceived lack of competence will affect future practice patterns.

# Lifestyle Intervention Programs for Women With Polycystic Ovary Syndrome

## *Is There Room for Improvement?*

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**OBJECTIVE:** To determine perceived value, attitudes, and obstacles toward lifestyle and educational programs available for women with polycystic ovary syndrome (PCOS).

**MATERIALS AND METHODS:** A retrospective analysis of an unsolicited online survey available for 8 months on the

PCOStrategies Web site ([www.pcostrategies.org](http://www.pcostrategies.org)). The survey sought information about respondents' maintenance of a healthy lifestyle, perceived personal success, and satisfaction with results from participation in lifestyle programs.

**RESULTS:** Among the 1,354 respondents, 85% had been diagnosed with PCOS; 58% previously attempted a lifestyle program; 71% felt lifestyle programs could make a difference in health and fertility. Respondents most frequently participated in weight-loss (52%), exercise (43%), and dietitian-directed (13%) programs. Paradoxically, a minority of respondents noted positive attitudes or personal success with these endeavors. Respondents' most significant challenges for ongoing participation in lifestyle programs were "sticking to the regimen" (30%), "affordability" (28%), "staying motivated" (25%), and "making time" (12%). Although 55% of respondents believe PCOS education is the most important aspect of a program, only 2% indicated they had participated in such a program.

**CONCLUSION:** Women with PCOS understand the importance of lifestyle interventions for improving their health, fertility, and emotional well-being. Many respondents had already attempted such a program in the past with mixed results. Although weight loss is the strongest motivator for ongoing participation, PCOS education was also an important component for respondents. We conclude that women with PCOS would benefit from individualized, practical, and affordable lifestyle programs that incorporate PCOS education and motivational coaching along with nutritional and exercise information.

## GYNECOLOGY

# Sexual Functioning and Quality of Life After Oophorectomy in Premenopausal Women

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**OBJECTIVE:** To compare sexual functioning and quality-of-life outcomes among premenopausal women who undergo bilateral salpingo-oophorectomy (BSO) compared with ovarian conservation at the time of hysterectomy.

**METHODS:** Premenopausal women were recruited to participate in the Medicine or Surgery Randomized Trial. Our analysis includes all subjects from this study who underwent hysterectomy with BSO or ovarian conservation. Bilateral salpingo-oophorectomy was performed at the patient's request or to treat abnormal ovarian findings. Sexual functioning and health-related quality-of-life outcomes were assessed using the Medical Outcomes Study 36-Item Short Form Health Survey (MOS SF-36) and Sexual Problems Scale, as well as several other measures at 6 months and 2 years after hysterectomy.

**RESULTS:** Mean age at hysterectomy was higher for the 47 women who underwent BSO compared with the 88 women



with ovarian conservation (45 years compared with 40 years,  $P < .0001$ ). Women who underwent BSO had a lower frequency of sex with a partner ( $P = .01$ ) or sex without a partner ( $P = .04$ ) at 2 years. There were no differences in the sexual problems score, orgasm frequency and quality, or satisfaction with sex between the groups. At 6 months, there were higher scores on the Mental Component Summary among women with ovarian conservation ( $P = .05$ ), but this difference did not persist at 2 years. Subjects in both groups reported similar rates of hot flushes, urinary symptoms, sleep problems, and other quality-of-life outcomes.

**CONCLUSION:** Bilateral oophorectomy may decrease the frequency of sexual activity among premenopausal women after hysterectomy. However, overall health-related quality of life does not seem to be significantly affected by bilateral oophorectomy at 2 years of follow-up.

## Endocervical Dysplasia

### *A Predictor of Cervical Squamous Cell Carcinoma*

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**OBJECTIVE:** Loop electrocautery excision procedure (LEEP) is commonly used as a diagnostic procedure after an abnormal Pap test. Endocervical dysplasia is known to correlate to recurrence and persistence of cervical dysplasia. The primary aim of this study was to evaluate treatment outcomes in patients with endocervical curettage (ECC) revealing cervical intraepithelial neoplasia (CIN) at the time of LEEP.

**METHODS:** The study population comprised patients who underwent cold knife cone biopsy on the gynecologic oncology service between July, 1997 and June, 2004. All patients were referred because ECC at the time of LEEP had shown CIN. Pathologic findings of the cold knife cone biopsy, additional cold knife cone biopsy and hysterectomy if performed were obtained by chart review.

**RESULTS:** A total of 146 patients were identified, and 133 patients (91.1%) had residual CIN on cold knife cone biopsy. Of these patients, 117 patients (88%) had CIN III or invasive carcinoma. Twenty-three patients (15.8%) were ultimately diagnosed with invasive cervical carcinoma (15 stage IA, 7 stage IB, and 1 stage IIB). Age, race, parity, HIV status, and smoking habits were not correlated to the diagnosis of cervical cancer. Cervical intraepithelial neoplasia on cold knife cone biopsy and exocervical and endocervical margins were associated with the diagnosis of cervical carcinoma ( $P < .001$ ,  $P = .011$  and  $P = .010$ , respectively).

**CONCLUSION:** Endocervical dysplasia at the time of LEEP is a worrisome pathologic finding. These patients are at high risk for having residual CIN or invasive carcinoma. Endocervical curettage showing dysplasia at the time of LEEP should prompt aggressive further investigation.

## Posttreatment Compliance After Loop Electrocautery Excisional Procedure and Cold Knife Cone Biopsy

### *A Cohort Study*

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**OBJECTIVE:** Loop electrocautery excisional procedure (LEEP) and cone knife cone biopsy are equally effective as diagnostic and therapeutic modalities. There are limited data on posttreatment patient compliance as it relates to type of excisional procedure. Our study examined rates and predictors of compliance with follow-up recommendations in low-income women from a county hospital clinic undergoing LEEP or cone knife cone biopsy.

**METHODS:** A retrospective cohort study of 135 patients who underwent LEEP or cone knife cone biopsy was performed. Demographic data, results of cytology, colposcopy biopsy, excision specimen pathology, and indication for the LEEP or cone knife cone biopsy were collected. Compliance was determined by whether the patient adhered to the recommended follow-up within 1 year from the date of the procedure. Univariate and multivariate analyses were performed using Poisson regression.

**RESULTS:** A total of 135 patients were included for analysis (107 LEEP and 80 cone knife cone biopsy). Type of procedure was significant in predicting compliance: 74.1% of cone knife cone biopsy patients were compliant compared with 43.2% of LEEP patients (relative risk 2.19, 95% confidence interval 1.20–3.99). There was a trend in older patients being more compliant than younger patients. After adjusting for age, LEEP patients were still significantly less compliant than cone knife cone biopsy patients. Pathologic indication (severity of disease), race, payor source, and gravidity were not significant predictors of compliance and not included in multivariate analysis.

**CONCLUSION:** Compared with LEEP, cone knife cone biopsy patients were significantly more compliant with follow-up. Reduced compliance in LEEP patients may be related to its being a less invasive and outpatient procedure. Educational interventions may improve compliance.



# Leiomyomata and Adenomyosis

## Symptoms and Pathologic Correlation

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**OBJECTIVE:** Both leiomyomata and adenomyosis can lead to menstrual disturbances. Some evidence suggests an association between these pathologic findings, which may affect conservative therapy. The objective of this study was to determine whether there is an association between leiomyomata and adenomyosis in hysterectomy specimens and correlate these findings to preoperative symptomatology.

**METHODS:** All hysterectomy specimens from our hospital in 2004 were examined for the presence of leiomyomata, adenomyosis, and other pathologic findings. Patient charts were examined for preoperative symptoms, diagnoses, and demographic data.

**RESULTS:** Of the 294 hysterectomy specimens analyzed, leiomyomata were present in 64.2%. Adenomyosis was present in 38.9%. The likelihood of finding both leiomyomata and adenomyosis was 25.0%, assuming independence. The actual presence of both was 24.9% ( $P = .95$ ). Our power to detect a 10% increased incidence with 95% confidence was 98%. Menorrhagia and dysmenorrhea were more frequently found in patients with leiomyomata than those without (53.2% compared with 36.8%,  $P = .007$ ). However, these symptoms were not more frequently associated with adenomyosis ( $P = .61$ ). Our ability to detect the same magnitude increase in symptoms of menorrhagia and dysmenorrhea as seen in leiomyomata cases with 95% confidence was 96.5%.

**CONCLUSION:** Leiomyomata and adenomyosis are independent pathologic findings. Patients with preoperative menorrhagia or dysmenorrhea or both were more likely to have leiomyomata, but not adenomyosis.

## Understanding a Sticky Situation

### A Retrospective Case Review of Labial Adhesions

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**OBJECTIVE:** The aim of this study was to describe the characteristics and outcomes of patients with labial adhesions; and in doing so to expand current knowledge regarding the cause and treatment.

**METHODS:** A retrospective chart review of all patients seen in a vulvar specialty clinic over a 6-year period revealed 20 patients, aged 9 months to 60 years, with

primary or secondary labial adhesion. Data were abstracted, including demographics, relevant history, coinciding conditions, treatment regimen, and symptoms before and after treatment of the labial adhesion, if available.

**RESULTS:** Thirteen prepubertal cases were treated primarily with estrogen cream, of which 4 required eventual surgical lysis. Three other cases of childhood labial adhesions were noted to resolve after treatment of another coexisting vulvar condition. Four adults were seen with primary diagnoses of lichen sclerosus and secondary labial adhesion. Each was treated with triamcinolone for the lichen sclerosus as well as surgical lysis for release of the labial adhesion. No recurrences were recorded. Thirteen of the patients presented with varying degrees of vulvar symptoms, including 1 or more of the following: burning, itching, pain, dyspareunia, and unusual vaginal discharge. After treatment, only 5 patients still experienced symptoms, and the severity of those symptoms had decreased.

**CONCLUSION:** Both the treatments used and the success rates are consistent with previous literature. We found that in patients with labial adhesion, vulvar symptoms were not uncommon and often resolved after treatment.

## Prepubertal Unilateral Soft Fibrous Tumor of Labium Majus Without Palpable Border in Girls

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This is a report of 7 girls between 4 and 11 years of age presenting with an asymptomatic, unilateral, poorly circumscribed, deep tumor of the labium majus, measuring from 3 cm to 6 cm and with overlying peau d'orange skin, which developed in a few months. Five were right and 2 were left. Six patients were Ashkenazi Jewish. One of the authors (A.A.) operated on 4 in which the tumor could not be completely removed because it infiltrated into the surrounding tissue. Simultaneous surgery with negative results included inguinal exploration, vaginoscopy, and biopsies of cervix and vagina. Grossly, the tumor appeared fibrous, with shiny 4-mm particles of fat. The histology results showed dense fibrous tissue rich in elastic fibers infiltrating mature adipose tissue. There were no mitoses. The bland stromal cells were variably positive for CD34 but negative for muscle markers and progesterone receptors. Estrogen receptors were positive in 4. Electron microscopy was confirmatory. Magnetic resonance imaging revealed that the labial mass extended into the contiguous pelvic floor and persisted after surgery. One case had a local small recurrence within a few months. Tissue culture karyotype done in 3 cases was 46,XX. In 2 cases addition of dehydroepiandrosterone sulfate to the culture speeded mitosis. Serum adrenal hormones in 3 patients showed physiologic increase. The tumors are considered to be a variety of fibromatosis, possibly responsive to adrenal hormones.



# Metabolic Complications in Subsets of Women With Polycystic Ovary Syndrome Defined by the New Rotterdam Criteria

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**OBJECTIVE:** Women with polycystic ovary syndrome (PCOS), defined as hyperandrogenism and oligomenorrhea by the National Institutes of Health (NIH) definition, are at an increased risk for non-insulin-dependent diabetes mellitus and metabolic syndrome. The new Rotterdam criteria expanded the NIH definition to include 2 of 3 features: hyperandrogenism, oligomenorrhea, and polycystic ovaries on ultrasonography. Currently there are no data comparing metabolic risks in all 3 subsets of the Rotterdam definition. The aim of our study was to determine the risk of metabolic complications in the newer PCOS phenotypes (groups 2 and 3) that have arisen from these criteria compared with the NIH phenotype (group 1).

**METHODS:** Retrospective chart review in the Reproductive Endocrinology clinic for PCOS criteria and metabolic information (N = 500 from 2002–2005).

**RESULTS:** A total of 183 patients had adequate information to define PCOS by the Rotterdam Criteria and metabolic syndrome, defined as 3 of the following 5 criteria: body mass index 30, triglycerides 150 mg/dL, high-density lipoprotein less than 50 mg/dL, blood pressure 130/85 or treated, and glucose 110 mg/dL or known non-insulin-dependent diabetes mellitus. No significant differences were detected between groups 2 or 3 compared with group 1 (Table 1).

**CONCLUSION:** Our data suggest that PCOS women defined by the newer phenotypes of the expanded Rotterdam

criteria have similar risks of metabolic syndrome, insulin resistance, and glucose intolerance as PCOS women defined by the previous NIH criteria. Larger studies may be needed to support our findings. In the meantime, all women with PCOS should be counseled and screened for their increased risks for these complications.

# Benefits and Pitfalls of Food and Drug Administration Summary of Safety and Effectiveness Data and Manufacturer and User Facility Device Experience Database Related to Endometrial Ablation Devices

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**OBJECTIVE:** Summary of Safety and Effectiveness Data (SSED) and the Manufacturer and User Facility Device Experience (MAUDE) database are available on the Food and Drug Administration Web site. The SSED documents provide safety, efficacy, and performance information. The MAUDE database represents reports of adverse events involving medical devices. This study assesses the value of this information related to endometrial ablation devices.

**METHODS:** Summary of Safety and Effectiveness Data documents and the MAUDE database for endometrial ablation systems were analyzed to assess the quality of data related to treatment protocols, clinical results, and adverse events.

**RESULTS:** Summary of Safety and Effectiveness Data provides detailed treatment protocols and objective data sources for evaluating a range of performance measures

Table 1.

	Group 1 (NIH Criteria) Oligomenorrhea + Hyperandrogenism + PCO (n = 137)	Group 2 Oligomenorrhea + PCO (n = 23)	Group 3 Hyperandrogenism + PCO (n = 12)
Age (y)	27 ± 0.04	29 ± 0.2	28 ± 0.2
Metabolic syndrome	38.7 (53)	21.7 (5)	47.8 (11)
NIDDM	4.4 (6)	0	4.3 (1)
Impaired glucose tolerance	15.3 (21)	8.7 (2)	17.4 (4)
Glucose (mg/dL)	93.3 ± 1.6	89.4 ± 2.4	91.1 ± 2.7
Cholesterol (mg/dL)	194.9 ± 3.4	184.5 ± 9.4	189.5 ± 7.7
Triglycerides (mg/dL)	145.3 ± 7.0	137 ± 25.7	159.1 ± 16.4
HDL (mg/dL)	50.6 ± 1.5	50.3 ± 2.9	47.6 ± 2.9
LDL (mg/dL)	118.8 ± 3.1	114.9 ± 9.1	109 ± 6.8
QUICK-1	1.6 ± 0.03	1.7 ± 0.07	1.7 ± 0.08
Glucose/insulin	8.4 ± 0.58	7.9 ± 1.4	7.7 ± 1.3

NIH, National Institutes of Health; PCO, polycystic ovarian syndrome; NIDDM, non-insulin-dependent diabetes mellitus; HDL, high-density lipoprotein; LDL, low-density lipoprotein; QUICK-1, Values are mean ± standard error or % (n).



when assessing these technologies and can be useful for validating marketing claims. The MAUDE database allows for review of adverse events reported during commercial use. Although a valuable tool, MAUDE was found to have significant limitations and pitfalls if used to compare various technologies (ie, occasional duplicate reporting, inability to assess the true rate of adverse events without knowing the total number of cases performed (denominator), and often subjective description of events).

**CONCLUSION:** Summary of Safety and Effectiveness Data and MAUDE data are valuable sources of information when evaluated in proper context. Clinical results reported in the SSED are credible but should only be expected if strict adherence to the protocol described is followed. One should exercise caution in interpretation of information from MAUDE database. Use of these data for competitive purposes are inappropriate and not the intent of MAUDE database. Examples of objective comparative SSED data and examples illustrating value and limitations of MAUDE data will be presented.

## The Economic Burden of Endometriosis

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*Jackie K. Outley, PharmD, MBA, Marc Botteman, PhD,  
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Chris L. Pashos, PhD*

**OBJECTIVE:** To comprehensively review and evaluate the direct medical and indirect nonmedical costs of endometriosis among adults and adolescents.

**METHODS:** Studies published since 1999 were systematically reviewed and augmented with an analysis of publicly available national databases (Healthcare Cost and Utilization Project and National Ambulatory Medical Care Survey/National Hospital Ambulatory Medical Care Survey) in the United States. Assessments were made of 1) the overall economic effect of endometriosis and related key symptoms, 2) the direct costs associated with specific medical and surgical treatments, and 3) the indirect costs of endometriosis, including those associated with reduced work productivity.

**RESULTS:** Thirteen published studies met the inclusion criteria, 11 (85%) of which addressed direct costs. Few studies addressed outpatient costs or indirect costs, and no study quantified the economic effect among adolescents. Direct endometriosis-related costs were considerable and seemed driven by hospitalizations. Our analysis from 1993 to 2002 showed a steady decline in hospital length of stay but a 61% increase in per-patient cost, which was nearly 2.7 times the medical care inflation rate. Adolescents (aged 10–17 years) also experienced hospitalizations due to endometriosis. Further analysis found that more than 600,000 ambulatory patient visits involved endometriosis, nearly half of which required specialist care (eg, obstetrics and gynecology). Our analysis also found that women aged 23 years or younger constituted more than 20% of outpatient visits for endometriosis.

**CONCLUSION:** Existing health economic and outcomes research information for endometriosis is scarce, limiting our understanding of its overall economic effect. Nevertheless, the published literature and other available data suggest endometriosis places a considerable burden on patients and society.

## Health-Related Quality of Life Burden for Women With Endometriosis

### A Literature Review

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**OBJECTIVE:** To provide a more comprehensive, updated evaluation of the quality of life burden of endometriosis in both the adolescent and adult populations based on literature review.

**METHODS:** A systematic review was conducted of studies published since 1999. Assessments were made of 1) measures that have been used to assess quality of life in patients with endometriosis, 2) the overall quality of life and psychosocial effect of endometriosis and related key symptoms, 3) the effect of specific pharmacologic and surgical treatments of women with endometriosis on quality of life, and 4) the presence and effect of endometriosis in adolescents.

**RESULTS:** Thirty-three relevant studies were reviewed. Generic and disease-specific instruments used to measure the quality of life burden included the Medical Outcomes Study 36-Item Short Form Health Survey and EUROQoL 5-item questionnaire as well as the Endometriosis Health Profile-30 and its subset, the Endometriosis Health Profile-5. Disease-specific instruments seemed to be more responsive to quality of life changes. Pelvic pain was the most commonly assessed symptom and quality of life dimension and was shown to result in pronounced psychosocial effects. Literature assessing the quality of life effect of endometriosis-related infertility and endometriosis in the adolescent population is minimal. Instruments specifically developed to measure quality of life in adolescents were not identified.

**CONCLUSION:** Endometriosis significantly impairs women's quality of life. Pain and social function are among the most heavily affected domains. Endometriosis may also have a profound adverse effect on quality of life in adolescents. Further clinical and outcomes research is needed to fully understand this disease and its effect on quality of life.



# The Effect of Abnormal Uterine Bleeding on Health-Related Quality of Life

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**OBJECTIVE:** To perform a systematic literature review assessing the effect of abnormal uterine bleeding on health-related quality of life.

**METHODS:** We searched PubMed and the Cochrane Reviews database for English-language studies on abnormal uterine bleeding not caused by organic or systematic causes and reporting health-related quality of life using the Medical Outcomes Study Short Form 36 (SF-36) (1980 to 2005). The SF-36 is commonly used to measure generic health status. Central values of mean scores for abnormal uterine bleeding across studies were compared with national norms (weighted average across age groups for women aged 18–54 years). Noncomparative studies were excluded.

**RESULTS:** The SF-36 was used in 16 studies (14 were randomized controlled trials, and 2 were observational studies). Women with abnormal uterine bleeding had lower SF-36 scores (worse health) in all 8 subscales; the most significantly affected were Physical Role and Emotional Role subscales that mainly concern the productivity at work and other daily activities. In 6 of the 8 subscales, the scores for abnormal uterine bleeding were below the 25th percentile of those for national norms Table 1.

**CONCLUSION:** Women with abnormal uterine bleeding have significantly lower health-related quality of life compared with U.S. general women's population of similar ages. Treatment of abnormal uterine bleeding should include improving health-related quality of life status.

## Cytohistologic Assessment of Uterine Blood in Patients With Abnormal Bleeding

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**OBJECTIVE:** Cytohistologic correlation between uterine blood and its content with that of the endometrium in a

patient with abnormal uterine bleeding has not been reported previously. The purpose of this study was therefore to 1) assess potential usefulness of the uterine blood and its content for diagnosis and 2) compare cytohistologic findings of the uterine blood with that of endometrium.

**MATERIALS AND METHODS:** Using cytobrush, chix, or aspiration, a sample of uterine blood and its content was obtained from the vagina or the endocervix of 20 patients with abnormal uterine bleeding. Endometrial sampling was performed simultaneously in 16 of these cases using pipette. Cell suspension and filtration were used for cytohistologic recovery and preparation.

**RESULTS:** Cytohistologic interpretation was considered satisfactory in 10 patients (intact stromal cells and endometrial glands), comparing favorably with that of endometrial sampling.

**CONCLUSION:** Contrary to the generally believed concept that the uterine blood contains only desquamated, degenerated, and necrotic cells, the present study demonstrated its potential diagnostic value through appropriate sampling and processing.

## MENOPAUSE

### Drospirenone and 17-β Estradiol Reduces 24-Hour Blood Pressure in Postmenopausal Women With Hypertension

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**OBJECTIVE:** Drospirenone, a novel progestin with antimineralocorticoid activity, has been combined with 1 mg of 17-β estradiol (E2) for the treatment of symptoms of menopause.

**METHODS:** We assessed the efficacy and safety of 3 doses of drospirenone and E2, E2 alone, and placebo on clinic and 24-hour blood pressure (BP) in 748 postmenopausal women with stages 1 and 2 hypertension at baseline and after 8 weeks of double-blind therapy.

**RESULTS:** Patient characteristics (mean age, 56.5 years, 73–77% white, 13–17% African American) and clinic (152/95 mm Hg) and 24-hour BP (139/83 mm Hg) mea-

**Table 1. Medical Outcomes Study Short Form 36 Subscale Score Comparison (Highest Health-Related Quality of Life = 100)**

		Physical Function	Role/Physical	Pain	General Health	Vitality	Social Function	Role/Emotion	Mental Health
National norms*	25th percentile	83.3	83.2	60.9	64.2	46.2	72.1	70.4	63.6
	Mean	87.5	84.0	76.7	73.8	59.3	83.1	81.1	73.1
AUB	Central value	82.1	56.9	58.9	70.0	43.2	68.7	60.0	63.6

AUB, abnormal uterine bleeding.

\*Source: SF-36 Health Survey Manual & Interpretation Guide.



**Table 1.**

Change Measures	3 mg DRSP and E2 (n = 151)	2 mg DRSP and E2 (n = 149)	1 mg DRSP and E2 (n = 151)	E2 Only (n = 150)	Placebo (n = 147)
Clinic BP (mm Hg)	-13.9*/-8.6*	-12.1 <sup>†</sup> /-8.9*	-9.6/-6.9 <sup>‡</sup>	-7.8/-6.0	-8.7/-4.8
24-hr BP (mm Hg)	-6.4*/-3.8*	-4.7 <sup>†</sup> /-2.9 <sup>†</sup>	-3.7/-3.1 <sup>†</sup>	-1.4/-1.3	-1.5/-0.5
Serum K <sup>+</sup> (mEq/L)	0.06	0.03	-0.02	-0.07	-0.03
Aldosterone (pg/mL)	68.2*	41.0	13.1	7.5	8.7
LDL-C (mg/dL)	-13.6	-10.4 <sup>†</sup>	-12.2 <sup>†</sup>	-11.5 <sup>†</sup>	-1.3
Triglycerides (mg/dL)	-9.8	-4.1	-2.1	-1.0	-5.4

DRSP, drospirenone; E2, estradiol; BP, blood pressure; LDL-C, low-density lipoprotein cholesterol.

\*  $P < .001$ .

<sup>†</sup>  $P < .01$ .

<sup>‡</sup>  $P < .05$  compared with placebo.

surements were similar at baseline. Systolic and diastolic BPs were reduced significantly on drospirenone at 2 (-12.1/-8.9 mm Hg) and 3 mg (-13.9/-8.6 mm Hg) with E2 compared with placebo (-8.7/-4.8 mm Hg), whereas drospirenone 1 mg and E2 had lesser effects (-9.6/-6.9 mm Hg) and E2 alone (-7.8/-6.0 mm Hg) was similar to placebo. Changes in serum aldosterone showed significant dose-related increases on drospirenone and E2 (Table 1). Changes in potassium levels and the incidence of elevated potassium ( $K^+ \geq 5.5$  mEq/L) on drospirenone and E2 were not different from placebo or E2 alone. Total and low-density lipoprotein cholesterol were lowered significantly, whereas triglycerides did not change on drospirenone and E2.

**CONCLUSION:** Drospirenone and E2 at doses of 2 mg and 3 mg drospirenone daily induced significant reductions in clinic and 24-hour BP in postmenopausal women without causing clinically important increases in potassium. This attribute could offset some of the untoward cardiovascular events that have been observed in studies of other progestins and estrogens in postmenopausal women.

## Evaluation of Eszopiclone 3 mg in the Treatment of Insomnia Associated With the Menopausal Transition

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**OBJECTIVE:** This study evaluated 1) eszopiclone 3 mg in the treatment of insomnia associated with menopausal transition, and 2) the effect of treating insomnia on changes in mood, menopause-related symptoms, and quality of life.

**METHOD:** This double-blind, placebo-controlled study included 410 women meeting Stages of Reproductive Aging Workshop (STRAW) criteria stages -2, -1, or 1a, who reported sleep latency 30 minutes or more and total sleep time 6 or less hours/night. Subjects received eszopiclone or placebo nightly for 4 wks. Sleep was reported daily. Physi-

cian global evaluations of menopause, menopause-specific quality-of-life questionnaire, Greene Climacteric Scale, the Montgomery Asberg Depression Rating Scale, and the Sheehan Disability Scale were collected at baseline and end of treatment.

**RESULTS:** Subjects receiving eszopiclone reported significantly greater improvements in sleep latency, sleep maintenance (awakenings and time awake at night), total sleep time, sleep quality ( $P = .001$  for all compared with placebo), and awakenings due to hot flushes ( $P = .001$ ). No differences in the number or severity of daytime hot flushes were found. Subjects treated with eszopiclone had significantly greater improvements in Montgomery Asberg Depression Rating Scale scores ( $P < .03$ ) and physician global evaluations of menopause ( $P < .001$ ); total Greene Climacteric Scale score and the vasomotor and psychological subscales ( $P < .05$  compared with placebo); vasomotor and physical domains of the menopause-specific quality-of-life questionnaire ( $P < .05$ ); and family life and home disability domain using the Sheehan Disability Scale ( $P < .05$ ). The most common adverse event was unpleasant taste in those receiving eszopiclone (18.1% compared with 0.5%). Other adverse events (ie, headache and pain) were similar in the 2 groups.

**CONCLUSION:** In this study, eszopiclone produced significant improvements in sleep and positively affected mood, quality of life, and menopause-related symptoms in perimenopausal and menopausal women.

## Patient Preference for Once-Monthly Ibandronate Compared With Weekly Alendronate in Postmenopausal Osteoporosis

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**OBJECTIVE:** To assess patient preference for once-monthly ibandronate compared with once-weekly alendronate in



postmenopausal women with osteoporosis in an open-label, crossover trial.

**METHODS:** Eligible patients were randomly assigned to once-monthly ibandronate 150 mg followed by once-weekly alendronate 70 mg for a total of 6 months (Sequence A) or weekly alendronate followed by monthly ibandronate for a total of 6 months (Sequence B); patients took each regimen for 3 months at a time. Preference was assessed by a self-administered questionnaire.

**RESULTS:** Of the 342 patients enrolled, 170 were randomly assigned to Sequence A and 172 to Sequence B. For patients who reported a preference ( $n = 276$ ), once-monthly ibandronate was preferred in 71.4%, and once-weekly alendronate was preferred in 28.6%. The preference rate for ibandronate was statistically significant ( $P < .001$ ). The sequence in which medications were taken did not affect preference (Gart-order-effect  $P = .1855$ ). The most common reasons given for preference were 1) ease of after treatment for a long time (ibandronate 169/278, alendronate 70/276) and 2) dosing schedule better fitting their lifestyle (ibandronate 152/276, alendronate 59/276). Among women who expressed an opinion on convenience ( $n = 264$ ), 74.6% of women found once-monthly ibandronate to be more convenient, and 25.4% found once-weekly alendronate to be more convenient. The convenience rate for ibandronate was statistically significant ( $P < .0001$ ).

**CONCLUSION:** Significantly more women preferred the once-monthly ibandronate regimen and found the once-monthly regimen to be more convenient. Many patients preferred ibandronate, considering it easier to follow over a long time, suggesting that the once-monthly regimen may contribute to improved long-term adherence to therapy and therapeutic outcomes.

## Better Adherence to Bisphosphonate Therapy Is Associated With Reduced Nonvertebral Fracture Risk

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**OBJECTIVE:** To determine the effect of adherence to bisphosphonates on the incidence of nonvertebral fractures, a major cause of mortality and morbidity in women with postmenopausal osteoporosis.

**METHODS:** Two MarketScan databases covering medical and pharmaceutical claims from 6 million individuals were analyzed retrospectively during the years 1999–2003. Included were women aged 45 years or older who received an index prescription for a bisphosphonate (alendronate or risedronate) and with continuous data from the 6-month baseline and 24-month follow-up periods. Adherence was assessed by Medication Possession Ratio (drug available  $\geq 80\%$  of the time) and persistence (no gaps in refills  $> 30$  days). Fisher exact test was used to compare fracture rates between adherent and nonadherent subjects. Estimates of

relative risk (RR) were obtained using logistic regression to adjust for baseline covariates, including age, past medical diagnoses, and medications used in prior 6 months.

**RESULTS:** Among the 35,537 women analyzed, 2,856 had nonvertebral fractures during the 24-month follow-up period. Of those, 62% were in noncompliant women ( $n = 1,769$ ) and 38% were in compliant women ( $n = 1,087$ ) ( $P < .001$ , adjusted RR 20%). The RR for hip fracture alone was reduced by 37% in compliant compared with noncompliant women. By persistence, 84% of the fractures occurred in nonpersistent women ( $n = 2,403$ ) and 16% were in persistent women ( $n = 453$ ) ( $P < .001$ , RR 29%). The RR for hip fracture alone was reduced by 46% in persistent women.

**CONCLUSION:** Better adherence (compliance and persistence) to bisphosphonate therapy in a medical and pharmaceutical database was significantly associated with reduced nonvertebral fracture risk, particularly for hip fracture.

## OBSTETRICS

### The Effect of Maternal Body Mass Index on Efficacy of Dinoprostone Vaginal Insert for Cervical Ripening

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**OBJECTIVE:** Both the incidence of induction of labor and prevalence of obesity are increasing in the United States. Little is written in regard to the efficacy of cervical ripening agents in obese patients. We sought to determine whether induction of labor in patients with a higher pregravid body mass index (BMI) was associated with a different number of dinoprostone insertions.

**METHODS:** This institutional review board–approved cohort study was done at St. Mary’s Health Center. Only patients who underwent an induction of labor with dinoprostone cervical ripening, gestational age more than 37 weeks, singleton, vertex presentation, and unscarred uteri were included. After review of 393 records, 195 patients were eligible for study. Pregravid BMIs were determined. Patients with a BMI more than 30.0 were classified as obese. Comparisons between the obese and nonobese patients were made using Student *T*, linear regression, and  $\chi^2$ , with a significance level of  $P < .05$ .

**RESULTS:** Gestational age, age, race, and preinduction Bishop scores were similar for both groups. Nonobese patients had higher pregnancy weight gains (43.1 pounds compared with 29.1 pounds,  $P < .001$ ). More obese patients required 2 or more dinoprostones to become active (23.5% compared with 40.9%,  $P < .045$ ). The time to active labor was shorter for the nonobese patients (21.2 hours compared with 29.7 hours,  $P < .001$ ). The number of dinoprostone ( $P < .007$ ), time to active labor ( $P < .004$ ), time to delivery ( $P < .003$ ), and frequency of cesarean delivery ( $P < .001$ ) each increased with increasing BMI.



**CONCLUSION:** Maternal obesity increases both the length of induction of labor and the number of dinoprostone doses necessary for induction of labor. Increasing BMI is associated with a higher rate of cesarean delivery as well as higher dinoprostone requirements.

## The Effect of Gestational Hypertension and Gestational Diabetes on Neonatal Outcome

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**OBJECTIVE:** To determine whether pregnancies complicated by mild gestational hypertension with or without gestational diabetes delivered at term have higher rates of neonatal morbidity as compared with controls.

**METHODS:** Nulliparous women with singleton pregnancies delivering at 37–40 weeks of gestation between May 1995 and May 2004 were identified from a database. Neonatal outcomes of pregnancies complicated by gestational hypertension only, gestational diabetes only, or the combination of gestational hypertension and gestational diabetes were compared with singleton pregnancies without gestational hypertension or gestational diabetes (control). Statistical analysis included Pearson's  $\chi^2$  and analysis of variance.

**RESULTS:** The study group included 14,880 patients. Management of gestational diabetes involved dietary restrictions and insulin or oral hypoglycemic agents in 22.8% of gestational diabetes–only patients and 33.7% of patients with gestational hypertension and gestational diabetes ( $P = .002$ ). Rates of macrosomia (greater than 4,000 g) were significantly increased in women with gestational hypertension and gestational diabetes compared with controls. Cesarean delivery and macrosomia occurred most frequently in pregnancies complicated by both disorders (Table 1).

**CONCLUSION:** Pregnancies complicated by gestational hypertension or gestational diabetes are associated with increased rates of macrosomia, cesarean delivery, and neonatal intensive care unit admission compared with controls. The coexistence of gestational hypertension and gestational

diabetes further increases the risk of macrosomia, cesarean delivery, and neonatal intensive care unit admission.

## Sickle Cell Trait Is Not Associated With Adverse Perinatal Outcomes

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**OBJECTIVE:** To examine the perinatal outcomes of African-American women affected by sickle cell trait compared with African-American women without sickle cell trait.

**STUDY DESIGN:** We performed an institutional review board–approved, retrospective cohort analysis of African-American women receiving prenatal care at the Medical University of South Carolina from 1996–2004. The study group consisted of patients with sickle cell trait as diagnosed by hemoglobin electrophoresis. The control group was matched in a 2:1 ratio by year of prenatal care enrollment and number of outpatient visits. Data were abstracted from a research quality perinatal database. Statistical analysis was conducted using Student  $t$  test,  $\chi^2$ , and logistic regression where appropriate. Odds ratios (ORs) with 95 % confidence intervals (CIs) were calculated for stillbirth, preterm delivery, low birth weight, intrauterine growth restriction, and maternal preeclampsia.

**RESULTS:** A total of 1,689 patients were included, with 563 patients in the sickle cell trait group and 1,126 patients in the control group. No demographic differences were observed between the groups except for maternal age, with study patients being younger than controls (24 years old compared with 28 years old,  $P < .001$ ). There were no differences observed in perinatal complications between the groups, including stillbirth (OR 1.53, 95% CI 0.63–3.78), preterm delivery (OR 1.1, 95% CI 0.84–1.47), low birth weight (OR 1.01, 95% CI 0.8–1.27), intrauterine growth restriction (OR 1.2, 95% CI 0.9–1.6), preeclampsia (OR 0.87, 95% CI 0.55–1.39).

**CONCLUSION:** Maternal sickle cell trait does not seem to be associated with an increase in adverse perinatal outcomes, including stillbirth, preterm delivery, low birth weight, intrauterine growth restriction, or preeclampsia.

Table 1.

	Control (n = 11,349)	GHTN Only (n = 2604)	GDM Only (n = 728)	GHTN+GDM (n = 199)
Cesarean delivery	2,925 (25.8)	1,056 (40.6)*	277 (38.0)*	99 (49.7)*
NICU admission	646 (5.7)	191 (7.3)*	58 (8.0)*	20 (10.1)*
Perinatal death	20 (0.2)	2 (0.1)	3 (0.4)	1 (0.5)
Birth weight (g)	3,204 ± 440	3,207 ± 505	3,283 ± 480*	33,48 ± 521*
> 4,000 g	435 (3.8)	145 (5.6)*	50 (6.9)*	17 (8.5)*

GHTN, gestational hypertension; GDM, gestational diabetes mellitus; NICU, neonatal intensive care unit.

Values are mean ± standard deviation or n (%).

\*  $P < .05$  compared with controls.



# Ultrasound Findings and the Decision to Terminate Down Syndrome Pregnancies

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**OBJECTIVE:** To evaluate the association of abnormal ultrasound findings with the decision to terminate trisomy 21 pregnancies. The association of factors such as maternal age, gravidity, parity, race, marital status, and gestational age at diagnosis with the decision to terminate was also assessed.

**METHODS:** Pregnancies diagnosed with trisomy 21 before 24 weeks of gestation were identified using a database of abnormal karyotypes from 1997–2005. We performed a retrospective review of the medical records and ultrasound databases for each affected pregnancy. Logistic regression,  $\chi^2$  test, and Fisher exact test was used for statistical analysis.

**RESULTS:** Fifty-nine pregnancies were eligible for study. The overall termination rate was 72.9%. We found no difference in gravidity, parity, race, marital status, and gestational age at diagnosis between those who terminated and those who continued their pregnancies. The mean age in those who terminated was higher (36.1 years old compared with 32.3 years old), but this did not reach statistical significance ( $P = .059$ ). Major and minor ultrasound abnormalities were associated with significantly lower termination rates, 50% and 64%, respectively, as compared with those with normal or limited ultrasound examinations, 92% ( $P = .026$  and  $P = .022$ , respectively).

**CONCLUSION:** Surprisingly, patients with abnormal ultrasound results were more likely to continue a trisomy 21 pregnancy than patients with normal ultrasound examinations. This may be due to difference in plans for termination among patients who undergo amniocentesis for age or maternal serum screening compared with those who are counseled only after an ultrasound abnormality is found. Unfortunately, this information was not available from our retrospective database.

## Adverse Pregnancy Outcomes Are Associated With Coronary Artery and Cardiovascular Disease Risk

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**OBJECTIVE:** To determine the relationship between pregnancy outcomes and risk of coronary artery (CAD) and cardiovascular disease later in life.

**METHODS:** We used a case-control design to study pregnancy outcomes, CAD, and cardiovascular disease using merged data from the Duke University Medical Center Perinatal-Health Services Outcomes Database and the Duke Information System for Cardiovascular Care. Pregnancy outcomes included abruption, preeclampsia, preterm birth, gestational diabetes, in utero fetal demise, small for gestational age (SGA), large for gestational age, oligohydramnios, postpartum hemorrhage, stillbirth, and twins. Women were identified based on International Classification of Diseases, 9th Revision codes and a history of cardiac catheterization. Univariate and multivariate analyses were performed.

**RESULTS:** Mean age at delivery was 28.5 years, and at first myocardial infarction, 42 years. Sixty-five percent of women were African American, 32% were white, and 3% other ethnicity. In univariate analysis, preterm birth ( $P = .03$ ), SGA ( $P = .03$ ), gestational diabetes ( $P = .04$ ), and any adverse outcome ( $P = .02$ ) were associated with cardiovascular disease risk. Having any adverse pregnancy outcome was also associated with CAD ( $P = .03$ ). After adjusting for age at delivery, race or ethnicity, diabetes and hypertension, preterm birth ( $P = .03$ ), SGA ( $P = .053$ ), and any adverse outcome ( $P = .02$ ) were still associated with risk for cardiovascular disease. Adverse pregnancy outcomes were not associated with adjusted risk of CAD.

**CONCLUSION:** In the adjusted model, preterm birth, SGA, and any adverse pregnancy outcome were associated with risk of cardiovascular disease. A prospective investigation of adverse pregnancy outcomes as a risk factor for cardiovascular disease in women is needed. Women identified as being at risk for cardiovascular disease later in life based on pregnancy complications may benefit from early preventive interventions.

## Is Severe Perineal Damage Increased in Women With Prior Anal Sphincter Injury?

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**OBJECTIVE:** There is conflicting data in the literature regarding the risk of obstetric anal sphincter laceration in patients with a prior laceration. We sought to examine the risk of recurrence of obstetric anal sphincter lacerations at a single institution.

**METHODS:** Patients who sustained anal sphincter laceration at delivery during a 12-year period were identified. All subsequent deliveries in this group of patients were extracted. Chart review was performed on all subsequent deliveries with specific attention to maternal age, race, parity, maternal weight, fetal weight, presence of maternal diabetes, induction or augmentation of labor, instrumentation at delivery (vacuum or forceps), use of episiotomy, and degree of perineal laceration.

**RESULTS:** There were 23,451 vaginal deliveries at Temple University Hospital between 1991 and 2003. Anal sphincter



laceration was noted in 778 subjects. Subsequent deliveries among the group of patients with prior sphincter tears were 271. Six (2.4%) patients had recurrence of anal sphincter lacerations, and 5 of them were third-degree lacerations. The rate of recurrent lacerations was not significantly different from the rate of initial lacerations (2.4% compared with 3.3%; odds ratio 0.72, 95% confidence interval 0.33–1.59;  $P = .4$ ). Women who sustained recurrent laceration were older, more obese (mean weight 203 pounds compared with 181 pounds), had larger babies (3,506 g compared with 3,227 g), and were more likely to have episiotomies (66.7% compared with 7%) or instrumental deliveries (33.3 compared with 6.5%).

**CONCLUSION:** Prior anal sphincter laceration does not result in an increased rate of recurrence. Operative vaginal delivery, particularly with episiotomy, increased the rate of both initial and recurrent lacerations.

## Effect of the 1999 American College of Obstetricians and Gynecologists Guidelines on the Risk of a Cesarean Delivery in Women With Genital Herpes

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**OBJECTIVE:** This study was designed to determine whether women with a history of genital herpes giving birth after the 1999 American College of Obstetricians and Gynecologists guidelines for herpes management during pregnancy were less likely to undergo a cesarean delivery than women giving birth before 1999.

**METHODS:** We conducted a population-based, quasi-experimental study using data from the Missouri linked birth-death certificate registry. The study population included women reporting a history of genital herpes who delivered a full-term singleton birth in Missouri from 1997–1998 compared with 2000–2001. The population was further restricted to women without labor or delivery complications or a repeat cesarean delivery. A total of 938 women before 1999 and 873 women after had either a vaginal delivery or a primary cesarean delivery and satisfied these criteria. A crude risk ratio was calculated, and the presence of effect modifiers and confounders were determined by stratified analysis.

**RESULTS:** Before 1999, 307 primary cesarean deliveries were performed (32.7%); after 1999, 225 (25.8%) were performed. The crude risk ratio was 0.79 (95% confidence interval 0.68–0.91). There was no evidence of effect modification or confounding for maternal ethnicity, adequacy of prenatal care, maternal age, parity, birth weight, or gestational age.

**CONCLUSION:** The risk of a primary cesarean delivery in women reporting a history of genital herpes decreased significantly in the study population after 1999. Women giving birth after the 1999 guidelines were 21% less likely to

have a primary cesarean delivery than women giving birth before the guidelines.

## Predicting Postpartum Hemorrhage

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**OBJECTIVE:** To determine whether estimated blood loss is an accurate predictor of postpartum hemorrhage as defined by a 10-point drop in hematocrit and to determine whether the postpartum hematocrit measurement is necessary.

**METHODS:** This was a retrospective analysis of 215 women who delivered from October 2003 to March 2004. Hematocrit on admission and at 24 hours postpartum was recorded. The primary explanatory variable was estimated blood loss, and the outcome was a 10-point drop in hematocrit. Estimated blood loss was calculated at delivery by the attending physician. Additional risk factors for postpartum hemorrhage were evaluated. Statistical analysis was performed with SAS, analyzing predictive values, and multivariable logistic regression was performed.

**RESULTS:** The patients had a mean age of  $26 \pm 7$  years, 83% Hispanic, 74% were multigravid; mean body mass index was  $31 \pm 6$ , 64.4% had a vaginal delivery, 35.6% had a cesarean delivery, and 28 patients had vaginal birth after cesarean delivery. Eight percent (17) of the patients had a postpartum hemorrhage by estimated blood loss, and 9.9% (21) patients had a postpartum hemorrhage by a 10-point drop in hematocrit. The relative risk for postpartum hemorrhage by estimated blood loss was 12.0 ( $P < .001$ , 95% confidence interval 6.3–25.4). There was a sensitivity for estimated blood loss of 52%, a specificity of 97%, a positive predictive value of 65%, and a negative predictive value of 95%.

**CONCLUSION:** Postpartum hemorrhage by estimated blood loss was a strong predictor of postpartum hemorrhage by a 10-point drop in hematocrit. Routine postpartum measurements of hematocrit may be unnecessary in patients without postpartum hemorrhage by estimated blood loss.

## Pregnancy Outcomes After Loop Electrosurgical Excision Procedure

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**OBJECTIVE:** To examine the relationship between loop electrosurgical excision procedure (LEEP) and pregnancy outcomes in an indigent population.

**METHODS:** This was a case-control study reviewing 334 LEEP patients and a control group. Patients with a prior



preterm birth were excluded. Data analysis was performed using SAS.

**RESULTS:** Ninety-six patients included had a pregnancy after LEEP; 84 patients had a gestational age greater than 37 weeks; and 12 patients delivered at less than 37 weeks. Controls were matched 3:1. There was an association between gestational age at delivery and LEEP (odds ratio [OR] 1.3); the confidence interval (CI) crossed 1 (CI .50–3.49), making it nonsignificant. There was an association between age less than 18 years and delivery less than 37 weeks (OR 1–56, CI .31–789). Comparing multiparous to nulliparous patients, there was a slightly lower risk for delivery of an infant less than 37 weeks (OR .438, CI .33–1.67). The only demographic that was significant in the control group compared with the LEEP group was smoking ( $P \leq .03$ ).

**CONCLUSION:** There was no significant difference between the LEEP group and the control group with respect to delivery less than 34 weeks. There was a slight association with increased risk of preterm delivery after LEEP, but it was nonsignificant. Patients who were younger than 18 years and nulliparous also had a slightly increased risk for premature delivery.

## Blunt Suture Needle Use in Laceration and Episiotomy Repair at Vaginal Delivery

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**OBJECTIVE:** Approximately 800,000 needle-stick injuries occur annually among health care workers with potential exposures to infectious bloodborne pathogens. We sought to survey obstetricians regarding their experience with the use of blunt suture needles for laceration and episiotomy repair at vaginal delivery, and to determine whether blunt suture needles represent a safe and effective alternative to sharp needles.

**METHODS:** Blunt suture needles were made available from November 2004 through June 2005 for all laceration and episiotomy repairs. Participating physicians completed questionnaires indicating their previous experience using blunt suture needles and personal history of needle-stick injuries. Participants rated their blunt suture needle experience and indicated whether they would use blunt suture needles in the future. Categorical variables were analyzed using Fischer exact test, and a 2-tailed  $P < .05$  was considered significant.

**RESULTS:** Eighty surveys were completed by 29 attending physicians, 31 upper level residents (PGY-2–4), and 20 interns. The vast majority of physicians reported previous needle-stick injuries (83%), and all (100%) admitted concern regarding needle-stick injuries. Blunt suture needles were rated as excellent or good by 92.5% (95% confidence interval 84.6–96.5%) of participants, and 77.5% (95% confidence interval 67.2–85.3%) would consider using blunt suture needles for repairs at vaginal delivery in all future patients. Physicians with more surgical experience (PGY-2

or greater) rated blunt suture needles more favorably than interns ( $P < .001$ ). No needle stick injuries or glove perforations occurred during blunt needle repairs.

**CONCLUSION:** Needle-stick injuries are ubiquitous among obstetricians. Technical satisfaction with blunt suture needles is high, especially among those with greater surgical experience. Widespread use of blunt suture needles may reduce the incidence of percutaneous needle-stick injuries.

## Chorionicity and Twin Fetal Growth

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**OBJECTIVE:** To compare mean estimated fetal weights of diamniotic–dichorionic and diamniotic–monochorionic twins at comparable gestational ages in 4-week intervals (20 weeks to delivery) by ultrasonography.

**METHODS:** This retrospective study used a database from Madonna Perinatal Services at NY Methodist Hospital for twin gestations from 1998–2005. Variables were maternal age, gestational age, estimated fetal weight, chorionicity, and birth weight. Included were twin gestations that were viable at delivery with documented chorionicity and 2 or more measurements of estimated fetal weight at comparable gestational age. Hadlock standard composite formula was used for estimated fetal weight. Estimated fetal weight and birth weight of dichorionic and monochorionic twins were compared. Mean estimated fetal weight was plotted as a function of gestational age for dichorionic and monochorionic twins.

**RESULTS:** There were 89 (68.4%) dichorionic and 41 (31.5%) monochorionic twin pairs. Mean maternal ages were comparable ( $P = .55$ ). At gestational ages of 20, 24, 28, and 32 weeks, the mean estimated fetal weight of dichorionic twins was higher ( $P < .001$ ). In the preterm group, the birth weight of dichorionic twins was higher than that of monochorionic twins ( $P = .014$ ). If the twin gestation proceeded to term, the difference in estimated fetal weight between groups disappeared at 36 weeks. Mean birth weight of twins was lower than that of singletons (reported in a recently published national nomogram based on 6,690,717 singleton birth weights).

**CONCLUSION:** Chorionicity had an effect on estimated fetal weight and preterm birth weight, with diamniotic–dichorionic twins having consistently higher values. This difference was less noticeable for twins delivered at term. The birth weight of preterm and term twins was lower than that reported for singletons.



# The Correlation of Estimated Blood Loss With Predelivery and Postdelivery Hemoglobin

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**OBJECTIVE:** To evaluate the accuracy of estimated blood loss at vaginal and cesarean deliveries by correlating it with the postpartum drop in hemoglobin.

**METHODS:** This retrospective cross-sectional study reviewed the delivery records of 1,622 consecutive singleton deliveries at New York Methodist Hospital. A *z* score was calculated for each provider that gave a measure of how deviant estimated blood loss for a given delivery was from that provider's mean estimated blood loss. A *z* score of + 2 represented an estimate that blood loss was excessive. A postpartum hemoglobin drop equal or greater than 3 mg/dL was defined as a clinically significant blood loss.

**RESULTS:** There were 934 vaginal and 496 cesarean deliveries. Mean estimated blood loss for vaginal and cesarean deliveries was 335.2 (95.6) mL and 801.5 (64.8) mL ( $P < .001$ ). Mean postdelivery hemoglobin drop was 1.3 (1.1) mg/mL for vaginal and 1.8 (1.1) mg/dL for cesarean deliveries ( $P < .001$ ). Clinicians' sensitivity for identifying excessive blood loss was 12% and 13% for vaginal and cesarean deliveries. The positive predictive value of a clinician's estimate of excessive blood loss was 23% and 54% for vaginal and cesarean deliveries. The specificity and negative predictive value of estimated blood loss was 97% and 94% for vaginal and 99% and 91% for cesarean deliveries.

**CONCLUSION:** Clinical estimated blood loss at the time of delivery is subjective and arbitrary. We demonstrated that clinicians are very poor at identifying women with excessive blood loss at the time of delivery. Delayed recognition of excessive blood loss may have serious consequences. Educating physicians on how to estimate blood loss is an important and undertaught clinical skill.

# The Effect of an American College of Obstetricians and Gynecologists Bulletin on Cesarean Deliveries for Macrosomia

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**OBJECTIVE:** To assess the effect of the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin, Shoulder Dystocia, on the use of "macrosomia" as an indication for cesarean deliveries.

**METHODS:** From January 1, 1997, through December 31, 2004, all births at Brigham and Women's and Massachusetts General Hospitals were reviewed. The number of births and cesarean deliveries were recorded for each year, as was the use of "macrosomia" as the indication for the cesarean delivery. A test of trend was performed on the data. Finally, the Massachusetts birth registry was accessed to determine the average birth weights recorded for each year.

**RESULTS:** There were 99,975 births and 24,451 cesarean deliveries. The rate of macrosomia as an indication rose from 6.5% in 1997 to 7.2% in 2001 but then significantly dropped to 5% in 2002, 5.1% in 2003, and 4.8% in 2004 ( $P = .023$ ). Meanwhile, the rate of infants weighing more than 4,000 g was stable.

**CONCLUSION:** In 2002, ACOG Practice Bulletin No. 40 on Shoulder Dystocia replaced ACOG Practice Bulletin No. 7. The new bulletin opined that the available scientific data supported a trial of labor with estimated fetal weights up to 5,000 g in nondiabetics and 4,500 g in diabetics. This represented a 500-g increase from prior recommendations. That same year, the rate at which obstetricians used macrosomia as an indication of cesarean delivery declined. We believe ACOG's support for trials of labor with larger infants enabled obstetricians to confidently provide care based on evidence rather than fear of lawsuits.

# Induction in Multiparous Women

## Are Cesarean Rates Increased?

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**OBJECTIVE:** To determine the effect of induction on the risk of cesarean delivery in nulliparous and multiparous women.

**STUDY DESIGN:** All term, singleton inductions performed at Thomas Jefferson University in 2003 were identified. Misoprostol, dinoprostone, Foley, or all 3 were used as cervical ripening agents in women with an unfavorable cervix. An equal number of gestational age-matched women in spontaneous labor on the same day served as controls. A modified Bishop score was calculated from dilatation, effacement, and station. Primary outcome was the frequency of cesarean delivery.

**RESULTS:** A total of 250 women underwent induction (136 nulliparas, 114 multiparas). Controls were 115 nulliparas and 135 multiparas. Cervical ripening was performed in 89% (122/136) of induced nulliparas and 41% (47/114) of multiparas. There were no significant differences in modified Bishop score, birth weight, or gestational age between nulliparas and multiparas in the induction group, but in controls modified Bishop score was significantly higher in multiparas compared with nulliparas ( $5.5 \pm 2.0$  compared with  $6.2 \pm 2.0$ ,  $P = .013$ ). Modified Bishop score was significantly lower in both induced nulliparas and multiparas compared with controls ( $2.7 \pm 2.0$  compared with  $5.9 \pm 2.0$ ,  $P < .001$ ). Overall, both nulliparas (odds ratio 3.0, 95% confidence interval 1.7–5.5) and multiparas (odds ratio 6.4, 95% confidence interval 1.5–25.5) had significantly increased risk of a cesarean delivery if they were



induced. This effect was not apparent in multiparas when stratified by modified Bishop score.

**CONCLUSION:** In this population, use of induction, despite the use of cervical ripening agents, increased the risk of cesarean delivery in both nulliparas and multiparas. Multiparas with an unfavorable cervix have an increased risk of cesarean delivery, whether induced or in spontaneous labor.

## The Effect of Parity on Maternal and Neonatal Outcomes in Twin Gestations

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**OBJECTIVE:** To compare maternal and neonatal outcomes of nulliparous twin gestations to that of multiparas.

**METHODS:** This was a retrospective chart review of nulliparous and multiparous patients who delivered twins at a tertiary care center from 1990–2004. The groups were compared for maternal and neonatal outcome variables. Logistic regression analysis was used to study the effect of parity on preterm delivery. The independent variables included were: in vitro fertilization, advanced maternal age, medical complications, preeclampsia, discordance, multiparity, and intrauterine growth restriction (IUGR).

**RESULTS:** Of 841 women analyzed, 333 (39.6%) were nulliparous, and 508 (60.4%) were multiparous. Nulliparas were more likely to be younger (aged  $28.1 \pm 5.4$  years compared with  $30.0 \pm 5.2$  years;  $P < .001$ ) and product of in vitro fertilization (23.1% compared with 4.5%;  $P < .001$ ). They were at a significantly increased risk of preterm labor (38.4% compared with 28.7%;  $P = .004$ ) and preterm delivery (55.6% compared with 46.3%;  $P = .010$ ) with lower gestational age at delivery ( $35.6 \pm 3.2$  weeks compared with  $36.2 \pm 3.0$  weeks;  $P = .004$ ). They had longer first and second stages of labor and higher cesarean delivery rate compared with multiparas (61.3% compared with 44.9%;  $P < .001$ ). Except for a higher intensive care nursery admission rate and longer nursery stay for twins of nulliparas, all neonatal morbidities were comparable. On multiple logistic regression analysis, multiparity (risk ratio [RR] 0.70, 95% confidence interval [CI] 0.51–0.97) and IUGR (RR 0.16, 95% CI 0.12–0.22) were protective against preterm delivery, while discordance (RR 2.24, 95% CI 1.40–3.60) was a predictor of preterm delivery.

**CONCLUSION:** Nulliparous women with twin gestations are at significantly higher risk for preterm labor, preterm delivery, and cesarean delivery compared with multiparas. These women should be monitored closely and counseled regarding these risks and their attendant morbidity.

## Probability of Prematurity by Cervical Dilatation and Gestational Age at Preterm Labor

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**OBJECTIVE:** To determine the influence of cervical dilatation and gestational age (GA) on the incidence of preterm delivery after stabilization of preterm labor in singleton pregnancies.

**METHODS:** Patients hospitalized with preterm labor at 20–33.9 weeks of gestation were identified from a database. Singleton gestations without cerclage or vaginal bleeding having cervical dilatation of 0–4 cm and treated homogeneously with continuous subcutaneous tocolysis after stabilization were included ( $N = 3,496$ ). Data were stratified by GA at preterm labor (20–23.9 weeks, 24–27.9 weeks, 28–31.9 weeks, and 32–33.9 weeks) and cervical dilatation (0–4 cm) at stabilization. Primary study outcome was incidence of delivery at less than 35, 32, or 28 weeks. Probabilities of delivery less than 35 weeks for the combined effects of GA at preterm labor and cervical dilatation were estimated using a logistic regression model.

**RESULTS:** Overall, 19.0%, 6.3%, and 1.5% delivered at less than 35, 32, and 28 weeks, respectively. When stratified by cervical dilatation (0–4 cm) delivery at less than 28 weeks occurred in 2.5%, 4.0%, 17.1%, 29.0%, and 75.0%, respectively, whereas delivery at less than 32 weeks occurred in 4.8%, 7.4%, 12.1%, 28.3%, and 38.8%. Predicted probability of preterm delivery less than 35 weeks by GA and cervical dilatation at preterm labor by logistic regression is presented in Table 1.

**CONCLUSION:** The degree of cervical dilatation and the GA at stabilization of an acute episode of preterm labor are predictive of subsequent pregnancy outcome. These data derived from a large database can be used when counseling patients with preterm labor as to expected prognosis.

Table 1.

Cervical Dilatation(cm)	20–23.9 wk (n = 181)	24–27.9 wk (n = 678)	28–31.9 wk (n = 1,554)	32–33.9 wk (n = 1,083)
0 (n = 1,387)	23.2	15.2	9.6	5.9
1 (n = 1,143)	45.0	29.0	17.0	9.3
2 (n = 575)	68.9	48.3	28.3	14.3
3 (n = 285)	85.7	68.1	43.3	21.4
4 (n = 106)	94.2	83.0	59.6	30.8

Values are %.



# The Rate Asymptomatic Intra-amniotic Infection in Women With Differing Degrees of Membrane Prolapse

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**OBJECTIVE:** Cervical dilatation greater than 2 cm is a known risk factor for asymptomatic intra-amniotic infection in the midtrimester. The amount of membrane prolapse has been proposed to be a potential risk for intra-amniotic infection. The objective of this study was to assess whether greater degrees of membrane prolapse to and beyond the external os have increasing rates of intra-amniotic infection in the midtrimester.

**METHODS:** We identified retrospectively all women with manually or ultrasound-detected cervical changes who underwent amniocentesis for intra-amniotic infection between 16–24 weeks of gestation at St. Luke's Hospital, Bethlehem, Pennsylvania. Rates of intra-amniotic infection for differing degrees of membrane prolapse were calculated. Intra-amniotic infection was defined as a positive culture of amniotic fluid.

**RESULTS:** Thirty-two women with cervical changes and amniocentesis were identified. More severe degree of membrane prolapse occurred at earlier gestations and was associated with higher rates of intra-amniotic infection. The microorganisms causing infection included *Ureaplasma*, *Streptococcus*, *Gardnerella vaginalis*, and *Candida* species (Table 1).

**CONCLUSION:** The more severe degrees of membrane prolapse occurred at earlier gestations and were associated with a higher rate of intra-amniotic infection. The rate of intra-amniotic infection correlated very closely with differing degrees of membrane prolapse. Women with membranes ballooning in the vagina or ruptured membranes have very high rates of intra-amniotic infection.

# Risks for Chorioamnionitis With Both Induction and Augmentation of Labor

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**OBJECTIVE:** Induction of labor rates are increasing. Some studies suggest an association between induction of labor and chorioamnionitis. Due to the effect of chorioamnionitis on uterine contractility, this study sought to determine whether either augmentation of labor or induction of labor (any method) increased the risk for chorioamnionitis.

**MATERIALS AND METHODS:** This was a retrospective review of the delivery records of patients attempting a vaginal delivery from 1996–1999 at the University of Illinois at Chicago (N = 7,377). Records were evaluated for augmentation of labor and induction of labor, as well as method of induction of labor (oxytocin, misoprostol, or Foley). Demographic data, delivery routes, and chorioamnionitis rates were determined. Comparisons between both augmentation of labor and induction of labor (and subgroups) patients and controls used  $\chi^2$  (significance  $P < .05$ )

**RESULTS:** There were 1,717 (23.3%) induction of labor patients (1,159 oxytocin, 457 misoprostol, and 69 Foley). Vaginal delivery rates were similar for controls (n = 5,651) and induction of labor patients (85.5% compared with 84.9%,  $P < .533$ ). Vaginal delivery rates by induction of labor type (compared with controls) were oxytocin 87.8% (odds ratio [OR] 1.2, 95% confidence interval [CI] 1.01–1.5,  $P < .001$ ), misoprostol 78.8% (OR 0.6 95% CI 0.5–0.8),  $P < .001$ ), and Foley 82.6% (OR 0.8 95% CI 0.4–1.5,  $P < .492$ ). More induction of labor patients developed chorioamnionitis (OR 2.6, 95% CI 2.0–3.4; controls 2.4% compared with induction of labor 6.1%). More chorioamnionitis was seen for both oxytocin 5.6% (OR 2.4 95% CI 1.8–3.3) and misoprostol 7.7% (OR 3.4, 95% CI 2.3–5.0), but not for Foley 4.3% (OR 1.8, 95% CI 0.6–5.9). Augmentation of labor patients (n = 1,436) had both a higher vaginal delivery rate (90.1%, OR 1.9, 95% CI 1.6–2.3) and more chorioamnionitis (5.5%, OR 4.2, 95% CI 3.0–6.0) than controls.

Table 1.

Membrane Status	Gestation(wk)	Amniotic Fluid Glucose	IAI(%)
Ultrasound changes only	22.2 ± 1.0	32.4 ± 15.4	9
Membrane seen in canal	23.0 ± 0	39.0 ± 0	0
Membrane at external os	21.8 ± 1.1	31.4 ± 7.7	0
Membrane < 2 cm past os	21.2 ± 1.5	29.2 ± 9.2	0
Membrane ballooning in vagina	19.7 ± 1.2	17.4 ± 16.9	72
Membrane ruptured	23.0 ± 0.8	16.0 ± 11.3	67

IAI, intra-amniotic infection.

Values are mean ± standard deviation unless otherwise specified.



**CONCLUSION:** Both augmentation of labor and induction of labor (misoprostol and oxytocin) increase the risk for chorioamnionitis. Due to the higher rate of chorioamnionitis, social and elective induction of labor should be avoided. Patients should be informed of the increased risk for chorioamnionitis before induction of labor.

## The Diagnosis and Treatment of Lymphoma During Pregnancy

### *Maternal and Fetal Outcomes*

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**OBJECTIVE:** To report the pregnancy outcomes of women diagnosed with lymphoma.

**STUDY DESIGN:** Eighteen pregnant women diagnosed with lymphoma participated in a prospective cohort study. Information was collected regarding diagnosis, treatment, and delivery outcome. Maternal and neonatal follow-up occurred yearly.

**RESULTS:** Twelve women were diagnosed with Hodgkin's Disease, the majority nodular sclerosing type. Six were diagnosed with non-Hodgkin's disease, mostly B cell lymphoma. The most common presenting symptom was cough. Mean ( $\pm$  standard deviation) maternal age at diagnosis was 33 ( $\pm$  3.5) years. Mean gestational age at diagnosis was 16 ( $\pm$  7) weeks. Seventeen women received a mean of 6 cycles of chemotherapy during pregnancy, all after 12 weeks. Agents and doses were identical to protocols for nonpregnant women in 16 cases. All deliveries were liveborn, at a mean gestational age of 35.1 ( $\pm$  2.4) weeks. A single malformation, syndactyly of 2 fingers, was surgically repaired. Mean age of offspring at follow-up was 32 months; the oldest was 87 months. Ninety-four percent were meeting developmental milestones; 1 was followed up for delayed expressive speech. For Hodgkin's disease, chemotherapy included doxorubicin, bleomycin, vinblastine, and dacarbazine; for non-Hodgkin's disease, chemotherapy included cyclophosphamide, hydroxydaunomycin, vincristine, and prednisone chemotherapy. Complications included preterm labor in twins, and intrauterine growth restriction in a singleton. Four women (all Hodgkin's disease) died of recurrent disease, at a mean of 3 years after delivery. Two were stage 3 at diagnosis, 1 receiving 3, not 4, standard agents due to pregnancy. The third woman was stage IIB and received lower doses of chemotherapy compared with nonpregnant women.

**CONCLUSION:** Lymphoma can be safely diagnosed and treated during pregnancy. Pharmacokinetic studies are necessary to ensure that pregnant women requiring chemotherapy are not undertreated.

## Histopathology of Adnexal Cysts Diagnosed Incidentally at Cesarean Delivery

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**OBJECTIVE:** To determine the histopathology of adnexal tumors diagnosed incidentally during cesarean delivery.

**METHODS:** Using our computerized database, all adnexal masses diagnosed and excised during cesarean delivery from January 1980 to December 2003 were identified. Charts were reviewed for demographic characteristics and the pathologic examination of the masses.

**RESULTS:** A total of 39 cases were identified (35 cystectomies and 4 oophorectomies). The mean maternal age was  $28.9 \pm 6.0$  years. Cesarean delivery was performed at a mean gestational age of  $37.7 \pm 3.5$  weeks. The distribution of the cysts was as follows: right-sided ( $n = 16$ , 41.0%), left-sided ( $n = 21$ , 53.8%) and bilateral ( $n = 2$ , 5.2%). The mean largest diameter was 6.0 cm (range 1.0–10.0 cm). The most common histopathologic diagnoses were mature cystic teratomas (33.3%), followed by serous cysts (12.8%) and endometriomas (15.3%). Other histopathologies were mucinous cysts (7.7%), paraovarian cysts (10.2%), luteomas (7.7%), corpus luteum cyst (2.6%), fibroma (2.6%), inclusion cyst (2.6%), combined serous and mucinous cyst (2.6%), and a borderline serous cystadenoma (2.6%).

**CONCLUSION:** Although most of the adnexal tumors excised during cesarean delivery are benign, the case of borderline tumor is alarming. This reemphasizes the need for close inspection of the adnexa at the time of cesarean delivery.

## Neonatal Morbidity Associated With Preterm Premature Rupture of Membranes Between 32 and 36 Weeks

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*Reinaldo Figueroa, MD, and Dev Maulik, MD, PhD*

**OBJECTIVE:** To examine neonatal morbidity for singleton deliveries occurring between 32 to 36 weeks after preterm premature rupture of membranes (PROM).

**METHODS:** We reviewed the medical records of women admitted to Winthrop University Hospital with singleton pregnancies complicated by preterm PROM from January 2000 to June 2004. Management included antibiotics, betamethasone if less than 34 weeks of gestation, and expectant management if clinically stable until 36 weeks of gestation. Medical records of the maternal-infant pairs were reviewed. Neonatal outcomes evaluated were mortality, respiratory distress syndrome, sepsis, intraventricular hemorrhage, necrotizing enterocolitis, seizures, meningitis,



**Table 1.**

Outcome	32 wk (n = 12)	33 wk (n = 17)	34 wk (n = 39)	35 wk (n = 78)	36 wk (n = 82)	<i>p</i>
% NICU admissions	91.7	100	97.4	39.7	12.2	< .001
NICU LOS (d)	16.8	9.5	7.2	5.5	5.2	< .001
% RDS	83.3	52.9	43.6	12.8	6.1	< .001
%IVH	16.7	5.9	2.6	2.6	0	.005
% Inc Bili	83.3	82.4	79.5	38.5	14.6	< .001

NICU, neonatal intensive care unit; LOS, length of stay; RDS, respiratory distress syndrome; IVH, intraventricular hemorrhage, Inc Bili, hyperbilirubinemia.

hyperbilirubinemia, neonatal intensive care unit (NICU) admission, and length of stay in NICU. Neonatal morbidities were stratified by gestational age and results were analyzed by analysis of variance and Cochran Armitage Trend Test. Length of stay in NICU was analyzed by Tukey's test.

**RESULTS:** There were 228 maternal-infant pairs that met the study criteria. All cases of intraventricular hemorrhage were Grade I. There was 1 culture-positive neonatal sepsis identified and no cases of necrotizing enterocolitis, seizures, meningitis, or neonatal deaths. Table 1 refers to significant neonatal outcome by gestational age.

**CONCLUSION:** Respiratory distress syndrome was the most common major neonatal morbidity after preterm PROM at 32 to 36 weeks. The greatest decline in neonatal morbidity was observed after 34 to 35 weeks.

## Medicaid Compared With Commercially Insured Twin Pregnancies

### Equivalent Outcomes After Preterm Labor Treatment

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**OBJECTIVE:** To compare pregnancy and neonatal outcomes between Medicaid and commercially insured twin pregnancies receiving continuous subcutaneous terbutaline after a diagnosis of preterm labor.

**METHODS:** Twin pregnancies treated with subcutaneous terbutaline after diagnosis and stabilization of acute preterm labor at a gestational age of less than 34.0 weeks were identified in a database. Data were stratified by insurance status (Medicaid, n = 153, or commercial, n = 1,686). Maternal demographics, preterm birth risk factors, pregnancy prolongation, and neonatal outcome were compared using Fisher exact, Student *t*, and Mann-Whitney *U* test statistics.

**RESULTS:** There was a preponderance of preterm birth risk factors in the Medicaid compared with commercial groups (teenager 15% compared with 2.5%, African-American race 35.3% compared with 8.4%, smoker 19.6% compared with 3.6%, unmarried 59.5% compared with 8.5%, less than high

school education 19.0% compared with 1.6%, and prior preterm birth 19.6% compared with 9.5%, all *P* < .001). Despite a greater preterm birth risk among Medicaid women, pregnancy and neonatal outcomes were similar to commercially insured women. Discontinuation of subcutaneous terbutaline for noncompliance occurred in 4.6% of Medicaid and 2.0% of commercially insured patients, *P* = .076 (Table 1).

**CONCLUSION:** Despite a preponderance of sociodemographic factors clearly identifying Medicaid status as a surrogate measure of preterm birth risk, similar pregnancy and neonatal outcomes were achieved after stabilization of preterm labor in twin pregnancies. Medicaid recipients can achieve similar pregnancy prolongation with subcutaneous terbutaline after preterm labor as commercially insured women.

**Table 1.**

	Medicaid (n = 153)	Commercial (n = 1,686)	<i>P</i>
GA at PTL (wk)	28.8 ± 2.9	28.8 ± 3.5	.988
Pregnancy prolongation after PTL (d)	40.9 ± 20.1	42.9 ± 24.1	.241
< 14 days prolongation	7.8	7.2	.746
GA at delivery (wk)	34.7 ± 2.4	35.0 ± 2.4	.151
< 32 weeks at delivery	11.8	9.4	.320
Very low birth weight	9.8	7.4	.143
Small for gestational age	7.5	6.7	.635

GA, gestational age; PTL, preterm labor.

Values are mean ± standard deviation or %.

## Does Body Mass Index Affect the Sensitivity and Specificity of the Glucose Challenge Test?

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**OBJECTIVE:** Standard gestational diabetes screening is a 50-g glucose challenge test. Obesity is a risk for gestational diabetes. Given this link, we examined glucose challenge test values in the context of body mass index (BMI) to



determine whether doing so improves upon glucose challenge test sensitivity and specificity.

**METHODS:** A retrospective analysis of 1,566 gravidas with singleton gestations who underwent a glucose challenge test between 24 and 34 weeks of gestation. A 100-g glucose tolerance test (GTT) was performed for a glucose challenge test of 140–199 mg/dL. A positive GTT was defined by Carpenter and Coustan criteria. Abnormal glucose challenge test screens were evaluated using 6 cutoff points: 140, 150, 160, 170, 180, and 190 mg/dL. Body mass index was divided in 3 categories: underweight and normal (< 24.9), overweight (25–29.9), and obese (> 30). Glucose challenge test sensitivity and specificity were calculated for the 3 BMI categories at the 6 cutoff points.

**RESULTS:** A total of 252 gravidas had a positive glucose challenge test; 69 had gestational diabetes. Using a 140 mg/dL cutoff for underweight and normal gravidas, glucose challenge test sensitivity and specificity were 18.9% and 84.9%, respectively. For obese gravidas at this cutoff, sensitivity and specificity were 21.6% and 84.9%, respectively. Using a 190 mg/dL cutoff for underweight and normal gravidas, glucose challenge test sensitivity and specificity were 2.5% and 99.8%, respectively. For obese gravidas at this cutoff, sensitivity and specificity were 0% and 99.2%, respectively. There was no substantial improvement in glucose challenge test sensitivity and specificity at any cutoff points in relation to BMI.

**CONCLUSION:** Although obesity is a risk for gestational diabetes, considering glucose challenge test scores in relation to BMI did not effect the sensitivity or specificity of the screen.

## Inhibin-A

### *A Screening Marker for Preeclampsia*

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**OBJECTIVE:** To determine whether maternal serum inhibin-A levels during the second trimester of pregnancy has a prediction value of subsequent preeclampsia development.

**METHODS:** This was a prospective, institute research board-approved study. Single serum inhibin-A level was measured from maternal blood drawn at the time blood for alpha fetoprotein was drawn. Patient risk to develop preeclampsia, pregnancy course, and outcome were recorded. Inhibin-A level was measured in 123 patients who had a normal pregnancy and delivery. Inhibin-A was measured in serum using the ultrasensitive Oxford Bioinnovation kit, based on the 2 subunit-specific antibodies enzyme-linked immunosorbent assay method. Interplate and intraplate variations were less than 10%.

**RESULTS:** Serum maternal inhibin-A level in 115 pregnant women during second trimester who had a normal pregnancy and a noncomplicated delivery was statistically significantly lower ( $124 \pm 108$  pg/mL) compared with women who developed preeclampsia without a prior risk factor to

develop preeclampsia ( $n = 4; 287 \pm 38$  pg/mL,  $P < .002$ ) and statistically higher compared with women with a prior risk factor to develop preeclampsia ( $n = 4; 59 \pm 21$  pg/mL,  $P < .05$ ).

**CONCLUSION:** Maternal serum inhibin-A levels during the second trimester of pregnancy have a predictive value of subsequent preeclampsia development. Inhibin-A levels should be correlated with the patient's prior risk factor to develop preeclampsia.

## Brachial Plexus Palsy After Cesarean Delivery

### *An Intrauterine Phenomenon?*

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**OBJECTIVE:** Rare cases of brachial plexus injuries after uneventful vaginal or cesarean deliveries have been reported in the literature, suggesting the possibility that these injuries may originate in utero. The purpose of this report is to describe a case of permanent brachial plexus injury after cesarean delivery with a uterine anomaly, with electromyographic evidence suggesting brachial plexus injury pre-dating delivery.

**METHODS:** A 36-year-old gravida 3, para 0 at 39+ weeks of gestation presented with prolonged rupture of membranes in latent labor. Despite augmentation, labor arrested at 8 cm. An uneventful cesarean delivery was performed delivering a male infant, 3,540 g. Exploration of the uterine cavity revealed an undiagnosed uterine septum.

**RESULTS:** Neonatal diagnosis of Erb's Palsy, confirmed by electromyography and magnetic resonance imaging. Electromyograph findings were consistent with nerve injury occurring greater than 10 days preceding infant delivery.

**CONCLUSION:** Brachial plexus injuries may occur in utero, possibly correlated with the presence of uterine anomalies, thus suggesting a possible unidentified cause of brachial plexus injury in atraumatic deliveries occurring regardless of delivery mode.

## A Comparison of Glyburide and Insulin in Management of Gestational Diabetes Mellitus

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**OBJECTIVE:** To compare the cost-effectiveness and efficacy of glyburide with insulin on maternal glycemic control, fetal anomalies, neonatal hypoglycemia, and macrosomia in mothers with gestational diabetes refractory to diet.



**METHODS:** Eighty-six pregnant women were randomly assigned prospectively to treatment with either glyburide (n = 41) or insulin (n = 42). If maximum dose of glyburide was not able to control glucose within a 2-week period, treatment was shifted to insulin (n = 3). An intent-to-treat analysis was used.

**RESULTS:** There was no difference in the 2 groups with glucose tolerance results or past obstetric history, but the insulin group showed a higher Hgb A<sub>1c</sub> (7.3 compared with 5.9, *P* < .05) and earlier gestational age for diagnosing diabetes (18.7 compared with 23.2 weeks, *P* < .05). The fasting blood glucose of the insulin group was significantly lower than the glyburide group (88.7 compared with 96.2, *P* < .05). However, there were no significant differences between the groups in birth weight or birth defects. There was a significantly lower mean neonatal glucose level recorded in the glyburide group (44 compared with 61.7, *P* < .05). The mean cost of glyburide was lower than insulin (\$7.20/month compared with \$20.00/month).

**CONCLUSION:** In this pilot study, insulin compared with glyburide showed better maternal and neonatal glucose control but with no differences in birth weight or birth defects. By chance, the insulin group seemed to have included more severe diabetics. This suggests that insulin maybe more effective in severe diabetics, but glyburide therapy overall may be more economic. The results of this study are limited by small numbers.

## Low Molecular Weight Heparin in Pregnancy

### A Case–Control Study

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**OBJECTIVE:** To compare bleeding complications in pregnant patients treated with low molecular weight heparin to untreated controls.

**METHODS:** A retrospective case–control study of patients who received prophylactic or therapeutic low molecular weight heparin during pregnancy was performed. Indications for low molecular weight heparin included current or prior thromboembolism, thrombophilia, or heart valve replacement. Exclusion criteria were low molecular weight heparin discontinuation or pregnancy termination before the third trimester. Controls were chosen in a 2:1 ratio to cases, matched for delivery route, and selected as the next 2 consecutive deliveries. Estimated blood loss, postpartum hemorrhage, and blood transfusion rates were compared. Odds ratios (ORs) were calculated with 95% confidence intervals (CIs).

**RESULTS:** Forty-nine women treated with low molecular weight heparin delivered 55 infants with a 37% cesarean rate. Current or prior thromboembolic disease was the anticoagulation indication in 47% and 25% of patients, respectively. The cases were either switched to heparin at

36 weeks (27%) or continued on low molecular weight heparin (73%) until delivery. One case of postpartum pulmonary embolism resulted in a maternal mortality. There were more obese gravidas in the low molecular weight heparin group (OR 3.91, 95% CI 1.70–9.09). Labor induction was more common in the low molecular weight heparin group, 22 of 55 (45%) compared with 29 of 110 (26%), *P* = .01. There was no difference in estimated blood loss (295 ± 145 compared with 308 ± 111 mL, *P* = .62 vaginal; 687 ± 251 compared with 765 ± 313 mL, *P* = .34 cesarean), postpartum hemorrhage (6/55, 11% compared with 9/110, 8.2%; OR 1.37, 95% CI 0.16–11.5), or transfusion (3/55, 5.4% compared with 4/110, 3.6% OR 1.50, 95% CI 0.3–7.48) between the cases and controls.

**CONCLUSION:** Bleeding complications, including postpartum hemorrhage and transfusion rates, in patients treated with low molecular weight heparin during pregnancy were not increased when compared with controls matched for delivery route.

## Amniocentesis Before Rescue Cerclage

### Does Ruling Out Subclinical Infection Influence Outcome?

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**OBJECTIVE:** The objective of this study was to evaluate whether performing amniocentesis before rescue cerclage makes a significant difference in outcomes in women with differing levels of membrane prolapse.

**METHODS:** Asymptomatic women with a singleton gestation who had rescue cerclages placed because of manual or speculum cervical changes were identified retrospectively. Membranes had to be visible on examination. Women were divided into 2 groups based on whether an amniocentesis was done. Analysis was performed for 3 groups of women: the overall group, women with membranes before or at the external os, and women with membranes past the external os.

**RESULTS:** Thirty-one women were identified, of whom 7 had a precerclage amniocentesis and 24 did not. In the overall group of women, comparing amniocentesis to no amniocentesis, there was no difference in perinatal outcomes (Table 1). In separate subanalyses in women with membranes before or at the os and in women with membranes past the os, again there was no difference in perinatal outcomes. (data not shown)

**CONCLUSION:** There was no difference in perinatal outcomes in any of our 3 analyses when comparing the use of amniocentesis to no amniocentesis before rescue cerclage placement. Larger randomized trials are necessary.



**Table 1.**

	Amniocentesis (n = 7)	No Amniocentesis (n = 24)	P
Mean age (y)	26.1	29.9	.37
Parous	3 (43)	12 (50)	.74
Prior PTB	1 (14)	7 (100)	.42
Mean latency (hr)	42.4	49.8	.72
GA at delivery (wk)	27.2	27.2	.99
PTB (wk)			
< 35	6 (86)	18 (75)	.55
< 32	5 (71)	18 (75)	.85
< 28	4 (57)	15 (63)	.80
< 24	2 (29)	10 (42)	.53
Mean birth weight (g)	1,226.8	1,275.1	.92
neonatal survival	3 (43)	11 (46)	.85

PTB, preterm birth; GA, gestational age.  
Values are n (%) unless otherwise specified.

## The Incidence of Preterm Labor in Women With Previous Preterm Delivery Treated With 17 $\alpha$ -Hydroxyprogesterone Caproate Compared With Home Uterine Activity Monitoring

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**OBJECTIVE:** To compare the incidence of preterm delivery between women receiving 17 $\alpha$ -hydroxyprogesterone caproate for prematurity prevention and women not receiving 17 $\alpha$ -hydroxyprogesterone caproate but who had daily outpatient surveillance and home uterine activity monitoring for early detection of preterm labor.

**METHODS:** Women with previous preterm delivery enrolled for outpatient services (home uterine activity monitoring with perinatal nursing assessment) or weekly nursing visits with 17 $\alpha$ -hydroxyprogesterone caproate injection were eligible. Singleton gestations with a history of at least 1 preterm delivery, without diagnosis of preterm labor or vaginal bleeding and less than 26 weeks at enrollment were included. Patients receiving 17 $\alpha$ -hydroxyprogesterone caproate were matched 1:1 to patients receiving home uterine activity monitoring by maternal age, marital status, tobacco use, number of preterm deliveries, and cerclage. Primary study outcome was incidence of preterm delivery.

**RESULTS:** Data were compared for 305 matched pairs. The incidence of preterm premature rupture of membranes (8.5% compared with 7.9%,  $P = .174$ ) and preterm labor with preterm delivery at less than 32, 35, and 37 weeks were similar between the groups. The incidence of hospitalization for suspected preterm labor, use of tocolysis, and

**Table 1.**

	17P (n = 305)	No 17P (n = 305)	P
Hospitalized for			
suspected PTL	73 (23.9)	138 (45.2)	< .001
Tocolysis	56 (18.4)	139 (45.6)	< .001
PTL with or without			
PTD	136 (44.6)	177 (58.0)	.002
PTL with delivery			
< 37 wk	102 (33.4)	104 (34.1)	.927
GA at delivery			
(wk)	36.5 $\pm$ 3.2	36.4 $\pm$ 3.6	.928

17P, 17 $\alpha$ -hydroxyprogesterone caproate; PTL, preterm labor; PTD, preterm delivery; GA, gestational age.  
Values are n (%) or mean  $\pm$  standard deviation.

diagnosis of preterm labor with and without preterm delivery was decreased in patients receiving 17 $\alpha$ -hydroxyprogesterone caproate (Table 1).

**CONCLUSION:** Among women with previous preterm birth there was no difference in the rate of preterm delivery between those treated with 17 $\alpha$ -hydroxyprogesterone caproate and those treated with daily outpatient surveillance and home uterine activity monitoring without 17 $\alpha$ -hydroxyprogesterone caproate. Women treated with 17 $\alpha$ -hydroxyprogesterone caproate had a lower incidence of hospitalization for preterm labor and tocolytic use, suggesting that these 2 interventions reduce the preterm delivery rate through different, possibly complimentary, mechanisms.

## Utility of the 1-Hour Glucose Challenge Test at the First Prenatal Visit to Screen for Pregestational Diabetes

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**OBJECTIVE:** The purpose of this study was to determine whether performing first-visit glucose challenge tests makes a difference in detecting patients with pregestational diabetes during pregnancy.

**METHODS:** A retrospective medical record review was done on all antenatal patients at an inner city public hospital in 2003. Patients were included if they met the following criteria: full prenatal care and delivery at the same institution, singleton gestation, a 50-g, 1-hour glucose challenge test was done at the first visit with appropriate testing if positive, and then subsequent testing at 24–28 weeks if necessary. Data collected included age, parity, ethnicity, body mass index, gestational age at delivery, fetal weight, and mode of delivery. Statistical analysis was done using  $\chi^2$  and the unpaired Student  $t$  test.

**RESULTS:** A total of 756 patients were eligible, and the average gestational age at first visit was 14 2/7 weeks. Our



patients were predominantly of Hispanic or South Asian descent. Gestational diabetes was diagnosed in 6.7%. Of these patients, 64.7% had an abnormal first visit screen ( $P < .05$ ), and 45% were diagnosed with gestational diabetes based on their early screen alone. Maternal ages were statistically higher and birth weights were statistically lower in women with abnormal first-visit glucose challenge tests than their screen-negative controls ( $P < .04$ ). Almost 50% of the gestational diabetics were South Asian, and more South Asians were diagnosed with gestational diabetes based on early screening alone.

**CONCLUSION:** Early screening protocols may be important in certain populations who are at higher risk for diabetes.

## Intrauterine Balloon Tamponade in the Management of Postpartum Hemorrhage

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**OBJECTIVE:** The purpose was to review our experience with the use of intrauterine tamponade with balloon catheters in the management of severe postpartum hemorrhage.

**METHODS:** This was a 2-year retrospective review of 24 cases of postpartum hemorrhage unresponsive to therapy, managed with intrauterine balloon tamponade. We identified these patients by International Classification of Diseases, 9th Revision codes for postpartum hemorrhage and by review of hospital charts, and labor and delivery logs.

**RESULTS:** Balloon tamponade was attempted in 24 patients. In 3 cases, technical difficulties led to placement failure. When properly placed, catheters controlled postpartum hemorrhage in 19 of 21 cases (90.4%). In 2 cases, hysterectomy was required despite successful placement of the catheter (1 due to placenta accreta and 1 due to amniotic fluid embolism). For hemorrhage due to uterine atony, our success rate was 100% (12 of 12 cases). For bleeding due to retained products of conception, our success rate was 80% (4 of 5, failure with placenta accreta). Vaginal bleeding was stopped with the catheter in 2 of 3 cases of amniotic fluid embolism and in 1 case after dilation and curettage for postpartum septic shock.

**CONCLUSION:** Balloon tamponade is an effective adjunct in the treatment of severe postpartum hemorrhage, especially when due to uterine atony.

## Maternal Morbidity Associated With Obstructive Sleep Apnea in Pregnancy

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**OBJECTIVE:** To determine the maternal morbidity associated with pregnancies in women with obstructive sleep apnea syndrome.

**STUDY DESIGN:** A retrospective case-control study was performed. Cases were pregnant women with polysomnography confirmed obstructive sleep apnea who delivered at a tertiary care center between 2000 and 2005. Controls were selected from a perinatal database. Charts were reviewed for demographic and clinical data. Postpartum complications were defined as any infectious morbidity requiring intravenous antibiotics, blood transfusion, wound complications, thromboembolism, or readmission to the hospital. The data were analyzed using  $\chi^2$  and Mann Whitney  $U$  test where appropriate. A  $P$  of .05 was considered significant.

**RESULTS:** Eleven cases and 48 controls met criteria. Women with obstructive sleep apnea syndrome had a higher median body mass index (52 kg/m<sup>2</sup> [interquartile range 41–65 kg/m<sup>2</sup>] compared with 35 kg/m<sup>2</sup> [interquartile range 30–43 kg/m<sup>2</sup>],  $P < .001$ ), were more likely to have chronic hypertension (45.5% compared with 13%,  $P < .02$ ), gestational diabetes (27.3% compared with 2.9%,  $P = .02$ ) and more than 1 medical condition (63.6% compared with 7.2%,  $P < .001$ ). There was no difference in the rate of preeclampsia (58% compared with 37.3%,  $P = .06$ ), medically indicated preterm delivery (36.4% compared with 25.8%,  $P = .38$ ), or cesarean delivery (62.7% compared with 42 %,  $P = .06$ ). There was no difference in the rate of postpartum complications (9.1% compared with 13.7%,  $P = .53$ ), but the sleep apnea cohort had a longer median hospital length of stay (5 days compared with 3 days,  $P = .04$ ).

**CONCLUSION:** Patients with obstructive sleep apnea have more comorbid conditions than the general population and a longer length of hospital stay. These findings may be mediated by obesity.

## Homeopathic Pulsatilla to Stimulate Version of the Breech Fetus Near Term

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Holistic practitioners frequently recommend homeopathic Pulsatilla nigricans to stimulate version of the persistently breech fetus near term. We explored efficacy with 2 different doses of Pulsatilla in 22 patients (26 pregnancies) over a 5-year period in an urban private obstetric practice, with ultrasound-confirmed breech presentations after 34 weeks gestation. Eleven fetuses (42%) spontaneously verted after maternal sublingual administration of 1 or more doses of



Pulsatilla in 200C or 1M potency (10–400, 10–2,000 concentration) compared with a 17% spontaneous version rate after 34 weeks in the literature. Subsequent external version with tocolysis was unsuccessful in 9 of 10 Pulsatilla failed versions. External version was contraindicated in 2 patients whose fetuses verted with Pulsatilla. One patient who had cesarean delivery for breech in her first pregnancy had 3 subsequent breeches at 35–38 weeks, and verted with Pulsatilla. In our experience, success was more likely when Pulsatilla was given before breech descent into the maternal pelvis. However, reversion was also more likely, and up to 3 weekly doses were needed in a few cases. There were no adverse events. Homeopathic medicines are highly dilute preparations derived from a variety of plant and other substances, classically chosen based on individual characteristics rather than by diagnosis. In the United States, manufacture is regulated by the Food and Drug Administration. Because of their standardized preparation and high dilution factor; theoretically they should be safe in pregnancy. These findings suggest a potential role for Pulsatilla in diminishing the need for external version and cesarean delivery for breech. A randomized trial is needed.

## Epidural Analgesia, Maternal Pyrexia During Labor and Their Relationship to Infectious Complications

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**OBJECTIVE:** To investigate the relationship between maternal pyrexia during labor, epidural analgesia, and chorioamnionitis.

**METHODS:** All singleton deliveries with gestational ages greater than 36 weeks identified in a statewide perinatal database were included. Cross tabulation followed by logistic regression with maternal pyrexia (temperature equal or greater than 38.0°C) during labor as outcome variable and epidural analgesia, clinical chorioamnionitis, parity, operative vaginal delivery, internal fetal heart rate monitoring, labor induction, artificial rupture of membranes, premature rupture of membranes, obesity, and prolonged labor as independent variables was used.

**RESULTS:** Of 170,258 deliveries in the database, 158,973 met inclusion criteria. The incidence of maternal pyrexia and chorioamnionitis in patients with epidural was 3.4 % and 1.8 %, respectively, compared with 0.4 % and 0.6 %, respectively, in patients without epidural ( $P < .001$ ). The incidence of chorioamnionitis in patients with compared with without epidural was 1.8 % compared with 0.6 % ( $P < .001$ ). Postpartum maternal pyrexia was found in 0.8 % of patients with and in 0.6 % without epidural analgesia ( $P < .001$ ). In patients with epidural analgesia, the odds ratio of maternal pyrexia was 5.8 (95 % confidence interval 5.1–6.6), whereas the odds ratio for chorioamnionitis was 1.2 (95 % confidence interval 1.1–1.5).

**CONCLUSION:** Our data show a strong association between epidural analgesia and pyrexia during labor independently from a small increase in incidence of chorioamnionitis.

## OFFICE PRACTICE

### Do Patients Really Know What a “Pap” Test Is?

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Joseph Jaeger, MPH

**OBJECTIVE:** To assess patients’ knowledge regarding the Papanicolaou (Pap) test.

**METHODS:** Patients at our obstetrics and gynecology clinic completed a questionnaire in English or Spanish, answered as true or false. Question 7 listed organs the Pap test would detect cancer from.

1. The “Pap” test can show if I have Gonorrhea or *Chlamydia* infection. True/False.
2. The “Pap” test is done in the emergency room if I go there for a vaginal discharge. True/False.
3. If my doctor tells me my “Pap” test is not normal, I definitely have cancer. True/False.
4. If my “Pap” test is not normal then I will need a hysterectomy. True/False.
5. If I have treatment for abnormal “Pap” test, then I can never have children. True/False.
6. Cancer of the cervix is closely related to HPV (human papilloma virus) infection. True/False.
7. The “Pap” test is done to detect cancer of the uterus cervix ovary colon.

Table 1.

Question No.	1		2		3		4		5		6		7	
	Eng	Spn	Eng	Spn	Eng	Spn	Eng	Spn	Eng	Spn	Eng	Spn	Eng	Spn
Correct	54.2	67.9	59.4	52.8	48.4	50.9	46.4	45.9	47.4	37.1	42.2	35.8	62.5	28.9
Incorrect	45.8	32.1	40.6	47.2	51.6	49.1	53.6	54.1	52.6	62.9	57.8	64.2	37.5	71.1
<i>P</i>	.009*		.219		.640		.934		.053*		.227		< .001*	

Eng, English; Spn, Spanish.

Values are percentages.

\* Statistically significant.



**RESULTS:** A total of 351 patients completed the questionnaire, 192 in English and 159 in Spanish (Table 1).

**CONCLUSION:** Misconceptions prevail about the Pap test. Language does not seem to be a factor. Patient education efforts are needed to dispel misinformation and provide accurate information about the Pap test as a screening method for prevention of cervical cancer.

## Assessing Feasibility of Text Messaging to Improve Medication Adherence

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**OBJECTIVE:** Patient nonadherence with prescribed medications is a major public health issue estimated to cost \$100 billion annually. The World Health Organization estimates that one half of patients take their medication improperly. Wireless text messaging is a new technology that could be used to improve compliance with medications. We assessed the feasibility of using this technology in an urban population for medication dosing and appointment reminders.

**METHODS:** We approached patients waiting for family planning services in 4 community health clinics. Subjects completed a survey of wireless telephone and text messaging access, use and interest. Surveys were available in English and Spanish.

**RESULTS:** We collected 2,521 surveys from women aged 13 to 83 years; 97% were younger than age 40. Overall, 66% of our subjects have wireless telephones that receive text messages. Ninety percent can open and read text messages and 88% can write and send them. One-third of subjects report that they forget to take medications. More of the 243 subjects reporting current prescription medication use would like to receive free text message dosing reminders than subjects not taking medications ( $P = .001$ ). Forty-five percent of subjects would prefer to receive appointment reminders by a call to their wireless telephones and another 23% would like a text message.

**CONCLUSION:** Urban women would like to receive medication and appointment reminders by text messages on their wireless telephones. Text messaging is a promising technology that may remove an obstacle to medication adherence and result in a healthier population and health care savings.

## ETHICS/PROFESSIONAL LIABILITY/RISK MANAGEMENT

### Distortions of Risk in Obstetric Decision Making

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*Lisa H. Harris, MD, Elizabeth Armstrong PhD, MPA, Miriam Kupperman PhD, MPH, Rebecca Kukla PhD, Margaret O. Little, PhD and Lisa Mitchell, PhD*

**OBJECTIVE:** To examine how the perception and communication of risk are distorted in medical decision making about pregnancy and delivery.

**METHODS:** We analyzed 3 common scenarios in obstetrics: 1) medical management of nonobstetric conditions, such as suspected appendicitis; 2) delivery decisions, such as practice and policies surrounding vaginal birth after cesarean delivery; 3) decision making about prenatal genetic testing, including age- and risk-based thresholds for invasive testing. We conducted interdisciplinary analysis of these scenarios, drawing on methods from clinical epidemiology, philosophy, bioethics, sociology, anthropology, and history.

**RESULTS:** We found 3 distortions in these scenarios, including the tendency to 1) regard numeric risk estimates alone, in isolation from women's values and social contexts, as determinative of individual clinical decisions and health policy; 2) focus on the risks associated with undertaking medical interventions during pregnancy to the exclusion of demonstrable risks to both woman and fetus of failing to intervene; and 3) abjure even minor risks to the fetus, even those that would in other contexts be deemed acceptable and which involve medical considerations important to the well-being of the pregnant woman and her fetus. In each instance, the evidence base for best practice is often ignored and women's autonomy may be seriously compromised.

**CONCLUSION:** Distortions in the perception, communication, and management of risk in obstetrics can lead to care that is neither evidence-based nor patient-centered, often to the detriment of women and infants alike. Physicians and policy makers should be aware of risk distortions and work to overcome them in clinical care and public policy.



## REPRODUCTIVE ENDOCRINOLOGY/INFERTILITY

### Use of Letrozole in Polycystic Ovary Syndrome Patients Resistant to Clomiphene

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**OBJECTIVE:** The treatment of choice for ovulation induction in patients with type II anovulatory infertility is clomiphene citrate. In patients resistant to clomiphene, injectable gonadotropins are the next treatment. The cost of the drug, risks of multiple pregnancies, ovarian hyperstimulation syndrome, and the monitoring associated with gonadotropins have prompted the search for alternatives. Preliminary studies suggest that letrozole (aromatase inhibitor) can be used as an alternative to clomiphene for ovulation induction. The objective of this study was to reconfirm the role of aromatase inhibitors in patients with polycystic ovary syndrome resistant to clomiphene.

**STUDY DESIGN:** Observational prospective cohort trial.

**MATERIALS AND METHODS:** Fourteen patients with polycystic ovary syndrome under age 35 who were unresponsive to clomiphene 150 mg daily for 5 days were included. Letrozole was administered for at least 2 cycles in a dose of 2.5 mg daily from days 3 to 7. Ovulation was triggered with hCG 10,000 units followed by timed intercourse or intrauterine insemination.

**RESULTS:** Ovulation induction was successful in 10 (71.4%) of subjects. All the patients had an endometrial thickness greater than or equal to 8.5 mm. Six (42.9%) patients reported a positive pregnancy test. One patient experienced a miscarriage. Fetal heart tones were identified in the remaining 5 (35.7%) patients

**CONCLUSION:** Our data suggest a benefit of letrozole as an ovulation-inducing agent in patients resistant to clomiphene. Letrozole is an oral medication without the risks of hyperstimulation and multiple pregnancies.

## HIV/ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) PROGRAM

### The Antiretroviral Pregnancy Registry

#### *Ten Years of Progress and Ten Years of Data*

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**BACKGROUND:** The epidemiologic approach to registration of drug-exposed pregnancies and follow-up of the infants born for possible birth defects, the so-called pregnancy registry, is an institution in American pharmacoepidemiology.

**OBJECTIVE:** We will review the experiences of the Antiretroviral Pregnancy Registry. Points to be reviewed are: the genesis for formation of the registry; governance structures; scientific follow up protocols; monitoring, analysis, and termination plan; privacy protections; dissemination strategies; and review of the data collected to date.

**METHODS:** The Antiretroviral Pregnancy Registry monitors prenatal exposures to antiretroviral drugs to detect increases in the risk of birth defects through a prospective exposure-registration cohort. For all defects combined, a cohort of 200 is required to detect a doubling of risk compared with Centers for Disease control and Prevention's expected prevalence, (80% power and Type I error rate 5%). For specific defects, the power varies with the population's frequency of the defect and the size of the exposed group.

**RESULTS:** The Antiretroviral Pregnancy Registry monitors pregnancy exposures and their outcomes for 29 products for the treatment of human immunodeficiency virus (HIV) disease or prevention of maternal-fetal transmission. Measured against 5,168 live births with exposure at any time during pregnancy, there were 132 outcomes with birth defects identified, a prevalence of 2.6 birth defects per 100 live births (95% confidence interval 2.1-3.0).

**CONCLUSION:** The significance of the findings and the lessons learned over the past decade demonstrate the evolution of a successful multisponsored program. Although no major teratogenic signal has been detected, the population monitored is only sufficient to detect a 2-fold risk of relatively common defects.



## Screening for Depression in HIV-Infected Women in Pregnancy

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**OBJECTIVE:** The purpose of this prospective study was to determine the usefulness of screening for depression in human immunodeficiency virus (HIV)-infected pregnant women.

**METHODS:** Human immunodeficiency virus-infected women receiving prenatal care at an inner-city institution between March 2004 and September 2005 were offered the Beck Depression Inventory, a screening tool to detect depressive symptomatology. The Beck Depression Inventory is a 21-item questionnaire that was orally administered to each patient during one of their routine prenatal visits. A cutoff score of greater than 9 was considered a positive screen.

**RESULTS:** Forty-five HIV-infected pregnant women were eligible and 43 (96%) agreed to participate in this study. Most women (74%) had been diagnosed with HIV infection before the pregnancy. Forty percent of women had a history of sexual abuse or domestic violence and 42% had a history of substance abuse. Nearly one half (49%) had a history of psychiatric illness. The median and mean Beck Depression Inventory scores were 13 and 17.4, respectively, range 0 to 55. Twenty-five patients (58%) screened positive for depression. Of those that screened positive, nearly one third (32%) had no prior history of psychiatric illness. In comparing those diagnosed with HIV infection during pregnancy with those diagnosed before pregnancy, the mean and median scores on the Beck Depression Inventory were higher, 24.1 compared with 15.0 and 21.0 compared with 10.0, respectively, as was the percent of positive screens, 64% compared with 56%, although these differences were not statistically significant.

**CONCLUSION:** HIV-infected women should routinely be screened for depression during pregnancy. Those with positive screens should be offered formal psychological evaluation.

## INFECTIOUS DISEASES

### Use of the Contraceptive Ring in Women With Recurrent or Chronic Vaginitis Who Take Oral Contraceptives

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**OBJECTIVE:** To determine whether women complaining of chronic or recurrent vaginitis receive vaginal benefit after switching to a contraceptive ring.

**METHODS:** Ten oral contraceptive users previously experiencing chronic or recurrent vaginitis were switched to contraceptive rings and followed up for 3 months to detect changes in Nugent score, the number of documented episodes of bacterial vaginosis and vulvovaginal candidiasis, and the symptoms of vaginitis as determined by vaginal symptom questionnaires. Data were collected at screening, 6 weeks, and 12 weeks, as well as during any episodes of symptomatic vaginitis during the study period.

**RESULTS:** A nonstatistically significant improvement in Nugent score of  $-0.83$  occurred from baseline to week 12 ( $P = .52$ ). There was a statistically significant improvement in the vaginal symptom questionnaire score from baseline to 12 weeks of  $-5.04$  ( $P = .001$ ), which was evident by 6 weeks. Subjects reported 34 cases of vaginitis in the 3 months before the study, whereas 8 cases of vaginitis were documented while the same subjects used the contraceptive ring, a 76.5% reduction. Vulvovaginal candidiasis was reduced from 22 to 5, a 77.3% reduction, and bacterial vaginosis was reduced from 12 to 3, a 75% reduction.

**CONCLUSION:** Oral contraceptive users identified as chronic vaginitis sufferers may have a significant improvement in the symptoms of vaginitis through the use of the contraceptive vaginal ring. Controlled, prospective trials will determine whether the reduction in infections can be reproduced.

### Seroprevalence of Toxoplasma Infection Among Pregnant Women in Lebanon

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**OBJECTIVE:** To determine the seroprevalence of toxoplasma in the first trimester of pregnancy and the yield of amniocentesis in patients suspected of having acute infection.



**METHODS:** A cohort of pregnancies at the American University of Beirut Medical Center 2000–2004 had their sera tested for anti-Toxoplasma immunoglobulin (Ig) G and IgM antibodies. In nonimmune cases, the test was repeated at 28 weeks. Cases suspected of having acute maternal infection were advised amniocentesis.

**RESULTS:** A total of 75.9% (n = 931) of 1,227 sera tested had positive IgG-negative IgM antibodies, whereas 20.0% (n = 245) were negative for both antibodies. The remaining 4.1% had either IgG or IgM results missing (n = 32) or both IgG and IgM positive (n = 19). Immunoglobulin G was positive in 61.8%, 73.3%, and 82.4% of those aged less than 20, 21–30, and more than 30 years ( $P = .001$ ), respectively, and in 70.5%, 78.7%, and 80.0% of primigravidas, gravida 2–4, and gravida more than 4, ( $P = .008$ ), respectively. Two patients (0.8%) seroconverted in the late second trimester. Of the 21 sera that tested positive for both antibodies during pregnancy, amniocentesis was performed in 14 cases (66.7%), with negative polymerase chain reaction in all. The remaining 7 did not have amniocentesis, because repeat IgM titers were negative (n = 4), procedure was refused (n = 2), and spontaneous abortion (n = 1). Spiramycin was given throughout pregnancy in all except 5. All infants had negative cord blood IgM antibodies and none manifested symptoms of Toxoplasma infection.

**CONCLUSION:** Three quarters of Lebanese pregnant women are immune to Toxoplasma infection. The seroconversion rate during pregnancy is 0.8%. The yield of amniocentesis in women positive for both IgG and IgM in early pregnancy is low.

## Bacterial Vaginosis

### Reliability of Testing in Low-Risk and High-Risk Populations

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*David E. Soper, MD*

**OBJECTIVE:** To evaluate the clinical performance of the new QuickVue Advance pH and Amines test in a multicenter study and to determine its performance in populations with high and low prevalence of bacterial vaginosis.

**METHODS:** Clinical performance of the pH and Amines test was evaluated at 5 sites in North America and Canada. These 5 sites had varying prevalence of bacterial vaginosis. Vaginal fluid specimens from 464 consenting women were used. Diagnosis of bacterial vaginosis for each woman was also obtained with the Amsel clinical criteria, reconciled with Nugent Gram stain scores. The prevalence of bacterial vaginosis and clinical performance of the product at each site were calculated, as was the overall performance of the device.

**RESULTS:** The prevalence of bacterial vaginosis varied from 6.5% in an infertility clinic (n = 92) to 68.4% in a public health clinic (n = 98). Accuracy of the device varied from 93.5% in the infertility clinic to 92.9% in the public health clinic and in between depending on the demographics. Overall accuracy (all sites combined) was 94.0%. Overall

incidence of bacterial vaginosis was 35%. The positive predictive value ranged from 50% (infertility clinic) to 96.9% (public health clinic) and the negative predictive value ranged from 98.8% (infertility clinic) to 85.3% (public health clinic).

**CONCLUSION:** The QuickVue Advance pH and Amines test is a reliable tool for diagnosis of bacterial vaginosis in areas where the incidence of bacterial vaginosis is very high or low as well as in the overall population.

## ONCOLOGY

### Randomized Trial Comparing Concurrent Radiotherapy With Cisplatin Compared With Paclitaxel in Cervical Cancer

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**OBJECTIVE:** Comparison of weekly cisplatin compared with paclitaxel as concurrent chemoradiotherapy for advanced cervical carcinoma.

**MATERIALS:** Thirty-one women were randomly assigned to receive weekly cisplatin 40 mg/m<sup>2</sup> (group I; 16 patients) or 50 mg/m<sup>2</sup> paclitaxel (group II; 15 patients) during pelvic irradiation. Patients with International Federation of Gynecology and Obstetrics stage IB2–IVA, were eligible for enrollment. External beam radiation to 40 Gy in 20 fractions followed by high-dose-rate brachytherapy was administered. Median dose to point A was 74 Gy for group I and 65 Gy for group II. Median follow-up was 23 months.

**RESULTS:** Age, performance status, disease stage, mean tumor diameter, mean number of chemotherapy cycles (4.6 0.9 compared with 4.3 1.3), mean duration of radiation (53.1 9.9 compared with 55.8 9.0 days;  $P = .55$ ), and mean time to progression (37.7 compared with 32.3 months;  $P = .56$ ) were similar in both groups. Five patients (33.3%) of group IVs 8 (53%) in group II experienced tumor relapse. Pelvic control rates at 2 years were 60% and 62.5% in groups I and II, respectively ( $P = .76$ ). Survival rates at 3 years were 49.0% compared with 50.9% for groups I and II ( $P = .37$ ). Two patients in group I had grade II transient peripheral neuropathy. In group II, chemotherapy was discontinued in 2 patients because of severe allergic reactions. Grades III and IV diarrhea occurred in 37% and 54% in groups I and II, respectively ( $P = .27$ ).

**CONCLUSION:** Paclitaxel is equivalent to cisplatin as weekly concurrent chemoradiation for advanced carcinoma of cervix. Distant failure remains high in both.



# Ovarian Cancer Risk Assessment

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**OBJECTIVE:** To determine whether menopausal status, CA 125, and prealbumin can be used to accurately predict the likelihood of ovarian cancer in women with pelvic masses.

**METHODS:** A prospective cohort study with 130 consecutive patients 18 years or older referred for management of a pelvic mass. Preoperative serum CA 125, prealbumin, and menopausal status were determined. These results were formulated into the ovarian cancer risk assessment index and then compared with final surgical pathology.

**RESULTS:** A total of 129 of 130 women underwent exploratory surgery for a pelvic mass. For all types of cancer ( $n = 67$ ), including nongynecologic and borderline ovarian tumors, the ovarian cancer risk assessment index had a sensitivity of 96%, specificity of 95% and positive predictive value of 95% (60/63). Ovarian cancer specifically was found in 49 patients. When the ovarian cancer risk assessment index cutoff value of 200 was evaluated for its ability to predict ovarian cancer, the sensitivity was 100%, specificity was 83%, and positive predictive value was 78%.

**CONCLUSION:** The ovarian cancer risk assessment index is able to correctly predict preoperatively which women with a pelvic mass are likely to have ovarian cancer. It can be easily applied clinically and may help facilitate the appropriate referral of women to gynecologic oncologists for proper care. The ovarian cancer risk assessment has been shown to be a better predictor than other indices.

## PRIMARY CARE

### Reasons for Use of a Women's Emergency Care Facility for Nonemergent Problems

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Sherry Weitzen, PhD, Donna LaFontaine, MD, and Andrea Montagno, MSN, RNC

**OBJECTIVE:** Given the problem of emergency room overcrowding, this study was designed to investigate why women with medically nonemergent conditions seek care in a primarily obstetric and gynecologic emergency facility

**METHODS:** Data were collected from 188 women presenting to the Women and Infants Hospital Emergency Room determined to be "nonemergent" by trained triage staff and who consented to participate. Participants completed a survey about their reasons for choosing the emergency room for care, current symptoms, health history, and de-

mographic characteristics. Data were analyzed using STATA.

**RESULTS:** Among women completing the survey, the mean age was 26.6 years, and 73% reported no past medical conditions. Eighty-three percent had a regular physician and 35% had sought care in this emergency room for nonpregnancy related problems in the past year. Forty-three percent of women were told to present to the emergency room by their physician. Only 35% of participants felt they had a true emergency. The most common symptoms were pelvic pain (40%), vaginal bleeding (23%), vaginal discharge (14%), and headache (10%).

**CONCLUSION:** In this nonemergent population seeking care in a primarily obstetric and gynecologic emergency facility, the majority had a regular physician and identified themselves as not having a true emergency. A less acute setting may have been appropriate for their care. Emergency facility overcrowding has a negative effect on patient care. Identifying why women seek care in this setting for nonemergent conditions may help to formulate strategies to reduce the volume of such visits and potentially improve patient care.

### A New Tool for Assessing the Folate Status of Reproductive-Aged Urban Latina Women

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Carolyn Westhoff, MD, MS

**OBJECTIVE:** Reproductive-aged women should consume 400  $\mu\text{g}$  of dietary folate equivalents daily to reduce the incidence of fetal neural tube defects. The mean reported daily dietary intake in this population ranges from 325  $\mu\text{g}$  to 718  $\mu\text{g}$  of dietary folate equivalents; reported consumption is lower in nonwhite, young women. The Willett Food Frequency Questionnaire, Version 88GP, is a validated food recall tool that assesses nutrient intake using a 4-page, 126-food-items questionnaire. We evaluated whether a shorter, simpler, focused Food Frequency Questionnaire performed as well as the Willett.

**METHODS:** We developed a short Food Frequency Questionnaire that assessed intake of the 53 folate-rich foods most commonly eaten by our clinic population. We administered both the shortened Food Frequency Questionnaire and the Willett Food Frequency Questionnaire to 100 English-speaking, Hispanic women seeking pregnancy testing at a family planning clinic.

**RESULTS:** Participants, reporting on the past week's diet, consumed a mean of 403  $\mu\text{g}$  of dietary folate equivalents according to the Willett Food Frequency Questionnaire and 718  $\mu\text{g}$  of dietary folate equivalents according to the shortened questionnaire (correlation coefficient 0.79, 95% confidence interval 0.70–0.85). Using the shortened questionnaire, 68% of subjects met the recommended daily allowance of folate, whereas 36% met the recommended daily allowance on the Willett.

**CONCLUSION:** Most of our population consumes more than the recommended folate allowance. The shortened



Food Frequency Questionnaire focuses on folate-rich foods consumed by urban, reproductive-aged Latina women. It correlates well with the “gold standard” Willett Food Frequency Questionnaire; however, the short Food Frequency Questionnaire seems to be more sensitive. A short Food Frequency Questionnaire focusing on folate-rich foods is easier for patients to complete and may provide a better estimate of their folate intake.

## An Evaluation of Lamotrigine on Mood in Women With Epilepsy and Comorbid Depressive Symptoms

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**OBJECTIVE:** This analysis evaluated the effects of the anti-epileptic drug lamotrigine on mood in a subset of women with epilepsy and comorbid depressive symptoms from a larger study.

**METHODS:** In this multicenter open-label study, lamotrigine was added onto a stable antiepileptic drug regimen in the adjunctive phase and became a single agent in the monotherapy phase. Patients were eligible if they had epilepsy, exhibited at least minimal depressive symptoms (Center for Epidemiological Studies Depression Scale 12 or greater) but excluded if they had major depression determined by a Mini International Neuropsychiatric Interview. Patients were evaluated using the Beck Depression Inventory-II, Center for Epidemiological Studies Depression Scale, and Profile of Mood States at baseline, end of adjunctive phase (week 19) and end of monotherapy phase (week 36).

**RESULTS:** A total of 102 women (mean age 38.6 years) were evaluated of a total population of 159. Sixty-six patients completed the adjunctive phase, and 46 completed the monotherapy phase. Mild or moderate depression was present at baseline, which improved to mild or minimal after lamotrigine therapy. Mean baseline, end of adjunctive, and monotherapy scores for the Beck Depression Inventory-II were: 18.3, 12.5, and 8.1, respectively; for the Center for Epidemiological Studies Depression Scale, 25.7, 16.3, and 12.3, respectively; and for total Profile of Mood States were 57.7, 39.1, and 24.1, respectively. All change scores from baseline were highly significant at  $P < .001$ . The most common adverse events were headache, dizziness, nausea, insomnia, and back pain. These results were consistent with those of the entire study population.

**CONCLUSION:** The addition of lamotrigine to antiepileptic drug therapy demonstrated antidepressant activity in this subgroup of women with epilepsy.

## UROGYNECOLOGY

### Wound Infections in Patients With Interstim Sacral Nerve Stimulators

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Blair Washington, MD, and Brian Hines, MD

**OBJECTIVE:** To identify risk factors for the development of wound infections in patients with an Interstim sacral nerve stimulator and to describe the management of these infections.

**METHODS:** The charts of 53 patients who underwent Interstim implantation were reviewed. Regression analysis was performed and odds ratios were calculated to identify variables that were associated with the development of wound infection.

**RESULTS:** Wound infections developed in 9.4% (5/53) of patients. The interval between implantation and the development of symptoms was 2–44 weeks, with a median of 6 weeks. All patients were initially managed conservatively with antibiotics for 3–5 weeks, and then all patients had the implant removed. Wound cultures were obtained. All 5 patients underwent reimplantation of the implant on the contralateral side. Body mass index more than 35 was significantly associated with the development of a wound infection, odds ratio 2.7, 95% confidence interval 1.1–4.3.

**CONCLUSION:** Patients with a body mass index more than 35 are at increased risk for wound infection after Interstim implantation. Wound infections may present remote from the initial surgery. Most infections require removal of the neurostimulator.

### Vaginal Paravaginal Repair With a Polypropylene Mesh Graft

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**OBJECTIVE:** The objective of this study was to describe outcomes of a technique of vaginal paravaginal repair using a polypropylene mesh graft in patients with recurrent stage III/IV anterior vaginal wall prolapse.

**METHODS:** This was an observational study. Twenty-four women underwent a vaginal paravaginal repair using a polypropylene graft. The same surgeon performed all of the repairs. Pelvic organ prolapse was staged according to the pelvic organ prolapse quantification system. Outcomes measured included recurrence of prolapse, changes in functional status, and surgical complications. Risk factors for recurrent anterior wall prolapse were evaluated.

**RESULTS:** The mean age was 71.2 years, and all patients had previously undergone a standard anterior colporrhaphy and now had either stage III or IV prolapse. Patients were evaluated at 6-month intervals, and the median length of



follow-up was 18 months. Postoperatively, 4 women had asymptomatic stage II anterior wall prolapse, for a failure rate of 18%. No risk factors for recurrent anterior wall prolapse were identified. Pelvic pressure resolved in 20 of 23, urinary frequency resolved in 17 of 23, and urgency resolved in 18 of 23 ( $P < .05$ , 2-tailed Fisher exact test). Eleven women were sexually active preoperatively, and 3 reported postoperative dyspareunia. Complications included 2 erosions of the mesh into the vagina.

**CONCLUSION:** Vaginal paravaginal repair with a polypropylene mesh graft is associated with very good anatomic cure rate, significant improvements in functional status, and a low rate of complications.

## Predicting Voiding Dysfunction After Incontinence Surgery

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**OBJECTIVE:** To determine whether age, body mass index (BMI) or ethnicity affected length of catheterization after incontinence surgery or affected postoperative complications.

**METHODS:** This was a retrospective study of 134 women who underwent incontinence procedures between January 2003 and April 2005. All patients who underwent incontinence surgery and had complete medical records available for review were included. Type of surgery, age, ethnicity, BMI, days of postoperative catheterization, and complications were analyzed. Statistical analysis was performed with a variance type of modeling performed in a stepwise fashion. A subanalysis was also performed using logistic regression on patients who had postoperative complications.

**RESULTS:** A total of 134 patients were reviewed. There was no association between age ( $P = .271$ ), ethnicity ( $P = 9.70$ ), or BMI and length of catheterization. There was a slight association between surgery types and days of catheterization ( $P = .05$ ); however, this became nonsignificant when controlling for age. The postoperative complications included 7% with a urinary tract infection, 13% with urinary retention, .8% wound separation, 3% cuff abscess, and 2% with takedown of the incontinence procedure. Logistic regression revealed no correlation between age, ethnicity, or BMI and complications. There was an association between complications and more extensive surgery.

**CONCLUSION:** There was no correlation between age, BMI, or ethnicity and length of catheterization and complications. There was an association between type of surgery (additional procedures) and complications.

## Urethral Diverticulum, Vesicovaginal, and Rectovaginal Fistula Repairs Using a Xenograft

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*Amber Cohn, MD*

**BACKGROUND:** Urogenital and rectovaginal fistulae are significant, although uncommon, complications of gynecologic surgery, and fistula repair can be a challenging surgery for even the most experienced gynecologist. An interposition xenograft (acellular bovine collagen matrix), derived from bovine pericardium, has been used to accomplish successful repairs.

**CASE:** The first patient developed a vesicovaginal fistula after an abdominal hysterectomy, and a successful laparoscopic repair was accomplished using an interposition xenograft. The second patient presented with a vesicovaginal fistula after a transvaginal tape procedure, the third patient presented with a urethral diverticulum resulting in a urethrovaginal fistula, and both had a successful transvaginal repair with an interposition xenograft. The fourth patient presented with a rectovaginal fistula as well as vaginal vault prolapse and a long history of a pessary use, and the fifth patient developed a rectovaginal fistula 17 years after a forceps delivery. After 2 previous unsuccessful repairs, a successful transvaginal repair was accomplished in both using an interposition xenograft.

**CONCLUSION:** Using an interposition xenograft may be a successful option in urogenital and rectovaginal fistula repair.

## A Randomized Comparison of GYNECARE TVT and Boston Scientific Lynx Suprapubic Mid-Urethral Sling

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**OBJECTIVE:** A randomized prospective comparison of 2 synthetic slings was undertaken to evaluate efficacy, complication rates, and training of residents.

**METHODS:** Eighty-three women with stress urinary incontinence were consecutively assigned to GYNECARE TVT tension-free vaginal tape or Lynx Suprapubic Mid-Urethral Sling between January 2004 and August 2005. Intraoperative complications, ease of trocar placement, postoperative voiding difficulties, subjective and objective cure rates, and postoperative interventions were assessed.

**RESULTS:** Both groups were similar in mean age, parity, weight, preoperative post-void residual, cystometric capacity, flow rate, and urethral closure pressures. Postmenopausal status and previous surgery rate was also compara-



ble. One half of the patients underwent multiple procedures. Trocar injuries were 2 and 3, respectively. Early postoperative voiding dysfunction was 24% compared with 17% ( $P < .001$ ), whereas prolonged catheterization for 2 weeks was similar at 5%. Urinary tract infection rate was (11% compared with 15%, respectively,  $P = .02$ ). Subjective cure rates were 93% for both. Urethral closure pressure less than 14 cm H<sub>2</sub>O was the identifiable risk for failure. Objective cure rates were 97.5% and 95.3%, respectively, suggesting that the subjective failure was likely due to overactivity. One sling in the Lynx group was removed for skin cellulites, and 1 sling slit in the TVT group for voiding dysfunction due to duplicated ureter.

**CONCLUSION:** Despite similar efficacy, complication rates and failure rates, the incidence of postoperative voiding difficulties was better with Lynx, likely due to midurethral seal, but it was difficult to place the Lynx trocar in patients with prior surgeries, probably due to the blunt needle and notch. Residents favored the Lynx trocar due to its light weight and greater stability.

## Modified Perineoplasty and Sphincteroplasty for the Treatment of Fecal Incontinence

### A Case Series

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**OBJECTIVE:** This study was undertaken to collect preliminary data on outcomes of a new surgical procedure for the treatment of fecal incontinence.

**METHODS:** This is a retrospective study of 20 women with fecal incontinence and anterior external anal sphincter disruption who underwent a modified perineoplasty and sphincteroplasty for the treatment of fecal incontinence. The sphincteroplasty was performed in an overlapping manner, and the perineoplasty was performed in a standardized fashion.

**RESULTS:** Before surgery, 15 (100%) women reported incontinence of flatus, 15 (100%) reported incontinence of liquid stool, and 10 (67%) reported incontinence of solid stool. Number of incontinence episodes per week ranged from 1 to 8, with a mean of 3. Four women had prior surgery for fecal incontinence, including sphincteroplasty (3) and rectocele repair (1). Eleven (73%) were completely continent at 1 year and 18 months after surgery. Ten (100%) women who reported incontinence of solid stool before surgery were continent of solid stool at 18 months. Of women with preoperative incontinence of liquid stool, 14 (93%) were continent at 18 months. One (7%) reported a significant decrease in incontinence episodes per week. Fourteen (93%) women with preoperative complaint of incontinence of flatus were continent at 1 year, but only 11 (73%) were continent of flatus at 18 months.

**CONCLUSION:** The modified perineoplasty and sphincteroplasty seems to have good short-term efficacy in treating fecal incontinence in women with known external anal sphincter disruption.

## The Effect of Childhood Dysfunctional Voiding on Urinary Incontinence in Adult Women

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**OBJECTIVE:** To estimate whether a history of childhood dysfunctional voiding is associated with urinary incontinence in adulthood.

**METHODS:** Using a case-control study, we surveyed patients presenting with or without urinary incontinence. Cases were patients referred to a tertiary urogynecology clinic, and controls were patients referred to a general gynecology clinic. Patients completed a validated childhood questionnaire on dysfunctional voiding. A total score of 6 or more in girls is indicative of dysfunctional voiding; a condition characterized by urgency, frequency, constipation, urinary or fecal incontinence, or urinary tract infections. Using an  $\alpha$  of 0.05, a power of 80%, and a baseline prevalence of dysfunctional voiding of 8%, 170 patients were needed to show a 3-fold difference between groups.

**RESULTS:** Cases ( $n = 84$ ) and controls ( $n = 86$ ) had similar baseline characteristics except for body mass index and incidence of previous pelvic surgery. Although the total dysfunctional voiding score was higher in cases compared with controls (7.3 compared with 5.0, respectively;  $P = .001$ ), the difference in the number (%) of patients with history of childhood dysfunctional voiding between the 2 groups was not significant: 47 (56%) compared with 36 (42%), respectively; odds ratio 1.76, 95% confidence interval 0.96–3.24,  $P = .07$ . When all patients from both groups were combined, there was a higher prevalence of a history of childhood dysfunctional voiding in women with or without current urinary frequency ( $P = .004$ ), urgency ( $P = .03$ ), stress incontinence ( $P = .01$ ), and urge incontinence ( $P = .009$ ).

**CONCLUSION:** Women with adult lower urinary tract symptoms may have a higher prevalence of history of childhood dysfunctional voiding.



## ULTRASOUND

# Evaluation of Two Methods of Three-dimensional Fetal Volume Acquisition

## *Single-Pass Compared With Double-Pass Ultrasonography*

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**OBJECTIVE:** To compare a single-pass and double-pass technique for 3-dimensional ultrasound acquisition using several methods of antepartum weight estimation. A double-pass technique images the fetus from both the maternal left and right for 3-dimensional reconstruction, thus potentially improving resolution of deep fetal structures for measurement at term.

**METHODS:** An ATL 3500 and TomTec 3-dimensional system was used to image 32 patients at term within 1 week

of delivery. This system combines the ultrasound video with a position sensor to reconstruct a 3-dimensional volume. The transducer was moved either in a single pass once along the long axis of the fetus, or alternately up and then down the anterolateral aspect of the maternal abdomen to provide a complete fetal volume in a double pass. Delivery weight was then correlated with a 3-dimensional disk summation or rotational technique and standard 2-dimensional composite biometric method.

**RESULTS:** Correlations of fetal volumes with actual delivery weight for the single-pass method were 0.64 and 0.44 using the disk summation and rotational calculation techniques, respectively. The correlations using the double-pass method were 0.52 and 0.24 using the same techniques. Standard composite biometric measurement correlation with actual fetal weight was 0.79.

**CONCLUSION:** Although the double-pass technique should allow better visualization of the deep areas of the fetus, and thus improve accuracy of fetal volume determination, neither the disk summation nor rotational method provided better correlation with fetal weight when done with the double-pass technique.

