Speculum Gel Doesn't Compromise Cytology

BY HEIDI SPLETE
Senior Writer

WASHINGTON — Gel lubrication to ease the pain of vaginal speculum insertion does not adversely affect the quality or viability of cervical samples, William Griffith, M.D., reported at the annual meeting of the Association of Reproductive Health Professionals.

The results of his randomized study of 3,460 Pap smears and 5,535 combination DNA probe assays appear to refute dogma long etched in textbooks that warns clinicians to beware of gel lubrication because of purported interference with cervical microbiology or with interpretation of a Pap smear.

Results appear to refute longtime dogma that warns clinicians to beware of gel lubrication because of purported interference with cervical microbiology.

The study found no statistically significant difference in the integrity of samples when vaginal insertion was aided by a dime-sized dab of a water-soluble bacteriostatic gel lubricant, compared with samples in which water was used as a lubricant, Dr. Griffith of the University of Texas Southwestern Medical Center in Dallas said.

He cited data suggesting that the pain of speculum insertion may lead women to delay pelvic exams—87% reporting it a "significant barrier"—and called for efforts to minimize that pain. Dr. Griffith said he had no financial interest in the bacteriostatic gel product.

The study included 9,500 women, 20-44 years old, who underwent pelvic examinations involving a vaginal speculum from July 2003 to February 2004 at a rural family planning clinic. Each of the 8 months was randomly designated as a "gel month" or a "water month," and the assigned lubrication method was used on all patients that month. A total of 6,538 women had a Pap smear or a DNA assay to screen for sexually transmitted disease, or both.

There were 20 unsatisfactory Pap smear samples among 1,828 women screened during the gel months (1.1%), compared with 24 unsatisfactory samples among 1,632 women screened during the water lubricant months (1.5%). The difference between groups was not statistically significant.

In addition, the type of speculum lubricant did not affect chlamydia and gonorrhea detection rates.

Chlamydia was detected in 44 of 2,909 patients (1.5%) screened by combination DNA probe during the gel months and 28 of 2,626 patients (1.1%) screened during the water months, resulting in equal detection rates.

Gonorrhea detection rates were also similar: No cases of gonorrhea were detected among patients examined during the gel lubricant months, compared with 3 (0.1%) during the water lubrication months. ■

Depo-Provera Gets Black Box for BMD Loss With Long-Term Use

The U.S. Food and Drug Administration has added a black box warning to Depo-Provera to emphasize the potential for bone mineral density loss with long-term use of the injectable contraceptive.

Depo-Provera has been used throughout the world for decades and remains a safe and effective method of birth control, the FDA said in a statement. However, a recent review of the drug's long-term effects on bone mineral density (BMD) by the FDA and Pfizer Inc., which manufactures the drug, prompted the addition to the label.

Physicians should encourage patients to consider other contraceptive options for long-term use.

The black box warning notes that women who use Depo-Provera may experience a significant decrease in BMD that might not be completely reversible after discontinuing use. Consequently, Depo-Provera should be used as a long-term birth control method (more than 2 years) only if other methods are inadequate.

The warning also states that it's not known whether Depo-Provera use during adolescence or early adulthood will reduce peak bone mass and increase the risk of osteoporotic fracture in later life.

Since the U.S. approval of Depo-Provera in 1992, the prescribing information has included a warning that use of the contraceptive may be considered among the risk factors for development of osteoporosis, Pfizer noted in a statement. Additional clinical research was initiated in the 1990s to clarify the effects of Depo-Provera on BMD. Results of those studies were considered in the review and led to the labeling revisions.

One of the studies included 540 women aged 25-38 years who used Depo-Provera for 5 years and were then followed for 2 years.

The review also included data from an ongoing study of nearly 400 adolescents aged 12-18 years that will end in 2006 after 5 years of treatment and 2 years of follow-up, said Pfizer spokesperson Rebecca Hamm.

Physicians should encourage patients to consider other contraceptive options for long-term use, Ms. Hamm noted.

If women choose to continue using Depo-Provera long-term, physicians should consider periodic BMD tests and advise these patients to take calcium supplements, quit smoking, and engage in moderate exercise to help prevent BMD loss, she said.

—Heidi Splete

CLINICAL CAPSULES

Long-Term Irritable Bowel Therapy

Alosetron provides significant long-term relief for women with symptoms of severe, chronic, diarrhea-predominant irritable bowel syndrome, reported William D. Chey, M.D., of the University of Michigan, Ann Arbor, and his associates.

Compared with 290 patients randomized to placebo, significantly more of 279 patients randomized to the selective 5-HT_3-receptor antagonist alosetron (Lotronex) had adequate relief from irritable bowel syndrome (IBS) pain and discomfort (44% vs. 52%) and satisfactory urgency control rates (52% vs. 64%) after 48 weeks of treatment (Am. J. Gastroenterol. 2004;99:2195-203).

Significantly more alosetron patients reported adequate relief from IBS pain and discomfort as well as satisfactory urgency control rates regardless of whether they did or did not use rescue medication such as laxatives and antidiarrheals. But the two groups did not differ in rates of satisfactory control of stool frequency and consistency when rescue medications were used.

Constipation occurred significantly more often in alosetron (23%) than in placebo patients (5%), although in most cases it was a single episode that developed in the first month of treatment.

Endometritis and BV Linked

Bacterial vaginosis–associated organisms found frequently in women with pelvic inflammatory disease also were strongly associated with endometritis, Catherine L. Haggerty, Ph.D., of the University of Pittsburgh and her colleagues reported.

The investigators looked at the associations between endometritis and *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, anaerobic bacteria, facultative bacteria, lactobacilli, and bacterial vaginosis (BV) in 278 women from the PID Evaluation and Clinical Health Study.

Those who had acute endometritis were more likely to be infected with *C. trachomatis* (odds ratio [OR] 16.2), *N. gonorrhoeae* (OR 11.6), diphtheroids (OR 5.0), black-pigmented gram-negative rods (OR 3.1), and anaerobic gram-positive cocci (OR 2.1), they reported (Clin. Infect. Dis. 2004:39;990-5).

The associations between acute endometritis and black-pigmented gram-negative rods, anaerobic gram-positive cocci, and BV remained significant after excluding the 41% of women who were infected with *N. gonorrhoeae* and/or *C. trachomatis*.

Treatment in most PID patients is directed at *N. gonorrhoeae* and *C. trachomatis*, but these account for fewer than half of all cases. The frequency of BV-associated organisms in PID patients suggests that treatment with a regimen containing metronidazole to improve anaerobic coverage is warranted, the investigators said.

HIV: What Women Don't Know

Many women aged 50 years and older lack appropriate knowledge about HIV transmission and prevention, according to findings published in the September issue of the Journal of the American Geriatrics Society. Nearly two-thirds of women incorrectly identified kissing as a mode of HIV transmission, 76% overestimated oral sex as a mode of HIV transmission, and only 13% identified condoms as effective in preventing HIV. The study was based on a survey of 514 women at a hospital in Atlanta (J. Am. Geriatr. Soc. 2004;52:1549-53).

"The problem is that they don't realize that they're at risk for this life-threatening disease," said Lisa Bernstein, M.D., of Emory University, Atlanta, and one of the study's lead authors.

"Physicians have a tremendous role to play in educating patients—even those who are older than we normally think to be at risk." Health care providers need to talk to their older female patients about HIV risk factors and the basics of HIV transmission and prevention, the authors concluded.

Elective Induction and C-Section Rate

Elective induction does not adversely affect the C-section rate or maternal fetal morbidity, said David J. Bonilla, M.D., and colleagues in a poster presentation at the annual meeting of the American College of Obstetricians and Gynecologists' District VII in Washington.

They conducted a retrospective cohort study of 361 nulliparous patients between 37 and 41 weeks' gestation who had singleton pregnancies, with no medical indications for delivery.

Patients were divided into a spontaneous labor group and another group that had elective induction with a favorable cervix (Bishop score 5 or greater), according to the research team, headed by Dr. Bonilla of the Ochsner Clinic Foundation, New Orleans.

The C-section rate was 9.7% for 114 patients who had elective induction with a favorable cervix vs. a rate of 17.3% for 247 patients who had spontaneous labor. The induction group had a slightly higher rate of instrumental delivery, compared with the spontaneous labor group (31.88% vs. 22.6%).

There was a slight increase in admissions to the neonatal intensive care unit in the elective induction group, compared with the other group (1.45% vs. 3.23%), but it was not significant.

—From staff reports