

## Comfortable Intercourse for Breast Cancer Survivors With Dyspareunia: Use of Topical Lidocaine to Vulvar Vestibule

Written by Mary Beth Nierengarten

For breast cancer survivors who experience moderate or severe penetrative dyspareunia associated with vulvovaginal atrophy, application of a topical liquid lidocaine to the vulvar vestibule prior to penetration can prevent pain and offer these women comfortable intercourse.

Martha F. Goetsch, MD, MPH, of Oregon Health and Science University, Portland, Oregon, USA, reported outcomes of the Therapy to Prevent Sexual Pain in Breast Cancer Survivors trial (NCT01539317). This was a randomized, controlled, double-blind trial that was conducted to examine whether the use of an analgesic liquid to the vulvar vestibule in estrogen-deficient breast cancer survivors with moderate to severe dyspareunia could prevent pain from penetrative intercourse.

Forty-six estrogen-deficient breast cancer survivors were randomized to 4 weeks of either 4% liquid lidocaine or saline to be applied to the vulvar vestibule for 3 minutes prior to vaginal penetration. Study participants used a diary to document twice-weekly vaginal penetration by either intercourse or tampon insertion. This intervention phase of the study was followed by an 8-week open-label trial in which all patients received lidocaine.

The primary outcomes of the study were penetration pain (from either intercourse or tampon use) measured on a scale from 0 to 10, sexual distress as assessed by the Female Sexual Distress Scale (abnormal >11), and resumption of intercourse.

All women in the study had moderate to severe penetrative dyspareunia for more than 6 months. Women with significant pelvic muscle or organ pain, and those with vulvar dystrophy, were excluded from the study.

The study showed that during the 1-month intervention phase, women who used lidocaine had significantly less pain during intercourse compared with those who used saline (median score, 1.0 vs 5.3;  $p=0.015$ ).

After the 8-week open-label part of the study, completed by 41 of the 46 women, 90% (37 of 41) reported comfortable penetration as indicated by median scores of 0 and 1, and a significant decrease in the sexual distress score from a median of 30.5 at baseline to 14 (interquartile range, 3 to 20;  $p<0.001$ ). Of the 20 women who abstained from sex prior to the study, 17 (85%) resumed intercourse after the study.

Prof. Goetsch emphasized that these results suggest that dyspareunia is more of a pain condition than one of atrophy, because the atrophy remained unchanged in these women. She also emphasized that successfully managing penetrative pain was achieved by targeting analgesic treatment to the vulvar vestibule, suggesting that the treatment target should be the vestibule, not the vagina.

In conclusion, the study shows that women can prevent their own pain from intercourse by using the lidocaine solution.

## Low Perforation Rates With Intrauterine Devices Regardless of Device Type

Written by Mary Beth Nierengarten

The risk of perforation from the use of intrauterine devices (IUDs) is low and similar for levonorgestrel-releasing (LNG) IUDs and copper IUDs. Compared with copper IUDs, however, LNG-IUDs were noted to have a significant reduction in the incidence of pregnancy, including a marked reduction in ectopic pregnancy.

Klaas Heinemann, MD, PhD, MBA, of the Berlin Center for Epidemiology and Health Research, Berlin, Germany, presented the results of the European Active Surveillance Study for Intrauterine Devices (EURAS-IUD; NCT0046/1175), a large, multinational, prospective, controlled, noninterventional study, conducted to compare the risk of perforation during and after insertion of 2 types of IUDs: LNG-IUDs and copper IUDs.

Between 2006 and 2013, more than 60,000 women from 6 European countries were enrolled in the study and divided into 2 cohorts: those using LNG-IUDs ( $n=43078$ ) and those using copper IUDs ( $n=18370$ ).

Baseline characteristics between the 2 cohorts were comparable in body mass index, educational level, and medical and gynecological history. When stratified by age (<20 years, 20 to <30 years, 30 to <40 years, and 40 years), copper IUDs were used more often in women aged 20 to <30 years old (32% vs 15.9% for LNG-IUDs), and LNG-IUDs were used more often in women 40 years (43.6% vs 23.6% for copper IUDs). Women using copper IUDs also had higher rates of delivery at 12 months prior to IUD insertion (28.7% vs 19.8% for LNG-IUDs) and of breastfeeding at the time of insertion (14.6% vs 9.2% for LNG-IUDs).

To compare the perforation risk between the 2 cohorts, women and their attending physicians were asked to complete a questionnaire at 12 months



following IUD insertion. Along with documenting perforation or expulsion rates, the questionnaire also required documentation of IUD removal; adverse events, including pregnancy; and breastfeeding status.

At 12-month follow-up, the study found a total of 81 perforations in both cohorts with a comparable rate of perforations between the 2 cohorts. Women with the LNG-IUDs had 61 perforations (1.4 per 1000 insertions), and those with copper IUDs had 20 perforations (1.4 per 1000 insertions). After adjusting for risk factors (eg, age, body mass index, parity, time of last delivery), the incidence rates of perforations were 1.42 for LNG-IUD users and 1.09 for copper IUD users, representing a relative risk of 1.61 (95% CI, 0.96 to 2.70).

Dr. Heinemann emphasized that all perforations had benign outcomes, and none led to serious side effects.

Although the study showed no clinically relevant risk of perforations with either IUD type, Dr. Heinemann emphasized that drawing conclusions on the magnitude of the differences between the 2 IUD types in terms of perforation rates was difficult based on the observational design of the trial.

He did, however, highlight further findings of the study that showed that the use of LNG-IUDs was associated with a 10-fold reduction in the incidence of pregnancy as well as a marked reduction in ectopic pregnancy, compared with copper IUDs. Additional findings showed breastfeeding as a significant risk factor for perforation.

## Induction of Labor in Obese Women at 39 Weeks Provides Optimal Delivery and Cost Outcomes

Written by Mary Beth Nierengarten

Planning a vaginal delivery provides optimal delivery and cost outcomes, according to a study that used a computational model to estimate the effect of induction of labor compared to expectant management of term pregnancies in obese women. They found that induction at 39 weeks of gestation minimized cesarean deliveries, stillbirths, and delivery-related health care costs.

Lisa Gill, MD, of the Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, Minnesota, USA, reported the outcomes of the study, which used a decision analysis model to evaluate the optimal timing of delivery and cost outcomes in a hypothetical cohort of 100,000 pregnancies in obese patients. The model used existing data to predict outcomes (ie, stillbirths, cesarean deliveries, and delivery-related health care costs) from routine induction at 39

weeks of gestation compared with expectant management and routine induction at 40, 41, and 42 weeks.

The data used in the model were extracted from previously published research on the likelihood of spontaneous labor, the rate of cesarean section with spontaneous and induced labor, and the risk of stillbirth by gestational age in obese patients. Study data that pertained to health care costs associated with vaginal or cesarean delivery were also extracted from previously published data.

The study found that routine induction at 39 weeks of gestation was associated with a decreased number of stillbirths, a reduction in cesarean sections, and significant cost savings when compared with delivery at 40, 41, and 42 weeks via expectant management or induction of labor.

Compared with the worst-case model of expectant management with induction at 42 weeks, 387 stillbirths as well as 10,035 cesarean deliveries were avoided by routine induction at 39 weeks, with a savings in hospital costs of \$29.3 million.

Comparing outcomes of induction at 39 weeks with the 2 worse-case models of expectant management and induction at 40 or 41 weeks, more than 9000 cesarean deliveries were avoided (30,888 vs. 40,025 and 40,122, respectively).

Dr. Gill emphasized that although the study indicates a benefit of early induction of labor at 39 weeks for obese patients, she cautioned that the results are limited by the computational nature of the study and its potential for biases that may have been present in the studies that were used to develop the model. She also cited a recently published study that reported the opposite findings: that obese women induced at 39 weeks had a significant increase in cesarean delivery when compared to expectant management [Wolfe X et al. *Am J Obstet Gynecol* 2014].

She emphasized the need for a prospective trial to better understand the optimal timing for delivery in obese women and mentioned a trial currently under development that will help to address this question (NICHD ARRIVE; NCT01990612).

## No Disadvantages Associated With Abdominal Binder Use After Cesarean Section

Written by Toni Rizzo

Abdominal binders are effective for improving postoperative pain and distress following major abdominal surgery. An abdominal binder is a surgical body