CLINICAL TRIAL HIGHLIGHTS

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 deliveryrelated 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



garment used in the early postoperative phase to support the abdomen. The use of abdominal binders in women recovering from a cesarean section has never been studied. The purpose of the Use of Abdominal Binders in Patients Undergoing Caesarean Sections randomized, open-label efficacy study (NCT02129894), presented by Jennifer R. Myers, DO, of St. Luke's University Health Network, Bethlehem, Pennsylvania, USA, was to evaluate the efficacy of abdominal binders for alleviating postpartum pain and distress following a cesarean section.

The study participants were drawn from the population of all women aged 18 to 50 years who were admitted to the labor and delivery department at 2 hospitals from July 5, 2013, to November 28, 2013. Women who underwent cesarean section and provided informed consent were randomized to receive or not receive an abdominal binder for postsurgical use. On postoperative Days 1 and 2, the women were asked to complete a visual analog scale (VAS) for pain and the validated Symptom Distress Scale (SDS). Postoperative hemoglobin and hematocrit values and pain medication use were recorded. Data analysis was performed using Student's *t* test.

A total of 150 women were enrolled in the study. Baseline characteristics were well balanced between the binder and no-binder groups, including age (30.1 and 28.0 years, respectively), gravity (2.6 and 2.6), parity (0.9 and 0.8), number of prior cesarean sections (0.7 and 0.7), gestational age (38.8 and 38.5), and body mass index (34 and 32.5 kg/m2).

On postoperative Day 1, VAS scores were 3.0 in the binder group compared with about 3.75 in the no-binder group (Figure 1). On average, women in the binder group used almost 1200 mg of ibuprofen per day compared with 800 mg in the no-binder group.

On postoperative Day 2, VAS scores were significantly lower in the binder group compared with the no-binder group (p=0.010). Pain medication use was significantly lower in the no-binder group compared with the binder group (p<0.001).

There were no differences in SDS scores or hemoglobin and hematocrit values between the groups on postoperative Day 1 or 2. The dropout rate was much higher in the no-binder group than in the binder group.

The use of postoperative abdominal binders in women who underwent cesarean section was associated with a significantly lower VAS score on postoperative Day 2, but ibuprofen use was increased compared with women who did not use abdominal binders. There was no difference in patient distress between the 2 groups. The higher dropout rate in the no-binder group may suggest a preference for using abdominal binders. Given that there were no significant differences in most of the measurements and that there appears to be no medical disadvantages associated with the use of abdominal binders after cesarean section, Dr. Myers suggested that abdominal binders continue to be used postoperatively.



