allele carriage among Caucasian women, thin or obese women homozygous for the high-risk allele gained more weight than low-risk allele carriers; however, among women of average pregravid BMI, weight gain was similar regardless of allele carriage. These results suggest that it may be important to consider baseline BMI in longitudinal studies of genetic determinants of weight trajectory.

Multiple testing is a concern. To address this issue, we limited our analysis to candidate SNPs that have been validated in multiple large studies. Nevertheless, we recognize that some of our findings may be false positives.

In conclusion, we found evidence that maternal diabetes and obesity risk allele genotype interact with pregravid BMI to affect gestational weight gain. These results suggest that excessive or inadequate gain may be a marker for maternal genotype and that these differences in genetic risk may explain some observed associations between gestational weight gain and long-term health outcomes for mothers and infants. Further studies in larger cohorts will be needed to delineate further the

role of genotype in maternal weight gain during pregnancy.

CLINICAL IMPLICATIONS

- Genetic variants associated with diabetes and obesity in nonpregnant populations predict both gestational weight gain and risk for excessive weight gain.
- These variants may partially explain the relationship between excessive gestational weight gain and adverse health outcomes for mothers and infants.

Randomized controlled trial of wound complication rates of subcuticular suture vs staples for skin closure at cesarean delivery

Suzanne L. Basha, MD; Meredith L. Rochon, MD; Joanne N. Quiñones, MD, MSCE; Kara M. Coassolo, MD; Orion A. Rust, MD; John C. Smulian, MD, MPH

OBJECTIVE: The purpose of this study was to determine the wound complication rates and patient satisfaction for subcuticular suture vs staples for skin closure at cesarean delivery.

STUDY DESIGN: This was a randomized prospective trial. Subjects who underwent cesarean delivery were assigned randomly to stainless steel staples or subcuticular 4.0 Monocryl sutures. The primary outcomes were composite wound complication rate and patient satisfaction.

RESULTS: A total of 435 patients were assigned randomly. Staple closure was associated with a 4-fold increased risk of wound separation (adjusted odds ratio [aOR], 4.66; 95% confidence interval [CI], 2.0710.52; P < .001). Having a wound complication was associated with a 5-fold decrease in patient satisfaction (aOR, 0.18; 95% Cl, 0.09 – 0.37; P < .001). After confounders were controlled for, there was no difference in satisfaction between the treatment groups (aOR, 0.71; 95% CI, 0.34 - 1.50; P = .63).

CONCLUSION: Use of staples for cesarean delivery closure is associated with an increased risk of wound complications. Occurrence of a wound complication is the most important factor that influenced patient satisfaction.

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BACKGROUND AND OBJECTIVE

Approximately 2.5-16% of women who have a cesarean delivery will have a wound complication. Complications are disruptive for the new mother and increase health care costs. There are no data regarding the effects of skin closure method on wound healing at the time of cesarean delivery.

The purpose of our study was to compare wound complication rates and patient satisfaction for stainless steel staples vs subcuticular suture for wound closure at the time of cesarean section.

From the Department of Obstetrics and Gynecology, Lehigh Valley Health Network, Allentown, PA.

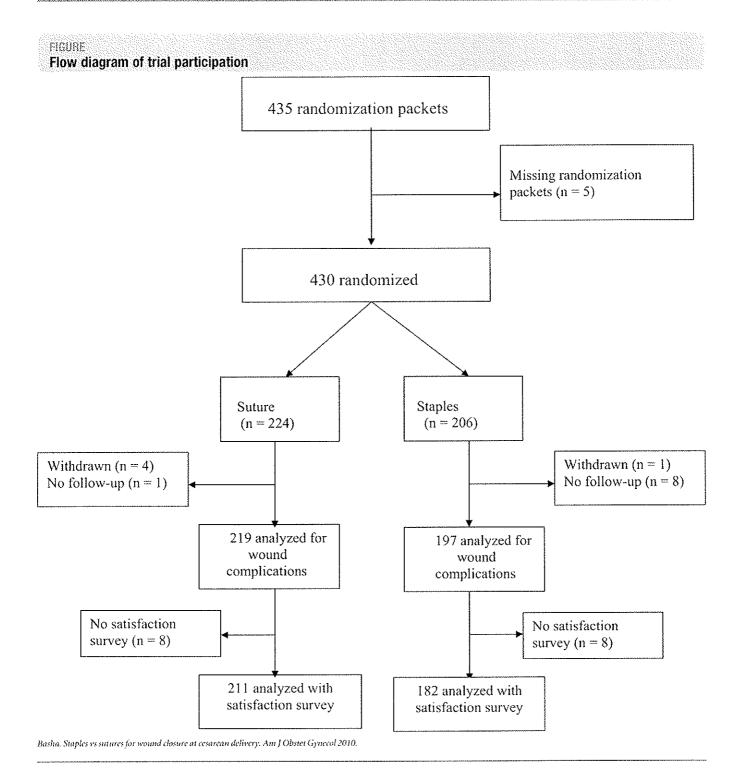
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MATERIALS AND METHODS

A randomized prospective clinical trial was conducted at Lehigh Valley Health Network in Allentown, PA. Eligible women were offered enrollment on admission to labor and delivery or the antepartum unit. Those who delivered by



cesarean delivery were assigned randomly to either suture or staple closure at skin incision, at which time a sequentially numbered, opaque, sealed enve-

Neither the patient nor the treating physician was blinded to closure method after randomization. Delivery data were collected from the medical record. Two

lope was opened by the circulating nurse.

to 4 weeks after surgery, patients were contacted for a telephone interview by a single investigator for a wound complication assessment and patient satisfaction survey.

Subjects who were assigned randomly to staples had their wound closed with stainless steel staples. Timing of staple removal after delivery was at the discretion of the obstetrician. Adhesive closure strips were placed with benzoin after staple removal. Subjects who were assigned randomly to sutures had their wound closed with subcuticular 4-0 Monocryl sutures on a PS2 needle, and adhesive closure strips were applied with benzoin in the operating room. Surgeons were in-

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structed to close the subcutaneous tissue if it was >2 cm in depth.

Details regarding wound complications after discharge were obtained at 2-4 weeks after delivery. Patients were asked to evaluate overall satisfaction with their wound outcome and desire to have the same skin closure for a future delivery and to assess pain and anxiety.

Our primary outcome was 2-fold: to compare a composite wound complication rate between sutures and staples and to assess patient satisfaction with the method of skin closure.

RESULTS

From March 13, 2008, through May 31, 2009, 430 women were assigned randomly to the 2 types of closure. Fourteen women subsequently were excluded for a final cohort of 416 women: 219 women in the suture group and 197 women in the staple group.

Baseline maternal characteristics were similar in both groups. Women who received staples were more likely to be undergoing repeat cesarean delivery (50% vs 39%; P = .03) or to have chorioamnionitis (9% vs 4%; P = .04). Peripartum medication use was similar in both groups.

Median operative time was 8 minutes longer in the suture group (57 vs 49 minutes; P < .001). Delivery outcomes were otherwise similar between groups.

The overall composite wound complication and wound separation rates for the entire cohort were 15.1% and 10.3%, respectively. Both wound separation and composite wound complication occurred significantly more often in the staple group (17% vs 5% and 22% vs 9%, respectively; P < .001 for both). Women in the staple group were more likely to be seen in the office for any reason before the postpartum visit (36% vs 11%; P < .001) and more likely to be seen for a wound problem (10% vs 5%; P = .03).

In unadjusted analysis, only wound closure with staples was found to be a

predictor of wound separation, with a relative risk of 3.67 (95% confidence interval [CI], 1.86–7.25; P < .001). This finding persisted after we controlled for potential confounders, with an adjusted odds ratio of 4.13 (95% CI, 1.87–9.11; P < .0001).

The satisfaction survey was completed by 91% of women (Figure). Overall, 87% of the women were satisfied with their wound closure, and 83% of the women indicated that they would request the same closure method in a subsequent delivery. Patient satisfaction was lower in women with any wound complication or a need to return to their provider before the 6-week postpartum visit. When we controlled for wound separation, there was no difference in satisfaction with wound closure between staple and suture closure methods (odds ratio, 0.68; 95% CI, 0.35–1.3; P = .27).

COMMENT

Our study is the first prospective randomized trial to be designed to compare wound complication rates between subcuticular sutures and stainless steel staples at the time of cesarean delivery. Our data suggest that women whose skin incision is closed with staples are more likely to have a wound separation than those whose incision is closed with 4-0 Monocryl subcuticular sutures that were placed according to our protocol.

Not surprisingly, we found that patients were less satisfied in the setting of a wound complication. However, when we controlled for wound complications, we also found no difference in satisfaction between the 2 closure groups.

Median operative time was 8 minutes shorter in the staples group, which is consistent with other studies. We do not believe that a difference of 8 minutes, although statistically significant, is clinically significant. We believe that the small increase in operative time is more than offset by the increased number of office visits that are required for both sta-

ple removal and management of incisional problems in the staple group.

Our study had many strengths that included its relatively large prospective randomized design and high rate of follow-up evaluation. Broad inclusion criteria allowed for generalizability, although this may be limited to populations with high rates of comorbidities. Performing the study at a single institution over a short time assured relative uniformity of care to minimize confounders. Follow-up evaluation of patients after discharge by telephone interview enabled us to capture complications that occurred after discharge.

In summary, the use of staples for cesarean delivery closure is associated with an increased risk for wound complications and postoperative visits. Despite the popular notion that patients prefer subcuticular closure, our data suggest that there is no difference in patient satisfaction at 2-4 weeks after delivery between sutures and staples and that the occurrence of a wound complication is the most important factor that influences patient satisfaction regarding cesarean incision. Therefore, subcuticular sutures may be the preferred method of skin closure for cesarean delivery.

CLINICAL IMPLICATIONS

- The use of staples for cesarean delivery closure is associated with an increased risk for wound complications and postoperative visits.
- Despite the popular notion that patients prefer subcuticular closure, our data suggest that there is no difference in patient satisfaction at 2-4 weeks after delivery between sutures and staples and that the occurrence of a wound complication is the most important factor to influence patient satisfaction regarding cesarean incision.
- Subcuticular sutures may be the preferred method of skin closure for cesarean delivery.