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

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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], 2.07–10.52; $P < .001$). Having a wound complication was associated with a 5-fold decrease in patient satisfaction (aOR, 0.18; 95% CI, 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.

Key words: cesarean delivery closure, patient satisfaction, staple, suture, wound complication

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The cesarean delivery rate in the United States has been rising steadily, from 24% in 1995 to 31% in 2007.[1] With this rise, there has been a concomitant increase in cesarean delivery complications. Approximately 2.5-16% of women who have a cesarean delivery will have a wound complication, which includes seroma, hematoma, wound infection, wound separation, and wound dehiscence.[2] Complications are disruptive for the new mother and increase health care costs.

Risk factors that are associated with cesarean delivery wound complications include maternal medical disease, preeclampsia, obesity, infection, frequent vaginal examinations, internal monitors, and a need for emergent cesarean delivery.[2] Failure to close or drain the subcutaneous tissue >2 cm in thickness has also been associated with increased wound complication rates.[3,4] However, there are no data regarding the effect of skin closure method on wound healing at the time of cesarean delivery. The data on skin closure technique that are available are limited to postoperative pain, cosmesis, and patient satisfaction.[5-7]

The ideal skin closure would be safe and effective, associated with minimal patient discomfort, and have a good cosmetic result. It would also be inexpensive and require fewer health care resources by being fast and easy to apply, require minimal follow-up evaluation, and be associated with a low rate of complications. Methods for closing the skin at the time of cesarean delivery include stainless steel staples, subcuticular absorbable staples, subcuticular suture, adhesive closure strips, and tissue adhesives (cyanoacrylates). Each of the methods has its postulated benefits for wound outcomes; however, none of these have been compared in a prospective trial.

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

Materials and Methods

A randomized prospective clinical trial was conducted at Lehigh Valley Health Network (LVHN) in Allentown, Pennsylvania. The Lehigh Valley Health Network is a 951-bed tertiary care community hospital that functions as a regional perinatal center with 3900 deliveries each year; it has its own obstetrics and gynecology residency program with 5 residents per year. Institutional review board approval at the Lehigh Valley Health Network was obtained. Women were recruited from March 13, 2008, until May 31, 2009. Inclusion criteria were

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≥18 years old, cesarean delivery, and gestational age of ≥24 weeks. All women who underwent cesarean delivery were eligible, which included elective, nonelective, emergent, primary, or repeat cesarean delivery. Women were excluded if they did not provide informed consent, were <24 weeks of gestation, or had a fetal death. Eligible women were offered enrollment on admission to labor and delivery or the antepartum unit. After informed consent was obtained, the patient was treated clinically in the usual fashion by her obstetrician. Patients that subsequently delivered vaginally were not assigned randomly; those women who delivered by cesarean were assigned randomly to either suture or staple closure at skin incision, at which time a sequentially numbered, opaque, sealed envelope was opened by the circulating nurse. Randomization was performed by a computer-generated sequence in blocks. Neither the patient nor the treating physician was blinded to closure method once randomization occurred. Delivery data were collected from the medical record. Two 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 to staples had their wound closed with stainless steel staples (Proximate Skin Stapler 35mm wide; Ethicon Endo-Surgery, LLC, Guaynabo, Puerto Rico). Timing of staple removal postoperatively was at the discretion of the obstetrician and was typically on day 3 or 4. Adhesive closure strips (Steri-Strip, 12 × 100 mm; 3M Health Care, St. Paul, MN) were placed with benzoin after staple removal. Subjects who received sutures had their wound closed with subcuticular 4-0 Monocryl on a PS2 needle (Ethicon, Juarez, Mexico), and adhesive closure strips were applied with benzoin in the operating room. Surgeons were instructed to close the subcutaneous tissue if it was >2 cm in depth. The remainder of the surgical practice and postoperative care was at the discretion of the surgeon.

Data that were collected from the medical record included age, ethnicity, obstetrics service (private obstetrician vs resident service), parity, body mass index (BMI), weight gain, maternal comorbid conditions, medication use, gestational age at delivery, indication for cesarean delivery (including urgency or if the patient was in labor), surgical details, date of discharge, wound management, complications, and neonatal outcomes. The telephone interview assessed wound complications and patient satisfaction. All patients who reported a complication were evaluated by their provider. The office records of several patients with complications were chosen randomly for confirmation, and the medical records for all readmissions were reviewed by a single investigator. For those patients who were unable to complete a telephone interview, information regarding wound complications was obtained by reviewing medical records from the obstetrician's office, when available. Women were considered lost to follow-up evaluation if a telephone interview was not performed and if there were no medical records available for review (the patient had not returned for a postpartum check and was not admitted to our institution). Details regarding wound complications after discharge that were obtained at 2-4 weeks after delivery included the need for additional physician visits for wound care (both routine and unscheduled), postdischarge fever or antibiotic therapy, readmission to the hospital, wound separation, and requirement of additional treatment. *Wound separation* was defined as any separation of the wound that was identified as such by the patient or the medical record and varied in size from small skin defects to separation of the entire wound. In the satisfaction portion of this interview, the patients were asked to evaluate overall satisfaction with their wound outcome and to assess pain and anxiety and whether they would desire to have the same skin closure for a future delivery. This survey was modeled after a previously validated patient satisfaction survey[8] and was scored on a Likert scale (1-5, with 5 representing strongly agree and 1 representing strongly disagree).

Our primary outcome was 2-fold: first to compare a composite wound complication rate between suture and staples and second to assess patient satisfaction with the method of skin closure. *Composite wound complication* rate was defined as any 1 of the following occurrences: wound separation, antibiotics for wound treatment, readmission to the hospital for wound care, or an office visit for a wound problem. Our secondary outcome was difference in postoperative length of stay.

Assuming a 10% wound complication rate, we calculated a priori that we would need 437 women in each arm to detect a 50% difference in the wound complication rate, with a power of 80% and alpha of .05. Although an interim analysis was not planned, data were analyzed after 14 months of recruitment to enable presentation of preliminary data as a resident research project. Because the results demonstrated a statistically significant difference between closure methods, accrual was halted after 435 patients were enrolled.

Comparisons between the women in the 2 treatment groups were performed with standard bivariate statistics (Student *t*, χ^2, and Fisher's exact tests, when appropriate); relative risks and 95% confidence intervals (CIs) were also reported. Logistic regression analysis was used to generate adjusted odds ratios.

Results

From March 13, 2008, to May 31, 2009, 430 women were assigned randomly (Figure). Fourteen women subsequently were excluded (5 women were withdrawn by the attending physician before skin closure, and 9 women were lost to follow-up evaluation) for a final cohort of 416 women: 219 women in the suture group and 197 women in the staple group. Of the women who were withdrawn from the study by the attending physician, 4 women were in the suture group: in 2 cases, a shorter operative time was desired (1 case of inadequate anesthesia and 1 was a combative patient); in the other 2 cases, the attending physician believed there was a clinical indication to close with staples instead of sutures (1 patient with coagulopathy and 1 patient with significant skin edema be-