OBSTETRICS

A randomized trial comparing metallic and absorbable staples for closure of a Pfannenstiel incision for cesarean delivery

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OBJECTIVE: The purpose of the study is to compare postoperative pain, cost, speed of closure, and patient satisfaction of Pfannenstiel skin incisions closed with traditional metallic staples vs absorbable staples after cesarean delivery. It is hypothesized that incisions closed with absorbable staples will cause less postoperative pain than traditional metallic staples.

STUDY DESIGN: A randomized, controlled trial was conducted from July 2010 through May 2011. Patients undergoing a scheduled cesarean delivery via a Pfannenstiel skin incision were recruited. Patients were randomized into the control group (metallic staples) or the experimental group (absorbable staples). The postpartum nurse and patient were blinded to the type of staples. Postoperative pain was assessed using a visual analog scale on both postoperative day 1 and day of discharge, and the total dose of oral narcotics taken during the postoperative period was assessed.

RESULTS: In all, 100 patients enrolled in the study: 50 in each group. Based on visual analog scale scores, there were no significant differences between the 2 groups on postoperative day 1 or day of discharge. There were no significant differences in the total dose of oral narcotics taken or in wound complication rates. The time for skin closure was significantly different: 3.5 ± 1.7 for absorbable and 1.39 ± 0.7 minutes for metallic staples ($P < .0001$). The calculated cost of each device, including placement and removal, was $285.60 for the absorbable and $150.79 for the metallic staples.

CONCLUSION: Postoperative pain is comparable for both devices. The absorbable staple skin closure time, and therefore cost, is significantly greater than for metallic staples.

Key words: absorbable staples, cesarean delivery, Pfannenstiel, postoperative pain, skin closure

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Cesarean delivery continues to be the most common surgical procedure in the world, and it is expected that the rates will continue to rise due to multiple factors including declining vaginal birth after cesarean rates, maternal request for cesarean delivery, and macrosomia. With rapidly rising rates of cesarean deliveries, a well-designed study in an obstetrical population that compares different skin closure techniques would provide surgeons with more definitive information when choosing a method of skin closure.[1,2] The ideal method of closing the skin following a Pfannenstiel incision has not yet been established. Virtually all the studies in the Cochrane Review in 2012 addressing skin closure compare metallic staples and absorbable subcuticular suture. Similar outcomes have been noted in regards to wound infection, pain, and cosmesis.[3] Currently, the method of skin closure is a matter of surgeon preference. There is limited evidence regarding which method is considered superior in terms of postoperative pain, patient satisfaction, and cost. This information would be valuable in helping guide surgeons in their choice of skin closure technique.

There are even fewer studies that have examined the outcomes associated with some of the newer products on the market for skin closure. One stapling device, INSORB (Incisive Surgical Inc, Plymouth, MN), is a subcuticular absorbable skin stapler. There has been 1 study evaluating this new absorbable stapling device in the obstetrical population, which was retrospective, and revealed less nonsteroidal antiinflammatory drug use, but not postoperative narcotic use.[4]

Although the manufacturer of the INSORB skin closure device claims that it yields better patient satisfaction compared with traditional staples, there are no clinical outcome data to support these claims. Closure times with the subcuticular staples are estimated to be comparable to traditional metallic staples. Documentation of clinical experience with the absorbable stapling device comments on high levels of patient satisfaction, particularly with respect to reduced anxiety and discomfort associated with removal of traditional metallic staples; but again, there are limited data to support this.[5-7]

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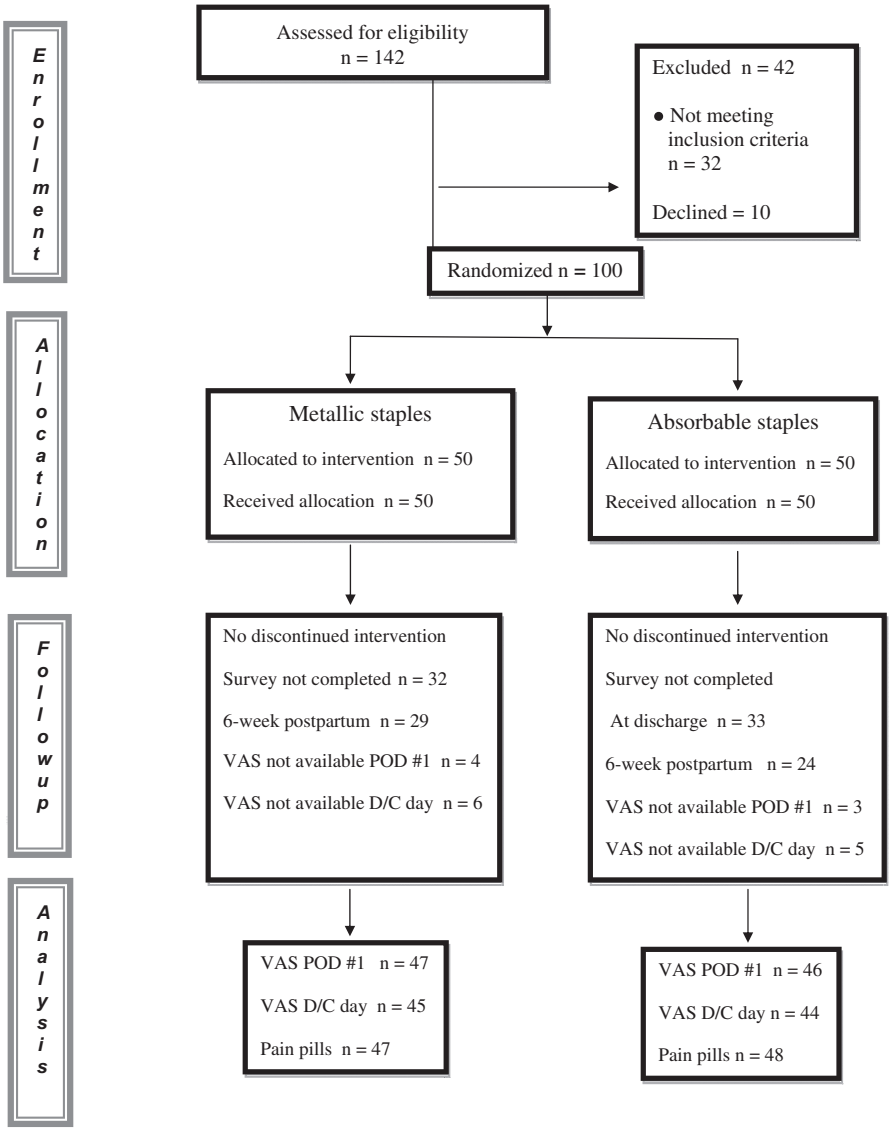
FIGURE
Flowchart of patients from enrollment to analysis



VAS, visual analog scale.

Feese. Staple skin closure at cesarean delivery. Am J Obstet Gynecol 2013.

The purpose of the study is to compare postoperative pain, cost, speed of closure, and patient satisfaction of Pfannenstiel skin incisions closed with traditional metallic staples vs absorbable staples after cesarean delivery. Our hypothesis is that absorbable staples will result in less pain as compared with metallic staple wound closure.

Materials and Methods

A randomized, controlled trial was performed using patients recruited from Good Samaritan Hospital in Cincinnati, OH, who were undergoing a scheduled delivery via cesarean delivery. Approval to conduct this study was obtained from the TriHealth Institutional Review Board. The study was also registered with National Institutes of Health registry of both federally and privately funded clinical trials (identifier no. NCT01198691).

Participants

The cohort for this study comprised women presenting to Good Samaritan Hospital for a scheduled cesarean delivery via Pfannenstiel skin incision, and who met all of the following inclusion criteria: (1) singleton gestation; (2) ≥18 years of age; and (3) obtained prenatal care through the Good Samaritan Hospital Obstetrics/Gynecology Resident Clinic or the maternal-fetal medicine attending private practice. Excluded from the study were those patients with a history of drug or alcohol abuse, contraindications to postoperative nonsteroidal antiinflammatory drugs or narcotics, and undergoing emergent cesarean delivery. Patients were recruited from July 2010 through May 2011. The Figure reveals the patient flowchart from enrollment to analysis.

Interventions

All patients provided informed consent, and were randomized, via sealed envelopes, using a random number generator. The control group received metallic staples using a Proximate PXW35 Skin Stapler (Ethicon Endo-Surgery Inc, Cincinnati, OH) and the experimental group received subcuticular absorbable polylactic/polyglycolic acid staples using a Food and Drug Administration–approved sterile, single-patient-use stapling device. All patients received antibiotics preoperatively within 60 minutes of skin incision. The nursing staff and the patient were blinded to the type of skin closure throughout the postoperative period, and both groups of patients received identical dressings that remained in place until the day of discharge. Prior to using the device, the resident physicians and faculty received an in-service from the company representative on how to place the absorbable sutures.

All data were extracted by the primary investigator from the patients' electronic medical records in OB Trace View (Phillips, Andover, MA). Prenatal records and surveys were obtained either from the Good Samaritan Hospital Obstetrics/Gynecology Resident Clinic or the maternal-fetal medicine attending private practice.

Objectives

The primary outcome was pain on postoperative day 1, and on the day of