Subcutaneous Tissue Reapproximation, Alone or in Combination With Drain, in Obese Women Undergoing Cesarean Delivery

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OBJECTIVE: To compare the efficacy of subcutaneous suture reapproximation alone with suture plus subcutaneous drain for the prevention of wound complications in obese women undergoing cesarean delivery.

METHODS: We conducted a multicenter randomized trial of women undergoing cesarean delivery. Consenting women with 4 cm or more of subcutaneous thickness were randomized to either subcutaneous suture closure alone (n = 149) or suture plus drain (n = 131). The drain was attached to bulb suction and removed at 72 hours or earlier if output was less than 30 mL/24 h. The primary study outcome was a composite wound morbidity rate (defined by any of the following: subcutaneous tissue dehiscence, seroma, hematoma, abscess, or fascial dehiscence).

RESULTS: From April 2001 to July 2004, a total of 280 women were enrolled. Ninety-five percent of women (268/280) had a follow-up wound assessment. Both groups were similar with respect to age, race, parity, weight, cesarean indication, diabetes, steroid/antibiotic use, chorioamnionitis, and subcutaneous thickness. The composite wound morbidity rate was 17.4% (25/144) in the suture group and 22.7% (28/124) in the suture plus drain group (relative risk 1.3, 95% confidence interval 0.8–2.1). Individual wound complication rates, including subcutaneous dehiscence (15.3% versus 21.8%), seroma (9.0% versus 10.6%), hematoma (2.2% versus 2.4%), abscess (0.7% versus 3.3%), fascial dehiscence (1.4% versus 1.7%), and hospital readmission for wound complications (3.5% versus 6.6%), were similar ($P > .05$) between women treated with suture alone and those treated with suture plus drain, respectively.

CONCLUSION: The additional use of a subcutaneous drain along with a standard subcutaneous suture reapproximation technique is not effective for the prevention of wound complications in obese women undergoing cesarean delivery. (Obstet Gynecol 2005;105:967–73. © 2005 by The American College of Obstetricians and Gynecologists.)

LEVEL OF EVIDENCE: I

Obesity is a major medical and public health problem in the United States.[1,2] The growing obese population has resulted in an increased number of overweight women becoming pregnant. The obese gravida is at increased risk for obstetric complications such as fetal anomalies (neural tube defects, congenital cardiac disease), gestational diabetes, pregnancy-induced hypertension, macrosomia, shoulder dystocia, postterm pregnancy, peripartum infection (chorioamnionitis, endometritis, wound infections), and primary cesarean delivery.[3–10] Of particular concern is the increased rate of cesarean delivery in the obese patient. Twenty-three percent of women over 200 lb and 30% of those over 250 lb underwent cesarean delivery in a recent study of obesity from our institution in contrast to a cesarean delivery rate of only 14.4% for nonobese women.[3] Others have also demonstrated that obese women undergoing cesarean delivery are at markedly increased risk for postpartum endomyometritis and wound complications such as infection, seromas, dehiscence, and hematomas.[10–12]

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Because of the risk for wound complications in obese women, efforts to reduce these complications are of great importance. Reduction in operative time, use of perioperative prophylactic antibiotics, irrigation of the operative site, adequate hemostasis, avoidance of dead space, and meticulous surgical technique have been shown to help reduce the risk for postoperative wound complications.[13] The obese patient poses additional concerns with respect to increased abdominal wall thickness.[11] Vermillion and colleagues[11] have previously demonstrated that subcutaneous tissue thickness of 3 cm or more is an independent risk factor for wound infection following cesarean delivery. Theoretically, reapproximation of subcutaneous tissue should reduce the potential for wound complications, not only by decreasing tension placed on tissues, but also by decreasing potential dead space for seroma and hematoma formation. Although suture reapproximation of the subcutaneous space appears to be efficacious in reducing the rate of postcesarean wound complications, the efficacy of subcutaneous drainage in this population has been inconsistent among studies (White A, Ramsey PS. Subcutaneous stitch closure versus subcutaneous drain to prevent wound disruption after cesarean delivery: a randomized clinical trial [letter]. Am J Obstet Gynecol 2003;188:861-2).[14–24] These disparate findings may result from differences in study design, study population, and sample size among investigations.

Because wound complications represent a serious surgical morbidity, identification of methods to reduce wound complications are of utmost importance. We hypothesized that the concurrent use of subcutaneous suture closure with a drain in women undergoing cesarean delivery would result in a significant reduction in postoperative wound complications compared with management by suture closure alone. To evaluate this hypothesis, we conducted a multicenter, randomized clinical trial designed to compare the 2 wound closure techniques in a subset of women at high risk for wound complications (obese women with ≥ 4 cm subcutaneous tissue thickness).

MATERIALS AND METHODS

This trial was conducted as a multicenter, randomized clinical investigation in accordance with the published CONSORT guidelines[25] with full institutional review board approval at 5 clinical sites: University of Alabama at Birmingham (Birmingham, AL), Denver Health Medical Center (Denver, CO), University of Colorado Medical Center (Denver, CO), St. Luke's Hospital of Kansas City (Kansas City, MO), and the University of Texas Health Sciences Center at Houston (Houston, TX). All women with a body mass index (BMI) greater than 30 kg/m^2 at time of admission who presented to the 5 participating labor and delivery units were approached for study participation. Women were excluded from participation if any of the following criteria were encountered: 1) inability to obtain informed consent, 2) moribund cesarean delivery required, or 3) no plan for follow-up postpartum care in the recruitment center's clinic system. Women who met the above requirements were invited to participate, and those who gave informed consent were followed through delivery in the event that cesarean delivery was required (Fig. 1). All women who consented to participate and required cesarean delivery underwent standard perioperative management (surgical preparation and prophylactic antibiotics). Intraoperatively, following closure of the fascia, the patient's subcutaneous tissue depth was measured with a sterile ruler. Women with a subcutaneous tissue thickness of 4.0 cm or more were then formally enrolled and randomized to one of the two subcutaneous closure techniques. Randomization was accomplished by using sequentially numbered and sealed opaque envelopes located in the operating suite to maintain concealed treatment allocation. Separate block randomization schedules (block size = 20) for each center, which were generated centrally at the University of Alabama at Birmingham by an independent statistician using a computer-generated random number table, were used for the investigation.

Randomized women were assigned to treatment with either subcutaneous tissue reapproximation alone using a running, nonlocking 3–0 Vicryl closure or to subcutaneous suture closure with the additional placement of a Jackson-Pratt surgical drain (10 mm flat full perforated drain; Zimmer LTD, Dover, OH). Before suture or drain placement, the subcutaneous space was thoroughly irrigated, and subcutaneous bleeding was secured with cautery. For those women randomized to the drain group, the drain was placed below the suture closure, exiting the wound via a separate stab site lateral to the skin incision. The drain was then secured with a single 3–0 silk suture. After subcutaneous closure, the skin incision was reapproximated with staples. All randomized women received standard postoperative wound care. For women in the subcutaneous drain group, the drain was maintained with bulb (grenade) suction, and the drain was removed on postoperative day 3 (72 hours after surgery) or earlier if drain output was less than 30 mL/24 h. Wound complications that occurred at any time during the initial 6-week postoperative period were recorded. All study patients had a scheduled follow-up visit 7–14 days after hospital discharge, at which time the skin staples were removed and formal wound assessment performed by trained study

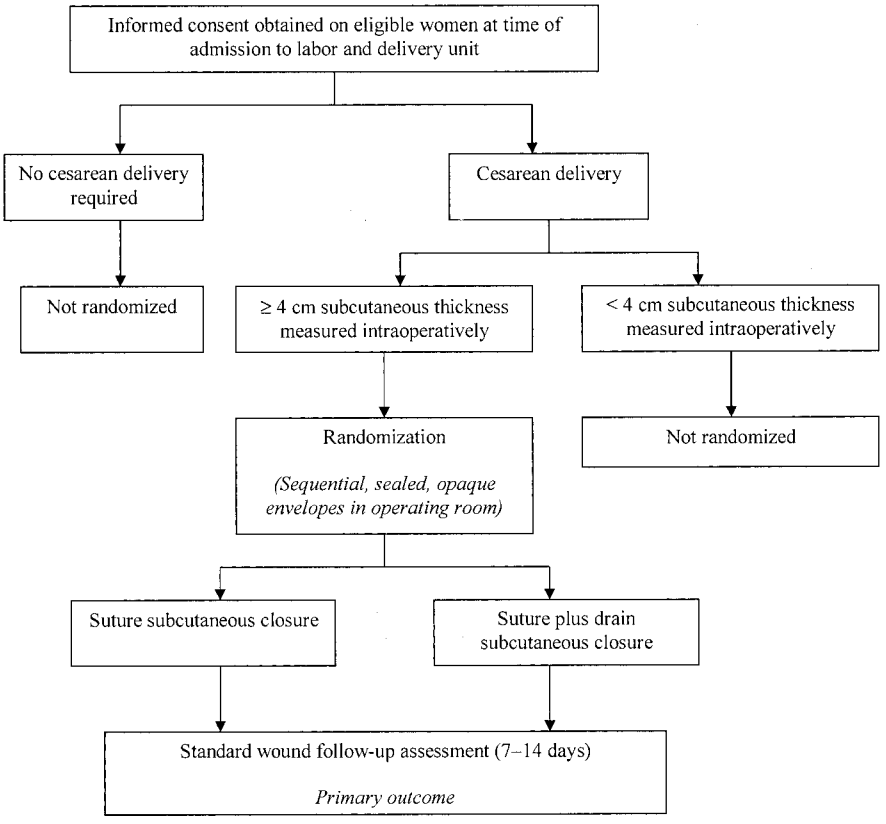

Fig. 1. Chart showing the flow of patients through the study.
Ramsey. Cesarean Wound Closure RCT. Obstet Gynecol 2005.

personnel. A second wound follow-up assessment was performed 4–6 weeks later at the time of postpartum evaluation.

The primary study outcome for the investigation was the overall composite wound morbidity rate, defined as any of the following noted during the post–hospital discharge wound follow-up assessments: subcutaneous dehiscence (> 1 cm), seroma, hematoma, abscess, or fascial dehiscence. Secondary study outcomes included the individual wound complication rates for subcutaneous dehiscence (> 1 cm), seroma, hematoma, abscess, fascial dehiscence, and hospital readmission for wound complication.

Planned sample size for this investigation was based on a clinically significant difference in the composite wound outcome. With $\alpha = 0.05$ and $\beta = 0.2$ (2-sided), a sample size of 130 women per group would be required to detect a 67% reduction in the composite wound complication rate between the treatment groups (as from 18% to 6%). Analysis was by intent-to-treat. Statistical analyses were performed with SAS 9.0 (SAS Institute Inc, Cary, NC). Proportional data were compared with the χ^2 or Fisher exact tests, as determined by the expected cell size. Continuous data were compared with either the Student *t* test or the Wilcoxon rank-sum test, as determined by the Shapiro-Wilk statistic. Logistic regression analyses were performed to control for confounding variables. Statistical significance was defined as $P \leq .05$.

RESULTS

From April 2001 through July 2004, a total of 280 women were enrolled and randomized into the trial. Ninety-five percent of women (268/280) had a follow-up wound assessment. Baseline characteristics of the study participants, including maternal age, weight, BMI, parity, race, and recruitment site were similar between the study treatment groups (Table 1). Delivery gestational age, cesarean indication, and labor status were also similar between the study groups (Table 2). Surgical risk factor characteristics, including diabetes, hypertension, preeclampsia, corticosteroid use, intrapartum and postoperative antibiotic use, clinical chorioamnionitis, meconium passage, subcutaneous thickness, length of surgery, and type of skin incision were also similar between the study treatment groups (Table 2).

Mean (± standard deviation) interval from cesarean delivery to initial wound assessment was similar between the suture-alone group (11.1 ± 7.2 days, median 9 days)

Table 1. Baseline Characteristics of Study Cohort

	Suture Alone (n = 149)	Suture + Drain (n = 131)	*P*
Maternal age (y)	27.5 ± 6.4	28.4 ± 72	.289
Weight (kg)*	118.4 ± 25.3	123.8 ± 29.4	.108
Body mass index (kg/m^2)*	45.0 ± 9.2	48.0 ± 11.4	.019
Nulliparous (%)	34.2	29.8	.426
Race (%)			.764
African American	42.3	43.0	
White	27.5	30.2	
Hispanic	30.2	26.6	
Clinical site (%)			.556
University of Alabama, Birmingham	57.7	55.0	
Denver Health Medical Center	26.9	23.7	
University of Colorado, Denver	2.7	5.3	
St. Luke's Hospital, Kansas City	9.4	13.7	
University of Texas, Houston	3.4	2.3	

Data are expressed as mean ± standard deviation or percentage, as indicated.
* At time of study enrollment.

and the suture plus drain group (12.8 ± 14.0 days, median 9 days ($P = .21$). The interval from surgery to diagnosis of wound complication was similar between the suture-alone group (11.1 ± 7.1 days, median 10 days) and suture plus drain group (9.7 ± 7.4 days, median 8 days) ($P = .49$). The incidence of composite wound morbidity was similar between the suture-alone and suture plus drain groups (Table 3). Individual wound complication rates, including subcutaneous dehiscence, seroma, hematoma, abscess, fascial dehiscence, and hospital readmission for wound complications were also similar between the study groups (Table 3). Composite wound morbidity, as well as individual wound complications, were not significantly associated with the subcutaneous tissue closure technique after controlling for participant BMI (Table 3).

We explored the efficacy of suture alone compared with suture plus drain subcutaneous closure within sev-

Table 2. Surgical Risk Profile Characteristics of Study Cohort

	Suture Alone (n = 149)	Suture + Drain (n = 131)	*P*
Delivery gestational age (wk)	38.0 ± 5.2	37.8 ± 5.8	.816
Cesarean delivery indication (%)			.663
Elective	51.4	48.9	
Labor arrest	30.1	28.2	
Nonreassuring fetal status	18.5	22.9	
Labor status (%)			.621
None	51.0	46.1	
Spontaneous	15.7	19.5	
Induced	33.3	34.4	
Insulin requiring diabetes (%)*	30.2	26.0	.431
Chronic hypertension (%)	14.8	19.1	.346
Preeclampsia (%)	23.8	24.6	.876
Corticosteroid use (%)	13.3	15.5	.602
Intrapartum antibiotic use (%)	87.8	90.7	.433
Clinical chorioamnionitis (%)	10.7	6.8	.278
Meconium (%)	11.0	14.2	.422
Subcutaneous thickness (cm)	5.2 ± 1.4	5.6 ± 1.5	.545
Length of surgery (min)	64.4 ± 25.3	70.0 ± 26.3	.078
Skin incision type (%)			.056
Horizontal	63.5	49.2	
Vertical	30.4	45.4	
Paramedian	4.1	5.4	
Postoperative antibiotics (%)	20.3	22.5	.654

Data are expressed as mean ± standard deviation or percentage, as indicated.
* Includes pregestational diabetics and insulin-requiring gestational diabetics (A2).

Table 3. Study Outcomes

	Suture Alone (n = 144)	Suture + Drain (n = 124)	RR (95% CI)	Adjusted OR (95% CI)*
Wound dehiscence (%)	15.3	21.8	1.43 (0.86–2.37)	1.36 (0.72–2.58)
Seroma (%)	9.0	10.6	1.17 (0.56–2.43)	1.01 (0.44–2.32)
Hematoma (%)	2.2	2.4	1.16 (0.24–5.65)	0.96 (0.18–5.0)
Abscess (%)	0.7	3.3	4.68 (0.53–41.35)	3.89 (0.42–36.09)
Fascial dehiscence (%)	1.4	1.7	1.21 (0.17–8.46)	1.15 (0.16–8.51)
Readmission for wound complication (%)	3.5	6.6	1.89 (0.63–5.62)	1.62 (0.50–5.21)
Composite wound morbidity (%)†	17.4	22.7	1.30 (0.80–2.11)	1.21 (0.65–2.26)

RR, relative risk; CI, confidence interval; OR, odds ratio.

* Adjusted for body mass index at time of study enrollment using logistic regression.

† Composite wound morbidity rate was defined by any of the following noted at time of the wound assessment: wound dehiscence, seroma, hematoma, abscess, or fascial dehiscence.

eral specific population subgroups at high risk for postcesarean wound complications. Within a subgroup of women with insulin-requiring diabetes, no significant differences were noted between the suture-alone (n = 40) and suture plus drain (n = 31) groups with respect to the composite wound morbidity rate (32.5% versus 32.2%, $P = 1.0$). Individual postcesarean wound complication rates, including subcutaneous dehiscence (27.5% versus 29.0%, $P = .89$), seroma (20.0% versus 19.4%, $P = 1.0$), hematoma (5.0% versus 3.2%, $P = 1.0$), abscess (2.5% versus 6.5%, $P = .58$), fascial dehiscence (5.0% versus 0%, $P = .50$), and hospital readmission for wound complications (10.0% versus 6.5%, $P = .69$), were also similar between women treated with suture alone and those treated with suture plus drain, respectively. Within the subgroup of women with clinical chorioamnionitis, the rate of composite wound morbidity (7.1% versus 37.5%, $P = .12$), subcutaneous dehiscence (7.1% versus 37.5%, $P = .12$), seroma (7.1% versus 25.0%, $P = .53$), hematoma (0% versus 0%, P value not calculable), abscess (0% versus 4.6%, $P = .36$), fascial dehiscence (0% versus 0%, P value not calculable), and hospital readmission for wound complications (0% versus 4.6%, $P = .36$) were also similar between women treated with suture alone (n = 14) and those treated with suture plus drain (n = 8), respectively. No differences were also noted between the suture-alone (n = 41) and suture plus drain (n = 54) groups among the subgroup of study participants with extreme subcutaneous thickness (≥ 6 cm) with respect to the rates of composite postcesarean wound morbidity (34.1% versus 27.8%, $P = .50$), subcutaneous dehiscence (29.3% versus 27.8%, $P = .87$), seroma (19.5% versus 13.0%, $P = .39$), hematoma (7.3% versus 1.9%, $P = .31$), abscess (2.4% versus 3.7%, $P = 1.0$), fascial dehiscence (2.4% versus 3.7%, $P = 1.0$), and hospital readmission for wound complications (4.9% versus 11.3%, $P = .45$), respectively.

DISCUSSION

Wound complications remain a major concern for women undergoing cesarean delivery.[11,12] Subcutaneous tissue reapproximation with suture has been shown to be effective in reducing rates of postcesarean wound complications.[14–17,19,20] Naumann et al[14] from our institution evaluated the effectiveness of subcutaneous suture closure for the reduction of wound complications in women with 2 cm or more of subcutaneous tissue and noted a 30% reduction in the rate of wound disruption with closure of the subcutaneous tissue layer. Based on these data, our standard practice at our institution is to perform subcutaneous tissue closure on women undergoing cesarean delivery who have 2 cm or more of subcutaneous tissue. Chelmow and colleagues[22] confirmed the benefits of subcutaneous suture closure in a recent meta-analysis of 5 randomized trials that demonstrated that subcutaneous suture closure in women with 2 cm or more of subcutaneous tissue thickness was associated with a significant reduction in the rate of wound disruption and seroma when compared with wounds with no suture closure.

The potential benefits of subcutaneous drainage, however, are conflicting in the literature.[15,16,18,21,23,24,26–28] To date, 5 previous studies have evaluated the independent use of subcutaneous drainage to prevent wound complications in women undergoing cesarean delivery.[15,16,18,21,23] Allaire et al[15] compared the use of subcutaneous suture closure with subcutaneous drain in women undergoing cesarean delivery. These investigators demonstrated a reduction in the wound complication rate in women who received subcutaneous drain when compared with women treated with suture closure or those receiving neither drain or suture subcutaneous closure.[15] Magann and colleagues[16] further evaluated to the efficacy of subcutaneous drain through a prospective trial of 964 women undergoing cesarean delivery and noted comparable major wound complication rates

among women who received no subcutaneous closure (8.7%) compared with those receiving subcutaneous drain (9.7%) or subcutaneous suture closure (9.9%) ($P = .83$) (White and Ramsey letter, 2003). Three other studies have similarly reported that subcutaneous drainage in women undergoing cesarean delivery does not reduce wound complication rates.[18,21,23]

For our investigation, we evaluated the concurrent use of a drain with suture subcutaneous tissue reapproximation under the hypothesis that the concurrent use of postsurgical drainage of the subcutaneous space theoretically would provide further reduction in potential dead space and removal of residual fluid and blood from the wound that could serve as a medium for bacterial growth. We selected women with 4 cm or more of subcutaneous tissue thickness for randomization into our trial to evaluate efficacy in a population at greatest risk for postcesarean wound complications. In spite of our selection of a high-risk population for study, the additional use of a subcutaneous drain along with a standard subcutaneous suture reapproximation technique was not effective for the prevention of wound complications in obese women undergoing cesarean delivery.

Although the 2 closure techniques were statistically similar for the composite wound morbidity rate and individual morbidities, the composite wound morbidity rate and rates of wound dehiscence and wound abscess were higher in women in the subcutaneous drain plus suture group than in women in the suture-alone group. Although this difference was not significant, the observation is of interest and raises potential concerns regarding the role of subcutaneous drainage in obese women undergoing cesarean delivery.

Two previous investigations have reported that the use of subcutaneous wound drains may increase risk for wound complications.[18,29] Cruse et al[29] noted in a prospective study of 23,649 surgical patients that those who had wound drain placed and brought out through the wound had a higher rate of wound infection (4.0%) than those with no drain (1.5%). The rate of wound infection was decreased when the drain was brought through the skin via a separate stab wound (2.4%) but was still increased compared with patients with no drain.[29] Loong et al[18] similarly observed a higher proportion of women with subcutaneous drain 13/66 (19.7%) with postcesarean wound infections when compared with no drainage 7/69 (10.2%). Although the higher rate of wound complications in women treated with subcutaneous suture plus drain in our investigation was not a statistically significant difference from that observed in women treated with suture closure alone, there are several theoretic mechanisms by which subcutaneous drains may increase risk for wound complications. First, drains may provide a route by which bacteria can gain access to devitalized tissues within the wound, thus inciting inflammation and setting the stage for infection. Second, a drain is a foreign body that may serve as a reservoir for bacteria in clean contaminated or contaminated surgical cases, which may promote wound infection and inflammation. The culmination of these effects may negate any potential benefit that wound drainage may have in reducing wound dead space or removing residual blood or serous fluid.

Based on the findings from our investigation, concurrent use of a subcutaneous drain with suture reapproximation is ineffective in preventing, and may actually potentiate, postcesarean wound complications. Review of the available literature from studies that have evaluated the independent use of subcutaneous drain have also questioned benefit related to the use of a subcutaneous drain in women undergoing cesarean delivery. Because wound complications represent a serious surgical morbidity that dramatically increases health resource expenditures, identification of methods to further reduce wound complications are of utmost importance.

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