OBSTETRICS

Skin closure at cesarean delivery, glue vs subcuticular sutures: a randomized controlled trial

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BACKGROUND: The optimal choice of skin closure at cesarean delivery has not yet been determined.

OBJECTIVE: This study compared wound complications and scar healing following cesarean delivery between 2 methods of skin closure: glue (Dermabond; Ethicon, Somerville, NJ) and monofilament (Monocryl; Ethicon) epidermal sutures.

STUDY DESIGN: We conducted a randomized controlled trial in which pregnant women undergoing a scheduled cesarean delivery were randomly assigned to skin (epidermis) closure with glue or with a monofilament synthetic suture. The subcutaneous tissue was sutured for all patients. Outcome assessors were blinded to group allocation. Scars were evaluated >8 weeks. Primary outcome measures were Patient and Observer Scar Assessment Scale scores. Secondary outcome measures were surgeon satisfaction, duration of surgery, duration of hospitalization after the cesarean delivery, and complications of surgical site infection or wound disruption (hematoma or seroma). A sample of 104 women was needed to achieve a clinically significant effect with a power of 80%.

RESULTS: Demographic characteristics, patients' clinical background, prepregnancy body mass index, and subcutaneous thickness were similar in both groups. Length of surgery between the groups (37 ± 10 minutes for glue vs 39 ± 13 minutes for sutures, $P = .515$) was similar. Scores immediately after the wound closure were similar for both groups regarding surgeons' time estimate of closure ($P = .181$) and closure appearance ($P = .082$). Surgeons' satisfaction with the technique was significantly higher in the suture group ($P = .003$). No significant differences were found between the groups in blood loss, surgical site infection, length of postpartum hospitalization, or wound disruption. Glue and suture skin closure scores using Patient and Observer Scar Assessment Scale were similar 8 weeks after surgery, at $P = .710$ for patients and $P = .568$ for a physician observer.

CONCLUSION: Skin closure using glue or a monofilament synthetic suture had similar results. Both methods were shown to be safe and successful for skin closure after a scheduled cesarean delivery and, therefore, can be used based on surgeon and patient preferences.

Introduction

Cesarean delivery (CD) rates have increased during the last few decades and it has become the most common surgery during women's reproductive years.[1] However, despite its prevalence, data regarding many aspects of the preferred surgical technique are sparse.

Skin closure is an integral step of CD. It influences postoperative pain, wound healing, cosmetic outcome, and surgeon and patient satisfaction.[2]

There is currently no definite evidence regarding the best method for skin closure after CD.[3-5] Staples have been suggested as inferior to other techniques.[3] Given the conflicting data available, obstetricians are forced to base their decisions on personal preference.

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Dermabond glue (Ethicon Inc, Somerville, NJ) is a liquid monomer that forms a strong tissue bond with a protective barrier that adds strength and inhibits bacteria. An in vitro study found that glue inhibits both gram-positive (methicillin-resistant *Staphylococcus aureus* and *S epidermidis*) and gram-negative (*Escherichia coli*) bacteria.[4] In addition, glue has the potential advantages of rapid application and repair time. It has been shown to achieve cosmetically similar results compared to staples within 12 months of the repair.[5,6] Also, glue was shown to be well-accepted by patients.[5]

To date, there have been no randomized controlled trials comparing skin closure with glue to sutures using the Patient and Observer Scar Assessment Scale (POSAS). The POSAS is a validated and reliable instrument that is practical for assessing scars.[7-9] It is comprehensive and correlates well with patient ratings.

Previous studies regarding skin closure with glue were small, retrospective, and included mixed populations and varying surgical techniques. Therefore, clear, conclusive recommendations are lacking.

This prospective study compared the outcomes of skin incision wound closure using glue or sutures after a scheduled CD.

Materials and Methods

This randomized, controlled trial was conducted in a single, tertiary care medical center over a 6-month period. The study was approved by the local institutional review board and was registered with the clinical trials registry (Clinical-Trials.gov identifier NCT02831946).

Patients were recruited consecutively 1-3 days prior to an elective (prelabor, scheduled) CD during the routine preoperative assessment. All patients scheduled for an elective CD for various indications who agreed to participate in the study were included and provided signed informed consent.

Inclusion criteria were patients with a routine indication for an elective CD (eg, previous CD, breech presentation), maternal age 18-45 years, previous CD

performed using the Pfannenstiel method, at 37-41 weeks of gestation based on first-trimester ultrasound, and a viable fetus.

Exclusion criteria were an emergency CD, previous CD not using Pfannenstiel method, clinical signs of infection at the time of CD, uncontrolled diabetes mellitus (defined as Hemoglobin A1c > 6%, unbalanced daily glucose measurements, and fasting glucose >95 mg/dL), history of keloids, known hypersensitivity to any of the suture materials used in the protocol, or any disorders requiring chronic corticosteroids or immune suppressants.

Participants were randomized for skin closure with glue or sutures prior to surgery using designated software (Randomizer for clinical trial, iOS app version 2.0; Medsharing, Paris, France). Prophylactic cephalosporin was administered to all patients within 60 minutes before skin incision, based on American Congress of Obstetricians and Gynecologists recommendations.[10]

Scars from previous CD were removed at the beginning of the surgery. The same incision site was used for the current CD. The skin and dermis were opened using a sharp technique with scissors and with coagulation when indicated. In both groups after closure of the rectus fascia, the subcutaneous fat layer was closed with 3-4 interrupted, coated Vicryl plus antibacterial 2-0 sutures using a V 26 needle (coated polyglactin 910 suture with triclosan; Ethicon, Somerville, NJ). In the glue group, we used 2 layers of Dermabond to close the outer skin layer. Based on manufacturer's recommendations, the first layer of glue was applied to attach the skin edges. Sixty seconds later, a second layer was added to improve the strength of the adhesion and to create a barrier intended to decrease wound infections.

Dermabond is a liquid monomeric (2-octyl cyanoacrylate) formulation that undergoes an exothermic reaction upon exposure to moisture, changing to polymers that form a strong tissue bond. The wound was not dressed with an abdominal pad or adhesive tape according to manufacturer's instructions. In the suture group, the skin was closed with Monocryl (poliglecaprone) 3-0 placed under the skin using a blind suture technique. Steri-Strips (3M Corp, St Paul, MN) were used to cover the wound according to manufacturer's instructions. They were placed vertically along the entire incision.

Five surgeons participated in the study. We evaluated their satisfaction with each closure method (glue vs sutures) based on 3 questions asked immediately upon completion of surgery: (1) How comfortable were you with the technique? (not at all [1] to totally comfortable [5]); (2) Was the estimated total operating time longer using glue/sutures compared to skin closure with staples? (not at all [1] to yes, a lot longer [5]); and (3) Were you satisfied with the final closure appearance? (not at all [1] to yes, very satisfied [5]). The surgeons did not participate in the recruitment process. They operated using glue or sutures according to the patient randomization schedule.

The appearance of the scars was evaluated 8 weeks after the CD by both the patient and a physician, who was blind to the technique used for skin closure. For scar evaluation, we used a validated scale: POSAS.[7-9]

The Observer Scar Assessment Scale rates 5 variables: vascularity, pigmentation, thickness, relief, and pliability. Each variable is ranked from 1-10, with 1 representing normal skin. Ratings are summed to obtain a total score ranging from 5-50. The Patient Scar Assessment Scale consists of 6 items: scar-related pain, itchiness, color, stiffness, thickness, and irregularity. Each item is ranked from 1-10, with 1 representing normal skin. Total score ranges from 6-60.[11]

The primary outcomes were the POSAS score[7,8] 8 weeks after the CD. Secondary outcomes were surgeons' satisfaction scale, duration of surgery, duration of hospitalization after the CD, and complications such as surgical site infection (SSI) or wound disruption (hematoma or seroma).

Statistical analysis

We calculated the power analysis based on the assumption that a 20% (5-point) difference in POSAS score would influence our clinical decision regarding the preferred method for skin closure, similar to previous studies that used this scoring system.[11] The sample size calculation indicated 52 participants were needed for each arm of the study, using $\alpha = 0.05$ and 80% power.

Nominal data were described as numbers and percentages. Continuous data were assessed for normal distribution (Shapiro-Wilk test) and were described as mean ± SD or median (minimum-maximum). Quantitative data were analyzed using χ^2 test or Fisher exact test and continuous variables were compared between groups using t test or Mann-Whitney nonparametric test, as appropriate. $P < .05$ was considered statistically significant. Data were analyzed using statistical software (SPSS, V23, IBM Corp, Armonk, NY).

Results

A total of 110 women agreed to participate in the study. Three patients delivered vaginally prior to randomization. One was scheduled for a CD for breech presentation that spontaneously turned to vertex. The other 2 were scheduled for an elective CD for breech presentation, but had external cephalic rotation performed after spinal anesthesia.

A total of 107 patients were randomized and allocated to 2 intervention groups included in the data analysis. Three patients (2.8%) had an initial evaluation, but were lost to follow-up and did not arrive at the 8-week scar evaluation. The final analysis included 104 (97.2%) participants, 52 in the glue closure group and 52 in the suture group.

Demographic and obstetric characteristics are shown in Table 1. All the patients were Caucasian. There was no difference between the 2 groups regarding parity, maternal age, smoking, previous CD, or indications for CD. The prepregnancy body mass index (BMI) was not statistically different between the groups ($P = .457$).

Surgeons' scores, which are summarized in Table 2, include their estimation regarding closure time ($P = .181$) and final closure appearance ($P = .082$). These did not differ between groups. The mean satisfaction score was higher for

TABLE 1
Demographic and clinical characteristics of study participants (n = 104)

Variable	Glue n = 52	Suture n = 52	*P* value
Maternal age, y, mean ± SD	35 ± 4.3	34.44 ± 4.9	.581
Gravidity, median (minimum–maximum)	3 (1–8)	3 (1–8)	.125
Parity, median (minimum–maximum)	2 (0–6)	1 (0–6)	.086
BMI, kg/m^2, mean ± SD (range)	28 ± 5.8 (18.7–40.8)	29.1 ± 7.3 (17.9–56.2)	.457
Smokers, n (%)	3 (5.2)	3 (5.2)	1
Patients with previous CD, n (%)	37 (71.1)	34 (65.3)	.527
No. of previous CD, median (minimum–maximum)	2 (1–4)	1 (1–3)	.160
Surgical indications, n (%)			
Breech presentation	14 (26.9)	17 (32.6)	.520
Previous CD	37 (71.1)	34 (65.3)	.527
Placenta previa	1 (1.9)	1 (1.9)	1

BMI, body mass index; *CD*, cesarean delivery.

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the suture group ($P = .003$). The variability between surgeons was not significant.

No significant differences were detected between the suture and glue groups in patients with hemoglobin decrease ≥2 g% ($P = .646$), need for blood transfusion ($P = .314$), operative time ($P = .515$), postoperative fever ($P = 1$), and prolonged hospitalization time >5 days ($P = 1$) in either group (Table 3). In all, 103 patients received prophylactic treatment with cephalosporin (1 patient in the glue group had a penicillin allergy and received clindamycin). The percentage of women with subcutaneous thickness >2 cm was similar in both groups ($P = .431$).

The overall SSI rate was 3.8% (4/104). In the glue group, it was 5.7% (3/52) vs 1.9% (1/52) for the suture group ($P = .212$). Overall wound disruption without signs of infection rate was 1.9% (2/104), and was not significantly different between groups (2 [3.8%] vs 0 [0%], $P = .153$). Prepregnancy BMI, subcutaneous fat thickness, and duration of surgery were similar between groups. There were no cases of deep organ infection.

No differences in subjective and objective scar ratings were detected between the groups at 8 weeks after surgery (Table 4). Subcutaneous thickness >2 cm did not affect scar assessment either (Patient Scar Assessment Scale, $P = .500$; Observer Scar Assessment Scale, $P = .883$). We calculated the data separately for primary and repeat CD and the results were similar.

Comment

The major findings of our study are that closure of skin incision after CD with glue is as good as with sutures based on POSAS performed 8 weeks after surgery. Furthermore, parameters of SSI, length of postoperative hospitalization, and wound disruption were similar between the 2 study groups.

We found that total operating time was similar between the sutures and glue groups. Previous studies showed longer operating time when closing the skin with sutures compared to staples.[12,13] Interestingly, a recent Cochrane review[14] that included 14 randomized clinical trials indicated significantly faster closure with sutures compared to tissue adhesives. In our cohort, closure time between glue and sutures were similar.

In our institution, surgeons are experienced with sutures, staples, and glue closure methods. In this study, we evaluated their satisfaction using glue or sutures, based on 3 questions asked

TABLE 2
Surgeon's satisfaction survey[a]

Survey question	Glue group	Suture group	*P* value
Skin closure technique–personal preference	3.8 ± 1 (1–5)	4.4 ± 0.6 (2–5)	.003
Operating time estimated as longer	3.5 ± 1.1 (1–5)	3.8 ± 0.9 (2–5)	.181
Closure appearance at end of CD	4.1 ± 1 (1–5)	4.4 ± 0.7 (3–5)	.082

Values are expressed as mean ± SD (range).

CD, cesarean delivery.

[a] (1) How comfortable were you with technique? (not at all [1] to totally comfortable [5]); (2) Was estimated total operating time longer using glue/sutures compared to skin closure with staples? (not at all [1] to yes, a lot longer [5]); and (3) Were you satisfied with final closure appearance? (not at all [1] to yes, very satisfied [5]).

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TABLE 3
Surgical characteristics

Variable	Glue n = 52	Suture n = 52	*P* value
Operative time, min, mean ± SD	37.4 ± 10.4	39 ± 13.4	.515
Subcutaneous thickness >2 cm, n (%)	26 (50)	30 (58)	.431
Patient with hemoglobin decrease ≥2 g%, n (%)	3 (5.7)	2 (3.8)	.646
Blood transfusion, mean ± SD	1 (1.9%)	0	.314
Postpartum fever >38°C, n (%)	1 (1.9)	1 (1.9)	1
Prolonged hospitalization ≥5 d, n (%)	1 (1.9)	1 (1.9)	1
Surgical site infection, n (%)	3 (5.7)	1 (1.9)	.212
Wound disruption n (%)	2 (3.8)	0	.153

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immediately after surgery. The survey results indicated that surgeons were more satisfied with the suture technique. Our results are in agreement with those of Mackeen et al,[15] who found that obstetricians tended to have a strong preference for staples or sutures. Importantly, the glue has other advantages that should be taken into consideration, as it provides a waterproof barrier with antimicrobial properties.[14,16]

Wound complications remain an important source of morbidity after CD and can result in considerable costs to the patient and to the health care system. We did not find significant differences between the groups in blood loss, SSI, length of post-CD hospitalization, or wound disruption. Two study patients from the glue group (3.8%) experienced wound disruption and none of the patients from the suture group. These differences did not reach statistical significance, but require further investigation. These results are in agreement with a retrospective study conducted by Siddiqui et al[5] that investigated wound separation and SSI rates with glue compared to staples and subcuticular sutures. In contrast, according to a review[14] designed to compare tissue adhesives with conventional skin closure techniques, sutures were better than tissue adhesives in rates of wound disruption. This review included only 1 small study on CD.[14] Differences in the results might be related to different anatomical surgical sites and study designs. Our study was a randomized controlled trial with more participants. Therefore, our conclusions related to CD are likely to be more reliable.

In our study, glue and suture skin closure received similar POSAS scores 8 weeks after surgery by both patients and physicians. The POSAS was developed to evaluate all scar types (eg, linear scars, burn scars). It has been validated in numerous studies, especially among dermatologists and plastic surgeons.[7-9] A study conducted by Cromi et al[11] was the first attempt to use this scale to evaluate abdominal wound healing in obstetrical care. Using POSAS, they found equivalent cosmetic appearance of CD scars when comparing staples and subcuticular sutures. A scar assessment scale, which subjectively evaluates the recovery of surgical wounds, is an important evaluation tool. To our knowledge, our study is the first to compare glue and subcuticular sutures in CD using POSAS.

The strengths of this study are that it compared the results of wound closure techniques using randomized controlled methods. In addition, it was powered to answer the research question. All CD were performed at a single academic institution with a uniform surgical technique, which strengthens the comparisons between the study groups.

This study is not without limitations. Despite being powered to answer the primary outcome of the research question, it included a relatively small sample that was underpowered to answer the secondary outcomes of the study. Further investigation with larger sample sizes is indicated. We should also take into consideration that the POSAS is a subjective scoring system. However, biases of the patients and the observers could have potentially influenced both arms of the study. Therefore, despite its limitation, POSAS has been previously validated and is considered acceptable for scar assessment.[7-9] Genetic and personal tendencies of skin incision healing and scar tissue formation were not evaluated. It has been previously shown that these factors can affect scar tissue formation.[17] Also, a larger study group would enable comparison of the effect of the number of previous surgeries as well as variations in subcutaneous thickness.

It would be interesting to investigate skin closure outcomes in patients with higher prepregnancy BMI and in patients undergoing emergency CD in future studies. Also, the study was powered for scar appearance but not to look at differences in SSI or wound disruption, which are clinically important

TABLE 4
Patient and Observer Scar Assessment Scale

Score	Glue	Suture	*P* value
PSAS	16.4 ± 6.4 (4–36)	16.9 ± 6.2 (5–28)	.710
OSAS	12.4 ± 5.6 (6–27)	11.7 ± 5.2 (4–25)	.568

Values are expressed as mean ± SD (range).

OSAS, Observer Scar Assessment Scale; *PSAS*, Patient Scar Assessment Scale.

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outcomes that need to be investigated further.

In summary, our study suggests that skin closure with glue following CD has similar results to subcuticular sutures. Both methods can be used interchangeably based on surgeon and patient preferences. Future randomized controlled trials focusing on long-term cosmetic results of these techniques are still needed. ■

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