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Is There a Benefit to Suturing vs. Stapling in Cesarean Section Closure When Comparing Postoperative Pain and Patient Satisfaction?

Jennifer Pilchman
Philadelphia College of Osteopathic Medicine, jenniferpi@pcom.edu

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Jennifer Pilchman, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not there is a benefit to suturing vs stapling in cesarean section closure when comparing postoperative pain and patient satisfaction.

STUDY DESIGN: Review of three English language primary studies published in 2009 and 2010.

DATA SOURCES: Three randomized control trials (RCTs) comparing the surgical closures for cesarean section delivery. All RCTs were found by the author using MEDLINE, PUBMED, and COCHRANE databases. They are all published articles written in English.

OUTCOME MEASURED: Outcomes were measured by assessing patient satisfaction, postoperative pain, cosmetic appearance and wound complications. Rousseau et al used the analog pain scale to assess postoperative pain. In this study a photograph was taken to evaluate the appearance of the incision, which was done by three independently blinded physician observers. Basha et al used telephone interviews to follow-up on patient satisfaction and wound complication rates. During these interviews the Likert scale was used to assess patient satisfaction. Lastly, Cromi et al used objective (observer) components, the VSS and OSAS, and subjective (patient) components PSAS and VAS. These scales were used to examine the outcome of the postoperative scar and wound complications.

RESULTS: Basha et al determined that staples were associated with increased risk of wound infection. Wound complications led to a decrease in patient satisfaction, however it was not statistically significant to associate staples with decreased satisfaction. Rousseau et al found that postoperative pain was less in the staple group. Cromi et al and Rousseau et al both found there were equivalent cosmetic outcome amongst closure methods.

CONCLUSION: Postoperative pain and patient satisfaction with regards to each surgical closure remains inconclusive. While wound complications and wound dehiscence were more apparent in the use of staples, this had no bearing on overall patient satisfaction. Cosmetic appearance of the post-surgical scar was equivalent amongst both closure methods. A conclusion for the optimal method of cesarean closure is still one for future analysis.

KEYWORDS: Cesarean section, c-section, subcuticular sutures, staples, skin closure, patient satisfaction, wound complication, pain, cosmesis.

INTRODUCTION

A cesarean section, also known as a c-section, is defined as "the birth of a fetus through incisions in the abdominal wall (laparotomy)."[2] Over the past 10 years rates of this mode of delivery have been increasing, 24% in 1995 to 31% in 2009.[1] The etiology of this upsurge is unknown. Patients often request this procedure over vaginal delivery due to "avoidance of pelvic floor injury during vaginal birth, reduced risk of fetal injury, avoidance of the uncertainty and pain of labor, and convenience." [2]

Due to the increasing popularity of c-sections, it is imperative that all health care professionals be knowledgeable about the risks and benefits of this procedure to aid patients in making an informed decision about their care. Delivering a baby in general is expensive (on average $8,802).[4] Vaginal delivery is less expensive at approximately $7,737 and cesarean delivery is more expensive at $10,958.[4] There are approximately 4 million births annually, accounting for a large amount of healthcare costs.[4] Depending on the patient's insurance, extent of complications, and length of hospital stay the cost could be greater. These factors, mixed with the daunting task of parenthood can be overwhelming, especially for new parents.

It is known that this form of delivery is not without obstacles; approximately 2.5% -16% of women who have cesarean delivery will have wound complications.[1] Complications include: "seroma, hematoma, wound infection, wound separation, and wound dehiscence".[1] Alleviating burden post-surgically can make a difference in quality-of-life for a new mother, something surgeons often undervalue. Even a successful delivery can lead to an inevitable scar and the pain that comes from a healing wound. Younger mothers, in particular, value a more favorable cosmetic appearance of their scars.[3] Choosing the most appropriate means for closure can make a substantial difference.

The most widely used known methods of closure for cesarean section are sutures or staples. Each method comes with its own risks and benefits; however, much has yet to be studied. An ideal closure for a c-section would have minimal discomfort, good cosmetic outcome, be inexpensive, and require fewer follow-ups visits.[2] Recently, improvements have been made regarding research on cesarean section closure techniques. Currently, however, there is limited data on which to base a solid recommendation, therefore leaving much unknown.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not there is a benefit to suturing vs. stapling in cesarean section closure when comparing postoperative pain and patient satisfaction?

METHODS

All randomized control trials (RCTs) were found by the author using MEDLINE, PUBMED, and COCHRANE databases. Keywords used to aid in this search included: cesarean section, c-section, subcuticular sutures, staples, skin closure, patient satisfaction, wound complication, pain, and cosmesis. Only published peer-reviewed studies in English were considered for this review. Caution was made to ensure that no meta-analysis or systematic review of this topic had ever been published. Inclusion criteria incorporated randomized control trials, human subjects and patient oriented outcomes. Using this precise criterion three RCTs were found and included in this paper.

The three RCTs compared the use of the subcuticular sutures (Monocryl 4.0 or 3.0) vs. staples (metallic, stainless steel, and disposable) in cesarean section closure. Common inclusion criteria for all three RCTs were pregnant women over the age of 18 who provided informed consent to participate.[1,3,5] Exclusion criteria was more article dependent; the majority excluded

women with known risk factors for complications such as patients with DM or BMIs >30. However, Basha et al was the only paper to include these higher risk patients in the research. Specific inclusion/exclusion criteria can be found in Table 1. The outcomes measured in the RCTs were postoperative pain and patient satisfaction including wound complications and cosmesis. Statistics reported include Ps, confidence intervals (CI), number needed to treat (NNT), and number needed to harm (NNH).

Table 1: Demographics and characteristics of included studies

Study	**Type**	**# Pts**	**Age (yrs)**	**Inclusion criteria**	**Exclusion Criteria**	**W/D**	**Interventions**
Basha, 2010[1]	RCT	416	≥ 18 y/o	Women ≥ 18 years old, cesarean delivery, gestational age of ≥ 24 wks. Including elective, none-elective, emergent, primary or repeat cesarean delivery.	Women did not provide informed consent, were < 24 weeks of gestation, or had a fetal death.	5	Stainless steel staples (Proximate skin stapler 35 mm wide) closure at skin incision
Cromi, 2010[3]	RCT	123	≥ 18 y/o	Women undergoing cesarean section for any indication who were at least 18 years old.	History of keloids, transversal suprapubic scars or tattoos, hypersensitivity to any materials used in this study, disorders that could affect wound healing (ex: DM, severe malnutrition requiring chronic corticosteroids).	57	Staples (disposable Weck Visistate stapler)
Rousseau, 2010[5]	RCT	101	≥ 18 y/o	≥ 18 years old, elective term cesarean with regional anesthesia, Pfannestiel incision, follow-up in Quebec	Refusal to participate, DM1 or DM2, BMI > 35, ETOH or drug abuse, post-op use of NSAIDs	9	Metallic staples

OUTCOMES MEASURED

All outcomes measured were centered on patient-oriented evidence that matters (POEMs): patient satisfaction, postoperative pain, wound complications, and cosmetic appearance of the incision. Rousseau et al addressed the results of postoperative pain and patient satisfaction. For pain, an analog pain scale was used postoperatively on day 1, 3, and 6.[5] This scale was from 0 (no pain) to 10 (severe pain). The evaluation of patient satisfaction, incision complications, and treatment were collected at these visits as well.[5] Lastly, a photograph was taken of the incision site for estimation of scar quality.[5] Three independently blinded physician observers evaluated these photographs based on five criterions.[5] Scoring was based on width, elevation, color, marks, and general appearance of the wound.[5] Each section was scored 0 to 1 with the best total score being a 5.[5]

The second randomized control trial by Basha et al took a similar approach and focused on patient satisfaction and wound complication rates. Telephone interviews were completed 2-4 weeks after surgery to compile information.[1] Any patient who reported complications was chosen randomly by a single investigator for confirmation, which encompassed reviewing patient medical records. Those who did not complete a telephone interview had their medical records reviewed automatically. During the phone interview, patient satisfaction was gauged using a survey called the Likert scale, "1 (representing strongly agree) and 5 (representing strongly disagree)."[1] Overall satisfaction represented a combination of wound outcome, pain, anxiety, and whether they would desire the same skin closure for future deliveries.[1]

The last RCT is by Cromi et al; this paper examined most extensively the cosmetic outcome of the postoperative scar. Evaluations took place 2 and 6 months postoperatively by using 5 scales.[3] There were two objective components in this study, the Vancouver Scar Scale

(VSS) and the observer scar assessment scale (OSAS).[3] First, the VSS, "rated 4 physical characteristics of the scar: vascularity, pigmentation, pliability, and height".[3] Ranking was from 0-13, with 0 representing normal skin.[3] An advisory panel, representing the objective component of the study, did the scoring. The OSAS scored 5 different areas: "vascularity, pigmentation, thickens, relief, and pliability."[3] Each section was scored from 1-10, with a total score of 5 representing normal skin.[3]

The subjective assessment was the patient scar assessment scale (PSAS) and the visual analog scale (VAS).[3] The PSAS was performed the same day as the VSS scale, however patients were blinded to the observer rating.[3] The PSAS has 6 items on scar-related pain, extent of pruritis, color, stiffness, thickness, and irregularity.[3] Each item was scored 1-10, a total score of 6 meant normal skin healing.[3] The VAS was performed after taking the PSAS.[3] Here, patients were asked to rate their overall satisfaction of the appearance of their scars using a scale from 0 (worst appearance) to 10 (best appearance).[3]

The primary outcomes were assessed 6 months after surgery, which consisted of the POSAS (a combination of PSAS and the OSAS).[3] Secondary outcomes consisted of the VSS and VAS; these assessments were done at 8 weeks (follow-up) and 6 months post-surgery.[3] The 8-week evaluation was centered on the initial healing wound in regards to wound complications.[3] The 6-month visit focused on the cosmetic outcome of the scar.[3]

RESULTS

A study, performed by Rousseau et al, compared staples vs. sutures in skin closure of a cesarean section. The primary outcomes were presented as continuous data that can be converted into dichotomous data. This data was analyzed using intention to treat. This study took 101 women, designating them randomly into two groups, 52 in the suture group and 49 in

the staples group.[5] The completed data used 47 for sutures and 45 for staples; the other patients were lost during follow-up.[5] In this study postoperative pain was less in the staple group (0.17 vs. 0.51) with a P of 0.04.[5]

When evaluating patient satisfaction of incision appearance there was not a strong correlation. The P was 0.9 and was not statistically significant. In order for a P to be statistically significant it needs to be less than 0.05. The incision appearance was equivalent among the use of staples or sutures.[5] When converting this data to dichotomous data, numbers needed to treat (NNT) was used. In doing the calculations, NNT was -20 indicating that the intervention is harmful thus expressing it as NNH is more appropriate. Therefore, for every 20 women treated with the experimental intervention, one less patient was satisfied with wound appearance compared to those treated with the control intervention. The absolute risk reduction (ARR) was calculated to be -0.05 and the relative risk reduction (RRR) was approximately -0.00132. NNT is the inverse of ARR. (Table 2)

Lastly, while wound complications were not measured in this study as an outcome, it was noted that there was one wound infection present in the suture group.[5]

Table 2: Statistical Significance and Efficacy using NNT

Study	CER	EER	RRR	ARR	NNT	P
Rousseau et al,[5]	0.38	0.33	-0.00132	-.05	-20	0.90

In the study performed by Basha et al there were 430 women chosen for the initial study but 14 were excluded (5 were withdrawn by their physician, 4 of which were from the suture group and 9 did not follow up for their evaluation).[1] This left 416 women, 219 for the suture group and 197 in the staple group.[1] From these groups, 16 total, 8 from the suture group and 8 from the staple group, did not complete a satisfaction survey, leaving 211 for the suture group

and 182 for the staple group as a final group who completed the study and did telephone interviews.[1]

A total of 23 had wound separation and had their medical records reviewed for accuracy and further detail.[1] Overall the wound separation rates were more common in the staple group (17% vs. 5% in the suture group).[1] This correlated with a P of <0.001, which is a statistically significant correlation. This is a primary outcome that is presented as continuous data but was converted to dichotomous data. The data was analyzed using an intention to treat analysis as number needed to harm (NNH). The absolute risk increase (ARI) was calculated to be 0.12 and the relative risk increase (RRI) was calculated to be 2.4. Using this analysis the NNH is 9. This means that for every 9 people treated during a cesarean section with staples 1 person will be harmed (have a wound separation). (Table 3)

Table 3: Statistical Significance and Efficacy using NNH

Study	CER	EER	RRI	ARI	NNH	P
Basha et al,[1]	0.5	0.17	2.4	0.12	9	<0.001

Wound complication rates showed a similar trend, staples producing a 22% complication rate and sutures producing 9%.[1] This also correlated with a statistically significant P value of 0.001.[1] Women who were treated with staples were also seen more often in the office for follow-ups and wound complications.[1] All staples were removed on day 3 or 4 postoperatively.[1]

In the satisfaction portion of this study it was noted that 83% of women were satisfied with their wound closure method and would request the same mode of closure for future surgeries.[1] Patient satisfaction decreased for those with wound complications or those who had unscheduled follow-ups.[1] Statistically, however, there was no significance, p = 0.27 using a CI of 95%.[1] This means that even though there were higher wound separation rates and follow-ups

in the staple group, it did not correlate well to satisfaction. Therefore, there was no difference amongst the two groups for satisfaction based on wound closure.

Lastly, Cromi et al evaluated the cosmetic outcome when comparing different wound closure methods. Primary outcomes were presented as continuous data only and were unable to be converted to dichotomous data. In this study a total of 180 women participated in the trial and were assigned to 4 different groups: metallic staples, or three different types of running sutures (absorbable monofilament sutures, nonabsorbable monofilament sutures, or a short-term synthetic absorbable braided and coated suture with low molecular weight polyglycolic acid). [3] 153 patients completed follow-ups, though only 123 went through the final assessment of cosmetic outcome.[3]

Prior to the two-month follow up visit one patient in the absorbable braided suture group developed a wound infection.[3] Also, two patients developed wound dehiscence in the staple and nonabsorable monofilament suture group.[3] These complications resolved by the next follow up date at the 2-month visit.[3] At this 2 month visit there was no difference in the scar appearance ($p = 0.52$). [3] At the 6-month visit scars were considered either mature or hypertrophic.[3] Those that were hypertrophic were similar across the different methods of closure ($p = 0.87$).[3] Among the PSAS, VSS, and the OSAS, there was no difference in ratings at 2 and 6 months.[3] In accordance to patient satisfaction ratings from the VAS and PSAS, the results showed there was no difference from the 2 and 6 month rating ($p = 0.34$).[3] None of the Ps in this study were statistically significant, noting that there was no difference in cosmetic appearance or patient satisfaction among the groups.

DISCUSSION

Many previous studies have shown the use of staples has significantly decreased operating time (8-minute difference).[1] Due to this information, it may be more cost-effective to use staples. However, cost may remain the same due to sutures being less expensive. One study stated their hospital sutures cost $1.66 and staples cost $7.00 dollars.[1] This information also does not take into account length of stay and wound complications, which also factor into delivery cost. This information indicates that this paper is imperative in filling in the gaps.

The systematic review evaluated three RCTs looking for relevance, efficacy, safety, and significance of data. The preponderance of the information was not statistically significant. Safety was paramount in these studies as two lives were involved in the process of delivery. This was no doubt the reason for the extensive list of exclusions, the majority of which were risk factors for surgical complications.

The limitations in the RCTs are evident such as not all the RCTs used double-blind approaches and sample sizes that were not particularly large. Another limitation included problems with compliance in follow-up evaluations thus further decreasing the sample size. Cromi et al, was unable to follow up with the 57 women, therefore, they were not included in the results.[3] Basha et al, had 5 patients withdrawal from the study but they were included in the final results because their medical records were reviewed.[1] Rousseau et al, lost 9 patients, however, all were used in the results using intention to treat analysis.[5]

CONCLUSION

The current investigation as to the preferred technique of skin closure for cesarean section shows that the evidence is inconclusive. Cromi et al, Rousseau et al, and Basha et al concluded that there was no method that correlated to a higher patient satisfaction rating.[1,3,5]

Basha et al noted that those with more wound complications had a lower satisfaction rate.[1] According to their study there was more wound complications in the staple group.[1] The correlation between the use of staples and satisfaction, however, was not statistically significant. Rousseau et al and Cromi et al noted that there was no difference when comparing wound appearance.[3,5] Rousseau et al, however, noted that pain 6 months postoperative was more significant in the suture group.[5] Taking into account that none of these results have statistical significance and were ever replicated in any other study proves that much research is still needed.

Further investigation is required to provide a definitive response. For example, while all of the RCTs were well developed they lacked continuity when it came to known risk factors for cesarean delivery, including obesity and co-morbid conditions such as diabetes mellitus. In this "day and age", these are the populations that are increasing in size in society, thus making these studies not representative of the current times. Wound complication rates would undoubtedly increase under those circumstances and therefore influence the "preferred method of closure".

Similarly, using different suture varieties in comparison to different staple varieties would have been more informative as well. Although Cromi et al was the only study that initiated this, only one staple type was used. More studies using a variety of materials would be beneficial.

In conclusion, further research in these two areas alone could be useful to resolve this controversial issue. This would allow for a broader population of patients and a wide variety of materials to achieve a more comprehensive assessment on which to base an informed recommendation. The evidence from these studies would not only help alleviate surgeon concerns in the operating room, but also ease some of the initial burden of parenthood. The

focus post-delivery could then be on the child and not the healing mother. With an abundance of research accomplished in the last 2 years, it is hoped that the future will bring an answer to this important question.

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