International Research Journal of Medicine and Medical Sciences
Vol. 6(4), pp. 94-100, November 2018
DOI: 10.30918/IRJMMS.64.18.050
ISSN: 2354-211X
Full Length Research Paper

A comparison of subcuticular and staple skin closure techniques for Caesarian Section: A randomized controlled trial in King Abdul-Aziz Medical City, Riyadh, Saudi Arabia

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Accepted 22 October, 2018

ABSTRACT

The objective of the study is to compare the outcome of different closure techniques (subcuticular suture vs. stapler) on patient satisfaction and operative complications post cesarean section. The design is prospective randomized controlled trial. The setting of this study is the Department of Obstetrics and Gynecology, King Abdul Aziz Medical City, Riyadh, KSA. The population or sample includes all pregnant patients with planned elective Caesarian section (CS) to eliminate the effect of confounders such as wound complications resulting from the emergency nature of CS. We calculated our required sample size to be 240 patients. Consequently, 120 subjects were required in each group in order for us to reject the null hypothesis. Both groups were equal with a probability (power) of 80%. The probability of a Type I error (α) associated with this test was calculated as 0.05. Computer-based randomization was performed and the numbers generated were coded to represent the two-different skin closure techniques. Primary outcome measures were wound complications, mainly infection and wound dehiscence, postoperative pain, analgesia requirement and the length of postoperative hospital stay. The secondary outcome measure was patient satisfaction score. Both methods of skin closure were comparable in terms of short- and long-term patient satisfaction although the incidence of wound complication was higher with subcuticular stitches (OR = 2.41; 95% CI: 1.17 - 4.98; p = 0.02). In conclusion, both methods of skin closure were comparable in terms of short- and long-term patient satisfaction although the incidence of wound complication was higher with subcuticular stitches. However, this finding could relate to the increased incidence of diabetes and high BMI in our pregnant population, as well as the relative experience of the operative surgeon performing the procedure.

Keywords: Cesarean section, skin closure, suture, technique, wound complication.

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INTRODUCTION

Caesarean section (CS) is one of the most common obstetric procedures, and on average, 20 to 25% of pregnancies are delivered by CS. However, the rising incidence of CS has also led to an increase in

complications, which are now reported to occur in 2.5 to 16% of cases (Owen and Andrews, 1994). Most of the major steps during CS have been evaluated and evidence-based recommendations made to enhance best practice (Hofmeyer et al., 2008). With regards to skin closure, skin can be reaproximated by a subcuticular suture immediately below the skin or by staples.

Skin wounds are the only step of CS in which patients are able to see and evaluate. It can be distressing for patients if they can see that their CS wound has not healed appropriately and this can impact upon their quality of life. Worryingly, the precise technique used for wound closure following CS is the only step in this common operation that is not supported by conclusive evidence. Consequently, there is significant debate as to which technique and material should be used for CS skin closure (Alderdice et al., 2003).

There are many different techniques used to close skin wounds, including subcuticular stitches with absorbable or non-absorbable sutures, interrupted stitches, staples and skin adhesives. Staples and subcuticular stitches are the most popular techniques. The most commonly used sutures are synthetic polyfilament sutures made from polyglycolic acid (Dexon) or polyglactin (Vicryl). Surgeons generally select the closure method and material according to personal preference. Existing studies on the rate of complications, the degree of patient satisfaction and the cost-effectiveness of CS have not yet identified the best evidence-based recommendation for wound closure technique and material; furthermore, existing data are contradictory (Basha et al., 2010).

Some studies report increased rates of postoperative pain with sutures, while others describe increased rates of postoperative pain with staples (Rousseau et al., 2009; Fishman et al., 1997). Other papers show no difference in cosmetic outcome and patient satisfaction when comparing between staples and sutures (Fishman et al., 1997; Gaertner et al., 2008), although some have shown improved cosmetic outcomes with sutures (Rousseau et al., 2009). Worryingly, wound separation data are also contradictory. Staples have been associated with a shorter procedural time than subcuticular sutures, but with a higher incidence of wound separation (Basha et al., 2010).

Wang et al. (2016) conducted a meta-analysis describing a reduced incidence of wound complications with subcuticular sutures as compared to staples. Operative time was also significantly reduced in the stapler group, although both groups showed similar cosmetic outcomes, pain scoring and patient satisfaction. Interestingly, the most recent Cochrane database (Alderdice et al., 2003) failed to draw any conclusive evidence with regards to CS closure recommendations, but noted that existing RCTs were limited by small sample sizes. Moreover, NICE clinical guidelines (CG132, 2011) state that there is insufficient evidence to recommend any specific technique or material for skin closure. No research has been undertaken on this subject in any Arab countries, including Saudi Arabia. This is worrying as such research may provide recommendations that suit our particular demographic population. In view of such non-conclusive results, the lack of information regarding the best method for CS skin closure, and to identify specific recommendations for the best method for CS skin closure, we conducted a prospective RCT to compare wound outcome, patient satisfaction and cost effectiveness of the subcuticular CS skin closure technique compared with staples.

MATERIALS AND METHODS

Setting

We aimed to compare wound outcome, patient satisfaction and cost effectiveness of subcuticular stitches as compared to staples for the closure of skin following lower transverse incision (Pfannenstiel) for CS. This prospective RCT was carried out at King Abdul Aziz Medical City (KAMC) Riyadh, King Fahad National Guard Hospital (KFNGH), Department of Obstetrics and Gynecology from January 2013 to December 2015. KAMC is a tertiary care referral centre with annual delivery rates of 8000 to 9000 babies per year, and a CS rate of approximately 20%; of these, 34% of procedures are performed on an elective basis.

Study design (randomization, concealments and blinding)

Computer-based randomization was performed and the numbers generated were coded to represent the two-different skin closure techniques. These numbers were then placed in to opaque envelopes and handed over to the labor and delivery nurse manager who was not part of the research team and had no conflict of interest that may have biased the research results.

Ethics approval

All of the patients who participated in this trial provided informed written consent and the trial was approved by the King Abdullah International Medical Research Center (KAIMRC) research and ethical committee and the Institute Review Board (IRB).

Study interventions

The interventional arm of this RCT involved skin closure using subcuticular sutures (polyglactin; vicryl 3-0). The control arm involved a group of patients in which skin incisions were closed by staples. Primary outcome measures were wound complications, mainly infection and wound dehiscence, postoperative pain, analgesia requirement and the length of postoperative hospital stay. The secondary outcome measure was patient satisfaction.

Study subjects (inclusion and exclusion criteria)

We included all pregnant patients with planned elective CS to eliminate the effect of confounders such as wound complications resulting from the emergency nature of CS. Patients with co-morbidities such as diabetes, and immune-compromised patients, were excluded to eliminate the possible effect of disease upon wound healing and its final cosmetic outcomes. Patients who were planned for CS were counseled to participate in the research by

one of the co-investigators. If they agreed, they signed an informed consent form and a sealed envelope, containing computer generated randomization, was selected by an independent person/nurse who had no association with the research or the work of the operating room (OR). The obstetrician performing the procedure was informed about the result of the randomization and the required CS skin closure method was deployed. A co-investigator was responsible for recording patient data and monitoring the duration of the procedure, as well as the duration of skin closure.

Data collection

A patient information sheet was used to collect demographic data such as patient name, age, weight and height, along with the past obstetric and medical history of each patient. Skin closure technique, closure duration in minutes and total procedure time were also recorded. The level of experience of the surgeon performing the CS (resident, registrar or consultant) was also recorded on this sheet.

Standardized anesthesia and analgesia was used both intra- and post-operatively. Post-operative pain scoring was carried out on days 1, 3 and 5. Daily wound inspection was performed by the surgical team to assess patients for signs of infection and dehiscence; this information was recorded on a standardized form.

An evaluation of patient satisfaction was performed at the time of their discharge from the hospital, usually day 3-4 post-delivery, at the 6 weeks post-natal visit and at 6 months by telephone interview to avoid loss of follow up. Cosmetic wound appearance and resultant patient satisfaction scoring was performed using the visual analogue scale by the team, and a patient observation scale. We used a standard questionnaire that included information relating to the patient's experience of wound appearance, pain, discomfort and other possible restrictions (back to work date and sexual activity). We scaled patient satisfaction from 1-4 (very unhappy, unhappy, happy and very happy).

Sample size

This was a prospective study of two independent groups with a patient ratio of 1:1 in each group. Previous data indicated that among patients who had CS skin closure by staples, 13.4% may develop wound infection compared to 6.6% for subcuticular closure. Based on this observation, we calculated our required sample size to be 240 patients. Consequently, 120 subjects were required in each group in order for us to reject the null hypothesis. Both groups were equal with a probability (power) of 80%. The probability of a Type I error (α) associated with this test was calculated as 0.05.

Data analysis

Data were analyzed using SPSS Statistical Analysis Package version 20. Descriptive statistics (means, standard deviations, frequencies) were used to summarize the maternal characteristics of the participating mothers. The student t-test and chi-square test were used for univariate analysis, after assessing the normality of the variables to decide the potential covariates, and a p-value of less than 0.05 was selected to show statistical significance. Logistic regression analysis was used to select which factors among the potential covariate variables were significant predictors of wound infection and other complications. Univariate analysis was then used to compute the adjusted odds ratio (OR) and associated 95% confidence interval (CI) for confounding factors after the assessment of normality for residuals and excluding the effect of any possible interactions.

RESULTS

As shown in Table 1, there was no significant difference in terms of any of the patient characteristics when compared across the two groups: maternal age ($p = 0.83$), parity ($p = 0.06$), and maternal body mass index (BMI) ($p = 0.51$). There were no statistical significant differences between the two groups in terms of maternal comorbidities ($p = 0.53$).

Table 2 shows the effect of skin closure on patient outcome. The mean total operative and skin closure time were both significantly higher in the subcuticular group (G2) ($p < 0.01$ and $p < 0.01$, respectively). There was no statistically significant difference identified between the two groups in term of blood loss ($p = 0.36$). The post-operative length of stay in the hospital was higher ($p < 0.001$) in the stapler group (G1) compared to the subcuticular group (G2). More than 88% of patients were able to be discharged from the subcuticular at day three compared to only 69% from the stapler group ($p < 0.01$).

Table 3 shows the effect of skin closure technique on wound healing. Patients in the subcuticular group (G2) had a risk of developing overall wound complications that was double that for the group of patients treated by staples (OR = 2.41; 95% CI: 1.17-4.98; $p = 0.02$). Wound separation of more than 1 cm was detected to a higher extent among patients in the subcuticular group (G2), but this difference was not statistically significant ($p = 0.19$). Moreover, all forms of wound infection, in terms of fever, discharge and gapping, were found to be higher among patients in the subcuticular group, but with no statistically significant difference ($p = 0.08$).

Table 4 shows the effect of skin closing procedure on post-operative pain. Post-operative pain score on day 1 was more intense among patients in the subcuticular group (G2) (3.83 ± 1.54) compared to 3.43 ± 1.57 in the stapler group (G2). This difference was statistically significant ($p = 0.02$). There was no statistical difference, however, when assessed on day 2 post-CS. As a result, patients in the subcuticular group (G2) required statistically more analgesia on day 1 when compared to the stapler group (G2) ($p = 0.04$), while the overall number of analgesics required by both groups was statistically comparable.

Tables 5 and 6 show patient satisfaction scores at 6 weeks and 6 months, respectively. Patients in the subcuticular group showed slightly higher grades of satisfaction than the group treated with staples in terms of pain, appearance, color and limitation of movements. However, overall, both groups showed almost identical mean total satisfaction scores by 6 weeks post-CS. No statistical differences were detected between the two groups for any of the different parameters.

Almost the same trend was observed at the 6 month follow-up with no statistical evidence for any differences in the satisfaction scores relating to wound healing and wound appearance between the two groups.

Table 1. Maternal characteristics.

Maternal characteristics	Stapler (mean ± SD)	Subcuticular (mean ± SD)	P-value
Maternal age	32.44 ± 5.09	32.37 ± 5.45	0.83
Maternal parity	3.33 ± 2.37	2.83 ± 2.19	0.06
Maternal height	155.78 ± 5.74	156.13 ± 5.89	0.92
Maternal weight	84.97 ± 18.68	83.32 ± 16.36	0.64
Maternal BMI	34.87 ± 7.1	34.17±6.43	0.51
No. of previous CS	1.85 ± 1.48	1.61 ± 1.35	0.20
	Stapler No (%)	**Subcuticular No (%)**	**P-value**
Primary C-section	37 (24.7)	44 (29.3)	0.36
Repeated C-sections	113 (75.3)	106 (70.7)	0.36
Any maternal medical diseases	53 (35.3)	49 (32.7)	0.63
Maternal GDM	19 (12.7)	12 (8.0)	0.184
Maternal hypertension	3 (2.0)	9 (6.0)	0.07

SD standard deviation, OR – odds ratio, GDM – Gestational diabetes mellitus, BMI - body mass index, c/s – cesarean section.

Table 2. Surgical out come by skin closure technique.

Outcome	Staples	Subcuticular	P value
Total operative time (minutes)			
Mean ± SD	55.52 ± 20.94	61.35 ± 16.35	0.001
Median (interquartile range)	53 (25)	60 (20)	
Skin closure time (minutes)			
Mean ± SD	1.89 ± 1.51	8.91 ± 3.93	<0.001
Median (interquartile range)	2 (1)	8.5 (5)	
Title of operating physician			
□ Resident /staff physician	122 (84.1)	115 (79.9)	
□ Assistant / Associated consultant.	17 (11.7)	23 (16.0)	0.603
□ Consultant.	6 (4.1)	6 (4.2)	
Blood loss			
Mean ± SD	617.13 ± 436.34	593.35 ± 182.58	0.36
Median (interquartile range)	500 (100)	500 (200)	
Type of Anesthesia.			
- Spinal	131 (90.3)	123 (84.2)	0.38
- General	13 (9.0)	18 (12.3)	
Post-operative hospital stay			
3 DAYS	104 (69.0)	133 (88.7)	
5 DAYS	44 (29.3)	16 (10.7)	<0.001
MORE THAN 5 DAYS	2 (1.3)	1 (0.7)	
Clinic visits for clips removal.	Not available		

SD - standard deviation, p value – probability value.

Table 3. Wound complications by skin closure technique.

Parameter	Staples	Subcuticular	OR (CI)	P value
Wound complications	12 (0.08)	26 (2.6)	2.41 (1.17-4.98)	0.02
Wound separation > 1 cm	5 (3.3)	10 (6.7)	2.07 (0.69-6.21)	0.19
Wound infection	7 (4.7)	16 (10.7)	2.44 (0.97-6.11)	0.08
Fever	0 (0.0)	3 (0.03)		
Gapping	0 (0.0)	2 (0.02)		
Discharge	4 (0.04)	4 (0.04)		
Fever and discharge	1 (0.01)	1 (0.01)		
Discharge and gapping	0 (0.0)	5 (3.3)		
Fever and gapping	1 (0.01)	1 (0.01)		
Need for antibiotics	5 (3.3)	11 (7.3)	2.29 (0.78-6.77)	0.12
Readmission due to wound Complications	1 (0.01)	0 (0.0)		

SD - standard deviation, OR - odds ratio, CI - confidence interval, p value - probability value.

Table 4. Post-operative period characteristics.

Characteristics	Staples (mean ± SD)	Subcuticular (mean ± SD)	P-value
Post-operative pain score:			
- D1			
Mean ± SD	3.43 ± 1.57	3.83 ± 1.54	0.02
Median (interquartile range)	4 (1)	4 (1)	
- D2			
Mean ± SD	1.86 ± 1.81	1.67 ± 1.68	0.34
Median (interquartile range)	2 (3)	2 (3)	
Post-operative analgesia used:			
- D1			
Mean ± SD	1.61 ± 0.5	1.73 ± 0.48	0.04
Median (interquartile range)	2 (1)	2 (1)	
- D2			
Mean ± SD	0.37 ± 0.61	0.30 ± 0.59	0.22
Median (interquartile range)	0 (0)	0 (1)	
Overall no. of analgesia used per patient (day 1 and day 2)			
Mean ± SD	1.97 ± 0.81	2.03 ± 0.84	0.57
Median (interquartile range)	2 (1)	2 (1)	

SD – Standard deviation, p value- probability value.

DISCUSSION

In this randomized controlled trial, we describe the outcomes of two skin closure techniques for lower transverse caesarean section operation. Our results revealed that the duration of operation, and skin closure time, were reduced using the staple technique. However, the length of hospital stay was higher in the stapler group. The stapler technique was associated with less wound complications, pain and analgesia requirements compared with the subcuticular technique. The overall patient satisfaction was similar when compared across the two groups.

The mean duration of CS operation reported in our study was significantly reduced when staplers were used for skin closure as compared to the subcuticular technique with consequential reductions in operating time, duration of anaesthesia and the provision of better

Table 5. Patient satisfaction score at 6 weeks.

At 6 weeks	Staples (n = 142)	Subcuticular (n = 139)	P value at 6 weeks
Pain	4.49 ± 1.10	4.53 ± 1.06	0.87
Appearance	4.51 ± 1.18	4.61 ± 1.08	0.41
Color	4.46 ± 1.17	4.57 ± 1.02	0.59
Itching	4.54 ± 0.79	4.41 ± 0.99	0.41
Limitation of movement	4.72 ± 0.87	4.80 ± 0.72	0.49
Discomfort	4.72 ± 0.76	4.61 ± 0.88	0.13
Overall satisfaction	27.56 ± 3.67	27.56 ± 4.36	0.61

P value - probability value, n - number.

Table 6. Patient satisfaction score at 6 months.

At 6 months	Staples (n = 132)	Subcuticular (n = 125)	P value
Pain	4.83 ± 0.57	4.88 ± 0.45	0.38
Appearance	4.73 ± 0.81	4.76 ± 0.83	0.37
Color	4.73 ± 0.84	4.76 ± 0.76	0.82
Itching	4.77 ± 0.52	4.69 ± 0.74	0.96
Limitation of movement	4.95 ± 0.21	4.95 ± 0.31	0.59
Discomfort	4.89 ± 0.43	4.81 ± 0.59	0.12
Overall satisfaction	28.90 ± 2.27	28.86 ± 2.72	0.99

p value – probability value, n – number.

obstetrics services in the limited time frame of a busy obstetric unit. This difference was observed mainly due to clinicians having more experience with the stapler than the subcuticular technique at the study centre. This concurs with a previous study which found that increased levels of expertise with subcuticular stitches than with the stapler led to better outcomes (Fishman et al., 1997).

We also found that post-operative pain score was significantly more intense in the subcuticular group during the early post-operative period with an increase in analgesic requirements; however, this difference was not significant on day-2 post-CS. The same pattern was observed in the study by Roseau et al. (2009) who found increased levels of pain with subcuticular stitches in the early post-operative period in contrast to another study conducted by Frishman et al. (1997) who found an increase in pain scoring with staplers. In our present study, this difference was mainly due to the early mobility observed in the subcuticular group, with an associated increase in analgesia requirements in this group.

Regarding wound complications with two closure techniques, we observed an increased incidence of wound complications with the subcuticular technique which was in contrast to the observation by Wang et al. (2016) (involving the meta-analysis of 10 RCTs) who reported an increased risk of complications with skin staplers. Another systemic review by Alderdice et al. (2003) (Cochrane database), however compared both techniques of skin closure and failed to demonstrate any significant difference regarding wound complications. The difference in the observations in our study was mainly due to the high prevalence of obesity (BMI > 35) among the Arab population, as well as operator experience and skill. Zaki et al. (2016) studied the relative effects of sutures and staples in terms of body mass index (BMI >30 kg/m^2) and identified a greater risk of wound complications with subcuticular sutures.

Cosmetic wound appearance and resultant patient satisfaction scoring was performed using the visual analogue scale by the team, and a patient observation scale, as described by Basha et al. (2010). We found out no difference in patient satisfaction between the two groups, either at 6 weeks post-CS or 6-month post-CS. However, we cannot completely exclude observer bias as it was almost impossible to blind the observer and the patient.

There was no direct cost analysis performed in our present study, but the cost of a stapler is higher than the subcuticular stitches and requires an additional hospital visit for removal which will inevitably contribute to the overall cost. Additionally, we observed that patients with staples had an extended stay in the hospital (88% vs. 69%) with a consequential increased burden upon hospital resources

There are certain limitations of our study for example all CS were not done by a single operator. This brings the question of intersurgeon variations of the skill of closure method. In our study, most of the CS operations were performed by residents with little contribution from senior staff. The level of expertise regarding closure with the

subcuticular technique was also limited as stapler closure remains the most popular method of skin closure at this study centre. We have included primary and repeat elective CS which might have differences in wound healing and cosmetic appearance.

In future more, broad scale research is required to recommend a single closure method over the other. Additionally, different suture materials for pfenensteil and vertical incision should be investigated. Different absorbable suture materials (vicryl and monocryl), absorbable and non absorbable skin staples should also be compared.

Conclusion

Both methods of skin closure were comparable in terms of short- and long-term patient satisfaction although the incidence of wound complication was higher with subcuticular stitches. However, this finding could relate to the increased incidence of high BMI in our pregnant population, as well as the relative experience of the operative surgeon performing the procedure.

ACKNOWLEDGEMENT

This work was sponsored and funded by King Abdullah International Medical Research Centre (KAIMRC).

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Citation: Al-Kadri H, Elsherif EI, Khan L, Fillimban HM, Kurdi SF, Fayed AA, Qureshi S, 2018. A comparison of subcuticular and staple skin closure techniques for Caesarian Section: A randomized controlled trial in King Abdul-Aziz Medical City, Riyadh, Saudi Arabia. Int Res J Med Med Sci, 6(4): 94-100.