



Comparing Subcuticular Sutures versus Percutaneous Staples for Skin Closure after Caesarean Delivery: A Randomized Controlled Study

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Authors' contributions

This work was carried out in collaboration between all authors. Authors LCI and EII designed the study, wrote the protocol, and wrote the first draft of the manuscript. Authors CCD and ACAB managed the literature searches, performed the spectroscopy analysis while authors HUE and CKO carried out the statistical analysis. All authors read and approved the final manuscript.

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ABSTRACT

Background: Wound complications following caesarean delivery are significant causes of morbidity and financial strain especially in low resource countries. Use of appropriate technique in skin closure could reduce the emotional burden of an already difficult period of adjustment.

Objective: To compare the outcome of surgical metallic staples versus absorbable subcuticular suture for skin closure at caesarean delivery.

Methods: This was a randomised interventional study of pregnant woman booked for caesarean delivery in two hospitals in Enugu, south east Nigeria. Data was analysed using SPSS computer

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software version 20.0 for windows (Chicago IL, USA). Proportions were compared using Pearson's Chi Square or Fisher's test as appropriate. P value of ≤ 0.05 was considered statistically significant.

Results: Two hundred and twenty women booked for elective and emergency caesarean section were randomised into surgical metallic staples and absorbable subcuticular sutures groups. Outcome in the staples and sutures groups are; composite wound complications, (11.9%) vs (3.8%) $p=0.041$, mean operation time (minutes), (50.7 ± 6.88) vs (69.5 ± 5.71) $p<0.001$, mean post operation pain, (1.8 ± 1.18) vs (1.1 ± 0.99) $p<0.001$ and maternal satisfaction (8.05 ± 0.54) vs (9.5 ± 0.75) $p=0.011$.

Conclusion: Women in Enugu, Nigeria are more satisfied with subcuticular absorbable suture for skin closure following caesarean delivery.

Keywords: Skin; metallic; staple; absorbable; subcuticular; caesarean section.

1. INTRODUCTION

Caesarean section is one of the commonly performed major abdominal operations in women in both high and low income countries. It is a lifesaving procedure for both the mother and the baby.

Although unevenly distributed, approximately 15% of pregnant women worldwide deliver by caesarean section and this procedure are on the increase [1]. The rate in many high income countries varies between 32.8% and 37.4% [2,3]. In Nigeria, the rate ranges from 10.9% to 34.5% in some tertiary institutions which serve as referral centres [4,5].

As the rate caesarean delivery increases, so does the associated complications. Wound complications following caesarean delivery occur in 2.5%-16% of cases [6]. Wound complications from caesarean delivery such as disruption or infection are a significant emotional or economic burden in obstetric care [7]. The post-partum period is challenging for women as a result of recovery from the delivery process. A post-operative wound complication further worsens an already difficult period of adjustment.

Methods of closing the skin at the time of caesarean delivery include stainless steel staples, subcuticular absorbable staples, subcuticular sutures, adhesive closure strips and tissue adhesives [7,8]. A number of studies have compared these techniques with conflicting results [8,9]. Subcuticular sutures have been associated with lower wound complications rates, reduced pain, improved cosmetic outcome and cost effectiveness in some studies [1,10]. However it has been postulated that sutures are absorbed over time and act as foreign bodies thereby eliciting more tissue reaction leading to increased infection rates [6,11].

Metal staples are attractive because of speed of application which shortens operation time and considerably reducing the risk of developing post-operative wound infection [1,12]. There has also been mixed results when comparing wound pain and cosmetic between staples and subcuticular sutures [9,11]. However, steel staples are more expensive than suture materials and leave hatch marks especially when left in place longer [11,12]. Wound closure with absorbable subcuticular staples eliminated the need for staple removal and potential for railroad track scar as with percutaneous metal staples [7].

Most studies on the skin closure after caesarean delivery dwelt more on cosmetic aspect, patients' satisfaction and post-operative pain [1,8,12] with only a few on wound complications [13,14]. Furthermore those studies were done in high income countries. This study was carried out to determine composite wound complication rates, post operation pain and patient satisfaction for subcuticular suture versus staples for skin closure at caesarean delivery. It is hoped that this randomised controlled trial would guide healthcare providers regarding safety, cosmetic and infectious wound outcomes with these techniques of skin closure.

2. MATERIALS AND METHODS

2.1 Study Centres

The study was carried out at the University of Nigeria Teaching Hospital (UNTH) and Blessed Assurance Specialist Hospital for women (BASH), both in Enugu, South eastern Nigeria. UNTH covers an area of about 200 acres and the current bed capacity is 800. It attends to 2000-2500 deliveries annually and up to 20% of these women are delivered through caesarean section. BASH is a specialist hospital for women which

offer purely gynaecological and obstetrics services. The hospital is located within the densely populated area of Enugu metropolis. The hospital has a total 24 beds for both obstetrics and gynaecological cases. It attends to an average of 125 deliveries per month out of which about 25% are delivered through caesarean section.

2.2 Ethical Compliance

The study was commenced after approval by the Institutional Review Board (IRB) of the hospitals. Each woman eligible for the study was counselled and written consent obtained. She was assured of the confidentiality of any information given and if consent was refused, it would not affect the quality of care.

2.3 Inclusion Criteria

The inclusion criteria include consenting pregnant women at ≥ 28 weeks gestational age booked for caesarean section at the study centres, women who will have follow up at the study centres after delivery and caesarean sections performed under regional anaesthesia.

2.4 Exclusion Criteria

The exclusion were history of previous caesarean sections, established or gestational diabetes, absolute weight ≥ 115 kg, intra uterine fetal death, women living with human immunodeficiency virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS), chronic steroids use and history of prolonged rupture of membranes. Patients on cytotoxic drugs, or anticoagulants and those with haematological disorders or malignancy were also excluded from the study.

2.5 Study Design

This was a randomised study of eligible pregnant women booked for caesarean section at the study centres from 1st July 2014 to 30th June 2015. The randomization of the patients was accomplished utilizing a computer generated randomized schedule, placed into consecutively numbered opaque, sealed envelopes. This was prepared by a statistician before the commencement of the study and was not made available to the researcher. The eligible women were assigned by means of these computer generated random numbers into 2 sample groups; staple group (A) and subcuticular suture

group (B). Thereafter, a third party who was blinded to the study objectives/outcome and not directly involved in the patients care was responsible for keeping the envelopes and was contacted to open the corresponding envelope for the purpose of treatment allocation.

2.6 Determination of Sample Size

Sample size was determined using the formula for calculating minimum sample size for an interventional study comparing use of staples and subcuticular sutures in the study and control groups [15]. With $Z_{\alpha}=1.96$ at 0.05 level of significance, power of 80% and 11% as incidence of wound infection following caesarean section in a study in Awka, Nigeria [16] the calculated minimum sample size was 109. For the study, each arm consisted of 110 pregnant women, giving a total sample size of 220 for the two groups.

2.7 Techniques for Caesarean Section

The caesarean section was carried out using the UNTH protocol. Under regional anaesthesia, the patient was placed in supine position with 15° left tilt. The abdomen was cleansed twice with 1% hibitane solution and dried. It was then painted with povidone iodine 3 to 4 minutes before the operation started. The skin incision was pfannenstiel and a prophylactic antibiotic (ceftriazone) was administered in all patients immediately after clamping the cord.

After stitching the uterus, the parietal peritoneum was closed with vicryl No 2/0 (Ethicon) suture and the recti muscles approximated in the midline using vicryl No 2 (Ethicon) suture. The rectus sheath was then closed with No 2 nylon (Ethicon) suture. The subcutaneous layer was closed with vicryl 2/0 (Ethicon) suture for all women. Those in the subcuticular suture group had their skin closed in one continuous subcuticular closure using 2/0 vicryl (Ethicon) suture with knots buried at the lateral edges of the wound. Women in the surgical staple group had their skin edges ever led and approximated using a toothed dissecting forceps and the stapler (Kaydee Medical Appliances Limited, China) positioned over the centre of the everted skin edges before staple application by squeezing the handle completely. The staples were applied 1.5 cm apart. Consultants and senior registrars trained on the use of staples and unaware of the study protocols closed the wounds. Only round bodied needles were used

in the surgeries. Post operation analgesia was achieved with intramuscular pethidine, 100 mg 8 hourly for 48 hours in both groups of patients. When bowel sounds returned, the parenteral analgesia was converted to tablets paracetamol 100 mg 8 hourly for five days.

The wound dressing was removed and the wound inspected and cleansed on the 2nd day post operation. The staples were removed on the 6th day post operation. All patients were discharged on the 6th day post operation.

2.8 Data Collection

At enrolment, information on maternal age, tribe, educational status, parity, gestational age, duration of rupture of membranes, and type of caesarean was collected used proforma (a case record form). The indication for the caesarean section was clearly stated.

Anthropometric measurements such as weight and height were performed and recorded by the researcher assisted by four trained nurses in the antenatal and labour wards using standard methods [17]. The operation time was noted by the circulating nurse in theatre.

A standardized physical examination of the wound was performed independently by the researcher and one of the two trained research assistants on post operation days 2, the day of hospital discharge and at the post natal visits (6 weeks post operation) for wound complication (separation and infection). Where there were conflicting results of assessment, the assessment of the third research assistant served as a tie breaker.

The women also completed a visual analogue scale ranging from 0-10 [1,11] for pain on the 2nd and 6th day post operation and 6 weeks post operation, with 0 indicating no pain and 10 indicating highest pain level and the degree of pain grouped as mild (0.1-3.9), moderate (4-6.9) and severe (7-10) [18]. Maternal satisfaction at the 6 weeks post operation visit was also recorded on a visual analogue scale [11] of 0-10, with 0 meaning not satisfied and 10 being most satisfied. Reminder phone calls were made by the researcher to patients two days before their post-natal appointment to ensure follow up. Home visits were also made by the researcher and the assistants to assess the wounds and

complete data collection for nine participants who were not able to make the follow up visit.

2.8.1 Primary outcome measure

The primary outcome measure was prevalence of composite wound complication following skin closure with staples and subcuticular sutures.

2.8.2 Secondary outcome measures

The secondary outcome measures included; analogue post-operative pain score, the average operation time and analogue patients' satisfaction score.

2.9 Statistical Analysis

Data collected were keyed into the Statistical Package for Social Sciences (SPSS) computer software version 20.0 for windows. Continuous variables were analysed using mean \pm SD and compared between the two groups using student t test. Proportions were compared using the Pearson's chi square or Fisher's exact test as was appropriate. Relationships were expressed using relative risks at 95% confidence interval. All tests were two sided and p value of ≤ 0.05 was considered statistically significant.

2.10 Definition of Terms

2.10.1 Wound separation

Separation of the wound varying in size from small skin defects to separation of the entire wound.

2.10.2 Wound infection

Purulent drainage, cellulitis, abscess or wound requiring drainage, debridement or use of antibiotics associated with a clinical diagnosis of infection [1,9,12].

2.10.3 Composite wound complications

When a participant had either or both wound separation or infection.

2.10.4 Operation time

Time from incision of the skin to the end of the skin closure.

2.10.5 Prolonged premature rupture of membranes

Rupture of membranes 12 hours or more before caesarean section [12].

3. RESULTS

Two hundred and twenty eligible pregnant women booked for elective and emergency caesarean section were recruited from the study centres as follows; 137(62.3%) from UNTH and 83(37.7%) from BASH. Among those recruited, 110 had skin closure using staples while the other 110 had skin closure using subcuticular sutures. One participant from the staple group and four participants from the suture group were lost to follow up at the 6 weeks post natal visit hence the number analysed was 109 for staple group and 106 for suture group.

Table 1 shows that the basic characteristics of the participants in both groups were similar. The mean ages of participants were 29.9 ± 3.97 years and 30.0 ± 5.54 years for the staples and suture groups respectively.

Most participants had emergency caesarean section in both the staple and suture groups (67.9%) vs (55.7%) $p=0.070$.

Table 2 shows the effect of skin closure technique on wound complications. Composite wound complications occurred in 13(11.9%) participants of the staple group as against 4(3.8%) women in the suture group. The

observed difference was statistically significant ($P=0.041$, RR 3.5 95% CI 1, 09-10.96). Wound separation observed on the 6th post operation day was significantly higher in the staple group when compared with the suture group (11.9%) vs (3.8%), $p=0.021$.

Furthermore, wound infection on 6th day post operation was observed on 4(3.7%) participants in the staple group and non in the suture group.

The mean operation time in the staple group, 50.7 ± 6.88 (range: 40-70) minutes was significantly shorter than 69.5 ± 5.71 (range: 55-80) minutes observed in the suture group ($P<0.001$). Most surgeries, 104(95.4%) in the staple group lasted 1 hour or less unlike in the suture group where 7.5% of cases lasted 1 hour or less ($p<0.001$).

Table 3 shows the analogue score for pain according to skin closure technique. Post operation pain was more in staple group when compared to the suture group on both 2nd and 6th post operation day. This difference was statistically significant for both days ($p<0.001$). The degrees of pain observed in the participants were within the mild range except for 2 participants who had moderate pain on the 2nd day post operation.

Table 1. Participants' basic characteristics

Characteristics		Staple group (n=109)	Suture group (n=106)	P value
Age (years)	Mean \pm SD	29.9 ± 3.97	30.0 ± 5.54	0.834
	<20	4(3.7%)	6(5.7%)	0.069
	20-29	49(45.0%)	43(40.6%)	
	30-39	56(51.4%)	51(48.1%)	
	≥ 40	0(0.0%)	6(5.7%)	
Parity	1	70(64.2%)	63(59.4%)	0.130
	2 – 4	39(35.8%)	39(36.8%)	
	≥ 5	0(0.0%)	4(3.8%)	
Ethnic group	Igbo	95(87.2%)	94(88.7%)	0.872
	Hausa	2(1.8%)	2(1.9%)	
	Yoruba	6(5.5%)	3(2.8%)	
	Others	6(5.5%)	7(6.6%)	
Highest educational status	Informal	2(1.8%)	0(0.0%)	0.377
	Primary	5(4.6%)	8(7.5%)	
	Secondary	33(30.3%)	37(34.9%)	
	Tertiary	69(63.3%)	61(57.5%)	
Rupture of membranes	Yes	36(33.0%)	27(25.5%)	0.235
	No	73(67.0%)	79(74.5%)	
Weight (kg)	Mean \pm SD	87.5 ± 9.38	89.0 ± 6.72	0.179
	<90	54(49.5%)	45(42.5%)	0.339
	≥ 90	55(50.5%)	61(57.5%)	

Table 2. Effect of skin closure technique on wound complication

Wound complication		Staple group (n=109)	Suture group (n=106)	P value	RR(95% CI)
Wound separation (2 nd DPO)	Yes	0(0.0%)	4(3.8%)	0.057	-
	No	109(100.0%)	102(96.2%)		
Wound infection (2 nd DPO)	Yes	0(0.0%)	0(0.0%)	-	-
	No	109(100.0%)	106(100.0%)		
Wound separation (6 th DPO)	Yes	13(11.9%)	4(3.8%)	0.021	3.5(1.09-10.96)
	No	96(88.1%)	102(96.2%)		
Wound infection (6 th DPO)	Yes	4(3.7%)	0(0.0%)	0.122	-
	No	105(96.3%)	106(100.0%)		
Wound separation (6 weeks)	Yes	0(0.00%)	0(0.0%)	-	-
	No	109(100.0%)	106(100.0%)		
Wound infection (6 weeks)	Yes	0(0%)	0(0.0%)	-	-
	No	109(100.0%)	106(100.0%)		
Composite wound complication	Yes	13(11.9%)	4(3.8%)	0.041	3.5(1.09-10.96)
	No	96(88.1%)	102(96.2%)		

Table 3. Analogue score for pain according to skin closure technique

Analogue score and degree of pain		Staple group (n=109)	Suture group (n=106)	P value
2nd DPO	Mean±SD	1.8 ± 1.18	1.1 ± 0.99	<0.001
No pain		22(20.2%)	36(34.0%)	0.022
Mild pain		85(78.0%)	70(66.0%)	
Moderate pain		2(1.8%)	0(0.0%)	
Severe pain		0(0.0%)	0(0.0%)	
6th DPO	Mean±SD	0.6 ± 0.76	0.2 ± 0.51	<0.001
No pain		64(58.7%)	94(88.7%)	<0.001
Mild pain		45(41.3%)	12(11.3%)	++
Moderate pain		0(0.0%)	0(0.0%)	
Severe pain		0(0.0%)	0(0.0%)	
6 weeks	Mean±SD	0.0 ± 0.19	0.1 ± 0.24	0.345
No pain		105(96.3%)	99(93.4%)	0.370
Mild pain		4(3.7%)	7(6.6%)	
Moderate pain		0(0.0%)	0(0.0%)	
Severe pain		0(0.0%)	0(0.0%)	

However, at 6 weeks, post-operative pain did not differ between the two groups ($p=0.345$). Maternal satisfaction was significantly higher among participants in the suture group than those in the staple group (9.5 ± 0.75) vs (8.05 ± 0.54), $p=0.011$.

4. DISCUSSION

The risk of developing any wound complication in women who had staple skin closure in this study (11.9%) was significantly higher than that

of those whose skin were closed with subcuticular absorbable sutures (3.8%). These findings are supported by reports from related studies in Alabama USA [1], Pennsylvania USA [8] and Durban South Africa [12]. In Switzerland, Geartner et al. [9] reported no significant difference in wound complication between the staple and suture groups. The reason for this could be due to the broader criteria used for exclusion and the small number of participants in their studies.

The wound complications, which were higher in the staple group, were noticed on the 6th day post operation wound evaluation. No wound complication was noticed on the 6th week post operation visit unlike in the report by Figueroa et al. [1] which showed more composite wound complications at 6 weeks. Similarly, Chunder et al. [12] reported 84% of the wound complications occurring after hospital discharge. Both studies included vertical abdominal incisions and repeat caesarean section, which were excluded in the present study. These could have resulted in the difference due to less strength and healing outcome of wounds and higher risks of wound infection in such patients as reported by Orji et al. [19]. In a review of 130 women undergoing emergency caesarean section without previous abdominal delivery as in our study, Sharma et al. [10] observed comparable wound complications at 6 weeks after skin closure with staples or subcuticular sutures thus highlighting the importance of proximate patient characteristics in these cross-study comparisons.

Overall, surgical staples were significantly observed to be associated with higher incidence of composite wound complications up to 6 weeks after caesarean section. This may be attributed to the higher incidence of wound separation. Mackeen et al. [20] observed that closure of the transverse skin incision with subcuticular sutures significantly decreases wound morbidity, specifically wound separation, and their concealment below the skin without connection to the external environment reduces the entry of bacteria unlike in the staple closure [6]. This is particularly important in our environment where personal hygiene may not be optimal. Additionally, subcuticular sutures which stay longer provide increased tensile strength to the incision because of their increased time of re-absorption [8]. Several studies reported variable post operation day of removal of staples [1,6]. A 2012 Cochrane review reported a higher incidence of wound dehiscence with early (<4 days) removal of staples in women with Pfannenstiel incisions [21]. In this study, staples were removed on the 6th post operation day and this may have contributed to the low incidence of wound separation.

In this study, the mean operation time was significantly shorter in the staple group compared to the suture group. This is in line with other reports [1,6,9]. The shorter operation time

with staples may be an advantage in reducing over scheduling and intra operative costs in busy referral centres like ours. Although cost was not evaluated in this study, several studies suggest that the aggregate costs of wound closure technique were significantly higher for the staple group compared to the suture group [1,22,23]. Consequently, the gains in intra operative costs may be blighted by costs of logistics and staples/applicators especially in our environment without insurance coverage for health services [24].

In our study, post operation pain which was generally mild, was significantly higher in the staple group on the 2nd day and 6th day post operation. There was however no significant difference in post operation pain felt by the participants in both groups at 6 weeks. This observation differed with findings of similar studies [1,6] that reported no significant difference in post operation pain up to 6 weeks post operation in the staple and suture groups. This may be attributed to the fact that in our study, staples were removed on the 6th day post operation as against 3rd to 4th day post operation in other studies [1,6]. The allergic or inflammatory reactions occasioned by the delayed removal of the metallic percutaneous staples may have contributed to the increased duration of pains felt by the patients in our study.

Maternal satisfaction was significantly higher in the participants that had skin closure with subcuticular suture compared to those that had staple closure. This is in consonance with other reports [6,13]. Conversely, other reports showed higher satisfaction with staple suture [8,9]. There are also several reports from related studies which showed that patients' satisfaction for the two closures techniques was equivalent [1,20]. The extra cost and the higher incidence of wound complications and pains at removal of the metallic staples may have affected the level of satisfaction in this study. Patients in the subcuticular suture group may have been elated to know that their stitches did not require removal.

5. LIMITATION

We did not evaluate specific suture techniques or surgeons' skill. Murphy et al. [25] suggested that poor surgical techniques and accuracy of suture or staple closure may have an effect on wound healing.

6. CONCLUSION

The women in Enugu, Nigeria preferred subcuticular sutures to surgical staples. Staples were associated with higher wound complication rate, mean post operation pain and lower maternal satisfaction than subcuticular sutures. Our study recommends the use of absorbable subcuticular suture instead of staples among women undergoing caesarean delivery, especially after a transverse skin incision.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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