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Skin Staples versus Nylon Mattress Sutures for Closure of Low Midline Cesarean Section Incisions: A Randomized Controlled Trial

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ABSTRACT

Objective To compare post-operative pain after cesarean section, time taken in skin closure, rates of wound infection and wound dehiscence from two skin closure techniques—skin staples and interrupted vertical mattress nylon suture.

Study design Randomized controlled trial.

Materials and methods Pregnant women undergoing cesarean sections through a low midline incision at Khon Kaen Regional Hospital from August 1st, to December 31st, 2006 were randomized into two groups. The first group received skin closure using staples. The other received interrupted vertical mattress suture with 3/0 nylon. Time taken in skin closure and wound length from each operation were recorded for comparison in the dimension of seconds per centimeter (sec/cm). Post-operative pain was determined on the second day after the operation using 100 mm visual analog scale (VAS). Additional doses of opiate and non-opiate drugs were also recorded.

Results Thirty nine of eighty one participants were in the stapled group. The other forty two were in the sutured group. The mean pain scores for the staples and the suture were 4.7 and 3.90 respectively (p-value 0.003). Additional doses of opiate drug needed in the staples and the suture were 0.21 and 0.31 doses per participant (p-value 0.477). Mean doses of non-opiate drug per participant in the staples and the suture were 3.6 and 3.0 doses respectively (p-value 0.006). The mean time for closure with staples and suture were 7.48 sec/cm and 29.61 sec/cm respectively (p-value 0.000). Wound infection and wound dehiscence occurred in neither group.

Conclusion Staples was superior to conventional suturing in time consuming but had higher pain level with statistical significance.

Keywords: Low midline incision, Cesarean section, Skin closure, Staples, Nylon

Introduction

There are two kinds of incisions in cesarean section: low midline incision and Pfannenstiel incision.[1] Which incision is to be chosen, it is much dependent on preferences and experience of surgeons as well as the indication of the surgery. Focusing on low midline incision, a variety of skin closure techniques can be used; for example interrupted suture, subcuticular suture or even skin staples. Most of obstetricians working in Khon Kaen Regional Hospital preferred interrupted vertical mattress for midline skin closure because it was considered a good choice for eversion of skin.[2]

Skin staples are an alternative method of midline skin closure. In theory, staples are attractive because there is less chance of bacterial migration into the wound and the subcuticular layer capillaries are not damaged during placement of the clips.[3] Although staples are as strong as nylon and less reactive to tissue than other non-absorbable sutures,[2] staples are not widely used by obstetricians. On the other hand, staples become more popular in the surgery department. The fundamental reasons of this difference might be from the difference in patient groups and the type of operations. Because of more abdominal distention in pregnant women, obstetricians are skeptical about post-operative outcomes, namely post operative pain, rate of wound infection or wound dehiscence; all of which make pregnant women different from patients in surgery department.

From the previous studies,[4-7] there were some issues that had never been studied before. There was one study[4] that studied in pregnant women underwent in Pfannenstiel incisions (not in low midline incisions). This study was then intended to focus on such areas including:

1 Post-operative pain
2 Speed of skin closure
3 Wound infection or wound dehiscence

All above were studied within groups of pregnant women who underwent vertical incisions.

Materials and Methods

The pregnant women undergoing cesarean sections through a midline incision at Khon Kaen Regional Hospital from August 1st, 2006 to December 31st, 2006 were recruited to this study upon achieving approval of Khon Kaen Regional Hospital ethic committee. All the pregnant women provides informed written consents. Pregnant women who had the following conditions were excluded from the study.

1 Previous Pfannenstiel incision
2 Body mass index (BMI) > 30
3 HIV infection
4 All types of gestational diabetic mellitus (GDM)
5 Any kind of cancers
6 Private case

There were 81 pregnant women enrolled in this study. They were randomly separated into two groups by block design randomization. The first group underwent skin closure using staples while the other group used interrupted vertical mattress suture with 3/0 nylon. A sealed envelope signifying the specific skin closure arm was placed with the patient's index card.

Different obstetricians contributed to skin closure in the 81 pregnant women. For every wound, the fascia layer must be sutured by polyglycolic (Dexon) 1/0 and the subcuticular layer must be sutured by plain catgut. The envelope was opened by a circulating nurse in the operation room just prior to skin closure. That was when the surgeon knew the skin closure technique to be used.

Measurement of time spent in skin closure was made starting from the time devices were picked up until the devices were returned. The time was recorded in seconds by a circulating nurse. The length of wound was measured using the centimeter scale provided on a scalpel. The surgeon measured the length of wound after skin closure just before applying povidine.

All wounds were applied with povidine before gauze and adhesive patch were placed. No further wound cleansing or opening was required until the 7th day after the operation which was the same day

staples were removed or sutures were stitched off. However, the exception could be applied to wound infection and wound dehiscence. Wound infection and wound dehiscence were observed through oozing of hematoma, seroma or pus, unknown fever causing body temperature higher than 38 °C, pres ence of swelling or erythematous skin around the adhesive patch.

Post-operative pain was determined using 100 mm visual analog scale on the second day after operation. Every pregnant woman received continuous intravenous opiate drug within the first 24 hours after the surgery. All additional opiate and non-opiate drug usage, if occurred, would be recorded.

Sample variables including demographic data (age, body mass index, gravidity, indication of surgery, surgeons classified by level of experience, length of wound) were recorded prospectively.

Statistical analysis was performed using SPSS PC version 11.0 for Windows and Epi Info version 3.3.2. The baseline characteristics were calculated and compared using unpaired t-test for parametric data while categorical data were calculated using Fisher's exact test. The outcomes were compared using independent unpaired t-test and exact probability test as appropriate. The level of statistical significance was p-value < 0.05.

Sample size calculation

From the prior study, Ranaboldo CJ and Rowe-Jones DC[5] found a group difference of 0.68 cm, with standard deviation (SD) = 0.9cm.[5] For the primary outcome of pain rating (100 mm visual analog scale) at the second day after cesarean section, the study had 95% power and a type I error rate of 0.05. Under these conditions, 27 pregnant women in each group would be needed to demonstrate a significant difference.

Results

Out of 81 pregnant women, 39 pregnant women received stapled skin closures and 42 pregnant women received skin closures with vertical mattress nylon sutures. There are no significant differences in body mass index, gravidity, indication of cesarean section, surgeons, and length of wound between the two groups of pregnant women; except for the age parameter as shown in Table 1.

Wound Closure

The average (SD) length of wound was 11.39(1.36) cm. for patients receiving stapled skin closures while for patients receiving vertical mattress nylon sutures was 11.19(1.51) cm.

The average (SD) time spent in stapled skin closures was 83.18(31.97) seconds. It was 326(83.43) seconds for vertical mattress nylon sutures.

The mean (range) number of staples used in skin closures was 11.39(8-14) staples. For vertical mattress nylon sutures, each case used only one pack of nylon.

The rate of wound closure for each patient was calculated using time spent (in seconds) divided by wound length (cm). For the stapled group, the mean (SD) time was 7.48(2.69) seconds per cm while it was 29.61(7.99) seconds per cm for the sutured group. The difference in the closure rate between the two groups of patients was highly significant (p-value 0.000).

Post-operative Pain Score

The mean (SD) pain scores, assessed on the second day after operation, were 4.79(0.95) and 3.90(1.60) for patients receiving stapled skin closures and for patients receiving vertical mattress nylon sutures respectively. The difference in the two groups' pain scores was significant (p-value 0.003).

The additional doses of non-opiate drug using 1000 mg of paracetamol (tablet) per dose were requested more in stapled group than the other group. The average (SD) doses were 3.62(0.71) and 3.0(1.20) doses, respectively (p-value 0.006).

The additional doses of opiate drug using 3mg of morphine (intravenous form), were required at an average (SD) of 0.21(0.46) doses in the stapled group and 0.31(0.81) doses in the sutured group (p-value 0.477) as shown in Table 2.

No pregnant women from both groups had wound infection or wound dehiscence before

discharged.

Cost

Since Khon Kaen Regional Hospital used reusable staplers; only the cost of staples, 5 baht per staple, was taken into account. On average, the cost of stapled skin closures in each patient was 57 baht (5x11.39) while a pack of nylon cost 100 baht. Both groups of patients required a follow-up for stapled removal or sutured stitch-off on the 7th day after the operation, but no additional costs were considered.

Table 1. Demographic characteristics of participants (n=81 cases)

	Staples (n=39) Mean (SD)	**Sutures(n=42) Mean (SD)**	**p-value**
Age (years)†	24.41 (5.65)	27.60 (8.05)	0.042
BMI † (body mass index)	24.61 (1.99)	24.53 (2.09)	0.858
Gravidity †	1.82 (1.02)	2.00 (1.08)	0.454
Length of wound † (centimeter)	11.13 (1.36)	11.19 (1.51)	0.846
Surgeon (persons)*			0.6345
1st Year of Residents	25	26	
2nd Year of Residents	13	13	
Staffs	1	3	
Indication of surgery (cases)*			0.568
CPD	10	16	
Previous c/s	8	6	
Breech presentation	12	4	
Others	9	16	

Values are mean (standard deviation)

* Chi-square test

† Independent t test

Table 2. Outcomes (n=81 cases)

	Staples (n=39) Mean (SD)	**Sutures(n=42) Mean (SD)**	**p-value**
Pain score (by 10 cm Visual Analog Scale) †	4.79 (0.95)	3.9 (1.60)	0.003
Additional doses of opiate drug (doses) †	0.21 (0.46)	0.31 (0.81)	0.477
Additional doses of non opiate drug (doses) †	3.62 (0.71)	3.0 (1.20)	0.006
Time spent in skin closure (seconds) †	83 (31.97)	326 (83.43)	0.000
Speed (seconds/cm.) †	7.4 (2.69)	29.6 (7.99)	0.000

† Independent t test

Values are mean (standard deviation)

Discussion

These results were consistent with those of Ranaboldo CJ and Rowe-Jones DC.[5] They found higher pain level in patient receiving midline incision when using staples compared with subcuticular skin closure. The results were also the same as the study of Frishman GN, Schwartz T and Hogan JW[4] who studied staples compared with subcuticular suture in cesarean section but in Pfannenstiel incision.

It is worth noting that although there is a statistically significant difference in age parameter between the two groups from this study, age is not a primary factor used in choosing a skin closure approach. The difference was caused by accidental randomization of participant's age as the sutured group contained a few participants with relatively higher age (39, 42, 44, and 49) compared to the rest of participants in this study. (The average age of 81 participants was approximately at 26 years old.)

The assessment in pain score resulted in the stapled group experiencing more pain than the sutured group. The additional doses of non-opiate drug were more requested in stapled group. Morphine carrying strong analgesic effect was used as the opiate drug in this study, however, the comparison of doses in opiate drug showed no statistical significant difference. The clinical significance was unclear because the pain level was a subjective outcome. It could vary through different pain thresholds of the participants. It seemed that pregnant women in the stapled group suffered a higher pain level, but just a few doses of paracetamol were adequate to relieve the pain.

The study also showed that no wound infection or wound dehiscence occurred within 3 days after the operation. Unfortunately, no one-week post-operative visits were performed because most postpartum women selected to follow up at a nearby local hospital rather than at Khon Kaen Regional Hospital. Therefore, the assessment on wound infection and wound dehiscence could not be carried out on the 7th day after the operation.

From the study; skin closure using staples offered better time savings, more convenience to the surgeon and the patient spent less time in the operation room. These results led to more productiveness as the staple approach could save the amount of time spent in each operation from around 1 minute 50 seconds to 5 minutes 10 seconds.

There were some different outcomes in cost issue from the previous study by Gatt D, Quick CR and Owen-Smith MS.[6] They studied skin staples compared with interrupted skin closure with polypropylene suture and polyglactin suture in speed, convenience, effectiveness and cost. It turned out that staples yielded advantages on speed, convenience but with the trade-off in cost. At Khon Kaen Regional Hospital, the comparison in cost incurred by the two approaches showed that staples were more cost effective due to the use of reusable staplers.

The best materials or techniques of skin closure in low midline cesarean section were not conclusive. The decision should also consider the benefit of outcomes to patients, surgeon preference and cost effectiveness. The cosmetic result was another outcome that should be concerned. Because of the limitation in our study to follow up the postpartum mothers as mentioned earlier, we would mention the result of previous study by Lubowski D and Hunt D.[7] They studied in vertical abdominal wound closure comparing staples with 3/0 prolene sutures. The main part of their study was about the cosmetic result in the sixth post-operative week. The result showed that both materials of skin closure gave almost equal cosmetic results in vertical incisions.

Our findings would encourage new innovation of skin staples to decrease pain level; especially in terms of other materials than stainless steel. Reabsorbable staples used in internal pelvic surgery are a good example. Then the further study should be focused on long-term cosmetic appearance.

In conclusion, although the staples give advantages over the suture on time savings, the higher pain level is another factor that should be considered in the selection of skin closure materials.

References

1. Cunningham FG, Leveno KG, Bloom SL, Hauth JC, Gilstrap III, Wenstrom KD. Cesarean delivery and peripartum hystrectomy. In: Williams obstetrics. 22nd ed. New York: McGraw-Hill; 2005.p.593.
2. Grabb WC, Smith JW, Grabb and Smith's plastic surgery. 4th ed. London: Little, Brown and Company; 1997.p.13-7.
3. Alderdice F, McKenna D, Dornan J. Techniques and materials for skin closure in caesarean section (Review). Cochrane Database of Systematic Review [online] 2007 [cited 2007 Jun 5]; Issue 2:3. Available from:URL:http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003577/pdf fs.html.
5. Ranaboldo CJ, Rowe-Jones DC: Closure of laparotomy wound: staples versus sutures. Br J Surg 1992;79:1172-3.
4. Frishman GN, Scwartz T, Hogan JW. Closure of Pfannenstiel skin incisions; staples versus subcuticular suture, Journal of Reproductive Medicine 1997;42:627-31.
6. Gatt D, Quick CR, Owen-Smith MS. Staples for wound closure: a controlled trial, Ann R Coll Surg Engl 1985;67:318-20.
7. Lubowski D, Hunt D. Abdominal wound closure comparing the proximate staplers with sutures, Aust N Z J Surg 1985;55:405-6.

การเย็บปิดแผลผิวหนังแนวตั้งในการผ่าตัดคลอดบุตรด้วยการใช้ staples เปรียบเทียบกับการใช้ nylon

มณีรัตน์ พิชิตรณชัย, สมศักดิ์ ประฏิภาณวัตร, อุษณีย์ สวัสดิ์พาณิชย์.

วัตถุประสงค์ *: เพื่อศึกษาผลของการเย็บปิดแผลผิวหนังแนวตั้งในการผ่าตัดคลอดบุตรด้วย*

การใช้ *: staples เปรียบเทียบกับการใช้ nylon ในเรื่องระดับความปวดของแผล เวลาที่ใช้ในการเย็บ อัตราการเกิด แผลแยก และการติดเชื้อที่แผล*

รูปแบบการวิจัย *: Randomized controlled trial*

วัสดุและวิธีการวิจัย *: สตรีตั้งครรภ์ที่มาคลอดบุตรด้วยวิธีผ่าตัด โดยแผลผ่าตัดชั้นผิวหนังเป็นแนวตั้งที่โรงพยาบาลศูนย์ขอนแก่น ตั้งแต่เดือนสิงหาคมถึงเดือนธันวาคม ปี พ.ศ. 2549 ขณะผ่าตัดจับเวลาในการเย็บชั้นผิวหนังและวัดความยาวแผล และในวันที่สองหลังผ่าตัด ทำการวัดระดับความปวดแผลโดยใช้ pain score (100 mm visual analog scale) และบันทึกจำนวนครั้งของการได้รับยาแก้ปวดรวมถึงประเมินการติดเชื้อของแผลผ่าตัด*

ผลการศึกษา *: สตรีตั้งครรภ์เข้าร่วมการศึกษา 81 คน แบ่งกลุ่มที่เย็บแผลด้วย staples 39 คนและกลุ่ม nylon 42 คน pain score กลุ่ม staples และ nylon เฉลี่ย 4.79 และ 3.90 ตามลำดับ (p-value 0.003) การได้รับยาแก้ปวด opiate drug กลุ่ม staples และ nylon เฉลี่ย 0.2 และ 0.31 doses ตามลำดับ (p-value 0.477) non-opiate drug กลุ่ม staplesและ nylon เฉลี่ย 3.6 และ 3.0 doses ตามลำดับ (p-value 0.006) การเย็บแผลกลุ่ม staples และ nylon ใช้เวลาเฉลี่ย 7.48 และ 29.61 วินาทีต่อเซนติเมตร ตามลำดับ (p-value 0.000) ไม่พบการติดเชื้อและแผลแยกทั้งสองกลุ่ม*

สรุป *: การเย็บปิดแผลผิวหนังแนวตั้งในการผ่าตัดคลอดบุตรด้วยการใช้ staples ใช้เวลาน้อยกว่าแต่พบระดับ การปวดแผลมากกว่าการใช้ nylon อย่างมีนัยสำคัญทางสถิติ*
