Comparative Study of Single Layer versus Double Layer Closure of Lower Transverse Uterine Incision at Cesarean Delivery

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Research Article

Abstract: **Objective(s):** To assess intraoperative and postoperative outcome following single layer closure of lower transverse uterine incision at cesarean section as compared to double layer closure. **Method(s)**: In this prospective randomized controlled study, 200 women scheduled for lower segment cesarean section through Pfannenstiel or sub umbilical midline incision were randomized to either single layer (n = 100) or double layer (n=100) closure of uterine incision. Primary outcome measures studied were operating time, intraoperative blood loss, febrile morbidity, and endomyometritis. Secondary outcome measures studied were number of additional hemostatic sutures needed, postoperative pain, perioperative hemoglobin fall, cystitis, wound infection, and hospitalization period. Student t test was used for comparing continuous variables. Categorical variables were compared by Chi square test or Fisher exact test. **Results:** The maternal demographic factors, indications for cesarean sections and high risk factors were similar between the two groups. There was significant reduction in operating time (P=0.022), intraoperative blood loss (P=0.04), febrile morbidity (P=0.024, OR 0.41, 95% CI (0.17-0.95), perioperative hemoglobin fall (P=0.044), endomyometritis (P=0.03, OR 0.36, 95% CI 0.16-0.90, and period of hospitalization (P=0.00005) in the subjects as compared to controls. There was no significant difference between the two groups regarding number of additional hemostatic sutures needed, postoperative pain, and cystitis or wound infection. **Conclusion(s):** Single layer closure of lower transverse uterine incision at cesarean section is associated with lesser operating time, intraoperative blood loss, febrile morbidity, endomyometritis, and hospitalization period, as compared to double layer closure.

Key words: single layer closure, double layer closure, uterine incision, cesarean section.

Introduction

Recommendation of suturing of the uterine incision following cesarean section by Sanger in 1882 was an important milestone in the history of evolution of surgical technic of cesarean section, which markedly reduced maternal mortality from an otherwise potentially fatal surgical procedure. Since the time Kerr in 1926 first advocated two layer closure of low transverse uterine incision, it is still the most commonly followed method of uterine closure.[1] Traditional lower uterine incision closure in two layers; first continuous locking stitch followed by a continuous imbricating layer is not based on clinical evidence. On the other hand a number of studies have reported advantages of single layer closure over double layer closure.[2-3] Theoretically single layer closure takes lesser operating time, causes lesser tissue trauma, ischemia and necrosis, introduces lesser foreign material in the uterus, results in lesser blood loss, better uterine wound healing, and lesser scarring of the myometrium, and thus carries better prognosis in subsequent pregnancy. Various types of suturing technics, which have been used for single layer closure in various studies are-continuous locking[3], continuous non-locking[4], simple interrupted[6], figure of eight[7], and special sutures.[8] Suture materials commonly used have been plain or chromic catgut , and delayed absorbable synthetic sutures like polyglactin.[4,6] There have been a few prospective randomized controlled trials comparing intraoperative and postoperative morbidity following single Vs double layer closure of uterine incision [7,8] Most of the early trials had addressed perioperative and early postoperative morbidity, and reported decreased operating time, blood loss, infectious morbidity and hospitalization period. Some studies also reported safety of single layer closure with reference to vaginal delivery during subsequent pregnancy with no increased risk of uterine rupture or dehiscence.[9,10] A Cochrane review has concluded that there appear to be no advantages or disadvantages for routine use of single layer closure compared to two-layer closure, except perhaps a shorter operation time.[11] The present study was undertaken to assess intraoperative and postoperative morbidity following single layer closure of low transverse uterine incision at cesarean section as compared to that with double layer closure.

Methods

From October 2011 to December 2012, in Krishna institute of medical sciences, Karad, a total of 200 women were recruited for this prospective randomized controlled study. Informed consent was taken

from all of them. Women undergoing emergency or elective cesarean section were randomly allocated to either single or double layer closure. 100 women were allocated to single layer closure and 100 to double layer closure. Randomization was by computer generated random numbers and the randomized allocations were kept secure in sealed envelopes, which were opened in the operation room. All women were eligible for the study, regardless of indication of cesarean delivery, type of skin incision, medical complications, high risk factors, and history of previous cesarean section. Both Pfannenstiel and sub umbilical midline incisions were used and all uterine incisions were low transverse type. All women received prophylactic antibiotics before surgery. Uterus was exteriorized after delivery of placenta. In the single layer group, uterine closure was done with continuous nonlocking No.1 polyglactin, while in the double layer group an additional imbricating non-locking suture of the same material was employed. Visceral and parietal peritoneum were closed. Rectus fascia was approximated with No. 1 polypropylene. Skin was approximated with subcuticular closure. Tubal ligation if requested by the women was done by modified Pomeroy's technique. Intraoperative blood loss was calculated by measuring blood in the suction apparatus and on sterile drapes, and by evaluating the blood in abdominal swabs and gauzes. Day of operation was considered as day 0. Perioperative, intraoperative and postoperative management decisions were made without reference to treatment groups. The outcome measures noted were operating time, intra-operative blood loss, number of additional hemostatic stitches required, postoperative pain as assessed by both Visual Analog Scale (VAS) and number of analgesic doses given in the first postoperative day, perioperative fall in hemoglobin, febrile morbidity, endomyometritis, cystitis, wound infection, and period of hospitalization. In the absence of complications, women were discharged on the 6^{th} postoperative day. Postoperative pain was measured once administrating a 10 cm VAS (no pain = 0, worst pain ever =10) at approximately 24 hours after surgery. Women were asked to indicate the average intensity of pain experienced during the last several hours. Analgesics were given as needed, and the number of doses of analgesics administered during the first postoperative day was recorded. Febrile morbidity was defined as temperature more than 38° C on two occasions 12 hours apart, excluding the first postoperative day. Perioperative fall in hemoglobin was calculated from pre-operative and third postoperative day hemoglobin estimation. Endomyometritis was diagnosed if uterine tenderness and fever were present. Cystitis was diagnosed by a positive urine culture growth. The presence of purulent discharge from the incision with erythema or induration, with or without fever, indicated wound infection. Operation time was abstracted from operation notes. The length of postoperative hospital stay was calculated from medical records. Data was collected on a standardized data form designed for the study. Women were followed-up after 2 weeks and 6 weeks, and were advised to report to the hospital in case of any complaints or complications.

Statistical methods

A sample size and power analysis were undertaken prior to the study. One hundred women were required in each arm to show a reduction in febrile morbidity from 22% to 11% between double and single layer closure (Power=0.80, alpha=0.05 and beta= 0.2). Student t test was used for analysis of continuous variables. Categorical variables were analyzed by Chi square test or Fisher exact test (if numbers were small) $P < 0.05$ was considered the probability level to reflect significant differences. Odds ratios (OR) and 95% confidence intervals (95% CI) were calculated for categorical data.

Table 1: Maternal demographics and procedure statistics

	Single layer (N=100)	Double Layer (N=100)	Significance
Maternal age (years)	25.5 ± 4.5	26.4 ± 3.5	P=0.05
Parity	2.2±0.9	1.8 ± 0.6	P=0.06
Gestational age (weeks)	37.2 ± 1.5	37.8 ± 1.8	P=0.12
Preoperative Hb (g/dL)	10.55 ±0.88	10.57 ± 0.83	P=0.76
Cesarean section			
Primary	66 (65.6)	67 (65.0)	P=0.80
Repeat	36 (33.4)	34 (35.0)	
Cesarean section			
Elective	63 (63.7)	73 (69.7)	P=0.35
Emergency	37 (36.3)	27 (28.3)	
Anesthesia			
Spinal	65 (63.7)	67 (65.2)	P=0.71
General	32 (31.4)	31 (34.9)	
Epidural	03 (2.9)	02 (1.9)	
Abdominal incision			
Pfannenstiel	78 (76.5)	83 (80.1)	P=0.30
Midline	22 (23.5)	17 (16.9)	
Tubal ligation	29 (28.4)	23 (21.7)	P=0.25

Mean ± SD
Values in parentheses indicate percentages
None of the differences was significant

Table 2: Indications for cesarean delivery

	Single layer (N=100)	Double layer (N=100)	Significance
Previous cesarean	28(27.4)	30(28.3)	P=0.88
Dystocia	24(24.5)	19(18.9)	P=0.32
Fetal distress	13(12.7)	13(12.7)	P=0.74
Breech	12(11.8)	13(13.0)	P=0.46
Others	23(23.6)	25(23.6)	P=0.92

Values in parentheses indicate percentages
None of the differences was significant

Table 3: High risk factors

	Single layer (N=100)	Double layer (N=100)	Significance
Bad obstetric history	30 (30.4)	30 (28.5)	P=0.24
Premature rupture of membranes	17 (16.6)	14 (13.8)	P=0.40
Hypertensive disorders	15 (14.7)	10 (9.4)	P=0.24
Antepartum hemorrhage	4 (3.9)	3 (2.8)	P=0.47
Intrauterine growth restriction	7(6.8)	6 (5.9)	P=0.72
Others	5 (4.9)	5(4.9)	P=0.74

Values in parentheses indicate percentages
None of the differences was significant

Table 4: Operative factors and postoperative morbidity

	Single layer (N=100)	Double layer (N=100)	Significance	OR (95% CI)
Operating time (minutes)	3 0.3 ±6.4	33.1 ± 4.6	P=0.022	
Additional hemostatic sutures	28 (27.4)	23(21.6)	P=0.202 NS	1.50 (0.76-2.90)
Intraoperative blood loss (mL)	600.0 ± 99.5	628.6 ± 105.7	P=0.04	
600 mL or more blood loss	60(59.7)	79(75.4)	P=0.015	0.46 (0.25-0.91)
Postoperative Hb (g/dL)	9.61±1.0	9.50 ± 0.95	P=0.44 NS	
Perioperative Hb fall (g/dL)	0.84 ±0.27	0.92 ±0.24	P=0.038	
1.0 g/dL or more fall	63 (63.7)	83(82.0)	P=0.0045	0.40 (0.20-0.80)
Postoperative pain				
VAS score	2.90 ±0.65	3. 00 ± 0.42	P=0.10 NS	
Number of analgesic doses	3.40 ± 0.51	3.50 ± 0.49	P=0.10 NS	
Febrile morbidity	11 (10.8)	23 (22.6)	P=0.025	0.41 (0.17-0.95)
Endomyometritis	7 (6.8)	17(16.9)	P=0.03	0.36 (0.16-0.90)
Cystitis	6 (5.9)	12 (11.3)	P=0.16 NS	0.340 (0.16-1.35)
Wound infection	05(4.9)	09 (8.5)	P=0.17 NS	0.44 (0.14-1.47)
Hospitalization period (days)	6.65 ± 0.8 1	7.20 ± 0.85	P=0.00005	
>7 days	10 (9.8)	20(21.6)	P=0.019	0.40 (0.16-0.93)

Mean ± SD
Values in parentheses indicate percentages
NS - Not significant

Results

There was no significant difference between the two groups with respect to maternal demographics or procedure statistics (Table 1). There was no difference either with respect to the indications for cesarean section or various high risk factors (Tables 2 and 3). There was significant reduction in operating time in single layer closure as compared to double layer closure (30.3 ± 6.4 Vs 33.1 ± 4.6 minutes, P=0.022) (Table 4). There was no significant difference in the number of women needing additional hemostatic stitches between the two groups. There was significant reduction in the mean intraoperative blood loss in the single layer group as compared to that in the double layer group (600 ± 99.5 Vs 628 ± 105.7 mL, P=0.04). Proportion of cases with a blood loss of 600 mL or more was also significantly less with single layer closure (P=0.015, OR 0.46, 95% CI 0.25-0.90). Mean perioperative hemoglobin fall was significantly lower in the single layer group as compared to that in the double layer group (0.84 + 0.27 Vs 0.92 ± 0.24 g/dL, P=0.038). Proportion of cases with perioperative hemoglobin fall of 1.0 gm /dL or more was also significantly less with single layer closure (P=0.0045, OR 0.40, 95% CI 0.20-0.80) .Two cases in each group needed blood transfusion (P=1.0). Febrile morbidity was 11.8 % in the single layer group as compared to 22.6 % in the double layer group (P=0.025, OR 0.41, 95% CI 0.17-0.95). Incidence of endomyometritis was also significantly less in the single layer group as compared to that in the double layer group viz., 6.8% Vs 16.9%, (P=0.03, OR 0.36, 95% CI 0.16-0.90). The two groups did not differ significantly with regard to postoperative pain, incidence of cystitis, and of wound infection. Period of hospitalization was significantly shorter with single layer closure (6.65 ± 0.81 Vs 7.20 ± 0.85 days, P=0.00005). Proportion of cases with hospital stay beyond 7 days was also less with single layer closure (P=0.019, OR 0.40, 95% CI 0.16-0.93).

Discussion

Two-layered closure of low transverse uterine incision is based more on tradition rather than on clinical evidence. It is also contrary to the accepted surgical principles regarding wound repair. The main purpose of wound suturing is to coapt tissues, assist hemostasis, and resist stress and strain on wound edges till healing gives it intrinsic strength. Continuous locking suture everts the wound edges and does not provide good coaptation. Postpartum, the uterus goes through rapid involution, so that any type of suture becomes loose. Because of the same reason it is unlikely that there is any stress on the wound edges. Only apparent function of the suture appears to be hemostasis, which also primarily depends on uterine contraction and retraction. There is no evidence to show that second suture layer gives increased strength to the wound. Additional suture material may result in more tissue ischemia and necrosis, and more foreign tissue in the body, which is a potential nidus for infection, impairing wound healing. Lai and Tsomo[12] reported radiological evidence of a substantially higher

number of abnormal hysterograms with double layer closure. Ultrasonography studies in the postoperative period have shown no difference except a thinner uterine scar with single layer closure in a study by Heidenreich and Bruggenjurgen[8]. On the other hand several studies have reported superiority of single layer closure with decreased intraoperative and postoperative morbidity in the form of reduced operating time, blood loss, febrile and infectious morbidity, and hospitalization period [2,3,5,13]. Recent experimental studies in dogs and sheep have shown that non-closure of uterine incision has no adverse effect on operative or postoperative morbidity, and shows histological evidence of lesser muscular necrosis, scar fibrosis and endometriosis.[14,15] In a Cochrane review by Enkin and Wilkinson[11], which included two studies[3,12], it has been concluded that there appear to be no advantages or disadvantages for routine use of single layer closure compared to two layer closure, except perhaps a shorter operation time, which in itself may be an important advantage, provided the technic is safe. The evidence available, however, is so limited that no recommendation to change the current practice can be made. The decreased operating time observed in the present study is similar to that reported in other studies[3,4,13]. Increased operating time has been associated with increased infectious morbidity rate at cesarean delivery, entails the use of longer-acting agents for regional anesthesia, and results in the use of supplemental general anesthesia, prolonged exposure of the abdominal contents, and possibly more blood loss. Decreased intraoperative blood loss and perioperative hemoglobin fall reported in some studies have been replicated in our study[2,13]. However others have found no difference[3,4]. Hemostasis is achieved mostly after first layer closure. Second layer suturing prolongs operating time and increases the number of needle punctures in the uterine wall. The number of additional hemostatic sutures needed have differed in various studies; some reporting more with double layer,[4,13] while Hauth et al[3] reporting more with single layer. The present study showed no difference between the two groups. There was no difference in the postoperative pain as assessed by both VAS score and number of analgesic doses required. Postoperative pain has not been assessed in other studies. Significantly lower febrile morbidity found in the present study with single layer closure is similar to that reported by others[2,5,7], while Jelsema et al[4] reported no difference. Lower febrile morbidity has been attributed to reduced qperating time. Decreased endomyometritis, noted in the present study is similar to that reported earlier[2,5,13], and is possibly due to decreased tissue ischemia and necrosis with single layer closure. However some studies have reported no difference[3,4,8] Length of hospital stay depends primarily on the infectious morbidity. Decreased length of hospital stay with single layer closure is similar to that reported earlier.[5,13]

Post-hoc power analysis showed that between single and double layer closure, the present study (with an alpha of 0.05) has 100 % power to detect decrease in blood loss of 600 mL or more from 76.4% to 59.7%, 76.1% power to detect decrease in febrile morbidity from 22.6% to 11%, and 57.4 % power to detect decrease in endomyometritis from 16.9% to 6.8%. Moreover our study addressed various intraoperative and postoperative complications in the index pregnancy only. Most women come for antenatal care and delivery to a service hospital from native place for a short period. Due to frequent transfers women are lost to long term follow up and may deliver subsequently at a different hospital. Late morbidity and maternal or perinatal outcome in subsequent pregnancy including incidence of uterine rupture or dehiscence were not assessed. Two recent retrospective studies have reported the impact of a single-layer or double-layer closure in the index pregnancy on uterine rupture during subsequent delivery.[13,16] Bujold et al[16] in their study found that a single-layer closure was associated with a four-fold increase in the risk of uterine rupture compared with that in a double-layer closure. Durnwald and Mercer[13] reported association of single layer closure with five times greater incidence of uterine windows (dehiscence) noted at subsequent cesarean delivery. Both have advocated single layer closure for women not desiring trial of labor during subsequent pregnancy and double layer closure for others. To validate the superiority or otherwise of the single layer closure larger multicentric prospective studies are needed aimed at assessing late morbidity with particular reference to scar integrity during subsequent labor and delivery along with maternal and perinatal outcome, with standardized protocols regarding type of suture material and suturing technic.

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