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Comparison of Various Uterine Closure Techniques of Caesarean Section: A Randomized Controlled Trial

Neha Garg[1*], Rajkeerthi N[2] and Shobha Dhananjaya[1]

[1]Department of Obstetrics and Gynaecology, JJM Medical College, Davangere, Karnataka, India

[2]Department of Radio-diagnosis, JJM Medical College, Davangere, Karnataka, India

[*]**Corresponding author:** Dr. Neha Garg, Junior Resident, Department of Obstetrics and Gynaecology, JJM Medical College, Davangere, Karnataka, 577 004, India

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Abstract

Background: The rate of caesarean section (CS), an essential component of comprehensive emergency obstetric and neonatal care has been on a worldwide rise. The resultant uterine scar is defined as detectable myometrial thinning at that site and can be detected reliably by ultrasound imaging. Proper healing of the uterine scar after CS is of paramount importance to avoid various obstetrical complications in future pregnancies. Uterine scar defect is related to the method of uterine closure, which encompasses various methods. At present, there is no consensus on the method of uterine closure following caesarean delivery. Thus, an attempt to figure out a suitable method of uterine closure in our population has been made in this study. Objective: To compare 3 types of uterine closure techniques of caesarean section- Double layer with first layer locked including the decidua and Double layer with first layer unlocked excluding the decidua with the commonly used locked single layer closure including decidua.

Materials and Methods: A double-blind randomized controlled trial of 108 women with singleton pregnancies undergoing an elective primary caesarean delivery ≥ 38 weeks' gestation. Uterine scar closure was carried out by a locked single layer including the decidua, double layer with locked first layer including the decidua, or double layer with unlocked first layer excluding the decidua with second layer unlocked. Outcomes analyzed after 6 months of delivery using transvaginal ultrasound were Residual Myometrial Thickness (RMT), and Total Myometrial Thickness (TMT) above the uterine scar, healing ratio, estimated blood loss, operative time, need for additional sutures and neonatal outcomes. The statistical analysis was done through SPSS for Windows (v 24.0).

Results: Complete follow-up was obtained from 100 (92.6%) out of 108 participants. Compared to single-layer closure, double-layer closure with unlocked first layer was associated with thicker RMT (3.04 ± 1.24 mm vs 6.92 ± 2.9 mm; p=0.001) and greater healing ratio (57 ± 22% vs 75 ± 31%, p=0.003). In contrast, double-layer closure with locked first layer was not significantly different than single-layer closure in either RMT (5.62 ± 1.74mm, p=0.041) or healing ratio (63 ± 29%, p=0.238).

Conclusion: Double-layer uterine closure with unlocked first-layer at caesarean delivery appears to maximize postpartum uterine scar thickness compared with other techniques.

Keywords: Caesarean section; Uterine closure; Double-layer first layer locked; Double-layer first layer unlocked; Single-layer

Introduction

Caesarean section (CS), an essential component of comprehensive emergency obstetric and neonatal care is associated with increased morbidity and mortality compared with vaginal delivery. There has been a worldwide rise in CS rate during the last three decades. The average rate of CS in India is 17.2% (in 2015-16) ranging from 5.8% in Nagaland to 58% in Telangana, which has increased from 8.5%in 2005-2006 [1,2]. This is due to advances in our knowledge and technique to detect antepartum and intrapartum complications early and the increased safety of surgical procedures. Also, a substantial leap in neonatal care has made us more confident in delivering a low birth weight baby abdominally. In the western countries, increasing fear of lawsuits compel the obstetrician to take a quicker recourse to an abdominal delivery.

Deficient caesarean scars, defined as detectable myometrial thinning at the site of CS can be detected reliably by ultrasound imaging [3-5]. Proper healing of the uterine scar after CS is of paramount importance so that various obstetrical complications in future pregnancies like ectopic scar

pregnancy, placenta accreta, placenta previa, and uterine rupture can be avoided. Various gynaecological problems are also associated with uterine scar defects such as dysmenorrhea, postmenstrual spotting, and pelvic pain [6].

Uterine scar defect is related to the number of previous caesarean deliveries, the position of the uterus (retroflexed) and the method of uterine closure [4-7]. There are various methods of uterine closure and controversial results have been obtained in the previous studies. More than 230 randomized controlled trials (RCTs) have been published on varying technical aspects of caesarean delivery, yet uncertainty remains regarding the optimal approach to minimize maternal and perinatal morbidity. At present there is no consensus on the method of uterine closure following caesarean delivery whether single or double layer, locking or not for the first layer, decidua should be included or not [7-9]. Thus, the importance of undertaking this study.

Objective

This study aims to compare 3 types of uterine closure techniques of caesarean section-2 types of double-layer closure i.e.

a. Double layer with the first layer locked including the decidua and second layer unlocked and imbricating the first layer

b. Double layer with the first layer unlocked excluding the decidua and including the deep part of myometrium and second layer unlocked including the remaining part of the myometrium

c. with the commonly used locked single layer closure including the decidua

Materials and Methods

With level III evidence, a double-blinded randomized controlled trial was performed from July 2018 to June 2019 in the department of Obstetrics and Gynaecology, Bapuji hospital, Chigateri Government General hospital, Women and Child Health hospital attached to JJM Medical College, Davangere, Karnataka, India. The patients for this study were recruited by convenient sampling technique. A total of 108 women (randomized into 3 groups with 36 participants in each group) with singleton pregnancies undergoing an elective primary caesarean delivery ≥ 38 weeks gestation who satisfied the inclusion and exclusion criteria were taken for the study.

Women with singleton pregnancies undergoing an elective primary caesarean delivery ≥ 38 weeks' gestation (Women in latent labor up to 3 cm cervical dilatation included) were included in the study. Women with multiple pregnancy, Mullerian anomalies and placenta previa, women with medical disorders complicating pregnancy like diabetes, hypertensive disorders of pregnancy and thrombophilia, women with previous caesarean or uterine scar and at active labour (with regular uterine contractions and cervical dilatation ≥ 4 cm) at time of caesarean and women with known chronic inflammatory disease were excluded from the study.

After getting IEC clearance from the institute and informed written consent from the patients enrolled in our study, they were subjected for a thorough examination. The baseline characteristics such as maternal age, BMI, previous vaginal birth, gestational age at delivery, and reason for the caesarean delivery were collected. Randomization was computer generated and supervised by a statistician. Preoperatively, each participant was given the next sealed opaque consecutively numbered envelope containing a description of the suture technique to be used by the surgeon for the particular case.

A total of 108 women were allocated to three groups-

1. Group A (36 patients): Single-layer locked including the decidua (controls) **(Figure 1).**

2. Group B (36 patients): Double-layer with the first layer locked including the decidua and second layer unlocked and imbricating the first layer **(Figure 2).**

3. Group C (36 patients): Double-layer with the first layer unlocked excluding the decidua and including the deep part of myometrium and second layer unlocked including the remaining part of the myometrium **(Figures 3 and 4)**.

All sutures were continuous using synthetic absorbable thread (vicryl, no 1). After delivery, the following information was collected: need for additional suture; whether or not the vesicouterine and parietal peritoneum were closed; duration of surgery, estimated blood loss, intrapartum and postpartum complications and birth weight of the baby.

Follow up

Uterine scar healing is complete after a minimum of 6 months following delivery. Each participant was invited for a transvaginal ultrasound examination of the uterine scar at between 6-12 months after the caesarean delivery. All of the measurements were taken using ultrasound machines Philips iu22, GE logiq s7 expert and logiq p9 equipped with 7 mHz convex probe. The following data were collected: the position of the uterus (anteverted or retroverted), Residual Myometrial Thickness (RMT), and Total Myometrial Thickness (TMT) above the uterine scar.

Statistical analysis

The statistical analysis was done through SPSS for Windows (v 24.0). For the primary outcome, the student t-test was used to compare the mean ± SD and Fischer exact test was used to compare the proportions between each double-layer subgroup to the control group. A p-value<0.05 was considered significant.

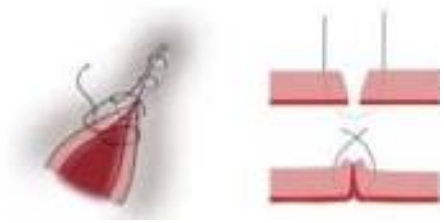


Figure 1: Locked single-layered closure including decidua.

Figure 2: Double-layer closure with first layer locked and second layer unlocked and the imbricating first layer.

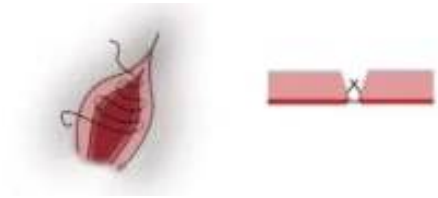


Figure 3: Double-layer closure with the first layer unlocked, excluding decidua and including deeper part of myometrium.

Figure 4: Second layer of double-layer closure, unlocked and taking the remaining part of myometrium.

Results

In the current study, the total number of deliveries in the hospitals attached to JJM Medical College, Davangere in the study period was 10,427 out of which 1635 were caesarean deliveries making the caesarean section rate to be 15.68%.

Among 108 cases of LSCS performed included in the study, 36 cases were allotted to each uterine suture technique. 8 patients were lost to follow up in the postpartum visit. The final number of cases satisfied the required sample size **(Figure 5).**

Baseline characteristics like age, gestational age and BMI, birth weight, and peritoneal closure (both vesicle and parietal) were similar between groups **(Table 1)**. The mean maternal age was 32.1 years in group A, 33.5 years in group B and 32.9 years in group C. All the included patients were either overweight or obese according to revised consensus BMI for Asian Indians. (17) Birth weight of babies delivered in all three groups were 3293.47 ± 594.72 g in single layer, 3163.18 ± 451.38 g in double layer with first layer locked and 3561.63 ± 342.61 g in double layer with first layer unlocked closure which was statistically significant (p=0.03). Multiparas accounted for 28.7% totally. The most common indication of elective LSCS was malpresentation (91.6%) in this study. The vesicle peritoneal closure was done in 10.62% of cases in single layer closure, 14.93% in double layer with first locked and 16.47% in double layer with first unlocked uterine closure; with statistical significance (p<0.001). Similarly, parietal peritoneal closure in all the groups 45.61%, 49.73%, 46.72% respectively showed statistical significance (p=0.04) **(Table 1).**

In the study, intraoperative complications were higher in single layer locked group as compared to the other two groups with double-layer closure. Complications such as extension of incision were comparable in single-layer and double-layer first locked groups (19.44%), which was higher than double layer first unlocked (8.33%). Hematoma formation was seen in 11.11% cases of single-layer and 2.77% of double-layer first locked with none in double-layer first unlocked. Similarly, atonic PPH was highest in single layer (30.55%), as compared to double-layer locked (25%) and double layer unlocked (11.11%). The differences in each case were statistically insignificant (p>0.05) **(Table 2 and Graph 1)**.

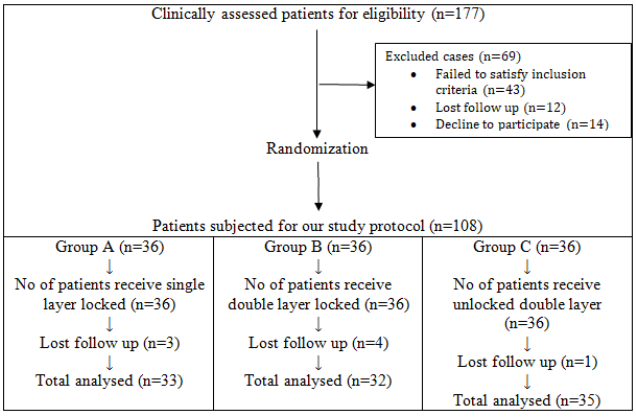


Figure 5: Patient's selection.

Incidence of postoperative complications like the fever was 30.55% in single layer, 25% in double-layer first locked, and 19.44% in double-layer first unlocked. Abdominal distension was seen in 7 cases (19.44%), 5 cases (13.88%) and 4 cases (11.11%), respiratory infection in 2 cases (5.55%), 4 cases (11.11%) and none (0%) and subinvolution of uterus in none

Table 1: Baseline parameters.

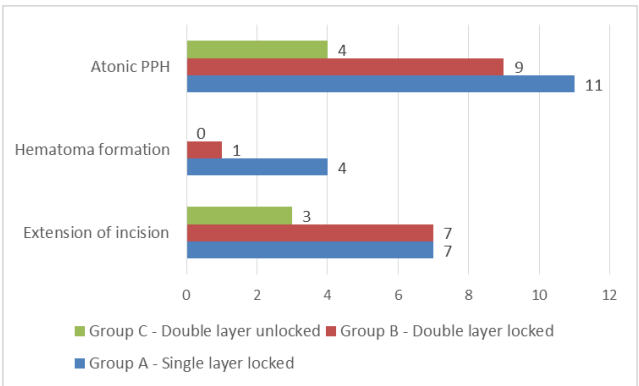
Parameters	Group A-single layer locked (n=36)	Group B-double layer locked (n=36)	Group C-double layer unlocked (n=36)	p-value
Age (years)	32.14 ± 5.39	33.51 ± 3.04	32.91 ± 4.61	2.31
Gestational age at delivery (weeks)	38.93 ± 0.73	39.41 ± 0.69	39.34 ± 0.86	0.75
BMI (kg/m^2)	24.51 ± 3.94	25.41 ± 4.56	25.60 ± 3.33	0.43
Birth weight (grams)	3293.47 ± 594.72	3163.18 ± 451.38	3561.63 ± 342.61	0.03
Previous vaginal birth	23.94	29.13	33.63	0.78
Noncephalic fetal presentation	89.45	94.56	91.28	1.02
Vesicouterine peritoneum closure	10.62	14.93	16.47	<0.001
Parietal peritoneum closure	45.61	49.73	46.72	0.04

p-value<0.05 is considered significant; Values were expressed as mean ± SD or as percentage (%)

Table 2: Intraoperative complications.

Intraoperative complications	Group A-Single layer locked (n=36)	Group B-Double layer locked (n=36)	Group C-Double layer unlocked (n=36)	p-value
Extension of incision	7 (19.44%)	7 (19.44%)	3 (8.33%)	0.72
Hematoma formation	4 (11.11%)	1 (2.77%)	-	0.94
Atonic PPH	11 (30.55%)	9 (25.00%)	4 (11.11%)	1.05

p-value<0.05 is considered significant



Graph 1: Intraoperative complications.

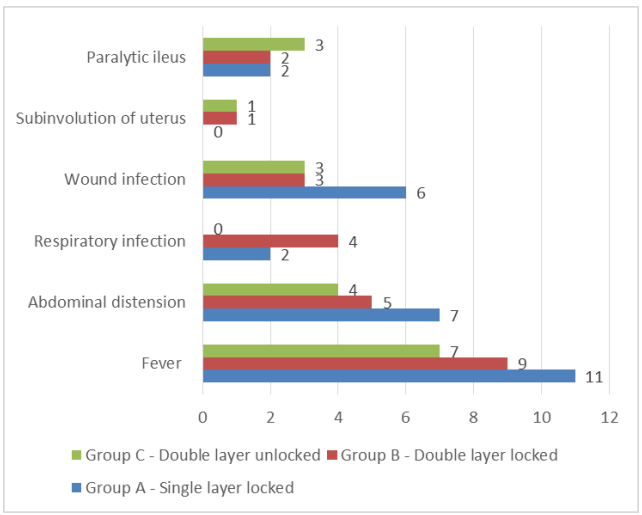
(0%), 1 case (2.77%) and 1 case (2.77%) respectively in groups A, B and C. The difference between the three groups in all these complications were statistically insignificant (p>0.05).

Table 3: Postoperative complications.

Postoperative complications	Group A-Single layer locked (n=36)	Group B-double-layer locked (n=36)	Group C-double-layer unlocked (n=36)	p-value
Fever	11 (30.55%)	9 (25.00%)	7 (19.44%)	2.13
Abdominal distension	7 (19.44%)	5 (13.88%)	4 (11.11%)	0.24
Respiratory infection	2 (5.55%)	4 (11.11%)	-	1.25
Wound infection	6 (16.66%)	3 (8.33%)	3 (8.33%)	0.04
Subinvolution of uterus	-	1 (2.77%)	1 (2.77%)	0.61
Paralytic ileus	2 (5.55%)	2 (5.55%)	3 (8.33%)	0.025

p-value<0.05 is considered significant

However, wound infection was higher in a single-layer group with 6 cases (16.66%) as compared to both groups of double layers with 3 cases (8.33%) each; which was statistically significant (p=0.04). On the other hand, paralytic ileus was significantly higher in double layer with first layer unlocked with 3 cases (8.33%) as compared to the other two groups of single layer and double layer with first layer locked; p=0.025 **(Table 3 and Graph 2)**.



Graph 2: Postoperative complications.

The double-layer with an unlocked first layer (6.92 ± 2.90 mm) was associated with greater Residual Myometrial Thickness (RMT) than the single-layer locked technique (3.04 ± 1.24 mm) (p<0.001) (**Figure 6**). Furthermore, RMT in a double-layer with a locked first layer (5.62 ± 1.74 mm) was greater than a locked single layer, also being statistically significant

(p=0.041) (**Figures 7 and 8)**. Similarly, a double-layer with an unlocked first layer closure was found to have statistically significant greater Total Myometrial Thickness (TMT) of 9.94 ± 2.17 mm and healing ratio of 75 ± 31 than the control group (7.31 ± 2.19 mm and 57 ± 22); p=0.027 and 0.003 but not the double-layer with locked first layer (8.26 ± 3.71 mm and 63 ± 29) with p=0.145 and 0.238. No statistically significant difference was observed between the double-layer with unlocked first layer group and double-layer with locked first-layer group with respect to the control group in terms of estimated blood loss (7639.83 ± 129.79 ml, 724.94 ± 302.81 ml, 636.23 ± 143.43 ml respectively with p=0.432 in group C vs group A and 0.126 in group B vs group A), operative time (28.71 ± 2.03 min, 28.54 ± 5.13 min, 30.13 ± 4.53 min respectively; p=0.761 and 0.563 respectively) need for additional sutures (32, 29,27 respectively; p=0.126 and 0.712 respectively) and number of additional sutures 1.14 ± 1.71, 1.00 ± 0.81, 1.03 ± 1.35 respectively; p=0.945 and 0.801 respectively) **(Table 4)**.

Table 4: Functional outcomes.

Parameters	Group A-single layer locked (n=33)	Group B-Double layer locked (n=32)	p-value	Group C-Double layer unlocked (n=35)	p-value
Residual myometrial thickness (RMT) (mm)	3.04 ± 1.24	5.62 ± 1.74	0.041	6.92 ± 2.90	0.001
Total myometrial thickness (TMT) (mm)	7.31 ± 2.19	8.26 ± 3.71	0.145	9.94 ± 2.17	0.027
Healing ratio (%)	57 ± 22	63 ± 29	0.238	75 ± 31	0.003
Estimated blood loss (mL)	636.23 ± 143.43	724.94 ± 302.81	0.126	7639.83 ± 129.79	0.432
Operative time (mins)	30.13 ± 4.53	28.54 ± 5.13	0.563	28.71 ± 2.03	0.761
Need for additional suture	27	29	0.712	32	0.126
Number of additional sutures	1.03 ± 1.35	1.00 ± 0.81	0.801	1.14 ± 1.71	0.945
p-value<0.05 is considered significant					

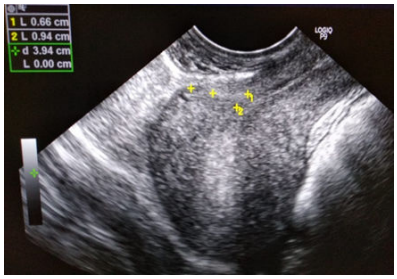


Figure 6: USG image showing a double-layer unlocked sutured technique.

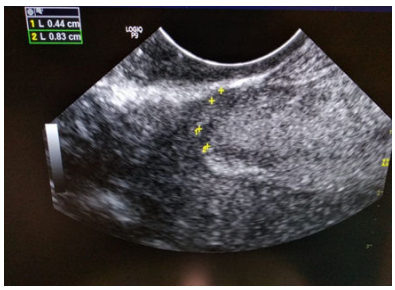


Figure 7: USG image showing a double-layer locked sutured technique.

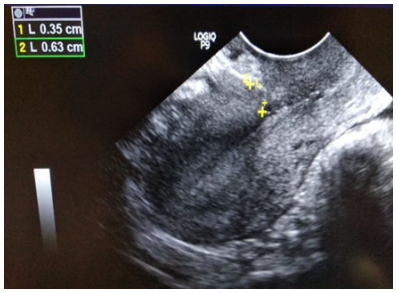


Figure 8: USG image showing a single-layer locked sutured technique.

Discussion

Residual Myometrial Thickness (RMT) is an indirect measure of uterine scar healing and is a surrogate outcome for the prediction of uterine rupture or other adverse outcomes due to uterine scar [3,6]. Our study demonstrates that double-layer uterine closure with the first layer unlocked excluding the decidua is associated with greater RMT, TMT, and healing ratio as compared to locked single-layer closure including the decidua. This suggests that the former technique has better healing of the uterine scar. Similar findings were not observed with the double layer with a locked first layer including the decidua, but the lack of statistical power did not allow us to draw a definitive conclusion. Finally, we observed no

difference in the need for additional hemostatic suture, estimated blood loss and operative time between single- and double-layer closure. This is in agreement with literature suggesting no difference between types of closure for these outcomes [7,9-11].

Most of the previous studies (Bujold E et al. [8] and Roberge S et al. [10]) have shown that locked single-layer closure has a 4-fold increase in uterine rupture in subsequent pregnancies as compared to double-layer closure. Similarly, Sevket et al. [12] observed a greater RMT with the double-layer, locked first-layer technique compared to a locked single-layer suture in a randomized controlled trial including 36 women and hydrosonographic assessment of the uterine scar 6 months after caesarean. Yasmin et al. [11] compared 3 techniques: locked single layer; double layer with the first locked; and double-layer with interrupted first layer. They observed a significantly thicker RMT with the last technique but their findings were limited by the presence of previous caesareans in all women and ultrasound performed before complete uterine scar healing (6 weeks after caesarean).

In a quasi-randomized trial, Hayakawa et al. [13] compared the interrupted single layer including the decidua, interrupted double layer with the first layer including the decidua, and continuous double-layer with a first unlocked layer excluding the decidua, similar to the third technique used in the current study. Their study was limited by the short delay before ultrasound examination (1 month after caesarean). They observed a significantly lower risk of a wedge defect in the uterine scar with the third technique compared to the single-layer (5.6% vs 34%; odds ratio, 0.08; 95% confidence interval, 0.01-0.49) similar to our study. A systematic review and metanalysis in 2014 [7], including 20 out of 1278 citations compared single with double-layer and locking vs unlocking uterine closure techniques. Single-layer closure and locked first layer were coupled with thinner residual myometrial thickness.

Interestingly, a recent randomized controlled trial conducted in France [14] observed no difference in RMT between an unlocked single-layer closure excluding the decidua and a double-layer closure with a similar first layer. Turan et al. [15] showed that a locked single-layer suture was associated with a thinner healing ratio than unlocked single-layer suture (62% vs 76%; $p<0.001$). Recently, a three-arm 1:1:1 RCT including 81 participants done by Roberge et al. [16] comparing single locked layer including the decidua (25 analyzed) with double-layer with first layer locked and including the decidua (22 analysed); and double-layer with first layer unlocked excluding the decidua (26 analysed) showed that the latter technique was associated with better uterine scar healing (thicker RMT, TMT and healing ratio) than the single-layer locked.

All these studies along with ours strengthen not only the decade long debate that double-layer uterine closure is better than single layer but also suggest that exclusion of the decidua with a continuous unlocked first layer is associated with maximal uterine scar healing. This could be explained by the reduction of pressure and the strength of the scar in unlocked sutures, causing less strangulation of the tissue with less interference with vascular supply. Moreover, excluding the decidua while suturing gives a better coaptation (myometrium to myometrium and decidua, to decidua). In our institution as well as a survey [17] done elsewhere showed that it was the locked technique that was primarily being used. Thus, the need was the conversion from such a technique to the one advocated by this study i.e. double-layer with the first layer unlocked excluding the decidua, which would only require minor adjustments without any financial burden. Combined with a uterine scar evaluation during the third trimester, better scar healing would allow more women to consider a vaginal birth after caesarean without complications.

Limitation

Our study is limited to caesarean performed in women before or in early labor done electively and the results cannot be extrapolated to caesarean done in later stages of labor. Since in latter condition, myometrium might be extremely thin and performing double-layer technique may not be possible or with similar benefits.

The loss to follow-up was different in the three groups, leading to low marginal power for our comparison between single layer and double layer with a locked first layer. Thus, conclusions about this comparison could not be done definitely.

Conclusion

Double-layer uterine closure with unlocked first-layer excluding the decidua at caesarean delivery appears to maximize postpartum uterine scar thickness compared with other techniques. However, it remains unclear, if this improves short-or long-term outcomes in the long run. Given the rarity of uterine dehiscence and uterine rupture, and based on the current RCTs, we cannot yet recommend a specific technique for uterine closure, and larger trials are needed. Before RMT measurement may be included in the assessment of women with a previous CS, more studies are needed to elucidate when and how these measurements are best evaluated and to determine the efficiency of these measurements in predicting uterine rupture.

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