Usefulness of delayed primary closure in unplanned caesarean section to reduce surgical site infection in a resource-poor high population country: a randomised controlled trial

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Abstract

Objective: Surgical site infection (SSI) is a common complication, especially following emergency caesarean section (CS) leading to maternal morbidity and prolonged hospital stay. Results are conflicting regarding the ideal method of skin closure after abdominal surgery in clean contaminated and contaminated wound. To compare the outcome of wound health between primary and delayed primary closure (DPC) of skin incision in emergency CS.

Material and Methods: A total of 70 pregnant women undergoing emergency caesarean deliveries with a history of membrane rupture were randomized into group A (n=40) and group B (n=30). In group A monofilament sutures were placed in skin incision but the wound was left open for daily dressing with normal saline. It was closed by tying the monofilament sutures on fifth day and stitches were removed on seventh day. In group B skin was apposed by a routine primary closure procedure.

Results: No patient in group A required secondary wound closure following SSI ($p<0.001$) and duration of hospital stay was also significantly reduced ($p<0.05$).

Conclusion: This trial demonstrated that DPC is effective in reduction of requirement of secondary stitches due to SSI in emergency CS. (J Turk Ger Gynecol Assoc. 2025; 26: 1-6)

Keywords: Caesarean section, surgical site infection, primary closure, delayed primary closure, membrane rupture

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Introduction

Worldwide, the current rate of caesarean section (CS) is around 21% and it has been steadily increasing over the last three decades. By 2030, the global CS rate is projected to reach nearly 30%, making it a very common mode of delivery, particularly in Latin America and Eastern and Western Asia (1). Surgical site infections (SSI) are the second most common type of infection following caesarean deliveries, surpassed only by urinary tract infections (2). Though SSI rarely becomes life-

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threatening, it is associated with significant morbidity, often leading to prolonged hospital stays and increased economic burden on the healthcare system. The incidence of SSI is much higher (23.2%) in resource-poor countries despite adjustment for related factors including diseases, operative procedures, hospitals, and safety (3). The overuse of antibiotics in the postoperative period further exacerbates antimicrobial resistance, thereby increasing the risk of SSI (4).

Caesarean deliveries performed in emergency situations with ruptured amniotic membranes are considered clean-contaminated procedures, and are associated with a 10-20% rate of wound disruptions (5-7). While antibiotic prophylaxis is recommended for clean-contaminated wounds, it may not fully prevent the complications arising from intraoperative contamination (8).

Wound dehiscence, or the separation of the incision, complicates 2-7% of CS. It often occurs due to the formation of a wound hematoma or seroma, which serves as a nidus for infection (9,10). Studies have shown that delayed primary closure (DPC) may effectively reduce wound infection rates compared to primary closure (PC) of skin margins. DPC offers advantages over PC, including lower infection rates and improved wound strength at 20 days (11).

The value of DPC in managing contamination has long been recognized by military surgeons. There are fundamental physiological concepts of wound healing that support the mechanism of DPC. In PC, epithelialization produces an airtight seal within 24 hours, allowing bacteria to become trapped in the subcutaneous tissue. In areas with poor vascularization, blood clots and wound debris, this creates an ideal environment for bacterial growth in contaminated wounds. In addition, collagen tissue is not produced until the 4^{th} to 5^{th} postoperative day. In contrast, DPC involves both primary and secondary intention healing, allowing for accelerated tensile strength due to more effective cross-linking between collagen subunits (12). DPC is proven to be highly effective in complex, contaminated abdominal wall repairs, leading to reduced wound complications and faster healing times (13). In this randomized trial, our aim was to compare the outcomes of wound healing between DPC and PC following emergency CS.

Material and Methods

An open-label randomized controlled trial was conducted at a tertiary care centre in Kolkata, India. Pregnant women undergoing emergency CS were enrolled between March and June 2021. The study was initiated after receiving approval from the Calcutta National Medical College Institutional Ethics Committee (approval number: 91, date: 04.09.2020), following the principles of Helsinki Declaration of 1975, as amended in 2013, and was registered on ClinicalTrials.gov with Identifier: NCT04587960. Written informed consent was obtained from each eligible participant. During the study period, only those participants with ruptured membranes were included. The wound was classified as either clean-contaminated (if membrane rupture was less than 12 hours) or contaminated (if more than 12 hours), as previously described (14,15). Women with ruptured membranes who were undergoing CSs were counselled about the two different types of skin closure techniques and were screened for eligibility. Women with intact membranes, those requiring an incision other than a Pfannenstiel incision, or those exhibiting features of chorioamnionitis were excluded from the study. In addition, women who were on immunosuppressive medications, had a history of chemotherapy, or had conditions that could interfere with wound healing, such as diabetes mellitus, tuberculosis, or collagen vascular disease, were also excluded. Once the decision for emergency CS was made, participants were randomized through a computer generated number sequence into group A (study group) and group B (control group). All participants received a 1-gram ampicillin injection prophylactically within thirty minutes of the abdominal incision. In group A, after the rectus sheath was closed with 1-0 polyglactin at the end of the procedure, the skin and subcutaneous tissue were left open. Stitches were placed with 1-0 monofilament, but knots were not tightened. From the second day onwards, wound dressing was performed using normal saline after cleaning the skin with 5% povidone-iodine solution for three consecutive days. On the fifth day, the stitches were tightened under local anesthesia to approximate the skin margins, and they were removed on the seventh day. In group B, the skin incision margins were approximated using routine PC, with 1-0 monofilament, and the stitches were removed on the sixth day after the CS. For any abnormal discharge from the wounds, swabs were taken for bacterial culture and sensitivity testing. In cases of wound dehiscence, secondary closure was performed once adequate granulation tissue had developed after wound dressing with normal saline and antibiotic ointment. Demographic information, indications for CS, and other variables such as age, parity, body mass index (BMI), previous surgical scars, medical comorbidities, and whether labor was induced or augmented were recorded. Surgery-related data included the duration of the procedure, preoperative and postoperative hemoglobin and hematocrit levels, as well as the length of hospital stay in days.

Statistical analysis

In calculating the sample size, we assumed the need for secondary sutures in 17% of participants in group A and 32% in

group B, based on a previous meta-analysis. Based on a superiority margin of -10%, assuming 80% statistical power and an alpha level of 0.05; a sample size of 36 in each group was needed. For data analysis, continuous data are represented as mean ± standard deviation for normally distributed variables, and as median (interquartile range) for non-normally distributed variables. Categorical data are represented as percentage (frequency). Mean comparisons were conducted using the Mann-Whitney U test. Proportions were compared using the chi-squared test or Fisher's exact test, where applicable. For variables with multiple levels of ordered categories, unadjusted p values were reported with Bonferroni correction to control for the family-wise error rate. In the cross-tabulation of the need for secondary sutures against groups (A or B), quasi-complete separation of data was observed (no secondary sutures were needed in group A). Multivariate modeling with logistic regression, with the former as the dependent variable and the latter as one of the independent variables, were corrected using the Bias-Reduced Logistic Regression (firth regression). All statistical analyses were performed using SPSS, version 20 (IBM INC., Armonk, NY, USA).

Results

Overall, 70 patients were included in the study with a mean age of 25.1±4.46 years, and 45.7% (32/70) were nulliparous. Patients were randomized into two groups: DPC (group A, n=40) and PC (group B, n=30) (Figure 1). The demographic and clinical details of both groups are provided in Table 1. The groups were comparable in terms of the presented parameters. The duration of the operation (OT) did not differ significantly between the groups, with group A having an average duration of 58.5±15.8 minutes and group B averaging 58.7±18.5 minutes (p=0.96).

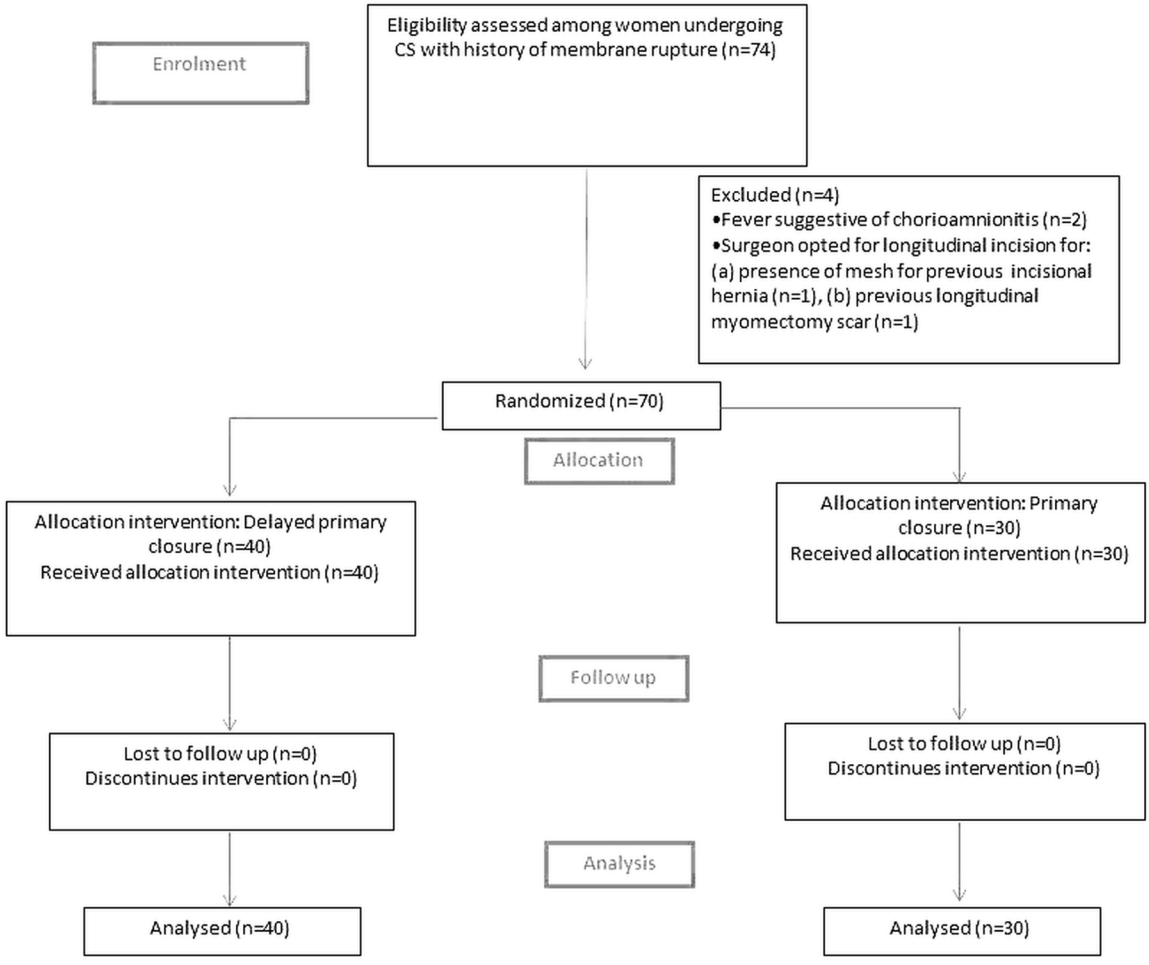

Figure 1. CONSORT flow diagram
CS: Caesarean section

The need for secondary sutures was absent in group A but was required in one-third of the patients in group B (Table 2) and this was significant (p<0.0001). Other secondary outcome measures are also given in Table 2. The duration of hospital stay was significantly shorter for patients undergoing DPC (7.6±3.4 vs. 5.6±0.5, p=0.003).

Prediction of secondary suture requirement

Univariate and multivariate regression results (Table 3) showed only one significant predictor for the need for secondary sutures in pooled data, the OT [odds ratio (OR): 1.06, 95% confidence interval (CI): 1.01-1.11, p=0.029].

Table 1. Baseline demographic and clinical information

Parameters		Primary closure group, (n=30)	Delayed primary closure group, (n=40)
	Age in years	24.6 (3.9)	25.6 (4.9)
	BMI in kg/m^2	21.3 (1.8)	22.8 (3.5)
Indications for CS	Post CS in labor	4 (13.3%)	10 (25%)
	Nullipara with medical complications	5 (16.6%)	4 (10%)
	Induction failure/non-progress of labor	5 (16.6%)	4 (10%)
	Post CS with medical complications	5 (16.6%)	6 (15%)
	Obstructed labor	3 (10%)	3 (7.5%)
	Elderly primigravida	1 (3.3%)	2 (5%)
	Placenta previa	2 (6.67%)	1 (2.5%)
	Fetal distress	3 (10%)	5 (12.5%)
	Breech presentation	2 (6.67%)	5 (12.5%)
	Presence of abdominal scar other than CS	9 (33.3%)	16 (25%)
	Presence of previous unhealthy scar	2 (6.67%)	5 (12.5%)
Parity	Nullipara	15 (50%)	17 (42.5%)
	Parity = 1	13 (43.3%)	19 (47.5%)
	Parity = 2	2 (16.67%)	3 (7.5%)
	Parity = 3	0	1 (2.5%)
	OT duration in minutes	58.5 (15.8)	58.7 (18.5)

BMI: Body mass index, CS: Caesarean section, OT: Operation

Table 2. Outcome measures

Parameters	Primary closure group, (n=30)	Delayed primary closure group, (n=40)	p
Secondary suture rate	9 (33.33%)	0	0.0001
Post OT haemoglobin level (gm/dL)	10.6±1.3	10.1±1.6	0.26
Duration of hospital stay in days	7.6±3.4	5.6±0.5	0.003

OT: Operation

Table 3. Prediction of need for secondary suture

	Univariate			Multivariate		
Variable	**OR**	**95% CI**	**p**	**OR**	**95% CI**	**p**
Age	0.99	0.85-1.16	0.98	NA		
OT duration	1.06	1.01-1.12	0.0009	1.06	1.01-1.11	0.029
BMI	0.88	0.68-1.14	0.8	NA		
Parity >0	3.38	0.65-17.63	0.15	NA		
Post OT hemoglobin	0.68	0.43-1.07	0.09	0.82	0.1-1.31	0.41

OR: Odds ratio, CI: Confidence interval, BMI: Body mass index, OT: Operation

Discussion

The National Nosocomial Infections Surveillance System of the Centers for Disease Control and Prevention risk adjustment index to stratify the risk of SSI involves three major factors: the patient's health status before surgery; the type of wound reflecting degree of contamination; and the duration of the OT. As the risk index score increases, so does the infection rate. However, this relationship has not been firmly established for SSIs after CS (16). An obstetric-specific risk factor is the duration of membrane rupture prior to caesarean delivery. Once the membrane rupture, the amniotic fluid is no longer sterile and can act as a medium for bacteria to contaminate uterine and skin incisions, thereby increasing the risk of wound infection (17,18). In the present study, all participants had a history of membrane rupture, with their wounds classified as either clean-contaminated or contaminated when the duration of membrane rupture exceeded 12 hours. Tran et al. (19) demonstrated that CSs lasting more than one hour were associated with a 2.4-fold increased risk of wound infection in univariate analysis, although they did not find its independent predictive value. In contrast, the present study found that both univariate and multivariate analyses identified the duration of the surgical procedure as a significant predictor of SSI requiring secondary suturing (OR: 1.06, 95% CI: 1.01-1.11, p=0.029). The risk of post-operative infection is proportional to the volume of blood loss during caesarean deliveries (20,21). A high volume of blood loss is associated with poor control of bleeding, prolonged retraction and use of more sutures, which can promote more contamination and reduce the local resistance mechanisms (19). In our study, we attempted to assess operative blood loss by recording pre- and post-operative haemoglobin levels. However, we did not find any causal relation between the post-operative decrease in haemoglobin values and the occurrence of wound infections requiring secondary suturing. One-third of participants required secondary stitches due to SSI when skin incisions were closed using PC (p=0.0001). This morbidity also significantly prolonged hospital stay (p=0.003). Therefore, DPC of skin incisions after caesarean deliveries appeared to play an important role in reducing SSIs, preventing further surgical interventions, and minimizing other related morbidities. A significant bacterial presence can delay wound healing after PC by directly "stealing" oxygen or increasing oxygen demand due to phagocytosis of bacteria. This leads to poor oxygen tension, which can compromise collagen synthesis, or the release of collagenase by bacteria or granulocytes may further inhibit collagen production (22). In addition, wound healing may be delayed due to inadequate blood supply in conjunction with infection (23). DPC, unlike delayed wound healing, is performed as a therapeutic intervention. Several animal studies have demonstrated that DPC results in superior mechanical strength, attributed to significantly higher perfusion, increased partial pressure of oxygen, and enhanced collagen synthesis and remodelling activity (24-26). Furthermore, in a propensity matched study, negative pressure wound therapy-assisted DPC was shown to have excellent effects on wound healing (13). Two retrospective studies of DPC have shown mixed results, while a meta-analysis of seven randomized controlled trials in the surgical literature demonstrated 0.50 relative risk reduction with DPC. One case report involving an obese parturient with a BMI of 61 kg/m^2 who underwent caesarean delivery due to failed induction of labor reported a favorable outcome with no complications (15). A recent review article also highlighted the beneficial effects of DPC in patients with comorbidities that might impair wound healing. However, it is important to note that although all studies included in the review were comparative, a significant portion were not randomized controlled trials, underscoring the need for further research to confirm these findings (27). Given this context, we undertook this clinical trial to strengthen the evidence supporting our conclusions. In the present study, we found that DPC was a safe and highly effective method for managing clean-contaminated or contaminated wounds after caesarean deliveries.

Study Limitations

The major limitation of this study was the small sample size. Due to the limited data available from a small number of studies, large-scale clinical trials are needed to more comprehensively evaluate the role of DPC in preventing SSIs, reducing prolonged hospital stays, and minimizing other morbidities following obstetric surgeries.

Conclusion

DPC of clean-contaminated skin incisions in CSs with prolonged membrane rupture may be a suitable option for preventing SSIs. This may be particularly true in high-population settings where procedure-related conditions may not always be optimal.

Ethics

Ethics Committee Approval: *The study protocol received approval from the Calcuttaa National Medical College Instituitional Ethics Committee (approval number: 91, date: 04.09.2020).*

Informed Consent: *Written informed consent was obtained from each eligible participant.*

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Footnotes

Author Contributions: *Surgical and Medical Practices: J.B., S.D., M.D., P.S., N.B., M.K., Concept: J.B., S.D., M.D., P.S., N.B., M.K., Design: J.B., S.D., M.D., P.S., N.B., M.K., Data Collection or Processing: J.B., S.D., M.D., P.S., N.B., M.K., Analysis or Interpretation: J.B., S.D., M.D., P.S., N.B., M.K., Literature Search: J.B., S.D., M.D., P.S., N.B., M.K., Writing: J.B., S.D., M.D., P.S., N.B., M.K.*

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