

**Original Article****Early Vs Late Removal of Dressing in Scheduled Cesarean Section: A Randomized Controlled Study**

Authors

**Dr Neelu Singh, MS DNB¹, Dr Vishal Prakash MS², Dr Shikha Pathak MS DNB³,
Dr Gourisankar Kamilya⁴, MS DNB, Dr Anirban Mitra, MS⁵**^{1,2,3}Senior Resident, ⁴Professor, ⁵Assistant Professor^{1,5}Dept. of obstetrics and gynecology, NBMC, Darjeeling²Dept. of orthopedics, RIMS, Ranchi⁴Dept. of obstetrics and gynecology, SSKM, Kolkata

Corresponding Author

Dr Neelu Singh

North Bengal Medical College, Darjeeling

Abstract

Introduction: Wound dressing of the primarily sutured surgical wound immediately after its closure with a sterile dressing is considered a routine and is essential to antiseptic operation and dressing is left for a minimum of 3 to 5 days. CDC Guidelines for prevention control of surgical site infections has recommended that the primarily closed surgical incision should be covered with a sterile dressing for 24 to 48 hours.

Method: This is an Open Label Parallel group Randomized control study in which a total 206 post cesarean women age between 18 to 44 years randomized for wound dressing removal at either 48 hours or 5th day post-surgery.

Result: Two patients (2%) of Group C were developed wound complication in which seroma in 1% and wound infection in 1% and in Group-S, three patients (2.9%) were developed wound complications out of which seroma in 1.0%, wound infection in 1% and wound disruption in 1%. The differences of wound complications among two groups was statistically insignificant ($p=0.563$). Patient satisfaction in Group-C was 62.1% and Group-S was 40.8%. The differences of patient satisfaction among two groups was statistically insignificant ($p=0.517$). The mean duration of hospital stay (days) in Group-C was 7.03 ± 0.29 days and in Group-S was 7.13 ± 0.64 days. The difference of mean duration of hospital stay among both groups was statistically insignificant ($p=0.1269$).

Conclusion: Wound dressings do not play a significant role in wound healing as early removal of the wound dressing at 48hrs hours instead of 5th postoperative did not have a detrimental effect on wound complications (wound infection, dehiscence, hematoma, or seroma) in women undergoing scheduled cesarean sections. The mean duration of hospital stay was reduced by early removal of dressing, However apprehension of infection was increased on early removal of dressing.

Keywords: Cesarean section, Infection, Wound dressing.

Introduction

The custom of dressing surgical wounds is as old as the history of surgery. Wound dressing of the primarily sutured surgical wound immediately after its closure with a sterile dressing is considered a routine, essential to antiseptic operation and dressing left for a minimum of 3 to 5 days.^[5] The functions of a dressing are to protect wound from trauma, contamination by bacteria, foreign material, absorb exudates from the wound, provide mechanical compression to minimize edema, obliterate dead space, prevent fluid loss, non adherence and provision of a warm, moist environment which is desirable to maximize healing. Neither single dressing can provide all of these functions optimally, nor all functions required for all wounds. Experimental studies have shown that a precisely sutured incision with good hemostasis gets sealed with fibrin within 6 to 24 hours, and wounds become adequately protected against outside moisture and bacterial contamination^[6]. In hot climates, the surgical site become moist, warm, and darken, that all prevail beneath surgical dressing are optimum conditions for bacterial colonization.^[8] It is thus obvious that a surgical dressing might, in fact, under certain circumstances, predispose to the development of around infection.^[9] The incidence of wound complications after cesarean section ranges from 2.8% to 26.6%.^[10] CDC Guidelines in 1999 for prevention control of surgical site infections recommended that the primarily closed surgical incision should be covered with a sterile dressing for 24 to 48 hours.^[11] However, it is our conventional practice to remove dressing at the time of stitch removal on day 5 of cesarean section. An attempt, keeping these factors in mind, whether early wound dressing removal has an effect on wound complications such as infection, disruption, Hematoma or seroma. Early removal would allow women to wash or shower sooner. Therefore, we are also interested in determining whether early removal of dressing increased satisfaction of patients in the postoperative period.

Methods

This is an Open Label Parallel Group Randomized control study in which all low risk women randomized for wound dressing removal at either 48 hours or 5th day post-surgery. A total 206 low-risk women aged between 18 to 44 years at term with singleton pregnancies having a scheduled cesarean. This study was carried out at Institute of Post-Graduate Medical Education and Research (IPGMER), Kolkata in period between June 2017 to May 2018. The study was started after taking approval by institute ethical committee. Written and informed consent was taken from all patients. All surgeries were performed under spinal anesthesia. Women with known pregnancy complications such as fever, diabetes, or Preeclampsia, patients in labour, patient with premature rupture of membrane, patients with BMI ≥ 35 were excluded from the study. The primary outcome of this study was to compare the incidence of wound complications (like infection rate, disruption, hematoma or seroma) between early removal of wound dress with its late removal. Women having more than one complication were categorized as the more significant in the order given above. Women were permitted to wash or shower after wound dressing removal, and our secondary outcome was patient satisfaction with their postoperative care which was measured by 5 point short assessment of patient satisfaction scale (SAPS).^[2] The SAPS consists seven items assessing the core domains of patient satisfaction which include treatment satisfaction, explanation of treatment results, clinical care, participation in medical decision making, respect by the clinician, time with the clinician and satisfaction with the hospital/clinic care.

Pregnant mothers after fulfilling inclusion and exclusion criteria are recruited and demographic details are obtained. All cesareans were performed in a similar fashion. All women received a single dose prophylactic antibiotic within 1 hr of skin incision. All abdominal preparations were by

povidone iodine wash. Skin incisions were all Pfannenstiel. The bladder flap, rectus muscles and parietal peritoneum was not be closed. Closure of the fascia will be by polyglactin 910. Skin incisions was closed using mattress with synthetic non absorbable nylon suture 2-0. A standard adhesive non-woven wound dressing was applied. Dressing was removed at the designated time. All women were moved to a chair at 12 hours post-operatively. Use of the bathroom for personal hygiene (washing or showering) was permitted only after wound dressing removal (48 hours or 5th day post op). Women were routinely discharged on post-operative day six unless requiring management of wound complications. Prior to discharge, women were reminded of the two arms of this study, and patients were given a set of questionnaire as per SAPS scale in order to assess their level of satisfaction.

Wounds are examined prior to removal of stitches for evidence of any complication. Post-operative intravenous antibiotics were prescribed in women with various indications such as fever, endometritis, or wound infection, but were counted as the latter only in the presence of indurations or purulent discharge from the incision site. Sutures were removed on sixth postoperative day. The provider, who will be unaware of the patient's group designation, assessed the incision site for wound complications and this information was given to the investigators. Patients were followed after 6 weeks at OPD for any surgical site infection developed later.

Sample size for the study has been calculated on the basis of incidence of surgical wound site infection as a primary outcome parameter, our observation suggests that the incidence of infection with current practice of dressing change with suture removal at 5th day postop associated with 7% incidence of infections. Anticipating 2% of improvement (reduction to 5%) with early removal of dressing with 80% power at 5% type 1 error rate the estimated sample size was 93 patients in each group. We have taken a total 206 patients (103 in each group) considering further

10% of drop out. Sample size calculated by M. master 2.0 (dept of biostatistics cmc, vellore). Data were entered into a Microsoft excel spreadsheet and statistical analysis done by using SPSS 24.0. and Graph Pad Prism version 5.

Results

We assessed 210 patients for eligibility, of which 4 did not meet the inclusion criteria. Figure 1 depicts the CONSORT flow diagram of patient progress through the study. All the patients enrolled for the study, 103 patients in each group completed the study. Enrolled patients had similar demographic characteristics, and no clinically important differences existed between the study groups (Table 1). Two patients (2%) of Group C were developed wound complication in which seroma in 1 % and wound infection in 1% [Table 2]. Among above complications in Group C one patient (1%) required in-hospital treatment in the form of dressing with antibiotic and (1.0%) patient had secondary suturing with antibiotic. In Group-S, three patients (2.9%) developed wound complications out of which seroma occurred in 1.0%, wound infection in 1% and wound disruption in 1% [Table 2]. Among above complications in Group S, four patients (3.9%) required treatment in the form of dressing with antibiotic and one patient (1.0%) taken treatment as secondary suturing with antibiotic. However, the differences of wound complications among two groups was statistically insignificant ($p=0.563$). The association of treatment required for wound complication among two group was also statistically not significant ($p=0.397$). Patient satisfaction in Group-C was 62.1% and Group-S was 40.8% [Table 2].The differences of patient satisfaction among two groups was statistically insignificant ($p=0.517$). The mean duration of hospital stay(days) in Group-C was 7.03 ± 0.29 days and in Group-S was 7.13 ± 0.64 days. [Table 1] The difference of mean duration of hospital stay among both groups was statistically insignificant ($p=0.1269$).

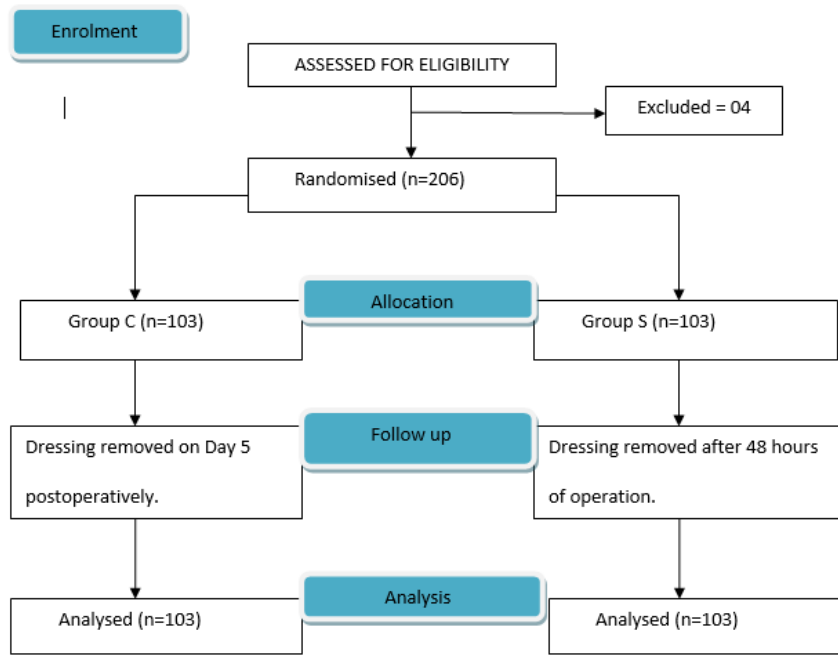


Figure 1: Consort flow chart

Table 1: Demographic parameters

Patient Characteristics	Group C (n=103)		Group S (n=103)		P-value
	Mean	SD	Mean	SD	
Age (years)	25.97	4.48	25.70	4.59	0.679
Period of gestation (weeks)	38.35	2.05	38.63	2.08	0.319
BMI (kg/m ²)	23.99	2.06	24.25	2.69	0.442
Length of operation (minutes)	37.44	11.30	38.56	7.99	0.410
Distribution of mean hospital stay (days)	7.03	0.29	7.13	0.64	0.127

Distribution of parity	Group C(n=103)	Group S(n=103)	P VALUE=0.6092
0	68	60	
1	27	33	
2	6	9	
3	1	1	
5	1	0	
Distribution of indication of LSCS	Group C	Group S	P VALUE = 0.8639
POSTDATED PREGNANCY	1	3	
SEVERE OLIGOHYDRAMNIOS	18	14	
PREVIOUS 1 LSCS	23	24	
PREVIOUS 2 LSCS	3	4	
CPD	12	11	
IUGR WITH FETAL DISTRESS	10	12	
FETAL DISTRESS	16	14	
INDUCTIONFAILURE	12	14	
ABRUPTIO PLACENTAE	0	1	
ELDERLY PRIMIGRAVIDA	1	3	
IVF PREGNANCY WITH SEVERE OLIGOHYDRAMNIOS	1	0	
IVF WITH IUGR	3	1	
CERVICAL FIBROID	2	1	
HISTORY OF MYOMECTOMY WITH SCAR TENDERNESS	0	1	
BAD OBSTETRIC HISTORY	1	0	

DISTRIBUTION OF PREVIOUS LSCS	Group C	Group S	P VALUE = 0.8116
0	74	70	
1	26	29	
2	3	4	

Table 2: Outcomes variables [complication, treatment, patient satisfaction]

Variables		Group C	Group S	P value
Wound complication	No complication	101	98	0.563
	Seroma	1	3	
	Wound infection	1	1	
	Dehiscence/ Disruptiion	0	1	
	Total Complication	2	4	
Patient satisfaction	Very dissatisfied	0	1	0.5174
	Dissatisfied	64	60	
	Satisfied	30	36	
	Very satisfied	9	6	
	Total satisfied	39	42	
Treatment of wound complication	No treatment	101	98	0.3975
	Dressing with antibiotics	1	4	
	Secondary suturing with antibiotics	1	1	
	Total patient taken treatment	2	5	

Discussion

The absence of a significant difference in the SSI rates between the study and control groups in the two strata supports the concept of early exposure of Caesarean wounds as being a good method. Due to the multi-factorial aetiology of SSI, a successful randomisation and adjusting for important confounding factors are vital for the internal and external validity of this study. As the baseline characteristics were similar in both groups, randomisation was considered successful. The absence of any significant difference in the SSI rate between the two groups in this study could be considered to be consistent with the findings of previous studies carried out with other surgical procedures. The study performed by Law in 1987^[1] suggested that there could be benefit from early exposure of the wound but the estimate was very imprecise and did not reach statistical significance because of the very small sample size. The studies performed by Phan in 1993^[3] and Chrintz in 1989^[3] had methodological flaws as they had performed per protocol analyses in the presence of significant numbers being lost to follow up and therefore they had high risks of bias. In the study conducted by Heal in 2006 participants were patients from a primary care setting who were undergoing minor skin excisions, and the timing of dressing removal in the comparison groups was 12 hours and 48 hours^[4]. This was a multicentre trial of sound

methodology; therefore its findings are valid. However, the findings cannot be generalised to major skin incisions, which was the focus of the current study. Two Cochrane reviews regarding early (<48 hours) versus delayed dressing removal and postoperative bathing reported limited data, but no significant difference in SSI rate was shown^[1,3]. Early (6 hours) compared to delayed (24–48 hours) removal of the wound dressing was also recently examined in a RCT. The authors reported comparable wound complications that included infection, disruption, and seroma/hematoma formation. More women were pleased and satisfied with early removal^[7]. Although in our study there were no significant difference related to the satisfaction of the two group, it may be due to increased apprehension of the patient regarding early removal of dressing which in patient's view could increase the rate of wound infection. A meta-analysis of randomized trials comparing different wound dressings found no difference in rates of infection, pain, scar or acceptability between dressings^[1,3]. A review of studies examining early removal of the dressing in non-obstetric patients (within the first 48 hours) versus delayed removal (after 48 hours) has been published¹. It was shown that early removal does not have a detrimental effect on outcomes, but does allow for shorter hospitalization and reduced costs. Few randomized trials have questioned whether wound dressings are at all necessary,

leaving the wound exposed in one of the groups^[3]. In these studies there was no difference in wound complications allowing the authors to conclude that dressings do not play a significant role in wound healing. The overall SSI rate following LSCS in this study was 3.39%. Wound dehiscence (partial and complete) in our study was approximately 1% and 0% in the study and control group, respectively, whereas one study reported these figures as 0% and 1.3% in the two groups^[12]. In the same study, there were no reported cases of abscess or localised inflammation, in our study 1% of wound infection in both study and control group and 2.9% and 1% of seroma formation seen in study and control group respectively. In present study, the patients were told to remove the dressing after 48 hours and wash the wound with soap and water gently. It was confirmed by asking the patient the next day. A number of studies have been conducted to compare the standard management of wound (keeping wound dry till suture removal) with washing the wound with soap and water or with water alone within or after 24 hours after minor skin excisions with respect to the postoperative wound complications. These studies suggest that getting suture wet does not increase the infection rate, which is again in conformity with the present study. There was no incidence of wound infection in these studies while our study had 4.85% incidence of wound infection^[13,14,15,16,17]. Carragee et al. conducted a prospective clinical trial of 100 consecutive patients undergoing posterior spinal surgery with historical control to determine if early bathing (2-5 days after surgery) resulted in increased wound problems. They did not observe any wound infection in the experimental group, which is not significantly different from the present study. Similarly Clare et al. in a prospective randomized control multicentric trial of 857 patients compared standard management of keeping the wound dry and covered with allowing wounds to be uncovered and wet in the first 48 hours after minor skin excision and showed that infection in intervention group (8.4%) was not

inferior to the incidence in the control group (8.9%) ($p < 0.05$). However, in the present study the wounds were exposed and made wet after 48 hours. The incidence of wound infection (4.85%) in the present study is significantly lower as compared to that reported by Clare et al. (8.4%).^[18] The findings of the present study reveal that patients are very well compliant and heed to the postoperative advice to prevent trauma to the wound that, in turn, suggests that one of the primary indications of dressing of a wound, i.e., protection from injury is not necessary. The 4.85% incidence of wound infection in clean surgical wounds in the present study suggests that dressings in the fresh surgical wounds may not be required in the context of preventing bacterial contamination. The third indication of dressing of surgical wound that it helps in absorption of secretion may also be done away with as the present study revealed that in the primarily closed surgical wounds, there was no appreciable flow after 24 hours; the wound being by then effectively sealed by fibrin and epithelium.

Conclusion

Wound dressings do not play a significant role in wound healing as early removal of the wound dressing at 48 hours instead of 5th postoperative did not have a detrimental effect on wound complications (wound infection, dehiscence, hematoma, or seroma) in women undergoing scheduled cesarean sections. The mean duration of hospital stay was reduced by early removal of dressing. However apprehension of infection was increased on early removal of dressing. Many more studies would be required to confirm this finding.

Conflict of interest: Nil

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