DOI: http://doi.org/10.4038/sljog.v38i1.7784
www.slcog.lk/sljog

Comparison of surgical site infections and patients' comfort level with caesarean section wounds following early exposure versus delayed exposure

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Abstract

Key Words: Wound infection, Caesarean section wounds, Surgical site infection, Early dressing removal, Delayed dressing removal

Introduction: In the prevention of surgical site infections (SSIs), the ideal timing for removal of dressing remains unresolved.

Objectives: To determine the outcomes of early removal of wound dressing in terms of surgical site infections (SSI), patients' comfort level and whether it was acceptable to the patients

Methods: The study was conducted at the Obstetric Unit of the Professorial Unit of Colombo South Teaching Hospital from September 2012 to February 2013.Out of 498 patients assessed for eligibility, 400 were randomised using a stratified [emergency versus elective caesarean sections (CS)] design into the intervention and control groups. There were 281 and 119 patients in the emergency CS and elective CS groups respectively. In the total sample, 205 patients underwent the intervention (removal of dressing between six and 12 hours after CS) and 195 patients underwent delayed wound exposure between 24 to 30 hours after CS (controls). Patients were reviewed before discharge and in two weeks: On the 1st post-operative day, using a visual analogue scale, their ability to sit up, get off the bed, walk and squat was assessed. The acceptability of early wound exposure was assessed in the intervention group with a structured closed ended questionnaire administered on the 1st post-operative day

Results: There was no significant difference in the SSI rates between the two groups, in both strata. Patients in the intervention group were able to perform all the given tasks more easily than in the control group ($p < 0.001$). Of the 183 respondents in the intervention group, 85% would prefer to have the wound dressings removed early for their next CS, 78% thought early removal of dressing improved their hygiene and 90% thought it improved their overall comfort.

Conclusion: Clean, primarily sutured CS wounds ,exposed within six to 12 hours after surgery do not have an increased incidence of SSI compared to those that are exposed within 24 to 36 hours. The patients were more comfortable and better able to carry out simple tasks after early exposure compared to delayed exposure, and early exposure was well accepted by the majority of patients who had this intervention.

INTRODUCTION

The covering of the primarily sutured surgical wounds with sterile dressings is considered to be a routine, traditional conclusion to an aseptic surgical procedure. Infections that occur in wounds after an invasive surgical procedure are referred to as surgical site infections (SSIs). The ideal timing of dressing removal to prevent SSI is an unresolved issue, and the published literature on this subject is sparse. Some professionals prefer to leave wounds uncovered from the moment of closure, others uncover them after a certain time period, and still others keep them covered until suture removal.[1] Some guidelines recommend covering surgical incisions with a dressing for a period of 48 hours postoperatively, as uncovered or early exposed wounds could be associated with an increased risk of contamination and surgical site infections.[2,3] However, other studies have suggested that longer periods of dressing have no benefit.[4,5,6,7] Several randomised controlled trials have shown that short dressing times and the early exposure of clean surgical wounds not only reduce the workload but also reduce the need for costly dressing material and made observation of the wound easier while the patients' personal hygiene and comfort improved, with no significant difference in wound-related complications.[5,6,7,8]

SSIs after a caesarean section (CS) increase maternal morbidity and medical costs[9]. The occurrence of SSIs after CS is multifactorial. These risk factors have only been investigated in observational studies and not in any randomised controlled trials. Based on the current recommendation according to the NICE clinical guidelines on CS (2011), routine wound care should include removal of the dressing 24 hours after the CS and this is based on level four evidence[10].

This study was designed with the following objectives.

- To compare the rates of SSIs in the intervention (early exposure of the wounds) and control (delayed exposure of the wounds) groups.
- To compare patient comfort level on the 1st postoperative day in the intervention and control groups by assessing their ability to perform certain tasks based on a visual analogue scale.
- To assess the patient's acceptability regarding the early wound exposure method in the intervention group.

MATERIALS AND METHODS

The study was conducted at the Obstetric Unit of the Professorial Unit of Colombo South Teaching Hospital from September

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Competing interests: None

2012 to February 2013. Ethical approval was obtained from the Ethical Review Committee of Colombo South Teaching Hospital. Informed written consent was obtained from all patients undergoing CS who were eligible for the study. Exclusion criteria were prior surgical site skin infection, pyrexia before surgery, and a body mass index (BMI) of 35 kg/m² or more and any history of Elastoplast allergy. After the CS, while in the postnatal ward, skin incision other than a Joel Cohen incision, and any CS that resulted in additional procedures due to complications, were also excluded prior to randomisation to the intervention and control groups.

This was a stratified randomised control trial. Out of 498 patients assessed for eligibility, 400 were randomised using a stratified design (emergency CS and elective CS) into the intervention and control groups. Within the two strata, patients were randomly allocated; using computerized random numbers and a simple randomisation method in to two groups. (Intervention and control groups) The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes.

There were 281 and 119 patients in the emergency CS and elective CS groups respectively. In the total sample 205 patients underwent the intervention (removal of dressing between six and 12 hours after CS) and 195 patients underwent delayed wound exposure between 24 to 30 hours after CS (controls). Patients were reviewed before discharge and in two weeks. Patient comfort level was assessed on the 1st post-operative day, using a visual analogue scale, and their ability to sit up, get off the bed, walk and squat was assessed. The acceptability of early wound exposure was assessed in the intervention group with a structured closed ended questionnaire administered on the 1st post-operative day. All patients had standard gauze dressing covered with Elastoplast. A standard surgical technique was adhered to in all the cases according to the NICE LSCS clinical guidelines [10]. This included a Joel Cohen incision, placental removal by controlled cord traction, intra-peritoneal repair of the uterus with double layer closure, non-closure of the visceral and parietal peritoneum, and closure of the subcutaneous tissue space if there was more than 2 cm of fat tissue. The skin was approximated by subcuticular method with absorbable 3/0 polyglycolic acid sutures. Due to practical difficulties of recruiting an adequate sample, two operators including the principal researcher conducted the CS. All patients were administered a similar antibiotic regime as per unit policy. This included an intravenous (IV) loading dose of cefuroxime 1.5 g at the time of the skin incision followed by IV cefuroxime 750 mg 8 hourly for two doses and IV metronidazole 500 mg 8 hourly for two doses followed by an oral antibiotic regime of cefuroxime 250 mg bd and oral metronidazole 400 mg tds for three days. All patients were also administered the same analgesic regime (diclofenac sodium suppository 100 mg bd) until the 2nd day of surgery. The wound management protocol is given below. (Figure 1)

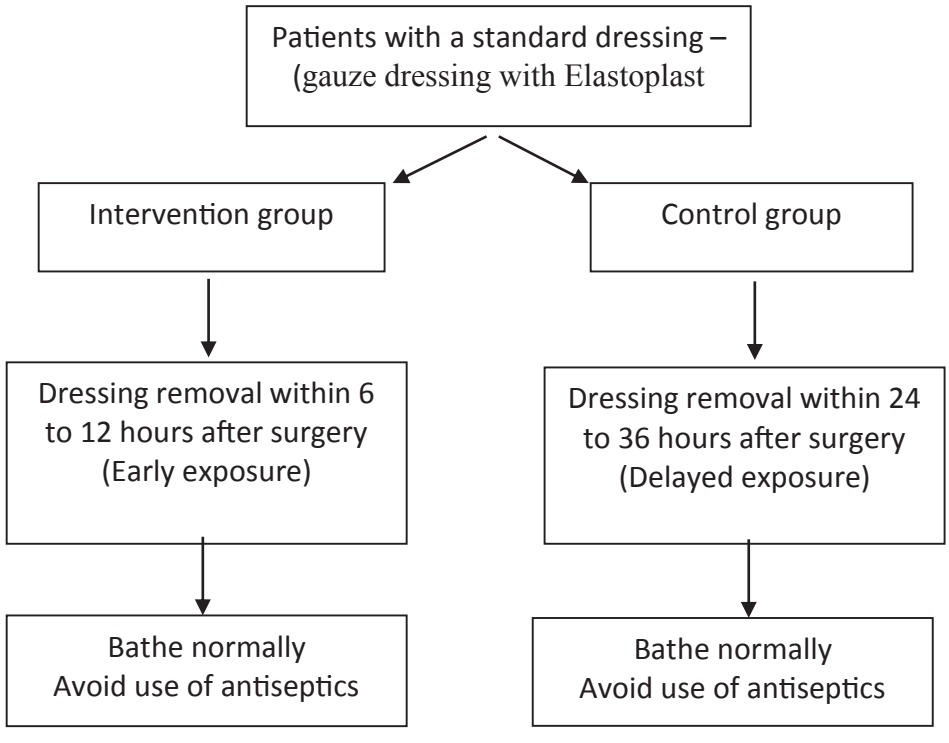

Figure 1 – Wound management protocol in early exposure (intervention) and delayed exposure (control) groups

Primary outcome was the SSI rate. All participants were reviewed on two occasions; on the third post-operative day and at the postnatal clinic after two weeks to detect the occurrence of SSI. If complications were detected, appropriate management was done irrespective of the study group. The definition and the method of SSI detection were adopted from the CDC/NNIS criteria.[11] According to these guidelines, superficial incisional SSI must meet the following criteria:

Infection occurs within 30 days after the operative procedure

- *And* involves only skin and subcutaneous tissue of the incision
- *And* patient has at least 1 of the following:
  a. Purulent drainage from the superficial incision. This was an indication for obtaining a culture swab.
  b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
  c. At least one of the following signs or symptoms of infection: pain or tenderness, localised swelling, redness, or heat, and superficial incision is deliberately opened by the surgeon and is culture positive or not cultured. A culture-negative finding does not meet this criterion.
  d. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Wound swabs were obtained for culture and antibiotic sensitivity if there was a purulent discharge from the wound.

Secondary outcomes were patient comfort level and the acceptability of the intervention method. Patient comfort level was assessed on the 1st post-operative day in both groups. It was recorded using a self-administered visual analogue score assessing the ability to perform the following tasks: sitting up, getting off the bed, walking and squatting. Patients' acceptability regarding the early wound exposure method was assessed in the intervention group. This qualitative assessment used standardised and structured close-ended interviews conducted at the second review at the second week.

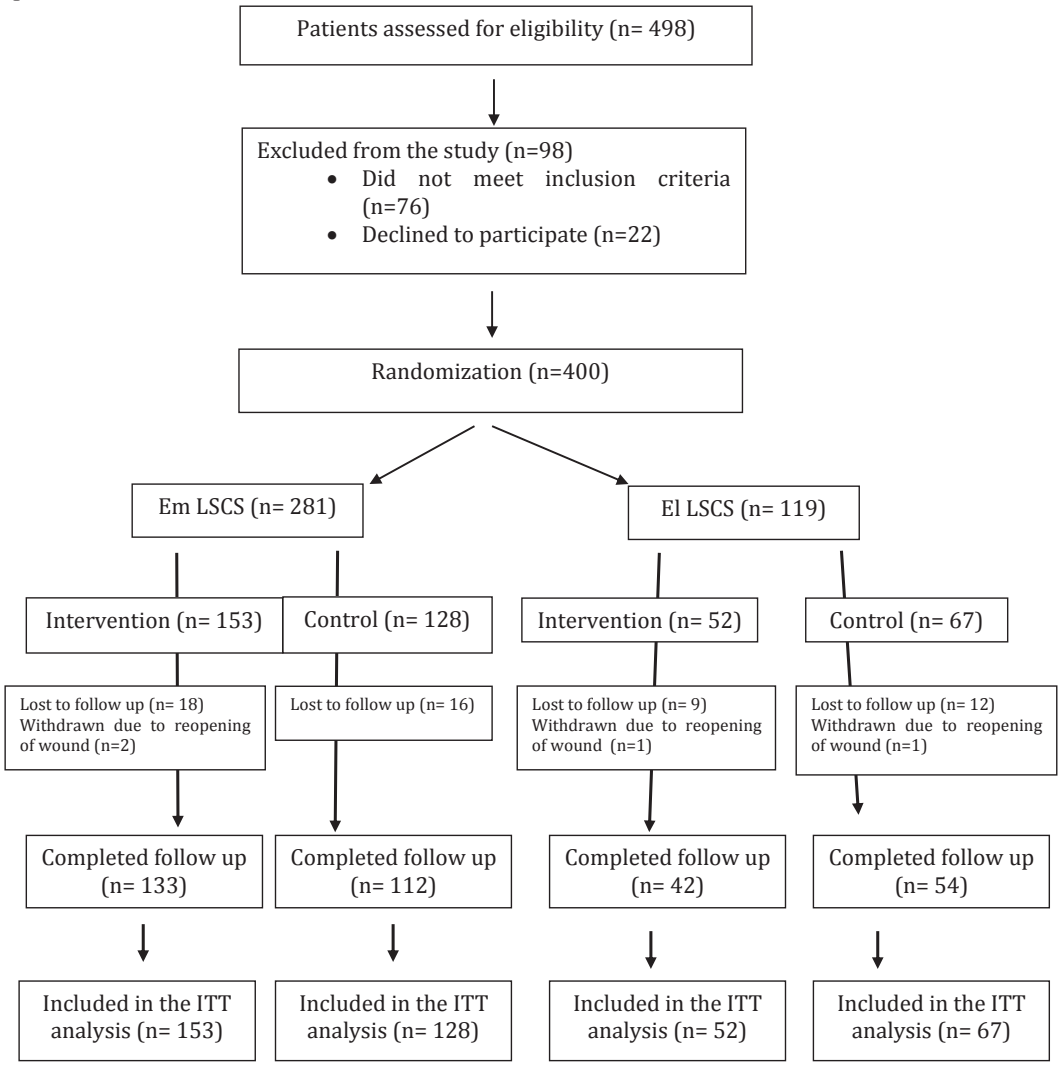

Figure 2 – Flowchart of enrolment, randomisation and follow up of patients

Em LSCS – Emergency lower segment caesarean section, El LSCS – Elective lower segment caesarean section, ITT – Intention to treat analysis

The sample size was calculated based on the study performed by Law in 1987.[12] In this randomised trial, the rate of SSI in the exposed group (without any dressing) was 1/53 (1.8%), and the rate of SSI in the unexposed group (with dressing) was 3/59 (5.08%) but the confidence intervals were very wide and the differences in the rates did not reach statistical significance because of the very small sample size. Assuming a power of 80% and a Type 1 error of 2% for the detection of a reduction of the SSI rate by approximately 3% in the early exposure group, the minimum sample size for each group was calculated to be 592 subjects per arm. Due to practical difficulties in collecting such a large sample involving approximately 1200 patients, it was decided to carry out a pilot study on a total of 400 patients. A total of 498 patients were assessed for eligibility and 400 were included in the study. (Figure 2)

Baseline characteristics were compared using unpaired sample t test. An intention to treat analysis was carried out. The primary endpoint was the SSI rates in the two groups, which were compared, using chi-square test. The secondary outcome (patient's comfort level) was analysed by comparing the mean scores obtained for the visual analogue scale using unpaired sample t test. All tests were 2-tailed, and $p < 0.05$ was considered significant. Possible confounding by the stratified variable (emergency CS and elective CS) in this study was assessed by the Breslow-Day test for interaction of risk ratio over strata.

RESULTS

There were no significant differences between the intervention and the control group in terms of the demographic and clinical characteristics in the two strata (elective CS and emergency CS). Therefore, randomisation was considered successful. (Table 1)

As per the intention to treat analysis, the difference in the SSI rates between the intervention and control groups among the two strata (elective CS and emergency CS) were not significant (Table 2)

Furthermore, when the difference in the SSI rates between the intervention and control groups irrespective of the two strata (elective CS and emergency CS) were analysed, the adjusted relative risk

	Early exposure (n=205)	**Delayed Exposure (n=195)**	**p value**
Mean age (SD) 95% CI	29.6 (4.8) 28.9 - 30.2	29.8 (4.9) 29.1 - 30.5	0.62
Median Parity (IQR)	1 (1-2)	1 (1-2)	0.41
Gestation in days when LSCS performed (SD) 95% CI	271 (10.2) 269 - 271.8	270 (10.4) 268.8 - 271.6	0.89
BMI at delivery (kg/m^2) 95% CI	24.6 (3.1) 24.2 - 25.1	24.2 (3.2) 23.8 - 24.6	0.23
Chronic DM or GDM	12(5.8%)	10(5.1%)	0.75
LSCS Performed by surgeon 1	73	75	0.55
LSCS Performed by surgeon 2	132	120	
Duration of surgery in minutes (SD) 95% CI	38.4 (10.6) 37.1 - 40.0	37.1 (9.4) 35.8 - 38.5	0.17
Preoperative Hb% - g/l (SD) 95% CI	10.6 (1.1) 10.4 - 10.7	10.6 (1.1) 10.3 - 10.7	0.94
Postoperative Hb% - g/l (SD) 95% CI	10.3 (1.1) 10.1 - 10.4	10.3 (1.0) 10.2 - 10.5	0.63

Table 1- Baseline characteristics of the intervention and control groups

LSCS – lower segment caesarean section, Chronic DM/GDM – Diabetes Mellitus / Gestational Diabetes Mellitus BMI – Body Mass Index, IQR – Inter Quartile Range, Hb% - Haemoglobin

(intervention and control) was 1.003 (95% CI 0.63 - 1.57). This value can be accepted because there was no confounding by the stratified variable (emergency CS and elective CS) in this study as indicated by the Breslow-Day test for interaction of risk ratio over strata.(chi square= 1.003, p= 0.31)

		SSI	SSI Rate (%)	Relative Risk (95%CI)
El CS	Intervention Group (n = 52)	10	19	1.44 (0.62 - 3.36) p = 0.39
	Control Group (n = 67)	9	13	
	Total	19	15	
Em CS	Intervention Group (n = 153)	22	14	0.86 (0.50 - 1.47) p = 0.30
	Control Group (n = 128)	23	18	
	Total	45	16	

Table 2- Intention to treat analysis of the surgical site infection rates among patients who underwent elective CS and emergency CS

El CS – Elective lower segment caesarean section, Em CS – Emergency lower segment caesarean section, SSI – Surgical site infections

The most frequently observed wound complications were localised swelling and tenderness, which were observed at the 2nd review (after two weeks). However, none of the wound complications exhibited a significant difference between the intervention and control groups. (Table 3)

Of the 64 cases of SSI diagnosed in both groups, wound swabs were taken from 21 patients and 10 of them were culture positive. (Figure 3)

Patients in the intervention group were able to perform all the given tasks more easily than in the control group ($p < 0.001$). (Table 4) Of the 183 respondents in the intervention group, 85% would prefer to have the wound dressings removed early for their next CS, 78% thought early removal of dressing improved their hygiene and 90% thought it improved their overall comfort.

Wound Complications	El CS		Em CS	
	Intervention Group (n = 52)	**Control Group** (n = 67)	**Intervention Group** (n = 153)	**Control Group** (n = 128)
Purulent Drainage (%)	3 (6)	1 (1)	6 (4)	11 (9)
Pain or Tenderness (%)	8 (15)	6 (9)	13 (8)	11 (9)
Localised Swelling (%)	10 (19)	8 (12)	11 (7)	6 (4)
Erythema (%)	7 (13)	5 (8)	9 (6)	12 (10)
Fever (%)	9 (17)	7 (11)	7 (5)	9 (7)
Wound Dehiscence (%)	2 (4)	2 (3)	2 (1)	1 (1)
Abscess (%)	1 (2)	1 (2)	2 (1)	4 (3)
Positive Culture (%)	2 (4)	1 (2)	2 (1)	5 (4)

Table 3 – Wound complications in the intervention and control groups

El CS – Elective lower segment caesarean section, Em CS – Emergency lower segment caesarean section

DISCUSSION

The absence of a significant difference in the SSI rates between the intervention and control groups in the two strata (emergency CS and elective CS) support the concept of early exposure of CS wounds as being a good method. However these results have to be interpreted with caution on account of the small sample size, and larger multi centre studies should be carried out to confirm the benefits of exposure of the CS wound between six to 12 hours of surgery.

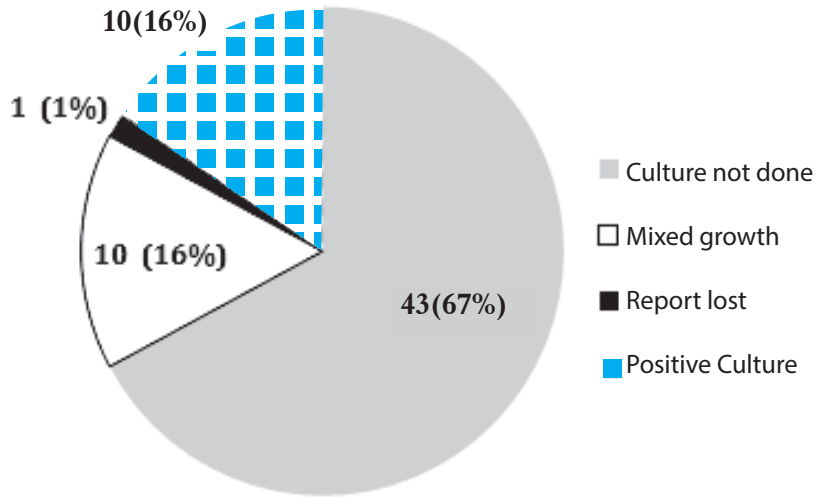

Figure 3: Swab cultures among the diagnosed cases of surgical site infections (n=64)

Patient Response	Intervention Group (n = 205)		Control Group (n = 195)		pvalue
	Mean Score (SD)	95% CI	Mean Score (SD)	95% CI	
Can sit-up easily	8.5 (0.8)	8.3 - 8.6	7.4 (0.6)	7.3 - 7.5	<0.001
Can get off bed easily	7.7 (0.6)	7.7 - 7.8	7.0 (0.6)	6.9 - 7.1	<0.001
Can walk easily	7.6 (0.6)	7.5 - 7.7	7.1 (0.8)	7.0 - 7.2	<0.001
Can squat easily	5.8 (0.7)	5.7 - 5.9	5.1 (0.5)	5.0 - 5.2	<0.001

Table 4 – Patient comfort level (assessed by visual analogue scale of 1 to 10) in the combined intervention and control groups

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. Previous studies have identified emergency delivery, as an important factor for SSI occurrence.[13] Therefore; this study was adjusted for this major confounding factor (emergency CS versus elective CS) by using a stratified design. No confounding effect was found on statistical testing for cofounding. However this study would have been underpowered to detect any difference between the stratified variables (emergency CS and elective CS).

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 (Figure 4)

A study carried out in 2004 in Sri Lanka concluded that early removal of dressings after a CS did not increase wound related complications.[13] However, a direct comparison of the results of these two studies is not possible because the timing of dressing removal was different and that study measured wound related complications rather than the SSI related classification system used in the current study.

Pooling of the results in Figure **4** with the current study is not possible due to the heterogeneity of the studies. The study

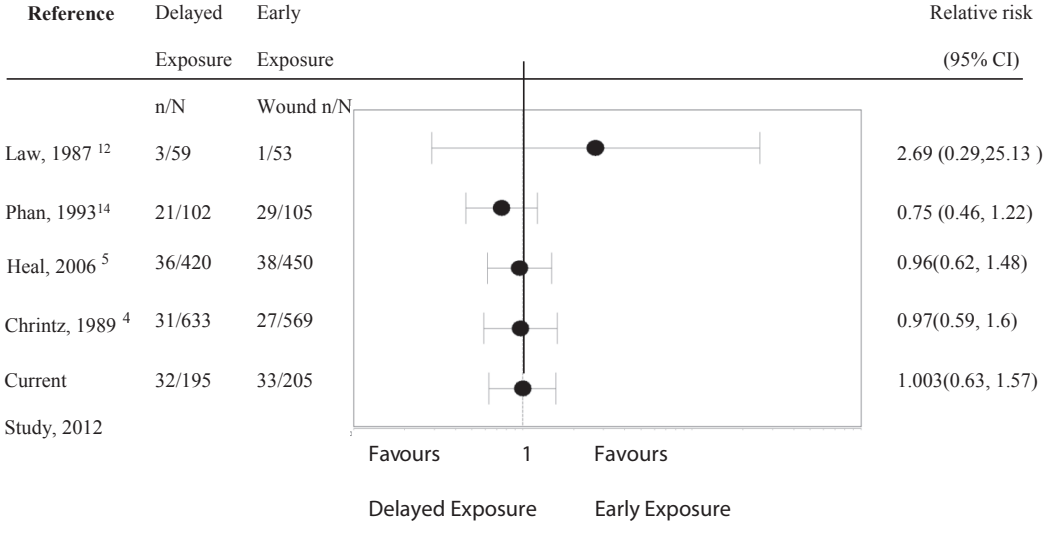

Figure 4: Occurrence of surgical site infection with delayed exposure compared with early exposure following basic wound contact dressings

performed by Law in 1987[12] 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[14] and Chrintz in 1989[4] 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.[5] 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.

The overall SSI rate following LSCS in this study was 15.9% during the follow up period of two weeks, which was much higher than expected. Much lower SSI rates have been reported in other studies.[15,16] All these trials may have underestimated the SSI rate because the follow up in these studies were only for 3-5 days. Therefore, the fact that our study involved a follow up visit at two weeks may have contributed to the higher wound infection rate. An overcrowded ward and a less hygienic environment may be explanations for the higher rate of SSI in the current study compared to the above-mentioned studies, which were predominantly performed in well-resourced countries.

Although there were wound related complications, none of these occurred at a significantly higher rate in either of the two groups, nor was an increasing trend observed in the intervention group. Only two studies in the literature allow direct comparison with our study.[13, 15] Wound dehiscence (partial and complete) in our study was approximately 2% and 1.5% in the intervention and control group, respectively, whereas one study reported these figures as 0% and 1.3% in the two groups.[13] In the same study, there were no reported cases of abscess or localised inflammation, whereas in the current study the incidence of abscess formation was approximately 1% and 3%, and the incidence of localised inflammation was approximately 10% and 7% in the intervention and control groups. Overall, there was a higher incidence of these complications in the current study compared to the previously mentioned study. These may possibly be due to the current study being a follow up study for two weeks and the difference in case definitions. The incidence of febrile morbidity was low in the current study, being approximately 8% in each group. The study conducted in Sri Lanka in 2004 reported high febrile morbidity values of 18.2% and 22.4% in the intervention and control groups' respectivly.[13] The differences observed in these two studies may be due to the different antibiotic policies, resulting in a lower incidence of febrile morbidity in the current study. It was encouraging to note that early wound exposure was well accepted by the patients and they felt more comfortable with this intervention which also enabled them to carry out simple day to day tasks Acceptability and preferences of the patients were evaluated only in one study related to CS where early wound exposure was well accepted by the patients.[13]

There were several limitations. Firstly, this trial was not registered in the Sri Lanka Clinical Trials Registry. The diagnosis of wound infection, although performed using standard guidelines[16], is subjective and has previously been shown to have inter-observer and intra-observer variation.[17,18] The secondary outcomes (patient comfort level and acceptability) were also subjective measurements. Similar to all randomised trials related to wound management, our study also suffered the inherent problem of investigator and patient bias as blinding is not possible with the wound exposure method. Therefore, patient and investigator bias cannot be eliminated when interpreting the above findings. The incidence of SSI may have been underestimated, as the follow period was only two weeks. According to the CDC/ NNIS criteria, a surgical site infection may be diagnosed up to 30 days following surgery. There are other confounding factors such as the number of previous CS scars and the thickness of the subcutaneous fat layer of the abdominal wall, which would ideally need to be adjusted for.

In conclusion, this pilot study has shown that clean, primarily sutured CS wounds, exposed within six to 12 hours after surgery and thereafter left undressed do not have an increased incidence of SSI compared to those that are exposed within 24 to 36 hours and thereafter left undressed. The patients were more comfortable and were more easily able to carry out simple day to day tasks after early exposure compared to delayed exposure, and early exposure-was well accepted by the majority of patients who had this intervention

ACKNOWLEDGEMENTS

Professor Malik Goonewardene (Senior Professor and Chair of Obstetrics and Gynaecology, University of Ruhuna) reviewed and edited the article for publication.

Dr. Dhammike Silva (Senior Lecturer in Obstetrics and Gynaecology, University of Sri Jayewardenepura) for the valuable assistance and guidance provided.

Medical officers and Nursing staff of ward 21, for their participation. ■

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