Section: Obstetrics and Gynaecology

Original Research Article

IMPACT OF ASEPSIS BUNDLE ON CAESAREAN SURGICAL SITE AMONG WOMEN UNDERGOING REPEAT CAESAREAN DELIVERY: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Surgical site infections are complications associated with caesarean section leading to a substantial effect on the mother's health and significant association has been observed between repeat caesarean deliveries and wound infection. Asepsis bundle includes a set of evidence-based measure that have shown a significant improvement in patient care. Therefore, this study aims to determine the impact of ASEPSIS bundle on caesarean surgical site among women undergoing repeat caesarean delivery.

Materials and Methods: This was a randomized controlled trial, where woman undergoing repeat elective caesareans were randomized in two groups (n=130) i.e., Asepsis bundle group (n=65); and control group (n=65). Women in the Asepsis bundle group (Group A) were managed according to bundle components which included hair removal by clippers, Preoperative chlorhexidine bath, antimicrobial prophylaxis, skin preparation with 4% chlorhexidine and 70% isopropyl alcohol and preoperative vaginal cleansing by chlorhexidine only, Skin closure with Nylon sutures, bath with chlorhexidine till suture removal with enhanced patient education. In control group (Group B), the patients will be managed according to the standard hospital protocol.

Results: The total incidence of surgical site infection in this study was 26 (20%). In Asepsis bundle group 8 (12.3%) patients and in the control group 18 (27.7%) patients were diagnosed with surgical site infections.

Conclusion: Implementing Asepsis bundle minimises the surgical site infection in women undergoing repeat caesarean delivery.

Keywords: Surgical site infection, caesarean delivery, chlorhexidine gluconate, Asepsis bundle.

INTRODUCTION

Surgical site infection (SSI) term was coined by 'The Surgical Wound Infection Task Force' in 1992.[1] SSI is defined as an infection that occurs within 30 days after the operation and involves the skin and subcutaneous tissue of the incision (superficial incisional) and/or the deep soft tissue (for example, fascia, muscle) of the incision (deep incisional) and/or any part of the anatomy (for example, organs and spaces) other than the incision that was opened or manipulated during an operation.[2]

Surgical site infections (SSI) are one of the common and potential complication associated with caesarean section which is amongst one of the common procedures performed in India. The 2015-16 NFHS found that, the rate of C-sections has doubled, from 9 percent to 17 percent in 2015-16.[3] In case of lower segment caesarean section, surgical site infection complicates 2 to 15% of caesarean delivery and is a major cause of prolonged hospital stay and pose a burden to healthcare system.[1]

Many risk factors for caesarean surgical site infection following caesarean delivery have been reported, like

chorioamnionitis, smoking, obesity (more than 30 or 35 kg/m2), prolonged second stage of labor, pre gestational diabetes and gestational diabetes, premature rupture of membranes, moderate to severe anaemia, previous caesarean sections, immunocompromised state etc. Also, there are many operative-related factor that determines the risk of infection like skin antisepsis, preoperative shaving, skin preparation of the surgical site, duration of operation, blood loss during operation, antimicrobial prophylaxis, surgical technique etc.[4–7]

Various literatures have been published throughout the world on affect of bundled approach in reducing the surgical site infection in non-obstetrical surgeries. A bundle approach is identified as a set of key interventions derived from evidence-based guidelines that, when implemented, are expected to improve health outcomes of patients. Together they have a greater effect on the outcome than the isolated implementation of individual fundamentals of healthcare associated infections measures. Adherence to bundles helps in consistent and reliable delivery of the patient care.[2] Each hospital has the opportunity to create its own caesarean section surgical bundle to reduce SSI.

Therefore, in this study we have developed an ASEPSIS bundle and have studied its impact on the surgical site in an effort to decrease the caesarean surgical site infections.

MATERIALS AND METHODS

This study was a randomized controlled trial (open label), conducted at University College of Medical Sciences, in the department of Obstetrics and Gynaecology from January 2021 to May 2022. The study was approved by the Institutional ethical committee and informed consent was taken from all the patients. A detailed history and examination which included general physical examination, systemic examination and local examination were done. It was done on total of 130 patients with period of gestation more than 28 weeks scheduled for repeat caesarean delivery and not in labor. They were divided into two equal groups based on block randomization into Asepsis Bundle group and the control group.

Patients with leaking per vaginum or chorioamnionitis, Moderate or Severe anemia, Gestational or pre-gestational diabetes mellitus, Immunocompromised patients, BMI >30 kg/m2, history of SSI, active infection, allergic to chlorhexidine were excluded.

For the patients in Asepsis bundle group evidence based interventions were implemented like , hair removal with clippers if needed, pre-operative bath with 4% chlorhexidine gluconate soap, single dose preoperative intravenous antibiotic of 2 gm cefazolin within 1 hour of incision and repeat dose in case of more than 1500 ml blood loss or more than 2 hours of duration of surgery, pre-operative cleaning of vagina with chlorhexidine gluconate and skin preparation with 4% chlorhexidine gluconate solution and 70% isopropyl alcohol, skin closure with interrupted mattress suturing technique and Nylon suture material, post-operative bath with 4 % chlorhexidine for 14 days and stitch removal on day 14.

In the Control group the patients were managed according to the routine protocol followed in the department of obstetrics and Gynaecology, New Delhi. The conventional protocol includes hair removal cream for part preparation, bath with non-medicated soap, pre and post operatively, antibiotic prophylaxis, skin preparation with povidone-iodine and skin suturing with silk sutures. Dressing removal after 48 hours. All the subjects were followed up for 30 days and the outcome measures were compared between the 2 groups.

The primary outcome of our study was to compare the incidence of surgical site infections between both the groups according to the CDC criteria. Superficial incisional surgical site infection was defined as an infection of the skin or subcutaneous tissue with at least one of the following: purulent wound discharge, pathogenic organisms isolated from the incision, or erythema, induration, or tenderness. Deep wound infection was defined as an infection of deep soft tissues with at least one of the following: purulent wound discharge, spontaneous dehiscence, or evidence of deep tissue abscesses. Organ or space surgical site infection was defined as infection involving organs or space other than the incision, which was opened or manipulated during an operation and the presence of at least one of the following: purulent drainage, organisms isolated from organ or space, and evidence of abscess involving the organ or space.

Our other outcomes were to compare the length of hospital stay in both the groups and also to compare the incidence of infections between previous and previous 2 caesareans.

All the data was entered in MS Excel. The incidence rate of surgical site infection and other parameters between the two groups was compared by Chi-squared test/Fisher's exact test.

P-value <0.05 was taken as significant.

RESULTS

In our study a total of 130 patients were recruited after excluding the patients based on various inclusion and exclusion criteria's. The maternal demographic variables [Table 1] were not statistically significant between both the groups. The mean ± SD age of the study population was 26.6 ± 3.25 years. Nearly, 72.3% of the females were Hindu by religion and rest were Muslims and majority of the patients were educated up to secondary level and maximum number of the patients belonged to lower middle class (p=0.47). Total of 81.5% of pregnancies were booked and 16.9% in Asepsis bundle group and 13% in the

Control group were un-booked. All the patients in our study were undergoing repeat caesarean, where 9 in Asepsis bundle group and 10 in control group had previous two caesareans rest had only one previous cesarean. In terms of period of gestation, majority of the subjects were term pregnancies, 2 in Asepsis bundle group and 2 in Control group had late preterm caesareans and the mean gestational age was 38.7 weeks. The duration of surgery in majority of the patients was less than 2 hours and intraoperative blood loss was less than 1500 ml and distribution in both the groups was statistically insignificant.

The total incidence of surgical site infection in this study was 20%, where 26 patients out of 130 sample size were diagnosed with surgical site infection. It was observed that 8 (12.3%) patients in the Asepsis Bundle group had Surgical Site Infection. Whereas, in the control group 18 (27.7%) patients were diagnosed with surgical site infections [Table 2, Figure 1]. There was a significant difference between the Asepsis bundle group and control group in terms of incidence of Surgical Site Infection ($\chi2 = 4.808$, $p = 0.028$). Out of 26 patients, 7 patients had in-patient development of SSI, and 19 patients were diagnosed with surgical site infection after discharge. Incidence of SSI among previous 1 caesarean is 17.1% and previous 2 is 36.8%, and the difference was not significant. 26 patients were diagnosed with surgical site infection and majority (80.8%) of the patients were categorized under superficial infection as defined by the CDC criteria of surgical site infection. 22.2% in the control group and 12.5% in Asepsis bundle group infected patients needed re-admission and further re-closure. There was a statistically significant difference in the terms of length of hospital stay amongst the patients in the Asepsis bundle group and the control group (P=0.008). Only 1 patient in the Asepsis bundle group had a hospital stay of more than 7 days contrary to the control group where 9 patients had hospital stay for more than 7 days [Table 3-5].

Table 1: Comparison of baseline variables between study groups

Parameters	Group		p value
	Asepsis Bundle (n = 65)	Control (n = 65)	
Age (Years)	26.65 ± 3.25	26.32 ± 3.05	0.6571
Age			0.1252
20-25 Years	26 (40.0%)	29 (44.6%)	
26-30 Years	26 (40.0%)	31 (47.7%)	
31-35 Years	13 (20.0%)	5 (7.7%)	
Religion			0.6952
Hindu	48 (73.8%)	46 (70.8%)	
Muslim	17 (26.2%)	19 (29.2%)	
POG (Weeks)	38.56 ± 1.28	38.67 ± 1.17	0.6531
POG			1.0003
34-36+6 Weeks	2 (3.1%)	2 (3.1%)	
37-39+6 Weeks	54 (83.1%)	54 (83.1%)	
40-41+6 Weeks	9 (13.8%)	9 (13.8%)	
Previous CS			0.8042
1 CS	56 (86.2%)	55 (84.6%)	
2 CS	9 (13.8%)	10 (15.4%)	
Booking Status			0.6512
Booked	54 (83.1%)	52 (80.0%)	
Unbooked	11 (16.9%)	13 (20.0%)	
Education			0.802
Illiterate	6 (9.2%)	9 (13%)	
Primary	32 (49.2)	25 (38.46%)	
Secondary	19 (29.2%)	27 (41.5%)	
Graduate	8 (12.3%)	4 (6.5%)	
Socioeconomic status			0.472
UPPER	0	0	
UPPER MIDDLE	13 (20.45%)	28 (43.07%)	
LOWER MIDDLE	46 (70.7%)	28 (43.07%)	
UPPER LOWER	5 (7.6%)	9(13.8%)	
LOWER	1(1.5%)	0	

1: Wilcoxon-Mann-Whitney U Test, 2: Chi-Squared Test, 3: Fisher's Exact Test

Table 2: Comparison of Incidence of surgical site infection between Asepsis Bundle group and Control group (n = 130)

Surgical Site Infection	Group			Chi-Squared Test	
	Asepsis Bundle (n=65)	Control (n=65)	Total (n=130)	$\chi2$	P Value
SSI (present)	8 (12.3%)	18 (27.7%)	26 (20.0%)	4.808	0.028
SSI (no)	57 (87.7%)	47 (72.3%)	104 (80.0%)		
Total	65 (100.0%)	65 (100.0%)	130 (100.0%)		

Table 3: Comparison Between number of Previous CS and Surgical Site Infection (n = 130)

Surgical Site Infection	Number of caesareans			Fisher's Exact Test	
	Previous 1 (n=111)	Previous 2 (n=19)	Total (n=130)	χ2	P Value
SSI (present)	19 (17.1%)	7 (36.8%)	26 (20.0%)	3.945	0.062
SSI (no)	92 (82.9%)	12 (63.2%)	104 (80.0%)		
Total	111 (100.0%)	19 (100.0%)	130 (100.0%)		

Table 4: Comparison of both groups in terms of CDC classification of SSI (n = 26)

Class Of SSI	Group			Fisher's Exact Test	
	Asepsis Bundle (n=8)	Control (n=18)	Total (n=26)	χ2	P Value
Superficial	7 (87.5%)	14 (77.8%)	21 (80.8%)	0.337	1.000
Deep	1 (12.5%)	4 (22.2%)	5 (19.2%)		
Total	8 (100.0%)	18 (100.0%)	26 (100.0%)		

Table 5: Comparison of two group in terms of length of hospital stay (n = 130)

Total Hospital Stay	Group			Chi-Squared Test	
	Asepsis Bundle (n=65)	Control (n=65)	Total (n=130)	χ2	P Value
≤7 Days	64 (98.5%)	56 (86.2%)	120 (92.3%)	6.933	0.008
>7 Days	1 (1.5%)	9 (13.8%)	10 (7.7%)		
Total	65 (100.0%)	65 (100.0%)	130 (100.0%)		

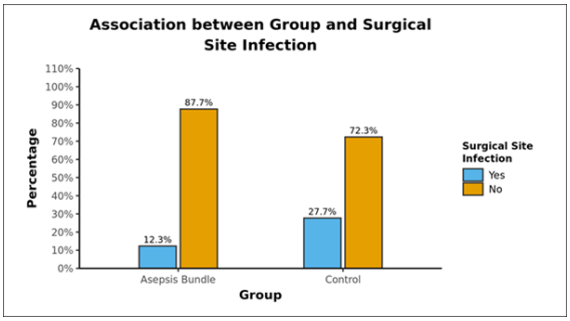

Figure 1: Comparison in terms of incidence of surgical site infection between both the groups

DISCUSSION

The motive of this trial was to assess the effect of Asepsis bundle on the surgical site infection rates in repeat caesarean delivery, and we found that this bundle approach was associated with a statistically significant reduction in the incidence of SSI and also lead to decrease in the hospital stay.

According to an Indian study done by Jain et al,[8] the incidence of surgical infections in emergency versus elective caesareans were statistically significant which were observed as 16.6% to 12.5% respectively (p=0.0084). Since our study has only included the elective repeat caesareans, the difference in the incidence rates of infections may be explained by the difference in study population.

The measures included in our bundle had been adapted considering the local settings and best suited to the patient care culture of our hospital. The evidence based Asepsis bundle we implemented in our study is in the lines of recent recommendations given by various bodies throughout the world including WHO, ACOG, NICE and Indian guideline by ICMR.[9-12] In similar study by Davidson et al,[13] blood glucose monitoring, double gloves by scrubbed staff, were some different components of their bundle contrasting to our Asepsis bundle. Another study by Dieplinger et al,[14] components like normothermia and blood glucose monitoring were some components different from our bundle. Our study did not include the removal of indwelling catheter in 24 hours as it was routinely practiced in our institution. Also, placental removal by umbilical cord traction was another component which was routinely practiced in our conventional protocol.

In study done by Dieplinger et al,[14] the incidence rate of SSI in pre-intervention period was 1.50% and 0.56% in the post intervention period with a p value=0.02, thus leading to a significant reduction in the infection rates. A similar study by Davidson et al,[13] the overall incidence if SSI was 1.89%, in the pre bundle period the surgical site infection rates came out to be 2.44% which were significantly reduced to 1.1% following the implementation of the SSI care bundle. (p=0.013)

Another study by Kawakita et al,[15] the pre implementation infection rates were 4.1% and the post implementation rates were 1.9% with a p value of <0.01, thus significant reduction after bundle application.

Another similar study in Indian set up was done by Bagga et al,[16] where on implementation of prevention bundle the incidence of infection rates were reduced from 11.1% to 3.7% after implementation of bundle.

A recent meta-analysis by Ebony et al,[17] on the evidence-based bundle and caesarean delivery surgical site infection reported similar results, where a total of 17,399 patients across the included fourteen studies were in the post implementation group and received the bundle care and 13,774 patients were in the pre implementation group. They concluded that there was a significant reduction in the rates of surgical site infection in post implementation period where the pooled baseline surgical site infection rates were 6.2% and 2.0% in the post-intervention group, thus leading to a significant reduction. Our study is not without limitations as the investigator and patients were not blinded about the Asepsis Bundle

implementation. Results were limited to one hospital that may not be generalized for all settings. Study population did not include Emergency caesareans. Chances of intra observer variability could be present. Patients with risk factors like anemia, diabetes, premature rupture of membranes etc were not included in this study. Owing to the study design of randomized controlled trial aids to the strength of our study.

CONCLUSION

By implementing our Asepsis bundle which included sum of evidence based measures used pre, intra and post-operative period, we are able to minimise the surgical site infection in women undergoing repeat caesarean delivery and also decreases the overall hospital stay and thus leading to a decrease in maternal morbidity, better turnover of hospital beds and cost reduction. Also, appropriate counselling and encouragement of the patients and the care takers should be done in the pre-operative and post-operative period, for better implementation and compliance of the Asepsis bundle.

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