

STUDY ROLE OF SURGICAL BUNDLE AND VAGINAL CLEANING IN PREVENTION OF POST-OPERATIVE INFECTION IN EMERGENCY LSCS IN OBESE WOMEN A PROSPECTIVE RANDOMIZED TRIAL

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Abstract

Background: There is a constant raise in the caesarean sections in the past decade inadvertently bringing up the associated complications of surgery such as post-surgical infectious morbidity in form of SSI. The incidence of post-CS SSI worldwide is between 0.63% and 9.85%. whereas in India, it ranges from 3.1% to 24.2% . However, there is a significant lack of uniformity in the administration of antibiotics for preventing surgical site infections (SSI) following caesarean deliveries. **Methodology: Study design:** Prospective randomized interventional study. **Study setting:** Department of OBGY of District Hospital Billari. **Study duration:** October 2023 to June 2024. **Study population:** All Patients undergoing emergency caesarean section with no recent injury or active infection in the area being operated with BMI >30 kg/sq. M such cases were included in the study. **Sample size:** 100 **Result:** majority of study participants were from 26-30 years age group 38 cases followed by 21-25 years age group 29 cases, 20 cases in 31-35 years age group, 9 cases in 18-20 years age group and 4 cases in >35 years age group. incidence of SSI in Group 1 was 18 (36%) and in Group 2 was 7 (14%), fever 12 (24%) in Group 1 and 6 (12%) in Group 2, Endometritis 1 case and UTI 2 cases found in Group 1. incidence of Different Types of SSI in Group 1 shows superficial SSI was 10 (20%) Deep SSI was 1 (2%) and Organ specific 1 (2%) and In Group 2 superficial SSI incidence was 5 (10%) and Organ specific SSI was 1 (2%). In Group 1 Mild anemia 6 cases, Moderate anemia 5 cases and severe anemia 1 case, HTN 2 cases, DM 2 cases. In group 2 Moderate anemia 5 cases and 1 case with severe anemia, HTN 1 case and DM 2 cases. Association of risk factors with SSI in Emergency LSCS in obese women statistically not significant at p<.05 **Conclusion:** Association of risk factors with SSI in Emergency LSCS in obese women statistically not significant at p<.05. Incidence of SSI in Group 1 was 18 (36%) and in Group 2 were 7 (14%).

Key words: Surgical site infections (SSI), Post-operative infection, Emergency LSCS, Obese women, Surgical bundle, Vaginal cleaning.

Introduction

Caesarean section (CS) is a considered to be a life-saving operative intervention for women and new-borns in certain antepartum conditions. Globally, CS is the most common major surgical intervention in pregnancies [1]. As per the World Health Organization (WHO), CS rate between 10–15% is considered optimum at the population level. Globally,

the reported rate of CS is 21.1% and varies between 4.1% in West and Central Africa and 44.3% in the Latin America and the Caribbean region and increasing by 4% annually [2, 3].

In India, the overall CS rate has increased from 8.5% to 21.5% in the last 15 years [4]. According to the last national-level survey, a substantial variation exists between the states- from as low as 5.2% in Nagaland to as high as 60.7% in Telangana [4]. As a surgical procedure, caesarean delivery may be accompanied by several complications including surgical site infections (SSI) [5].

SSIs increase the morbidity and mortality of the mothers and babies and increases the length of hospital stay and thereby the cost of care [6, 7]. To prevent SSI, the WHO recommend using a single dose antibiotic, mostly the first generation cephalosporins or penicillin before 30 to minutes of incision for all women undergoing CS [8].

According to reports, the incidence of post-CS SSI worldwide is between 0.63% and 9.85%. [9–13] whereas in India, it ranges from 3.1% to 24.2% [7, 14–16]. However, there is a significant lack of uniformity in the administration of antibiotics for preventing surgical site infections (SSI) following caesarean deliveries.

Surgical site infections are graded as superficial, deep and organ and space infection. Superficial infections include skin and subcutaneous tissue; deep infections include fascia and muscular layer. Organ and space infection constitute the one in which any organ or space is infected. Risk reduction of SSI post-surgery is of prime concern and so multiple evidence-based interventions were proposed by the Institute of Healthcare Improvement (IHI) known as care bundles.

Care bundles are collective and systematic strategies implemented to prevent SSI with potential to improve patient outcome. Individual intervention may vary between different bundles but success depends on application of all measures consistently and persistently in a bundle. Optimal care bundle includes maintaining normothermia, glycaemic control, timely and appropriate administration of antibiotic and clipping of hair. These are the core elements of care bundle and apart from it further additions can be made which may be synergistic or neutral.

Aim And Objectives

Aim: To assess the role of application of surgical bundle and vaginal cleaning before caesarean section in preventing postoperative infectious complications.

Primary Objectives:

1. Study Clinical profile of post-operative infection in Emergency LSCS in obese women.

Secondary objectives:

1. Study various risk factors associated with post-operative infection in Emergency LSCS in obese women.

Material And Methods

Study design: Prospective Randomized control trial

Study setting: Department of OBGY of District Hospital Billari

Study duration: October 2023 to June 2024.

Study population: All Patients undergoing emergency caesarean section with no recent injury or active infection in the area being operated with BMI >30 kg/sq. M such cases will be included in the study.

Sample size: 100

Inclusion criteria

1. Age 18 years to 40 years Patients undergoing emergency caesarean section with no recent injury or active infection in the area being operated with BMI >30 kg/sq. m

Exclusion criteria

1. Patients with history of allergy to antimicrobial agent.
2. Patients requiring dose adjustment of antibiotic- chronic renal disease or liver disease or any other medical comorbidity
3. Patients having chorioamnionitis or any other preoperative infectious disease at time of making decision of caesarean section.
4. Patients had any other surgical procedure requiring spinal anaesthesia or general anaesthesia within 1 month prior to caesarean section

Sample size estimation

Sample size is estimated by using n Master software Version 2.0 by applying following details in the above formula. Based on the study by Nagori A *et al.* [20] where at an alpha of 0.05 (2 sided) and precision level of 7 % the estimated sample size using the sample size formula for Single proportion.

$$n = \frac{z_{1-\alpha/2}^2 P(1-P)}{d^2}$$

The above parameter and formula give us a sample size of **100 subjects**.

Sample size with 10% drop out rate =110

Method of Data collection

Women fulfilling the eligibility criteria was considered after taking informed consent and demographic details, patients were divided randomly in two equal groups i.e. 50 each through lottery method. Single blinding, And by block randomization method with block size of 10 and no of blocks 10.

In Group A, women undergoing emergency C-Section whom conventional preoperative preparation done using povidone iodine as skin antiseptic and a 5-day postop prophylactic antibiotic regime will be administered.

In Group B, surgical bundle which includes pre-operative antibiotics, bathing, safe operative room practices, surgical hand rub and vaginal cleaning with povidone iodine solution prior to shifting to OT was done but postop prophylactic antibiotic regime reduced to 3 day

All patients were examined daily during hospitalization. In presence of adequate wound healing and absence of signs and symptoms of any infection, patients were discharged from hospital on day 4 or day 5. Stitch removed on day 9 or day 10. Subsequently patients were examined after 6 weeks postpartum.

In presence of any clinical features suggestive of an infectious morbidity, patients to be examined for presence of fever, urinary tract infections (UTI), upper respiratory tract infection (URTI), wound discharge, induration or dehiscence, endometritis and pelvic abscess. SSIs were classified according to CDC criteria. Further investigations and appropriate management were done accordingly.

Operational definitions

Surgical site infections (SSI), which occur in the wound created by any invasive surgical procedure reflects an important cause of infectious morbidity. Thus, post caesarean SSI is common in obstetrical scenarios, specifically in emergency caesareans

Southampton Criteria of SSI

GRADE	DEFINITION
0	Normal healing
1	Normal healing with mild bruising or hematoma
2	Erythema plus other signs of inflammation
3	Clear or haemoserous discharge
4	Pus
5	Deep or severe wound infection with or without tissue breakdown ; haematoma requiring aspiration

Surgical bundle approach to prevention of SSI

1. Safe operating room practices
2. Preoperative bathing/showering
3. Skin antiseptic preparation
4. Surgical antibiotic prophylaxis
5. Surgical hand scrub/preparation

WHO classify adult body weight as underweight <18.5, normal range 18.5–24.9, overweight ≥ 25.0 and obese ≥ 30.0 . Obesity is further classified into three separate classifications: Class I Mild 30–34.9, Class II Moderate 35.0–39.9, and Class III Morbidly obese ≥ 40 .

Statistical analysis:

Data Entry done using Microsoft excel 2013 and analysis done using SPSS V 16.

Qualitative data was expressed in frequencies and percentages and Quantitative data in mean and standard deviation. Non-Parametric tests include chi-square test for intergroup comparison to be used. Bar diagrams and pie chart to represent the data. p value of 0.05 was considered statistically significant.

Result And Observations

This prospective randomized study was conducted among 100 cases of Patients undergoing emergency caesarean section with no recent injury or active infection in the area being operated with BMI >30 kg/sq. m

Table No.1: Distribution of study participants as per age (n=100)

Age (in Years)	Frequency	Percentage
18-20	9	9%
21-25	29	29%
26-30	38	38%
31-35	20	20%
>35	4	4%
Total	100	100 (100%)

Above table shows that, majority of study participants were from 26-30 years age group 38 cases followed by 21-25 years age group 29 cases, 20 cases in 31-35 years age group, 9 cases in 18-20 years age group and 4 cases in >35 years age group.

Table No.2: Incidence of infectious complications in different study groups (n=100)

Incidence of infectious complications	Group 1 (N=50)	Group 2 (N=50)

Fever	12	6
SSI	18	7
Endometritis	1	0
UTI	2	0
Total	33	13

The above table shows incidence of SSI in Group 1 was 18 (36%) and in Group 2 was 7 (14%), fever 12 (24%) in Group 1 and 6 (12%) in Group 2, Endometritis 1 case and UTI 2 cases found in Group 1.

Table No.3: Incidence of Different Types of SSI (n=100)

Different Types of SSI	Group 1 (N=50)	Group 2 (N=50)
Superficial	10	05
Deep	01	00
Organ specific	01	01
Total	12	06

The above table shows incidence of Different Types of SSI in Group 1 shows superficial SSI was 10 (20%) Deep SSI was 1 (2%) and Organ specific 1 (2%) and In Group 2 superficial SSI incidence was 5 (10%) and Organ specific SSI was 1 (2%)

Table No.4: Association of risk factors with SSI in Emergency LSCS in obese women (n=100)

Risk factors	Group 1 (SSI =12)	Group 2 (SSI=6)	P value
Anemia	Mild anemia 06 Moderate 05 Severe 01	Mild anemia 00 Moderate 05 Severe 01	Not Significant
HTN	02	01	Not significant
DM	02	00	

The above table shows In Group 1 Mild anemia 6 cases, Moderate anemia 5 cases and severe anemia 1 case, HTN 2 cases, DM 2 cases. In group 2 Moderate anemia 5 cases and 1 case with severe anemia, HTN 1 case and DM 2 cases. Association of risk factors with SSI in Emergency LSCS in obese women statistically not significant at $p < .05$

Discussion

Surgical site infections are graded as superficial, deep and organ and space infection. Superficial infections include skin and subcutaneous tissue; deep infections include fascia and muscular layer. Organ and space infection constitute the one in which any organ or space is infected. Risk reduction of SSI post-surgery is of prime concern and so multiple evidence-based interventions were proposed by the Institute of Healthcare Improvement (IHI) known as care bundles.

Care bundles are collective and systematic strategies implemented to prevent SSI with potential to improve patient outcome. Individual intervention may vary between different bundles but success depends on application of all measures consistently and persistently in a bundle. Optimal care bundle includes maintaining normothermia, glycaemic control, timely and appropriate administration of antibiotic and clipping of hair. These are the core elements of care bundle and apart from it further additions can be made which may be synergistic or neutral.

In current study majority of study participants were from 26-30 years age group 38 cases followed by 21-25 years age group 29 cases, 20 cases in 31-35 years age group, 9 cases

in 18-20 years age group and 4 cases in >35 years age group. Similar study conducted by Basany K *et al* [17] He conducted study included 2,015 participants with a mean age of 24.1 years. Asad *et al.* [18] He reported that The mean age was 28.4 years in group A and 27.5 years in group B. Magdy R *et al.* [19] The mean age was 28.8 years in intervention group, while it was 29 years in control group.

In current study Incidence of SSI in Group 1 was 18 (36%) and in Group 2 was 7 (14%), fever 12 (24%) in Group 1 and 6 (12%) in Group 2, Endometritis 1 case and UTI 2 cases found in Group 1. Similar study conducted by Nagori A *et al.* [20] He reported that the Most common infection was SSI with incidence of 15.70% in Group 1, and 7.01% in Group 2. The infection was lower in Groups 2 in which care bundle was applied as compared to Group 1, the difference was statistically significant. Febrile morbidity (fever>100.4F) occurred in 9.80% in Group 1, 4.38% in Group 2. The febrile morbidity was lower in Group 2, as compared to Group 1 however, the difference was statistically insignificant in both the groups. Rates of endometritis, UTI and URTI remained almost similar.

In current study Incidence of Different Types of SSI in Group 1 shows superficial SSI was 10 (20%) Deep SSI was 1 (2%) and Organ specific 1 (2%) and In Group 2 superficial SSI incidence was 5 (10%) and Organ specific SSI was 1 (2%). Basany K *et al.* [17] He reported that the Ninety two participants (4.6%, 95% CI: 3.7% to 5.6%) developed surgical site infections, with 91 (98.9%) having superficial and 1 (1.1%) having a deep infection.

In current study In Group 1 Mild anemia 6 cases, Moderate anemia 5 cases and severe anemia 1 case, HTN 2 cases, DM 2 cases. In group 2 Moderate anemia 5 cases and 1 case with severe anemia, HTN 1 case and DM 2 cases. Association of risk factors with SSI in Emergency LSCS in obese women statistically not significant at $p<.05$. Nagori *et al.* [20] He found that the No Significant association was noted between haemoglobin levels <8g/dl and number of >4 vaginal examinations with risk of development of SSI ($p<0.05$)

Conclusion

Infectious morbidities after CS impose a major women health challenge. It is important to prevent these complications by implementing appropriate measures. Present study shows that application of surgical bundle with 3 day postoperative antibiotic regimen and vaginal cleaning can reduce postop infectious complications. Association of risk factors with SSI in Emergency LSCS in obese women statistically not significant at $p<.05$. Incidence of SSI in Group 1 was 18 (36%) and in Group 2 were 7 (14%).

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