DOI: https://doi.org/10.53350/pjmhs0202418610

ORIGINAL ARTICLE

Use of Infection Prevention Bundle for Cesarean Section to Control Post-Surgical Infections: A Causal-Comparative Study

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ABSTRACT

Aim: To compare the effectiveness of the infection prevention bundle approach with the traditional injectable and oral prolonged antibiotic method to control cesarean section surgical site infection (CS-SSI) in a predominantly unbooked and low-income population.

Methods: A prospective causal comparative study in a tertiary care hospital. One hundred and eighty-four pregnant women planned for cesarean sections, with no recent infection, were chosen by simple random sampling method and divided into two groups. Group A patients (92) were managed by an infection prevention bundle that consisted of pre-operative bathing, a single dose of injectable cephalexin (1-2 grams) intravenously within one hour of incision, and spontaneous removal of the placenta. Group C patients (92) were managed by the traditional method, which is injection of ceftriaxone (1-2 grams) intravenously for 48 hours, followed by oral antibiotics for 5 days.

Results: The infection rate in group A was 2.2% versus 1.1% in group C patients, with no statistically significant difference between the two groups (pp value: 0.259). A significant difference is observed in pre-op Hb levels (p-value = 0.003), with <9 gm/dl being 4 (4.3%) in Group A and 9 (9.8%) in Group C, 9-11 gm/dl being 69 (75%) in Group A and 47 (51.1%) in Group C, and >11 gm/dl being 19 (20.7%) in Group A and 36 (39.1%) in Group C. Pre-operative total leucocyte count, anesthesia type, duration of C-section, complications, and blood loss show no significant differences between the groups.

Conclusion: The infection prevention bundle approach is simple, cheap, applicable, and effective in controlling cesarean section surgical site infection in low income populations.

Keywords: infection prevention bundle, infection rate,Cesarean Section, Post-Surgical Infections

INTRODUCTION

The cesarean section rate has been on the rise internationally, in developing countries as well as in developed countries (32% in the USA.[1] However, cesarean section surgical site infection (CS-SSI) has been much higher in developing countries as compared to 3-18% and 6-15% in developed countries.[2] Cesarean section is the commonest surgical procedure in women and one of the commonest causes of healthcare acquired infections as well; hence, its safety is crucial to ensuring safe motherhood.[3] Cesarean Section-SSIs contribute significantly to postpartum infections associated with maternal morbidity (5-20%) and mortality.[4] In Pakistan, high cesarean section rates have been indicated by institutional data, as there is a lack of national statistics. There has been no consensus on prophylactic antibiotic protocol, and generally prolonged use of multiple injections of various classes of antibiotics has been the strategy to prevent cesarean section surgical site infections with no evidence[5-6].

Third-generation cephalosporins, metronidazole, first- and second generation cephalosporins, and amoxicillin have been used alone or in combination, adding to the cost of treatment, prolonged hospital stay, need for re-admission, increased risk of drug resistance, untoward side effects of antibiotics for both mother and baby, and no reduction in sepsis rate[7-8]. Normal wound healing involves an inflammatory phase followed by proliferative, angiogenesis, and remodeling of the wound. In addition to patient characteristics like age, weight, and hemoglobin level, multiple other factors influence the risk of wound infection during the preoperative, intraoperative, operative, and postoperative periods[9]. So prophylactic antibiotics should be selected according to the type of potential invading organisms, and proper selection of antibiotics is essential to reduce infection and MDR. The risk of CS-SSI can be reduced more effectively using the infection prevention bundle approach. A pre-operative bath has been recommended by WHO, CDC, and ASIC guideline[10]; a pre-operative single dose of first-generation cephalosporin in a BMI-based dosage within one hour before incision has been effective in reducing SSIs after cesarean sections[11]. Azithromycin has also been used as an additional agent to prevent endometritis. Preparation of the vagina using an aqueous povidone iodine solution and spontaneous removal of the placenta has been other important components of the infection prevention bundle approach[12].

Good diet, early mobility, and euglycemia further add to healing. The infection prevention bundle approach has been found more effective than individual approaches. Implementation of infection prevention bundles by a team educated and trained for this purpose is the key to success.[13]Consistency, clarity, and good communication among team members are essential for the application of all components of the infection prevention bundle before, during, and after the cesarean section. Bundle approach in cesarean sections has been associated with a marked reduction in CS-SSIs from 6.2% to <2% (226).

The objective of the study was to find out the efficiency of the bundle approach to reduce the risk of post-C/S-surgical site infections, prolonged hospital stays, re-admission, and the overall cost of treatment. To compare the outcome of the bundle approach with the conventional approach

OPERATIONAL DEFINITIONS:

Surgical site infection (SSI): SSI is defined as infection occurring near an incision site within 30 days of operation.

Superficial incisional SSI: redness, swelling, discharge from wound,

Deep incisional SSI: involvement of deeper softer tissues) (wound gaping),

Organ space infection: abscess Systemic

COMPLICATIONS:

Drug resistance: when bacteria develop the ability to defy the medicines meant to kill them

Tool to be used to assess wound healing: observation of the wound for abnormal discharge, redness, gaping of deep tissues;

on second day of operation(V2),
on day 10 of operation(V3) and
on day 30 post operatively.

Received on 05-05-2024
Accepted on 15-06-2024

MATERIAL & METHODS

Sample size was calculated for causal comparative study: Causal comparative study was conducted after permission from hospital Ethical Committee, in Lahore Care Hospital Lahore, Pakistan, a tertiary care hospital from April 2023 to April 2024.
Group allocation by simple randomization: 184 females
(92 in group - A receiving bundle treatment) and
(92 in group – C receiving conventional treatment) {Epi Info 7}
Sampling technique: simple random sampling.
Inclusion criteria: All willing females undergoing elective and emergency cesarean sections >24 weeks gestation
Exclusion criteria:

- Severe anemia: <7 grams/deciliter
- cases with Uncontrolled Diabetes mellitus,
- Cushing syndrome,
- immunosuppressant therapies,
- steroid therapy.

Common steps for both groups

- Consultant level of surgeons
- Strict disinfection & sterilization while scrubbing & draping patients.
- Wound lavage with povidone-iodine after closing rectus sheet
- Closure of subcuticular fat
- Dressing change & discharge at 48 hours
- Stitches removal at day 10

Group A:Infection prevention bundle approach:

- pre-operative bath taking,
- prophylactic antibiotic according to weight of the patient
- Inj. Cephalexin IV within one hour of incision (1-2 grams IV stat)
- spontaneous removal of placenta (SRP),

Group C: Undergoing traditional preparation for operation and post-operative care.

- Pre-operative: inj. Ceftriaxone 1-2 grams IV stat before shifting to operation theater (2-3 hours pre-operatively)
- Followed by inj. Ceftriaxone 1-2 grams IV BD for 48 hours (till discharge from hospital)
- Followed by oral antibiotics cefaclor tablet 500 mg. Three times a day for 5 days,
- Peri-operative Care Team was trained for smooth and timely application of interventions

Data Collection was done through open and close ended Performa Written permission was obtained from the patient. Data collected was entered in SPSS 26. The data was entered and analyzed using SPSS vr 26. Mean±S.D and Median IQR (inter quartile range) were applied for quantitative data. Independent sample t-test (when data was normal) or Mann Whitney U test (when data was non normal) were applied. Cross tabulations were made for categorical data and Chi-square test / Fisher's exact test was applied. P-value ≤ 0.05 was considered as significant.

RESULTS

Both groups were compared for age, socio-economic status, weight, gravity, parity, no. of previous cesarean sections, comorbidities, previous infections, use of antibiotics in the week preceding the operation, duration of the operation, blood loss, intraoperative morbidities, etc. and revealed no. statistically significant differences except prevalence of anemia.

An overall high prevalence of anemia in both groups 79.3% in group A and 60.9% in group C patients, showing a statistically significant difference and an important risk factor for infection.

Post cesarean section follow-up reveals no difference at the time of discharge 48 hours after cesarean section (V2).

Conditions of patients at the time of suture removal (V3) were satisfactory except for two patients in group A, who developed mild superficial infection managed by daily provide one iodine dressing and addition of oral antibiotics for five days. Another patient developed hematoma that settled with conservative management.One of group C patients developed wound infection and complete wound gaping at day 10, managed by prolonged use of injectable antibiotics, re-admission, wound debridement, and re-suturing.The rest of the patients in both groups healed well and was apparent at the time of the removal of stitches. There is no statistically significant difference for CS-SSI was observed between the two groups.The final visit was on day 30 after the cesarean section had a slack response. 66% of group A and 53.3% of group C patients confirmed their well-being and made no complaint about their cesarean wound scar on their mobile phones. A large number of patients could not be contacted even on mobile phones.

In Table 1, the age comparison between Group A and Group B shows no significant difference, with a p-value of 0.210. Group A (n = 92) has an age of 28.17 ± 5.34 years and a median age of 26.50 ± 9.0 years, while Group B (n = 92) has an age of 27.28 ± 3.48 years and a median age of 28.00 ± 4.50 years. The weight comparison, with Group A (n = 33) having a weight of 74.61 ± 1.46 kg and a median weight of 73.00 ± 26.0 kg, and Group B (n = 33) having a weight of 72.50 ± 1.34 kg and a median weight of 71.50 ± 24.75 kg, also shows no significant difference (p-value = 0.362). The gravida values between Group A (2.83 ± 1.86; median = 2.50 ± 2.25) and Group B (2.28 ± 1.27; median = 2.00 ± 2.00) are statistically similar (p-value = 0.842). Similar non-significant differences are seen in para (Group A: 1.50 ± 1.34; median = 1.00 ± 2.25 vs. Group B: 1.17 ± 1.20; median = 1.00 ± 2.00; p-value = 0.922), number of miscarriages (Group A: 0.33 ± 0.69; median = 0.00 ± 0.25 vs. Group B: 0.11 ± 0.32; median = 0.00 ± 0.00; p-value = 0.951), and number of previous C-sections (Group A: 0.94 ± 1.06; median = 1.00 ± 2.00 vs. Group B: 0.72 ± 0.75; median = 1.00 ± 2.00; p-value = 0.811). Lastly, the HbA1c levels between Group A (n = 22) with 5.39 ± 0.95 and a median of 5.35 ± 1.47 and Group B (n = 22) with 5.29 ± 0.86 and a median of 5.15 ± 1.15 show no significant difference (p-value = 0.337).

Table-1: Mean Comparison of age, weight, gravida, para, miscarriage, no of previous C-section and Hba1c in both study groups

		Mean± S.D	Median± IQR	p-value
Age(years)	Group-A (n=92)	28.17±5.34	26.50±9.0	0.210[a]
	Group-B (n=92)	27.28±3.48	28.00±4.50	
Weight (kg)	Group-A (n=33)	74.61±1.46	73.00±26.0	0.362 [a]
	Group-B (n=33)	72.50±1.34	71.50±24.75	
Gravida	Group-A (n=92)	2.83±1.86	2.50±2.25	0.842[b]
	Group-B (n=92)	2.28±1.27	2.00±2.00	
Para	Group-A (n=92)	1.50±1.34	1.00±2.25	0.922 [b]
	Group-B (n=92)	1.17±1.20	1.0±2.00	
No of Miscarriage	Group-A (n=92)	0.33±0.69	0.00±0.25	0.952 [b]
	Group-B (n=92)	0.11±0.32	0.00±0.00	
No of Previous c-sections	Group-A (n=92)	0.94±1.06	1.00±2.00	0.811[b]
	Group-B (n=92)	0.72±0.75	1.00±2.00	
Hba1c	Group-A (n=22)	5.39±0.95	5.35±1.47	0.337 [a]
	Group-B (n=22)	5.29±0.86	5.15±1.15	

Table 2 compares socio-demographic factors between Group A (n=92) and Group C (n=92). The educational levels are not significantly different between the groups (p-value = 0.920). In Group A, 16(17.4%) are uneducated, 7(7.6%) have primary education, 21 (22.8%) have secondary education, 14(15.2%) have intermediate education, 21(22.8%) are graduates, 5(5.4%) have a master's degree, 7(7.6%) did not mention their education, and 1(1.1%) has a doctorate. Similarly, in Group C, 12(13%) are uneducated, 12(13%) have primary education, 18(19.6%) have secondary education, 15(16.3%) have intermediate education, 19(20.7%) are graduates, 6(6.5%) have a master's degree, 9(9.8%) did not mention their education, and 1(1.1%) has a doctorate. Socioeconomic status (SES) also shows no significant difference (p-value = 0.496), with 21(22.8%) in the lower class and 71 (77.2%) in the middle class for Group A, and 25(27.2%) in the lower class and 67(72.8%) in the middle class for Group C.

Table 3 presents the comparison of maternal outcomes. The duration of pregnancy (DOP) between Group A (n= 92) and Group C (n=92) shows no significant difference (p-value = 0.529), with term pregnancies being 64(69.6%) in Group A and 60 (65.2%) in Group C, and preterm pregnancies being 28(30.4%) in Group A and 32(34.8%) in Group C. Co-morbidities are also not significantly different (p-value = 0.697), with no co-morbidities in 77(83.7%) of Group A and 75(81.5%) of Group C, and co-morbidities present in 15 (16.3%) of Group A and 17(18.5%) of Group C. There were no previous week infections or antibiotic use in both groups. The type of C-section, though not significant (p-value = 0.104), shows a trend with emergency C-sections being 44(47.8%) in Group A and 55(59.8%) in Group C, and elective C-sections being 48(52.2%) in Group A and 37(40.2%) in Group C. A significant difference is observed in pre-op Hb levels (p-value = 0.003), with <9 gm/dl being 4(4.3%) in Group A and 9(9.8%) in Group C, 9-11gm/dl being 69(75%) in Group A and 47(51.1%) in Group C, and >11 gm/dl being 19 (20.7%) in Group A and 36 (39.1%) in Group C. Pre-operative total leucocyte count, anesthesia type, duration of C-section, complications, and blood loss show no significant differences between the groups

Table-2: Socio-demographic comparison in both groups

		Group		p-value
		Group A	Group C	
Education	Uneducated	16(17.4%)	12(13%)	0.920[c]
	Primary	7(7.6%)	12(13%)	
	Secondary	21(22.8%)	18(19.6%)	
	Intermediate	14(15.2%)	15(16.3%)	
	Graduate	21(22.8%)	19(20.7%)	
	Masters	5(5.4%)	6(6.5%)	
	Not mentioned	7(7.6%)	9(9.8%)	
	Doctorate	1(1.1%)	1(1.1%)	
SES	Lower class	21(22.8%)	25(27.2%)	0.496[c]
	middle class	71(77.2%)	67(72.8%)	

Chi-square test was applied, d| Fisher's exact test was applied

Table-3: Comparison of maternal outcome in both groups

		Group		p-value
		group A (n=92)	group C (n=92)	
DOP	Term	64(69.6%)	60(65.2%)	0.529 [c]
	Preterm	28(30.4%)	32(34.8%)	
Co-morbidity	No co-morbidity	77(83.7%)	75(81.5%)	0.697 [c]
	Yes co-morbidity	15(16.3%)	17(18.5%)	
Prevwk infection	No infection	92(100%)	92(100%)	--
Antibiotic in prwk	No	92(100%)	92(100%)	--
Type of C-section	emergency C-section	44(47.8%)	55(59.8%)	0.104 [c]
	elective C-section	48(52.2%)	37(40.2%)	
pre op Hb	<9 gm/dl	4(4.3%)	9(9.8%)	0.003*
	9-11 gm / dl	69(75%)	47(51.1%)	
	>11	19(20.7%)	36(39.1%)	
Pre op TLC	<11k	59(64.1%)	58(63.0%)	0.878 [c]
	>11k	33(35.9%)	34(37%)	
Anesthesia	Regional anesthesia	88(95.7%)	89(96.7%)	>0.99[d]
	General anesthesia	4(4.3%)	3(3.3%)	
Duration of C-section	<1hour	92(100%)	92(100%)	--
Complications	No complication	91(98.9%)	92(100%)	>0.99 [d]
	Yes complication	1(1.1%)	0(0%)	
Blood loss	<1 liter	91(98.9%)	92(100%)	0.99
	>1 liter	1(1.1%)	0(0%)	
Additional antibiotic	No	92(100%)	92(100%)	--

c| Chi-square test was applied, d| Fisher's exact test was applied

Table 4 focuses on the follow-up comparisons. During visit 2, serous exudate was present in all patients of Group A (100%) and 91 (98.9%) of Group C, with erythema in 0% of Group A and 1(1.1%) of Group C, showing no significant difference (p-value = >0.05). However, visit 3 reveals significant differences (p-value <0.001), with serous exudate present in 72(78.3%) of Group A and 91(98.9%) of Group C, purulent exudate in 2(2.2%) of Group A and 0% of Group C, separation of deep tissues in 0% of Group A and 1(1.1%) of Group C, no information in 17(18.5%) of Group A and 0% of Group C, and hematoma in 1(1.1%) of Group A and 0% of Group C. The final telephonic visit also shows a significant difference (p-value =0.019), with complete healing in 61(66.3%) of Group A and 49(53.3%) of Group C, no response in 3(3.3%) of Group A and 0% of Group C, and wrong numbers in 28(30.4%) of Group A and 43(46.7%) of Group C.

Table-4: Follow up Comparison in both groups

		Group		p-value
		group A (n=92)	group C (n=92)	
Visit2	Serous exudate	92(100%)	91(98.9%)	>0.99 [d]
	Erythema	0(0%)	1(1.1%)	
Visit3	Normal healing	89(96.7%)	91(98.9%)	0.259
	Purulent exudate	2(2.2%)	0(0%)	
	Separation of deep tissues	0(0%)	1(1.1%)	
	Hematoma	1(1.1%)	0(0%)	
Final visit telephonic	Complete healing	61(66.3%)	49(53.3%)	0.015[d]
	Wrong no.	31(33.7%)	43(46.7%)	

c| Chi-square test was applied, d| Fisher's exact test was applied *Significant

DISCUSSION

This study was performed in a tertiary care hospital predominantly on unbooked low income patients (Sehat Sahulat program).Although socio-demographic and other factors were insignificant between groups, anemia was the only significant difference (79.3% in group A and 60.9% in group C) that might have affected the risk of infection.Overall infection rate in this study was 1.6%. In group A, was 2.3 % an% .02 % in group C at the time of stitch removal on day 10 of LSCS (VLSCS (V3). up group A, results reveal, the inflectional and super superficial (despite e high prevalence of anemia in this group) and managed amicably within a few days, requiring readmission, injectable antibiotics, her measures. While in group C, although only one patient got infected, it was a deep tissue infection entailing complete gaping of the wound and required longer treatment, re-admission, and injectable antibiotics the results with prior studies[14-15].

Final visit on day 30 (final visit) was not in person except for two patients. The rest of the patients of both groups were contacted on mobile phones, with a response rate of 66.3% in the group A category and 53.3% in the group C category. Mobile phone links have been used in other studies in case of need. All were well completely healed, and there were no complaints related to wounds. Reasons for no response were either a mistake in noting cell no. or a relative' cell no. who declined to reply and the results were supported with prior studies[16-17].

These results are generally reassuring about the disinfection and sterilization procedures at the hospital, surgical techniques adopted, and low complication rate in our patients. The infection rate in this study is comparable to that in developed countries.The infection prevention bundle approach enabled systematic application of standard procedures in a timely fashion and led to lower comparative cost of treatment, no side effects of antibiotics, and no readmission in hospital or prolonged injectable antibiotics the results were supported with prior studies[18-19]. Although according to these figures, group A patients did well, however, high numbers of non-responders may have an impact on the overall assessment of the outcome of the study. Research studies have established that single-dose prophylactic antibiotics have been as effective as multiple injections of antibiotics administered over a

number of days, thus reducing the cost of treatment, side effects of antibiotics, and development of drug resistance.A single-dose antibiotic of first-generation cephalosporin within one hour of the incision further protected us from contracting infection at the time of the incision and during the procedure in our study, and no prolonged use of oral or injectable antibiotics was required. Intraoperatively, the delivery of fetal head 10 units of oxytocin injection facilitated spontaneous delivery of the placenta with its associated low blood loss and no manual removal, further reducing the risk of infection, So the easy, cheap combination of pre-operative bath taking, single dose prophylactic antibiotics, and spontaneous removal of the placenta (the infection prevention bundle in this study) performed well with reduced cost of treatment, fewer side effects of antibiotics, and no readmission to the hospital. The IPB approach is in reality a logical and matter-of-fact answer combining important preventive the results were supported with prior studies[20-22].

Measures in a structured manner to ensure safe and healthy motherhood for women undergoing cesarean sections by preventing CS-SSIs. Although statistically group A, patients were doing well, the need for a larger randomized controlled study in our local population seems urgently required in order to lower injudicious and unsafe use of antibiotics and reduce the risk of post-cesarean section surgical site infections in our country.

CONCLUSION

The infection prevention bundle approach to prevent cesarean section surgical site infection is a simple, cheap, and effective method with low cost and no risk of drug resistance in a low-income population.

Acknowledgement: Thanks to All our Team Members especially Miss Timer & Miss Iqra for their dedication and hard work

Authorship and contribution declaration: Each author of this article fulfilled following Criteria of Authorship:

1. Conception and design of or acquisition of data or analysis and interpretation of data.
2. Drafting the manuscript or revising it critically for important intellectual content.
3. Final approval of the version for publication.

All authors agree to be responsible for all aspects of their research work.

Funding: No funding was provided for this research.

Conflict of interest: There is no conflict of interest.

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This article may be cited as: Toheed R, Shehzadi S, Attaria M: Use of Infection Prevention Bundle for Cesarean Section to Control Post-Surgical Infections: A Causal-Comparative Study. Pak J Med Health Sci, 2024;18 (6): 40-43.