

Comparative Evaluation of Single Dose of Prophylactic Antibiotics against the Post-Operative Antibiotic Therapy in Lower Segment Caesarean Section

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ABSTRACT

Introduction: The antibiotics with high activity against microbial agents commonly involved in surgical-site contamination and actual infection are selected for such surgeries. Combination of clindamycin and aminoglycosides are one of the most common formulation of antibiotics used for treating post-caesarean infection since they cover most of the pathogenic bacteria commonly involved in post-caesarean infection. Hence, we compared the effectiveness of single dose of prophylactic cefazolin versus postoperative caefazolin's multiple doses for prevention of post-caesarean infection.

Material and methods: A total of 600 patients reporting in the community medical centre in the gynae department were included in the study. All the deliveries occurring from March 2012 to May 2014 were included in the study. All those pregnant women who required emergency caesarean section from the year March 2012 to May 2014 were included in the study. All the patients were divided into two groups: Group A and Group B depending upon the time in which antibiotic therapy was given i.e. pre-operative or post-operative. Evaluation of post-caesarean surgical-site infection was done 72 hours after caesarean section, as well as on follow-up days (day 7 and day 30 post-caesarean section). Assessment was done by two separate clinicians who were unaware of the study. All the data were analysed by SPSS software.

Results: 4.1% patients in group A showed febrile morbidity as compared 3.5% patients in group B. All other parameters except for cost factor showed statistically non significant difference between group A and Group B patients. As far as average cost factor was concerned, patients in Group A had less cost expenditure on antibiotics as compared to group B patients.

Conclusion: Therapeutic concentration of antibiotic in serum, tissues and wound during contamination is assured by pre-operative antibiotic prophylaxis. Choice of antibiotic should be such that the picked antibiotic should be active against the bacteria that will be encountered during the surgery.

Keywords: Antibiotics, Caesarean, Cefazolin

aminoglycosides as they cover most of the pathogenic bacteria commonly involved in post-caesarean infection.^{9,10} Literature quotes evidences that demonstrate the efficacy of prophylactic antibiotics in the reduction of rates of post-partum infection among patients who underwent caesarean section.¹¹ Hence, we compared the effectiveness of single dose of prophylactic cefazolin versus postoperative caefazolin's multiple doses for prevention of post-caesarean infection.

Null hypothesis: Standard treatment difference selected was $\pm 5\%$ on the proportion of post-caesarian section infection in the subjects of the two groups.

Alternative hypothesis: The treatment difference on the proportion of post-caesarian section infection in the two arms should be less than or equal to $\pm 5\%$.

MATERIAL AND METHODS

The study was carried out in the form of two-armed, randomized, single-centre trial conducted at community medical centre in the gynae department. All the deliveries occurring from March 2012 to May 2014 were included in the study. All those pregnant women who required emergency caesarean section were included in the study. Written consent was taken from all the patients with prior information about the study protocol and procedure. Ethical clearance was taken from the Hospital Ethical Committee by giving written form of all the study procedures and steps. Patients with history of any other system illness, acute features like fever, malaise etc, any known drug/antibiotic allergy, prolonged obstructed labor, and prolonged and premature rupture of membranes were excluded from the present study. Sample size selection was done by using Lyimo et al criteria of sample estimation.¹² A total of 600 patients were included in the present study and were randomly divided into two study groups as shown in Table-1.

Group A included patients who received a single dose of 1 gm cefazolin intravenously at cord clamping while Group B included patients who were given 500 mg b.d orally for six days

INTRODUCTION

One of the top causes of pregnancy-related maternal mortality across the world is the postpartum infection.¹⁻³ The approximate incidence of post-caesarean infection is two and half percent to twenty percent worldwide.⁴⁻⁶ There is five to twenty times increased risk of postpartum infection in women undergoing caesarean section as compared to women having a vaginal delivery.^{7,8} Those antibiotics are selected for such surgeries that have activity against microbial agents commonly involved in surgical-site contamination and actual infection. One of the most common formulation of antibiotics used for treating post-caesarean infection are the combination of clindamycin and

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post-operatively.

Primary Outcome measures

The primary requisite of the study was evaluation of post-caesarean surgical-site infection. The assessment for any evidence of surgical-site infection was done 72 hours after caesarian section, as well as on follow-up days (day 7 and day 30 post-caesarean section). Assessment was done by two separate clinicians who were unaware of the study. Febrile morbidity was defined by temperature above 38°C at least 4 hours apart on two or more occasions, excluding the first 24 hours after delivery. Abdominal wound infection was defined by partial or total dehiscence, presence of purulent or serous discharge from the wound with indurations, warmth and tenderness.¹³ A diagnosis of surgical site infection was reached by using criteria put forth by Centers for Disease Control and Prevention (CDC).¹⁴⁻¹⁶ Removal of bladder catheter was done in both the groups after 24 hours. After 48 hours, the occlusive dressing was removed and the wound was left open. Assessment of for signs of infection was done on days 3, 7 and 30 post-operatively. Selection of these days was done because on day 3 the patient is normally discharged from the hospital if she is doing well, day 7 is when stitches on the wound are removed and day 30 is for final follow up according to CDC definition of surgical site infection. within 30 days of follow-up, the diagnosis of surgical site infection was made if the infection occurs. All the data were analysed by SPSS software. Calculation of cumulative incidence was done as the following proportion: number of cases noted over total number of participants in each study group. Time to develop post-caesarean infection was noted and used to calculate the incidence rate (IR) of post-caesarean infection. p-value of less than 0.05 was considered as significant.

RESULT

Figure-1 show the demographic and baseline details of the patient. 4.1% patients in group A showed febrile morbidity as compared 3.5% patients in group B. All other parameters except for cost factor showed statistically non significant difference between group A and Group B patients as shown in Table-2. As far as average cost factor was concerned, patients in Group A had less cost expenditure on antibiotics as compared to group B patients.

DISCUSSION

A high resistance of antibiotic resistance has been a globally concern regarding the misuse of antibiotics leading to suboptimal treatments.¹⁷⁻¹⁹ Antibiotic resistance is now regarded as a major public health issue because infections by multidrug resistant bacteria lead to increased mortality, morbidity and increased hospital stays and the armamentarium against these bacteria is dwindling rapidly. Many prescriptions are inappropriate and there is some evidence of compulsive antibiotic prescribing.²⁰ It is generally recommended that antibiotic prophylaxis is given in most types of surgery, but the choice of therapy is controversial.²¹ Hence we evaluated and compared the effect of single dose of prophylactic cefazolin versus postoperative caefazolin's multiple doses for prevention of post-caesarean infection. The results of the present study show that prophylactic use of a single dose of cefazolin is equivalent in efficacy to the postoperative caefazolin's multiple doses in caesarean section.

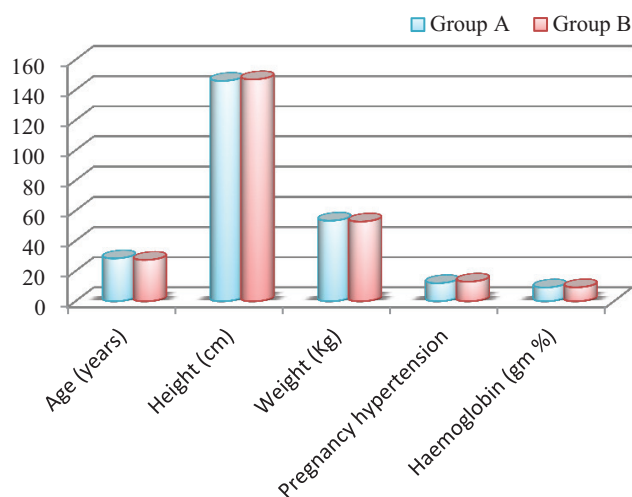


Figure-1: Demographic and baseline characteristics

Groups	No. of Patients	Parameter
Group A	300	Patients with pre-operative antibiotic prophylaxis
Group B	300	Patients with post-operative antibiotic prophylaxis

Table-1: Division of patients in the study group

Variable	Group A (% of patients)	Group B (% of patients)	p-value
Febrile morbidity	4.1%	3.5%	1.451
Endometritis	4.9%	5.1%	2.142
Urinary tract infection	2.4%	3.1%	0.784
Wound infection	6.7%	7.2%	1.684
Other antibiotics used	10.8%	9.7%	0.842
Hospital stay	9.1	9.5	0.945
Average cost	41	230	0.002

Table-2: Post-Operative Complications in the study

Cumulative incidence of surgical-site infection was statistically similar for the administration of prophylactic pre-operative single dose antibiotic as compared to post-operative multiple doses as shown in Table-2. The results of our study were in correlation with the results of Pore et al and Slobogean et al who observed similar results in their respective studies.^{22,23} One of the parameters which should also be considered while planning treatment protocol is the cost – effectiveness. Single dose regime is associated with lower medication cost as compared with multiple doses regime. Furthermore, Literature from the past previous studies have proved that the low prevalence of low-level resistance to gentamicin in same setting.^{24,25} In terms of most judicious practice, a single dose of a single antibiotic with a spectrum appropriate to cover the most common infecting organisms is usually sufficient. Literature quotes numerous facts that publish guidelines to cover most instances where prophylaxis is recommended and where it is not considered appropriate. Appropriate antibacterial selection remains the complex problem followed by frequency, duration and timing of each dose.²⁶ A caesarean section is classified as a clean-contaminated operation. Endometritis, wound infection, urinary tract infections are common adverse outcomes associated with caesarean section. Staphylococcus aureus, E.

coli and beta haemolytic Streptococci are the most common infecting organisms. It is a well established fact that antibiotic prophylaxis in LSCS surgery reduces the risk of infection and endometritis in all types of patients and has proven to be of benefit even to those at the lowest risk.²⁷ Shah et al also compared the single dose prophylactic antibiotics versus five days antibiotic in cesarean section and concluded that single dose antibiotics are effective as multiple doses in prevention of post-operative infections in caesarean sections. Therefore, Careful periodic surveillance of antibiotic prophylaxis should be done to detect the emergence of drug resistant strains of bacteria.²⁸

CONCLUSION

Therapeutic concentration of antibiotic in serum, tissues and wound during contamination is assured by pre-operative antibiotic prophylaxis. Choice of antibiotic should be such that the picked antibiotic should be active against the bacteria that will be encountered during the surgery. Also, to avoid resistance, the drug administration should be done for the shortest period to minimize the development of resistance. Also, the adverse effects of the drug should be minimal. Further studies with larger study group required in the same field to further explore the effects of pre-operative antibiotics in controlling post-operative infections.

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