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Original Research Article

Comparison of prophylactic versus regular use of antibiotics in elective major obstetrical and gynecological surgeries

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ABSTRACT

Background: Surgical site infections better prevented by parenteral antibiotic in sufficient doses generally should be given before the operation which helps to achieve the therapeutic drug level both in the blood and related tissue during the operation. Ceftriaxone, when administered together as a prophylaxis can fulfil the above criteria of a good antibiotic. Thus, this study was planned to assess the efficacy of prophylactic antibiotic usage to that of regular antibiotics usage in patients undergoing elective surgeries.
Methods: This randomized controlled study was conducted in a tertiary care teaching hospital during the study period of June 2017 to April 2018 with 140 cases. Group A received a single dose of Injection Ceftriaxone 1g. Group B, received Injection Ceftriaxone 1 gm and Injection Metronidazole 500 mg for five days. The data was entered in excel sheet and analyzed using SPSS (Version 16).
Results: The mean age group in Group A and Group B was found to be 34.24±10.5 and 35.97±11.89, respectively. There was no statistical significance between group A and B for incidence of infection in the post-operative period and duration of hospital stay. The mean value in group A for duration of surgery was found to be 67.5±13.5 and in group B mean value was 72.1±14.9. (p value <0.05).
Conclusions: This study demonstrated that administration of prophylactic antibiotic rather than conventional antibiotic at caesarean and gynecological surgeries are not associated with significant difference in post-operative morbidities.

Keywords: Ceftriaxone**,** Prophylactic antibiotic, Surgical site infection

INTRODUCTION

Surgical site infections (SSI), which accounts for 15-20% of all healthcare-associated infections, is the second most common preventable adverse outcome of major surgery. The incidence of SSI, which differs according to surgical procedure, is highest for gastrointestinal interventions.[1] SSI is associated with significant attributable morbidity and mortality, prolonged hospital length of stay and a high cost to the patient and the institution.[2] In clean-contaminated and contaminated surgery, such as elective major urogynaecology surgeries, the reported risk of SSI is high.[3] SSIs are increasingly used as performance indicators.[4] Postpartum SSIs, especially those following cesarean delivery are more common than those following other surgical procedures.[5]

This may be due to the nature of intrapartum care, which is often prolonged, involves close contact with lay personnel, as well as a wide range of professionals from different departments in the hospital, which may increase the risk of cross-contamination. Labor and delivery are

also associated with contamination by other body fluids and are often unplanned or due to emergency situations.

Antibiotic prophylaxis for women undergoing cesarean delivery has been proven to be beneficial in decreasing post cesarean delivery infectious morbidity both in high-risk or low-risk patients.[6] A single dose of antibiotics is as effective as multiple doses given peri-operatively, and the routine use of prophylactic antibiotics reduces the risk of infection by more than 50% from a baseline as high as 20-50%.[7,8] Broad spectrum antibiotics were associated with statistically significant reduction in surgical and non-surgical infection rates and endometritis compared to narrow range. Also, the length of the hospital stay was significantly shorter when broad spectrum antibiotics were used.[8]

Ceftriaxone is a third-generation cephalosporin that has a much higher serum level to minimum inhibitory concentration ratio when compared with aminoglycosides. Ceftriaxone not only covers gram positive organisms but also shows an enhanced coverage of gram-negative organisms and some anaerobic coverage than the first- and second-generation cephalosporin.[9] Ceftriaxone does not require any renal or hepatic dose adjustment and it can be safely administered during pregnancy and after delivery.

Based on the available literature, Metronidazole is still a mainstay drug in treating anaerobic infections. The combination of ceftriaxone and metronidazole is found to be superior in controlling operative site infection and also minimizes the drug expenditure.[10,11] Metronidazole (500mg every 12 hours) plus ceftriaxone (2g every 24hours) were recommended as a routine prophylactic antibiotic administered before the surgery.

Parenteral antibiotics should be continued until the patient is afebrile for 24-48hours and if needed, patient should subsequently receive oral antibiotics to complete a 14-day course of therapy. Patients should be switched to antibiotics based on culture and sensitivities when available. Based on these backgrounds, this study was planned to compare the efficacy of prophylactic antibiotic usage, to that of regular antibiotics usage in patients undergoing elective major obstetrical and gynecological surgery.

METHODS

This randomized controlled study, was conducted to compare the efficacy of prophylactic antibiotic usage to that of regular antibiotics usage in patients undergoing elective major obstetrical and gynecological surgery, in the Department of Obstetrics and Gynecology in Sri Venkateshwaraa Medical college Hospital and Research centre (SVMCH and RC), a tertiary care teaching hospital located in Ariyur, Pondicherry. All the patients undergoing surgery in the department of obstetrics and gynecology during the study period of June 2017 to April 2018 were included in the study. A total of 140 patients, who underwent obstetrics and gynecological surgeries during the study period were included in this study.

After taking the patient's written informed consent, they were allocated into two groups as Group A and Group B by randomization method. Group A received a single dose of Injection Ceftriaxone 1g intravenously one hour before the surgery. Ceftriaxone is administered after checking for allergic reaction by intradermal test. Group B received Injection Ceftriaxone 1g and Injection Metronidazole 500mg intravenously one hour before surgery and the second dose is given 12 hours after the initial dose followed by twice daily dosing for a total duration of five days. Surgical wound was examined on 3rd, 5th, 7th and 2^{1st} post-operative days for pus discharge, pain, tenderness, localized swelling, abscess formation and wound dehiscence. Infections, if any were classified according to CDC criteria. Outcome of post-operative infections were measured in terms of febrile morbidity, urinary tract infection and surgical wound infection. Ethical committee approval was obtained for this study. Only the observations from the patients who have been completely followed up till 21st post-operative day were taken up for statistical analysis.

Statistical analysis

The data was entered in excel sheet and analyzed using SPSS (Version 16). Descriptive statistics with mean, standard deviation, proportion (%) with 95% confidence interval was calculated for quantitative variables. For categorical variables like febrile morbidity, urinary tract infection and surgical site infection frequency and percentages was calculated. To test the hypothesis Chi Square test and Independent sample t test was used. P value <0.05 was considered as statistically significant.

RESULTS

The present study was conducted as a randomized control trial, among 140 patients, who have undergone obstetric and gynecological surgeries. Characteristics of the participants were given in Table 1.

In group A, majority of them (70%) the surgical procedure done was elective lower segment caesarean section (LSCS) whereas in group B, 61.4% were taken for elective LSCS. VH with PF was the surgical procedure among 14.3% and 20% of the study subjects randomized in Group A and B respectively. 12.9% and 14.3% of the participants had TAH with BSO.

Ovarian cystectomy was done for 2.9% of the participants in group A and 4.3% of the participants in group B. In this study 16.3% and 25.6% of the women were primi and 83.7% and 74.4% were multi gravid in group A and group B respectively (Table 1). The time duration for various surgeries was recorded in this study. It took less than 60 minutes for the surgical procedure for

54.3% of the participants in group A and 44.3% of the participants in group B. For 42.9% and 52.9% of the participants it took 60-90 minutes for the surgical procedure in Group A and Group B respectively. More than 90 minutes for surgery was taken for 2.9% of the participants in both the groups.

Table 1: Characteristics of the participants.

	Group A	Group B
Age group		
<30 years	43 (61.4)	39 (55.7)
31-40 years	8 (11.4)	6 (8.6)
41-50 years	10 (14.3)	10 (14.3)
51-55 years	9 (12.9)	15 (21.4)
Education		
Illiterate	6 (8.6)	10 (14.3)
Literate	64 (91.4)	60 (85.7)
Occupation		
Unemployed	54 (77.1)	60 (85.7)
Employed	16 (22.9)	10 (14.3)
Socio economic status		
High	10 (14.3)	16 (22.9)
Middle	39(55.7)	41 (58.6)
Low	21 (30)	13 (18.6)
BMI group		
Normal	33 (47.1)	31 (44.3)
Over weight	37 (52.9)	39(55.7)

Before the surgical procedure pre-operative haemoglobin (Hb) was assessed for the patients and in group A 37 (52.9%) patients had Haemoglobin value of 10-11gms/dl, 45.7% had 11.1-12gms/dl and one patient had 12.1-13gms/dl haemoglobin.

Among the patients assigned in group B 38 (54.3%) patients had Hb value of 10-11gms/dl, for 26 (37.1%) patients Hb value was between 11.1-12gms/dl and 6 (8.6%) had Hb value of 12.1-13gms/dl. Proportion of infections on post-operative day 3,5,7 and 21 were given in Table 2.

Table 2: Proportion of infections during post-operative days.

	Group A	Group B
Post-operative day 3		
Infection absent	66 (94.3)	66 (94.3)
Infection present	4 (5.7)	4 (5.7)
Post-operative day 5		
Infection absent	68 (97.1)	67 (95.7)
Infection present	2 (2.9)	3 (4.3)
Post-operative day 7		
Infection absent	70 (100)	69 (98.6)
Infection present	0 (0)	1 (1.4)
Post-operative day 21		
Infection absent	70 (100)	70 (100)
Infection present	0 (0)	0 (0)

In this present study done among patients 55 (78.6%) of them from group A and 60 (85.7%) of them group B had less than 10 days of hospital stay after surgery.15 (21.4%) and 10 (14.3%) had hospital stay of more than 10 days in group A and B respectively (Table 2 and 3).

Majority of group B participants (61.4%) were gravid mothers,8 had adenomyosis, and 10 patients with uterine prolapse, 2 patients were taken for surgery for precedential and 7 for fibroid uterus (Figure 1).

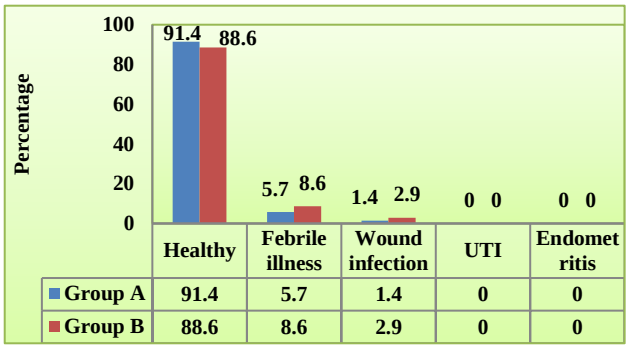

Figure 1: Types of infections.

Table 3: Comparison of continuous variables between groups.

Variable	Group A	Group B	Total	P value
Age in years	34.24±10.5	35.97±11.89	35.11±11.23	0.364
BMI	25.33±2.4	25.96±2.8	25.64±2.64	0.158
Hemoglobin	11.13±0.6	11.08±0.7	11.1±0.6	0.650
No. of cases with infections	6/70 (8.6%)	8/70 (11.4%)	14/140 (10%)	0.576
Duration of surgery	67.5±13.5	72.1±14.9	69.79±14.3	0.059
Duration of hospital stay	9.76±1.5	9.6±1.2	9.7±1.4	0.494

In group A 49 women were gravid mothers, 6 had adenomyosis, 3 patients were with uterine prolapse, 6 patients had precedential and other 6 were having fibroid uterus.

DISCUSSION

Appropriate choice of prophylactic antibiotics requires an understanding of the polymicrobial nature of the endogenous microflora each site.[12] There was no trial of antibiotic prophylaxis in low risk group worldwide, that is, the patient with aseptic surgery. They recommended the use of prophylactic antibiotic in high risk patients who have prosthetic implant, colorectal surgery etc. and also in those in whom the development of an infection might be associated with a catastrophic end result.[13]

Proportion of infections

In this study the overall infection rate was reported as 10% with 8.6% and 11.4% in single dose antibiotic group and conventional antibiotic group, respectively. Similarly, Saha et al, observed that in center-1 among ciprofloxacin plus metronidazole; the rate of infection was 10.6% and cephalosporin plus metronidazole group was 14.6% while that in center-2, the rate was 8% and 10.6% respectively.[14] The overall rate of infection was 11%. Among the 70 patients from group A febrile illness was found during the post-operative period in 5.7% of the patients and 1 (1.4%) patient had wound infection. In group B 8.6% of the patients presented with febrile illness in the post-operative period and 2.9% of them had wound infection. UTI and endometriosis was not found in both the groups during the post op period.

Urinary tract infection

In Tahseen et al, study the incidence of urinary tract infection (UTI) was high in both the groups 22.9% in multi dose group vs 14.4% in single dose group, but it was not statistically significant.[15] Dar LR, who showed significant reduction in UTI in single dose group compared to the group which received antibiotic for 10 days.[16] Two studies are quoted which state that duration of indwelling catheter has a significant role in developing UTI.[17,18] Also Ansari et al reported incidence of UTI was 3% in group A and 2% in group B with P value to be 0.34.[19] Shakya et al, reported that there were 2 (4%) and 0 (0%) urinary tract infection, in the single dose and multiple dose groups respectively.[20] Farouk et al, also reported that there was decrease in the occurrence of UTI among patients administered with single dose of prophylactic antibiotic.[21]

Surgical site infection

In Tahseen et al, study only six (2%) patients had wound infection, one in single dose group and five in multi dose group, which is quite encouraging as compared to that given in literature.[15] Besides, all patients with wound infection did not grow any organism on culture and were treated by local measure of washing with normal saline and dressing. Nisa M has shown 5% wound infection rate in their study and Siddiqui et al had wound infection rate of 13.27% in their study.[22,23] Ansari et al, reported that following antibiotic prophylaxis, wound infection was found to be 3% in group A and in contrast 2% in group B with overall P value 0.50.[19] Most of the authorities suggest prophylactic antibiotic should be considered for all elective caesarean deliveries in which the combined incidence of endometritis and wound infection exceeds 5%.[24] Munmum et al, reported 3 (6%) post-operative wound infection in Group-A and 2 (4%) in Group-B.[12] 1 patient of Group-A and 1 patient of Group-B developed wound infection after vaginal hysterectomy operation. So, there was no significant difference in post-operative wound infection between Group-A and Group-B in respect of vaginal hysterectomy.

Febrile morbidity

In Tahseen et al, study the febrile morbidity was observed in 12 patients (3.92%), five in single dose group and seven in multi dose group however these findings were not statistically relevant and the results present study was comparable to the findings of Rouzi et al, Dimitrov et al, and Bagratee et al.[15,25-27] Febrile morbidity in ten patients was associated with UTI and in one with wound infection. Only one patient in single dose group had with febrile morbidity that was not associated with any clinical features of infections nor was there any laboratory evidence of infection. Patients developing fever within 48 hours of surgery were considered as having febrile reaction. Several studies have compared single dose vs multiple doses of prophylactic antibiotics and all of them concluded that single dose of antibiotic is as effective as multiple doses.[23,27] Ansari et al, reported fever was 6% in group A and 4% in group B with statistically not significant p value of 0.26.[19] Shakya et al reported, 4% and 6% febrile morbidity in the single dose and multiple dose groups respectively.[20] In this present study done among patients 55 (78.6%) of them from group A and 60 (85.7%) of them group B had less than 10 days of hospital stay after surgery.15 (21.4%) and 10 (14.3%) had hospital stay of more than 10 days in group A and B respectively. Ansari et al, confirms that single dose antibiotic prophylaxis had a beneficial effect on women undergoing elective caesarean section where as similar rate of complications were observed in multiple dose antibiotic for 5 days.[19]

CONCLUSION

Prophylactic single dose antibiotic (Ceftriaxone) was compared to regular multi dose antibiotic (ceftriaxone with metroniodazole) in this study. Since there was no statistically significant difference in the rate of postoperative wound infection, febrile morbidity and urinary tract infections between the patients who received single dose as compared to multiple doses of prophylactic antibiotic for elective surgeries, so it may be argued that both regimens were equally effective against postoperative infectious morbidity. Also, the fact is that single dose antibiotic prophylaxis offers patients compliance, cost effectiveness and minimum side effect

but conventional antibiotic offers less patient compliance with expensive treatment cost and probability of more side effects. Hence, it is advocated that single dose prophylactic antibiotic can be given in caesarean section and in gynecological surgeries as it is as efficient as multi dose regimen. Postoperative wound infection not only depends upon antibiotic use but also on many other factors like age, nutritional status, hygienic condition, anaemic status and duration of operation, blood loss during operation and amount of blood transfusion. The findings of this study demonstrated that administration of prophylactic antibiotic rather than conventional antibiotic at caesarean and gynecological surgeries are not associated with significant difference in post-operative morbidities.

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