Original Research Article

Pattern of prophylactic antibiotics usage in caesarean section: An observational study

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Abstract

Background: Caesarean section is the most important factor associated with postpartum bacterial infections, with a infection rate reported to be 1-25%, which is 5-20 times higher than that of vaginal delivery. **Materials & Methods:** It was a prospective observational single centre study. The data was collected from the patient's file in the nursing station within the hospital premises. The hospital was a tertiary care hospital, West Bengal. The prospective study was conducted at a tertiary care hospital with all pregnant women undergoing elective and emergency caesarean section. The study was designed to assess the type of antibiotics was used prophylactically before undergoing a caesarean section. Interval between the time of administration of antibiotic & time of delivery was assessed. Data on the use of antibiotic prophylaxis in caesarean sections was collected using a customized proforma. Other data included were indication for caesarean section, route of administration of antibiotics, type of antibiotics, dosage of antibiotics, time of incision, and duration of operation. All the methods were compared to Hospital protocol and NICE protocol. **Results:** The maximum no.of patients were administered the combination of inj. cefotaxime & inj. metronidazole that is 49.8%. The mean time interval between administration of antibiotic and delivery (mean± s.d.) of the patients was 44.99±16.83 minutes with range 5-90 minutes and the median was 45 minutes. Most of the time interval 209 (68.5%) were as per hospital protocol which was statistically significant (Z=5.79; p=0.0001)**. Conclusion:** Antibiotic prophylaxis significantly reduces the postpartum infection rate & thus reduces maternal morbidity & mortality in caesarean section. In this study conducted at a tertiary care hospital, the prophylactic antibiotic usage data showed that combination of cefotaxime & metronidazole is most frequently used. The study describes that the usage of prophylactic antibiotic combination cefotaxime & metronidazole are most appropriate & have compliance with hospital protocol & NICE protocol.

Keywords: Antibiotic prophylaxis, postoperative infection, caesarean section, surgical site infection (SSI)

Introduction

Antibiotic prophylaxis refers to the prevention of infection complications using antimicrobial therapy (most commonly antibiotics). Even when sterile techniques are adhered to, surgical procedures can introduce bacteria and other microbes in the blood (causing bacteremia), which can colonize and infect different parts of the body. Antibiotics can be effective in reducing the occurrence of such infections. Patients should be selected for prophylaxis if the medical

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condition or the surgical procedure is associated with a considerable risk of infection or if a postoperative infection would pose a serious hazard to the patient's recovery and well-being [1].A proper regimen of antibiotics for preoperative prophylaxis of septic complications decreases the total amount of antimicrobials needed and eases the burden on hospitals. The choice of antibiotics should be made according to data on pharmacology, microbiology, clinical experience and economy. Drugs should be selected with a reasonable spectrum of activity against pathogens likely to be encountered, and antibiotics should be chosen with kinetics that will ensure adequate serum and tissue levels throughout the risk period [2].For prophylaxis in surgery, only antibiotics with good tolerability should be used. Cephalosporin remains the preferred drugs for preoperative prophylaxis due to their low toxicity. Parenteral systemic antibiotics seem to be more appropriate than oral or topical antibiotics because the chosen antibiotics must reach high concentrations at all sites of danger. It is well recognized that broad-spectrum antibiotics are more likely to prevent gram-negative sepsis. New data demonstrate that third generation cephalosporin are more effective than first and second generation cephalosporin if all preoperative infectious complications are taken into consideration. Dermatologic surgeons commonly use antibiotic prophylaxis to prevent bacterial endocarditic. Based on previous studies, though, the risk of endocarditic following coetaneous surgery is low and thus the use of antibiotic prophylaxis is controversial. Although this practice is appropriate for high-risk patients when skin is contaminated, it is not recommended for non-eroded, non-infected skin [3]. There are many factors that affect physicians'compliance with guideline recommendations,including cultural factors, educational background, training, nurse and pharmacist influences, medication supply, and logistics [4].

Caesarean section is the most important factor associated with postpartum bacterial infections, with a infection rate reported to be 1-25%, which is 5-20 times higher than that of vaginal delivery [5]. Postpartum infection remains to be among the top five causes of pregnancy-related maternal mortality & morbidity worldwide [6]. The incidence of post-caesarean infection varies widely world-wide ranging from 2.5% to 20.5%.There is clear evidence that prophylactic antibiotics for caesarean section reduce the risk of endometritis & other bacterial infections, even in low risk pregnancies. Following caesarean delivery maternal mortality & morbidity may result from a number of infections including urinary tract infection (UTI) & surgical site infection (SSI), which increase hospital stay & cost per case [7]. To reduce the post-operative infection rate universal prophylactic antibiotics has been widely accepted in guidelines for many countries, including USA & several Asian countries. Selection of antibiotics for prophylaxis follows the principle that the selected antibiotic regimen should have activity against microbial agents commonly involved in surgical site contamination & actual infection [8]. Antibiotic prophylaxis for women undergoing caesarean section has been proven to be beneficial in decreasing post caesarean section infections both in women high-risk(in labour after membrane rupture),or inlow –risk (non-labouring with intact membranes) [9]. A single dose of antibiotics is as effective as multiple doses given peri-operatively [10], & the routine use of prophylactic antibiotics reduces the risk of infections by more than 50% from a baseline as high as 20-50%. Antibiotics prophylaxis in elective CD has been shown to be cost effective [11].

Materials and methods

Study Design: It was a prospective observational single centre study.

Study Setting: The data was collected from the patient's file in the nursing station within the hospital premises. The hospital was a tertiary care hospital [Vision Care Hospital-a unit of AMRI (Advanced Medical Research Institute) Hospital, Kolkata]

Study Duration: The study was conducted over a period of 9 months starting from July 2014 & continued till March 2015.

Inclusion Criteria: All the pregnant women undergoing caesarean delivery in tertiary care hospital were included in the study.

Exclusion Criteria: Those women who were already on antibiotics were excluded from the study.

The prospective study was conducted at a tertiary care hospital with all pregnant women undergoing elective and emergency caesarean section. The study was designed to assess the type of antibiotics was used prophylactically before undergoing a caesarean section. Interval between the time of administration of antibiotic & time of delivery was assessed. Data on the use of antibiotic prophylaxis in caesarean sections was collected using a customized proforma. Other data included were indication for caesarean section, route of administration of antibiotics, type of antibiotics, dosage of antibiotics, time of incision, and duration of operation. All the methods were compared to Hospital protocol and NICE protocol. All raw data was recorded in Excel (Microsoft Windows 2007 Home-Basic version; Microsoft Office 2007) sheet. Results were expressed as proportions, percentages & as averages +/- standard deviation (SD) with corresponding ranges. Institutional ethics committee permission was taken.

Results

Data collection process for this study was started from July 2014 & continued till March 2015.Total data of 305 pregnant women undergone caesarean section was included in the study. The collected data were statistically analysed & compared with hospital protocol & NICE protocol.Statistical Analysis was performed with help of Epi Info (TM) 3.5.3. EPI INFO is a trademark of the Centers for Disease Control and Prevention (CDC). Descriptive statistical analysis was performed to prepare the tables with corresponding percentages. Test of proportion was used to find the Standard Normal Deviate (Z) to compare the difference proportions and Chi-square (x^2) test was performed to find the associations. p≤0.05 was taken to be statistically significant.

Table 1: Age distribution

Age Group (in years)	Number	%
<20	4	1.3%
20-29	173	56.7%
30-39	125	41%
≥40	3	1%
Total	305	100%

The mean age (mean ± s.d.) of the patients was 28.94±3.88 years with range 19 - 42 years and the median age was 29 years. Test of proportion showed that proportion of patients in the age group between 20-29 years (56.7%) was significantly higher than other groups (Z=1.98;p=0.04) [Table 1/Fig. 1].

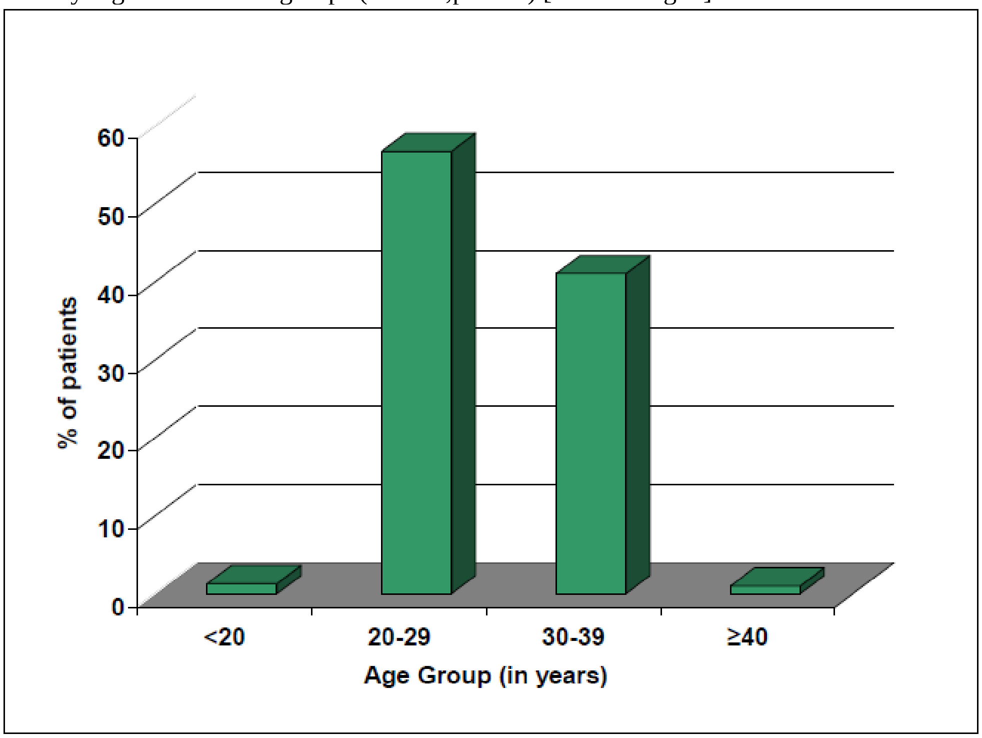

Fig 1: Graphical representation of age wise distribution of study population

Table 2: Distribution of parity

Parity	Number	%
P0+0	38	12.5%
P0+1	237	77.7%
P1+0	1	0.3%
P1+1	23	7.5%
P1+2	6	2.0%
Total	305	100%

Most of the patients 237 (77.7%) had parity as P0+1 followed by patients 38 (12.5%) parity as P0+0 which were significantly higher than other parities (Z=7.73; p=0.00001). Only 1 patient had P1+0 [Table 5]. Most of the caesarean section 26(8.5%) were underwent as per maternal wish (Z=1.21;p=0.47) [Table 2/Fig. 2].

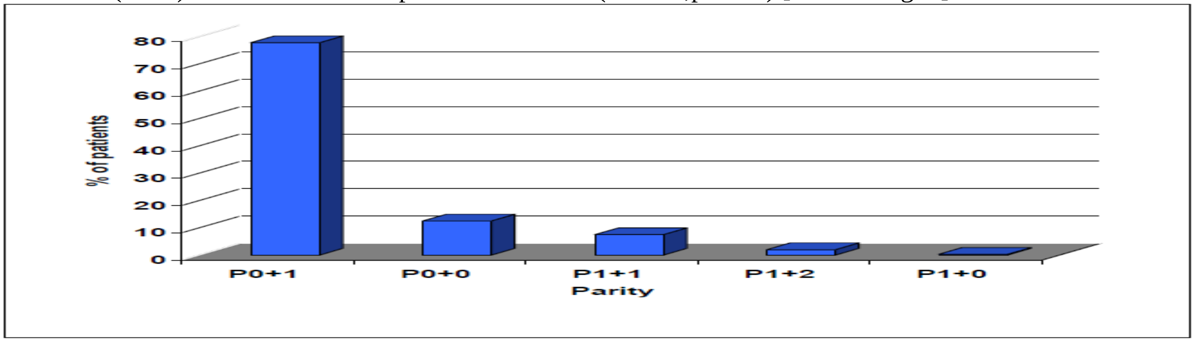

Fig 2: Graphical representation of distribution of parity

Table 3: Antibiotic administered (generic/trade/commercial name)

Antibiotic administered	Number	%
Inj. Cefotaxime, Inj. Metronidazole	4	1.3%
Inj. Augmentin [Amoxycillin (1000mg) + Clavulanic Acid (200mg)], Inj. Amikacin	3	1%
Inj. Metronidazole, Inj Gentamicin	4	1.3%
Inj. Ceftriaxone	8	2.6%
Inj. Ceftriaxone, Inj.Metronidazole, Inj Amikacin	4	1.3%
Inj. Ceftriaxone, inj. Metronidazole	3	1%
Inj. Cefuroxime, inj. Amikacin	3	1%
Inj. Cefotaxime, Inj. Metronidazole	4	1.3%
Inj. Augmentin	3	1%
Inj.Augmentin, Inj. Metronidazole	5	1.6%
Inj. Augmentin, Inj.Xone-xf	7	2.3%
Inj.Ciprofloxacin, Inj. Metronidazole	3	1%
Inj. Ceftriaxone	38	12.5%
Inj. Ceftriaxone, Inj. Metronidazole, Inj. Amikacin	8	2.6%
Inj. Ceftriaxone, Inj. Metronidazole	12	3.9%
Inj. Oframax forte (Ceftriaxone 1gm+Sulbactam 500mg), Inj. Metronidazole	18	5.9%
Inj. Cefuroxime, Inj. Metronidazole	34	11.1%
Inj. Cefotaxime, Inj. Metronidazole	8	2.6%
Inj. Cefotaxime, Inj. Metronidazole	136	44.6%
Total	305	100%

The maximum no.of patients were administered the combination of inj. cefotaxime & inj.metronidazole that is 49.8% [table 3].

Table 4: Time interval between administration of antibiotic and delivery

Time interval (in minute)	Number	%
<30	61	20%
30-60(As per hospital protocol)	209	68.5%
>60	35	11.5%
Total	305	100%

The mean time interval between administration of antibiotic and delivery (mean± s.d.) of the patients was 44.99±16.83 minutes with range 5-90 minutes and the median was 45 minutes. Most of the time interval 209(68.5%) were as per hospital protocol which was statistically significant (Z=5.79; p=0.0001) [Table 4/Fig. 3].

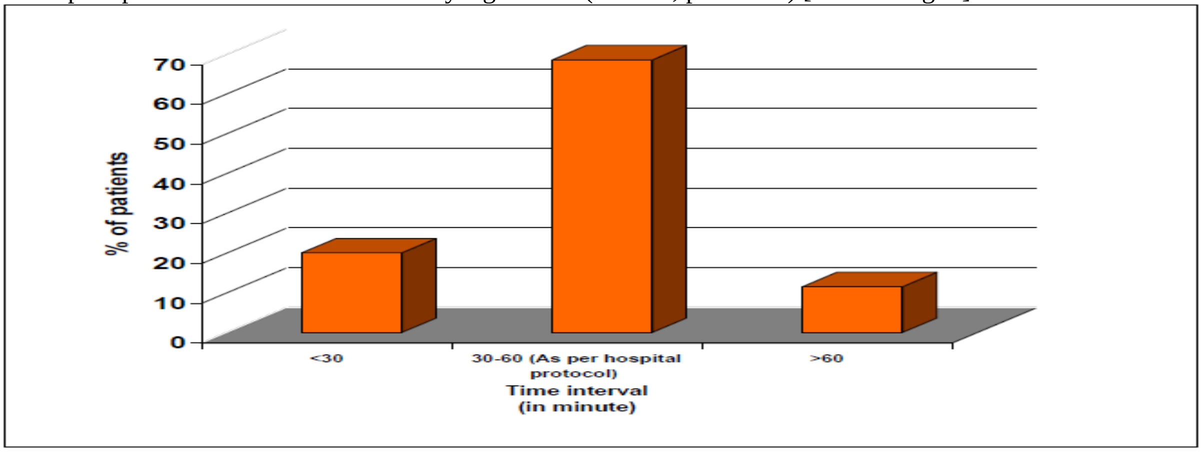

Fig 3: Comparison with hospital protocol

Table 5: Time interval between administration of antibiotic and delivery

Time interval (in minute)	Number	%
<15	8	2.6%
15-60 (As per nice protocol)	262	85.9%
>60	35	11.5%
Total	305	100%

The mean time interval between administration of antibiotic and delivery (mean± s.d.) of the patients was 44.99±16.83 minutes with range 5-90 minutes and the median was 45 minutes. Most of the time interval 262 (85.9%) were as per nice protocol which was statistically significant (Z=7.06; p=0.00001) [Table 5/Fig. 4].

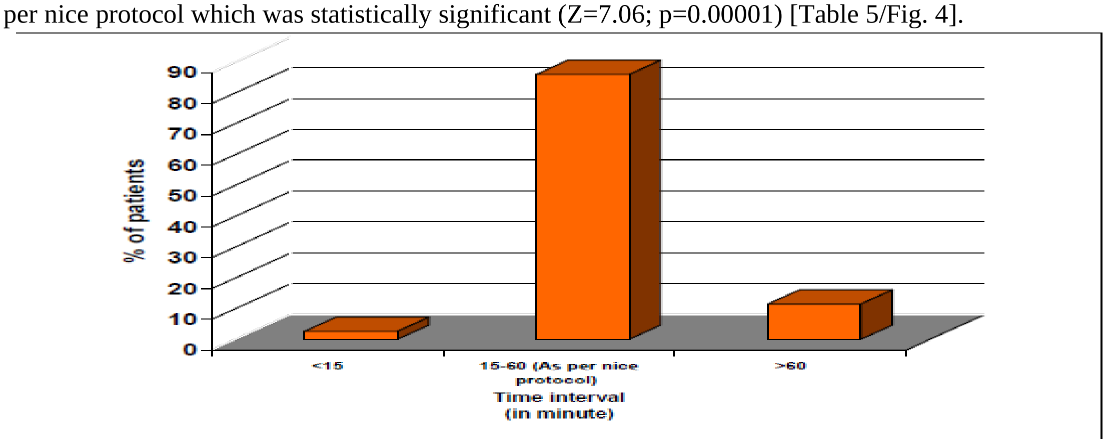

Fig 4: Comparison with hospital protocol

Table 6: Association of antibiotic administered and time interval between administration of antibiotic and delivery

Antibiotic administered	Time interval between administration of antibiotic and delivery (in minutes)			
	<30	30-60(As per hospital protocol)	>60	Total
Amoxicillin+ Clavulanic acid Row % Col %	0 0 0	3 100 1.4	0 0 0	3 100 1
Ceftriaxone Row % Col %	15 32.6 24.6	8 17.4 3.8	23 50 65.7	46 100 15.1
Cefotaxime+ Metronidazole Row % Col %	4 2.6 6.6	148 97.4 70.8	0 0 0	152 100 49.8
Amoxicillin+ Clavulanic acid + Metronidazole Row % Col %	0 0 0	5 100 2.4	0 0 0	5 100 1.6
Amoxicillin+ Clavulanic acid + Ceftriaxone Row % Col %	0 0 0	1 14.3 0.5	6 85.7 17.1	7 100 2.3
Amoxicillin+ Clavulanic acid + Ceftriaxone Row % Col %	0 0 0	0 0 0	3 100 8.6	3 100 1
Amoxicillin+Clavulanic acid + Amikacin Row % Col %	12 80 19.7	3 20 1.4	0 0 0	15 100 4.9
Ceftriaxone+ Metronidazole Row % Col %	0 0 0	34 100 16.3	0 0 0	34 100 11.1
Cefuroxime + Metronidazole Row % Col %	0 0 0	3 100 1.4	0 0 0	3 100 0
Cefuroxime + Amikacin Row % Col %	18 100 29.5	0 0 0	0 0 0	18 100 5.9
Ceftriaxone+Sulbactum+ Metronidazole Row % Col %	0 0 0	0 0 0	3 100 8.6	3 100 1
Ciprofloxacin + Metronidazole Row % Col %	4 100 6.6	0 0 0	0 0 0	4 100 1.3
Metronidazole + Gentamicin Row % Col %	0 0 0	4 100 1.9	0 0 0	4 100 1.3
Ceftriaxone+ Metronidazole+ Amikacin Row % Col %	8 100 13.1	0 0 0	0 0 0	8 100 2.6
Total Row % Col %	61 20 100	209 68.5 100	35 11.5 100	305 100 100

$X^2 = 400.21$; p=0.000001, S-Significant

Corrected Chi-square (X^2) test showed that there was significant association between antibiotic administered and time interval between administration of antibiotic and delivery (p=0.000001). Combinations of antibiotics cefotaxime+ metronidazole were most effective to maintain hospital protocol for time interval between administration of antibiotic and delivery 148 (70.8%) followed by combination antibiotics ceftriaxone+ metronidazole 34 (16.3%) [Table 6].

Table 7: Association of antibiotic administered and time interval between administration of antibiotic and delivery

Antibiotic administered	Time interval between administration of antibiotic and delivery (in minutes)			
	<15	15-60 (As per hospital protocol)	>60	Total
Amoxicillin+Clavulanic acid Row % Col %	0 0 0	3 100 1.1	0 0 0	3 100 1
Ceftriaxone Row % Col %	0 0 0	23 50 8.8	23 50 65.7	46 100 15.1
Cefotaxime+ Metronidazole Row % Col %	4 2.6 50	148 97.4 56.5	0 0 0	152 100 49.8
Amoxicillin+Clavulanic acid + Metronidazole Row % Col %	0 0 0	5 100 1.9	0 0 0	5 100 1.6
Amoxicillin+Clavulanic acid + Ceftriaxone Row % Col %	0 0 0	1 14.3 0.4	6 85.7 17.1	7 100 2.3
Amoxicillin+Clavulanic acid + Ceftriaxone Row % Col %	0 0 0	0 0 0	3 100 8.6	3 100 1
Amoxicillin+Clavulanic acid + Amikacin Row % Col %	0 0 0	15 100 5.7	0 0 0	15 100 4.9
Ceftriaxone+ Metronidazole Row % Col %	0 0 0	34 100 13	0 0 0	34 100 11.1
Cefuroxime + Metronidazole Row % Col %	0 0 0	3 100 1.1	0 0 0	3 100 1
Cefuroxime + Amikacin Row % Col %	0 0 0	18 100 6.9	0 0 0	18 100 5.9
Ceftriaxone+Sulbactum+ Metronidazole Row % Col %	0 0 0	0 0 0	3 100 8.6	3 100 1

Ciprofloxacin + Metronidazole Row % Col %	4 100 50	0 0 0	0 0 0	4 100 1.3
Metronidazole + Gentamycin Row % Col %	0 0 0	4 100 1.5	0 0 0	4 100 1.3
Ceftriaxone+ Metronidazole+ Amikacin Row % Col %	0 0 0	8 100 3.1	0 0 0	8 100 2.6
Total Row % Col %	8 2.6 100	262 85.9 100	35 11.5 100	305 100 100

X^2 = 334.91; p=0.000001 S-Significant

Corrected Chi-square (X^2) test showed that there was significant association between antibiotic administered and time interval between administration of antibiotic and delivery (p=0.000001). Combination of antibiotics cefotaxime+ metronidazole were most effective to maintain nice protocol for time interval between administration of antibiotic and delivery 148 (70.8%) followed by combination antibiotics ceftriaxone+ metronidazole 34(16.3%) [Table 7].

Discussion

Caesarean delivery is becoming more & more prevalent now a days. Caesarean section is the most important factor associated with postpartum bacterial infections, with a infection rate reported to be 1-25%, which is 5-20 times higher than that of vaginal delivery .Postpartum infection remains to be among the top five causes of pregnancy-related maternal mortality & morbidity worldwide [12]. Following caesarean delivery maternal mortality &morbidity may result from a number of infections including urinary tract infection (UTI) & surgical site infection (SSI), which increase hospital stay & cost per case [13]. This study assessed the pattern of antibiotic prophylaxis in various clinical conditions. This study was based in the eastern region of India, in a tertiary care hospital of a metropolitan city. This study evaluated the antibiotic prophylaxis in reducing post operative infection rate. The goal of the study is to initiate appropriate usuage of antibiotic prophylaxis in caesarean section.The study was based on data collection through data collection proforma based assessment amongst the all pregnant women undergone caesarean section in the tertiary care hospital. Data collection process was started from July 2014 & continued till March 2015.The data of total 305 pregnant women were included in this study. All the collected data in the customized proforma were compared with the hospital protocol & NICE protocol. In this study, table 1 shows that total 305 no. of patients the mean age (mean ± s.d.) of the patients was 28.94±3.88 years with range 19 - 42 years and the median age was 29 years. It was showed that proportion of patients in the age group between 20-29 years (56.7%) was significantly higher than other groups (Z=1.98; p=0.04). Jahan Ara Khanem et al in a similar study on antibiotics prophylaxis in caesarean section that in 100 women undergoing caesarean section in which 73.5% were in age group of 20-35 [14]. In table 2 shows that most of the patients 237(77.7%) had parity as P0+1 followed by patients 38 (12.5%) parity as P0+0 which were significantly higher than other parities (Z=7.73; p=0.00001). Only 1 patient had P1+0. RF Lamont et al in a study of current debate on the use of antibiotic prophylaxis for caesarean section show similar parities where P0+1 were significantly higher than other parities [15].In table 3 of the study demonstrated that most of the patients were administered with the combination of antibiotics cefotaxime and metronidazole 152(49.8%) followed by antibiotic ceftriaxone 46 (15.1%). N Morisaki et al on the WHO multicountry survey on Maternal & institutional characteristics associated with the administration of prophylactic antibiotics for caesarean section showed combination of cefotaxim & metronidazole is 51.17 % which is very similar to this study [16]. Smaill F et al on Antibiotic prophylaxis for caesarean section (review) showed combination of cefotaxime & metronidazole is significantly higher than other antibiotics i.e. 47.23 % [17].In table 4, 5 shows the mean time interval between administration of antibiotic and delivery (mean± s.d.) of the patients was 44.99±16.83 minutes with range 5-90 minutes and the median was 45 minutes. It was found that most of the time interval 209(68.5%) were as per hospital protocol which was statistically significant (Z=5.79; p=0.0001). In this study 209 patients out of 305 patients had compliance with Hospital protocol. David C Classen et al on timing of administration of prophylactic antibiotics & the risk of surgical wound infection showed in most of the patients (i.e. 71%) the interval between administration of antibiotic & delivery was in between 30-60 mins prior to skin incision [18]. In table 4, 5 it was found that the mean time interval between administration of antibiotic and delivery (mean± s.d.) of the patients was 44.99±16.83 minutes with range 5– 90 minutes and the median was 45 minutes. It observed that high percentage of the time interval 262 (85.9%) were as per nice protocol which was statistically significant (Z=7.06; p=0.00001). In this study 262 patients out of 305 patients had compliance with NICE protocol. David C Classen et al on timing of administration of prophylactic antibiotics & the risk of surgical wound infection showed in most of the patients (i.e. 89.01%) the interval between administration of antibiotic & delivery was in between 15-60 mins prior to skin incision [18].In table 6 shows Corrected Chi-square (X^2) test showed that there was significant association between antibiotic administered and time interval between administration of antibiotic and delivery (p=0.000001). Combination of antibiotics cefotaxime and metronidazole were most effective to maintain hospital protocol for time interval between administration of antibiotic and delivery 148 (70.8%) followed by combination antibiotics metronidazole and cefuroxime 34 (16.3%). Gyte GM et al on different classes of antibiotics given to women routinely for preventing infection at caesarean section showed most of antibiotics administered within 30-60 mins prior to skin incision is the combination of cefotaxime & metronidazole [19].In table 7 corrected Chi-square (X^2) test showed that there was significant association between antibiotic administered and time interval between administration of antibiotic and delivery (p=0.000001). Combination of antibiotics cefotaxime and metronidazole were most effective to maintain nice protocol for time interval between administration of antibiotic and delivery 148 (70.8%) followed by combination antibiotics metronidazole and cefuroxime 34(16.3%). Brubaker SG et al on patterns of use and predictors of receipt of antibiotics in women undergoing caesarean delivery showed most of antibiotics administered within 15-60 mins prior to skin incision is the combination of cefotaxime & metronidazole [20]. All this observations are well supported by standard literature & text books & guidelines.

Limitations of the study

The data of prophylactic antibiotics usage after the delivery of child (after the caesarean section operation) was not included in the study. The follow up data of the patients which describes the effect of prophylactic antibiotic usage in the caesarean section was not included in the study. The study was restricted in the upper class & upper-middle class of society (as it was a single centred base study) so the data didn't signify the total scenario.

Conclusion

Caesarean Section is becoming more & more frequent in present scenario. Due to unbearable labor pain during vaginal delivery of the child, caesarean section is becoming widespread choice among pregnant women in modern society. In emergency condition caesarean section is a safe option of child delivery as there is less risk of mother & child. But caesarean section is associated with postpartum bacterial infections such as bacterial endometritis, UTI & SSI; which are the main cause of maternal morbidity & mortality. Therefore to reduce the postpartum infection rate prophylactic antibiotics are used. Antibiotic prophylaxis significantly reduces the postpartum infection rate & thus reduces maternal morbidity & mortality in caesarean section. In this study conducted at a tertiary care hospital, the prophylactic antibiotic usage data showed that combination of cefotaxime & metronidazole is most frequently used. The study describes that the usage of prophylactic antibiotic combination cefotaxime & metronidazole are most appropriate & have compliance with hospital protocol & NICE protocol. This study demonstrates the pattern of appropriate prophylactic antibiotic usage in caesarean section, which will help to reduce the maternal morbidity & mortality in caesarean delivery. This study will help to enhance the knowledge of pattern of prophylactic antibiotics usage in caesarean section in a tertiary care hospital setting. In tertiary care hospital setting the usage of prophylactic antibiotics should be very appropriate & have compliance with the hospital protocol & NICE protocol, which will initiate the pregnant women to go for a caesarean delivery which is safer & less painful way of child delivery.

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