ORIGINAL ARTICLE

Presurgical Antibiotic Prophylaxis Pattern In An Indian Tertiary Care Teaching Hospital

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Abstract

The present study was performed to study the antibiotic prophylaxis pattern in patients admitted in Surgery and Obstetrics and Gynaecology wards of a Tertiary Care Teaching hospital in North India. It was an observational, non interventional and analytical study used to evaluate the patients undergoing surgery through period of one and half years. Information concerning demographic data, type of surgery, and parameters of antibiotic therapy (selection of antibiotic, dose, route and duration of therapy as well as cost) was collected from case records of 400 patients. Third generation cephalosporins were the most commonly prescribed class of antibiotics. No consistency was noted in the timing of administration of prophylactic antimicrobials agents which were prescribed 30 minutes to 6 hours before surgery. The dose was not repeated during surgery. Majority of antibiotics were prescribed from Essential Medicines List. Surgical prophylaxis was inappropriate in terms of choice of antimicrobial agent, timing of administration as well as the total duration of prescription, in majority of the cases. Interventions are warranted to promote the development, dissemination and adoption of evidence based guidelines for antimicrobial prophylaxis.

Key Words

Antibiotic Prophylaxis, Surgery, Rational Use of Medicines, Surgical Prophylaxis

Introduction

The irrational use of drugs is a major problem of present day medical practices and its consequences include ineffective treatment, development of resistance to antibiotics, adverse effects and economic burden on patients and society. Even though, there are programs on rational use of drugs and EM of WHO which are being promoted by various national and international agencies working on health sector such as MSF, INRUD, Ecumenical MN, DSPRUD, CSRUISM, EDM Department of WHO, etc., irrational prescription is still a common practice (1).

Antibiotics are the most frequently prescribed drugs among hospitalized patients especially surgical department (2). Widespread and indiscriminate use of broad spectrum antibiotics has contributed to the emergence of multidrug resistance. Existing evidence suggests that there is a causal association between antimicrobial usage in hospitals and antimicrobial resistance (3). Appropriate antibiotic prophylaxis has also been shown to be effective in reducing the incidence of surgical site infections (4). However, antibiotics costs have increased have increased dramatically over the years with an overall trend to prescribe expensive broad spectrum rather than narrow-spectrum antibiotics (5). Therefore audit is done to estimate the cost and find out the rationality of prescribing, and use of essential drug list in clinical practice.

Only very limited data on the usage of antimicrobials in India is available (6,7). This study was planned as a point-prevalence, analytical study to evaluate drug prescription patterns with special reference to antimicrobials in a patients undergoing various surgeries at tertiary care hospital in North India.

Materials and Methods

An observational, non interventional and analytical study was conducted by Department of Pharmacology in association with Department of Surgery and Department of Obstetrics and Gynecology of Era's Lucknow Medical College and Hospital after getting approval from Institutional Ethics Committee. Due permission was taken from The Chief Medical

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Superintendent for accessing the medical records. The period of study was one and half years-from December 2009 to June 2011. Data of patients matching inclusion criteria like age, sex, diagnosis, ongoing treatment was recorded from case records of patients. Identity of patient was kept confidential. All consecutive patients of any age of either sex including pregnant/lactating mothers undergoing surgery (elective as well as emergency) in department of general surgery and obstetrics and gynecology were eligible for inclusion into study. Patients who died preoperatively, absconded against medical advice and referred to higher centre were excluded. Data were collected on a pretested case record form which included information on patient demographic profile, surgical department under which admitted, type of operation, antimicrobial agents prescribed as well as their route of administration, and timing of administration prior to surgery. Antimicrobials prescribed from National List Of Medicines, India, 2011 (EML-I), and from WHO Model List of Essential Medicines, 17th edition, 2011 were also taken into consideration. Antimicrobials prescribed by generic name also taken into account. The cost on antimicrobials in one day estimated from Indian drug (Drug Today, April-June 2010; CIMS (Current Index of Medical Specialties) Oct'10- Jan'11). The above data was entered in SPSS versions 16.0 and analyzed.

Statistical Analysis

Comparison was done between Department of Surgery and Department of Obstetrics and Gynecology with respect to all above indications using two tailed unpaired t-test .Comparison was done among different surgeries using ANOVA followed by Post Hoc Dennett's T3 test. Since equal variance was not assured value < 0.05 was considered significant.

Result

A total of 400 patients were enrolled, out of which 151 were admitted in Surgery and 249 admitted in Obstetrics and Gynecology (OBG) wards. The most common surgeries were cholecystectomy (29), exploratory laparotomy (16), hydrocele (14) and other surgeries (92). Age of patients ranged between 17-60 yrs. The most common surgeries performed in Obstetrics and Gynecology (OBG) were emergency L.S.C.S (128), elective L.S.C.S (19), TAH (28). Other Gynaecological surgeries (74). In OBG the average mean age was 31.40±10.48. (*Table 1*).

All patients undergoing surgery were prescribed 1 to 3 antimicrobial agents .The average number of antimicrobial agents prescribed in surgery ward was 1.02 ±.57.The overall antimicrobials agents prescribed from EML- WHO 0.980± 0.5594.The antimicrobial agents included from EML-I was 0.9603± 0.5523.The antimicrobial agents prescribed by generic name in surgery wards was 0.0463±0.211.The average cost incurred by patients in surgery ward on antimicrobial agents was 59.37±60.19 and varied between 0.00 to 529.01INR .In majority of cases at least one antimicrobial agent was prescribed from essential medicine list WHO and EML-I. In patients undergoing exploratory laparotomy and choleystectomy the number of antimicrobials agents from EML- WHO and EML-I were same i.e. 1.0625±0.9979 and 0.931±0.2579 respectively .In hydrocele the number of antimicrobials agents from EML- WHO and EML-I were 0.9286±0.267and 0.7857 ± 0.4258 respectively and that of others surgeries were 0.9891 ±0.564 and 0.9783± 0.5341. Only a miniscule number was prescribed by generic name [choleystectomy (0.068±0.2579), exploratory laparotomy (0.187±0.4031) and other surgeries (0.0217±0.146)].In hydrocele sac none of antimicrobials agents prescribed by generic name. Total cost incurred by patients on antimicrobials agents was highest in other surgeries (65.02±73.12) INR followed by hydrocele (55.35±25.08) INR, exploratory laparotomy (50.44±47.65) and choleystectomy(48.30±15.32) There was a large variation in cost incurred on antibiotics by different patients undergoing same surgery (*Fig1*) .

In OBG 1 to 3 antimicrobials agents were prescribed to all patients undergoing surgery and the average was 1.07± 0.30.The overall antimicrobials agents prescribed from EML-WHO and EML-I in OBG ward were same i.e. 1.0361±0.351. The antimicrobials agents prescribed by generic name was 0.4618 ±0.499. The average cost incurred by patients in OBG ward on antimicrobial agents were (53.16±40.96) INR and varied between (22.38 to 434.06) INR.

At least one antimicrobials agent in most of cases was from EML- WHO and EML-I in emergency L.S.C.S ,elective L.S.C.S and transabdominal hysterectomy the number of antimicrobials agents from EML- WHO and EML-I were same i.e. 1.0625±0.391 ,1.00± 1.00 , 0.9286± 0.262 respectively(fig1). Other OBG surgeries showed different antimicrobial agents included from essential medicine list WHO and EML-I i.e. 1.0405±0.348, 11.183±0.348 respectively.

Only few antimicrobials were prescribed by generic name [emergency L.S.C.S (0.382±0.4880, elective L.S.C.S (0.684±0.4776), transabdominal hysterectomy (0.4286±0.504) and others (0.5541±0.5005)]. Total cost incurred by patients on antimicrobial agents was highest in transabdominal hysterectomy (56.41±46.26) INR followed by emergency L.S.C.S (54.70 ±44.61) INR, other gynecological surgeries (51.92 ±37.50) INR and

Table 1. Profile of Patients Undergoing Various Surgeries

Departments. Procedures	Total number	Male	Female	Age in years Mean±SD	Age in years 95% CI
Surgery					
Cholecystectomy	29	9	20	38.34± 13.75	33.11-43.58
Exploratory laparotomy	16	14	2	34.31 ± 19.21	24.08-44.55
Hydrocele(Jaboulay's Eversions of sac)	14	14	-	35.79 ± 12.14	28.78 - 42.80
Other Surgeries	92	60	32	42.51 ± 15.53	39.29-45.73
Total	151	97	54	40.22±15.52	37.72-42.71
OBG					
Emergency L.S.C.S	128	-	128	26.38 ± 4.01	25.67-27.08
Elective L.S.C.S	19	-	19	25.95 ± 3.27	24.37-27.53
TAH	28	-	28	44.21 ± 9.19	40.65-47.78
Other OBG Surgeries	74	-	74	36.65 ± 12.98	33.64-39.66
Total	249	0	249	31.40±10.48	30.09-32.71
ANOVA F				20.827	
P				**0.000**	

Table 2. Preoperative Prescription of Patients Showing Number of Antimicrobials Prescribed and Total Cost Incurred by Patients on Antimicrobials

	Department	Total	Mean	Std. Deviation
Number of antimicrobials prescribed	Surgery	151	1.02	0.57
	Obstetrics and Gynaecology	249	1.07	0.30
Total Cost on antimicrobials	Surgery	151	59.37	60.19
	Obstetrics and Gynaecology	249	53.17	40.97

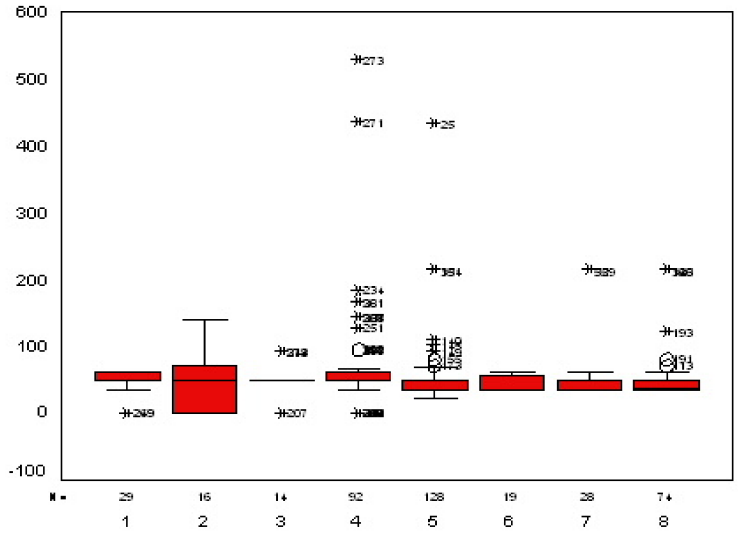
elective L.S.C.S (42.90±12.28) *Fig1*. There was a large variation in cost incurred on antibiotics by different patients undergoing same surgery. Each patient undergoing surgery like exploratory laparotomy, incision and drainage, diabetic foot, debridement with amputation of 2nd, 3rd, 4th metastasis, Emergency L.S.C.S and perforation peritonitis developed surgical site infection. The antibiotics were prescribed 30 minutes to 6 hours before surgery .The dose was not repeated during surgery. No proper time schedule was followed before administration of prophylactic antimicrobials agents.

No consistency was found in time of administration of antimicrobials before surgery. The antibiotics were prescribed 30 minutes to 6 hours before surgery .The dose was not repeated during surgery. No proper time schedule was followed before administration of prophylactic antimicrobials agents. Out of 400 patients, only 6 patients developed surgical site infection (1.5%).

Discussion

Our study is in confirmation of earlier studies on antimicrobials prophylaxis which show that adherence to international as well as local guidelines for antimicrobial prophylaxis is low among Surgeons and Gynecologists. A study by Dettenkofer *et al*, 2002 (8) in eight German hospitals found 30 to 90 % of antibiotics prophylaxis was inappropriate. An Indian study by Parulekar *et al*, 2009 (9) found that appropriateness of choice of antibiotic was seen in 68% cases. Barrier towards implementation of surgical prophylaxis guidelines have not been identified as lack of awareness, non-accountability, perception of guidelines as bureaucratic rather than education tool or perception of guidelines as cookbook medicine rather than

Table 3 Prescription of Patients Showing Total Cost incurred on Antimicrobial Agents Preoperatively



(TOTCOST- Total cost on antibiotics in Indian Rupee. Group: 1 =Cholecystectomy,2= Exploratory Laparotomy, 3=Hydrocele 4=Other surgeries,5=Emergency L.S.C.S, 6=ElectiveL.S.C.S,7=Transabdominal hysterectomy and 8= Others Gynaecological surgeries)

allowing oneself to make one's own medical decisions (11). Another major reason for non-compliances false belief that high-end/multiple antibiotics and prolonged therapy will be more effective in preventing surgical site infection as compared to short duration of narrow spectrum antibiotics. Measures to promote rational surgical antibiotic prophylaxis include drafting of guidelines, education and communication of guidelines to those concerned, frequent reminders and training and finally periodic compliance audits and communications of result to all concerned (12).

Our study is in confirmation with earlier studies which show that commonly prescribed drugs presurgical are cephalosporins. A study by Parulekar et al,2009[9] reported that prophylactic antibiotics prescribed include cefazoline in 46 cases and cefuroxime in 15 % cases out of 90 cases studied. A study by Rehan *et al,* 2010 (13) reported that 3rd generation cephalosporins (particularly ceftriaxone and cefotaxime) were the commonly prescribed antibiotics (80%) for all surgeries. Although cefazolin has been recommended as drug of choice for presurgical prophylaxis, it is not available in hospital supply hence not used even in single encounter.

No consistency was noted in the timing of administration of prophylactic antimicrobials agents. The antibiotics were prescribed 30 minutes to 6 hours before surgery .The dose was not repeated during surgery. This shows that no guidelines are being adherence to regarding timing of prophylactic antimicrobial administration. The practice of unnecessarily giving prophylactic antibiotics more than one hour before surgery should be strongly discouraged. One method of preventing this practice is to assign the prescription of antimicrobials to the anesthesiologist in charge only. Prevention could also be achieved by providing better staff training as to the benefits of adherence to standard international antimicrobial prophylaxis guidelines and the risks of unnecessarily dispensing antibiotics. Potential solutions to avoid both of these mistakes include better organization of work and specification of tasks among individuals on the surgical team, introduction of special forms for ordering antimicrobial prophylaxis, and use of an antibiotic prophylaxis chart in the operating theaters.

In a descriptive study without a control group, Prado *et al*,2002 (14) showed that when pharmacists were given a central role in the administration of prophylaxis, the appropriateness of the indication increased from 56% to 100%, while the costs decreased by 40%. Moreover, in a study of an intervention to reduce the prescribing of antibiotics for upper respiratory infections by general practitioners in Australia, Zwar *et al,* 2002 (15) found that giving feedback on prescription behavior increased the appropriateness of the prescriptions. The importance of the timely administration of pre-operative antibiotics is well established and is broadly applicable to all procedures for which prophylactic antibiotics are administered. It has been suggested that antimicrobial selection is a moot point if the agent is not delivered during the optimal 30-60 minute window just before incision. Another study on surgical antimicrobial prophylaxis in Dutch hospitals by Karsteren *et al,* 2003(16) found that timing was concordant with hospital guidelines. Only in 50% procedure and in three hospital prophylaxis then recommended in more than 80 % of cases. The error in

timing was mainly due to logistic in the surgical suite. The study found that lack of awareness of the appropriate guideline was the main barrier to guideline adherence regarding antimicrobial choice and dose. In our hospital timing was too early for almost all procedure because the first dose of prophylaxis was given in the ward instead of Operation Theater.

Acquaintance with guidelines may be improved by electronic distribution of the guidelines, and by pre-printing sections of the guideline on prescription charts. Testing the feasibility and acceptance of clinical guidelines among the target group is important for effective implementation (17-19). It is just as important to ensure that recommendations in the guideline agree with the current evidence base, and that links between recommendations and scientific evidence are made explicit (20). Therefore, more effort should be put into providing surgeons with evidence of the content of the guideline and in trying to achieve consensus, before implementing new guidelines. Finally, antibiotic policy makers are often unaware of logistical problems in the surgical suite or in the ward. Logistical constraints were the most important barriers to adherence to guidelines for timing and dosing intervals. Studying these logistical constraints in more detail can help to create conditions that facilitate guideline adoption. An Indian study by Rehan *et al*,2010 (13) reported that mean timing of administration of antibiotics was 3.22 ± 1.03 hours prior to first incision and the patients received post operative antibiotics for a mean duration of 5 days during their stay in the hospital which similar to our study.

The incidence of Surgical Site infection (SSI) was low. Only 6 out of 400 patients developed SSI (1.5%). Most studies (16, 21) on presurgical antibiotics prescribing have not studied the incidence of surgical site infection. A study by Arrigan *et al*, 2007 (22) on Peri-Surgical Antibiotics and Surgical Site Infections in Livingstone General Hospital, Zambia reported that occurrence of surgical site infection was 23% and is associated with significant cost of € 133.84 per infection.

A study by Rehan *et al*, 2010 (13) on surgical antibiotic prophylaxis in a tertiary care teaching hospital in India reported that development of surgical site infection on 14 % cases. The most significant factor influencing the healing of surgical wounds and subsequent development of surgical site infection is the level of bacterial burden at the incision site (23, 24). The primary source of this contamination has been found to be the skin (25).The low incidence of surgical site infection in our study shows that proper procedure of cleaning skin are being followed. A study by Sadiuqe *et al*, 2009 (26) concluded that it is the maintenance of standard sterilization technique of operation room which counts for the prevention of surgical site infection. It can be hypothesized from our result that proper maintenance of standard sterilization technique of operation theater rooms is being following in this institution. The cost of antimicrobials therapy varied between 65.02±73.12 INR in patients of other surgeries and 42.90±12.28 INR in patients undergoing elective L.S.C.S. A study by Shah and Shah, 2004 (27) on antimicrobials by the department of Obstetrics and Gynaecology of a tertiary care hospital M.P Shah Medical College, Jamnagar (Gujarat) found that out of total cost, 72% was found to be unnecessary .The author reported the average total cost on antimicrobials in Obstetrics and Gynecology department was 169.42INR. The total average cost on lower segment caesarean section was 419.42 INR which is similar to that reported in our study. Although most antimicrobial agents were prescribed from Essential Medicine List, the cost to patients was high due to prescription by brand names. An earlier study on prescription pattern in Kerala, India found that no prescription contained generic drugs (28), an issue which needs urgent attention.

Despite all efforts taken by the government and the WHO, the pattern of prescription in terms of completeness and rationality of drug prescription remains poor. There is urgent need to develop standards of drug prescription and develop ways and means to ensure that they are adhered to. Special attention needs to be given to the tertiary care institution hospitals where significant degree of irrational prescribing in terms of polypharmcy and relative absence of the directions about the use of drugs was evident. A considerable check on the pharmaceutical companies and their representatives is needed to minimize their influence on drug prescription by physicians. Proper hospital guidelines for pre-surgical antibiotics prophylaxis should be made in consultation with surgeons, microbiologists and pharmacologists. Hospital antibiotics policy should be made and antibiotic prescriptions should be audited periodically and feedback provided to prescribers as well as authorities.There is need for constant surveillance of prescriptions to maintain any improvement in standards.

Conclusion

Although most antimicrobial agents were prescribed from Essential Medicine List, the cost to patients was high due to prescription by brand names. Also, no consistency was noted in the timing of administration of prophylactic antimicrobials agents and no guidelines are being adherence to regarding prophylactic antimicrobial administration. Interventional measures are urgently needed to promote rational prescribing practices.

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