RESEARCH ARTICLE

USE OF ANTIMICROBIAL PROPHYLAXIS IN CLEAN ELECTIVE ORTHOPEDIC SURGICAL PROCEDURES AND IDENTIFYING COMMON INFECTIVE ORGANISMS

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ABSTRACT

Background: Prophylactic antimicrobials have an important adjuvant role in the prevention of Surgical Site Infection (SSI), which is one of the most preventable causes of post-operative complication. In India, due to lack of adequate information and guidelines for antimicrobial prophylaxis in surgery there is a need to generate baseline data on the pattern of use of prophylactic antimicrobials.

Aims & Objective: This study is aimed to analyze the pattern of surgical chemoprophylaxis and surgical site infection (SSI) rate in patients who underwent elective orthopedic surgical procedure.

Material and Methods: A prospective, observational study was performed on patients undergoing surgery, in a tertiary care teaching hospital. Data were collected in a pro-forma which included the patients' details, prescriptions from date of admission to discharge or any other outcome and operative notes. Surgical site infection as defined by Centre for Disease Control criteria was recorded.

Results: Total 305 patients were enrolled over a period of one year. In 237 (77.70%) patients antimicrobials prescribed by generic name. In preoperatively and intraoperatively, all the patients received parenteral antimicrobial. Postoperatively, 294 (96.40%) patients received only parenteral antimicrobials while in 11 (3.60%) patients received parenteral antimicrobials followed by oral antimicrobials. Preoperatively antimicrobials started 12 hours prior to surgery. Average duration of antimicrobials given postoperatively was 5.05 ± 1.14 days. Third generation Cephalosporins and Aminoglycosides were prescribed most frequently. Average number of antimicrobials used per patient was 4.40 ± 1.05. In follow up 37 (13.03%) patients developed SSI and most common isolated organism was Staphylococcus aureus.

Conclusion: Surgical chemoprophylaxis 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, leading to higher SSI. Interventions are warranted to promote the development, dissemination and adoption of evidence based guidelines for antimicrobial prophylaxis.

Key-Words: Antimicrobial Prophylaxis; Surgical Site Infection; Orthopedic

Introduction

Antimicrobials are the greatest discovery of the twentieth century. They are considered as "miracle drugs", our leading weapons in the treatment of infectious disease. In the pre-antimicrobial era, infectious diseases accounted for significant morbidity and mortality. All this changed with the use of antimicrobials and the 'golden era of antimicrobials' saw a dramatic fall in the mortality from infections. But the miracle seems to be short lived due to irresponsible and erratic use of these drugs has resulted in the emergence of drug resistance in many organisms. In June 2000 WHO issued warning that the widespread use of antimicrobials to treat diseases is producing increasingly drug-resistant infections all over the world.[1]

A surgical site infection (SSI) is an infection that occurs after surgery in the part of the body where the surgery took place.[2] Surgical site infections remain among the main causes of post-operative morbidity, prolonging hospitalization and increasing the cost of medical treatment in surgical units.[3] Antimicrobials play an important role in preventing and treating surgical site infections.[4,5] Surgical chemoprophylaxis is an important measure before any surgery to prevent SSI. Nearly 30-50% of antimicrobials used in hospitals are prescribed for surgical prophylaxis. Antimicrobials are often used in wrong doses, for too long and with too broad spectrum of antimicrobial activity.[6] Antimicrobials as

prophylaxis for SSI in orthopedic surgeries are indicated when prostheses are implanted, or when any sort of osteosynthetic materials such as nails, wires, plates and screws are used.[7]

That's why drug therapy should be scrutinized at international, national, regional and institutional level and efforts are required to evolve a consensus protocol and policy for the same. In India, due to lack of adequate information and guidelines for antimicrobial prophylaxis in surgery there is a need to generate baseline data on the pattern of use of prophylactic antimicrobials. Therefore, this study was undertaken with the following aims and objective: (1) to study the pattern of surgical chemoprophylaxis; (2) to find out the rate of wound infection in patients undergoing elective orthopedic surgical procedure; and (3) to find out common organisms causing post-operative wound infection.

Materials and Methods

Study Design

This was a prospective and observational study conducted for 1 year, from June 2011 to June 2012 in the Department of Orthopedics, P.D.U. Govt. Hospital, Rajkot.

Inclusion Criteria & Exclusion criteria

All patients aged 18 years or more, irrespective of their gender, scheduled for elective orthopedic surgical procedure and receiving prophylactic antimicrobials were included in the study. Patients with open fracture, secondary procedures, previously open fractures, history of allergy to any antimicrobials, preoperative infectious disease at the time of admission, receiving any antimicrobials more than 24 hours prior to surgery, any other procedure requiring spinal or general anaesthesia within 24 hours prior to surgical procedure during the hospital stay and patients not willing to give consent were excluded from the study. The study protocol, pro-forma, and other documents like patient information sheet and informed consent form in English and local vernacular language were approved by Institutional Ethics Committee P.D.U. Govt. Medical College & Hospital, Rajkot.

Study Procedure

All the patients who met the study criteria were enrolled in the study & reviewed daily. Following details were collected and recorded in the pre-decided proforma:

Name, Age and Sex of patients, hospital register number, diagnosis, vitals (Pulse rate, Respiratory rate, Blood pressure, Temperature), Routine investigations, any co-morbid conditions, duration of hospital stay prior to surgery, type of surgery, duration of surgery, Details of antimicrobials used including drug, its dose, frequency, route of administration, antimicrobials prescribed on discharge, Details regarding assessment of wound by on daily basis, relevant microbiological investigation. The principal investigator visited all patients included in this study to collect any further information. Case record files of the patients were analyzed daily until their discharge. Observation was started from day-1 of starting of antimicrobials for surgical prophylaxis. Follow up was carried out for all indoor patients every day till the day of discharge and for the discharged patients follow up was done on day 15 and day 30, on OPD basis.

Data Analysis

Data were presented as actual frequencies, percentage, mean and standard deviation. Analysis was carried out using Microsoft excel 2007 version.

Results

A total of 305 patients were enrolled in the study of which 214 (70.16%) were males and 91 (29.84%) were females. The mean age was 46.84 ± 19.12 years. Average number of antimicrobial used per patient was 4.40 ± 1.05. Most patients (35.09%) received four different antimicrobials during their hospital stay till discharge. Antimicrobials were prescribed by generic names in 237 (77.70%) patients and by brand names in 68 (22.30%) patients. After admission in ward, antimicrobial agents were started after average 2.77 ± 2.99 days. In 87 (28.52%) patients,

antimicrobials was started on day 1, while in 61 (20%) patients, it was started on 2nd day of admission in ward. In all cases antimicrobials were started on previous day of surgery. The mean duration of preoperative stay in hospital was 3.77 ± 2.99 days. Most common antimicrobial prescribed as preoperative prophylaxis was Ceftriaxone in 247 (80.98%) patients which started just 12 hours prior to surgical procedure. Most common antimicrobial prescribed intraoperatively was Cefotaxime in 251 (82.30%) patients, given at the time of induction of anesthesia. Most common antimicrobial prescribed postoperatively was Ceftriaxone in 208 (68.20%) patients and Amikacin in 184 (60.33%) patients (Table 1). Most of the patients 113 (37.05%) received Ceftriaxone and Amikacin combination. Most common antimicrobial prescribed at discharge was Cefixime in 169 (55.41%) patients (Table 2).

Table-1: Details of Antimicrobials Prescribed Postoperatively during Hospital Stay

Prescribed Antimicrobials	No. of Patients	% of Patients
Augmentin	31	10.16 %
Amikacin	184	60.33 %
Gentamicin	89	29.18 %
Cephoparazone & Sulbactam	23	7.54 %
Cefotaxime	46	15.08 %
Ceftriaxone	208	68.20 %
Metronidazole	21	6.89 %
Piperacillin & Tazobactam	10	3.28 %
Ciprofloxacin	1	0.33 %
Cefadroxyl	8	2.62 %

Some patients received more than one drug and therefore the total percentage exceeds 100%.

Table-2: Details of Antimicrobials Prescribed at Discharge

Prescribed Antimicrobials	No. of Patients	% of Patients
Cefadroxil	85	27.87 %
Cefixime	169	55.41 %
Ciprofloxacin	61	20 %
Levofloxacin	74	24.26 %

Some patients received more than one drug and therefore the total percentage exceeds 100%.

Table-3: Details of Duration of Prophylactic Antimicrobial Therapy Postoperatively

Prescribed Antimicrobials	No. of Patients	% of Patients
2	1	0.33 %
3	13	4.26 %
4	29	9.51 %
5	233	76.39 %
6	10	3.28 %
7	9	2.95 %
8	7	2.30 %
> 10	3	0.98 %
Total	305	

In all the patients, antimicrobials were started on previous day of surgery, on the day of operation and continued postoperatively. Average duration of antimicrobials given postoperatively was 5.05 ± 1.14 days (Table 3). All the patients at the time of discharge were prescribed antimicrobials for 5 days. In all (100%) patients most common group was Cephalosporins followed by Aminoglycoside group in 274 (89.93%) of patients (Table 4). All patients received single antimicrobial preoperatively and intraoperatively. During postoperative stay, 31 (10.16%) patients prescribed single antimicrobial (only cephalosporins), 264 (86.56%) were prescribed 2 antimicrobials in combination while 10 (3.28%) patients received 3 antimicrobial (Cephalosporins, Aminoglycoside and anti-anaerobic agent) in combinations. Most common combination prescribed during post-operative prophylaxis was combination of third generation Cephalosporin and Aminoglycoside in 248 (81.31%) patients. At the time of discharge, 221(72.46%) patients were prescribed single antimicrobial agent, while in 84 (27.54%) patients antimicrobials in combination were prescribed.

Table-4: Group wise Distribution of Antimicrobials Used

Group	Drugs	No. of Patients	% of Patients
Cephalosporins (100 %)	Ceftriaxone	253	82.95 %
	Cefotaxime	253	82.95 %
	Cefadroxyl	92	30.16 %
	Cefixime	170	55.74 %
Flouroquinolones (44.26 %)	Ciprofloxacin	62	20.33 %
	Levofloxacin	74	24.26 %
Penicillins (13.44 %)	Amoxycillin + Clavulanic acid	31	10.16 %
	Piperacillin + Tazobactam	10	3.28 %
Aminoglycoside (89.83 %)	Amikacin	187	61.31 %
	Gentamicin	89	29.18 %
Others (15.08 %)	Metronidazole	22	7.21 %
	Cephoparazone + Sulbactam	24	7.87 %

Table 5: Details of Escalation or De-escalation of Antimicrobials Therapy

Change in Anti-microbials Therapy	Type of Change	No. of Patients	% of Patients
Escalation	Antimicrobial Changed	5	1.64 %
	Antimicrobial Added	21	6.89 %
De-escalation	Decrease in Antimicrobial Number	31	10.16 %
No Change	No Change in Antimicrobial Therapy	248	81.31 %

All the patients received parenteral antimicrobial preoperatively and intraoperatively. Postoperatively, 294 (96.40%) patients received only parenteral antimicrobials while in 11 (3.60%) patients, parenteral antimicrobials was started

followed by oral antimicrobials. In postoperative antimicrobial prophylaxis, escalation was done in 26 (8.52%) patients while de-escalation was done in 31 (10.16%) patients. No change in antimicrobial therapy was done in 248 (81.39%) patients (Table 5). Out of total 305 enrolled patients, 21(6.89%) patients were lost to follow up. So from 284 patients, 247 (86.97%) patients showed satisfactory healing during 1 month follow up and remaining 37 patients (13.03%) developed infection. Culture & Sensitivity Test (CST) was done in total 37 patients. Most common organism isolated from pus discharged from wound was Staphylococcus aureus in 16 (43.24%) patients followed by Pseudomonas in 6 (16.22%) and E. coli in 5 (13.52%) patients and Kleibsella in 2 (5.40%) patients. No organism was isolated in 8 (21.68%) patients.

Discussion

Many studies on the efficacy of antimicrobial prophylaxis in orthopedic surgery have been reported; some have shown the efficacy of antimicrobial prophylaxis and have recommended that prophylactic antimicrobial use should be limited to the 24 h following surgery. Moreover, some studies have suggested that drug-resistant organisms appear at higher rates in association with the amount of postoperative antimicrobial usage.[8]

In our study, average antimicrobials used per patient were 4.40 ± 1.05 with most number of patients receiving 4 different antimicrobials (35.09%) during their hospital stay to discharge either single or in combinations. Our rate was higher than in study done by Giri et al in Nepal (2.1 ± 1.36 per patient), by Abula et al (2.17 per patients) in Ethiopia and by Prashanth et al in India (3.42 per patient).[9-11] In our study antimicrobials were prescribed by their generic name in 77.70 % patients and by brand name in 22.30 % patients. This finding is appreciable as prescribing drugs with generic name is a good habit. Rate of prescription with generic name is higher than studies done by Prashanth et al in (Nil) and Salman et al (Nil) in India.[11,12]

In our study average preoperative stay in hospital was 3.77 ± 2.99 days which is higher than 1.2 ± 2.1 days in a study by Kasteran et al in Netherlands.[13] In our study, third generation cephalosporins were the most common group used as antimicrobial prophylaxis for surgical site infection. So our results are similar to study done by Kulkarni et al in India in which more than 80% of the surgeons preferred single drug as third generation cephalosporins, particularly Ceftriaxone and Cefotaxime and preferred combination of cephalosporin with aminoglycoside for all types of surgeries.[14] Similar results were found in study done by Khorrami et al in Iran, Hassan et al in Egypt, Salman et al India, Kumar et al in India, Yeap et al in Malaysia, Vyas et al in India.[12,15-19]

A study by Patzakis reported that the combination therapy (cephalosporin + aminoglycoside) was associated with a 4.6% infection rate, whereas administration of only cephalosporin was associated with a 13% infection rate. So use of Cephalosporin with aminoglycoside in our study was justified.[20] Though in our study third generation cephalosporins were most commonly used for surgical prophylaxis, many studies recommended use of first generation cephalosporins. First-generation cephalosporins (particularly cefazolin) are the most suitable agents for orthopedic prophylaxis because their spectrum of activity includes Staphylococcus species and gram-negative bacilli (such as E. coli), they have desirable pharmacokinetic characteristics (adequate bone penetration) they are easy to administer, low in cost, and safe.[21]

First generation cephalosporins are highly active against gram positive cocci (Staph. aureus) and moderately active against gram negative bacteria (E. coli, Kleibsella) and second and third generation cephalosporins (active against gram negative organism) offer no major advantages over first-generation agents. Second- and third-generation cephalosporins are more expensive; furthermore, indiscriminate use is likely to promote resistance, particularly among nosocomial gram negative bacilli. Therefore, the use of a second- or third generation cephalosporin as orthopedic surgical prophylaxis should be avoided.[22]

Various guidelines also recommends cefazolin 1

gm intravenous single dose or maximum of 3 doses 8 hourly for 24 hours postoperatively as preferred antimicrobial for surgical prophylaxis of clean orthopedic surgical procedure with implant or clean contaminated surgical procedure.[23,24] Gram-positive bacteria, i.e., Staphylococci which are the most common cause of infectious complications associated with fracture surgery. Cephalosporins (such as cefazolin) are appropriate first line agents for most surgical procedures, targeting the most likely organisms while avoiding broad-spectrum antimicrobial therapy that may lead to the development of antimicrobial resistance.[25]

In our study antimicrobial prophylaxis was started 12 hours preoperatively, given intraoperatively at the time of induction of anesthesia and continued postoperatively for average 5.05 ± 1.14 days in wards and prescribed for 5 days after discharge. Our result is nearly similar to study done by Kulkarni et al (6.38 + 2.2 post-operative days) in India, Giri et al (6.38 ± 5.35 days) in Nepal, Chen et al (6.4 days) in Taiwan, Khorrami et al (6 + 5 days) in Iran but lower than study done by Hassan et al (12.4 ± 10.9 days) in Egypt.[9,14-16,26] Though in our study prolonged prophylaxis was given, but it is not recommended. Current US guidelines recommend administration of antimicrobial prophylaxis within 120 min or 60 min of incision.[27,28]

European guidelines recommend administration of prophylaxis within 60 min of incision.[23] The American Association of Orthopaedic Surgeons guideline showed that there is no evidence to support that antimicrobials continued beyond 24 hours provided additional benefits.[24] Most studies have demonstrated efficacy of postoperative antimicrobial prophylaxis for only 12 hours or less: whenever short and long courses are compared, the shorter course has proven equally effective.[30-31]

Dellinger et al demonstrated that a prolonged course of 5-days antimicrobial administration was not superior to a 1-day course for the prevention of fracture site infections.[28] Strachan advocates short-term antimicrobial prophylaxis.[32] Gaetani et al. also recommend short-term antimicrobial prophylaxis in orthopedic and traumatologic surgeries.[33] Current best evidence from the literature, based on data from meta-analyses.[34] Cochrane review has not shown a difference between single-dose preoperative antimicrobial prophylaxis and multiple-dose prophylaxis.[35] Our results were similar to different studies in which parenteral route was preferred for surgical antimicrobial prophylaxis.[10,15,16] The parenteral route is preferred because of its reliability to achieve adequate tissue concentrations.[28]

Frequency of escalation i.e. either a change or addition in antimicrobial therapy was seen in 8.52 % which was lesser than that found in an Italian study (37.6%). Reason for escalation of antimicrobial therapy during post-operative prophylaxis may be to give coverage to most likely pathogens. Frequency of de-escalation i.e. remove any antimicrobial in therapy was seen in 10.16% which was less than that found in Italian study (24%) by Malacarne et al. This shows that once antimicrobials are started, due to lack of conformity there remains a hesitation amongst clinicians, may be due to danger of development of surgical site infection, which prevent them from de-escalating antimicrobials.[36] infection rate in our study is higher than studies done by Khan S et al (9.5%), Hassan et al (4.7 %), Yohannes et al (5.94%), Wassef et al (8.2 %) and Goswami et al (7.2 %).[16,37-40]

In this study, most common isolated organism was Staphylococcus aureus in 43.24% followed by Pseudomonas in 16.22% and E. coli in 13.52% patients. Similar results were seen in studies done by Prokuski et al, Purghel et al, Hassan et al, Kalmeijer et al, Meehan et al and Kumar et al.[41,16,42-44] Since, staphylococcus aureus is the most common isolated organism in our study, it is better to use first generation cephalosporin like cefazolin which is highly active against gram positive organism, safe, cheap and has favourable pharmacokinetic profile as recommended by international guidelines.[22,25,23]

Conclusion

Present study has provided a baseline data of the prescription practices of antimicrobials for surgical prophylaxis in orthopedic surgical procedures in a tertiary care teaching hospital.

Such surveillance study and research help in recognition of areas of special concern which can guide the formulation of antimicrobial prescription policies at individual health care level.

Also, more research has to be conducted to develop new antimicrobial agents which are becoming an "endangered species" owing to loss of interest by pharmaceutical companies in developing newer drugs on one end and development of resistance on the other. If the current scenario goes unchecked, then mankind will not have an efficacious drug to treat serious infection in the near future. That's why appropriate and cautious use of antimicrobials particularly as surgical prophylaxis becomes a necessity so that we can use these wonder drugs in future also. Finally, the development of effective control programs through adoption of measures that restrict use of specific antimicrobials, establishment of therapeutic guideline, a constant monitoring of the antimicrobial resistance pattern of the common pathogenic organisms in the hospital are recommended in order to improve the usage of antimicrobials.

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