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Surgery Section

Original Article

Rational Use of Antibiotics in Postoperative Class 1 Wound: A Prospective Study

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ABSTRACT

Introduction: Surgical Site Infections (SSI) are the cause of significant postoperative morbidity. The role of antibiotics and its rational use for the prevention of operative wound infections has been an area of interest for research.

Aim: To compare the incidence of SSI in postoperative class 1 wound with single dose antibiotic use and its empirical doses.

Materials and Methods: The present study, was a prospective cross-sectional study in which two groups of patients were classified based on usage on antibiotics. Study Group included 100 patients who were given single dose antibiotic (Injection amoxicillin+clavulanic acid in a dose as per weight) within half an hour before the incision for the procedure with no antibiotics being prescribed after the surgical procedure. Control Group included 100 patients who were prescribed antibiotic (Injection amoxicillin + clavulanic acid in a dose as per weight) before the incision for the procedure as well as empirical antibiotics for five days or more after the surgical procedure. Operative wound was examined on day 5, day 8, day 10, day 15 postoperative days, for signs of SSI. Graph Pad online calculator was used for analysis.

Results: Of the 100 patients who underwent clean surgery and received only one dose of preoperative prophylactic antibiotic, three of these patients developed features of SSI (3%). Of the 100 patients who underwent clean surgery and received preoperatively single dose of antibiotics and postoperatively empirical antibiotics for more than five days, two of these patients developed features of SSI (2%) on day five. The difference between groups was statistically not significant (p-0.65). Similarly, the difference was not significant on day 8 (p-0.65) and day 10 (p-0.65), there was no difference between groups at day 15 (p=0.32).

Conclusion: Single dose of antibiotic prophylaxis was therapeutically almost as efficient in comparison with multiple doses of postoperative antibiotic usage for prevention of SSI in uncomplicated elective clean surgery in studied patients.

Keywords: Clean wound, Prophylactic antibiotics, Surgical site infection

INTRODUCTION

Agency for Healthcare Research and Quality defines the SSI as an infection related to an operative procedure that occurs at or near the surgical incision site within 30 days of the procedure or within 90 days to a year of prosthetic material implantation during surgery [1-3]. SSIs are a cause of discomfort, pain, poor surgical outcomes and increased cost of care. SSIs have a significant impact on the quality of life and socioeconomics [3-5]. The Centre for Disease Control guidelines for SSI risk assessment take into consideration; the patient's state of health before the procedure, the duration of the procedure and the surgical wound classification based on its state of contamination [3,5]. As per the Centre for Disease Control, US, The National Healthcare Safety Network Criteria for Classifying Wounds, the operative wounds are: (a) Class I/Clean, (b) Class II/Clean-Contaminated, (c) Class III/Contaminated and (d) Class IV/Dirty-Infected [6]. The guidelines regarding the rational use of antibiotics state that: (a) the prophylactic antibiotics should be started within one hour before the surgical incision or within two hours if the patient is receiving vancomycin or fluoroquinolones; (b) The prophylactic antibiotics given to patients must be appropriate for their specific procedure; (c) Prophylactic antibiotics should be discontinued within 24 hours of surgery completion (within 48 hours for cardiothoracic surgery) [7,8]. These guidelines have led to the improvement of outcomes concerning SSIs. However, the compliance with the guidelines has been a cause of concern, and the antibiotics are often used in empirical doses for longer than recommended duration even for class 1 or clean wounds. This overuse of antibiotics raises the concerns regarding adverse effects, increase in cost and antibiotic resistance [3,7-10].

The data regarding the SSIs in patients given single dose antibiotics and longer duration prophylactic antibiotics are lacking from our region.The study results will give insight regarding SSIs with these antibiotic regimens in our set up, hence present study was conducted with an aim to compare the incidence of infection in postoperative class 1 wound with single-dose antibiotic use and empirical doses at the Surgery department of a tertiary care hospital from the Marathwada region of Maharashtra, India.

MATERIALS AND METHODS

The present study was a prospective cross-sectional study done in the Department of Surgery at Government Medical College, Aurangabad in Marathwada region of Maharashtra state of India. Study duration was December 2014 to November 2016. Ethics Committee of the Institute approved the study protocol (Pharma/IEC-GMCA/458/2014). Informed consent was taken prior to enrolment in the study. Patients with clean surgical wound according to CDC Classification [6] admitted to Department of General surgery was considered eligible for the study, considering the exclusion and inclusion criteria. The Inclusion criteria were: (i) Routine Elective Class 1 wound surgical cases; (ii) Haemoglobin level of the patient more than 10gm%; (iii) Prophylactic antibiotics were administered within ½ hours before the first incision. Exclusion criteria were: (i) Emergency Cases; (ii) Associated co-morbid conditions like diabetic mellitus, immunocompromised status and infection in any other parts of the body; (iii) Prophylactic antibiotics were not administered within ½ hours before the first incision; (iv) Class II, III and IV wounds.

Two groups of patients were classified based on the usage of antibiotics. Group one (Study Group) included a 100 patients who were given single-dose antibiotics (Injection amoxicillin + clavulanic acid in a dose as per weight) within half an hour before the incision for the procedure with no antibiotics being prescribed after the surgical procedure. Group two (Control Group) included 100 patients who were prescribed antibiotics (Injection amoxicillin

+ clavulanic acid in a dose as per weight) before the incision for the procedure as well as empirical antibiotics for five days or more after the surgical procedure. Details of cases were recorded, including history and clinical examination. Routine preoperative investigations were performed in both groups. Regular preoperative preparation of patient was done, e.g., bathing on day of surgery, hair removal of the operative site. Painting of the operative site was done by 10% betadine followed by surgical spirit. Strict asepsis in the operative room was maintained. The best practices of strict asepsis were followed by the surgeon, staff, and the anaesthetist. The sterile postoperative dressing was done. The operative wound was examined on the day 5, day 8, day 10, day 15 postoperative days, for signs of SSI.

STATISTICAL ANALYSIS

Patients from both the study and control groups were compared for final analysis. The data were analysed by applying the chi-square test with Yates correction test. Graph Pad online calculator was used for analysis [11]. The p-value of <0.05 was considered statistically significant.

RESULTS

Mean age of subjects was 37.15±19.8 years. The study group had 56 males and 44 females with mean age 37.71 years±20.4 whereas control group had 60 males and 40 females with mean age 36.59±19.3 years. A total of 94 patients were above 40 years of age [Table/Fig-1]. Inguinal hernia Meshplasty was the most common surgical procedure performed in the subjects followed by breast surgery [Table/Fig-2]. Mean hospital admission time in study group (3.25 days) was significantly less than the mean admission time in control group (5.72 days) [Table/Fig-3].

Age groups (years)	Control group	Study group	Total	%
0-20	20	21	41	20.5
21-40	30	35	65	32.5
>40	50	44	94	47
Total	100	100	200	100

[Table/Fig-1]: Age distribution of control group and study group.

Diagnosis	Control group	Study group	Total	%
Breast surgery	18	14	32	16
Inguinal hernia meshplasty surgery	27	29	56	28
Umbilical hernias meshplasty surgery	7	4	11	5.5
Incisional hernia meshplasty surgery	4	3	7	3.5
Herniotomy	10	10	20	10
Herniorrhaphy	3	2	5	2.5
Testicular surgery	3	5	8	4
Hydrocele surgery	4	4	8	4
Excision surgery	15	19	34	17
Saphenofemoral junction ligation	3	3	6	3
Thyroid surgery	6	7	13	6.5
Total	100	100	200	100

[Table/Fig-2]: Distribution of control group and study group by diagnosis.

Time	Control group	Study group	p-value
Total patient admitted days	572	325	0.003
Total cases	100	100	
Mean duration±Standard deviation (in days)	5.72±5.5	3.25±1.8	

[Table/Fig-3]: Distribution of control group and study group by mean admission time.
Chi-square= 13.062 degree of freedom- 1

There were two infections out of 100 in Control Group and three infections out of 100 in Study Group on day-5 (p- 0.65), day-8 (p-0.65), day-10 (p- 0.65). The difference was statistically not significant. And at day-15; p-value was 0.32 which was also not significant. At the end of day 5, if there was infection on clinical or investigation data, there was appropriate treatment given irrespective of the study or control group. There were 12 wound soakage out of 100 in Control Group of which eight were serous, two haemorrhagic, one seropus, one purulent on day 5. There were 16 wound soakage out of 100 in Study Group on Day -8 and out of which 11 were serous, two haemorrhagic, three seropurulent. Altered healing rate of wounds (Wound Soakage) on day 15 was 9% in Control Group and 9% in Study group. Total wound soakage rate was 9% with no difference observed between the groups (p=1.00) [Table/Fig-4].

Post-Op wound soakage	Control group	Study group	Total	%
Day 5	12	12	24	12
Day 8	12	16	28	14
Day 10	12	16	28	14
Day 15	9	9	18	9

[Table/Fig-4]: Distribution of cases and control by postoperative wound soakage on the day 5, day 8, day 10 and day 15.

Altered healing rate of wounds was 16% in prophylactic antibiotic study Group and 12% in empirical antibiotic used Control group on day 8 and day 10. p-value (0.54) was statistically not significant. Two patients were febrile on day 5 in Control Group. Three patients were febrile on day 5 in Study Group. SSI on day 15 was in 1 patient in control group and in 0 patients in study group but it was not statistically significant as p-value is 0.32 [Table/Fig-5].

The organisms found on culture were: *Staphylococcus aureus* in one patient of control group and *Pneumococcus* in one patient of control group. *Staphylococcus Aureus* was found on culture in two patients of study group. *Klebsiella pneumoniae* was found on culture in one patient of study group.

DISCUSSION

As per present study observations in class I elective surgical wounds; the SSIs in patients with single-dose antibiotics use half an hour before incision were comparable to those in which additional empirical doses of antibiotics were used for five days or more postoperatively. The CDC based on systematic review of studies from1998 through April 2014 guided that antibiotics should be given before the incision such that the bactericidal levels are present in serum and tissues when the incision is made. Also, for clean surgical procedures, antibiotics should not be administered after the incision is closed [12]. Bangaru H et al., [13] studied single dose use of preoperative antibiotics half an hour before incision versus both preoperative and postoperative usage of antibiotics in laparoscopic appendicectomy for non-perforated appendicitis at a tertiary care centre in Telangana state of India. The study results were similar to present study findings with no significant difference between groups for SSIs. Hospital stay postoperatively was shorter in group with single dose antibiotic usage which was also similar to present study results. Agrawal NK et al., study done in Uttar Pradesh state of India has also recommended against use of postoperative antibiotics beyond 24 hours for prevention of SSIs in elective orthopaedic surgeries [14]. However, they have compared three doses of perioperative antibiotics within 24 hours of surgical procedure against more than five days of postoperative antibiotics. They found that longer duration postoperative antibiotics rather increase the morbidity, treatment cost, and increase the risk of antibiotic resistance [14]. The results of present study are in line with the study done by Agrawal NK et al., Karlatti S and Havannavar IB study done at

Complication	Day 5		Day 8		Day 10		Day 15	
	Control	Study	Control	Study	Control	Study	Control	Study
Fever	2	3	2	3	2	3	1	1
Erythema	3	3	3	3	3	3	3	3
Serous soakage	8	7	8	10	8	10	7	6
Seropurulent	1	3	1	3	1	3	0	0
Purulent	1	0	1	0	1	0	1	0
SSI	2	3	2	3	2	3	1*	0*

[Table/Fig-5]: Day wise Surgical Site Infection (SSI) complication.
* p-value is 0.32 i.e., statistically not significant

Belgaum in Karnataka state of India compared single dose of intravenous1 gram Ceftriaxone given half an hour before the incision under aseptic precautions in 105 patients (group A) with clean/Class I wounds against no use of antibiotic in 100 patients (group B) with clean/Class I wounds. There was no case of SSI in group A whereas an infection rate of 3.80% was noticed in group B [15]. This was also comparable with index study. Vinoth N et al., conducted randomised trial in clean/class I wound cases of open inguinal hernioplasty with one group of 30 patients receiving single dose 1g of Injection Cefotaxime half an hour before surgery and other group of 30 patients not receiving any antibiotics. The SSIs were 6.67% in antibiotic group and 10% in no antibiotic group with no significant difference between groups [16]. Shankar VG et al., also found no significant difference in randomised groups with or without single dose antibiotic prophylaxis in open mesh repair of inguinal hernia [17]. Similarly, Alagarsamy GS and Ramasamy R study found no significant difference in randomised groups with or without single dose antibiotic prophylaxis in Lichenstein's Hernioplasty [18].

This further stress the need for adherence to guidelines for judicious antibiotic use to reduce the risk of antibiotic resistance, drug adverse effects, and the cost of therapy, especially in developing countries.

Limitation(s)

It was a hospital based study design, and the study sample was not adequate and may not be representative of the target population. Randomised trials need to be done for assessing the SSI rates in these study groups to further consolidate the importance of following guidelines of single-dose antibiotic usage in elective class I surgical wounds.

CONCLUSION(S)

Single dose of antibiotic prophylaxis is an effective mode of prevention of SSIs. It was found to be almost as efficient as the multiple doses of postoperative antibiotic usage for the prevention of SSI in uncomplicated elective clean surgeries. Further studies are needed on the subject so that evidence based awareness can be undertaken to avoid excess use of antibiotics and thereby reduce the cost of therapy as well as the chances of antibiotic resistance.

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