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PROLONGED VERSUS SHORT COURSE OF ANTIBIOTIC PROPHYLAXIS IN CLEAN GENERAL SURGERY

Mohsin Ali, Muhammad Nadeem, Sayed Zamen Ali Shah, Mah Muneer Khan, Moshtaq Ahmad, Mian Asad Ullah

Department of Surgery, Khyber Teaching Hospital, Peshawar - Pakistan

ABSTRACT

Objective: To compare the effect of prolonged (5 day) versus short term (1 day) Antibiotic prophylaxis in preventing surgical site infection (SSI) in clean-non implant general surgery.

Material and Methods: This randomized control trial was conducted in Surgical "A" ward, Khyber Teaching Hospital, Peshawar from May 2009 to December 2009. Sixty eight consecutive patients aged 13-29 years who underwent clean, non-implant general surgery were included. They were equally divided into two groups. Group A received short term while group B received prolonged antibiotic prophylaxis. All the patients were assessed for 30 days post-operatively for the development of surgical site infection. Data was recorded and analyzed using SPSS version 10.0. Chi Square test was performed and P-value < 0.05 was considered significant.

Results: Out of 68 patients 3 (4.4%) developed SSI, 2 (5.9%) in group A and 1(2.94%) in group B. The SSI rate between two groups was statistically insignificant (p value 0.55).

Conclusion: Short term antibiotic prophylaxis in clean general surgery is sufficient to reduce the rate of SSI.

Key Words: Surgical site infection, clean non-implant general surgery, antibiotic prophylaxis.

INTRODUCTION

Surgical site infections (SSI) are the most common hospital acquired infection in surgical patients and are associated with increased morbidity and mortality as well as with prolonged hospitalization and treatment cost[1,2]. SSI is a complex process and influenced by many host, local and surgical factors but the level of bacterial contamination is the most significant risk factor[3]. Antibiotic prophylaxis is one of the many preventive measures. Its efficacy and impact has been clearly demonstrated to be significant, and it is generally agreed that antibiotic prophylaxis is warranted in all clean-contaminated and contaminated surgical procedures[3,4]. The use of antibiotic prophylaxis in clean surgery is controversial. It is generally not indicated in non-implant clean surgeries, in patients with no additional risk factors[3-5].

In this era of evidence based medicine there are clear recommendations and guidelines regarding the indications, choice, timing, route and duration of prophylactic antibiotic use[3,6]. A single preoperative dose of prophylactic antibiotics, at the time of induction, is used for clean-implant and clean-contaminated surgical procedures. Additional doses are generally only recommended when the operation lasts longer than 2-3 hours or there is massive blood loss causing low effective serum concentration of prophylactic antibiotics[3,6,7]. Unfortunately the recommendations are generally not complied with[8]. The degree of compliance fluctuates between countries and centers, duration being the most violated parameter[9]. This non compliance to guidelines of antibiotic prophylaxis associated with the emergence of resistant bacteria strains[10], has increased the cost of the treatment and occurrence of adverse effects[11].

An overzealous prophylaxis is one form of antibiotic misuse and must be discouraged. This study is an effort to evaluate the role of prolonged antibiotic prophylaxis in prevention / reducing the rate of surgical site infection in clean general surgery, as this is common practice in our hospital and in many other hospitals of the country.

MATERIAL AND METHODS

This randomized control trial was conducted in Surgical 'A' Ward, Khyber Teaching Hospital, Peshawar, from May 2009 to December 2009. A total of 68 patients were enrolled and were randomly divided into two equal groups, A and B. In both groups injection Co-Amoxiclav 1.2 gm (Augmentin) was given at induction of anesthesia, second dose after 8 hours

Address for correspondence:
Dr. Mohsin Ali
Former Trainee Medical Officer
Department of Surgery, Khyber Teaching Hospital,
Peshawar - Pakistan
Cell: 0333-9472332
E.mail: drmohsinjan@yahoo.com

and 3rd dose after 16 hours of the 1st dose, making a total of 3 doses. In group A, further antibiotics were stopped while in group B, the prophylactic antibiotics were continued for the next 4 days in the form of tablet Co-amoxiclav 1gm 12 hourly making a total of 5 days of prophylaxis.

Patients who underwent different non-implant clean general surgical procedures were included. Patients with diabetes, obesity, HIV and uremia, patients on steroids or antibiotics and patients who had a remote infection were excluded from the study. Also, patients whose wound status changed from clean non-implant to implant, clean contaminated, contaminated or dirty and those who were allergic to the chosen prophylactic antibiotic were excluded to control the confounder variables and bias.

The patients were admitted through OPD a day before surgery. Informed written consent was taken and thorough clinical examination and pre-operative investigations done to assess the patients for inclusion. The clean non-implant general surgery was defined as that surgery in which the incision was made through un-inflamed tissue at elective surgery under aseptic technique, closed primarily, with no use of an implant or prosthesis, no breach of the alimentary, respiratory and genitourinary tracts and the use of closed drainage system when needed. The operation site was shaved just before the incision, when needed, and the area was prepared with povidone iodine and wiped away with 70% ethanol. In case of hernia repair, suture repair with polypropylene (prolene) was done. In all cases no subcutaneous stitches were taken and the skin was closed with prolene suture.

The surgical wounds were assessed for surgical site infection on the 2nd post operative day and the patients were discharged on the same day. The patients were followed on the 7th-9th post operative days in the OPD and were assessed for surgical site infection and skin stitches removed. Further assessment was done on the 15th and 30th post operative days as follow up in the OPD, when feasible to the patient or through telephonic inquiry. All patients were educated about the signs and symptoms of surgical site infection and were asked to report if any occurred.

Surgical site infection was diagnosed if one or more of the following occurred: presence of purulent discharge from the surgical wound, bacterial growth in culture of non-purulent discharge from the wound and pain in the wound with presence of local (tenderness / erythema) and / or systemic signs of inflammation, within 30 days of surgery. The SSI was further divided into superficial, when only the skin and subcutaneous tissues were involved, and deep, when there was involvement of fascia and muscles. The discharge from the surgical wound was sent for cytology to know the WBC count and also was cultured. Data was recorded and was analyzed in SPSS version 10.0. Chi Square test was performed to compare the outcomes of both groups. P-value < 0.05 was considered as significant.

RESULTS

A total of 68 patients were recruited for the study. In group A (n= 34) the age ranged from 13 to 59 years. Mean age was 29.35 $\pm$ 12.00 years. In group B (n=34) the age ranged between 14 and 59 years. Mean age was 32.5 $\pm$ 13.32 years. In group A, 14 (41.2%) patients were male whereas 20(58.8%) patients were female. In group B, 10(29.4%) patients were male and 24(70.6%) patients were female. Ten different clean non-implant surgical procedures were performed. Excision of benign breast lump (10 in each group) was the most common, followed by inguinal hernia repair (9 in each group) and paraumbilical hernia repair (5 in each group as shown in Table 1.

A total of 2(5.9%) patients developed SSI in group A. One (2.94%) patient developed superficial

Table 1: Procedures performed in patients of both groups

Procedure	No. of patients		% age
	Group A	Group B	
Excision Biopsy of axillary L.node	2	2	(5.88)
Repair of Epigastric Hernia	2	2	(5.88)
Excision Biopsy of Breast Lump	10	10	(29.41)
Repair of Inguinal Hernia	9	9	(26.47)
Stripping of Varicose Veins	2	2	(5.88)
Excision Biopsy of Lipoma	2	2	(5.88)
Repair of Paraumbilical Hernia	5	5	(14.7)
Subtotal thyroidectomy	1	1	(2.95
Repair of Femoral Hernia	—	1	(1.47)
Excision of Parathyroid Adenoma	1	—	(1.47)
	34	34	
Total 68	(100)		

SSI while the other (2.94%) developed deep SSI. One (2.94%) patient developed SSI in Group B which was deep. All these patients presented with purulent discharge and local signs of inflammation on the 7th post-op day. In both deep SSIs, the discharge was positive for Staphylococcus aureus on culture, while no growth was obtained from superficial SSI. In Group A, superficial SSI occurred in one patient who underwent paraumbilical hernia repair while deep SSI occurred in a patient who had axillary lymphadenectomy. In group B, deep SSI occurred in a patient who underwent paraumbilical hernia repair. The SSI rate between two groups was statistically insignificant (p value 0.55).

DISCUSSION

In this randomized clinical trial, of a total of 68 patients, 3 (4.4%) developed SSI which is comparable to the SSI rate reported in literature, i.e 1.5%-4%[1,2,12-14]. There are very few studies available with the same objectives as most of the studies done have compared no antibiotic prophylaxis (ABP) versus only single intravenous dose of ABP given at induction[3,13,14]. Ali MN et al[15] found that only 1% of patients developed SSI out of 300 patients receiving 2 doses of I/V prophylactic antibiotics. Sajjad Ansari et al[16] compared 3 doses of intravenous antibiotics with no ABP in different clean surgical cases and found no statistically significant difference between the two groups. In one study[17] an increased SSI rate was noticed in the prolonged ABP group (3 patients) as compared to the short course (1 patient). Excision of fibroadenoma was performed in 10 (29.5%) patients in each group and no SSI occurred in these patients in either group. This finding is comparable to other studies[16,18-20]. The antibiotic prophylaxis should be considered in breast cancer surgery and breast reshaping procedures and is recommended in breast surgery with implants[21,22].

None of the patients who underwent inguinal hernia repair developed SSI. Lilani SP[19] found that 1 patient out of 57 (1.75%) operated for inguinal hernia developed SSI. The use of ABP for classical inguinal hernia surgery is controversial, where the reported rate of SSI varies from 1% to 14%[23-26]. Platt et al[23] and Lazarthes et al[24] found ABP to be of benefit in classic inguinal hernia repair, but others[25,26] failed to document any benefit in terms of prophylaxis. Two SSIs occurred in patients operated for paraumbilical hernia, one in each group, accounting for 20% of SSI rate in this group of patients. This finding is comparable to the finding of Farrow B at al[27] who documented 19% SSI rate. However this rate is significantly higher than the 1.8% to 11.5% SSI rate reported in other studies[28,29].

The first dose of prophylactic antibiotics was administered at the time of induction in both of the study groups. Early clinical trials in the 1950·s reported either no benefit or higher SSI rate with antibiotic prophylaxis[31]. Apart from other flaws, the faulty timing of the initial antibiotic administration, post operatively in the recovery room, was a major factor for the disappointing results of these early studies. It was in 1961, that Burke[32] established the importance of the presence of prophylactic antibiotics in tissues at the time of bacterial contamination and hence the rationale of administering the initial dose of prophylactic antibiotics before the incision is given. This led to clear reduction in the rate of wound infection[33].

In our study the patients were followed for 30 days according to international guidelines for defining SSI[34]. All the 3 SSIs in this study were identified on the 7th post operative day when they presented to the outpatients department for follow-up with purulent discharge and pain in the wound. This finding is comparable to other studies in which most of the SSIs were identified on post discharge surveillance[18,35]. Various studies have reported that the pathogen isolated from SSI varies according to the type of surgery as well as the organ and location[34]. Staphylococcus aureus has been described as the most common single pathogen involved in SSI[34,36].

The major limitations of this study are prolonged (5 days) ABP regime in group B and small sample size. Prolonged antibiotic use is a very common practice, even for clean surgery, in most of the hospitals of our country. It is commonly feared that in our set up, surgery is performed under sub-optimal conditions and the sterility is frequently breached. If this fear is correct even then the clean surgical procedures are classified as clean contaminated and only a single dose antibiotic as prophylaxis given just before the incision is recommended[37,38]. Different studies concluded that the duration of prophylactic antibiotics in surgery is the most commonly violated parameter[9,39,40].

CONCLUSION

Short term antibiotic prophylaxis is sufficient to reduce the rate of SSI in clean surgery.

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