Efficacy of Short Versus Extended Course of Prophylactic Antibiotic in Clean Surgery

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ABSTRACT

Background: Prophylactic drugs are one of the measure to prevent surgical site infection. It has been clearly demonstrated that it's impact are significant and guaranteed in all clean contaminated and contaminated surgical procedures.

Objective: To compare the efficacy of short term versus extended course of antibiotic prophylaxis in clean general surgery in terms of surgical site infection.

Material & Methods: This Randomized Control Trail was carried out at the General Surgery Department of Khyber Teaching Hospital, Peshawar, from 15th June 2016 to 14th May 2018. 1192 patients fulfilling the inclusion criteria were divided randomly into two groups A and B by lottery method. Injection augmentin 1.2g was administered to all patients of both groups at the time of induction of anesthesia, 2nd and 3rd doses after 8 hours and 6 hours respectively. Further antibiotic was stopped from group A and group B started with Tab augmentin 1g twice a day from 2nd post operative day for 5 days. The wound was evaluated for infection on 2nd, 7th, 15th and 30th post operative days in the OPD.

Results: Age range was from 17 to 59 years with mean age of 39.60± 9.46 years in Group A while 35.055± 8.04 years in Group B. Mean BMI was 27.952±2.88 Kg/m^2 in Group A and 27.624±3.30 Kg/m^2 in Group B. Mean duration of procedure was 44.664±15.79 minutes in Group A and 48.439±15.79 minutesin Group B. Surgical site infection was observed in 8.4% patients in Group A as compare to 3.4% in Group B.

Conclusion: Short term antibiotic prophylaxis is sufficient to reduce the infection rate of surgical site instead of prolonged use in clean surgery without implant.

Keywords: *Antibiotic Prophylaxis, Prolonged, Short, Clean Surgery, Surgical Site Infection.*

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INTRODUCTION

Surgical site infection (SSI) is still one of the feared complications of surgical procedures, increase patient morbidity , hospital stay and treatment cost. Clean surgical procedures account for approximately 60% of all procedures and 40% of all wound infections.[1] SSI is a multifaceted problem and is influenced by local, surgical and many host factors but the level of contamination with bacterial is the most important risk factor[2]. On the basis of microbial contamination and risk for infection, the US national research council classifies surgical wounds into clean, clean contaminated, contaminated and dirty. The infection rate for them is 1-2 % or less, 6-9%, 13-20% and 40% respectively[3].

It has been clearly demonstrated that the impact and efficacy of antimicrobial prophylaxis is significant and generally accepted is one of many measure in prevention of wound infection in clean contaminated and contaminated procedures.[4] In dirty surgical procedures the use of antibiotics are essentially therapeutic[5]. Antibiotics are generally not indicated in clean procedure without implant and with no additional risk factor[6]. In certain clean surgeries e.g cardiac or vascular grafting, placement of orthopedic implants, where the infection though rare may have fatal results, prophylactic antibiotics are indicated and beneficial[7]. Even in hospital undergoing renovation Osvaldo Iribarren, recommends no antibiotic prophylaxis for low risk patient and single does for high risk patient in clean surgery.[8] The prolonged antibiotic prophylaxis in clean general surgery is even not supported by the national studies.

The clinical studies have standardized the choice, route, duration and timing of antiboitic prophylaxis. A simple dose of antibiotic prophylaxis is used preoperatively for clean implants and clean contaminated surgery. Further doses are recommended only when the duration of surgical procedure lasts more than 2 to3 hours[9,10].

The rationale of the study was that unfortunately the prolonged (5-7 days) antibiotic prophylaxis, even for clean surgery, is still common in our setup. This may be due to the surgeon's fear of wound infection due to suboptimal surgical environment and sterilization. The antibiotics are

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Amongst the most misused drug, which not only increases the treatment cost unnecessarily, but also expose the patient to its toxicity and side effects. The misuse of antibiotics may cause resistance to antibiotics and should be dispirited.

The aim of this study is to evaluate the efficacy of short versus extended course of antibiotic prophylaxis in preventing the rate of wound infection in clean surgical procedures in our setup.

MATERIAL AND METHODS

This randomized control trial was conducted in the Department of General Surgery, Khyber Teaching Hospital, Peshawar from 15th June 2016 to 14th May 2018. Consecutive Sampling (Non Probability) technique was used and sample size was calculated with confidence level= 95%, alpha= 5%, power : 80%. P1= 2.94%.[11] and P2= 5.9%[11]. Estimated sample size was 1192.

Patients who underwent clean general surgery without implant above the age of 16 years and below the age of 60 years irrespective of the gender were included. Diabetic, obese, HIV and uremic patient, patient taking steroid, antibiotics, having remote infection, implanted clean, clean contaminated, contaminated or dirty and patient allergic to the antibiotic were excluded.

After approval from the Ethical Committee of Khyber Teaching Hospital and written informed consent from the patients fulfilling the inclusion criteria were admitted through OPD. All patients were admitted and detailed history, examination and investigations were done. All patients were divided into group A and group B randomly by lottery method.

Injection augmentin 1.2g was administered to all patients of both groups at the time of induction of anesthesia, 2nd and 3rd doses after 8 hours and 6 hours respectively, making total 3 dose. Further antibiotic was stopped in group A and Tab augmentin 1g twice a day was started in group B from 2nd post operative day for 5 days.

Adopting aseptic technique, the area was shaved if needed, at the time of procedure. The area was prepared with povidone iodine and was wiped away with 70% ethanol. Propylene suture was used for hernia repair and the same for skin closure. A closed system of drainage was employed if needed for hematoma prevention. Those who develop erythema, painful wound swelling with purulent discharge at surgical site or culture positive were considered as surgical site infection.

On 2nd post operative day the wound was assessed for SSI and patient discharged if indicated. Stitches were removed 7th postoperative day and also assessed for SSI on 7th, 15th and 30th postoperative days in OPD. The patients were also counseled regarding discharge, severe pain in the wound or fever and report in OPD or ward.

Data was collected by resident on duty using pre designed proforma and analyzed by using SPSS 22. Categorical variables were expressed in frequency and percentages while continuous in mean and standard deviation. Stratification was done with regard to age, type of surgery, duration of procedure and BMI to see the effect of these variables on surgical Site Infection. Chi-square test was applied to compare surgical Site Infection in both groups taken P =0.05 as significant.

RESULTS

A total of 1192 patients were studied in which age range was from 17 to 59 years with mean age of 39.60± 9.46 years in Group A while 35.05± 8.04 years in Group B. Mean BMI was 27.95±2.88 Kg/m^2 in Group A and 27.62±3.30 Kg/m^2 in Group B and Mean duration of procedure was 44.66±15.79 minutes in Group A and 48.43±15.79 minutesin Group B.

Frequency and percentage of type of surgery in both groups are shown in Table-I.

Surgical site infection was seen in 8.4% patients in Group A as compare to 3.4% in Group B (P=0.000).

In less than 60 minutes operation duration, SSI was 9.2% in group A while 3.3% in group B with P-value 0.000 and in more than 60 minutes operation duration, SSI was 3.3% in group A while 3.8% in group B with P- value 0.916.

In less than 30 years of age, SSI was 4.7% in group A while 2.2% in group B with P-value 0.0268 and in more than 30 years of age, SSI was 9.% in group A while 3.7% in group B with P-value 0.000.

Stratification of surgical site infection in both groups with regard to BMI and type of surgery are shown in Table-II, and III respectively.

Table-I: Frequency and Percentage of Type of Surgery in both groups

Type of Surgery	n=596	n=596
	Group A	Group B
Inguinal, epigastric, para umbilical hernia repair	190 (31.9%)	291 (48.8%)
Mastectomy, Fibroadenoma excision, lumpectomy	43 (7.2%)	48 (8.1%)
Soft tissue surgery: lipoma, lymph node biopsy	320 (53.7%)	199 (33.4%)
Surgery for varicocele and Hydrocele	43 (7.2%)	58 (9.7%)
Total	596 (100%)	596 (100%)

Table- II
Stratification of surgical site infection with respect to BMI in Both groups

For BMI ≤ 25 Kg/m^2			
Group	Surgical site infection		P value
	Yes	No	
A	19(9.7%)	176(90.3%)	0.020
B	6(3.6%)	162(96.4%)	
For BMI > 25 Kg/m^2			
Group	Yes	No	
A	31(7.7%)	370(92.3%)	0.004
B	14(3.3%)	414(96.7%)	

Table- III
Stratification of surgical site infection with respect to type of surgery in Both groups

Inguinal, epigastric, para umbilical hernia repair			
Group	Surgical site infection		P value
	Yes	No	
A	18(9.5%)	172(90.5%)	0.028
B	13(4.5%)	278(95.5%)	
Mastectomy, fibroadenoma excision, lumpectomy			
Group	Yes	No	
A	2(4.7%)	41(95.3%)	0.493
B	1(2.1%)	47(97.9%)	
Soft tissue surgery: lipoma, lymph node biopsy			
Group	Yes	No	
A	29(9.1%)	291(90.9%)	0.000
B	3(1.5%)	196(98.5%)	
Surgery for varicocele and Hydrocele			
Group	Yes	No	
A	1(2.3%)	42 (97.7%)	0.468
B	3(5.2%)	55(94.8%)	

DISCUSSION

The commonest hospital acquired infections in surgical patients are SSI which increase antibiotic usage, costs and prolonged hospital stay. The risk of postoperative wound infections can be reduced by appropriate antibiotic prophylaxis, but additional antibiotic use also increases the antimicrobial resistance[12,13].

The original antibiotic prophylaxis experiments in surgery were performed in pigs 40 years ago. The results concluded that 'the most effective period for prophylaxis begins the moment bacteria gain access to the tissues and is over in three hours[14].

Nowadays approximately 30-50% of antibiotics are used for surgical prophylaxis in hospital among which 30% to 90% is inappropriate. Most commonly, the antibiotic is given at the wrong time or continued for too long[15]. Controversy remains as to duration of prophylaxis and also as to which specific surgical procedures should receive prophylaxis[14]. The SSI rate reported in the literature is 1.5% to 4%[16-20] and we have observed similar result in our study which is 5.87%.

In a study by Ali M, et al. has showed that frequency of surgical site infection was 2.94% in prolonged versus 5.9% in short term use of prophylactic antibiotic in clean surgical operation[11]. We observed similar results in our study in which SSI was seen in 8.4% patients in Group A versus 3.4% in Group B (Prolonged course of antibiotic prophylaxis) with P- value 0.000 which statistically significant.

Various studies showed that single dose antibiotic is given prophylactically at the time of induction of anesthesia and compared it with without antibiotic prophylaxis (ABP)[19,20]. In our study we administered prophylactic antibiotics similarly at the time of induction but we compared short course (three doses) with prolong course i.e. for five days. Ali MN et al studied three hundred patients who received two doses of intravenous prophylactic antibiotics, only 1% of patients developed SSI[21]. In our study the SSI rate after three doses of prophylactic antibiotic was 8.4% out of 596 patients .

In a study conducted by Sajjad Ansari et al in which they compared three doses of antibiotics prophylaxis with no ABP in various clean procedures. They found that there is no statistically significant difference between the two groups[22]. In another study they found more SSI rate in the group of prolonged ABP (3 patients) than the short course (1 patient) of prophylactic antiboitics[23]. Similar findings were also noted in our and other studies[22,24-26]. The antibiotic prophylaxis should be considered in breast cancer surgery and breast reshaping procedures and is recommended in breast surgery with implants[27,28].

The use of antibiotic prophylaxis in inguinal hernia operation is controversial and various studies have reported various surgical site infection rate which varies from 1 to 14%. Regarding use of antibiotic prophylaxis Platt et al and Lazarthes et al found beneficial while others failed to document it's benefit[25,29-32]. 19% surgical site infections is also documented by Farrow B at al[33] which is high than our study and other studies as documented which varies from 1.8 to 11.5%[34,35]. It is reported in the early clinical trials in 1950, that the rate of SSI rate is either high or not beneficial with the use of prophylactic antibiotics[36]. The higher SSI rate in various studies may be due to administration of first prophylactic antibiotics in wrong time i.e. after surgery in the recovery room.

Burke recognized in 1961, that presence of prophylactic antibiotic in tissues is very important at the time of contamination with bacteria. So the first dose of prophylactic antibiotic should administered before giving the incision which reduces the rate of SSI[37,38].

We followed the patients for thirty days for SSI rate as defined by international guidelines[39]. In our study the SSI rate was noted on 7th post-operative day in OPD during follow up and presented with pain and pus discharge in the wound. Our findings are comparable to other studies in which they noted SSI rate on post discharge surveillance[24].

The use of prolong course of antibiotic is very common practice, even for clean surgical procedures in our setup. Most of the time we feared that the sterilization and environment is breached and sub-optimal. If it is correct then our clean surgical procedure may classified as clean contaminated surgery. For clean contaminated surgery, administration of a single dose of prophylactic antibiotic is recommended before giving the incision[40]. The duration of prophylactic antibiotic is most violated parameter in surgery as concluded in various studies[41]. The limitation of the study is heterogeneous group of patients treated.

CONCLUSION

Short term antibiotic prophylaxis is sufficient to reduce the infection rate of surgical site instead of prolonged use in clean surgery without implant. We are recommending short term use of antibiotics instead of prolonged use in clean surgery prophylactically in our setup.

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