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Original Research Article

Empirical Vs Single Antibiotic Therapy in Non Septic Orthopaedic Surgeries: A Comparative Assessment

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Abstract

The surveillance of SSI brings about the awareness to the present day modern ortho surgery the need of having knowledge of appropriate use of aseptic and antiseptic technique. Proper use of prophylactic antibiotic and therapeutic antibiotic and adequate monitoring and support with novel surgical and pharmacological as well as non-pharmacological aids. The present study compares the single antibiotic with empirical antibiotic in clean elective orthopedic procedures.

Objective: To compare the efficiency of single prophylactic antibiotic therapy with empirical antibiotic in clean surgical procedure**.**

Methodology: A sample of 100 patients were selected from amongst the IPD of VIMS Gajraula and were divided in 2 categories of I- Single prophylactic antibiotic usage in clean and other who received empiric therapy after surgical procedure.

Observations: 4/50 cases of Class I developed SSI whereas 3/50 cases of Class II developed SSI after empirical therapy. The overall p value when no antibiotic group was compared to empiric group was found 0.201/0.271.

Conclusion: The use of no antibiotic therapy in surgical procedure is near to as effective as that of empiric antibiotics in clean case I and II. This prevents the misuse of antibiotic, multi drug resistance and drug toxicity and cost efficient. The data was analyzed by z test, p value of < 0.05 was considered statistically significant.

Introduction

Because infection after any surgery is often catastrophic and can cause through airborne and contact contamination of the wound may be more significant in this procedure than in others because of the quantity of foreign material left in the patient, aseptic in the operating room is crucial. [1]

By definition the patient is the source of endogenous bacterial contamination; sealing off the skin edges from the rest of the wound and the use of water repellent surgical drapes help prevent this type of contamination. Whether laminar flow room should be used for total hip arthroplasties or whether the rate of infection is essentially the same when the operations are performed in conventional operating rooms is controversial. Charnley's rate of infection after surgery was once 8%; this was reduced to about 1% after he began using laminar flow rooms and hoods and gowns with body exhaust systems. Therefore, he believes that airborne bacterial contamination is important in infections after surgery [1,2].

Furthermore, whether the routine use of prophylactic antibiotics is necessary when the procedure is carried out in a laminar flow room is controversial too. We do not use such antibiotics in patients who have had no previous surgery on the hip. [3-5] The scientific basis for the use of prophylactic use of antibiotics in surgery was laid by Miles and Burke in the late 1950s. They demonstrated that infections could be prevented only when AMAs (anti-microbial agents) were given prior to or at the time of infectious challenge. They also concluded that AMAs administered after three hours after the infectious challenge were ineffective in preventing infection. Strachan and his colleagues performed the first prospective controlled trial, which investigated the proper post operative duration of administration of AMA in 1977. They concluded that there was no advantage of administering more than a single dose of AMA, preoperatively and no further doses were necessary postoperatively. [4-6] The surveillance of SSIs brings about the awareness to the present-day modern surgeon the need of having the knowledge of the appropriate use of aseptic and antiseptic technique, proper use of prophylactic and therapeutic antibiotics and adequate monitoring and support with novel surgical and pharmacological as well as non-pharmacological aids. Prophylactic antibiotic therapy is clearly more effective when begun preoperatively and continued though intra-operative period,

with the aim of achieving therapeutic blood levels throughout the operative period A single dose, depending on the drug used and length of the procedure, is often sufficient. Prophylactic antibiotic coverage for more than 12 hours for a planned operation is never indicated. [7,8]

Material and Method: The study sample comprised of 100 Patients admitted at Venkateshwara Institute of Medical Sciences and Hospital, Gajraula for the study group class I clean wound with single dose antibiotic therapy and while the control group class II clean wound received empirical antibiotic for 5-10 days.

Calculated Sample Size = 100 divided in 2 categories as follows

- Clean Surgery with single dose antibiotic = 50 cases
- Clean Surgery with empirical antibiotic = 50 cases

Inclusion criteria

a. Including both genders and adults.
b. Patients admitted in orthopedic ward
c. Patients able to provide consent.

Exclusion criteria

a. Patient with implants or prosthetic material.
b. Patient with diabetic mellitus or any systemic illness.
c. Patients on steroids, chemotherapy or immune suppression.
d. Contaminated cases are excluded.
e. Emergency cases were excluded.
f. Pregnant cases/patients were excluded.
g. Patients below 18 years were excluded.
h. Those patients who do not consent are excluded.

Method of Collection of Data: Details of cases were recorded including history and clinical examination. Routine pre-operative investigation was performed in both groups. The study group received a single dose of antibiotic while the control group received antibiotic post-operatively cloxacillin and gentamycin 12 hourly orally/IV/IM, as circumstances permit. Operative wound was examined on the second, fifth and eighth post- operative days for signs of surgical site infection on like seroma, oedema, erythema, tenderness, abscess, pus discharge and gaping of wound. Patient from both the study and control groups were compared for final analysis.

Observation: The study was conducted on total of 100 patient aged 18 – 70 years, of which 50 underwent clean surgical procedure with single antibiotic and 50 underwent surgical procedure of therapeutic antibiotics.

Table 1: Result in Class I

Single Dose Antibiotics	SSI	NO SSI	Percentage
	4	46	8%

Of the 50 patients who underwent Class I surgeries received single antibiotic; 4 of these patients develop feature of SSI (8%), 2 erythema and tenderness around the incision site, 1 seroma collecting with tenderness, 1 slight purulent discharge.

Table 2: Result in Class II

Empirical Therapy	SSI	No SSI	Percentage
	3	47	6%

In Class II samples, the 3 patients developed signs of Surgical Site Infection, which included 1 erythema and tenderness cases and 2 serous discharges around one and two stitching and no purulent discharge.

In present study, prophylactic antibiotics were used in 50 cases of class I group.

Discussion

Despite familiarity with recommendation that show no benefit of post-operative antibiotics prophylaxis, many surgeons continue to administer antibiotic post-operatively. Respondents in studies said that they would be willing to change their practices if a well performed study was published regarding the use of pre-operative antibiotic in closed orthopaedic trauma case [9-11]. Therefore, in present study we compare the study in two groups in clean cases. One group (I) of cases single antibiotic had been used before and after surgical interference and other group (II) of clean case uses empirical use of antibiotics post-operatively.

On comparing the single dose prophylaxis group with that of the group that received multiple post-operative doses of antibiotics by different authors, the p value was found to be 0.49 and similarly in the present study with no antibiotics in class I group and empirical therapy multiple post-operative doses in class II group found p value < 0.05, thus it was concluded that there was no statistical significance between the two groups as compared to other authors. [12-14]

Study	Percentage of SSI	P Value
Mohri et al	Empiric – 8.6% Prophylactic – 9.5%	< 0.05
Oostvogel et al	Empiric – 1.8% Prophylactic – 3.1%	< 0.05
Present Study	Empiric – 6% Single dose Antibiotic – 8%	< 0.05

The antibiotic selected should in general, be inexpensive, non-toxic and of limited spectrum. The most prevalent organism in prosthetic related infection are gram-positive, staphylococcus aureus and epidermidis. They are normally present as skin flora and can adhere to implant and multiply. National clinical practice guidelines on rationale use of antibiotic in orthopaedic surgery in Malaysia recommends cloxacillin combination with gentamycin as first choice. Second generation cephalosporin as second choice antibiotics in arthroplasty and open reduction and internal fixation of fracture. Second generation cephalosporins (cefuroxime) have been widely recommended as choice by many studies. [13,14]

Total 100 patients were taken in the present study and were divided into two groups; 50 patients of study group (class I) and 50 patients of control group. Patients in control group were treated with post-operative antibiotics. While patients in study group were treated with single dose antibiotics.

In this study of 100 cases out of which 17 cases were more than 50 years of age group and 83 were below 50 years of age group. Chhabra et al found the cases of ages more than 50 years most commonly developed SSI. Increasing age was found to be a significant influence on the rate of infection. Increased infection rates among the elderly may be attributed to low healing rate, mal absorption and low immunity. The above factors can't be ruled out as we don't know the status quo in patient. [15]

In this study 100 patients of which 57 were male and 43 were females. 5 out of 57 males developed SSI as compared to 3 of 43 females developed infection. In this study smoking was associated with higher incidence of SSI. 26 patients were smokers and 74 were nonsmokers. Of 26 patients 5 developed SSI and 2 out of 74 nonsmokers developed SSI. Masood et al showed 25% infection rate among smokers smoking has detrimental effect on tissue oxygenation, impairing reparative process of wound healing and neutrophile defense against surgical pathology. [16]

There is significant association present for complications like pain, swelling, wound discharge. Complications occurred in both study group and control group were more or less same. The same results were observed in the study of Thejaswi et al. 2012. [17]

There was no significant association of surgical site infection (0.400) in class I, surgical site infection occurred in both groups were same in manner. Similar findings were found by Rejab et al., 2012 [18].

The grades of infection (P value – 0.8167) occurred in both groups showed no significant difference. Bangaru et. al., 2017 studied using prophylactic and post-operative doses showed similar findings. [19]

The duration of post-operative hospital stay in control group is more (1-3 days – P value- 0.04(*), 4-7 days- 0.02(*), > 7 days 0.0198(*)) as compared to study group. This is due to multiple doses of antibiotic administered to control group. A study conducted by Shah et. al. 2015 showed the similar findings. [20]

Conclusion

Our study shows that single dose antibiotic was given prior or post-surgery in clean (class I) cases and post-operative multiple doses were administered to clean (class II) cases. There are many risk factors associated with SSI such as age >50, sex – male, hemoglobin percentage <10 gm pre operatively, total count >11,000, smoking, duration of the surgery >2 hours and so on. In present study all above factors were considered very meticulously.

The rate of surgical site infection was near to similar in patients who received single pre- or post-operative doses of antibiotic in comparison to those who received multiple doses of antibiotics post-operatively. The p value was found to be 0.29 (< 0.05), which was not significant. Studies focusing on this comparison are needed.

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