Ampicillin/Cloxacillin Antibiotic for Prevention of Surgical Site Infections in Clean Orthopaedic Surgeries

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Abstract

Post-operative surgical site infection pose large health burden and use of prophylactic antibiotics in the surgical treatment is well-established however, the duration and dosage of prophylaxis varies substantially among surgeons. To assess the prophylactic efficiency of Ampicillin/Cloxacillin (ampiclox) in two antibiotic regimen for prevention of surgical site infection in clean orthopaedic surgery. This is a prospective observational study conducted for 1 year, 96 patients of either sex of 7-45 years age were included in this study. Forty eight patients receive antibiotic regimen 1 Ampicillin/Cloxacillin vial intravenously 500 mg, 8 injectable doses, the first dose was given during induction of anaesthesia before tourniquet use, followed by every 6 hours dose. Then oral antibiotic Augmentin (amoxicillin + clavulenic acid 250 or 500 mg for 5 days) was taken. In addition, Forty-eight patients received Regimen 2: Ampicillin/Cloxacillin vial intravenously 500 mg 4 doses, the first dose given during induction of anaesthesia before tourniquet use, followed by every 6 hours dose. Patients followed up for 3 months. Postoperatively 6.24% of patients treated by regimen 1 were infected at day 10 while 10.41% of patients treated with regimen 2 were infected at day 10. Type of microorganism involved mostly was Pseudomonas.

As a conclusion, Ampicillin/cloxacillin (ampiclox) is good prophylactic antibiotic to prevent post-operative surgical site infection in clean orthopaedic surgery and may replace the commonly used 1st generation cephalosporin. Use of Ampicillin/cloxacillin (ampiclox) in four divided doses provide enough post-operative prophylaxis. Type of infection was commonly superficial and microorganism was commonly Pseudomonas.

Key words: Ampiclox; Prophylaxis; surgical site infection; Pseudomonas
Introduction

Hospital-acquired infections pose a large health burden. Fortunately, much can be done to improve infection control. The use of prophylactic antibiotics in the surgical treatment is well-established; however, the duration and dosage of prophylaxis varies substantially among surgeons. Surgical site infection defined as an infection that occurs at or near a surgical incision within 30 days of the procedure or within one year if an implant left in place.[1, 2]. The goal of antibiotic prophylaxis is to ensure effective serum and tissue levels of the drug for the duration of the surgery. The choice of antibiotic should be based on the local antibiogram. Antibiotic prophylaxis should be used in all clean and contaminated procedures and in some clean procedures in which a surgical site infection would have devastating consequences for the patient (placement of a prosthetic joint) [3]. There is no consensus with regard to optimum prophylactic antibiotic regimen in orthopaedic fracture surgery [4]. In a systematic review on antibiotic prophylaxis for surgery of proximal femoral and other closed long bone fractures, a single dose antibiotic prophylaxis found significantly reduce the risk of deep surgical site infections and the use of ceftriaxone was found to be a cost-effective intervention [5]. Current guidelines recommend the prophylactic antibiotics that end within 24 hours of surgery completion [6]. Ampicillin is a broad-spectrum, semi-synthetic penicillin that is bactericidal for several types of gram-positive and gram-negative bacteria. It has been effective against Enterococci, Proteus mirabilis, Salmonella, Shigella, and Escherichia coli; it is ineffective against penicillinase-producing Staphylococci and Gonococci. Cloxacillin formulated to resist the penicillinas that inactivate other penicillins. Cloxacillin beta-lactamase inhibitor is with a beta-lactam structure but little antibacterial activity. When combined with a penicillin, the beta-lactamase inhibitor protects the penicillin from destruction by the enzymes and extends the penicillin’s spectrum of anti-microbial activity. Thus, the drug combination may be effective in infections caused by bacteria that are resistant to a beta-lactam antibiotic alone.[7, 8] Penicillins are among the safest drugs, however, hypersensitivity and gastrointestinal problems were recorded.[9] This study performed to assess the prophylactic efficiency of Ampicillin/Cloxacillin in two antibiotic regimen for prevention of surgical wound infection in patients undergoing clean orthopaedic surgery.

Patients and Methods

Study Design

A prospective observational study conducted for 1 year; from 2013 to 2014 in Al-Hilla teaching hospital 96 patients of either sex of 7-45 years age were included in this study. This study performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Informed written consent obtained from all patients, and the local institutional ethics committee approved the protocol. 48 patients receive antibiotic regimen 1 and 48 patients received regimen 2 as prophylactic antibiotic regimen. Patients followed up for 3 months.

Inclusion criteria

All patients with closed fractures of upper and lower limbs, treated with Open reduction with internal fixation (clean surgery).

Exclusion criteria

Patients with open fracture, patients with diabetes mellitus, renal failure, on steroid therapy, and patients allergic to penicillin excluded.

Standardization

All patients treated under general anaesthesia, complete aseptic technique in orthopaedic theatre, internal fixator, proper dressing and by the same orthopaedic surgeon. Dressing changed 5 days after surgery; removal of stitches was 10-14 day post operatively.

Antibiotic regimen

1- Regimen 1: 8 injectable doses of Ampicillin/Cloxacillin vial intravenously
500 mg, the first dose was given during induction of anaesthesia before tourniquet use, followed by every 6 hours dose. Then oral antibiotic Augmentin (amoxicillin/clavulenic acid 250 or 500 mg for 5 days).

2- Regimen 2: 4 injectable doses of Ampicillin/Cloxacillin vial intravenously 500 mg, the first dose was given during induction of anaesthesia before tourniquet use, followed by every 6 hours dose.

**Study Procedure**

All the patients who met the study criteria enrolled in the study & reviewed at day 5, 10-14. Following details collected and recorded in the pre-decided preformats: Name, Age and Sex of patients, hospital register number, diagnosis, vitals (pulse rate, respiratory rate, blood pressure, temperature), routine investigations, any comorbid conditions, duration of hospital stay prior to surgery, type of surgery, duration of surgery, details regarding assessment of wound at day 5,10 and or 14, relevant microbiological investigation. The principal investigator visited all patients included in this study to collect any further information. Case record files of the patients analysed daily until their discharge. Observation 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 day5, 10,30,60 and 90.Data presented by percentages.

**Results**

The current study revealed that three patients of group one (table 1) had post-operative infection, two of them are superficial and one was deep infection (post-operative osteomyelitis).

The two superficial infections started 10 days after surgery. They were controlled after removal of stitches and by antibiotic cover (culture and sensitivity test showed *Pseudomonas*), the patient with deep-seated infection started 14 days post-operatively, the micro-organism was *Pseudomonas*.

In the second group (table 2), five patients were diagnosed with infection all of them were of superficial type; three of them were infected by *Pseudomonas* and two with Staph. Aurous (according to culture and sensitivity test) all of them treated conservatively by change of dressing and antibiotic cover.

### Table 1: Percentage of post-operative infection in patients treated with the first antibiotic regimen.

<table>
<thead>
<tr>
<th>Type of operation</th>
<th>No. of patients</th>
<th>Infection %</th>
<th>Type of infection</th>
<th>Time of infection occurrence</th>
<th>Type of microorganism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open reduction with internal fixation for upper and lower limbs using K wire, K nail, rush nail, plate and screw</td>
<td>48</td>
<td>6.25% (3)</td>
<td>2 superficial</td>
<td>10 and 14 days</td>
<td><em>Pseudomonas</em></td>
</tr>
<tr>
<td>36 male</td>
<td>12 Female</td>
<td>patients</td>
<td>deep infection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Table 2: Percentage of post-operative infection in patients treated with the second antibiotic regimen.

<table>
<thead>
<tr>
<th>Type of operation</th>
<th>No. of patients</th>
<th>Infection %</th>
<th>Type of infection</th>
<th>Time of infection occurrence</th>
<th>Type of microorganism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open reduction with internal fixation for upper and lower limbs using K wire, K nail, rush nail, plate and screw</td>
<td>48</td>
<td>10.41% (5)</td>
<td>superficial type</td>
<td>10 days</td>
<td>Pseudomonas and S. aureus</td>
</tr>
<tr>
<td></td>
<td>34 male</td>
<td>14 Female</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Discussion
Antibiotic play important role in post-operative infection control especially when chose and used properly.
Ampicillin \( \text{\textcopyright} \) cloxacillin (ampiclox) is abroad spectrum combination of antibiotics with tolerable side effect and low cost than other antibiotic in addition to its availability in research hospital. The administration of antibiotic during induction of anaesthesia and before tourniquet inflation provide good build-up of antibiotic concentration at surgical site and provide adequate prophylaxis during surgery [10, 11]. Antibiotics selection should based on their effectiveness against the pathogens most likely to encounter rather than against every possible pathogen. Skin florae (Staphylococcus organisms) are the usual target, so ampiclox chosen according to its effective against this pathogen, which is the most common in surgical site infection [12, 13].

According to the result of this study, the percentage of post-operative infection following both regimen of antibiotics is close to each other with increase in the percentage of infection in patients treated with regimen 2. Although, when the infected cases of regimen 2 discussed all were superficial infection and the time of infection was on day 10 so the infection may be due to change of dressing at day 5 rather than type of antibiotic or the regimen used.

This result agree with results of other studies state that continuing antibiotic prophylaxis for longer than twenty-four hours after wound closure is not beneficial and does not reduce rates of surgical site infection, but it may contribute to the development of antimicrobial resistance [14, 15, 16].

In this study, the relative increase in the percentage of infection in patients could be explained by small sample size or other factors related to operating room, team and room design which consider important factors in reducing surgical site infection rates [17]. The implementation of these factors explain the presence of Pseudomonas pathogen in surgical site infections.

Although, Ampicillin/\( \text{\textcopyright} \) Cloxacillin (ampiclox) combination is abroad-spectrum antibiotic but it is not effective against Pseudomonas pathogen, which is confirmed by culture sensitivity test neither amoxicillin/\text{\textcopyright} \) clavulanic acid combination used in the 1st regimen. This could explain infection percentage appear rather than the efficiency of antibiotic regimen used.

Reggiori [18] and his colleagues state that ampicillin single pre-operative dose is effective against surgical site infection after surgery. In addition, in a comparative study made by Menzel [19] and his colleague they found that ampicillin/sulbactam, cefoxitin and piperacillin/ metronidazole have no significant difference regarding post-operative infection prophylactic effect in elective colon and rectal surgery.

Regarding the type of surgical site infection which was commonly superficial infection with one deep infection this finding agrees with Meirhaeghe [20], who found that the percentage of superficial infections is more than deep infection in patients treated with flucloxacillin and those treated with cefazolin.
Conclusion
Ampicillin cloxacillin (ampiclox) antibiotic used in four doses (regimen 2) provide good post-operative prophylaxis in clean orthopaedic surgery and may replace the commonly used 1st generation cephalosporin. Type of infection commonly superficial and microorganism was commonly Pseudomonas. Further investigation about the source of pseudomonas pathogen are recommended.

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