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## Comparison between cefuroxime and amoxicillin+clavulanate in patients of inguinal hernia undergoing mesh hernioplasty, a randomised control study

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### Abstract

A randomized control study was conducted at Heritage Institute of Medical Sciences (HIMS) Varanasi to evaluate clinical efficacy of cefuroxime compared with amoxicillin+clavulanate for prevention of wound infection in patients undergoing open prolene - mesh hernioplasty in cases of inguinal hernia. There was minimal difference in overall wound infection rates between cefuroxime and amoxicillin+clavulanate group and side-effects in cefuroxime group were slightly less. Therefore, cefuroxime appears to be slightly more effective antibiotic for use as surgical prophylaxis.

**Keywords:** Hernioplasty. Wound infection. Antibiotic prophylaxis. Surgical site infection

### Introduction

Wound infection is very common problem worldwide. Surgical site Infections (SSI) are potential complications associated with any type of procedure and are among the most preventable hospital acquired infection. SSI effect on average 11% of patients undergoing a surgical procedure and second to third most frequent type of hospital acquired infection in US and Europe. At present, no country is free from the burden of diseases caused by HAI. Commonest causative organisms are staphylococci, streptococci etc.

Antibiotics are used to prevent infection at surgical site. The antibiotic selected should cover likely pathogens, should be given in right dose, at right time. They are usually given IV as a bolus on induction of anaesthesia to ensure adequate tissue concentration at the time of surgical incision.

Some of the traditionally used antibiotics like ampicillin, amoxycillin are no longer antibiotics of choice now a days because of increase in  $\beta$ -lactamase producing organisms. Second generation Cephalosporins and Amoxycillin+ Clavunate are reasonable alternatives because of their  $\beta$  - lactamase activity.

During the past few years, cefuroxime administered IV in the dose of 1.5 GMS before surgery has been the drug of choice for prophylaxis and treatment of clean surgeries. A disadvantage of cefuroxime is its increased cost.

### Material and methods

In an randomised control trial, 100 patients undergoing elective open inguinal hernia repair by prolene- mesh were included over a period of 3 years from January 2015 to January 2018.

Patients were divided in 2 groups of 50 patients each randomly. Patients included were from 40 to 80 years of age. All patients were males. Patients suffering from diabetes, on any immunosuppressive drugs or having hypersensitivity to cephalosporins or penicillin were excluded from study.

Patients were allocated into 2 groups based on their serial numbers. One group (odd serial no.) received injection cefuroxime 1.5 gm IV half hour before skin incision and then in 1.5gm TDS dose IV for 2 days followed by tab cefuroxime 500 mg BD for 5 days.

The other group (even serial no.) received injection amoxicillin+clavulanate 1.2 gm IV half hour before skin incision and then it was continued in 1.2 gm IV TDS dose for 2 days.

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The other group (even serial no.) received injection amoxicillin+clavulanate 1.2 gm IV half hour before skin incision and then it was continued in 1.2 gm IV TDS dose for 2 days. It was followed by tab amoxicillin+clavulanate 625 mg TDS for 5 days.

Antibiotics were given in full dose parenterally for two days, then by oral route because prolene mesh (foreign body) was implanted in all the cases.

In both patient groups, patients were discharged from hospital after wound dressing on 3<sup>rd</sup> day. All patients were asked to return on 7<sup>th</sup> day for stitch removal and again for follow up after 6 weeks and at 3 months. At follow-ups, wounds were examined for operative-site infection. Any s/s of wound – infection were recorded and information about any possible side-effects of drugs was also gathered by questioning the patients.

**Cure:** was defined as complete wound healing with no s/s of any wound infection at the end of treatment.

This study was approved by our hospital ethical committee.

**Results:** In all 100 patients were included in this study. Out of that, 50 patients - in cefuroxime group. 50 patients - in amoxicillin+clavulanate group. Age distribution in each group was similar. Average age was 40-70  $\approx$ 55.5 in cefuroxime group and 40-80  $\approx$  60 years in amoxicillin+clavulanate group.

**Response-rate:** A satisfactory outcome was observed in 96% patients of Cefuroxime group and in 94% patients with amoxicillin+clavulanate group.

Minor surgical site wound infection occurred in 4% of patients in cefuroxime group while in 6% of patients in amoxicillin+clavulanate group. These groups of patients were managed by daily dressings, change of antibiotics, anti-inflammatory drugs and ultimately problem was resolved in both groups. No patient landed in septicemia.

**Side-Effects:** All drugs were well tolerated and adverse effects affecting GI system were most commonly reported with nausea and vomiting more common in cefuroxime group (4%) while diarrhea most commonly observed in amoxicillin+clavulanate group affecting 8% patients.

### Discussion

Cefuroxime is a 2<sup>nd</sup> generation cephalosporin available for parenteral use as cefuroxime sodium and for oral use as a prodrug, cefuroxime axetil. The oral bioavailability of cefuroxime axetil is 50-60% when taken shortly after food. Cefuroxime is almost completely eliminated via kidneys (renal filtration and active tubular secretion). Since it is effective against several gram positive and gram negative organisms, it is used for treating a wide range of infections. Drug is well tolerated by adult and paediatric patients. The majority of adverse effects primarily GI disturbances are mild to moderate with very few serious adverse events reported. Because of its pharmacokinetic properties, it is given conveniently in twice-daily dosage orally.

Clavulanic acid is an irreversible inhibitor of  $\beta$  –lactamase and hence protects amoxicillin from inactivation by  $\beta$ -lactamase. It is clinically and bacteriologically superior to amoxicillin alone and at least as effective as numerous other comparative agents like cephalosporins, co-trimazole etc in treatment of most infections in adults and children. Clavulanic acid is stable against gastric acids and well absorbed following oral

administration with peak serum levels occurring within 1-2 hours. The absolute bioavailability of clavulanic acid is 60% and the main route of elimination is via urine. It is also available in both oral and injectable forms.

### Conclusion

Our results demonstrate that both the regimens were effective and safe for clean elective operations like- open inguinal prolene mesh hernioplasty. Cefuroxime was found to be slightly more effective and well tolerated than amoxicillin+ clavulanate. The differences, however, were not very significant.

The results in this study are consistent with results found by O'Donovan *et al* and Landan *et al*.

Both antibiotics have the advantage of good antibacterial activity and availability in both iv and oral forms.

It is imperative to use an appropriate antibiotic, at correct time, in correct dose, for appropriate duration according to the category of surgical procedures, for reducing post-operative wound infections. Hospital surgical antibiotic- prophylaxis protocols should be made and regularly reviewed because endemicity of multi-resistant bacteria in hospitals are subject to frequent change.

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