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Research Article

Comparative evaluation of short-term versus long-term post-operative antibiotic prophylaxis after mandibular fractures

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ABSTRACT

Background: No consensus is present among the clinicians regarding the use of post-operative antibiotics after the open reduction and internal fixation. This study evaluates the efficacy of short-term (48 hrs) versus long-term (5 days) post-operative antibiotics in preventing infection rates after the open reduction and internal fixation in mandible fractures.
Methods: A total of 80 patients of dentate mandibular fractures were divided randomly in 2 groups; Group 1 received post-operative intravenous antibiotics (amoxicillin+clavulanate 1.2 g+ metronidazole 0.5 g/100 cc) TDS for 48 hrs post-operatively Group 2 received same course for 5 post-operative days and patient were monitored for the signs of infection according to the centers for disease control and prevention criteria, rise in white blood cells counts and C-reactive protein (CRP) levels. Side effects were recorded in both groups.
Results: Out of 39 patients in Group 1 two patients showed rise in CRP levels and single patient developed abscess, whereas in Group 2 wound dehiscence was noted in 2 patients and both had prolonged rise in CRP levels at the 5th day.
Conclusions: No significant difference in post-operative infection rates was seen between two groups which suggests short-term post-operative antibiotic treatment is equally efficacious as long-term treatment.

Keywords: Mandibular fractures, Post-operative infection, Post-operative antibiotic prophylaxis

INTRODUCTION

Mandibular fractures are the one of the most commonly encountered facial fractures.[1] Nowadays these fractures are often treated surgically by open reduction and internal fixation method which gives stabilization and earlier return to the function; however, infection is the most common complication after any surgical procedure.[2] Until the early 1980s, the perioperative antibiotic prophylaxis was controversial in maxillofacial surgery,[3] but nowadays its efficacy is well-accepted. The benefit of antibiotic prophylaxis for the treatment of such fractures has been confirmed in different studies. Chole and Yee demonstrated that giving a dose of antibiotic 1 hr preoperatively and 8 hrs after the operation reduces the incidence of infection in facial fractures from 42.2% to 8.9%[4]; however, there is still no consensus about how long antibiotic prophylaxis should be given post-operatively. Published data on antibiotic prophylaxis in facial fractures varies from a single shot[5] to even 7-10 days post-operatively.[6] The use of antibiotics is not without adverse effects which include hypersensitivity reactions, direct toxic effects, drug interactions, and antibiotic resistance. In addition, some authors suggest that prolonged use of antibiotic can increase the risk of

complications from superinfections.[7] The standard practice is to administer prophylactic intravenous antibiotics only on the day of surgery in the western countries, however, in others prophylactic antibiotics are given for several days post-operatively and 1 day infusion is rare. As yet only a few randomized double-blind clinical trials have compared various prophylactic antibiotics regimens. These trials have many shortcomings. The purpose of conducting this study was to know whether prophylactic administrations of antibiotic for short-term can decrease post-operative morbidity, shorten hospitalization, reduce infection and prevent unnecessary use of antibiotics for longer periods after the elective open reduction, and internal fixation of mandibular fractures.

METHODS

This prospective randomized open-label comparative clinical study followed the principles outlined in the declaration of Helsinki and was approved by the Institutional Review Board. Study was conducted in accordance with the principles of good clinical practice. A total of 80 patients of either sex, more than 14 years of age with mandibular fractures, who were treated at department of oral and maxillofacial surgery at Postgraduate Institute of Dental Sciences (PGIDS), Rohtak (Haryana) India from November 2013 to June 2015 were enrolled. All patients supplied with a patient information sheet and a written informed consent for participation in the study was obtained.

Patients were excluded from the study when any of the following criteria was present; presence of multiple injuries (critical patient), presence of acute bacterial infection, gunshot wounds, pathological fractures (cysts or metastasis) hypersensitivity to penicillin or other beta lactam antibiotics, prolonged steroid therapy, cardiovascular disease, severe liver or kidney disease, compromised host defense (immunosuppression, malabsorption, maldigestion), cachexia, reduced body weight <40 kg, poor compliance, history of malignancy, or radiation to the head and neck area, etc.

Patients were divided into 2 groups of 40 each using computer generated randomization protocol Group I patients were given preoperatively amoxicillin+clavulanate 1.2 g 8 hrs intravenous (IV) 30 mins prior to operation and continued for first 48 hrs post-operatively, in addition to metronidazole 500 mg IV every 8 hrs. In Group II - patients were given preoperatively amoxicillin+clavulanate 1.2 g 8 hrs IV 30 mins prior to the operation and continued for 5 days post-operatively in addition to metronidazole 500 mg IV every 8 hrs.

Patients of both the groups were monitored for good oral hygiene and adequate nutrition during their hospitalization. Standard post-operative treatments for pain, infection, dressings were provided to all patients. Patients with post-operative wound dehiscence or superficial purulent infection were treated with local measures like drainage and daily wound irrigation with povidone iodine. In cases of deeper infection, broad spectrum antibiotics depending on culture sensitivity results were started immediately. A control group with no treatment was not included in the study due to ethical reasons.

Surgical technique

All patients were operated under general anesthesia by open reduction and internal fixation technique.

Efficacy assessment

All patients were evaluated by surgeons on the first, second, and seventh post-operative days for infection according to the criteria of infection for surgical site published by the centers for disease control and prevention (CDC).[8] These include purulent discharge, spontaneous wound dehiscence,* abscess, presence of signs and symptoms of infection such as localized pain, swelling, tenderness or fever (>38°C). The discharge of serosanguinous or suppurated type was considered as the secondary endpoint for short-term antibiotic prophylaxis regimen. Culture sensitivity of the discharge was done and further treatment was continued accordingly. Patients were monitored for the rise in the White blood cells (WBC) counts on the third and seventh day post-operatively and rise in the C-reactive protein (CRP) levels* was taken as the primary end point for the short-term antibiotic prophylaxis regimen.

*denotes the criteria not included in the CDC criteria for surgical site infection.

Primary end point

Raised CRP levels; treatment continued further.

Secondary end point

Serosanguinous or suppurated type empirical therapy changed to definitive after culture and sensitivity accompanied by local measures such as incision and drainage.

Safety assessment

Any possible adverse effect or allergic reactions were recorded on the preformed proforma preoperatively and post-operatively (3 hrs, 2nd and 5th day). Any withdrawal from the study due to serious side effects was also recorded.

RESULTS

A total of 79 patients are included in the study with 69 males and 6 females there is no significant difference between the age and gender distribution between the two groups.

There is no significant variation between the unilateral and bilateral fracture distribution and smoking habits between two groups.

The time period between the trauma and surgery varies from 3 days to 1 month as most patients belong to the rural background and do not have easy access to health care facilities.

All patients are in good health with no previous history of drug allergy.

In Group 1, 39 patients with mandibular fractures were treated with post-operative prophylactic antibiotics with IV amoxicillin and clavulanic acid 1.2 g plus metronidazole 500 mg every 8 hrs for 48 hrs showed marked improvement in post-operative pain, swelling, local temperature, no wound dehiscence, sinus and fistula formation or hardware failure was noted in any patient. WBC counts were within range of 6500-10500/mm with mean of 7219/cmm, however, raised CRP levels (primary end point) were noted in 2 patients out of which single patient showed abscess formation (secondary end point) at the site of surgery he was managed by incision and drainage under local anesthesia and healing occurred uneventfully. No definite conclusion regarding the efficacy of the short-term antibiotic treatment can be drawn from positive results in one out of 39 patients.

In Group 2, 40 patients received same antibiotic regimen post-operatively for 5 days showed almost similar results regarding the improvement in pain (visual analogue scale) score, swelling, local temperature. However wound dehiscence was noted in two patients, raised CRP levels were noted in 5 patients at third post-operative day and remained raised in two patients till 5th day and mean WBC count was 7280/cmm.

The results of our studies show that there is no additional benefit obtained from the prolonged post-operative antibiotics administration in operated cases.

Therefore, results of our study show that 48 hrs antibiotic prophylaxis is as effective as 5-day antibiotic prophylaxis in operated cases of mandibular fractures (Table 1).

Table 1: Results.

Variables	Group 1	Group 2
Total number of patients	39	40
Males	36	37
Females	3	3
Mean duration of surgery	58.6 mins	60.1 mins
Meantime lapse between injury and treatment	5.9 days	6.2 days
Average duration of preoperative antibiotics	3.6 days	3.7 days
Unilateral fractures	13	10
Bilateral fractures	26	30
Smokers	33	30
Raised CRP levels (primary end point)	2	5 (at the 3rd day)
		2 (at the 5th day)
Discharge (secondary end point)	1	0
Side effects	Diarrhoea 4	Diarrhoea 3
	Skin rash 1	Skin rash 1

CRP: C-reactive protein

DISCUSSION

Results of the present study revealed that there is no significant difference between the 2 day and 5 day post-operative course of prophylactic antibiotic treatment (amoxicillin+clavulanic acid 1.2 g combined with metronidazole 500 mg) on incidence of post-operative adverse outcomes (pain, swelling, fever, infection, pus discharge, and wound dehiscence) in patients with mandibular fractures.

The most common complication after mandibular fractures is wound infection[9] Chole and Yee reported that infection rate after the fracture of mandible without perioperative antibiotic prophylaxis is 44% compared to 13% when post-operative antibiotic are given perioperatively. Lower infection rates, i.e., 5.8% and 7% are also reported in patients with mandibular fractures treated with antibiotic chemoprophylaxis.[10,11] Infection rate can be varying depending on the site of mandibular fractures. Fractures of the tooth-bearing region, especially the region involving the third molar region have the highest incidence of infection[9,12] also open reduction and internal fixation is associated with higher infection rates compared to closed reduction technique[13] nowadays pre- as well as peri-operative antibiotic prophylaxis is commonly used as standard treatment in mandibular fractures treated by ORIF; however, duration of post-operative prophylaxis remains curtail reported regimen varies from 3 to 7 days after operation. Our results are in agreement with Abubaker; Rollert and Miles et al. Abubaker and Rollert have shown no improvement in the post-operative infection with the use of prolonged antibiotic treatment in 30 patients with mandibular fractures, compared to 12 hrs post-operative antibiotics with a 5 day course the infection rate was 13% for the 12 hrs regimen and 14% for 5 day regimen. These studies have some important shortcomings (treatment with closed reduction, did not evaluate teeth in line of fractures, duration of treatment was not consistent, short-term follow-up). Our results showed that use of post-operative antibiotic prophylaxis beyond first 48 hrs did not seem to have significant effect on post-operative infection rate the incidence of post-operative pain, swelling, local temperature rise, wound dehiscence, discharge, rise in the WBC counts, and CRP levels were comparable in both the groups. The infection rates in Group 1

and Group 2 are 5.12% and 5.0%, respectively. This is far lower than the earlier studies. This could be due to the study population being selected to include "clean case" fractures of dentate mandible, strict post-operative oral hygiene, management of tooth in line of fractures, proper dressing of extraoral wounds after irrigation with betadine. Other potential confounding factors such as smoking, duration of surgery, time lapse between trauma and surgery, duration of preoperative antibiotics, multiple fractures did not influence the results significantly.

Our study had certain limitations such as varying duration of preoperative antibiotic treatment, long time lapse between trauma and presentation, short follow-up; also our sample size was probably not large enough to detect significant differences in infection rates therefore a larger randomized double-blind, placebo - controlled trial will be necessary to provide further evidence.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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