ORIGINAL RESEARCH

Comparing the Efficacy of Postoperative Antibiotic Regimens in the Treatment of Maxillofacial Fractures: A Prospective Study

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Abstract

Aim: The present study was designed to investigate the difference in the effectiveness of a 3 day postoperative course and a single perioperative dose of antibiotics on the incidence of postoperative infection in the management of maxillofacial trauma patients.

Materials and methods: About 183 maxillofacial trauma patients requiring open reduction and internal fixation (ORIF) under general anesthesia were divided based on the type of fracture sustained, i.e., mandibular fractures, Le Fort fractures, and zygomaticomaxillary complex fractures. Patients from each fracture type were randomized into two groups, A and B. All patients were administered amoxicillin/clavulanate 1.2 grams intravenously 8 hours from the time of admission till the patient was taken up for surgery. Once the patients were taken up for surgery, a perioperative dose was administered. No antibiotics beyond this point were given to patients in Group A. Patients in Group B were administered the same antibiotic for 3 postoperative days additionally. Outcomes in terms of purulent discharge from the surgical site, an abscess or any other sign of infection, and wound dehiscence requiring reopening of the surgical site were considered. Patients were reviewed at 1 week, 2 weeks, 1 month, 2 months, and 3 months.

Results: No statistically significant difference was found between the two groups across all three fracture types in terms of postoperative outcomes. However, increased numbers of complications were noted in the patients treated with an intra-oral approach in each fracture type irrespective of group. All complications were managed with local measures.

Conclusion: A single perioperative dose of antibiotics is effective in minimizing postoperative complications following ORIF of maxillofacial fractures and there is no significant benefit in prolonging the course of antibiotics postoperatively with the need for further studies to be conducted considering comminuted, complex fractures and old fractures.

Clinical significance: In maxillofacial trauma, fractures frequently communicate with contaminated indigenous flora on the skin surface, oral cavities, or sinus cavities. Surgery is frequently performed using an approach across a contaminated area, even in closed fractures. Postoperative infections can be significantly decreased by using antibiotics in surgical procedures to treat facial fractures.

Keywords: Antibiotic prophylaxis, Maxillofacial trauma, Postoperative complications, Surgical site infection.

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Introduction

The maxillofacial region is the most significant part of the body, starting from the base of the skull to the hyoid bone. It is also connected to speech, hearing, vision, and other sensory and motor systems. Injury to the face that disfigures can have negative psychological and social effects. Fractures in the facial region are often treated by maxillofacial surgeons. Maxillofacial injuries are most frequently caused by falls (21.66%), traffic accidents (49.01%), and conflicts (22.38%).[1] Currently, open reduction and internal fixation (ORIF) is used to treat these fractures in order to improve stabilization, wound healing, and aesthetic results. Approaches that are extra-oral and intra-oral are both used to reduce broken bones. Due to the unavoidable contamination of these surgical wounds with oral cavity germs and nonsterile sinuses, they are typically referred to as clean-contaminated wounds.[2]

Postoperative infections are a common complication following maxillofacial surgery. A surgical site infection (SSI) is defined as one occurring within 30 days of surgery or within 1 year of implant placement. SSI are responsible for significant postoperative morbidity and mortality of patients.[3] Postoperative antibiotic prophylaxis has therefore been a subject of much interest to reduce,

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if not eliminate SSI. Antibiotic use is associated with factors such as adverse reactions, drug interactions, superinfections, patient compliance, and financial burden to the patient.[4]

Even though it has been the subject of several studies, there is no fixed protocol for the administration of postoperative antibiotics. Antibiotic protocols in literature are varied, with some limited to a single perioperative dose while some advocate antibiotic administration for up to 10 days postoperatively.[5]

Recent studies suggesting that a single perioperative dose is adequate for the management of moderate maxillofacial trauma patients are limited. Therefore, the present study was designed to investigate the difference in the effectiveness of a three day postoperative course and a single perioperative dose of antibiotics on the incidence of postoperative infection in the management of maxillofacial trauma patients.

Materials and Methods

Patient Selection

The present prospective, randomized study was conducted at the Kalinga Institute of Dental Sciences, Bhubaneswar, India from January 2019 to December 2020 following the principles detailed in the Declaration of Helsinki and approved by the Institutional Ethics Committee. Patient recruitment was done either from the outpatient department or from the emergency ward.

There are 200 maxillofacial trauma patients that required open reduction with internal fixation (ORIF) were recruited for the study of which 17 were lost to follow up leading to a total of 183 patients who completed the study. Formal informed consent was obtained from all patients. The inclusion criteria were as follows: Patients ≥18 years of age, patients with an ASA score of I or II, fractures that were treated within 24 hours of injury, simple fractures that did not communicate with the external surface through lacerations in the mucosa/skin, patients who had not received any treatment before reporting to us and patients who were willing to report for follow up period of 12 months. The exclusion criteria included: Signs of existing infection at the fracture site, ASA score ≥ III, prior treatment at other centers, fractures older than 24 hours, fractures that communicated with the external surface or comminuted fractures, compromised host defenses (immunomodulators, debilitating chronic illnesses, cachexia, BMI <17), a requirement of intensive care postoperatively, allergy or hypersensitivity to β-lactam antibiotics, patients unwilling to report for follow-up.

Fractures Considered for the Study

Mandibular fractures, including symphysis, para symphysis, body, angle, and condylar fractures were included in the study. Zygomaticomaxillary complex fractures (ZMC) and Le Fort fractures (Le Fort I, II, III) were also included in the study. Patients from each fracture type were randomized into two groups, A and B. Randomization was done using the envelope method.

Surgical Procedure

All surgeries were performed by the same surgical team under general anesthesia.

Mandibular Fractures

Arch bars were placed and inter-maxillary fixation was done. The trans-oral or extra-oral approach was used as decided by the surgical team based on the fracture site. Fracture reduction was done and fixation was done using titanium mini plates and screws. Teeth in the line of fracture were extracted if their prognosis was poor or if they interfered with the optimum surgical outcome.

Zygomaticomaxillary Complex Fractures

All fractures were approached intra-orally. Fixation was done based on the number of sites involved.

Le Fort Fractures

Upper and lower arch bars were placed and IMF was done. Vestibular incisions were placed and fracture sites were exposed. In the case of Le Fort II fractures, infra-orbital incisions were made as well for access to the fracture site. For Le Fort III fractures, lateral eyebrow incisions for access to the fronton-zygomatic suture were made.

Antibiotic Protocol

All patients were administered amoxicillin/clavulanate 1.2 grams intravenously 8 hours from the time of admission till the patient was taken up for surgery. During the procedure, a single perioperative dose was administered. No antibiotics beyond this point were given to patients in Group A for all fracture types. Patients in Group B were administered the same antibiotic for 3 postoperative days intravenously.

Defining a Surgical Site Infection

Surgical site infection was defined based on the criteria given by the Centers for Disease Control (1999).[6] The following criteria were considered: purulent discharge from the surgical site, an abscess or any other sign of infection, and wound dehiscence requiring reopening of the surgical site. Patients were reviewed daily during the course (on an average of 7–15 days) in the hospital. Post-discharge, they were reviewed at 1 week, 2 weeks, 1 month, 2 months, 3 months, 6 months, and 1 year.

Treatment of Infected Site

In cases of discharge from the operated site, swabs were sent for culture and sensitivity. Empirical antibiotic therapy was initiated till the reports of culture were available and subsequently modified, if necessary. Wound dehiscence was managed by daily irrigation with Povidone Iodine and re-suturing.

Statistical Analysis

Data analysis was done using STATA (ver. 16). Association between categories was calculated using the Chi-square test and Fisher's exact test where necessary. A p-value of < 0.05 was considered as statistically significant.

Results

A total of 200 maxillofacial trauma patients who met the inclusion criteria were operated under general anesthesia between the years 2019 and 2020. Of these, 17 patients were lost to follow-up. A total of 93 patients across all three fracture groups were assigned to group A (patients who did not receive antibiotics beyond perioperative dose), while 90 patients were assigned to group

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B (patients who were administered antibiotics for an additional three postoperative days).

Of these, 138 (75.41%) were male and 45 (24.59%) were female with a mean age of 34.26 and a standard deviation of 8.58 (Table 1). Of the 183 patients, 67 (36.61%) patients presented with mandibular fractures, 55 (30.04%) with ZMC fractures, and 61 (33.34%) with Le Fort fractures (Table 1).

About 53/67 (79.1%) of the mandibular fracture patients were male whereas 14/67 (20.9%) patients were female. After randomization, 34/67 patients were placed in group A while 33/67 patients were allotted to group B in the mandibular fracture group. Nine patients in group A and six patients in group B developed a postoperative infection. Of the nine patients in group A, four patients presented with wound dehiscence, two with purulent discharge, and three patients presented with concurrent wound dehiscence, and purulent discharge. Of the six patients in group B, four patients developed wound dehiscence and two developed purulent discharge. Postoperative follow-up for these patients was done at 1 week, 2 weeks, 1 month, 2 months, 3 months, 6 months, and 1 year.

In the ZMC group, 38/55 (69.1%) patients were male and 17 (30.9%) were female. After randomization 28/55 were allotted to group A while 27/55 patients were allotted to group B. About four patients in group A and three patients in group B developed postoperative infection. Three of the four patients in group A developed wound dehiscence which was associated with a purulent discharge while 1 presented with localized swelling and tenderness. All three patients in group B presented with only a breakdown of the wound (Table 2).

Table 1: Socio-demographic data of the present study

Demographic data	
Number of patients	183
Male	138 (75.41%)
Female	45 (24.59%)
Age (Mean)	34.26 (±8.58) years
Fracture	
Mandible	67 (36.61%)
ZMC	55 (30.04%)
Le Fort	61 (33.34%)

About 26/61 (42.63%) patients presented with isolated Le Fort I fracture, 21/61 (34.42%) patients presented with Le Fort II fracture, and 14/61 (22.95%) presented with Le Fort III fracture. 47/61 (77.05%) patients who presented with Le Fort fractures were male while 14/61 (22.95%) patients were female. After randomization, 31 patients were allotted to group A while thirty patients were allotted to group B. About seven patients from group A and four patients from group B developed an infection. Of the eleven patients across both groups, nine developed infection or had wound dehiscence in relation to the intra-oral surgical site while two patients in the Le Fort III group developed a purulent discharge from the infra-orbital region (Table 3).

Discussion

The use of postoperative antibiotics has been a matter of controversy and extensive scrutiny over the years. Although the value of antibiotics as an adjunct during surgery cannot be denied, the indiscriminate use of antibiotics has several drawbacks. Increases in cost, development of resistance, and increased morbidity of the patients are a few untoward effects of indiscriminate antibiotic use.

Penicillin derivatives in combination with beta-lactamase inhibitors are effective against bacteria present intra-orally and on cervicofacial skin.[7] Keeping this in mind, amoxicillin/clavulanate 1.2 grams was selected as the drug of choice in the present study.

The most common complication of mandibular fractures is infection.[8] Incidence of infection increases with involvement of tooth-bearing segments and lacerations involving mucosa. A study conducted by Chole and Lee stated that the incidence of a postoperative infection in the absence of the perioperative dose of antibiotic was 44%. However, when perioperative dose of antibiotic was given, the incidence of infection was 13%.[9] The site of fracture also affected the incidence of postoperative infection. Angle fractures were most commonly infected.[8,10] Open reduction and internal fixation was associated with a greater number of infected cases postoperatively than closed reduction.[11] Therefore, only cases treated by ORIF and not closed reduction were included to eliminate bias. Of the 67 mandibular fracture cases treated with ORIF in the present study, 15 (22.39%) cases developed postoperative infection across both groups (9 in group A and 6 in group B). Although not statistically significant, a greater number of complications were encountered in the single perioperative group as compared to the group that received antibiotics additionally for three postoperative days. No significant difference was observed in terms of the age

Table 2: Distribution of gender and type of fracture on postoperative infection

		Total subjects		*Subjects with postoperative infection*		
Fracture	*Gender*	*Single peri-operative dose*	*3-day group*	*Single peri-operative dose*	*3-day group*	*p-value*
Mandibular	Male	29	24	07	04	0.416
	Female	05	09	02	02	
	Total	34	33	09	06	
ZMC	Male	20	18	03	03	1.000
	Female	08	09	01	0	
	Total	28	27	04	03	
Le Fort	Male	22	25	05	03	0.348
	Female	09	05	02	01	
	Total	31	30	07	04	

Table 3: Evaluation of postoperative complications and their intervention with antibiotic protocol

		Infection				*Intervention*			
Fracture	*Group*	*Purulent infection*	*Wound dehiscence*	*Purulent discharge with wound dehiscence*	*Total*	*Antibiotic treatment*	*Local treatment*	*Combined treatment*	*Total*
Mandibular	Single peri-operative dose	02	04	03	09	02	04	03	09
	3-day group	02	04	0	06	02	04	0	06
	Total	04	08	03	15	04	08	03	15
ZMC	Single peri-operative dose	0	01	03	04	0	01	03	04
	3-day group	0	03	0	03	0	03	0	03
	Total	0	04	03	07				
Le Fort	Single peri-operative dose	02	05	0	07	02	05	0	07
	3-day group	01	03	0	04	01	03	0	04
	Total	03	08	0	11	03	08	0	11

of the patients and the location of the fractured segments in the present study. These results were similar to those obtained by Schaller et al.[5]

A randomized placebo-controlled study conducted by Abubaker et al. demonstrated no statistically significant difference in the incidence of postoperative infection between patients who received postoperative oral penicillin and patients who were given oral placebos.[12] A similar study was conducted by Miles et al. who concluded that postoperative antibiotic prophylaxis had no statistically significant benefit in open mandibular fractures.[13]

A retrospective study conducted by Lauder et al. suggested that there was no significant difference in the incidence of postoperative infection between patients who were administered a single perioperative dose of antibiotics and patients who received additional antibiotics with respect to complex trauma to the midface and frontal sinuses.[14] This is in agreement with the results obtained in the present study. The results of the present study were also similar to the results of a study conducted by Soong et al. who reported no statistically significant difference between the group of patients administered postoperative antibiotics for one day versus the group administered antibiotics for five postoperative days for ZMC and Le Fort fractures.[15]

No statistically significant difference was found between both groups in the Le Fort fracture category. Interestingly, in the Le Fort group, all but two patients who developed postoperative complications had Le Fort I fractures which were reduced intra-orally. The reason for this may well be the contaminated intra-oral region with abundant mixed flora contributing to infection and wound breakdown. Two patients in the Le Fort III group developed purulent discharge from the infra-orbital region which resolved upon administration of additional antibiotics. Zix et al. conducted a study to compare postoperative infection in patients who had undergone orbital floor reconstruction. They found no statistically significant difference between patients who received postoperative antibiotics for one day when compared to patients who were administered a five-day course of postoperative antibiotics.[16]

A recent study by Sethi et al. compared two antibiotic regimens for maxillofacial trauma patients. Patients treated within 72 hours of injury were given only a single perioperative dose of antibiotic. The other group consisted of patients who received perioperative doses along with a standardized regimen based on the type of treatment and the time interval between injury and surgery. They concluded that there was no statistically significant difference between both groups in terms of postoperative infection.[17] This was similar to the results obtained in the present study.

A systematic review conducted by Blatt et al. found good quality evidence in support of perioperative antibiotic prophylaxis for mandibular and Le Fort fractures. They concluded that an extended postoperative antibiotic regimen could not be recommended in maxillofacial trauma.[18] Another systematic review conducted by Habib et al. reported that all included studies that compared peri and postoperative antibiotic prophylaxis showed no statistically significant difference in terms of surgical site infection.[19]

The present study was not without limitations. Le Fort fractures were considered as a single group in the present study. As a result, the number of patients in each Le Fort fracture group was quite less as compared to the other two groups. A very small number of mandibular fractures were treated using the extra-oral approach for obvious esthetic reasons and as a result, the sample size was quite small. Also, only isolated Le Fort, ZMC, and mandibular fractures were considered for the present study. Often in clinical practice, a combination of fractures is encountered and not merely isolated fractures. Only fractures treated within 24 hours of injury were considered to avoid potential bias that might have arisen due to the difference in a number of antibiotic doses with patients presenting with older fractures.

The present study was conducted in an attempt to standardize postoperative antibiotic regimens following maxillofacial fractures. Considering the limited sample size for each fracture type, the small number of extra-oral approaches, and the exclusion of comminuted, complex fractures and old fractures, further studies need to be conducted considering these factors.

Conclusion

In conclusion, a prolonged course of postoperative antibiotics does not seem to be indicated in the management of maxillofacial trauma cases as a single perioperative dose of antibiotics is effective

in minimizing postoperative complications following ORIF of maxillofacial fractures. This also has the added advantage of greater patient compliance while being cost-effective at the same time.

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