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The role of postoperative administration of antibiotics in prevention of infection after open reduction of mandibular compound fractures: A randomized double-blind placebo controlled pilot clinical study

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ABSTRACT

Purpose: This study determines the effectiveness and/or necessity of applying postoperative antibiotics in the treatment of mandible fractures.

Materials and Methods: This is a randomized, double-blind clinical study using a placebo control. 65 patients diagnosed with mandibular fractures underwent open reduction and internal fixation surgery. The patients were randomly divided into 2 groups: antibiotic group (38 patients) and placebo group (27 patients), based on whether or not they received postoperative antibiotics. Both groups received preoperative as well as intraoperative antibiotics on the day of surgery. The antibiotic group was postoperatively given clindamycin 600 mg IV every 8 hours for 5-7 days. The placebo group received placebo using the same schedule for the same duration as the antibiotic group. Follow-up examination was performed at discharge, 2 and 3 weeks, postoperatively.

Results: A total number of 65 patients participated in this study; 50 (76.9%) males and 15 (23.1%) females. The evidence of surgical site infection was noted in 24 out of 65 patients within 3 weeks post-operation totally, 13 out of 38 patients in the antibiotic group (34.3%) and 11 out of 27 patients in the placebo group (40.7%) had evidence of surgical site infections. No statistically significant difference in the incidence of infection was noted between the groups (p<.368).

Conclusion: This study could not statistically prove any beneficial effect for post-operative administration of antibiotics in patients undergoing open reduction and internal fixation of mandibular fractures.

Keywords: Mandible fractures, Open reduction internal fixation (ORIF), Antibiotic, Antibiotic resistance, Infection.

Introduction

The benefit of preoperative and intraoperative administration of antibiotics in the treatment of mandibular fractures has been established in the literature. Administration of an appropriate antibiotic regimen has been shown to significantly reduce the incidence of postoperative infections when treating open mandibular fractures [1-3]. The necessity of administering postoperative antibiotics when treating mandibular fractures is

another matter which has not been extensively investigated. Additionally, enough explicit data are yet to be produced in order to establish a guideline for the duration of postoperative administration of antibiotics. However, variable treatment durations, from a single dose to a course of 7 to even 10 consecutive postoperative days, have been suggested by some studies [4-6]. Shariati & Sina Hospitals are the main centers for treatment of maxillofacial fractures in Tehran, Iran. Therefore, this preliminary randomized double-blind clinical study using a placebo control was conducted to evaluate the role of postoperative antibiotics in prevention of infection after open reduction sugary of mandibular compound fractures.

Materials and Methods

Sample

A total of 65 patients with mandibular fractures extended to the alveolar regions who underwent Open Reduction Internal Fixation (ORIF) at the Department of Craniomaxillofacial Surgery of the University Hospitals of Tehran, Iran, from September 2015 to September 2016, were enrolled in this study. Written informed consent for participation in the study was obtained from all the patients. Data were collected preoperatively and included age, gender, past medical history, smoking status, substance abuse, alcohol consumption, cause of injury, fracture location (s), presence of a tooth in the line of fracture (s).

Ethical consideration: The research committee of ethics approved the study.

Patients who met the following criteria were included in the study:

1. At least 1 fracture of the mandible.

2. Open reduction and internal fixation treatment.

3. Follow-up for at least 3 weeks.

Patients with the following characteristics were excluded from the study:

1. Comminuted fractures.

2. Infection of the fracture site initial presentation.

3. Associated systemic disease.

4. Pathologic fractures.

5. Skull base fractures.

6. A documented immunocompromised medical status.

Study design antibiotic protocol

The patients diagnosed with open fractures of the mandible were randomly assigned to 2 groups: antibiotic group (38 patients) and placebo group (27 patients), based on whether or not they received postoperative antibiotics. Both groups received preoperative as well as intraoperative antibiotics on the day of surgery. The antibiotic group antibiotic was postoperatively given clindamycin 600 mg IV every 8 hours for a period of 5-7 days. The placebo group received placebo using the same schedule for the same duration as the antibiotic group.

Surgical Technique

Surgical treatment of the mandibular fractures included placement of the arch bars and various forms of stable internal fixation. The surgery was performed under general anesthesia by oral and maxillofacial surgeons. Teeth in the fracture line were extracted if they prevented proper reduction or were mobile and grossly carious. A panoramic radiograph was post operatively performed as a routine procedure.

Follow-up

The surgeons evaluated all the patients using a standardized form. After discharge, follow-up reviews were conducted at the time of discharge, 2 and 3 postoperative weeks. Follow-up was not permitted after week 3 post operation since acquiring an infection after this period was unlikely to be related to whether or not the patient received antibiotics. The surgical site was evaluated by an investigator for infection at each postoperative visit. Clinical Criteria according to CDC for infection included [7]:

1. Purulent drainage from the surgical or fracture site.

2. Increased facial swelling beyond postoperative day 7.

3. Fistula formation at the surgical or fracture site, with evidence of drainage.

4. Fever associated with local evidence of infection (swelling, erythema, or tenderness).

Clinical criteria according to Miles study [17]:

Grade I: Erythema around suture line limited to 1 cm.

Grade II: 1 to 5 cm of erythema.

Grade III: Greater than 5 cm of erythema and induration.

Grade IV: Purulent drainage either spontaneously or by incision and drainage.

Grade V: Fistulae.

Statistic Alanalysis

The obtained data during this study included age, gender, duration between injury and treatment, duration of surgery, presence of infection and compliance with postoperative antibiotics administration. The data on the incidence of infection in both groups were collected was tabulated in a Microsoft Excel spread sheet and analyzed for statistical differences using SPSS software.

Results

A total of 73 patients were initially enrolled in the study, 8 of whom were excluded due to various reasons. Finally, 65 patients aged between 14 to 57 years old were included in the study and were divided into two groups; antibiotic group (mean age: 26.31±7.44 years) and placebo group (mean age: 28.30±9.3 years). Demographic data are summarized in (Table 1). The study population consisted of 50 (76.9%) males and 15 (23.1%) females. Most of the cases (45 patients) had at least 2 fractures. The most common mechanism of mandibular fracture was motor vehicle accident (MVA) and falling (32.30%). Other causes included assault (23,07%) and sport injuries (12.30%), respectively (Table 2).

The most common location of the fracture was the angle of mandible (52.3%), followed by body site (47.70%), Parasymphisis (36.90%), Subcondylar (27.70%) and Symphysis site (6.15%) (Table 3). Alcohol consumption was reported by 11 patients and 24 patients were smokers. The interval between the traumatic event and the surgical intervention varied from 6.6±6.41 days in the antibiotic group to 6.07± 3.64 days in the placebo group. Performing the surgical procedures lasted from 1:30 to 3:30 hours; it took 2 hours for most of the cases. in 46 (70.80%) patient in all of patients, teeth involved in fracture line. Among them 29 (76.30%) teeth belonged to the antibiotic group and 17 (63.00%) teeth to the placebo group (Table 4).

The antibiotic and placebo groups consisted of 38 and 27 patients, respectively. Totally, 24 patients presented postoperative surgical site infection; 13 out of 38 patients in the antibiotic group (34.3%) and 11 out of 27 patients in the placebo group (40.7%) (Table 5). This assessment was based on the Miles study. According to which the infection was reported in these 24 patients include Grade I and Grade II were successfully treated by administrating oral clindamycin 600 mg IV every 8 hours for a period of 5-7 days and irrigation with mouth wash (Chlorhexidine). (Table 6) None of the infected patients required hospitalization or hardware removal. No evidence of infection was noted considering the criteria defining a surgical site infection (SSI) provided by the center of disease control and prevention (CDC). Statistical analyses indicated no significant differences in the incidence of postoperative infection between the antibiotic and placebo groups ($p<.368$).

Discussion

Mandible is the second most commonly injured facial bone and accounts for 25 to 70% of all facial fractures [8,9]. Many mandibular compound fractures are treated using open reduction and internal fixation (ORIF) due to its superior stabilization of the fracture line, better healing, and faster recovery while minimizing the duration of immobilization of the mandible [10]. However, ORIF requires making an incision, which can lead to one of the most common complications of a mandibular fracture repair, postoperative surgical site infection. According to the classification of wounds based on their risk for infection [11-13], those associated with fractures of the mandible involving the tooth-bearing region (angle and body fractures) can be classified as Class III, known as the contaminated wounds.

In a prospective study [14] conducted on patients with compound fractures of the mandible who did not receive antibiotics, the incidence of infection was reported to be as high as 50% and the administration of prophylactic antibiotics was shown to reduce the incidence to as low as 6%. Chloe and Yee [15] have performed a randomized study on 101 patients with mandibular and facial fractures who were treated with either open or closed reduction. Their patients were divided into 2 groups; one received no antibiotics and the other received 1 preoperative and 1 postoperative 1g dose of intravenous cefazolin. They have found that perioperative antibiotics reduced the incidence of infection from 42% to 8.9% in patients with facial fracture [16]. Moreover, they

have reported that the rate of infection in mandibular fractures was reduced from 44% to 13%. The findings of both of these studies have confirmed the benefit of prophylactic antibiotics administration in preventing postoperative infection in mandibular fractures; however, neither of them evaluated the worth of postoperative antibiotics administration in reducing the rate of infection. The term "prophylactic antibiotics" refers to the antibiotics administered to prevent an infection in a surgical wound that may become contaminated during the surgical procedure.

It has been pointed out that the term "prophylactic antibiotics" may not be appropriated in the case of a fracture that is already contaminated before the surgical procedure. The purpose of the present study was to discover if postoperative administration of antibiotics are beneficial in the treatment of mandibular fractures involving the tooth-bearing segments. Abubaker and Rollert have conducted a study on 30 patients, all of whom received a postoperative regimen of 2 mIU penicillin G every 4 hours, up to 12 hours post operation [16]. In their study, 14 patients received penicillin VK 500 mg, postoperatively, every 6 hours for 5 days, while the other16 patients received placebo for the same duration of time.

Four patients suffered from postoperative infections in the mentioned study. No statistically significant difference was noted between the patients who received antibiotics and those who did not. The authors have concluded that "postoperative oral administration of antibiotics in uncomplicated fractures of the mandible had no benefit in reducing the incidence of infection". In 2006, Miles et al., have conducted a prospective randomized trial on patients treated for mandibular fractures using open reduction and internal fixation. Patients were excluded if their fracture was infected at the time of treatment [17].

A total of 181 patients were included in the final study sample. All the patients received preoperative antibiotics, not mandated by the study protocol. At the time of surgery, the patients were randomly divided into 2 groups; Ab and non-Ab groups, The Ab group received intraoperative antibiotics that consisted of 2g intravenous cephazolin (900 mg clindamycin if allergic to penicillin) as well as 2.4 mIU of intramuscular penicillin G benzathine at the conclusion of the procedure. Patients allergic to penicillin received intravenous clindamycin until being discharged, and then oral clindamycin for 5 to 7 days. The non-Ab group received intraoperative antibiotics (as above) but was not administered with postoperative antibiotics. The overall infection rate was found to be 12%. Moreover, the authors have stated that "they could not prove any statistically significant benefit to the administration of postoperative antibiotics in patients undergoing open reduction and internal fixation of mandibular fractures" [18].

The findings of the present study are in accordance with those reported by the above-mentioned studies. In conclusion, although antibiotics will continue to play a key role in the treatment of mandibular fractures, the results of our study indicated no statistically significant beneficial effect for postoperative administration of antibiotics in the treatment of open mandibular fractures when open reduction internal fixation techniques are used. In addition, administration of antibiotics results in advent of undesired issues. For instance, it can be associated with allergic or toxic reactions, drug interactions, and it contributes to increased bacterial resistance.

It is believed that, the reasons for excessively prolonged antibiotic administration could be due to the failure to identify and eliminate the foci of infection, failure to appreciate pharmacodynamics and impact of antibiotic trials on duration, limitations of performing antibiotic studies as cause for overuse, as well as failure to distinguish between contamination, infection, and inflammation [18]. Due to the relatively small sample size, the results of this study require to be supported by further studies using a larger sample size and providing more data on various confounding variables before it can be assuredly recommend to stop postoperative administration of antibiotics in the open reduction and internal fixation of facial fracture.

		Group Antibiotic	Group placebo
Age (mean)		26.31 ± 7.44	28.03 ± 9.3
Gender	Male	32 (84.2%)	18 (66.7%)
	Famale	6 (15.8%)	9 (33.3%)
Smoke		15 (39.5%)	9 (33.3%)
Alochol		8 (21.1%)	3 (11.1%)
PMH		6 (15.8%)	7 (25.9%)

Table 1. Demographic data of the antibiotic and non antibiotic (placebo) groups.

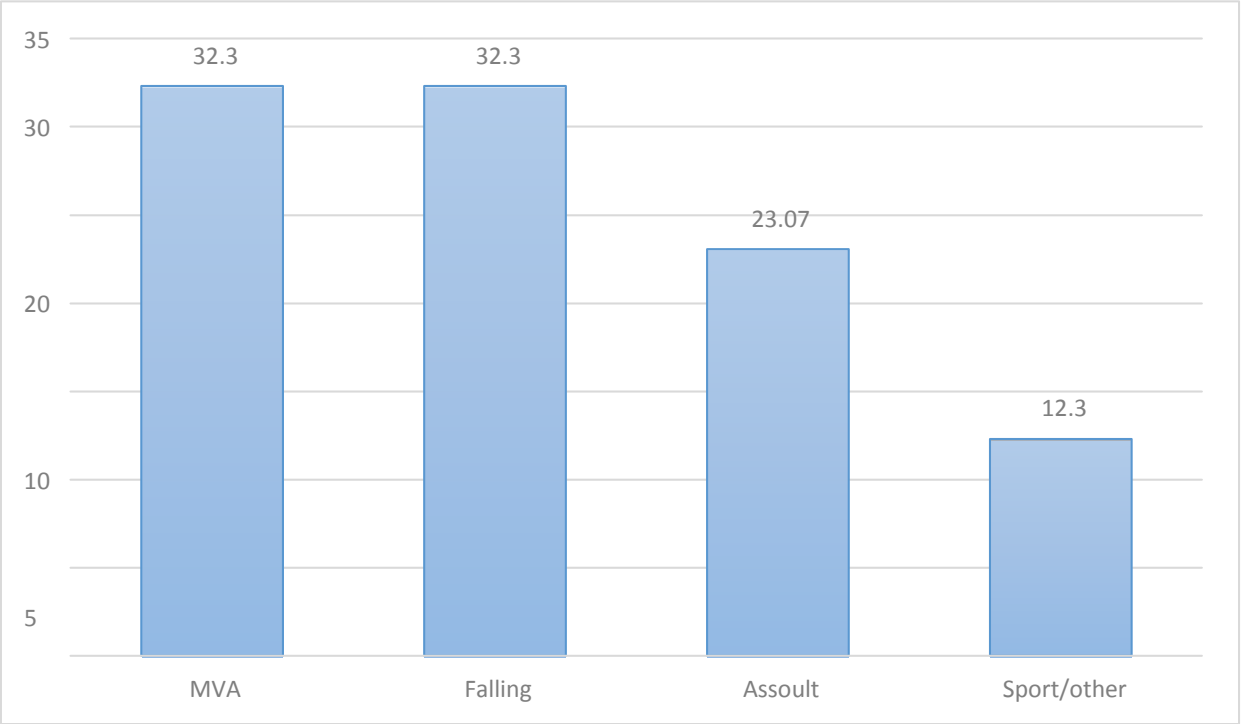

Table 2. Mechanism of fractures.

Site	Group Antibiotic	Total
	Group Placebo	
Angle	21	34
	13	(52.3%)
Body	18	31
	13	(47.7%)
Parasymphisis	13	24
	11	(36.9%)
Subcondylar	13	18
	5	(27.7%)
Symphysis	3	4
	1	(6.15%)

Table 3. Fracture location.

			Tooth		Total
			+	-	
Group	Antibiotic	Amount	9	9	38
		%	76.3%	23.7%	100%
	Placebo	Amount	17	10	27
		%	63%	37%	100%
	Total		46	19	65
			70.8%	29.2%	100%

Table 4. Teeth involved in the fracture line.

			Grade			Total
			0	1	2	
Group	Antibiotic	Amount	25	8	5	38
		%	65.8%	21.1%	13.2%	100%
	Placebo	Amount	16	3	8	27
		%	59.3%	11.1%	29.6%	100%
	Total		41	11	13	65
			63.1%	16.9%	20%	100%

Table 5. Incidence of postoperative infection.

Group	No need	Irrigation (Chlorhexidine)	Irrigation + Oral antibiotic	Total
Antibiotic	25	8	5	38
	65.8%	21.1%	13.2%	100%
Placebo	16	3	8	27
	59.3%	11.1%	29.6%	100%

Table 6. Additional treatment of the surgical site infection.

Conflict of Interest

There is no conflict of interest to declare.

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