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Efficacy of Cefazolin and Cefotaxime in the treatment of mandibular fractures and teeth involved- A comparative study.

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Abstract

Aim: The purpose of this study is to establish a relationship between mandibular fracture sites, vitality of teeth in the line of fracture, displacement of the fractured segments treated with open reduction and fixation and to evaluate the function and outcome of teeth retained after administration of Cefazolin and Cefotaxime.

Materials and Methods: Data was collected from 56 patients treated by open reduction and internal fixation for 71 mandibular fractures during a mean follow up of 14 months with a mean age of 34 years at oxford dental college. Outcome variables were pulp vitality of the teeth involved and post operative infection after intravenous administration of Cefazolin and Cefotaxime respectively. The relationship of demographic variables, teeth involved in the line of fracture and the management of fractured segments were analyzed using Mann Whitney and Chi Square test.

Results: The mean age of Group A was 30.6 years (SD of 11) and that of Group B was 31.3 years (SD of 10.2) and the p- value was 0.77[a] with a male to female ratio of 78.6%: 21.4% in Group A and 82.1%: 17.9% in Group B with a p- value of 0.74[b]. Out of 28 fracture sites in Group A; 20 teeth (71.4%) were retained in which 2 teeth (66.7%) showed post operative complications and required root canal treatment whereas, 1tooth (33.3%) got re- infected and was later extracted. On the other hand, out of 28 fracture sites in Group B; 23 teeth (82.1%) were retained in which 2 teeth (66.7%) teeth were re- infected and had to be extracted while 1 tooth (33.3%) required root canal treatment. Parasymphysis fracture was the most common type with an incidence of 39.3% in Group A and 21.4% in Group B respectively; while bilateral parasymphysis and body fracture were the least common with an incidence of 0% in Group A and 3.6% in Group B.

Conclusion: There is an increased risk for post operative complications when teeth in the line of fracture are extracted; though it is statistically insignificant. Evaluation of fate of retained teeth showed better prognosis of Type I and II as compared to Type III and Type IV. Results conclude that teeth involved in mandibular fractures need not be removed as a prophylactic measure and the administration of Cefazolin showed better post operative results as compared to Cefotaxime.

Keywords: Antibiotics, Line of fracture, Mandibular fracture, Tooth vitality, Retention.

Introduction

Surgeons have been in a never ending debate when it comes to retaining or extracting teeth involved in the line of fracture [1]. The successful attempts of retaining teeth in the line of fracture have made it a relative rather than absolute indication of extracting such teeth [figure 1 and 2]. As teeth involved in the line of fracture carry a potential risk of infection and challenge the manipulation and reduction of fractured segments; it has always been an easier option to extract them [1,2,3]. With the advent of antibiotics and strict adherence to sterilization protocol, it has been easier to retain teeth involved in the fracture line [4]. Such teeth not only yield overwhelming aesthetics and occlusion but also aid in the reduction and manipulation of the fractured segments [1, 2, 5].

Evidence suggests that surgical treatment without an antibiotic is incomplete [6] but recently the efficacy of prophylactic antibiotics was questioned due to lack of evidence in maxillofacial surgery [7]. Antibiotics like betalactam, clindamycin, aminoglycoside and flouroquinilone are commonly used in head and neck surgeries [8] and have shown a reduced rate of infection in patients compared to placebo [8, 9]. Cefazolin was proven better over penicillin and clindamycin in reducing surgical site infections in orthognathic surgeries [10]. One of the commonest conditions encountered by surgeons is a fractured mandible and the teeth involved with it [1, 11]. Cefazolin and Cefotaxime are widely used for surgical prophylaxis due their broad spectrum of activity, good tissue penetration and low toxicity [12- 15]. The purpose of this study is to evaluate the relationship between mandibular fracture sites and the teeth involved after administration of Cefazolin and Cefotaxime as a detailed evaluation of their in vivo effects has not been carried out so far to the best of our knowledge.

Materials and Methods

Enrolment

The study was performed from December 2015 to November 2017 in the department of oral and maxillofacial surgery, oxford dental college, Bangalore. 56 patients in the age group of 16-52 (mean age= 34) years having 71 mandibular fractures fulfilling the inclusion criteria were included in this study (Table 1) [Figure 3, 4 and 5].

Intervention allocation

The treatment protocol included open reduction and internal fixation with three dimensional titanium miniplates and screws performed under general anaesthesia. Maxillomandibular fixation was used intraoperatively to help achieve occlusion. Pulp vitality of the teeth involved was recorded pre and postoperatively with an electric pulp tester. Antibiotic culture sensitivity tests were performed and patients were administered IV cephalosporin 1gm twice daily (Cefazolin and Cefotaxime to Group A and Group B respectively) and IM diclofenac sodium 75 mg SOS (analgesic and anti inflammatory) postoperatively for 5-7 days. Patients were also prescribed an antiseptic (Chlorohexidine) mouthwash for 7 days.

Follow up

Periodic follow up was carried out for 12-16 (mean= 14) months, in which the patient was assessed clinically and radiographically. Teeth which were symptomatic i.e. showing presence of mobility, tenderness or radiographic changes were subjected to further treatment either root canal treatment or extraction after obtaining an informed consent from the patient. The diagnostic criteria for infection noted in this study was swelling, pain, purulent discharge, dehiscence and surgeon's diagnosis [10]. Whereas the fracture segments showing non-union with infection were re-treated with proper debridement, curettage and open reduction and re-fixation. Such patients were advised combination with Clindamycin for a broader antibacterial spectrum.

Analysis

The data collected from the patients included preoperative and postoperative radiographs; including CT scans and OPG (Figure 3, 4 and 5), age, sex, site and type of fracture and antibiotic sensitivity reports. Teeth involved were classified as per *Kamboozia's* [16] classification (Figure 2) [Table 1]:

Type I: Fracture line which follows the root surface from apical region to gingival margin with denudation of root surface.

Type II: Fracture line which follows the root surface from gingival margin but does not cross apical region.

Type III: Fracture line passing only through apical region.

Type IV: Fracture line crossing the root without passing through apical region or without producing denudation of root surface.

That means apical foramen is involved in Type I and Type III and is not involved in Type II & Type IV.

Results

The mean age of Group A was 30.6 years (SD of 11) and that of Group B was 31.3 years (SD of 10.2) and the p-value was 0.77[a] with a male to female ratio of 78.6%: 21.4% in Group A and 82.1%: 17.9% in Group B with a p- value of 0.74[b] [Figure 6 and 7]. A periodic follow up for 16-12 (14) months was carried out (Table 2). The patients were evaluated for pulp vitality and infection (Table 3). Parasymphysis fracture was present 39.3% of the time in Group A and 21.4% in Group B (Table 4) [Figure 8 and 9]. 12 teeth (21.4%) were non vital while 44 teeth (78.6%) showed minimal response [Figure 10 and 11]; from which 13 teeth (23.2%) were extracted (Table 5) [Figure 12 and 13]. Postoperative infection occurred in 3 patients (50%) of the patients. Type I (50% in Group A) and Type II (39.3% in Group B) fracture was seen more commonly as compared to other sites.

Group A showed better post operative results after administration of Cefazolin as compared to Group B which was administered Cefotaxime. 3 Patients had to undergo intraoperative-retrograde root canal treatment with apicectomy to reduce any post operative complications. The post operative follow up showed positive results for teeth retained when Cefazolin (Group A) was administered with lesser periapical radiolucencies at the apex of the teeth involved and the fractured segments showed negligible radiolucency with a good approximation indicating healing. This demonstrated that Cefazolin has a better bone penetrating potential as compared to Cefotaxime. Cefazolin also offered better results in terms of teeth vitality; as out of 20 retained teeth (71.4%) only 1 tooth (33%) was extracted due to re-infection. On the other hand, Cefotaxime (Group B) had to undergo extraction of 2 teeth (66.7%) due to residual infection and potential contamination be taken. The antibiotic regimen for such cases required Clindamycin for a broader antibacterial spectrum. Group A had a higher incidence of Gross fracture displacement (60.7%) while Group B had a higher incidence of Minimal fracture displacement (57.1%).

Statistical analysis

Statistical Package for Social Sciences [SPSS] for Windows, Version 22.0, Released 2013, Armonk, NY: IBM Corp., was used to perform statistical analyses

Descriptive statistics

It includes expression of the study variables with categorical data in terms of number & percentage whereas in mean & standard deviation [SD] for continuous data.

Inferential statistics

Chi Square Test was used to compare the different pre-operative study variables, Pulp Vitality & Tooth condition and Postoperative Complications between Group A & Group B.

The level of significance [P-Value] was set at P<0.05.

Discussion

Incidence of mandibular fracture ranks the first among all the fractures of facial skeleton due to its unique position [1, 11]. Mandibular fractures are more prone to infections due to vascularity, exposure and gravitational force which cause bacteria rich saliva to accumulate along the fracture sites [7, 17, 18]. Many studies believe that the difference in the rate of infection might just be in the fact that how long the fracture segments and the teeth involved were exposed to the oral cavity [17]. The prognosis of teeth involved in the fracture depends on multiple factors and the fracture site is considered open as it communicates with the oral cavity due to the presence of periodontal ligament [1, 19] and might act as a nidus of infection [2, 3, 4]. Teeth involved may get devitalised due to spread of existing infection [1, 2, 5], traumatic severance of vessels or due to thrombosis [1]. In the preantibiotic era, such teeth acted as foreign bodies, complicating healing [1, 2] and hence were extracted [20, 21] to decrease the risk of osteomyelitis, non union and delayed union [1, 2, 20, 21].

In the past, attempts have been made to re-establish new and improved guidelines for retention of teeth in the line of fracture [1, 4].

Easy reduction and complication free stabilization has always been the goal for fracture management. Literature suggests that conservatively managed teeth in the line of fracture have a favourable prognosis, provide better repositioning [1-5, 22], prevent telescoping of the fractured segments, provide occlusal reference and posterior stop and attain proper arch alignment [15, 22]. Extraction of teeth involved not only reduces the contact between fracture segments and causes bone loss but also hinders osteosynthesis leading to micromobility and increases the risk of contamination, as an empty alveolus is an open wound which requires suturing [1], making the use of antibiotics mandatory in the treatment of mandibular fracture [7]. Recent study suggests that surgical treatment with antibiotic prophylaxis for a week show a fourfold decrease in post operative infections [17].

The choice of antibiotics and the criteria for treatment are best described by the CDC guidelines [23].

The characteristics of an ideal surgical prophylactic regimen include cost effectiveness, prevention of pre and post operative infection with minimal side effects. The drug should be active against the organism most likely to cause infection, should have a good concentration in the system, should be effective in minimal concentrations without resulting in toxicity and should not develop resistance [24].

Cefazolin is a first generation cephalosporin, having a broad spectrum of activity and low toxicity. It is active against gram positive cocci such as pneumococci, staphylococci; gram negative rods such as *e.coli*, klebseilla pneumonia; anaerobs like peptococcus and streptococcus whereas; Cefotaxime is a third generation cephalosporin which has an extended spectrum of activity against gram negative coverage including citrobacter, enterobacter, *P. aerogenosa* and beta lactamase producing meningococci and *H. influenza* [25, 26]. Literature suggests that there are no apparent benefits for choosing any particular generation of cephalosporins but these are the most widely used groups because of their prophylactic and therapeutic indications [24]. Cephalosporins are similar to Penicillin in its chemical structure. They have a low molecular weight, comprise of beta lactam rings on which the antimicrobial activity depends [15, 26]. Newer cephalosporins have a wider spectrum of antimicrobial activity but no literature supports the fact that such benefits are needed for surgical prophylaxis in oral and maxillofacial surgery. Theoretically, the newer cephalosporins have enhanced pharmacokinetics but these properties have not produced any significant results [24]. Cefazolin and Cefotaxime have been used successfully in various orthopaedic and general surgeries with negligible side effects and complications [24]. Systemic use of

Cefazolin and Cefotaxime has shown improved post operative morbidity and a short term prophylaxis is equally as effective as longer regimes [14, 27] and results in no resistance [25]. Cefazolin shows excellent bone and soft tissue penetration after a single intravenous dose [13, 28]. The prophylactic use of Cefazolin apperars to be more effective than penicillin and clindamycin for preventing surgical site infection in orthognathic surgery [29] and its preoperative administration decreases post operative infections in fractures and head and neck surgeries [13, 17, 30].

Conclusion

We would like to conclude that there is an increased risk for post operative complications when teeth in the fracture line are extracted prophylactically. The retention of such non infected teeth with proper antibiotic coverage yield better results at healing, good fracture reduction and manipulation with occlusal reference. Hence, we would suggest that such non infected teeth should be retained with proper antibiotic coverage and routine post operative follow-ups. Conservative management with Cefazolin proved beneficial for patients although we believe that a comparison of the two drugs in the same patient would yield further evidence in support of the study. The findings and results of this study may make the base for further investigations in the same field to yield more significant results.

Limitations

The choice of antibiotic was purely based on the availability and cost effectiveness. The study was unable to access and compare the effect of other antibiotics for the same. Further studies with larger sample size need to be performed to determine the best antibiotic for the treatment of mandibular fractures with teeth involved.

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Compliance with Ethical Standards

Conflict of interest: All authors declare that they have no conflict of interests.

Ethical approval: All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional research committee 2017 standards.

Informed consent: Informed consent was obtained from all the individual participants included in the study.

Funding: No external funding, apart from the institution was used for the study. The drugs used in this study were purchased from the pharmacy situated in the institution and were purely chosen for their ease of availability. Drugs used were from Alkem (Gsk. Pvt. Ltd.).

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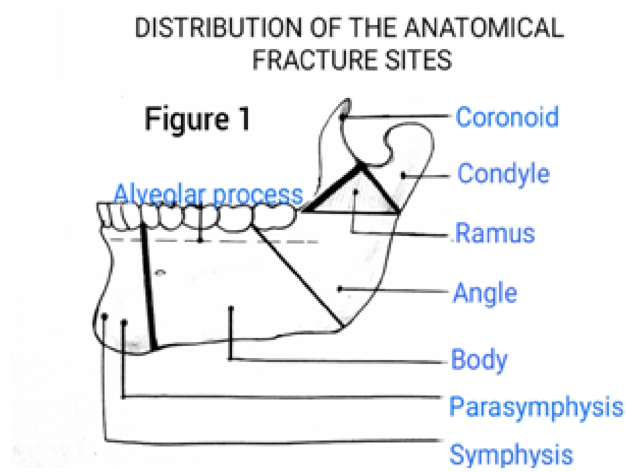

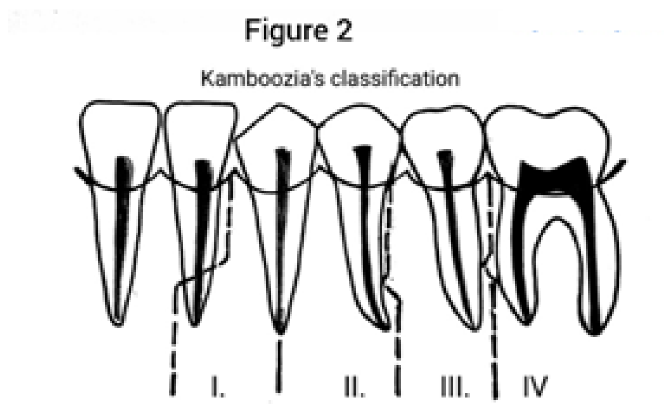

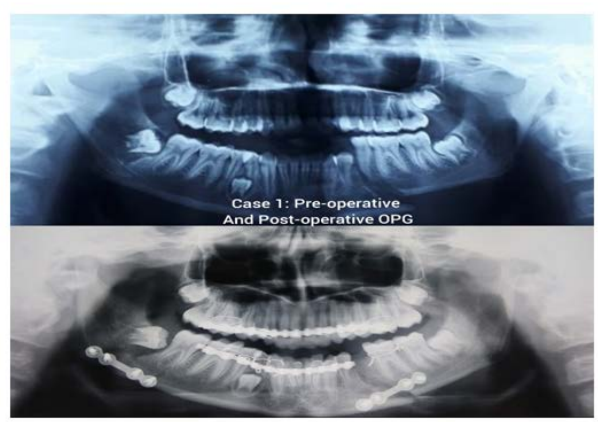

Figure 3: OPG of Pre and Post-operative left parasymphysis and right angle fracture with teeth retained in the line of fracture.

Figure 4: CT Fracture of right parasymphysis and left angle with teeth involved in the fracture line

Figure 5: OPG of Pre and Post-operative right angle fracture with tooth retained in the line of fracture.

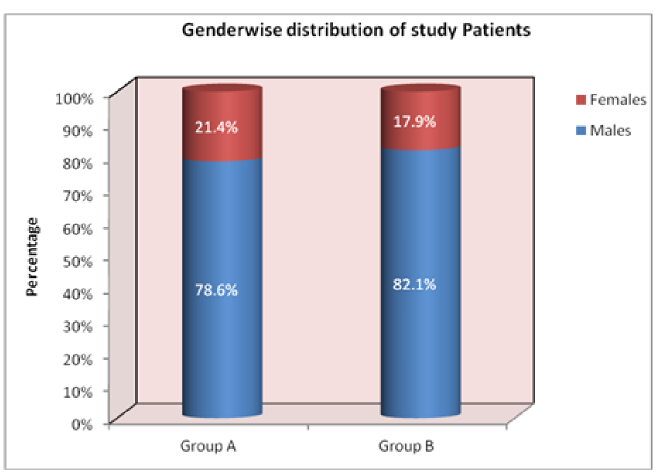

Figure 6: Gender distribution in Group A and Group B.

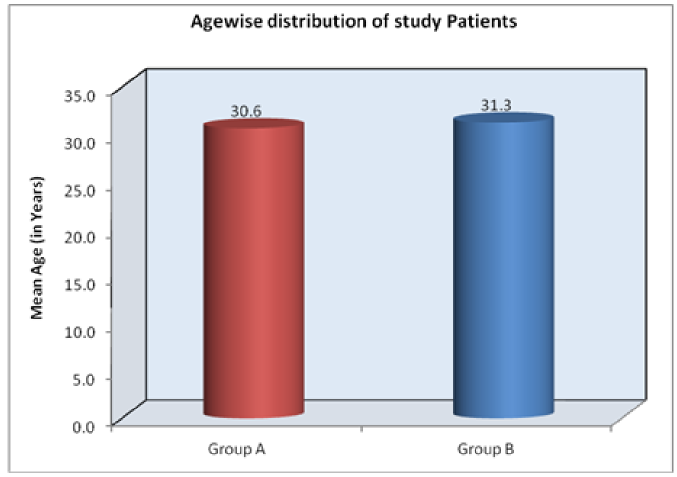

Figure 7: Age distribution of Group A and Group B

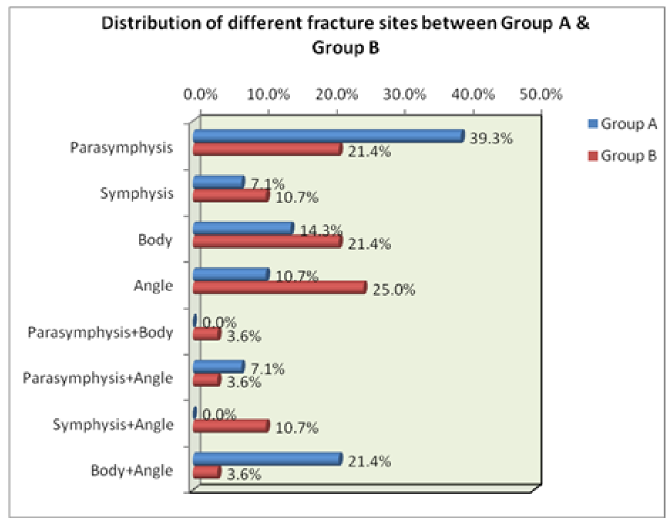

Figure 8: Distribution of different fracture sites between Group A and Group B.

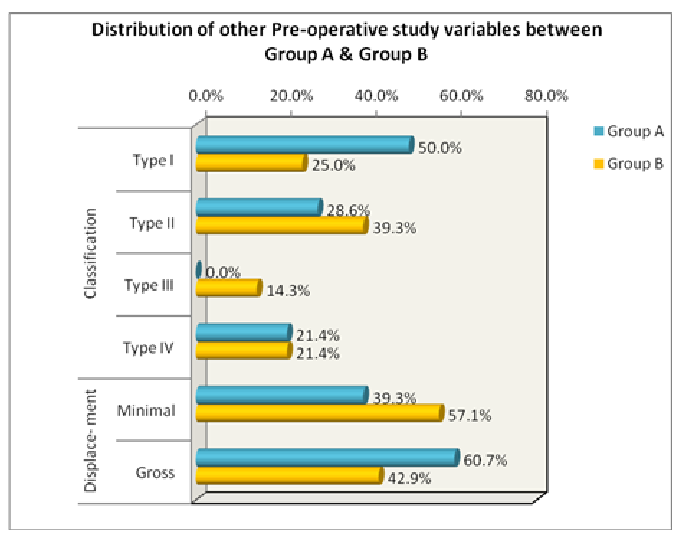

Figure 9: Distribution of other Pre-operative study variables between Group A and Group B.

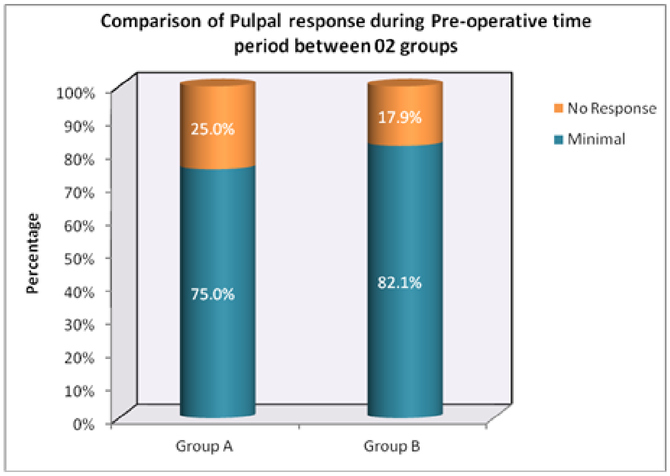

Figure 10: Comparison of Pulpal response during Pre-operative time period between 2 groups.

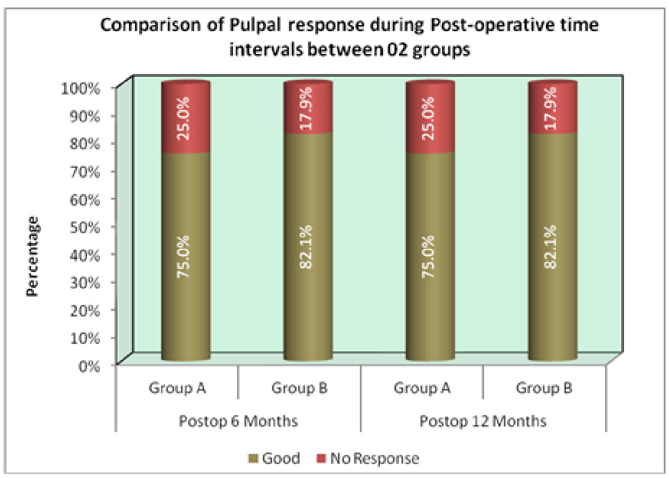

Figure 11: Comparison of Pulpal response during Post-operative time intervals between 2 groups.

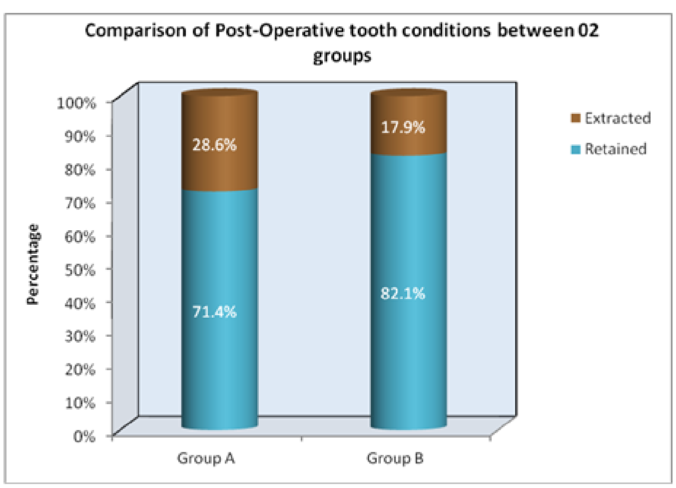

Figure 12: Comparison of Post-Operative tooth conditions between 2 groups.

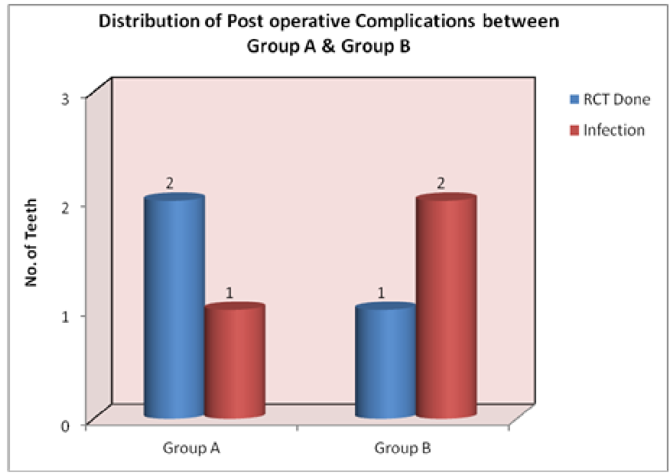

Figure 13: Distribution of Post operative Complications between Group A and Group B.

Table 1: Inclusion and exclusion criteria for the study

S.No.	Inclusion criteria	Exclusion criteria
1.	Clean, contaminated mandibular fractures and patients with good oral hygiene.	Multiple, communited and contaminated mandibular fractures and patients with poor oral hygiene.
2	Patients sensitive to Cefazolin and Cefotaxime.	Patients resistant to Cefazolin and Cefotaxime.
3.	Patients in the ASA category I and II.	Pregnancy and patients in the ASA category III, IV, V and VI.
4.	Teeth in the line of fracture with no mobility, periodontal pathology or endodontic lesion.	Teeth in the line of fracture with caries, mobility, compromised periodontium, endodontic lesion, root fractures or teeth not directly in the line of fracture.
5.	Fractures in symphysis, parasymphysis, body and angle of the mandible (Figure 1)	Fractures in condyle and coronoid of the mandible.

Table 2: Age and sex distribution of Group A and B.

Age and Sex distribution between 02 study groups						
		Group A		Group B		
Variables	Category	Mean	SD	Mean	SD	P-Value
Age	Mean ±SD	30.6	11.0	31.3	10.2	0.77[a]
	Range	16 - 51		16 - 52		
		n	%	n	%	
Sex	Males	22	78.6%	23	82.1%	0.74[b]
	Females	6	21.4%	5	17.9%	

Table 3: Comparison of Pulp Vitality between Group A & Group B

Comparison of Pulp Vitality between Group A & Group B at different time intervals using Chi Square Test									
		Group A		Group B		Total			
Time	Pulp Response	n	%	n	%	n	%	c^2 Value	P-Value
Pre Op	Minimal	21	75.0%	23	82.1%	44	78.6%	0.424	0.52
	No Response	7	25.0%	5	17.9%	12	21.4%		
Postop_6m	Good	21	75.0%	23	82.1%	44	78.6%	0.424	0.52
	No Response	7	25.0%	5	17.9%	12	21.4%		
Postop_12m	Good	21	75.0%	23	82.1%	44	78.6%	0.424	0.52
	No Response	7	25.0%	5	17.9%	12	21.4%		

Table 4: Comparison of different pre-operative study variables between Group A &Group B using Chi Square Test.

Comparison of different pre-operative study variables between Group A & Group B using Chi Square Test									
		Group A		Group B		Total			
Variables	Categories	n	%	n	%	n	%	c^2 Value	P-Value
Fracture site	Parasymphysis	11	39.3%	6	21.4%	17	30.4%	11.575	0.12
	Symphysis	2	7.1%	3	10.7%	5	8.9%		
	Body	4	14.3%	6	21.4%	10	17.9%		
	Angle	3	10.7%	7	25.0%	10	17.9%		
	Parasymphysis+Body	0	0.0%	1	3.6%	1	1.8%		
	Parasymphysis+Angle	2	7.1%	1	3.6%	3	5.4%		
	Symphysis+Angle	0	0.0%	3	10.7%	3	5.4%		
	Body+Angle	6	21.4%	1	3.6%	7	12.5%		
Classification	Type I	14	50.0%	7	25.0%	21	37.5%	6.807	0.08
	Type II	8	28.6%	11	39.3%	19	33.9%		
	Type III	0	0.0%	4	14.3%	4	7.1%		
	Type IV	6	21.4%	6	21.4%	12	21.4%		
Displacement	Minimal	11	39.3%	16	57.1%	27	48.2%	1.788	0.18
	Gross	17	60.7%	12	42.9%	29	51.8%		

Table 5: Comparison of Tooth condition and Postop Complications between Group A & Group B using Chi Square Test.

Comparison of Tooth condition and Postop Complications between Group A & Group B using Chi Square Test									
		Group A		Group B		Total			
Time	Tooth Condition	n	%	n	%	n	%	c^2 Value	P-Value
Tooth	Retained	20	71.4%	23	82.1%	43	76.8%	0.902	0.34
	Extracted	8	28.6%	5	17.9%	13	23.2%		
Complications	RCT Done	2	66.7%	1	33.3%	3	50.0%	0.667	0.41
	Infection	1	33.3%	2	66.7%	3	50.0%		