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Research Article

ROLE OF POSTOPERATIVE ANTIBIOTICS IN MAXILLOFACIAL FRACTURES: A RANDOMIZED CLINICAL STUDY IN CHENNAI POPULATION

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ABSTRACT

Despite the use of best aseptic surgical techniques maxillofacial fractures carry a high risk of wound infection which is greater as it has potential contamination with oral micro-flora. Studies on the use of prophylactic antibiotics have shown that there is a clear benefit to their use in preventing infection. However such studies did not establish a scientific basis for the duration of such use. One of the most common reason for misuse of prophylactic antibiotics is the excessive duration which can lead to increased bacterial resistance & prolonged use may also increase the risk of complication from super infection.

This study was aimed to determine efficacy of 1 day vs. 5 days antibiotic course in lowering the rate of infection in postoperative patients of mandibular, lefort, & zygomatic fracturers, by comparing the incidence of infection.The study suggested that postoperative 1day or 5days of oral antibiotics does not give an impact on the infection rate. In this note, antibiotic resistance can be easily steered off, unethical use of antibiotics can be shunned and can also be cost effective.

INTRODUCTION

Prior to mid-19th century, postoperative fever, purulent drainage from incisions, sepsis, and often death were common[1]. Following introduction of the principles of antisepsis, morbidity due to postoperative infections decreased substantially.

Antibiotics were originally used as therapeutic agents. Since no antisepsis could be fully effective and no living tissue could be absolutely impenetrable by pathogen, the concept of using antibiotic prophylaxis was considered. It was initially studied by Miles in 1957 and Burke in 1961[3].Antibiotic prophylaxis refers to preoperative administration of antibiotics for the prevention or reduction of post-operative infection, or can be described as the use of antibiotics to avoid infections at a surgical site in the absence of an established infection[4,5,6].

Postoperative infections can significantly reduce with appropriate antibiotics use in facial fractures surgical management[8]. In maxillofacial injuries communication is most often with the skin surface, oral cavity, or sinuses, which are contaminated with endogenous flora. Even in closed fractures, surgical management often necessitates an approach through a contaminated field thus influencing the chances of infection[2,8]. The role of antibiotics in infection prevention at the fracture site in the management of compound facial fractures has been well established[9].

To prevent surgical site infections most important factors are appropriate timing of prophylactic antibiotics administration (one hour before surgical incision), selecting the most efficacious antibiotic, and duration of postoperative antibiotic[10].The antibiotic duration differs from one single dose up to 10 days postoperatively but yet there is a lack of a consensus about most efficacious postoperative antibiotic regimen after facial fractures[8].

A number of prophylactic antibiotic regimens for maxillofacial trauma surgery have been studied. The antibiotics being used for prophylaxis must be bactericidal, act against bacteria that are most likely to cause infection, and be least toxic[5].On the other hand, antibiotics should not be used to cover up for poor surgical approach[3]. Due to the undesired effects of antibiotics such as antibiotic resistance, super infection, allergic reactions, toxic reactions, and secondary infections, prescribing an optimum dose of antibiotics is essential to prevent postoperative infections [11].

The department of Oral and maxillofacial surgery in Sri Ramachandra University is well-known for its excellence as a tertiary care centre in maxillofacial trauma management. The aim of the study was to evaluate the role of post-operative use

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of antibiotics duration (1day vs. 5day or more) on the incidence of infection after maxillofacial fractures and to determine if an extended regimen of prophylactic antibiotics after either open or closed reduction of these fractures is helpful in decreasing the rate of infection in post-operative patients. If there is no role of extended regimen of prophylactic antibiotic postoperatively, this excessive duration can be avoided which will help in preventing bacterial resistance & super infection as well as being cost effective.

Aim and Objectives

- To determine efficacy of prophylactic antibiotics on the incidence of infection in maxillofacial trauma.
- To determine efficacy of 1 day vs. 5 days antibiotic course in decreasing the infection rate in postoperative patients.

MATERIALS AND METHODS

Patients admitted directly under the Department of Oral and Maxillofacial Surgery at Sri Ramachandra University and Medical Centre Chennai with maxillofacial fractures during the year 2014-2015 were included in this study. Other important parameters such as whether the fracture had an alveolar extension, surgical approach used and anatomical classification were also noted.

Inclusion Criteria

- Healthy males or females
- Managed with open reduction and internal fixation / closed reduction under general anaesthesia
- Age >18 years
- Patients who gave informed written consent for study

Exclusion Criteria

- Presence of infection at the site of fracture onfirst presentation
- Dirty & infected wound pathological fracture (cysts / tumors)
- History of malignancy / radiation therapy to head or neck region
- Compromised host defence
- Hypersensitivity to antibiotics like β-Lactams
- Reduced body weight (<40kg or BMI<17)
- Poor compliance

METHODOLOGY

Forty patients (36 Males, 4 Females) who presented with maxillofacial fractures were included in the study. After accepting to participate in this study patients were randomly assigned into two groups (A & B). From admission until 24 hours post-operatively, all patients in both groups were given prophylactic antibiotic (IV amoxicillin/clavulanic acid 1.2g thrice daily). Patients in B group continued the antibiotic for additional 4 days (amoxicillin/clavulanic acid 625mg thrice daily orally). Chlorhexidine mouthwash 0.1% were also prescribed for all patients with intra-oral approach or with fractures with intra-oral communication. Patients were followed up and evaluated every day during their stay at the hospital. After discharge, they were followed up at 1, 2, 4, 6 weeks.

Infection Criteria

All patients were evaluated according to the criteria for infections of surgical site published by *The Centres for Disease Control and Prevention (CDC).*

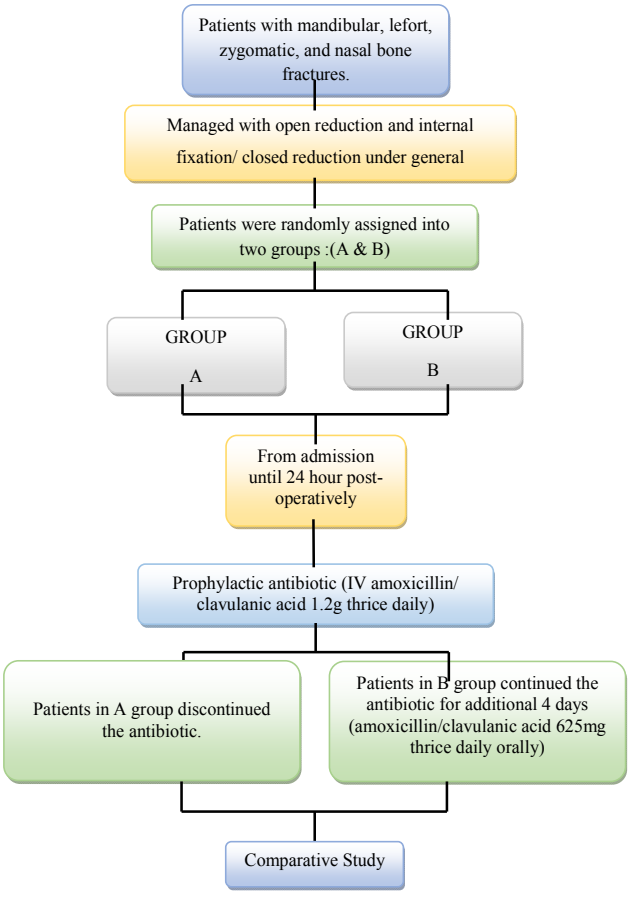
- Purulent discharge (with or without microbiological confirmation)
- Spontaneous wound dehiscence
- Abscess
- Deliberate opening of the wound by a surgeon in cases with signs and symptoms indicating infection
- Localized pain or tenderness
- Fever ≥38ºC
- Erythema
- Mild (<1 cm along the suture line)
- Moderate (1-5 cm)
- Severe (> 5 cm)

Post op radiographs were also evaluated

Grade I: Ossified fracture site/ no change from initial injury
Grade II: Localized radiolucenciesin relation to hardware or necrotic tooth
Grade III: Generalized radiloucencies of fracture or hardware

Treatment for Infection

Patients were treated with local measures like:



Flow Chart - Study Design

- Drainage
- Daily Povidone Iodine irrigation for wound

In case of deeper infections, broad spectrum antibiotics & modification according to pus Culture and Sensitivity reports were done.

RESULTS

Of these patients, 36 were males (90 %) and 4 were females (10 %). There were 2 females and 18 males in each group. Mean age of the patients was 34.07 years (range 19 to 58 years). Patients in Group A had a mean age of 34±10 years and those in Group B had a mean age of 35±10 years. All 20 (100%) cases in each group were performed under general anaesthesia. Infection was noted in 4 (20%) patients from each group with $p = 1.000 > 0.05$ suggesting no statistical significance between the rate of infection in Group A and B.

T- test done to compare infection with age, suggested $t = 0.096$ and $p = 0.924 > 0.05$ suggesting no statistical significance between age and infection.

When infection and gender are compared all 8 patients who got infected are males with a $p = 0.292 > 0.05$ suggesting no statistical significance between gender and infection.

The cases included in the study in Group A comprised of mandible fractures (n = 7), Zygomatic or zygomaticomaxillary complex fractures (n = 7), Le fort fracture (n = 1), nasal bone fracture (n = 1) and combined fractures (n = 4). While Group B comprised of mandible fractures (n = 8), Zygomatic or zygomaticomaxillary complex fractures (n = 7), Le fort fracture (n = 1) and combined fractures (n = 4).In group A infection was noted in 1 zygomatic fracture, 1 Le fort fracture, and 2 combined fractures. Whereas in group B it was noted in 2 mandible fracture, 1 zygomatic fracture, and 1 combined fracture.

Table 1 Types of fractures and infection rate in both groups

Fractures	Group A	Group B	Infected Group A	Infected Group B
Mandible fractures	7	8	0	2
Zygomatic or zygomaticomaxillary complex fractures	7	7	1	1
Le Fort fracture	1	1	1	0
Nasal bone fracture	1	0	0	0
Combined fractures	4	4	2	1

When infection and diagnosis are compared $p = 0.462 > 0.05$ suggesting no statistical significance between both.

In Group A, 17 (85%) patients underwent ORIF, 1 (5%) patient underwent closed reduction and 2 (10%) patients underwent ORIF for one fracture and closed reduction for other concomitant maxillofacial fracture. In Group B, 19 (95%) patients underwent ORIF, 1 (5%) patient underwent ORIF for one fracture and closed reduction for other concomitant maxillofacial fracture. $p = 0.488 > 0.05$.

Of the patients treated with ORIF 3 had infection in Group A and 4 in Group B. From Group A 1 patient treated with ORIF for one and closed reduction for other concomitant maxillofacial fracture had infection. When infection and surgery performed are compared $p = 0.744 > 0.05$ suggesting no statistical significance between both.

Table 2 Surgery done and infection rate in both groups

Surgery done	Group A	Group B	Infected Group A	Infected Group B
ORIF	17 (85%)	19 (95%)	3	4
Closed reduction	1 (5%)	0	0	0
ORIF for one and closed reduction for other concomitant maxillofacial fracture	2 (10%)	1 (5%)	1	0

9 (45%) patients in Group A and 10 (50%) patients in Group B had habits such as pan chewing, cigarette smoking or alcohol consumption. Of the patients with infection 3 (75%) form Group A and 2 (50%) from Group B had habits. When infection and habits are compared $p = 0.342 > 0.05$ suggesting no statistical significance between both.

2 (10%) patients in Group A and 4 (20%) patients in Group B had tooth in the line of fracture. Of the patients with infection 1 (25%) form Group A and 3 (75%) from Group B had tooth in the line of fracture. When infection and tooth in the line of fracture are compared $p = 0.002 < 0.05$ showed statistical significance difference between both suggesting that tooth in the line of fracture is a factor that may influence infection rate in post-operative patients with maxillofacial fractures.

7 (35%) patients in Group A and 9 (45%) patients in Group B had fractures extending to alveolar region. Of the patients with infection 2 (50%) form Group A and 3 (75%) from Group B had fractures extending to alveolar region. When infection and fractures extending to alveolar region are compared $p = 0.146 > 0.05$ suggesting no statistical significance between both.

In both group A as well as B, 2 (10%) patients extraoral approach, 11 (55%) patients intraoral approach and 7 (35%) both extraoral and intraoral approach was used to access to the fracture site. None of the patients with extraoral approach had infection in both the groups. Of the patients with infection 3 (75%) form from each group had intraoral approach. Whereas 1 (25%) of the patient in each group had both extraoral and intraoral approach. When infection and approach used are compared $p = 0.365 > 0.05$ suggesting no statistical significance between both.

Table 3 Comparison of factors influencing infection in both groups

Factors	Group A	Group B	Infected patients Group A	Infected patients Group B
Habits	9 (45%)	10 (50%)	3	2
Tooth in the line of fracture	2 (10%)	4 (20%)	1	3
Fractures extending to alveolar region	7 (35%)	9 (45%)	2	3
Extra oral approach	2 (10%)	2 (10%)	0	0
Intraoral approach	11 (55%)	11 (55%)	3	3
Extra oral and intraoral approach	7 (35%)	7 (35%)	1	1

The mean duration between time of injury and admission was 4.20 days in Group A and 3.55 days in Group B where as it was 4.25 in Infected Group A and 1.75 days in Infected Group B. The mean duration between time of injury and treatment was 7.25 days in Group A and 6.00 days in Group B where as it was 7 in Infected Group A and 4.75 days in Infected Group B.

Table 4 Time duration between injury, admission and treatment in both the groups and infected patients

Days	Group A	Group B	Infected Group A	Infected Group B
The mean duration between time of injury and admission	4.2	3.55	4.25	1.75
The mean duration between time of injury and treatment	7.25	6	7	4.75

T-test done to compare infection with duration between time of injury and admission suggested t = 0.627 and $p = 0.535 > 0.05$ which is statistically not significant.

Whereas T-test done to compare infection with duration between time of injury and treatment suggested t = 0.476 and $p = 0.637 > 0.05$ which is also statistically not significant.

All the Post-operative radiographs taken were classified as, Grade I (Ossification of fracture site/ no change from initial injury).

Regular irrigation with povidone iodine was done as a part of management of all 8 cases that developed infection. Oral antibiotic was advised for 1 (25%) patient with Erythema and swelling in 3rd postoperative week in Group A. Extraction of decayed tooth in the line of fracture was done for the 1 (25%) patient with Erythema and swelling in 3rd postoperative week in Group B.

Table 5 Intervention done for infection in both the groups

Intervention for infection	Infected Group A	Infected Group B
Irrigation with povidone iodine	4	4
Oral antibiotic	1	0
Extraction of decayed tooth in the line of fracture	0	1

In 1st post-operative week all patients had localized pain or tenderness and was not considered as an indicator for infection. 9 (45%) cases of Group A and 7 (35%) cases of Group B in 1st postoperative week had mild localized erythema was not considered as an indicator for infection.

Localised pain or tenderness was present beyond 1st post-operative (3rd week) in 1 (5%) patient from Group A and 2 (10%) patients from Group B. Moderate erythema in 1st postoperative week was present in 3 (15%) patients in Group A and 3 (15%) patients in Group B. Erythema with swelling in 3rd postoperative week was present in 1 (5%) patient in each group. Purulent discharge was present in 1 (5%) case from Group A and no patients from Group B.

Table 6 Signs of infection in both groups

Signs of Infection	Group A	Group B
Localised pain or tenderness was present beyond 1st post operative	1 (5%)	2 (10%)
Moderate erythema in 1st postoperative week	3 (15%)	3 (15%)
Erythema with swelling in 3rd postoperative week	1 (5%)	1 (5%)
Purulent discharge	1 (5%)	0
Spontaneous wound dehiscence	1 (5%)	0
Abscess	0	0
Fever ≥38degree Celsius	0	0
Deliberate opening of the wound	0	0

Spontaneous wound dehiscence present in 1 (5%) patient from Group A and no patients from Group B. No patients from both the group had Abscess, Fever ≥38°C or Deliberate opening of the wound.

1 (5%) patient in Group B had localized pain and tenderness in the 3rd post op week but had no signs of infection on clinical and radiographic examination. The pain was due to high points/occlusal discrepancy in relation to the premolars adjacent to operated fractured site and was relieved with coronoplasty of the teeth.

DISCUSSION

The principle of paramount significance in antibiotic prophylaxis is to do antibiotic administration scheduled such that high blood and tissue levels of antibiotic is present at the time when wound contamination by bacteria is anticipated. Achievement of the following two factors is important to avoid infection: 1) reducing bacterial load in the surgical wound, and 2) enhancing host defenses to avoid the bacterial invasion inevitably into the wound to cause clinically obvious infection.[3]

A landmark article demonstrated that the administration of antibiotic is maximally effective in preventing bacterial invasion when the antibiotic is administered prior to bacterial contamination. Administration of antibiotic three or more hours after bacterial contamination was ineffective in preventing bacterial invasion. This principle has been confirmed in human studies and is accepted today.[13]

Prior to the incision a prophylactic antibiotic should attain a high peak tissue concentration at the site of the wound and should be maintained till closure. The initial dose of antibiotic should be infused within 30 minutes prior to incision. If the operation is still continuing two half-lives following first dose to ensure adequate antimicrobial tissue concentrations, administration should be repeated intraoperatively.[14]

Despite using proper aseptic surgical procedures maxillofacial fractures have a major risk of wound infection as it has potential contamination with oral micro-flora. Studies on prophylactic antibiotic use shown clear benefit to their usage in infection prevention. How so ever a scientific basis for the duration of such use could not be established. The frequent reason for misuse of prophylactic antibiotics is the extended duration which can lead to increased bacterial resistance & may also increase the risk of super infection.

Chole *et al*[9] in 1987 stated antibiotic prophylaxis significantly diminished the post operative infections in facial fractures. Fractures involving the tooth-bearing regions of jaws have greater chances of infection when compared with other locations for example the subcondyle. It was following his work, that prophylactic antibiotics usage in maxillofacial fracture surgeries got popularized.

It has also been studied that prolonged antibiotic administration post-operatively does not help in reducing the chances of wound infection. For minor procedures, one single dose of preoperative prophylactic antibiotic is enough to avoid wound infection. For longer duration surgeries, as necessary intraoperative doses are administered, and finally a dose in the post-operative recovery area is enough for maximum infection prevention.

The overall infection rate in this study was 20% (8/40) which was in accordance with Benoit Schaller *et al* study on

mandibular fractures [15]lesser than that quoted by Chinmay *et al*[10] but was higher than those of some earlier studies[9,16,17,18] This could be because of the study population being selected and a wide variety of fractures being included. When wound infection rate was compared between the two groups A and B we found no significant difference, suggesting the infection rate in both the groups was similar.

Jürgen Zix *et al*[19] did not find any significant difference between the groups in the wound infection rate. Rabindra Singh *et al*[18] showed that decreasing the antibiotic prophylaxis duration from between 5 and 7 days to 2 postoperative doses gives no significant difference to the infection rate. Chinmay D.V *et al*[10] also found that infection rates were 32% and 32.2% in groups A and B respectively. In Matthias *et al*[8]studyGroup A had 125 patients who took 1 day of postoperative antibiotics, and Group B had 214 patients who took 5 or more days of postoperative antibiotics couldn't find statistical significance in the rate of postoperative infections.

And thus the suggestions is that an extended duration of antibiotic prophylaxis beyond 24 hours postoperatively does not influence the rate of infection post surgery

In our study potential risk factors that may influence infection rates were also noted down such as age, sex, type of fracture, ORIF or closed reduction, habits, tooth in the line of fracture, fractures extending to alveolar region, type of approach used extraoral or intra oral and duration between time of injury and admission as well as treatment were also noted down. There was no statistical difference between the above and infection rate, except in the case of tooth in the line of fracture ($P = 0.002 < 0.05$) suggesting that there can be a correlation between the tooth in the line of fracture and infection.

Comorbidities, tobacco and alcohol use, delayed presentation, operation duration, surgical site contamination and location of fracture in the dental arch can all be reasons for increased risk of infection[8,11,39]. Chinmay D.V *et al*[10] also found out that 67% of the patients having habits developed an infection while only 25% patients without them developed infection.

Matthias *et al*[8] presented five patients in 1day group A (4%) and seven patients in 5 days group B (3.27%) suffered infections. Out of these 12 patients, 7 had sustained multiple maxillofacial fractures. 11 infections occurred in those having mandibular fractures and 1 in a midfacial fracture. This clearly denotes that the extended use of postoperative antibiotics in midfacial fractures and uncomplicated mandibular showed no substantial benefits in decreasing the prevalence of infections.

An argument still persists about the management of the tooth in the line of fracture. A tooth in the line of fracture can act as a means of infection. If the tooth is still mobile and/or has an associated pathologies or causing danger it should be surgically removed. The effectiveness of high-dose perioperative antibiotic prophylaxis has been well established. Equally important is the fact that this type of prophylaxis has been associated with essentially a total absence of side effects and complications. One of the concerns that is frequently raised is the issue of encouraging the growth of resistant bacteria. However, it appears that resistant bacteria are prone to overgrowth only after the host's susceptible organisms are killed, which takes about 3 days of treatment with antibiotics. Generally it is accepted that perioperative antibiotic administration for 1 day decreases the colonization/super-infection risk.[20]Therefore, short-term (l day) prophylactic antibiotic usage has negligible role in the growth of resistant bacteria.[21]

Treatment with antibiotics and can differ from one dose to almost 7 to 10 days postsurgically. There is yet to be a common agreement in a single effective protocol postsurgically for antibiotic treatment after maxillofacial fractures.[18] There is no sure evidence that supports that the use of antibiotics for more than one day after surgery may decrease the risk of infection. Hence, it maybe deemed unnecessary to treat patients with antibiotics for more than this time period. A single administrative dose before the start of the surgery is probably all that is needed.[22]

Majid Eshghpour *et al*[15] also concluded that the use of aseptic technique and proper hygiene instructions following surgery is more important than the use of long-term antibiotic therapy to prevent postoperative infections.

CONCLUSION

To sum up in this study, no significance is seen between the infection rates of the two groups. This suggests that postoperatively 1day or 5days of oral antibiotics does not have an impact on the infection rate. In this note, antibiotic resistance can be easily steered off, unethical use of antibiotics can be shunned and can also be cost effective.

We also found a correlation between the tooth in line of fracture and the infection rate which was highlighted through this study. The duration of antibiotic prior to surgery was not the same for all the patients as we all know that trauma operations cannot always be scheduled as elective cases.

The need for sterile surgical technique and hygiene directions after a surgery is more important than the use of long-term antibiotic therapy to prevent postoperative infections.

On the other hand, the sample size in this study was not big enough to show and prove significant differences in the rates of infection and the presenting risk factors. In conclusion, large randomized studies are necessary in this to create guidelines on the use antibiotics for prophylaxis in maxillofacial fractures management but this study may be helpful for the basis of future research.

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