Comparison of Post-Operative Outcomes of Intermaxillary Fixation and Open Reduction with Internal Fixation of Simple Mandibular Angle Fracture: A Randomized Control Trial

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Abstract

Background: Surgical management of simple mandibular angle fracture is a very crucial process. Objective: The purpose of the present study was to compare the post-operative outcomes of intermaxillary fixation and open reduction with internal fixation of simple mandibular angle fracture. Methodology: This randomized control trial was conducted in the Department of Oral and Maxillofacial Surgery at Dhaka Dental College & Hospital, Dhaka and Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh from January 2010 to December 2010 for a period of one (01) year. Among all patients admitted/attended to the hospital IPD with fracture of mandibular angle with or without other associated fracture sites were selected as study subjects. After recruitment of the patients, they were assigned either as group A or group B after randomization. In group A the patients of this group were treated by open reduction and internal miniplate fixation with additional placement of intermaxillary fixation; in group B the patients of this group were treated by open reduction and internal miniplate fixation without any additional placement of intermaxillary fixation. During follow up period stability of fracture segments, post reduction alignment and inter-incisal opening were recorded. Result: A total of 30 patients presented with mandibular angle fractures were included in the study. They were allocated in two groups named miniplate osteosynthesis with Inter-maxillary fixation group (n=16) and without inter-maxillary fixation group (n=14) randomly. Time required to accomplish the surgical procedures was significantly high (p=0.000) group A (99.38±15.26 minutes) than group B (55.38±6.34 minutes). Among them 01 patient developed instability after inter-maxillary fixation. And 01 patient developed such in other procedure; however this difference is not statistically significant (p=0.724). In post operative radiography the mean score of post reduction alignment was slightly higher in group A than group B which was 2.50±0.516 and 2.21±0.426 respectively (p=0.107). The inter-incisal opening in baseline was 14.69 and 18.14 in group A and group B respectively. However, in review 3 it was found 36.19 and 37.64 in group A and group B respectively (p=0.8001). Conclusion: In conclusion significantly less operative time was required to accomplish the operative procedure in without IMF group as well as there was also a significant difference of inter-incisal opening between two procedures in subsequent review findings. [Journal of National Institute of Neurosciences Bangladesh, 2018;4(2): 108-112]

Keywords: Post-operative surgical infection; intermaxillary fixation; open reduction with internal fixation; mandibular angle fracture patients

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Introduction
Intermaxillary fixation is a difficult procedure. Immobilization for 8 weeks may cause marked thinning and disruption of the normal organization of the articular cartilage in growing period1. The use of wire however may be a harmful effect on the teeth and surrounding tissues. Splinting by the use of arch bar or wire loop fixation has been shown to affect the marginal condition adversely causing gingivitis and increased tooth mobility2. Wire ligatures, arch bars, splinting have some associated morbidity, including periodontal damage, decalcification under the splints and loosening and extrusion of supporting teeth. On the other hand this may prove fatal when emergency removal of the maxillomandibular fixation is necessitated by a compromised airway3.

The avoidance of the use of peroperative intermaxillary fixation is more economical in time and cost, is safer for the operator and more comfortable for the patient4. A study conducted in Bangladesh by Hasan5 stated that short term intermaxillary fixation after open reduction and internal fixation for mandible fracture gives good functional outcome. Treatment of mandibular fractures has changed over the last 20 years in Western societies. There has been a decrease in the use of wire osteosynthesis and intermaxillary fixation and an increase in preference for open reduction and internal fixation with miniplates6. There are controversies for the use of IMF in simple angle fracture in spite of the advancement of miniplate osteosynthesis.

Optimum treatment option for mandibular angle fracture is a debatable issue throughout the world. Different studies’ suggested different treatment protocol for managing such cases. Many studies were conducted to compare the treatment options in terms of complication rates. In Bangladesh no study was performed previously to assess the necessity of IMF for opens reduction and miniplate osteosynthesis. Therefore this present study was undertaken to compare the post-operative outcomes of intermaxillary fixation and open reduction with internal fixation of simple mandibular angle fracture.

Methodology
Study Settings and Population: This prospective observational study was conducted in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College & Hospital and Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh from January 2010 to December 2010. Patients attended to OPD or admitted to hospital with fracture of the angle of mandible of adult age group in both sex. Patients with permanent dentition having simple mandibular angle fracture those have given consent for open reduction and internal fixation and patients willing to bear the expenses regarding open reduction and stainless steel miniplate fixation under general or local anaesthesia were included in this study. Patients with associated condylar fracture or mid facial fracture, patients presenting with mixed dentition states, patients having infected or comminuted or severely displaced angle fracture, medically compromised patients, patients refusing to attend regular follow up and or refusing to be included in the study were excluded from this study. Particulars of the patient and injury were recorded following the organized data sheet. Special attention was paid to take history of any coexisting illness. Orthopantomogram (OPG) of mandible and P/A (Postero-anterior) view of mandible were taken pre-operatively to assess the fracture type and configuration and associated fracture. Standard laboratory investigations were done to assess the general conditions of the patients. Informed consents were taken from the patients or legal guardians after duly informing about the procedure of treatment, anticipated results and possible advantages, disadvantages and complications considering all ethical issues.

Randomization and Allocation: After recruitment of the patients, they were assigned either as group A or group B after randomization. In group A the patients of this group were treated by open reduction and internal miniplate fixation with additional placement of intermaxillary fixation; in group B the patients of this group were treated by open reduction and internal miniplate fixation without any additional placement of intermaxillary fixation. Teeth in the line of fractures were retained whenever possible (in both groups). Only the teeth that were mobile, had apical infection, had root exposure in markedly distracted fractures or interfere with either reduction or fixation of fractures were extracted. In group A open reduction and internal fixation was done with short term Intermaxillary fixation was given with Erich pattern arch bar. In group B open reduction was done with miniplate osteosynthesis without giving any additional intermaxillary fixation.

Followed up and Postoperative Outcomes Measurement: Operative time was measured from incision to closure of the wound including arch bar placement time for IMF in case of IMF group. Stability of fracture segments (assessed by manual pressure); Post reduction alignment: Post-reduction radiographs
(i.e., orthopantomograms) were taken for all patients before discharge. These radiographs were assessed using a score of from 1 to 3. A score of 3 was given to radiological evidence of precise anatomic reduction in the fracture site. A score of 2 was given to reduced fractures that were slightly displaced but had a satisfactory occlusion. The lowest score of 1 was for poorly reduced fractures that required a second operation to correct the poor alignment and unacceptable occlusion. Status of occlusion like whether any malocclusion such as open bite, cross bite present or not; mouth opening which was objective measurement of the inter-incisal distance after mouth opening was noted. All the patients received same standard antibiotic prophylaxis, analgesics and oral hygiene instructions. Patients of group A intermaxillary fixation was maintained for 2 weeks postoperatively with gentle elastic traction. Presentations were recorded in the follow-ups of 2 weeks, 4 weeks and 6 weeks postoperatively. During follow up period stability of fracture segments, post reduction alignment, mal-occlusion, inter-incisal opening and mal-union were recorded.

**Statistical analysis:** Data were analyzed by calculating the means and standard deviations, and Comparisons were made by Chi-Square and unpaired Student’s t-tests. P value <0.05 was considered significant. Statistical analysis was performed using a statistical software package STATA Data Analysis and Statistical Software, STATA version 10.0.

**Results**

A total of 30 patients presented with mandibular angle fractures were included in the study. They were allocated in two groups named miniplate osteosynthesis with Inter-maxillary fixation group (n=16) and without inter-maxillary fixation group (n=14) randomly. Data of a total number of 30 patients were analyzed. Among the 30 patients inter-maxillary fixation were done in 16(53.3%) patients and rest of the patients 14(46.7%) managed without giving Inter-maxillary fixation (Table 1).

| Surgical Procedure | Frequency | Percent |
|--------------------|-----------|---------|
| Group A             | 16        | 53.3    |
| Group B             | 14        | 46.7    |
| Total               | 30        | 100.0   |

Group A= With Inter-maxillary fixation; Group B= without inter-maxillary fixation

Age of the patients in group A was ranged from 17 to 43 years with the mean and SD of 28.1± 8.3 years and in group B ranged from 20 to 42 years with the mean and 28.7±6.3 years. Majority (60.0%) of the respondents were aged less than 30 years and only 12(40.0%) were between 30 to 50 years of age. Mean age of the patients was 29.5 years and median 30 years (Table 2).

**Table 2: Distribution of the respondents by age (Mean ± SD)**

| Study Groups | Mean Age | P value |
|--------------|----------|---------|
| Group A (N=16) | 28.1 ± 8.3 | >0.05   |
| Group B (N=14) | 28.57 ± 5.29 |         |

Group A= With Inter-maxillary fixation; Group B= without inter-maxillary fixation

Time required to accomplish the surgical procedures was significantly high (P=0.000) group A (Mean 99.38±15.26 minutes) than group B (Mean 55.38±6.34 minutes) (Table 3).

**Table 3: Operative times of study groups**

| Study Groups | Operative time(Minutes) | P value |
|--------------|-------------------------|---------|
| Group A      | 80-130                  | 99.38±15.26 | 0.0001 |
| Group B      | 50-70                   | 55.38±6.34  |         |

Group A= With Inter-maxillary fixation; Group B= without inter-maxillary fixation

Among them 01 patient developed instability after inter-maxillary fixation. And 01 patient developed such in other procedure; however this difference is not statistically significant (p=0.724) (Table 4).

**Table 4: Stability of Fracture Segments after Reduction**

| Surgical Procedure | Yes | No | Total | P value |
|--------------------|-----|----|-------|---------|
| Group A            | 15(94.0%) | 1(6.0%) | 16(100.0%) |         |
| Group B            | 13(93.0%) | 1(7.0%) | 14(100.0%) |         |
| Total              | 28(93.3%) | 2(6.7%) | 30(100.0%) | 0.724   |

In post operative radiography the mean score of post reduction alignment was slightly higher in group A than group B which was 2.50±0.516 and 2.214±0.426 respectively. However the difference between these two groups was not statistically significant (p=0.107) (Table 5).
The inter-incisal opening in baseline was 14.69 and 18.14 in group A and group B respectively. However, in review 1 it was 22.38 and 29.07 in group A and group B respectively. In review 2 the inter-incisal opening was 28.19 and 29.07 in group A and group B respectively. In review 3 it was found 36.19 and 37.64 in group A and group B respectively. There was a significant difference of inter-incisal opening between two procedures in subsequent review findings (Table 6).

Table 6: Inter-incisal Opening between Two Operative Procedures in 1st, 2nd and 3rd review

| Surgical procedure | Group A (mm) | Group B (mm) | P value |
|--------------------|--------------|--------------|---------|
| Baseline           | 14.69        | 18.14        |         |
| Review 1           | 22.38        | 29.07        | 0.0001  |
| Review 2           | 28.19        | 35.79        |         |
| Review 3           | 36.19        | 37.64        |         |

Discussion
This prospective study was carried out in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College & Hospital and Bangabandhu Sheikh Mujib Medical University from January 2010 to December 2010 with a sample size of 30 patients presented with non-committed simple mandibular angle fractures with or without displacement. They were randomly allocated into two groups named IMF group and without IMF group with sample sizes of 16 and 14 respectively to evaluate the outcome and complication rates between the two groups. Open reduction and internal fixation was done with a single stainless steel miniplate adapted in the Champy’s line of osteosynthesis with monocortical screws. Two weeks of Intermaxillary fixation was employed in one group.

In this study operative time was significantly less (p=0.000) in without IMF group than in IMF group. Mean operative time in without IMF group was 55.38±6.34 minutes. Sugar reported a mean operative time of 59.6 minutes in this group. Operators experience may contribute to the difference. Mean operative time for IMF approach was 99.38±15.26 minutes. Dimitroulis reported the average operating time for the IMF group was 98.5 minutes, and without IMF group was 40.2 minutes. Procedure of intermaxillary fixation is time consuming, which increases the operative time in IMF group.

Post operative instability developed 1 case (06%) in with IMF group and 1 case (07%) in without IMF group in this study. But this difference is not statistically significant (p=0.724). About fracture fragment stability treated by miniplate osteosynthesis the load resistance of mandibular angle fractures with miniplate according to Champy, the miniplate osteosynthesis offered a secure method in treatment of mandibular angle with sufficient stability.

Postoperative radiographs of mandible were assessed according to structured criteria for post reduction alignment scoring. In this study post reduction alignment score was slightly higher in IMF group (Mean 2.50 ±SD 0.516) than without IMF group (2.214 ± SD 0.426). However the difference was not statistically significant with p value 0.107. Result of this study is comparable with other studies. Mean post reduction alignment score in the study of Dimitroulis was 2.45. Another study showed mean score of 2.26 ± 0.62.

Inter-incisal mouth opening was regarded as a prognostic indicator in this study. Mean inter-incisal mouth opening at the baseline was 14.69 mm in IMF group and 18.14 mm in without IMF approach group. Inter-incisal mouth opening was gradually increasing. There was a statistically significant difference of inter-incisal opening between IMF group and without IMF group in subsequent review findings with a p value of 0.0001. Mehra and Murad reported mean inter-incisal opening of 42.6 mm in without IMF group and 40.8 mm in IMF approach group at last follow-up. Sugar reported mean inter-incisal opening of 37.68 mm in combined IMF approach group and 38.19 mm in without IMF group. In Bangladesh in a study it was reported mean inter-incisal opening of 35.03 mm in IMF approach group and 35.10 mm in conventional approach group at last review. Results of this study are comparable with the findings of other studies in terms of inter-incisal mouth opening. No case of malunion was noted in any group of patients. No case of malocclusion was observed in this study.

The present study had the following limitations. These should be kept in mind while deciding on the implications of the findings of the study. Relatively small sample size and short duration follow up was main limitation. A number of patients were reluctant to...
attend follow up visits, which caused some degree of interference.

Conclusion
In conclusion significantly less operative time is required in without IMF group. Interincisal opening is significant between two groups in subsequent review findings. In final outcome there is no statistically significant difference found between the two group in terms of various outcome and associated complications. All the post operative outcomes are negligible and are managed easily in the outpatient settings. Therefore, simple mandibular angle fracture can be managed by open reduction and internal fixation with miniplate osteosynthesis without any perioperative IMF. On the basis of the result of present study, it should not be always necessary of IMF placement for successful outcome of selected cases of non-commminated simple mandibular angle fracture managed by open reduction with miniplate osteosynthesis. Further rigorously conducted prospective randomized controlled trials should be carried out with larger sample sizes as well as with appropriate blinding of the investigators in a longer period of time.

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