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Functional outcome following fixation of fractures shaft of humerus-intramedullary nailing versus plate osteosynthesis: A comparative study

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Abstract

Background: The operative management of the fractures of shaft of humerus is most commonly accomplished with the help of Open Plate fixation or closed intramedullary interlocking Nails. Controversy exists so as to which modality is superior to the other. Hence the study was conducted with an aim to compare the functional outcome of humeral shaft fractures treated by two procedures - closed intramedullary interlocking nailing and open plate osteosynthesis.

Materials & Methods: This prospective observational study consisted of 32 participants who were recruited to both the study groups sequentially till the sample size was reached in each group. The participant allocation was done to either of the surgical procedures based on their preferences. Patients were evaluated both clinically and radiologically at the end of 1 month, 3 months, 6 months and 1 year from the day of surgery. Study group (Plating Vs Nail) was considered as a primary explanatory variable. Time to union, functional outcome as assessed by American shoulder and elbow society score were considered as primary outcome variables of interest. Need for bone grafting was considered as the secondary outcome variable.

Results: Both the study groups were comparable with respect to all the baseline variables. The proportion of subjects showing signs of the radiological union was 100% and 92.86% in plating and nailing group respectively. The proportion of subjects with radial nerve involvement was slightly higher in plating group, as compared to nailing group (12.5% vs 7.14%), but the difference was statistically not significant (P value=0.626). There was no statistically significant difference in the proportion of subjects needing bone grafting (18.75% in plating vs 14.29% in nailing group, P value 0.743). The meantime for union was slightly longer in plating group, as compared to nailing group (15.44 ± 2.39 vs 13.93 ± 1.85 Weeks, p value 0.067), which was statistically, not significant. The functional outcome at the end of follow up period as assessed by mean ASES score 26.44 ± 2.31 in plating vs 26.64 ± 1.65 in nailing group) was comparable between the two intervention groups.

Conclusions: The radiological and functional outcome following humeral shaft fracture treatment with plate osteosynthesis and intramedullary nailing were comparable.

Keywords: Shaft humerus, fracture, plate fixation, intramedullary nail, operative management

Introduction

Fractures of the humeral shaft are common orthopaedic injuries which results in a significant burden to society from lost productivity and wages. Fractures of the humerus comprise approximately 5 to 8% of all extremity fractures. Nonunion rates for diaphyseal humerus fractures treated nonoperatively range from 0 to 13%, with the incidence increasing to 15 to 30% for operatively treated fractures^[2, 3]. There is a bimodal distribution with peaks primarily in young male patients, 21-30 years of age, and a larger peak in older females from 60-80 years of age.

Absolute indications for surgical intervention in humeral shaft fractures were specific circumstances including open fractures, associated neurovascular injury, proximal and distal articular extension, patients with multiple injuries or polytrauma, floating elbow, progressive radial nerve deficits, significant soft tissue injury (unable to brace), pathologic fractures and failed non-operative management.

Other relative indications include obese patients, patients with associated brachial plexus injuries due to the loss of muscle co-contraction and its ability to maintain bony alignment; and non-compliant patients.

In patients with surgical indication two different models are available: compression plate and intramedullary nailing (with open and closed approaches) and each one has its advantages and disadvantages. With plate and screw fixation, we may achieve more rigid fixation; however, in intramedullary nailing, fracture site soft tissue manipulation. In patients with surgical indication two different models are available: compression plate and intramedullary nailing (with open and closed approaches) and each one has its advantages and disadvantages. With plate and screw fixation, we may achieve more rigid fixation; however, in intramedullary nailing, fracture site soft tissue manipulation is much less. Plating with rigid fixation, which is known to provide accurate anatomic reduction, can reduce the risk of malunion but requires wide intraoperative exposure associated with soft-tissue stripping. Furthermore, the over-stripping of soft tissue at the fracture site also lowers the blood supply, which might raise the risk of nonunion or infection closed nailing preserves the periosteal blood supply and promotes fracture union by utilizing the osteogenic potential of the pluripotent cells in the fracture hematoma. Thus, closed intramedullary nailing supports the concept of biological fixation. Moreover, closed nailing procedure is associated with fewer complications such as reduction in blood loss, infection rates, and hospital stay. This treatment method has been the subject of controversy since its inception because of concern of damage to medullary circulation, possibilities of fat embolism, complications arising from application of incorrect technique, and lack of understanding of the biomechanical principles of intramedullary interlocking nail fixation (IINF). Clinical series of fractures stabilized with humeral nails often report shoulder problems related to the insertion site, possible technical difficulties, more radiation exposure intraoperatively, and a higher rate of revision surgery. Choosing to plate or nail a humeral shaft fracture is becoming more a matter of patient preference or surgeon's choice with potential complications and surgeon familiarity. A meta-analysis that previously favored plating over nailing was recently updated and noted equivalent outcomes in rates of nonunion, infection, nerve palsy, reoperation, and total complications between humeral plating and nailing [12, 11, 13, 10, 9]. However, few studies clearly have stated that IM nailing was a better surgical option for the management of humeral shaft fracture. Hence, this study compared the functional outcome of humeral shaft fractures treated by two procedures - Closed intra medullary interlocking nailing and Open Plate Osteosynthesis.

Material and Methods

The study was a prospective observational study conducted in the department of orthopedic surgery, Aster Mims Hospital-Kottakkal between July 2019 and July 2020. The study population consisted of patients with fracture shaft of humerus (Middle and Proximal 3rd) aged 18 years or above. The participants with open fractures, fracture distal third of humerus, pathological fractures polytrauma, fractures associated with neuro vascular injury, established non-union from previous fracture and patients with multiple fractures were excluded from the study.

The study groups were divided into two group: Group - intramedullary nailing or Group 2-plate osteosynthesis. The

ethics committee of the hospital approved the study, and each subject gave written informed consent.

Sample Size

Sample size was calculated assuming the expected mean ASES score ($\mu_1 - \mu_0$) in each of the treatment Groups as 23.9 and 21.7 as per the study by Hashmi PM *et al.* The other parameter considered for sample size (N) calculation was a common standard deviation (σ_1, σ_0) of 2. 5% alpha error and 80% power of study. Here, the constant value of u was 0.84 for 80% power and the value of v was 1.96 for significance level of 5%. The sample size was calculated using the following formula.

$$N = \frac{(u + v)^2(\sigma_1^2 + \sigma_0^2)}{}$$

The sample size as per the above mentioned calculation was 14 subjects in each group. To account for loss to follow up it was decided to include an additional 10% of the subjects. Hence the final sample size decided was 16 subjects in each group.

The study participants were recruited to both the study groups sequentially till the sample size was reached in each group. The participant allocation was done to either of the surgical procedures, as per patient preference. The participants were explained about the relative advantages and disadvantages of each of the two treatment methods, based on the best available evidence and also the cost of treatment was explained. Based on their choice, they were allocated to either of the two groups.

Patients were evaluated both clinically and radiologically at the end of 1 month, 3 months, 6 months and 1 year from the day of surgery. Clinical and Radiological evaluation by using

- Subjective Pain or tenderness at fracture site (scored by Visual analog scale)
- Functional activities at the shoulder and Elbow joint.
- Documentation of Nerve (Radial Nerve) injury and Tinel's Sign
- Presence of Callus and Bony Trabeculae bridging the fracture site in follow up radiograph.
- American shoulder and elbow society score.

Statistical Analysis

Functional outcome (age, ASES score, shoulder abduction Rom, elbow flexion ROM, time for union) were considered as primary outcome variables. Study group (Plating vs nailing) was considered as Primary explanatory variable.

All Quantitative variables (age, ASES score, shoulder abduction Rom, elbow flexion ROM, time for union) were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro-wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

For normally distributed Quantitative parameters the mean values were compared between study groups using Independent sample t-test (2 groups).

Categorical outcomes were compared between study groups using Chi square test /Fisher's Exact test (If the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used.)

P value <0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Observation and Results

A total of 32 subjects were included in the final analysis, with 32 subjects each treated by plate osteosynthesis (Plating) and Intra medullary nailing (IMN)

Table 1: Comparison of age between study groups (N=32)

Parameter	Plating (N=16)	Nailing (N=16)	P value
Age (Mean \pm SD)	35.31 \pm 15.45	37.13 \pm 13.66	0.728
Gender			
Male	11 (68.8%)	12 (75%)	1.00
Female	5 (31.3%)	4 (25%)	
Limb dominance			
Dominant	11 (68.8%)	8 (50%)	0.280
Non-Dominant	5 (31.3%)	8 (50%)	

The mean age of subjects in plating group was 35.31 \pm 15.45 years and in nailing group, it was 37.13 \pm 13.66 years. The difference in the age between the two groups was statistically not significant (P Value=0.728). In plating group, 11 (68.8%) participants were male and 5 (31.3%) participants were female. In nailing group, 12 (75%) participants were male and 4 (25%) participants were female. The difference in the proportion of gender between study groups was statistically not significant (P value 1.000). In plating group, 11 (68.8%) participants had dominant upper limb. In nailing group, 8 (50%) participants had dominant upper limb. The difference in the proportion of dominant /non-dominant upper limb between study groups was statistically not significant (P value 0.280).

Table 2: Comparison of outcome scores between study groups (N=32)

Parameter	Plating (N=16)	Nailing (N=16)	P value
ASES score (Mean \pm SD)	26.81 \pm 2.54	26.88 \pm 1.75	0.936
Radial Nerve involvement			
Yes	3 (18.8%)	1 (6.3%)	0.600
No	13 (81.3%)	15 (93.8%)	
Need for Bone grafting			
Yes	4 (25%)	2 (12.5%)	0.654
No	12 (75%)	14 (87.5%)	
Radiological signs of union			
Yes	16 (100%)	15 (93.8%)	*
No	0 (0%)	1 (6.3%)	
Shoulder Abduction Rom (Mean \pm SD)	155.63 \pm 16.32	161.25 \pm 8.85	0.235
Elbow Flexion ROM 0 -140 de (Mean \pm SD)	132.5 \pm 7.75	136.25 \pm 9.57	0.233
Time for Union (Mean \pm SD)	21.31 \pm 3.59	19.31 \pm 2.7	0.085

* No statistical test was applied-due to 0 subjects in the cell

Among the Plating subjects 18.8% had radial nerve involvement, and in Nailing group this proportion was 6.3%. The difference in radial nerve involvement between the two groups was statistically not significant (P value=0.600). Among the Plating subjects 25% needed bone grafting, and in Nailing group this proportion was 12.5%. The difference in need for bone grafting between the two groups was statistically not significant (P value=0.654). The mean ASES score of subjects in plating group was 26.81 \pm 2.54 and in nailing group, it was 26.88 \pm 1.75. The difference in the ASES score between the two groups was statistically not significant (P Value=0.936). In plating group, all of them 16 (100%) participants had radiological signs of union. In nailing group, 15 (93.8%) participants had radiological signs of union. The Mean ROM of shoulder abduction in plating group

was 155.63 \pm 16.32 and in nailing group, it was 161.25 \pm 8.85. The difference in the shoulder abduction ROM between the two groups was statistically not significant (P Value=0.235). The mean elbow flexion ROM in plating group was 132.5 \pm 7.75 and in nailing group, it was 136.25 \pm 9.57. The difference in the elbow flexion ROM between the two groups was statistically not significant (P Value=0.233). The mean time for union of subjects in plating group was 21.31 \pm 3.59 (weeks) and in nailing group, it was 19.31 \pm 2.7 (weeks). The difference in the time for union between the two groups was statistically not significant (P Value=0.085).

Table 3: Comparison of complications between study groups (N=32)

Parameter	Plating (N=16)	Nailing (N=16)	P value
Neuropraxia	2 (12.5%)	1 (6.25%)	0.544
Preop Neuropraxia	1 (6.25%)	0 (0%)	*
Rotator cuff Impingement	1 (6.25%)	2 (12.5%)	0.544
Shoulder stiffness	1 (6.25%)	1 (6.25%)	1.000

*No statistical test was applied- due to 0 subjects in the cells

Discussion

Humerus fracture is unique amongst the long bone fractures in its tolerance of less than anatomical reduction. Shortening up to 3 cm, rotation 30⁰ and angulation up to 20⁰ are considered acceptable. Due to this fact, most of the humerus fractures are still managed conservatively and have good functional results. The most common indication of operative intervention is inability to achieve acceptable reduction, followed by associated vascular lesions, open fractures, radial nerve palsy, polytrauma patients, floating elbow and pathological fractures.

Intramedullary nailing in humerus fractures is a less invasive procedure which maintains the biology and gives a good, stable fixation. It is also assumed to result in quicker union, less blood loss and less chances of radial nerve injury. Even though many studies have reported on IMN fixation and plate fixation [13, 17-21] However, controversy still exists over the best method of fixation. In current study authors have aimed to compare the closed intra medullary Interlocking nailing and Open Plate Osteosynthesis interns of functional outcome of humeral shaft fractures treated by two procedures.

In the present study total of 30 subjects were included in the analysis. Among the study population, the plating was conducted in 16(53.33%) cases whereas Nailing was chosen in 14(46.67%) subjects. The mean age of subjects in plating group was 35.63 \pm 15.43 years and in nailing group, it was 36.14 \pm 11.8 years. The proportion of males among plating subjects were 68.75% and in Nailing group this proportion was 71.43%. The proportion of females in plating and nailing groups were 31.25% and 28.75% respectively. There was no significant difference in age and gender between the two study groups (P> 0.05). Similar study settings were found in few existing studies of literature conducted by Fan, Y., *et al.* (2015), Wali, M. G., *et al.* (2014), Yin, P., *et al.* (2013), Putti, A. B., *et al.* (2009), Changulani, M., *et al.* (2007). Study by Fan, Y., *et al.* (2015) recruited total Of 60 participants with humeral shaft fractures and were equally distributed to two study groups as IMN (N=30) and LCP (N=30). Mean age of patients in IMN group was 39.3 \pm 10.8 whereas in LCP group 39.2 \pm 10.3 year. In the IMN group the proportion of males were 60% and plating group it was 63.3%. Praportions of females in two study groups were 40% and 36.7% respectively. Wali, M. G., *et al.* (2014) for his study he selected 25 patients of humeral shaft fractures for ILN group

and 25 more patients were for DCP. Similar to our study majority of participants in two study groups were males (21 Vs 20 members) with mean age of 37.28 and 37.72 respectively. In Yin, P., *et al.* (2013) study also statistically significant difference was not found in age and gender between two study groups.

As per current study findings the proportion of subjects showing signs of radiological union was 100% among plating subjects and in Nailing group this proportion was 92.86%. Union rates in our study were comparable with other studies by Fan, Y., *et al.* (2015), Wali, M. G., *et al.* (2014), Putti, A. B., *et al.* (2009) and Changulani, M., *et al.* (2007). In the study of Fan, Y., *et al.* (2015) union rates were reported as 96.7% and 93.3% in IMN and LCP groups respectively. Wali, M. G., *et al.* (2014)'s study supported current study findings with 92 % union rates in two study groups and only 8% nonunion cases were found in two study groups. As per the study findings of Putti, A. B., *et al.* (2009) union rates reported were 100% and 94% in IMN and DCP groups respectively. Changulani, M., *et al.* (2007) study findings showed that 85.7% union rate in IMN group where as 87.5% in DCB group.

The mean ASES score was 26.44 ± 2.31 in plating group was and it was 326.64 ± 1.65 in nailing group and the difference between the two groups was statistically not significant (P Value=0.784) in our study population as has been reported by similar studies [13, 17, 20]. Results were similar in the study by Wali, M. G., *et al.* (2014) with mean AECS score was 43.2 in ILN group and 44.1 in DCP group whereas the difference was not significant. Mean AECS scores observed were 45.2 and 45.1 in IMN and DCP groups respectively, difference was not significant statistically in a study by Putti, A. B., *et al.* (2009). In Changulani, M., *et al.* (2007) study mean AECS scores were observed as 44min and 45 min in IMN and DCP groups respectively.

The proportion of radial nerve involvement among the Plating subjects was 12.5% and in Nailing group this proportion was 7.14% and there was no statistical significance for the difference in radial nerve involvement between the two groups (P value=0.626) and it was similar in few existing studies [13, 17-20]. In Fan, Y., *et al.* (2015)'s study radial nerve palsy was reported in 3(10%) patients from LCP group, but no case in IMN group. Similarly in the of Wali, M. G., *et al.* (2014) also reported radial nerve palsy in 2 cases from DCP group and no case in IMN group. As per study findings of Yin, P., *et al.* (2013) radial nerve injury was reported in 4 cases from LCP group but no case was found in IMN group. In the study of Changulani, M., *et al.* (2007) only 1 case of radial nerve palsy was found in DCP group but no case in IMN group. But in contrary study by Putti, A. B., *et al.* (2009) reported 2 had transient radial nerve palsies but none in DCP group.

In current study the proportion of subjects needed bone grafting were 18.75% and 14.29% in Plating and Nailing groups respectively, showing no significant difference (P=0.743). A similar proportion has been observed in most of the studies [13, 17, 20]. Study of Wali, M. G., *et al.* (2014) reported bone grafting was done as a secondary procedure in 2 patients in each study group (ILN and DCP). As per study findings of Putti, A. B., *et al.* (2009) bone grafting was done in only one case in DCP group but none in IMN group. Changulani, M., *et al.* (2007)'s study findings shows that the proportion of bone grafting was done in 9.5% cases in IMN group whereas this proportion was 4.5% in DCP group. In our study mean Elbow Flexion ROM in plating group was

133.75 ± 7.19 and in nailing group, it was 135.71 ± 10.89 . The Mean ROM of Shoulder Abduction in plating group was 156.25 ± 16.68 and in nailing group, it was 161.43 ± 8.64 . The difference in the Elbow Flexion ROM and difference in the Shoulder Abduction ROM both were statistically not significant between the nailing and plating groups. Similar to our study findings meta-analysis by Benegas, E., *et al.* (2014) reported that the patients' shoulder movement after DCP treatment was superior to the patients after IMN fixation (RR=9.27 95% CI: 2.22–38.72). Ma, J., *et al.* (2013)." study also supporting the current study findings and there is no significant difference was found with regard to shoulder function according to the University of California, Los Angeles scale between the minimally invasive plate and locking intramedullary nail (31.4 points vs 31.2 points, P ¼ .98). There was also no difference in elbow function (94.8 points vs 94.1 points, P ¼ .96).

In the current study reported mean time for union in plating group was 21.13 ± 3.74 days and in nailing group, it was 19.07 ± 2.79 days. Statistically significant difference in union time was not found between two study groups (P Value=0.560). Similar to current study findings in the study of Changulani, M., *et al.* (2007) mean union time for IMN group was 6.3 weeks and 8.9 weeks for DCP group with statistically significant difference (P< 0.001). Study findings of Wali, M. G., *et al.* (2014) reported that the mean duration of union in remaining patients in ILN group was 13.60 (SD 4.32) weeks and in DCP group was 15.2 (SD 5.65) weeks and the difference was statistically significant (P=0.376). Fan, Y., *et al.* (2015)'s study documented average union time as 6.7 weeks in the IMN group and 10.6 weeks in the LCP group with the statistically significant difference. (P< 0.001). In the study of Yin, P., *et al.* (2013) the average bone healing time was (11.77 +/- 0.75) weeks in LCP group and (11.38 +/- 0.82) weeks in IMN group and the difference was statistically not significant. (t=1.705, P=0.095).

Conclusions

There was no significant difference in the radiological and long-term functional outcome following humeral shaft fracture treatment with plate osteosynthesis and intramedullary nailing. No delay was observed in time to union.

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