

Patient Outcomes of Non-Operative Versus Operative Management of Humeral Shaft Fractures: A Randomized Controlled Trial

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ABSTRACT

Objective: To determine the non-surgical versus surgical outcomes in individuals who suffered from humeral shaft fractures.

Methods: A randomized controlled trial was undertaken at the Department of Orthopedics Bolan Medical College Hospital Quetta, Pakistan between 09-March-2019 to 08-October-2019.

A total number of 248 patients who presented with humeral shaft fractures having age 20-60 years were included in this study. Eligible patients were randomly grouped into two equal sets. Group I: were allotted to patients in whom non-operative management of humeral shaft fractures was done. In group II patients: operative management was done. Surgical outcomes were noted in terms of delayed union and radial nerve palsy. Study outcomes were noted after 1 month of principal procedure.

Results: The mean age of individuals included in this study was 45.46 ± 9.64 years. Mean body mass index (BMI) of patients was 25.44 ± 4.63 kg/m². Mean duration of fracture to surgery was 8.80 ± 8.07 days. There were 169 (68.15%) male patients and 79 (31.85%) female patients. Delayed union was found in 27 (21.80%) patients in non-operative groups versus 19 (15.30%) in patients who underwent operative management (p-value of 0.191). On comparison of frequency of radial nerve palsy between the groups, radial nerve palsy was found in 12 (9.70%) patients in non operative group versus 16 (12.90%) in patients in operative group (0.422).

Conclusion: The study revealed that the non-surgical management of humeral shaft fractures gives outcomes that are comparable to operative management. We did not find any evidence of significant difference in the frequency of delayed union and radial nerve palsy between the groups.

Keywords: humeral shaft fractures, operative management, non-operative management.

INTRODUCTION

The annual incidence rate for humeral shaft fractures is approximately 13%.¹ It is estimated that the humerus is involved in between 20% and 27% of all fractures, with humeral shaft fractures accounting for between 1% and 3% of all fractures.² The age and gender distribution of the incidence are bimodal, with the first peak occurring in young adult males (20- 30) and the second peak occurring in middle-aged and older females (60-70).³

Fractures of the humeral shaft can be treated surgically or non-surgically. Non-surgical treatments might range from casting and functional bracing to carefully observed do nothing.⁴ Surgical options include intramedullary nailing, plate osteosynthesis, and external fixation.⁵ The therapy of choice for humeral shaft fractures for quite some time was non-operative care.⁶ However, in recent years, several writers have advocated for minimally invasive surgical treatments to be considered the gold standard.⁷

A study conducted found a delayed union rate of 23.2% in the non-surgical group and 10.2% in the surgical group. While the nerve palsy rate was 20% in non-operative versus 39% in operative group.⁸ Clement and colleagues conducted a systematic review to compare the difference in the outcomes of surgical versus non-surgical procedures. However, the review revealed a major scarcity of literature on the subject and recommended that further trials should be undertaken to better understand the compared outcomes of surgical versus nonsurgical procedures for the management of humeral shaft fractures.⁹

There is no universal agreement on the most effective way of treatment; hence, the prescribing physician's own views typically take precedence. Existing research is lacking concerning whether surgical approaches produce distinct clinical results compared to non-surgical techniques. Consequently, the goal of the proposed study is to compare the efficacy of non-operative treatment against surgical treatment for humeral shaft fractures. The outcomes of this study could be utilized to compare the efficacy of non-surgical and surgical treatments for humeral shaft fractures.

The present study aimed to assess the patient outcomes for non-surgical versus surgical procedure in the management of humeral shaft fractures.

METHODS AND MATERIALS

A randomized controlled trial was undertaken at the Department of Orthopedics, Bolan Medical College Hospital Quetta, Pakistan between 09-March-2019 to 08-Oct-2019. After ethical approval was procured from the institutional review board (IRB) of the Bolan Medical College, the data acquisition was initiated.

Frequency of radial nerve palsy after non-op management = 20%⁸ Frequency of radial nerve palsy after op management = 39.0%⁸ By using the level of Significance = 10% and power of the test=95%, the calculated Sample Size was 124 patients. The calculated sample size for both groups is 248 patients.

A non-probability, consecutive sampling was utilized to recruit the participants with humeral shaft fractures, aged between 20 to 60 years, irrespective of male and female patients. Patients having humeral fractures other than the humeral shaft and those having pre-procedural radial nerve palsy were excluded because these patients would create biases in the outcome of the study.

Humeral Shaft Fracture was defined as a fracture that occurs below the surgical neck proximally and above the supracondylar ridge distally. Diagnosis of fracture was made using Plain X-rays. Presence of fracture lines on x-rays was used to diagnose humeral shaft fractures.

The primary outcome was measured in terms of delayed union and radial nerve palsy. Delayed Union was defined as failure of bone union after 24 weeks of principal procedure. Presence of fracture lines on X-rays after 24 weeks of procedure was labeled as delayed union. Radial Nerve Palsy was diagnosed by requesting all patients to extend and rotate their hands and comparison of the affected side was made with the normal side and presence of numbness or weakness (during extension and flexion of the hand) on the injured side was labeled as radial nerve palsy. Diagnosis was made after one month of the procedure.

The authors hypothesized that the clinical outcome would be better with operative management as compared to non operative management for the treatment of humerus shaft fractures.

All patients were included in the trial after providing their informed permission. Patients were split into two equal groups at random. I will create folded papers with the name of the therapy on

them and put them in a jar. Each patient was instructed to take one folded piece of paper out of the jar. Patients were grouped into two sets depending upon the treatment method chosen by them. Group I: were allotted to patients in whom non-operative management of humeral shaft fractures was done. In group II patients: operative management was done.

All the procedures were carried out by consultant orthopedic surgeons having at least two years post-fellowship experience. Functional bracing was applied in group I patients. While flexible intramedullary nailing or dynamic compression plates were used for the operative management of humeral shaft fractures.

Diagnosis of non-union and radial nerve palsy was made according to the criteria given in the operational definitions. Data regarding age, gender, type of fracture, duration of fracture to surgery was also collected. On a pre-made Proforma, all the data obtained was recorded.

The statistical analysis was carried out in SPSS 20.0. Various quantitative characteristics, such as age, height, weight, body mass index, and time that had passed from the fracture before the operation, were subjected to mean and standard deviation calculations. In this study, categorical parameters such as gender, fracture side, non-union, and radial nerve palsy were analyzed mathematically and presented statistically. We examined the differences in non-union and radial nerve palsy frequencies between Group I and Group II by employing the chi-square test. Stratification was used to control effect modifiers such as age, gender, BMI, time from fracture to surgery, and fracture side. To ascertain how these confounding factors affected the research results, the post-stratification Chi-square test was used. A statistical difference was deemed significant if the p-value was less than 0.05.

RESULTS

The average age of patients was 45.46 ± 9.64 years with the youngest participant of 20 years and eldest of 60 years. There were more male patients as compared to female patients. Mean duration of fracture to surgery was 8.80 ± 8.07 days. Minimum duration was 01 days and maximum duration was 30. 128 (51.61%) patients were diagnosed with left sided fracture versus 120 (48.39%) patients with right sided fracture. Delayed union was found in 46 (18.55%) patients and it was not found in 202 (81.45%) patients. Radial nerve palsy occurred in 28 (11.29%) patients and did not occur in 220 (88.71%) patients (Table 1).

Table 1: Characteristics of study population

Characteristics	Mean / n(%)
Age (years)	45.46 + 9.64
Height (cm)	162.4 + 9.71
Weight (kg)	67.31 + 14.17
BMI (kg/m ²)	25.44 + 4.63
Duration of fracture to surgery (days)	8.8 + 8.07
Gender	
Male	79 (31.9%)
Female	169 (68.1%)
Side fracture	
Left-sided	128 (51.6%)
Right-sided	120 (48.4%)
Delayed union	
Yes	46 (18.5%)
No	202 (81.5%)
Radial nerve palsy	
Yes	28 (11.3%)
No	220 (88.7%)

On comparison of post-operative complications between the groups, delayed union was found in 27 (21.80%) patients in non-operative groups versus 19 (15.30%) in patients who underwent operative management with insignificant p-value of 0.191. On comparison of frequency of radial nerve palsy between the groups, radial nerve On comparison of frequency of radial nerve palsy between the groups, radial nerve palsy was found in 12 (9.70%)

patients in non-operative group versus 16 (12.90%) in patients in operative group albeit the difference was not significant ($p=0.422$). There was no significant association of the effect modifiers such as age group, gender, body mass index, and the side of fracture with either delayed union or radial nerve palsy between the two study groups (Table 3).

Table 2: Comparison of patient outcomes between the study groups

Patient Outcome	Study group		p-value
	Non-operative	Operative	
Delayed union			0.191
Yes	27 (21.8%)	19 (15.3%)	
No	97 (78.2%)	105 (84.7%)	
Radial nerve palsy			0.422
Yes	12 (9.7%)	16 (12.9%)	
No	112 (90.3%)	108 (87.1%)	

DISCUSSION

In the present study, we made a comparison of the outcomes of operative management of humeral shaft fractures with non-operative management. The study revealed that the rate of delayed union and radial nerve palsy were comparable in both the groups. The difference was not statistically significant.

A meta-analysis of randomized studies found no advantage to surgical or non-surgical treatments for HSF.¹⁰ Intramedullary nailing and compression plating are two of the most used surgical methods for repairing fractures. Comparative studies reveal that both strategies have their advantages and disadvantages, making it difficult to conclude which is better. A meta-analysis by Heineman et al.¹¹ found that the rate of complications after ORIF was lower than expected.¹² The vast majority of research indicates that plate fixation is the best surgical method for HSFs.¹³ One year after treatment with a bridge plate and functional bracing, Matsunaga et al. analyzed the outcomes for 110 patients with HSF. Surgical patients had a 15% non-union rate compared to 0% in the non-surgical group, and patients with a varus-valgus malunion had a 2% mean malunion.¹⁴ Another study which was a retrospective cohort study on 126 patients by Harkin et al., undertaken in Australia over a 7-year period. Thirty of them underwent primary surgical intervention, while the other ninety-six were managed with non-invasive means.¹⁵ In the conservative group, 54% of patients achieved union within 6.5 months, 13% had delayed union, and 33% did not achieve union at all. In the surgical group, 63% of patients experienced timely union, 33% experienced delayed union, and only 4% did not reach union. According to the data the surgical group clearly outperformed the non-surgical group.¹⁵

A recent retrospective study by Mahabier et al. found no significant difference in the complication rates between the non-surgical and operative treatment of humeral shaft fractures.¹⁶ In a study spanning 5 years, 186 individuals aged 16 and up were identified by Mahabier et al. as having presented with a humeral shaft fracture. Of the total number of patients, 91 were treated non-surgically, and 95 were surgical. The radial nerve palsy probability was similar in the surgery and non-surgical groups (10% and 9%, respectively). The scientists did note, however, that 5 percent of patients reportedly got the disease as a direct result of surgery. This study did not include any nonunions, but it did include 36 cases of delayed union, which the authors characterized as failure to heal at 24 weeks post-fracture with no advancement to healing.¹⁶ Unlike the study mentioned earlier by Heinamen et al.; most patients underwent intramedullary nailing of the humerus ($n = 78/95$), which may explain why union rates were similar across the non-surgical and surgical groups.¹⁷

Another trial was undertaken to assess the efficacy of open reduction internal fixation (ORIF) with the functional Sarmiento brace in the therapy of humeral shaft fractures.¹⁸ The study concluded that the average union duration was significantly shorter in the surgical group than the non-operative group ($p=0.001$). Thus, considering the variation in the literature and our own findings, the

orthopedic surgeon must take into account the severity and type of fracture and make an informed clinical decision in the best interest of the patient.

Our study has limitations, but this is common for most scholarly investigations. For instance, no comparison of the cost of care between the two groups was undertaken. To overcome these limitations, more rigorous randomized controlled trials, ideally with bigger sample sizes and longer follow-ups, are required. Future high-quality randomized controlled trials with a larger sample size should be undertaken to shed light on the topic.

CONCLUSION

Outcomes of conservative management of humeral shaft fractures are comparable to operative management. In present study, we did not find any significant difference in the frequency of delayed union and radial nerve palsy between the groups.

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