



A PROSPECTIVE COMPARATIVE STUDY BETWEEN INTERLOCKING NAIL AND LOCKING COMPRESSION PLATE FOR MANAGEMENT OF DIAPHYSEAL FRACTURES OF THE HUMERUS AT DMCH, LAHERIASARAI, BIHAR

Orthopaedics

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ABSTRACT

Background: The aim of this study was to compare the outcomes between open reduction and internal fixation by locking compression plate (LCP) and closed reduction and internal fixation with antegrade interlocking nail (ILN) for the treatment of diaphyseal fractures of the humerus.

Methods: This is a prospective comparative study, with diaphyseal fractures of the humerus treated by LCP in 30 patients and with ILN in 30 patients. Patients were followed up to 18 months. The clinical and radiographic outcomes were assessed in terms of union, complications, reoperation rate and functional outcome using the American shoulder and elbow surgeons' score (ASES) and Stewart and Hundley's criteria.

Results: Union was achieved in 93.3% of patients in LCP group and 90% in ILN group. The mean blood loss in LCP group was 280 ± 22.10 ml (160-400 ml) and in ILN group was 110 ± 17.62 ml (70-150 ml) ($p=0.001$). The ASES score was 42.47 ± 5.532 in LCP group and 40.93 ± 6.330 in nailing group ($p=0.320$; $p>0.05$). Stewart Hundley criteria showed excellent and good results in 26/30 and 17/30 patients in LCP group and ILN group respectively ($p=0.070$; $p>0.05$). Complications and re-operation rate were higher in ILN group.

Conclusions: Our study concludes that LCP can be considered a better surgical option for the management of diaphyseal fractures of the humerus as it had lower incidence of complications, less re-operation rate and better union rate. However, there is no difference between the two groups in terms of union time and functional outcome.

KEYWORDS

Interlocking nail, Locking compression plate, Humeral diaphyseal fractures

INTRODUCTION

Diaphyseal fractures of the humerus account for 1-3% of all fractures. Most of these fractures can be treated non-operatively with several methods like coaptation splint, velpeau dressing, hanging cast and functional brace. Successful healing occurs in over 90% of the cases. However, all fractures cannot be managed with non-operative methods. The indications for operative management of these fractures are failed non-operative treatment, compound fractures, segmental fractures, pathological fractures, bilateral humeral diaphyseal fractures, floating elbow, fractures with vascular injuries and progressive neurological deficits. Open reduction and internal fixation of these fractures with plating remains the gold standard but it requires a large incision, extensive dissection, more blood loss, risk of radial nerve injury and mechanical failure in osteoporotic bone. With the advent of intramedullary nailing for humerus, it is considered that nailing is less invasive procedure, had biomechanical advantage of load-sharing and there are better chances of union as the surgery does not involve periosteal stripping, loss of fracture haematoma and the reamed material which is produced while reaming act as an autograft at the fracture site. Therefore, this study was conducted to know the advantages and disadvantages and to compare the functional outcome between open reduction and internal fixation by locking compression plate (LCP) and closed reduction and internal fixation with antegrade interlocking nail (ILN) for the treatment of diaphyseal fractures of the humerus.

MATERIAL AND METHODS

This is a prospective comparative study that was conducted at Department of Orthopaedics, Darbhanga Medical College and Hospital, Laheriasarai, Bihar between April 2018 and December 2019. Informed consent was taken from all the patients. The fractures taken into consideration were located from 4 cm distal to the surgical neck of the humerus to 5 cm proximal to the olecranon fossa. Patients with closed fractures, Gustilo-Anderson type 1 and 2 compound fractures, skeletally mature patients, patients presenting within 3 weeks of injury, those who gave consent for surgery and a minimum follow up of 18 months at the time of evaluation were included in our study. 12 Exclusion criteria were pathological fractures, Gustilo-Anderson type 3 compound fractures, neurovascular injuries, those who are unfit for surgery, patients with ipsilateral fractures of the upper extremity. The sample size was calculated based on reviewing previous research articles (based on incidence of complications) and by Cohen's D method. A total of 64 patients who fulfilled the inclusion criteria were

randomized using computer based random number table and were assigned into either of the 2 groups. Each group consists of 32 patients and were fixed with LCP and ILN. Fractures classified based on the AO classification system. 13 Surgeries were performed by consultants and senior residents, who were familiar with both the procedures. General anaesthesia combined with a regional block was used in all the cases. Third-generation cephalosporin (ceftriaxone) was administered just prior to surgery and in the postoperative period for 2 days for closed fractures. The same antibiotic was used for compound fractures (Gustilo-Anderson type 1 and 2) from the time of arrival to the hospital and till discharge. In LCP group, fixation was done with 4.5 mm LCP (Nebula surgical, India) using standard anterolateral approach in supine position or posterior approach in lateral position depending upon the fracture pattern and surgeon's choice. Fixation of at least six cortices, preferably eight cortices, was achieved in both proximal and distal segments of the fracture in every patient. In the ILN group, fixation was performed with antegrade interlocking nail (Nebula surgical, India) using anterolateral approach for proximal humerus in semi-inclined position. A 4-5cm incision was placed between the clavicular and the acromial part of the deltoid muscle extending from the lateral aspect of the acromion. The deltoid muscle was split along the line of the muscle fibres, entry was made with an awl just lateral to the articular cartilage and medial to the greater tuberosity under fluoroscopy. After closed reduction of the fracture, the nail was inserted, proximal locking was done using zig and distal locking with the freehand technique. To prevent damage to the neurovascular structures at the distal locking site, a 2-3 cm incision was made and blunt dissection was performed up to the bone. The limb was placed in an arm sling. Post-operative radiographs of both antero-posterior (AP) and lateral views of the entire arm were taken to check for reduction and any iatrogenic complication. Shoulder and elbow range of motion exercises were started on the second post-operative day. Patients were discharged and advised suture removal at their local hospital after 2 weeks. Patients were followed up at 6 weeks, 3, 6, 12 and 18 months. On each follow-up, radiographs of both AP and lateral views of the entire arm was taken, and the patients were assessed clinically and radiologically for pain, tenderness at the fracture site, shoulder and elbow range of motion, signs of infection, union, and any other complications. Radiological union was defined as the presence of bridging callus in minimum 3 out of 4 cortices on both AP and lateral radiographs. Delayed union was defined as signs of union between 4 and 8 months after surgery and non-union as no signs of union after 8 months. The primary outcomes measured were complications and

functional outcome. To assess functional outcome, we used American shoulder and elbow surgeons' score (ASES) and Stewart Hundlely criteria at final follow up. 14,15 Secondary outcome of the study was re-operation rate.

STATISTICAL ANALYSIS

The results of our study were analysed using the software statistical package of social science version 21 (SPSS). The comparison between two groups was assessed using the student t-test. Continuous variables were presented as mean $\pm$ SD (standard deviation); categorical data were expressed as numbers and percentages. Chi-square test (χ^2) or fisher's exact test were used as appropriate. $P < 0.05$ was considered to be statistically significant.

RESULTS

During our study period, a total of 64 patients were operated. In LCP group 2 patients were lost to follow up. In ILN group 1 patient died due to non-orthopaedic cause after 2 months of surgery and 1 patient lost to follow up. Finally, each group consists of 30 patients and results were analysed. Table 1 and Table 2 includes demographic data and clinical details. There was no significant difference between the groups. Mean interval between admission and surgery was 9 days (± 3) and 8 days (± 3) in LCP and ILN group respectively. In LCP group, 19 patients were operated using the anterolateral approach and 11 patients with posterior approach. In anterolateral approach the mean operative time was 74.6min (SD=9.45) while in posterior approach was 78.11min (SD=10.81). There is no statistical difference between the two approaches ($p=0.930$; $p>0.05$). The mean operating time in the LCP group (both approaches) was 76.4 min (SD 10.11) and 62.6 min (SD 7.60) in the ILN group, which was statistically significant ($p=0.001$).

Table 1 : Demographic Data

Variables	LCP group (n=30) N(%)	ILN group (n=30) N(%)	P value
Mean age in years	37.93±14.76	36.07±14.43	0.624
<25	6(20.0)	10(33.3)	0.654
26-35	10(33.3)	8(26.7)	
36-45	8(26.7)	8(26.7)	
>45	6(20.0)	4(13.3)	
Gender			
Male/female	24/6	26/4	0.731
Side			
Left/right	18/12	20/10	0.789
Mechanism of injury			
Road traffic accident	18(60.0)	22(73.3)	0.083
Fall from height	8(26.7)	6(20.0)	
Domestic	4(13.3)	0(0.0)	
Assault	0(0.0)	2(6.7)	

n: number of patients; $p>0.05$ not significant.

Table 2 : Clinical details

Variables	LCP group (n=30) N(%)	ILN group (n=30) N(%)	P value
Type of Fracture			
Closed fracture	26(86.7)	25(83.3)	0.353
Gustilo-Anderson Type I	3(10.0)	3(10.0)	
Gustilo-Anderson Type II	1(3.3)	2(6.7)	
AO Type			
A	18(60.0)	15(50.0)	0.987
B	10(33.3)	11(36.7)	
C	2(6.7)	4(13.3)	
Associated Injury			
No associated injury	21(70.0)	23(76.7)	0.635
Head injury	2(6.7)	0(0.0)	
Abdominal injury	1(3.3)	2(6.7)	
Lower Limb fracture	4(13.3)	2(6.7)	
Pelvic injury	1(3.3)	1(3.3)	
Chest injury	1(3.3)	2(6.7)	

n: number of patients; $p>0.05$ not significant.

Table 3 : Union rate and time

Variables	LCP group (n=30) N(%)	ILN group (n=30) N(%)	P value
Union (<16 weeks)	21(70.0)	23(76.7)	1.119

Delayed union (16-32 weeks)	7(23.3)	4(13.3)	
No. of patients union achieved	28(93.3)	27(90.0)	
Bon-union (>32 weeks)	2(6.7)	3(10.0)	
Mean duration for union in weeks			
Union time	14.05 $\pm$ 1.63	14.13 $\pm$ 1.49	0.843
Delayed union	24.86 $\pm$ 1.46	25.25 $\pm$ 1.15	0.255

n: number of patients; $p>0.05$ not significant.

Table 4 : Functional outcomes assessed using ASES and Stewart Hundlely criteria

Functional outcome	LCP group Mean $\pm$ SD	ILN group Mean $\pm$ SD	P value
ASES	42.47 $\pm$ 5.532	40.93 $\pm$ 6.330	0.320
Stewart Hundlely criteria	N(%)	N(%)	
Excellent	16(53.3)	11(36.7)	0.070
Good	10(10.3)	6(20.0)	
Fair	2(6.7)	9(30.0)	
Poor	2(6.7)	4(13.3)	

SD: Standard deviation; n: Number of patients; $p>0.05$ not significant.

Table 5 : Complications

Complications	LCP group (n=30)	ILN group (n=30)
Nil	24	18
Impingement	0	5
Shoulder stiffness	0	3
Non-union	1	2
Infected non-union	1	0
Superficial infection	2	0
Latrogenic radial nerve palsy	1	0
latrogenic fracture	0	1
Peri-implant fracture	1	0
Broken implant with aseptic non union	0	1

Blood loss in anterolateral approach was 276 ml (SD=21.02) while in posterior approach was 284 ml (SD=23.12) which had no statistical difference between the two approaches ($p=0.969$; $p>0.05$). The mean blood loss in LCP group (both approaches) was 280 $\pm$ 22.10 ml (160-400 ml) and in ILN group was 110 $\pm$ 17.62 ml (70-150 ml), the difference being statistically significant ($p=0.001$). 1 out of 19 patients in anterolateral approach 5.26% and 1 out of 11 patients in posterior approach 9.09% showed non-union which is not significant ($p=1.00$; $p>0.05$). Total 2 patients in LCP group and 3 patients in ILN group showed non-union. Union rate (percentage of patient's union achieved) for LCP group was 93.3% and 90% for ILN group which was not significant Table 3. No statistically significant difference was found in ASES score and Stewart Hundlely criteria among the groups (Table 4). Complications were listed in Table 5. All patients in both groups were able to resume their activities in 8 months, except for 2 patients in the LCP group and 3 in the ILN group who developed non-union. Table 6 shows patients who had undergone re-operation.

Table 6: Patients who had undergone re-operation

Re-operation	LCP group (n=30)	ILN group (n=30)
Impingement	0	5
Aseptic non-union	1	2
Aseptic non-union	1	0
Aseptic non-union with broken implant	0	1
Peri-implant fracture	1	0

DISCUSSION

Humeral diaphyseal fractures can be fixed internally with a plate or an intramedullary device. But plate osteosynthesis is a gold standard compared to other techniques. Number of studies which were reported by different authors had compared and analysed DCP versus ILN but very limited number of studies were conducted between LCP and ILN for humeral diaphyseal fractures. Therefore we conducted a study to compare the effectiveness of LCP and ILN. Sommer et al in their study used various LCP's in treatment of 169 different fractures in 144 patients and reported that LCP was a better option in treating complex fractures and in doing revision surgeries after implant failure. Karataglis et al evaluated 39 humeral diaphyseal fracture in 37 patients treated with antegrade interlocking nail concluded that nailing is a

better choice for those patients who had segmental, pathological fractures and patients with polytrauma who had diaphyseal fracture of humerus.²⁸ In our study, the important parameters which were taken into consideration were mean interval between admission and surgery, operative time, intra-operative blood loss, union rate, union time, functional outcomes, complications and reoperation rate. Yin et al concluded that there is no statistically significant difference ($p>0.05$) observed with respect to age, gender, side, mechanism of injury, associated injury, AO type of fracture and time from injury to surgery in between the two groups. They stated that intra-operative blood loss and operative time were significantly less in the ILN group compared with the LCP group. They also observed that the union time was 11.77 ± 0.75 weeks in LCP group and 11.38 ± 0.82 weeks in ILN group ($p=0.095$), union rate was 95.5% in LCP group and 91.7% in ILN group ($p=1.000$) and non-union was 1/22 (4.54%) and 2/22 (9.9%) patients in the LCP group and IMN group respectively which shows no statistically significant difference. They had radial nerve palsy in 4 patients in the LCP group and 6 patients had shoulder impingement in ILN group. They concluded that there is no significant difference between both the groups during the final follow up. Fan et al, observed that with respect to demographic data, mechanism of injury, and AO type of fracture there is no significant difference in between both the groups. They observed that intra-operative blood loss and operative time were significantly less in the ILN group compared with the LCP group. They reported that the average union time was 10.6 weeks and 6.7 weeks in LCP and ILN group respectively which was statistically significant. Union rate in LCP group was 93.3% and 96.7% in ILN group which was not significant. They assessed functional outcome by using ASES score which was found to be not significant between both the groups ($p=0.560$) and noticed radial nerve palsy in 3/30 (10%) patients which was recovered fully within 3 months. They reported that ILN can be considered as better surgical option than LCP. Wei et al conducted a study in which 58 patients underwent fixation with LCP and 54 patients with ILN. The operating time of LCP group was (97.20 ± 30.06 minutes), longer than that of ILN group (77.17 ± 15.46 minutes), the difference was significant ($p<0.05$). The intra-operative blood loss was (201.61 ± 71.03 ml), much more than that of the ILN group (110.5 ± 50.34 ml), the difference was significant ($p<0.01$). The union time of both groups were similar with no statistic difference ($p>0.05$). 6 patients 10.34% had radial nerve injury in the LCP group, but none in the ILN group. In the LCP group, there was 2 patients with superficial wound infection, and 2 patients with implant failure; and in the ILN group, there was 2 patients with non-union, and 2 patients with impingement; the difference was not significant $p>0.05$. They concluded that ILN group is superior to LCP group with respect to operation time, blood loss and radial nerve injury. In our study, there is no statistically significant difference $p>0.05$ observed with respect to age, gender, side, mechanism of injury, and AO type of fracture, associated injury, and time from admission to surgery in between the two groups which is similar to the study of Yin et al and Fan et al. Intra-operative blood loss and operative time were less in the ILN group compared with the LCP group which was significant and similar to Yin et al, Fan et al and Wei et al.²⁹⁻³¹ Union time was 14.05 ± 1.63 weeks in LCP group and 14.13 ± 1.49 weeks in ILN group ($p=0.843$; $p>0.05$) and union rate for LCP group was 93.3% and 90% for ILN group ($p>0.05$) which were not significant ($p>0.05$). ASES score was 42.47 ± 5.532 in LCP group and 40.93 ± 6.330 in nailing group $p=0.320$ which was not significant and similar to Fan et al. The outcome assessed by Stewart Hundley criteria showed excellent and good results in 26/30 patients and 17/30 in LCP group and ILN group respectively which was not significant ($p=0.070$; $p>0.05$). Non-union was seen in 2/30 (6.67%) in LCP group and 3/30 (10%) in the ILN group which was not significant and similar to Fan et al. 1 in LCP group and 2 in ILN group had aseptic non-union with implant in situ for which implant removal, dynamic compression plating with bone grafting was done. 1 in LCP group had infected non-union for which implant removal and antibiotic beads were placed in the first stage and after infection was ruled out by clinical and laboratory parameters second stage surgery was performed using dynamic compression plate and bone graft. 1 patient had aseptic non-union with broken nail who had undergone implant removal, dynamic compression plating and bone grafting. Hems and Bhullar reported that in 21 non-pathological fractures, 7 fractures had non-union 33%, even among the acute fractures the non-union rate was 29% (5/17).³² So they suggested that antegrade nailing affects fracture healing by distracting the fracture site.³² In our study radial nerve palsy was observed in 1/30 patient in LCP group which was recovered spontaneously after 6 weeks. The incidence of radial nerve palsy was lower in our study compared to Yin et al, Fan et al and Wei et al. Impingement and shoulder stiffness were the main disadvantages of

ILN. These problems are encountered due to prominent nail, peri-arthritis shoulder and other causes. In our study there are 3/30 (10%) and 5/30 (16.66%) cases of shoulder stiffness and impingement (Figure 1) respectively.

For stiffness 2 patients had manipulation under anaesthesia and 1 patient treated with physiotherapy sessions (range of motion exercises). Those who had impingement underwent nail removal after union. Chao et al reported that 3 patients had protrusion of the nail. This is due to the incomplete insertion of the nail distally because of fear of fracture, or from migration.³⁴ In our study in ILN group, 1 patient had an iatrogenic fracture in the distal segment during nail insertion which was managed conservatively with brace and arm sling which was later united. In LCP group 2 patients had superficial infection for which local wound debridement, regular dressings and intravenous antibiotics were administered and wound healed within 4 weeks after surgery. In the LCP group, 1 patient had a peri-implant fracture (Figure 2) for which implant removal and extra-articular LCP was applied. Reoperation rate was more in the ILN group ($n=8/30$; 26.6%) compared to LCP group ($n=3/30$; 10%). Fixation of humeral diaphyseal fractures with LCP, one can achieve good reduction and stable fixation but it carries extensive soft tissue dissection, more blood loss, increased risk of radial nerve injury and infection. ILN provides relative stability with biological fixation, less soft tissue dissection and blood loss however it is associated with an increased incidence of shoulder complications. In our study, nailing had an advantage over plating with respect to surgical time, blood loss and infection rate. But, with respect to union rate, complications, and reoperation rate, LCP had an advantage over ILN. Limitations of our study are a small sample size, patients operated by multiple surgeons, due to a smaller number of studies on humeral diaphyseal fracture management with LCP versus ILN the outcome could not be compared with the literature and larger randomized trial with long follow up may further improve the interpretation of the results.



Figure 1: Prominent nail causing impingement in a patient operated with ILN.



Figure 2: Peri-implant fracture in a patient operated with LCP.

CONCLUSION

No single treatment is superior in all cases for a particular fracture and each case has to be individualized according to the fracture pattern. Fixation by ILN can be indicated for a particular type of fracture pattern (e.g.: severe comminuted fracture, long spiral fracture) which are not amenable to plate fixation, but it is technically more challenging. Our study concludes that LCP can be considered a better surgical option for the management of diaphyseal fractures of the humerus as it had a lower incidence of complications, less reoperation rate and better union rate. However, there is no difference between the two groups in terms of union time and functional outcome.

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