A RANDOMIZED COMPARATIVE STUDY ON FUNCTIONAL AND RADIOLOGICAL OUTCOMES OF PROXIMAL HUMERUS FRACTURES TREATED CONSERVATIVELY VERSUS OPEN REDUCTION INTERNAL FIXATION WITH LOCKING PLATE

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Abstract

Locking-plate osteosynthesis is a well-established treatment option for proximal humerus fractures. The aim of the study on functional and radiological outcomes of proximal humerus fractures treated conservatively versus open reduction internal fixation with locking plate. From February 2021 to August 2022, 34 patients with fractures of the proximal humerus, out of which 18 were admitted and operated upon and 16 were treated conservatively by closed reduction without GA and U-Slab application was done. All cases were followed up for a period of 12 months to evaluate the result. Proximal humerus fractures were found to have high incidence in the 40 to 60 age group. Males predominated over females in our study. The most common mechanism of injury was the RTA (Road Traffic Accidents) in 24 (70%) patients. According to Neer's classification majority were 3-part fractures of 52.9% patients. 3 (8.82%) patients presented with 3 parts fracture associated dislocation of humeral head and 3 (8.82%) patients with 4 parts fracture associated with humeral head dislocation. 23% (8 patients with 9 complications) complication rate was seen, out of which 7 complications were implant related and 2 complications were non-implant related. Good to excellent results in 11 patients treated by surgical technique and 5 patients treated by conservative technique. To conclude, we believe that a locking plate for the treatment of proximal humerus fractures somewhat leads to a satisfactory functional result over long term follow up in maximum of the cases as compared to conservative treatment with U Slab application.

Keywords: Locking Plate, Proximal Humerus Fractures, Conservative, Open Reduction Internal Fixation.

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INTRODUCTION

Proximal humeral fractures consider for around 5% of all fractures. It's the 3rd most common fracture among the geriatric population after hip and lower end radius fractures. Another 70% of cases with these fractures are older than sixty years of age, and 75% are women. In the geriatric population, maximum of these fractures are related to osteoporosis. The threat factors for fracture of the proximal humerus include both osteoporosis and frequent falls. In the early 1930s, operative treatment for displaced fractures gained popularity, which continued in the 1940s and 1950s. Humeral head replacement for Comminuted displaced fractures of the proximal humerus was introduced in the 1950s. In the 1970s, AO/ ASIF group popularized plates and screws for fracture fixation, and humeral head prosthesis were redesigned. Yet, several complications have been reported with these methods, including implant failure, loss of reduction, nonunion or malunion of the fracture, impingement syndrome, and osteonecrosis of the humeral head.

The osseous framework of the humeral head with poor central cancellous bone stock, particularly in geriatric cases, leads to a high threat of fixation failure with classic plate and screw fixation.

Blade plate fixation may overcome this limitation with the advantage of a fixed- angle device but only affords a single primary point of fixation and can be technically problematic to work appropriately. Both methodologies necessitate soft-tissue stripping with concordant risk to the tenuous vascular supply of the humeral head. Presently, no agreement has been reached on the optimal approach of treatment for similar injures. There's no agreement about the management of displaced 3- and 4- part fractures. Poor conclusions are common in these types of fractures, and may be due to reduced humeral head blood supply and difficulties in achieving and maintaining exact fracture reduction with an suitable stabilization system. In addition, secondary loss of reduction often occurs. Likewise, joint replacement procedures have also led to disappointing results.

Recently plate osteosynthesis with angular stable implants have shown to address some of these problems. Broadening, the range of indication towards anatomic fracture stabilization truly for severely displaced three- and four- part fractures Rather than of replacing the humeral head with an endoprosthesis, as long as a stable fixation is possible. Concerns regarding the prospect of open reduction with plate and screw fixation responding in additional damage to blood supply and escalating the threat of avascular necrosis may be exaggerated. In one recent study, the Important predictors of humeral head perfusion were the length of middle metaphyseal fragment and complete medium soft tissue hinge as well as fracture pattern. Fractures that devitalize the humeral head articular fragments are felt to be at threat of avascular necrosis and are thus less suitable for open reduction and internal fixation. While it was formerly supposed that detachment of arcuate artery supply to the humeral head (a branch of the anterior circumflex artery) would lead to avascular necrosis, it's now clear that either a central metaphyseal extension of the humeral head fracture fraction or an intact middle capsule are sufficient to maintain humeral head blood supply in almost all cases.

The aim of proximal humerus fracture fixation is to gain an anatomic reduction, mechanical stability, and early recovery of the range of movement while conserving the blood supply of the humeral head. The angular stable locking plates have been introduced as a possible remedy to this problem. As with other locking plates, the stability in this construct comes from the plate- screw interface, which obviates the need for extended periosteal stripping and minimizing damage to the vascular supply. This interface creates a fixed angle device and is attained by threaded screw heads drilling appropriately into a threaded plate.

The locked screw mechanically acts as a load carrying lever beam, then on-locked screw being a fixation element that presses the plate onto the bone. This functionally creates an internal fixator that provides mechanical stability for fracture recovery. In addition this system doesn't depend on screw purchase in the bone for its strength, making it an appealing result for osteoporotic bone.

OBJECTIVES

1. To assess the functional outcome of conservative management of proximal humerus fractures.
2. To assess the functional outcome of open reduction internal fixation of proximal humerus fractures with locking compression plate
3. To compare the functional and radiological outcome of treatment by conservatively versus open reduction internal fixation with locking compression plate for proximal humerus fractures.

METHODOLOGY

This study was conducted between February 2021 - August 2022 in Mahatma Gandhi Hospital, a NABH affiliated, Tertiary care center in Jaipur, affiliated with Mahatma Gandhi University of Medical Sciences and Technology. This study includes the management of 34 patients with fractures of the proximal humerus, out of which 18 were admitted and operated upon and 16 were treated conservatively by closed reduction without GA and U-Slab application was done. In this study, after randomization by the chit in box technique. Patients were divided and allotted respectively in two groups of which Group A fixation was managed by open reduction and internal fixation using proximal Humerus interlocking plate system and Group B was treated conservatively by closed reduction without GA and U-Slab application. All cases were followed up for a period of 12 months to evaluate the result.

A general physical examination along with vitals was recorded. A thorough examination, of the injured limb, as well as other extremities, was done to rule out other associated injuries. The involved limb was examined for swelling, crepitus, abnormal mobility, deformity, shortening, skin integrity, discoloration, neurovascular status and signs or symptoms of compartment syndrome. Medical consultation was sought for geriatric patients and General surgeon consultation was sought to evaluate all high- energy accident victims.

Investigations: Radiographic evaluation was done of the affected shoulder in at least two planes at right angles to one another i.e. Anteroposterior and axillary lateral view. After this, the limb was immobilized in an U slab. Neer‟s classification was used at the time of admission and fractures were classified according to it. The patient in Group A patients had all their blood routine investigations sent which was followed by pre anesthetic check up that was done. The patient was counseled and consent taken for participation in the study. They were informed about all the possible complications that can happen during the surgery prior to their giving unconditional consent after which they were taken for elective surgical operative procedure using standard aseptic precautions.

Surgical Approach

Deltopectoral Approach: This approach was used for displaced two part, three part, and four part fractures with dislocation. Incision starts at anterior aspect of acromio-clavicular joint. The incision extended medially along the margin of lateral 1/3rd of clavicle. Then further down along anterior border of deltoid up to midpoint of its origin and insertion. The Deltopectoral groove, is identified where cephalic veins and deltoid branches of thoraco-acromial vessels lie. Cephalic vein is either retracted medially or ligated and cut. Then clavicular origin of deltoid muscle is detached by dividing it near its origin and then retracted laterally. Pectoralis major is retracted medially. This exposes the fracture site.

Open reduction and internal fixation of two part, three part and four part fracture using locking plate:

Procedure: An extended deltopectoral approach was used for open reduction and internal fixation of three and four part fractures. The long head of the biceps is important landmark for identification of fractures fragments. In most four part fracture the greater tuberosity is displaced from the shaft and from the head and lesser tuberosity as a separate fragment. The greater tuberosity fracture line is posterior to bicipital groove. The greater tuberosity was first reduced and stabilized to the head and lesser tuberosity with K-wire. Now the four part fracture was converted into two part fracture. The shaft was manually reduced and held using bone clamps. The reduced head, greater tuberosity and lesser tuberosity are attached to the shaft with the locking plate on the lateral side, the plate was initially held with k wires. Reduction was assessed under image intensifier. Definitive fixation with proximal humerus locking plate was done with plate positioned at least 5 mm distal to the upper end of the greater tuberosity and at least 2 mm posterior to the bicipital groove thus sparing the tendon of long head of biceps. Transosseous sutures with 2-0 vicryl were taken which aid in holding the reduction. Position of plate and reduction checked under image intensifier. Plate was fixed with multiple 3.5mm locking screws in the head and distally with three or four cortical/locking screws. Position of plate and reduction re-checked under image intensifier. Wound washed and closed in layers with drain in situ. Post operatively limb is immobilized in arm pouch. After surgery the patient was monitored for 48 hours in the orthopedics ward with appropriate analgesics and intravenous antibiotics .After 2nd and on 5th post operative day wound inspection was done and the patient was discharged if wound was healthy. Sutures were removed on 10th to 14th post-operative day.

Radiological Examination: Check x-ray (anterior-posterior and axillary view) was taken on 1st post operative day and assessed the reduction of fracture fragments and position of implants. Serial radiographs (antero-posterior and axillary views)

were taken at the end of 6 weeks, 3 months, 6, 12 months for final evaluation, and evaluated for bony healing, loosening of implant, loss of reduction, non-union, malunion and avascular necrosis of head of humerus. Assessment and analysis of any complications including impingement due to plate, malposition of greater tuberosity was done. Active shoulder and elbow exercises were started from 6th week as tolerated by the patient. Follow-up was done regularly at 6 weeks, 3 months 6 and 12 months.

Mobilization & Rehabilitation: The patient was started with active finger and wrist movements on the first post-op day. Passive range of motion of shoulder begun and active assisted forward flexion, backward flexion and abduction was started on 7 to 10 day post op An active internal and external rotation was allowed after 6 weeks Power building exercises was also started after 6 weeks. Functional outcome was assessed according to Constant-Murley score 6 weeks.

Follow up Protocol:
All patients were followed up for a period of 12 months; the follow up visits were done at 6 weeks Patient treated with Open Reduction and PHILOS plating - Check Xray done to look for fracture union and malalignment and Arm pouch removed Wound condition assessed and functional score checked by Constant Murley Scoring. At 6 weeks Patient treated with Closed Reduction and U-Slab application Check Xray done to look for fracture union and malalignment and U-Slab removed and functional score checked by Constant Murley Scoring. At 3rd month, 6th month, 12th month for both Groups-Check X-ray is done to look for fracture union and mal-alignment and functional score checked by Constant Murley Scoring.

STATISTICAL ANALYSIS

All the demographic details, base line data and postoperative data were recorded in the case report form over the course of the study. The Categorical data was presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data was presented as mean and standard deviation and were compared by student's t-test. Probability was considered to be significant if less than 0.05. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 22.0 statistical Analysis Software.

RESULTS

Proximal humerus fractures were found to have high incidence in the 40 to 60 age group. Males predominated over females in our study. Ratio of males to female was 3:1. Right sided was involved in 17 (50%) patients and 17 (50%) cases had Left side involvement i.e. both shoulders involved equally. The most common mechanism of injury was the RTA (Road Traffic Accidents) in 24 (70%) patients.

According to Neer's classification majority were 3-part fractures - 52.9% (18), 2-part fracture- 20.5% (7) and 4-part fractures 26.5% (9) in our series. 6 (17.60%) patients presented with proximal humeral fracture associated with dislocation of humeral head. In these 6 patients, 3 (8.82%) patients presented with 3 parts fracture associated dislocation of humeral head and 3 (8.82%) patients with 4 parts fracture associated with humeral head dislocation. In our series 23% (8 patients with 9 complications) complication rate was seen, out of which 7 complications were implant related and 2 complications were non-implant related.

In our series treated by surgical technique, excellent results in 5 (27.7%), good results in 6(33.3%) patients, moderate results in 2 patients (11.10%) and poor results in 5 patients (27.8%) and those treated conservatively had Excellent Results in 2 (12.5%), good results in 3 (18.7%) patients, moderate results in 6 patients (37.50%) and poor results in 5 patients (31.30%) according to Constant-Murley Scoring system (Table 1).

Table 1: Constant Score

Category			**Constant Score**				**Total**
			Poor	**Moderate**	**Good**	**Excellent**	
Surgical	**Diagnosis**	**2 Part**		2		2	4
				50%		50%	100%
		3 Part	3		3	3	9
			33.3%		33.3%	33.3%	100%
		4 parts	2		3		5
			40%		60%		100%
	Total		5	2	6	5	18
			27.8%	11.1%	33.3%	27.7%	100%

Conservative	**Diagnosis**	**2 Part**		2	1		3
				66.7%	33.3%		100%
		3 Part	1	4	2	2	9
			11.1%	44.4%	22.2%	22.2%	100%
		4 Part	4				4
			100%				100%
	Total		5	6	3	2	16
			31.3%	37.5%	18.7%	12.5%	100%

	Group statistics at 12 months			
	Category	**Mean**	**Std. Deviation**	**P**
Pain	Surgical	12.22	2.557	0.109
	Conservative	10.63	3.096	
Activities of Daily Living	Surgical	14.61	2.913	0.278
	Conservative	13.69	1.74	
Range of Motion	Surgical	20.89	3.771	0.203
	Conservative	19.38	2.895	
Strength of Power	Surgical	18.06	11.522	0.831
	Conservative	17.19	11.968	
Total Score	Surgical	65.78	15.299	0.364
	Conservative	60.88	15.731	

DISCUSSION:

Our study consisted of 34 patients of proximal humerus fractures treated conservatively and operatively with PHILOS plates in our Hospital. Published series of Proximal Humeral fractures treatment and their functional outcome was done and we took into account studies done by Moonot et al., Plecko et al., Chidambaram R et al., Haridas J et al. and we compared the results with our study. Our study done on 34 patients had an average follow up of 12 months and also showed a good functional result of 72.2% in comparison to the other mentioned above.

We subsequently compared a number of additional parameters and reported them below:-

Age: The average age of patients was 53 yrs (21 to 79 yrs) in our study. Other studies for proximal humerus fractures like Michael J. et al. reported an average age of 62 yrs, Moonot et al.[19] reported 59.9 yrs. C.P. Charalambous et al. reported 63 yrs and Plecko et al. reported the average age of 57yrs. With the increase in longevity and this being 3rd commonest fracture in the elderly osteoporotic bones, the health care delivery system should be prepared to offer a definitive solution to patients presenting with these fractures.

Gender: In our study, 23% (7 patients) females and 77% (27 patients) males were involved. The other studies of Plecko et al.[20] had 61% females and 39% males, Michael J. Gardner et al. 68% female and 31% males, N. Südkamp et al. 72% female and 28% males. In our series also 62% of the females were more than 60 years of age. The women were significantly older than the men, indicating that this fracture is common in elderly females because of Osteoporosis.

Side involved: Right sided was involved in 17 (50.00%) patients and 17(50.00%) cases had Left side involvement i.e. both shoulders involved equally. None had Billateral sides involved in the same patient. N. Südkamp et al. reported 54% involvement of dominant side, C.P. Charalambous et al. and reported 65% dominant side involvement, consistent with our study.

Mode of Injury: Mode of injury was fall (low energy trauma) in 18% (6) patients and road traffic accident (High energy trauma) in 69.6% (24) patients. Similar incidences of mode of injury have been reported in other series. N. Südkamp et al. reported low-energy injury in 87%. C.P. Charalambous et al. reported low-energy injury in 82% and Moonot et al. reported 81% low energy trauma.

Incidence: According to Neer's classification majority were 3-part fractures- 52.940% (18), 2-part fracture- 20.590% (7) and 4-part fractures 26.470% (9) in our series. Other authors like C.P. Charalambous et al. and Zhang H. et al. have also reported similar results.

Average follow up: Average follow up in our study was 12 months (9 to 15 months). Other studies

reported similar average follow ups. In Reto Babst et al. study average follow up was 12 months, P. Moonot et al. had 11 months of average follow up, Felix Brunner MD et al. 12 months of average follow up, MA Fazal et al. had 13 months of average follow up, and Shahid R. et al. had 21.7 months of average follow up.

Time for fracture union: Mean time taken for fracture union in our study was 9 weeks (with range of 6 to 12 weeks). SJ Haridas et al. reported mean fracture union time to be 10 weeks in their study, Moonot P et al.[19] reported average time of fracture healing in their study to be 10 weeks, Shahid R et al. Mean fracture union time 8 weeks and Egol KA et al. reported 10 weeks as fracture healing time. We used long philos plate in two patients with Neer's 3parts and 4 parts fractures (one each) as they were associated with fracture of humeral shaft and shown good fracture union. Same results was shown in the series of Zhang et al.

Functional results:

The Constant Murley scoring system has been used by different authors for shoulder function after fixation of proximal humerus fractures. We used this scoring system for evaluation of functional outcome in our patients. The mean constant score for two part fractures was 69.57±6.99 for three part fracture was 66.28±15.16 and four part fracture was 53.10±17.04.

The constant scores were higher for the patients who were younger in their respective groups. Almost all the fractures united by an average of 9 weeks (6-12 weeks). In the conservative group 31.30% of the patients had poor constant scores,37.5% had moderate constant scores,18.7% had good constant scores and 12.5% had excellent constant score. While in surgical group 27.8% had poor constant score 11.1% had moderate constant score, 33.3% had good constant score and 27.7% had excellent constant score suggesting that surgical group has better functional outcome at 12months follow up. This difference could not be proven statistically as the p value was 0.126 which is statistically insignificant and the independent values for pain, activities of daily living and range of motion were not showing significant difference suggesting that in patients above 60 yrs of age with displaced fracture of the proximal Humerus had no difference in functional outcome in long term follow up other than the initial pain relief in the surgically treated patients than conservative group. Our Study of 34 patients reported a mean constant score at final review as 65.9 points. Similarly Moonot P. et al. in a prospective series of 32 patients reported mean constant score at final review as 66.5 points, R. Chidambaram et al. in a prospective series of 126 patients reported average constant score was 78 points,

The most common complication observed was subacromial impingement in three patients and out of these three patients, one patient also had primary screw perforation of the articular surface of the humeral head. In three patients, malunion was noted. Superficial infection was seen in one case and adhesive capsulitis (frozen shoulder) was also seen in one case, Reassessment of the complications suggests that the majority (7/9) of the complications were technique related. Hence meticulous surgical discipline is pertinent. Intraoperative screening is essential to ensure that the placement of plate is at the proper level and there is no breaching of articular surface during insertion of the screw. Despite Intraoperative C-arm control, primary screw perforations through the articular surface can be overlooked at the time of surgery. Using measuring notations on drill bits and K- wires seems inadequate for achieving reliable screw length in osteopenic bone. One of the methods to avoid this as advocated by Brunner F et al. is drilling the lateral half of the track, followed by the use of a depth gauge to feel the resistance of the subchondral bone; the final screw length should be 2-3 mm shorter than the measured length. Primary malreduction with greater tuberosity improperly fixed resulted in malunion hence leading to poor functional out come in three of our patients. This type of complication may be avoided by proper reduction prior. In our series infection rate was low with only one case of superficial infection. The incidence of infection rate might be due to low profile nature of the implant and less soft tissue trauma than conventional ORIF techniques and early stable fixation was possible due to locking plates. One patient had frozen shoulder (adhesive capsulitis) with restriction of the shoulder movements.

The limitation of this study include small no. of cases (n=34). Another limitation of the present study may be the fact that the fracture classification system and the occurrence of complications were dependent on radiographic analysis. As the quality of the radiographs varies, this factor may be a potential source of error. In addition, the short average follow up (with 12 months being minimum follow up in some of the cases) may not be sufficient for drawing final conclusions long term complications like osteonecrosis after these challenging fractures.

Larger studies and longer follow up would help to determine the long term outcome and complications using PHILOS for fixation of proximal humerus. In our series 23% (8 patients with 9 complications) complication rate was present, out of which 4 complications were implant related and 4 complications were non-implant related, which is comparable to other series. Egol et al. reported complication rate of 24%; Moonot P. et al. prospective series of 32 patients with 3 and 4 part humeral fractures and reported complication rate of 28% (9 patients); Brunner F. et al. series of 157 patients with 158 proximal humerus fractures treated with proximal humeral locked plates reported complication rates of 9% implant related and 35% non implant related. Südkamp N. et al. in their series of 155 patients encountered 34% of complications. However the effective and successful use of PHILOS remains highly challenging and is associated with a steep learning curve and surgeons working must be well aware of the indication and technical tricks, advantages and limitation with these new implants.

CONCLUSION:

To conclude, we believe that a locking plate for the treatment of proximal humerus fractures somewhat leads to a satisfactory functional result over long term follow up in maximum of the cases as compared to conservative treatment with U Slab application. The Neer type 3 and type 4 fractures have poorer results as compared to type 2 fracture. The Results in type 3 fracture are good enough to recommend open reduction and internal fixation with locking plates in these cases. The surgery carries a steep knowledge curvature. Herein Still, proper use of locking plate principles and a careful soft tissue repair with aggressive post-operative recovery go a long way in guaranteeing a satisfactory functional result. The prospective design of our study, and a decent average follow up period (12 months) adds strength to our study but on the other side a small sample size weakens it.

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