J Shoulder Elbow Surg (2020) 29, 1758–1764

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Glenohumeral joint lavage does not affect clinical outcomes in open reduction and internal fixation of displaced intracapsular proximal humeral fractures: a prospective, randomized, double-blinded trial

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Background: This prospective, randomized, and double-blinded trial evaluates the effect of intraoperative glenohumeral joint lavage in open reduction and internal fixation of displaced intracapsular proximal humeral fractures.

Methods: Between January 2016 and April 2018, 86 patients (mean age: 65.2 ± 16.3 years) with a displaced intracapsular proximal humeral fracture were treated by open reduction and internal fixation using locking plates. Patients were randomized to either locked plating followed by intraoperatively performed glenohumeral joint lavage (group L, n = 36) or locked plating without the lavage (group NL, n = 36). Functional outcome assessment included range of shoulder motion, strength, and the Constant score, obtained 6 weeks, 3 months, 6 months, and 12 months postoperatively. A total of 62 shoulders could be reviewed for final investigation (86% follow-up).

Results: One year after open reduction and internal fixation, the mean Constant score was 70 ± 14 (group L, n = 31) compared with 73 ± 14 (group NL, n = 31, $P = .272$). The mean forward flexion and abduction in group L was 134 ± 33 and 128 ± 33 as compared with 139 ± 32 and 135 ± 32 in group NL, respectively ($P = .538$, $P = .427$). The mean external rotation was 40 ± 16 (group L) compared with 44 ± 16 (group NL) ($P = .210$). The overall complication rate was 9.6% and did not differ significantly between the groups ($P = .321$). In group L, there were 2 cases of avascular necrosis (6.5%) and 1 case of secondary displacement (3.2%). In group NL, 1 case of avascular necrosis (3.2%) and 1 case of secondary displacement were noted (3.2%, $P = .742$).

Conclusion: The results of this study do not demonstrate a need for glenohumeral joint lavage in open reduction and internal fixation of displaced intracapsular proximal humeral fractures with regard to shoulder function at 1-year follow-up.

Level of evidence: Level 1; Randomized Controlled Trial; Treatment Study

Keywords: Proximal humeral fracture; joint lavage; ORIF; locked plating; hemarthrosis; cytokines

Approval for this study was received from the Ethics Commission Ludwig-Maximilians University Munich (#526-16).

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1058-2746/$ - see front matter
https://doi.org/10.1016/j.jse.2020.04.026

Proximal humeral fractures account for 5%-10% of fractures in humans.[15,29] The majority of proximal humeral fractures show little or no displacement and can be treated conservatively with good clinical results.[7,24,34] However, in displaced fractures, the outcomes are heterogeneous and surgical treatment represents an option.[8,12,23] Open reduction and internal fixation by the use of locking plates is the most frequently performed surgical treatment for displaced proximal humeral fractures, and outcomes are often satisfying when anatomic reduction and bony healing is achieved.[3,6,9,12,20,27,32,33] However, in a number of cases, functional outcomes are limited and shoulder stiffness can be observed, despite an anatomic reduction and successful bony healing.[13,14,18,21,27]

Restricted range of shoulder motion (ROM) after open reduction and internal fixation of proximal humeral fractures may potentially be influenced by different factors, such as implant positioning, concomitant pathologies (eg, rotator cuff tear), post-traumatic arthrofibrosis, restrictive postoperative rehabilitation protocol, and others.[11,17,30] Most frequently, post-traumatic shoulder stiffness is related to soft tissue contracture and adhesions.[13,19] However, few factors have been investigated yet. Some authors have reported cytokines and growth factors to be related to fibrosis, which are typically increased in the joint fluid after articular fractures.[1,4,5,10] Morrey et al[22] showed that sequential biological processes support the onset and progression of arthrofibrosis and contracture formation inside the capsule after trauma. Although the evacuation of joint fluid after fracture may potentially decrease cytokines and growth factors and may reduce the risk for arthrofibrosis, little is known about the course of shoulder stiffness after proximal humeral fractures and no study has investigated the effect of intraoperative lavage of the glenohumeral joint in this circumstance.[2,25,26]

Therefore, the aim of this trial was to determine the effect of intraoperative glenohumeral joint lavage on ROM and functional outcomes after open reduction and internal fixation of displaced intracapsular proximal humeral fractures. We hypothesized that glenohumeral joint lavage would reduce the risk of post-traumatic arthrofibrosis and might improve ROM and shoulder function in the first year postoperatively.

Patients and methods

This prospective randomized controlled trial was conducted by ethical approval and according to the Consolidated Standards of Reporting Trials 2010 guideline respecting the declaration of Helsinki. It was registered in a public German trial registry (DRKS00017561). Between November 2016 and April 2018, 86 consecutive patients with displaced (>1 cm or >45° of angulation) intracapsular proximal humeral fractures were screened for eligibility into this trial at our institution. Eight patients were excluded because of a previous fracture of the proximal humerus (n = 1), concomitant nerve injury (n = 1) (axillary nerve), multiple (polytrauma) injuries (n = 3), dementia (n = 2), or previous shoulder surgeries (n = 1). Further exclusion criteria were lesions to the long head of the biceps (dislocation, instability, subluxation, and/or tear, n = 6) that resulted in opening of the rotator interval and intraoperative biceps tenodesis. No patient had an open fracture. Six patients refused to participate. A total of 72 patients were included into this study and randomized for open reduction and internal fixation followed by glenohumeral joint lavage (n = 36) or open reduction and internal fixation only (n = 36). The overall mean age of patients was 65.2 ± 16.3 years. All patients provided written informed consent into this trial.

Surgical technique and postoperative protocol

All surgeries were performed within 5 days from trauma by 3 experienced senior trauma surgeons using a deltopectoral approach with the patient placed in the beach chair position on a radiolucent table. All operations were conducted under general anesthesia in combination with an indwelling interscalene catheter for the first 48 hours, and all patients received 1 dose of intravenous antibiotics just before the procedure. Open fracture reduction and fixation was performed as previously reported by the use of an anatomically precontoured locking plate (PHILOS; DePuy Synthes GmbH, Oberdorf, Switzerland) placed 5 mm lateral to the bicipital groove and 5 mm inferior to the most lateral insertion of the supraspinatus tendon.[3,27,28] The rotator cuff was meticulously evaluated for full-thickness rotator cuff tears during the procedure and treated if present. Tuberosity sutures (FiberWire No. 5; Arthrex, Naples, FL, USA) were used in all cases. Screw tips were carefully placed in the subchondral bone stock not penetrating the articular surface. In all cases, 2 locking screws were placed in the inferior third of the humeral head (calcar screws). Anatomic fracture reduction, plate application, and screw positioning were confirmed by the use of a multiple-plane x-ray image intensifier in all cases. If necessary, the intended screws' lengths were changed to reach the exact subchondral bone stock. The quality of fracture reduction was assessed based on the criteria described by Schnetzke et al.[31]

No bone graft or synthetic screw tip augmentation was used in this study. Throughout careful fracture reduction and fixation, it was meticulously taken care that the glenohumeral capsule was not damaged.

Intervention (glenohumeral joint lavage)

After fixation of the fracture, glenohumeral joint lavage was conducted. A 1.8 × 43 mm (15G × 1¾ ") paracentesis needle was placed in the anterior glenohumeral joint space in between the humeral head and the glenoid rim superior to the palpated subscapularis tendon and inferior to the supraspinatus tendon. A 50-mL syringe filled with sterile Ringer solution (Tip 14G × 1¼″) was connected via a luer lock adapter; the fluid was gently infused inside the capsule (Figs. 1 and 2) and then aspirated. After aspiration, the humerus was abducted and rotated in order to mobilize clotted hematoma. A newly filled syringe was used for every flushing process. This procedure was repeated until no remnants of the hemarthrosis was detected, followed by the aspiration of residual fluid only. During movements of the arm, the tip of the needle was pulled back just enough to remain inside the capsule in

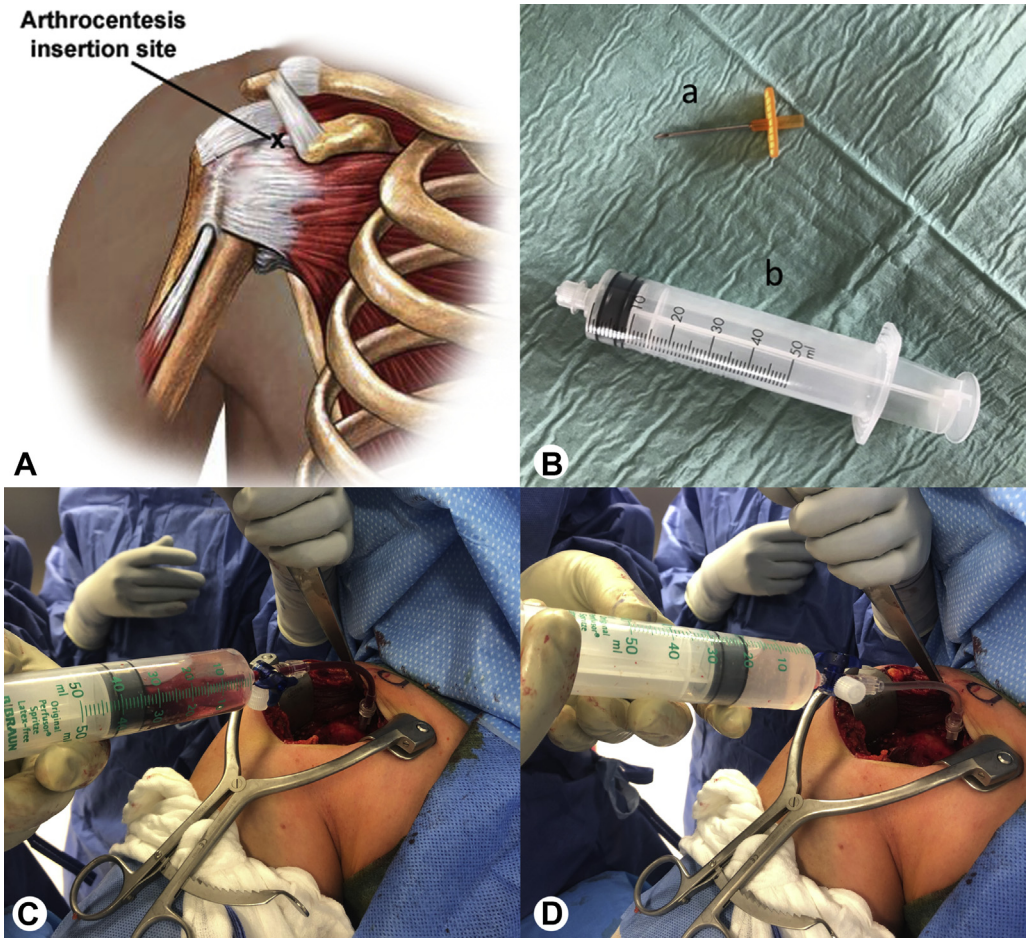

Figure 1 The insertion site of the arthrocentesis and glenohumeral lavage between the supraspinatus tendon and the subscapularis tendon (**A**). For the intervention, a standard 1.8 × 43 mm (15G × 1¾ ″) paracentesis needle (a) and a 50-mL syringe (Tip 14G × 1¼″) (b) were used connected via a luer lock adapter (**B**). After the arthrocentesis needle was inserted into the glenohumeral joint, the hemarthrosis was fully aspirated (**C**). After aspiration, the humerus was abducted and rotated in order to mobilize clotted hematoma and repetitive flushing, and the aspiration of the Ringer solution was performed to clear out further clotted hematoma. This procedure was repeated 5 times until no remnant of the hemarthrosis was detected, and only clear solution was aspirated (**D**). Finally, the joint was fully evacuated from fluid.

order to prevent damage to the glenohumeral cartilage. After the flushing process, the needle was removed and it was checked that there was no iatrogenic compromise of the capsule at the arthrocentesis insertion site. The arthrocentesis insertion site was not sutured after this procedure to avoid soft tissue scaring.

Rehabilitation

After the operation, the arm was placed in a sling for postoperative comfort and pain management during the first week. Passive- and active-assisted abduction and elevation until 90° were performed from the first day after surgery. Assistive rotation was allowed up to 20° postoperatively, progressing to 40° after 6 weeks. After 6 weeks, patients performed active exercises with no further restriction in ROM. Rehabilitation was monitored and followed 2 to 3 times a week until 6 months from surgery.[27,28]

Randomization and primary outcome measure

A total of 72 patients were randomized 1:1 into 1 of the 2 groups. Randomization was accomplished by an external operating system ''randoulette'' from the Institute of Biometry and Epidemiology of our institution. Randomization was concealed by the use of a closed envelope technique, which was opened by the surgeon just before performing the operation and kept blinded to the patient and the staff assessing the clinical follow-up for the whole study period. Two patients of group L and 1 patient of group NL deceased within the 1-year study period due to causes unrelated to the fracture treatment. One patient of group NL was lost to follow-up. In 3 patients of each group intraoperatively, a biceps tenodesis was performed due to concomitant injury of the long head of the biceps tendon (dislocation, instability, subluxation, and/or tear). Data analysis was executed as per protocol; therefore, these 3 patients of each group were excluded, and ultimately 31 patients in each group were compared (Fig. 2). In group L, there were 19 (61%) female and 12 (39%) male patients, and group NL consisted of 22 (71%) female and 9 (29%) male patients ($P = .361$). According to Neer's classification, the fracture pattern in group L was III-2: 18%, IV-3: 27%, V-3: 9%, and IV/V-4: 45%, and in group NL, it was III-2: 27%, IV-3: 27%, V-3: 6%, and IV/V-4: 39%. There were no statistical differences between the baseline characteristics of the 2 groups (Table I).

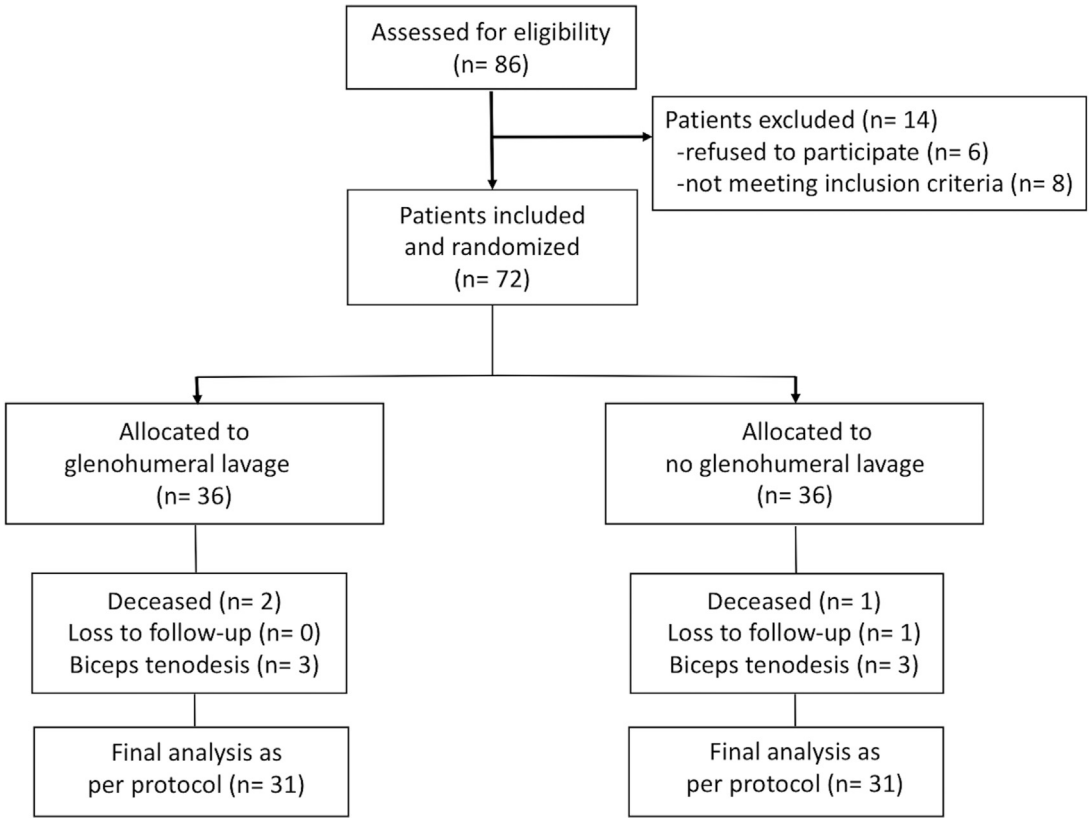

Figure 2 Systematic flow diagram of different stages during this prospective, randomized, and double-blinded trial.

The postoperative study protocol included a prospective examination of functional outcomes at 6 weeks, 3 months 6 months, and 12 months of follow-up. The standardized physical examination included ROM, strength, and the Constant score (CS) for the injured as well as for the uninjured shoulder. Strength was measured by the use of a digital spring balance (76000 Tara PS; Burg Wächter, Wetter/NRW, Germany). Functional examinations were assessed by experienced orthopedic surgeons who were blinded from the randomization and great care was taken that the double-blinded protocol was preserved throughout the study. Radiographs were taken routinely with every follow-up to verify fracture healing and were evaluated by the senior surgeon for secondary displacement, implant failure, and avascular necrosis.

Statistics

All data are presented as arithmetic means with standard deviation. Percentages and quantities were used for categorized variables. To compare the results of both groups, the Mann-Whitney *U*-test was used for non-normally distributed variables. For parametric data of linear variables between the groups, the Student *t*-test was used. Differences of categorical variables were analyzed by the χ^2 or Fisher test. A P value $<.05$ has been set to be significant for all tests.

A calculation indicated that 31 patients were needed in each group to detect a minimal clinical important difference of 10 points for the CS. Statistical analysis was performed using SPSS (IBM SPSS Statistics, Version 25.0; IBM, Armonk, NY, USA). There was no sort of funding for this trial.

Results

One year after open reduction and internal fixation of proximal humeral fractures, the mean CS of patients who received the glenohumeral joint lavage (group L, n = 31) was 70 ± 14 and in patients without the lavage (group NL, n = 31) the mean CS was 73 ± 14 ($P = .272$). The mean forward flexion and abduction of group L were 134 ± 33 and 128 ± 33 as compared with 139 ± 32 and 135 ± 32 of group NL ($P = .538$, $P = .427$). The mean external and internal rotation of group L was 40 ± 16 and 115 ± 2 and showed no significant difference to group NL with 44 ± 16 and 116 ± 2, respectively ($P = .210$, $P = .456$). The summary of ROM and functional results are given in Table II, and mean CS values are further presented in Fig. 3.

Radiographic evaluation revealed that the quality of fracture reduction was anatomic in 90.3% of group L and 93.5% of group NL. In 9.7% of group L and in 6.5% of group NL, the quality of reduction was acceptable. There was no malreduced fracture in this study. Primary screw perforation or plate malposition was not observed in either of the 2 study groups. The overall complication rate was

Table I Baseline characteristics of both groups shown as mean values and standard deviation as well as percentual quantities

	Group L (N = 31)	Group NL (N = 31)	*P* value
Age (yr)	67.1 ± 15.4	63.9 ± 17.3	.361
Sex, n (%)			.411
Male	12 (39)	9 (29)	
Female	19 (61)	22 (71)	
Dominant hand, n (%)			.581
Left	5 (16)	3 (10)	
Right	26 (84)	28 (90)	
Fracture type, n (%)			.212
Neer III-2	6 (18)	9 (27)	
Neer IV-3	9 (27)	9 (27)	
Neer V-3	3 (9)	2 (6)	
Neer VI/V-4	15 (45)	13 (39)	

The *P* value is set at .05.

Table II Mean Constant score and range of motion with standard deviation at 6 weeks, 3 months, 6 months, and 1 year postoperatively

	Group L	Group NL	*P* value
Constant score			
6 weeks	44 ± 6	46 ± 8	.321
3 mo	52 ± 7	56 ± 11	.138
6 mo	63 ± 13	67 ± 14	.243
12 mo	70 ± 14	73 ± 14	.272
Forward flexion			
6 weeks	52 ± 13	53 ± 13	.823
3 mo	97 ± 19	103 ± 24	.142
6 mo	121 ± 28	127 ± 28	.364
12 mo	134 ± 33	139 ± 32	.538
Abduction			
6 weeks	47 ± 13	49 ± 12	.674
3 mo	92 ± 18	99 ± 26	.211
6 mo	117 ± 28	121 ± 28	.502
12 mo	128 ± 33	135 ± 32	.427
External rotation			
6 weeks	18 ± 6	19 ± 7	.815
3 mo	23 ± 6	28 ± 10	.023
6 mo	32 ± 12	36 ± 12	.241
12 mo	40 ± 16	44 ± 16	.210
Internal rotation			
6 weeks	82 ± 1	84 ± 1	.132
3 mo	92 ± 1	107 ± 1	.042
6 mo	104 ± 2	110 ± 2	.072
12 mo	115 ± 2	116 ± 2	.456

The *P* value is set at .05.

9.6% and did not differ significantly between the groups ($P = .321$). In group L, there were 2 cases of avascular necrosis (3.2%) and 1 case of secondary displacement (1.6%). Group NL showed 1 case of avascular necrosis (1.6%), 1 case of secondary displacement with articular screw perforation (1.6%), and 1 case of adhesive capsulitis (1.6%).

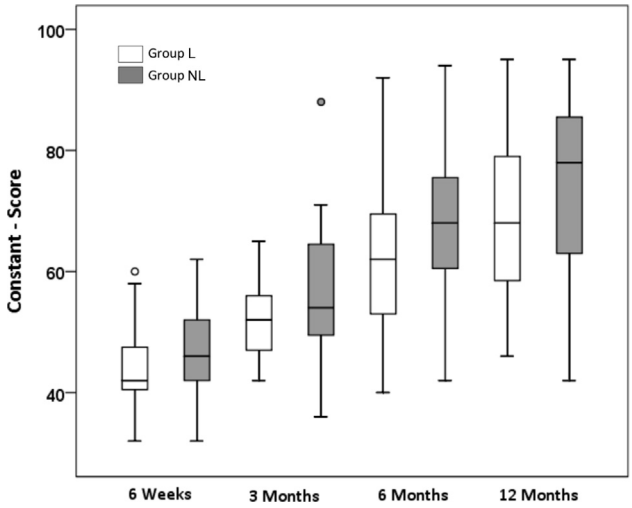

Figure 3 Box plots showing the Constant score of both groups at regular follow-ups.

Discussion

The most important finding of our study is that glenohumeral joint lavage does not positively affect functional outcomes in open reduction and internal fixation of intracapsular displaced proximal humeral fractures at 1 year of follow-up. The results of this trial do not demonstrate a need for lavage in open reduction and internal fixation for intracapsular displaced proximal humeral fractures.

After conservative and operative treatment of proximal humeral fractures, restricted ROM can be observed frequently.[10,14,18] Potential reasons for an impaired shoulder motion include nonunion or malunion of the fracture, malposition of implants, concomitant injuries of the rotator cuff or the long head biceps tendon, and others.[1,19] However, reduced shoulder motion can also be witnessed in the case of anatomic fracture healing and absence of concomitant injuries, and may be related to capsular fibrosis and soft tissue adhesions.[13,19] Some authors have reported a relevant amount of intra- and periarticular arthrofibrosis of the glenohumeral joint after anatomic fracture healing at the time of hardware removal, and capsular thickening has also been described after proximal humeral fractures.[10,16,18,21] Although post-traumatic contracture of the shoulder joint represents a striking problem for the patient suffering from a proximal humeral fracture, there is poor knowledge about its etiology and only few implications for treatment exist. Elhassan et al[1] reported that arthroscopic capsular release is an effective treatment for post-traumatic shoulder stiffness. Levy et al[19] also reported that arthroscopic capsular release is a useful

treatment to alleviate pain and restore a functional ROM; however, there is no study that investigates the value of glenohumeral lavage for the prevention of post-traumatic shoulder stiffness in the first place.

Over the years of treating proximal humeral fractures, we noticed shoulder stiffness in many of our own patients. As a result of our observation, we followed different approaches with the aim of reducing post-traumatic shoulder stiffness in this circumstance. One of these was the identification and elimination of hemarthrosis inside the glenohumeral joint. Hemarthrosis was noted from incising the glenohumeral capsule at the level of the rotator interval; however, we found no report in the literature how to interpret and handle with hemarthrosis of the glenohumeral joint in proximal humeral fractures. Nevertheless, several studies reported significant local inflammatory response, such as increased concentrations of proinflammatory cytokines tumor necrosis factor-alpha as well as of matrix metalloproteinases, in the joint fluid after articular fractures.[4] Morrey et al[22] reported that the genesis of joint contracture reflects an imbalance between pro- and antifibrotic expression and that cytokines may be involved in the process of contracture genesis and initiated at relatively early stages. Furthermore, Nogami et al[25] could show that arthrocentesis of joint fluid after fractures reduces the number of cytokines and that those patients improve with regard to ROM. However, in this study, ROM and the CS did not improve from arthrocentesis, whereas overall functional outcomes as well as complications were similar to prior studies.[11,14,17,33]

This study has several strengths and limitations. The primary strength is its prospective, randomized, and double-blinded design. It was emphasized that the patients as well as the physical examiners were blinded from randomization throughout the whole study period. In turn, the surgeons who performed the operation were not involved in the assessments of functional outcome.

Inclusion criteria were intracapsular fractures only; however, in 3- and 4-part fractures, the fracture may have extended the glenohumeral capsule and hemarthrosis may have been drained off itself along the fracture site. Finally, a follow-up period of 12 months may be too short to evaluate the full effect of glenohumeral joint lavage in proximal humeral fractures, as shoulder ROM may alter after the first 12 months. However, the prominent changes in ROM are observed within the first 12 months from trauma and differences may be minimal thereafter.

Conclusion

The results of this trial do not demonstrate a need for joint lavage in open reduction and internal fixation for displaced intracapsular proximal humeral fractures. In order to prevent postoperative shoulder stiffness in the first years of follow-up, its etiology needs further investigation.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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