

RESEARCH ARTICLE

Nonoperatively Treated Proximal Humerus Fractures: Randomized Trial of Immediate Versus Delayed Initiation of Exercises

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Received: 7 July 2020

Accepted: 26 August 2023

Abstract

Objectives: There is debate about when to start exercises in the nonoperative treatment of a proximal humerus fracture. This randomized trial compared immediate and one-month delayed shoulder exercises in the nonoperative treatment of fractures of the proximal humerus.

Methods: Twenty-six patients with a fracture of the proximal humerus who chose nonoperative treatment were randomized to start pendulum exercises within a few days and 24 were randomized to delayed exercises and started with active self-assisted stretching 1 month after fracture. Three and six months after the injury, patients completed the Disabilities of the Arm Shoulder and Hand questionnaire to measure capability, a measure of pain intensity, and had motion measurements.

Results: There was no significant difference in forward flexion (primary outcome) six months after injury between patients that started motion exercises immediately compared to 1 month after injury ($p = 0.85$). There was no difference in any motion measurement, pain intensity, upper extremity specific disability (DASH score) three or six months after injury.

Conclusion: Delaying exercises for a month does not affect recovery from nonoperative treatment of a fracture of the proximal humerus. People can choose whether to start exercises immediately or wait until they feel comfortable.

Level of evidence: II

Keywords: Exercises, Nonoperative treatment, Proximal humerus fracture

Introduction

Proximal humerus fractures with limited displacement are treated non-operatively. In randomized trials comparing early (within 1 week) vs. delayed (about 3 weeks) shoulder motion exercises in patients with a minimally displaced proximal humerus fracture, early exercises were occasionally associated with better shoulder motion for the first 3 months, but there were no benefits after that time point.¹⁻⁴ less is known about extending this tactic to all fractures treated nonoperatively.

This randomized trial addresses the null hypothesis that there is no difference in active forward flexion of the

shoulder six months after nonoperative treatment of a displaced or nondisplaced proximal humerus fracture when people are randomized to begin pendulum exercises at or before the first visit with a specialist or not. Secondly we addressed differences in pain intensity, internal and external rotation, abduction, and upper extremity specific disability both three and six months after injury and forward flexion three months after injury.

Materials and Methods**Study Design and Setting**

This was a two-center; randomized controlled trial

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conducted in academic teaching hospitals in the United States and the Netherlands. The Institutional Review Boards of both hospitals (blinded for review) approved the study. Study design and report were conducted according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.⁵ All enrolled patients had given written informed consent.

Participants

Outpatients were screened by a trained research assistant for proximal humerus fractures. If the surgeon and patient chose non-operative treatment, the research assistant assessed eligibility for the study. Any adult (age 18 or greater) patient with a fracture of the proximal humerus diagnosed by radiographs and enrolled within 2 weeks of injury was eligible. Displaced fractures were included. Patients with fractures at other sites were excluded.

Randomization

After informed consent was obtained by a member of the study staff, participants were randomized 1:1 according to a computerized random number generator by the research assistant to either immediate initiation of pendulum exercises or not. Both groups started active self-assisted stretching exercises one month after injury. Allocation to treatment groups was concealed. The research assistant responsible for recording the outcome measures was not blinded to the allocation.

Description of treatment

After randomization all patients completed the Disabilities of the Arm Shoulder and Hand (DASH) questionnaire.⁶ Patients randomized to early exercises were taught pendulum exercises. All patients started active self-assisted exercises one month after injury. Supervision by a physical therapist was optional.

Variables, outcome measures, data sources, and bias

The primary outcome in this study was active forward flexion of the shoulder six months after nonoperative treatment of a proximal humerus fracture. Secondary outcomes were pain intensity, internal and external rotation, abduction, and upper extremity specific disability both three and six months after injury and forward flexion three months after injury. Patients were seen at the outpatient clinic three months after the injury. Forward flexion, internal and external rotation, and abduction of the shoulder and pain intensity were measured by a research assistant using a goniometer. The same measures were completed 6 months after the injury. The research assistant was not blinded to the treatment allocation.

Sixty-five patients were assessed for eligibility; one patient did not meet the inclusion criteria and one patient declined to participate. Sixty-three patients with a proximal humerus fracture were enrolled. Of these 63 patients, 54 patients (28 early, 26 late) had non-or minimally displaced fractures and 9 (4 early, 5 late) had displaced fractures of the anatomic or surgical neck, but elected nonoperative treatment [Table 1]. Thirty-two patients were randomized to the early mobilization group and thirty-one patients to the late mobilization group.

Thirteen enrolled patients did not return for evaluation at either three or six months (six early, seven late) and were not analyzed. Among the remaining 50 patients, 10 (10 early, 10 late) returned at 3 months, but not at 6 months. We used last carried forward to address the missing data. There were no significant differences by follow-up category [Table 1].

Table 1. Baseline Characteristics				
		Early (n = 26)	Late (n = 24)	p-value
Sex	Men	5	9	*0.21
	Women	21	15	
Injured Hand	Dominant	9	12	*0.39
	Non-Dominant	17	12	
Age (mean)		63(13)	62(12)	^0.83
DASH at enrollment		61(16)	54(21)	^0.23
Completed three month follow-up		26	24	*0.99
Completed six month follow-up		16	16	
Non or minimally displaced fracture	Yes	22	19	*0.72
	No	4	5	

Numeric values are presented as means (standard deviations)

^Unpaired t-test, *Fisher's Exact test

Statistical Analysis

This study was designed to determine a 10 degrees mean difference in the shoulder forward flexion between the intervention and the control group at 3 and 6 months post treatment. We assumed a standard deviation of 10 degrees, which translates into an effect size of 1.0 ($\delta = 10/10$). A power analysis indicated that a sample size of 23 patients randomized to each of the two groups will provide 90% statistical power to detect this effect size between the groups ($\alpha = 0.05$, $\beta = 0.10$) using an unpaired Student t-test. To account for a possible loss to follow-up of 20-25%, we enrolled a total sample size of 60 patients with a 1:1

randomization plan with a Uniform (0, 1) model (30 patients to each arm of the study).

We used a Shapiro-Wilk test to assess normality of our data. We used the 2-tailed unpaired Student t test and the Mann-Whitney U test to compare means/medians. The level of significance of the primary outcome was set at $P < .05$. Mean imputation was used for missing data. Analysis was according to strict intention-to-treat.

Demographics

Baseline demographics and clinical characteristics were comparable for each cohort [Table 2].

Table 2. Characteristics by Amount of Evaluation

		All enrolled n = 63	Neither evaluation n = 13	3-month evaluation only n = 20	Both evaluations n = 30	p-value Comparing Neither evaluation with both evaluations
Randomization	Early	32	6	10	16	p = 0.91
	Late	31	7	10	14	
sex	Men	18	4	6	8	p = 0.95
	Women	45	9	14	22	
Injured Hand	Dominant	29	8	9	12	p = 0.43
	Non-Dominant	34	5	11	18	
Non- or minimally displaced	Yes	54	13	17	24	p = 0.23
	No	9	0	3	6	
Age (mean)		62	58	63	62	p = 0.64
DASH at enrollment		57 (36-68)	52 (48-68)	58 (51-64)	58 (52-62)	p = 0.70

Results

There was no significant difference in forward flexion six months after injury between patients starting exercises immediately or after 1 month ($p = 0.85$). There were no

significant differences in any motion measurement, pain intensity, upper extremity specific incapability (DASH score) three or six months after injury [Table 3]. There were no adverse events reported during the trial period.

Table 3. Study Results

	Early Mobilization n = 26			Late Mobilization n = 24			p-value
	Mean/Median	SD	95% CI, IQR	Mean/Median	SD	95% CI, IQR	
Primary Outcome							
Forward Flexion, 6 months	150	26	140-160	146	22	138-155	*0.63
Secondary Outcome, 3 months							
Flexion	122	43	106-139	126	33	113-139	*0.71
Abduction	115	43	98-131	101	41	84-117	*0.26
External Rotation	53	30	42-64	51	21	42-59	*0.72
NRS	3			3			^0.47
DASH	33	25	24-43	24	15	18-30	*0.10

Table 3. Continued

Secondary Outcome, 6 months							
Abduction	147	27	137-158	136	33	123-149	*0.20
External Rotation	70	17	63-76	66	26	57-76	*0.58
NRS	2		1.3-1.7	2		0.95-2.1	^0.83
DASH	18	12	13-23	14	7	11-17.	*0.17

CI = Confidence Interval, IQR = Interquartile Range, NRS = Numeric Rating Scale, DASH = Disability of Arm, Shoulder and Hand score

*Unpaired t-test, ^Mann-Whitney U test,

Discussion

There is an ongoing debate on the optimal timing of exercises in the nonoperative treatment of proximal humerus fractures; some surgeons recommend passive pendulum exercises in the early post-fracture period, others wait a month and start with active exercises after early fracture healing. While this debate applies to all nonoperatively treated fractures, data to date only address minimally or nondisplaced fractures. We randomized all nonoperatively treated fracture and found no advantage in terms of motion, pain, or disability to starting exercises immediately rather than waiting a month.

The results of this trial should be viewed in light of several limitations. This was a pragmatic trial in which patients were prescribed exercises, but adherence was not monitored. The results of this study reflect what happens when exercises are prescribed in actual practice, but not the efficacy of a specific set of exercises done consistently. The study was powered for the primary study question and may have been underpowered for some secondary study questions. We had a number of patients that did not show-up to any follow-up moment and therefore there was no data available for analysis. We believe most of these patients did not return because they felt better and did not see the need to return even though they were enrolled in a prospective trial. This speculation is supported by the overall very good recovery of patients in this trial and the fact that patients with nondisplaced fractures seemed more likely to skip follow-up visits. We don't believe these lost participants affected the results of the trial, because there were no significant differences between groups of patients with different levels of adherence to the protocol, although there might be important differences that we did not measure. We did not stratify for Neer or AO-fracture classification but these classifications have only 'slight' to 'fair' observer agreement⁷ and variations in fracture complexity should have been comparable as a result of randomization.

Our data are consistent with the other randomized trials performed to date except that we found no differences at the 3 months evaluation. Prior trials enrolled patients with

minimally displaced proximal humerus fractures, and instructions for exercises were monitored. Our study (a pragmatic trial) reflects actual practice in that all patients choosing nonoperative treatment were included no matter the fracture pattern or displacement and exercises were prescribed but not monitored.⁸ This coincides with evidence and trends that suggest initial nonoperative treatment followed by selective arthroplasty can be an effective strategy.⁹⁻¹²

Conclusion

The idea that waiting one month to start motion exercises will cause harmful stiffness is not supported by scientific data. Combined with the other randomized trials to date, we conclude that passive motion (so-called pendulum) exercises during the first month after injury does not improve the outcomes of nonoperative treatment of proximal humerus fractures—including displaced fractures--and can be safely omitted.

Acknowledgement

Not applicable

Conflict of interest: None

Funding: None

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