The impact of full-thickness rotator cuff tear on shoulder function and quality of life in patients who sustain a proximal þÿ h u m e r u s f r a c t u r e a p r o s p e c t i v e c o h o r t s t u d y

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The impact of full-thickness rotator cuff tear on shoulder function and quality of life in patients who sustain a proximal humerus fracture—a prospective cohort study

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Background: Only few studies have investigated the impact of rotator cuff integrity on patients with proximal humerus fracture (PHF). We aimed to determine if the presence of a rotator cuff tear impairs shoulder function and health-related quality of life (HRQoL) after nonsurgically treated PHF.

Methods: Sixty-seven patients with PHF were recruited prospectively in a cohort. Presence of a full-thickness rotator cuff tear was determined by ultrasound examination. After 6 and 12 months, Constant-Murley Score; Disability of the Arm, Shoulder and Hand; the Visual Analog Scale; EuroQol-5 Domain; and the 15D scores were compared between the patients with a rotator cuff tear and patients with an intact rotator cuff.

Results: The prevalence of a full-thickness rotator cuff tear was 34%. After 12 months, the mean Constant-Murley Score was 65.7 (standard deviation 16.3) in the intact rotator cuff group vs. 53.9 (16.0) in the rotator cuff tear group (mean diff. 11.8, 95% confidence interval 2.5; 21.2) and was found to be a clinically relevant difference. A significantly lower HRQoL was found on the EuroQol-5 Domain score after 12 months in the rotator cuff tear group with a median score of 1 (interquartile range 0.23) in the intact rotator cuff group vs. 0.75 (interquartile range 0.34) in the rotator cuff tear group ($P = .03$). In the remaining outcome measures, no statistically significant between-group differences were detected.

Conclusion: Rotator cuff tear in older adults with nonsurgically treated PHF may be considered a prognostic factor for poorer shoulder function and HRQoL. This knowledge can support the planning of treatment.

Proximal humerus fracture (PHF) is the third most common osteoporotic fracture in older adults and is most often attributed to fall from standing height.[1,6,20,26] The majority of the patients are elderly females.[6,20] A Finnish study from 2015 reported an adjusted incidence rate of 144 per 100,000 person-years among women and 47 per 100,000 person-years among men, and the incidence was found to increase with age.[20] In a prospective study with 1027 patients with PHF, the typical patient was reported to be relatively fit and independent at the time of injury, in spite of old age.[7] However, sustaining a PHF can have a substantial impact on the patient's functional outcome and is related to morbidity and mortality.[2,4,18]

A suspected rotator cuff tear in patients with PHF is rarely addressed by first approach, nor with same concern as the bony structures. Nevertheless, studies have found that rotator cuff injuries are commonly seen in patients with PHF with an estimated

Ethical approval for this study was received from the Regional Ethics Committee of Tampere University Hospital (ETL-code R10127). All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration.

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prevalence of 10% to 50%.[11,12,28,34] Rotator cuff tears are commonly seen in the general older population and is not always caused by a trauma.[16,22] Thus, a rotator cuff tear in PHF patients may have been present even before they suffered a PHF. Wilmanns et al described the longitudinal rotator cuff tear as the most frequent tear to accompany a PHF and the most likely to occur when the bony structures split. The transverse rotator cuff tear is often classified as chronic and interpreted as part of a degenerative process.[36] Early clinical signs of tendon injury damage after PHF can be subtle and often overshadowed by the symptoms from the fracture, and only in case of persistent pain or lack of progress in rehabilitation, further examinations will be carried out.[28] In spite of the relatively high prevalence of rotator cuff injuries found in patients with a PHF, only few studies have investigated if the integrity of the rotator cuff tendons can be considered as a predictor of poor shoulder function, and the reported results are inconsistent. Wilmanns et al. found that rotator cuff tears in patients with PHF correlate significantly with loss of shoulder function and suggested that a reconstruction of the rotator cuff might help avoiding displacement and prevent humeral head necrosis.[36] Similar findings were reported in a study by Fjalestad et al who found that the group with full-thickness tear had a significant lower Constant-Murley score (CS) (26.5 points) than the group with no tear (65.3 points).[11] However, Nanda et al found no statistically significant difference in functional outcome of nonsurgically treated patients with PHF with or without the presence of a rotator cuff tear. Thus, they suggested no routine imaging of the rotator cuff in patients with this type of fracture.[23] The existing studies provide little, but no clear, evidence to fully understand the impact of rotator cuff integrity in patients with PHFs.

Therefore, the aim of this study was to investigate if the presence of a full-thickness rotator cuff tear impairs shoulder function and quality of life in patients with a nonsurgically treated PHF, compared with patients with an intact rotator cuff. We hypothesize that a full-thickness rotator cuff tear impairs shoulder function and reduces quality of life after PHF.

Materials and methods

Study design

This was a prospective cohort study, nested in the ongoing Nordic Innovative Trial to Evaluate osteoPorotic fractures (NITEP) comparing nonsurgical to surgical treatment after PHF among elderly.[21] The specific details can be found in the protocol by Launonen et al.[19]

Reporting was carried out according to the STROBE Statement (STrengthening the Reporting of OBservational studies in Epidemiology).[35]

Patients

This study was based on data from patients randomized to the nonsurgically treated groups recruited at Tampere University Hospital or Central Finland Hospital.[19] Patients aged 60 years or older with a displaced 2-, 3-, or 4-part low-energy PHF, defined according to the classification of Neer,[24] were eligible for inclusion. Patients with an ultrasound examination (US) of the rotator cuff tendons in the fractured shoulder at 3 months follow-up were included in the analysis (n = 67). Inclusion and exclusion criteria for the randomized controlled trial are stated in Supplementary Appendix S1. Recruitment took place in the hospitals' emergency department and orthopedic ward between February 2011 and December 2019.

Radiographic examinations

After entering the emergency department, plain radiographs were obtained to verify the fracture. Furthermore, computed tomography was conducted to categorize the fractures into 2-, 3-, or 4-part PHF.[24] Additional information about the plain radiograph and computed tomography procedures can be found in the published protocol.[19]

To identify potential tears of the rotator cuff tendons, an US of the supraspinatus, infraspinatus, and subscapularis tendons was carried out 3 months after enrollment to the trial. A radiologist with substantial experience in musculoskeletal ultrasound diagnostics performed the US examinations. The examinations were carried out according to the European musculoskeletal ultrasound technical guidelines for the shoulder, and tendons were examined in both longitudinal and transverse planes.[10] Results of the US classified the supraspinatus tendon, the subscapularis tendon, and the infraspinatus tendons as either intact or with a full-thickness rotator cuff tear. A full-thickness rotator cuff tendon was defined as a tear that extended through both the articular and the bursal part of the tendon. No distinction was made between transverse or longitudinal tears, nor were they classified as traumatic or degenerative tears.

Nonsurgical treatment

All included patients followed the same standardized aftercare program (Table I) and training protocol. A sling was worn for the first three weeks to reduce pain, and pendulum movements were initiated from the first day. Elbow, wrist, and fingers were mobilized, and the use of the injured upper extremity in daily activities was encouraged. After three weeks, the assisted, active range-of-motion exercises were initiated under the supervision of a physiotherapist, and patients were scheduled to have five physiotherapist contacts within the first three months.

Outcome measures

Primary outcome

The primary outcome measure was the CS measured at 12 months follow-up.[5] The score ranges from 0 to 100 points with 35 points allocated to subjective assessments of pain and activities of daily living and 65 points allocated to objective measurements of range of movement and shoulder strength. A higher score indicates a better shoulder function. The minimal clinically important difference (MCID) has been estimated to be between 6.7 and 10.4 points for patients with rotator cuff tears undergoing surgical treatment.[8,17,32,37] The MCID threshold value used in this study was set to be 10.4.[17] The CS score is known to have a wide interobserver variation; therefore, a pretrial training for the investigators was arranged to standardize the measurements.[3] Furthermore, the investigators were blinded from the results of the US.

Secondary outcomes

The primary outcome measure CS was also included as a secondary outcome with 6 months follow-up.[5] Additional secondary outcome measures were the Disability of the Arm, Shoulder and Hand (DASH),[13] the Visual Analog Scale (VAS),[30] and the two health-related quality of life (HRQoL) questionnaires; the EuroQol-5 dimensions (EQ-5D[-3L]) and the 15D instrument (15D).[29,33] The DASH questionnaire measures the degree of symptoms and physical function with a score ranging from 0 (no disability) to 100 (most severe disability),[13] while VAS measures pain with a score

Table I
Rehabilitation regime for patients enroled in the study.

Week	Immobilization/mobilization	Exercises allowed	Aim
0-3	• Wearing arm sling day and night, except from when doing exercises	• Active exercises for the hand and elbow • Pendulum exercises, as allowed by pain • Posture correction	• To reduce edema • To maintain function in the fingers, wrist, and elbow • To reduce pain and reestablish ROM in the shoulder
4-6	• Wearing arm sling if needed	• Active assisted ROM exercises of the shoulder	• To reduce pain and reestablish ROM in the shoulder
7-12	• No arm sling • Free mobilization	• Active ROM	• To re-establish muscle strength and stability

ROM, range of movement.

ranging from 0 mm (no pain) to 100 mm (worst possible pain).[30] Both the EQ-5D and the 15D questionnaires have index scores from 0 to 1, where 0 represents worst possible health (death) and 1 represents full health.[29,33] At enrolment, baseline information was obtained by asking the patients to complete the DASH, EQ-5D, and 15D questionnaires, by recalling their shoulder function and HRQoL before they sustained the PHF. Additional radiograph assessments were conducted after 12 months, where fractures were categorized as healed or nonunions. Follow-up visits, included in this analysis, were carried out 6 and 12 months after the PHF.

Statistics

Baseline characteristics were analyzed with descriptive statistics. The primary and secondary outcomes were compared between the groups; if normally distributed, presented as mean values and 95% confidence intervals (95% CI); and compared with a student's t-test, computed with either equal or unequal variances. If values were skewed, logarithm transformation was performed before the t-test. In cases where logarithm transformation did not lead to an acceptable normal distribution, outcomes were presented as medians and interquartile range (IQR) and compared with Wilcoxon rank-sum test. In cases with missing data, available case analysis was carried out. Numbers of loss to follow-up are outlined in Figure 1. All *P* values were 2-sided. The analyses were computed by using the STATA 16 software (v. 16.1, StataCorp LLC, College Station, TX, USA).

Sample size calculation

This study was powered to detect an MCID in the CS between the groups of at least 10.4 points,[17] and the standard deviation (SD) was set to 13.5.[23,36] Based on estimates in the existing literature, the prevalence of rotator cuff tear in elderly patients with PHF was expected to be approximately 30%, from which the allocation ratio was set (3/7 = 0.43).[12,23] With a significance level of 0.05 and a power of 80%, the required sample size was 66 patients with 20 in the rotator cuff tear group and 46 in the intact rotator cuff group.

Results

Study population

Table II presents the demographic and clinical characteristics of the patients at the time of enrolment. Among 67 eligible participants (age range, 60-89 years; 78% women), 23 (34%) had an US-verified full-thickness rotator cuff tear in at least one of the tendons (rotator cuff tear group). There was no significant difference in the demographic and clinical characteristics between the intact rotator cuff group and the rotator cuff tear group (Table II).

In the rotator cuff tear group, the most common tear was an isolated full-thickness supraspinatus tear, which was found in 15 (65%) of the patients. Six (26%) patients had a combined supraspinatus and infraspinatus tear, and two (9%) patients had a combined supraspinatus and subscapularis tear. Table III shows how the combinations of tears are distributed between patients with 2-part fractures and patients with 3- and 4-part fractures.

The patient flow, including reasons for lost to follow-up, is outlined in Figure 1.

Primary outcome measure

At 12 months of follow-up, the mean CS was 65.7 (SD 16.3) in the intact rotator cuff group and 53.9 (16.0) in the rotator cuff tear group. The between-group difference was 11.8 points (95% CI 2.5;21.2) and was found to be statistically significant and clinically relevant (Table IV). Figure 2 illustrates the median CS scores at 6 and 12 months of follow-up.

Secondary outcome measures

Six months follow-up

The results of the prespecified secondary outcomes can be found in Table IV. After 6 months, the rotator cuff tear group reported a poorer functional outcome than the intact rotator cuff group. This was found on both the CS (mean diff. 12.8, 95% CI 3.5;22.2) and on the DASH (mean diff. 8.5, 95% CI -2.1;19.2), and the difference in the CS was both statistically significant and clinically relevant. Furthermore, the rotator cuff tear group reported a higher degree of pain on the VAS score than the intact rotator cuff group, with a mean difference of 12.4 mm (95% CI −1.8;25.3). Both EQ-5D and 15D detected a lower HRQoL in the rotator cuff group than that in the intact rotator cuff group, yet none of the estimated differences were statistically significant.

Twelve months follow-up

After 12 months, the rotator cuff tear group reported a higher degree of disability on the DASH score than the intact rotator cuff group (mean diff. 9.3 points; 95% CI −0.8;19.3); however, the difference was not statistically significant or clinically relevant; neither was the slightly higher degree of pain the rotator cuff group reported on the VAS score (mean diff. 2.5 mm, 95% CI −8.5;13.5) (Table IV)

The rotator cuff tear group reported a lower HRQoL than the intact rotator cuff group. With a median score on the EQ-5D equal to 0.75 (IQR 0.34) in the rotator cuff group vs. a median score of 1 (IQR 0.23) in the intact rotator cuff group, the difference was found to be statistically significant. Also, with the 15D score, the rotator cuff tear group had a lower HRQoL (mean diff.0.03, 95% CI −0.08;0.01), even so this was not found to be statistically significant (Table IV).

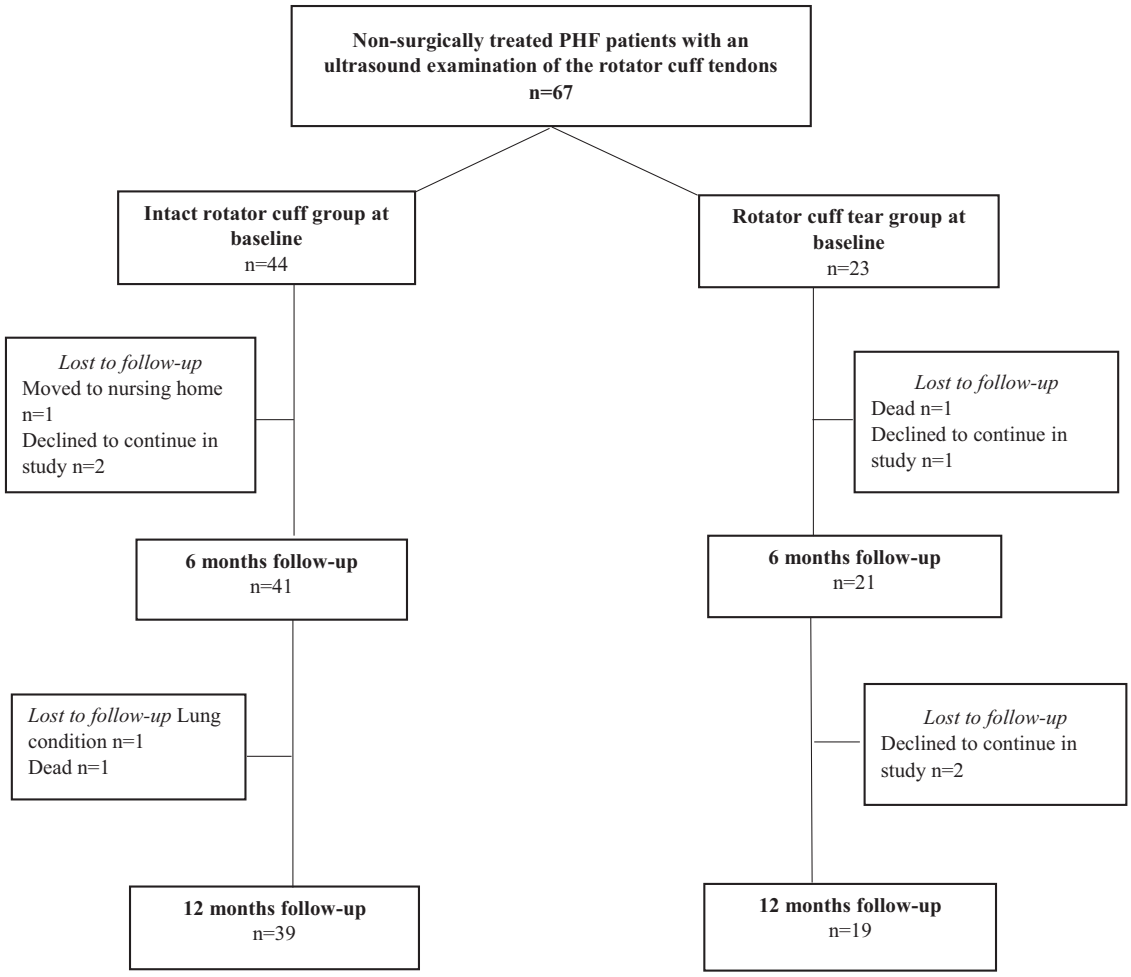

Figure 1 Flowchart outlining the patient flow from baseline to 12 months of follow-up.

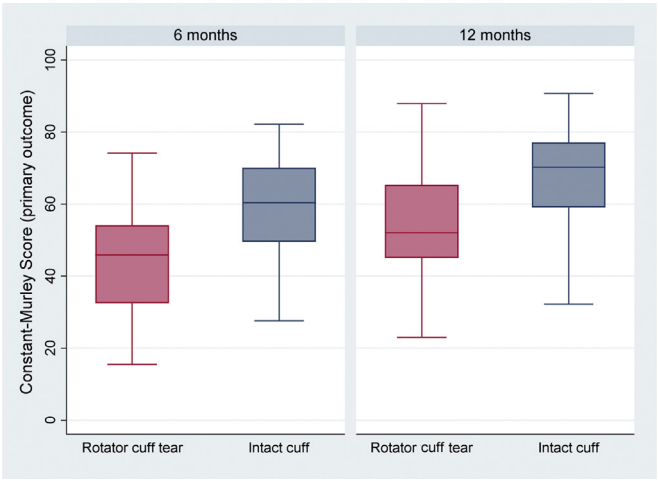

Figure 2 Box plot illustrating the Constant-Murley score with median and interquartile range at 6 and 12 months of follow-up.

At 12 months of follow-up, three nonunions were found; one in the rotator cuff tear group and two in the intact rotator cuff group.

Discussion

This study suggests that a full-thickness rotator cuff tear in patients with PHF may impair shoulder function. This impairment was detected in both 6 and 12 months of follow-up. Furthermore, we found the quality of life was significantly lower in patients with a rotator cuff tear than in those with an intact rotator cuff, 12 months after their PHF. No significant between-group differences were detected on the DASH, VAS, or 15D scores; however, on all outcome measures at all follow-up times, the rotator cuff tear group scored lower than the intact rotator cuff group.

The results of this study are aligned with two other studies, which also found an impaired shoulder function in patients with PHF with an additional rotator cuff tear.[11,36] However, our findings were not supported by Nanda et al who concluded that rotator cuff integrity was not found to be a predictor of shoulder function at 12 months after PHF.[23] Of note, there were several differences between the study populations in the two studies. Nanda et al did not report the mean age of their study population, but given their demographic data, 29 (34%) of the patients were younger than 60 years, whereas our study had a lower age limit at 60 years and a mean age of 73 years. Moreover, we excluded patients with a nondisplaced PHF contrary to Nanda et al who included 27 (32%) patients with an nondisplaced PHF.[23] It is not unlikely, that a younger population with less severe fractures have a better

Table II
Demographic and clinical characteristics of the included patients at time of enrollment.

Patient characteristics	Intact rotator cuff group, n = 44	Rotator cuff tear group, n = 23	Test for difference between groups *P* value
Mean age, yr (SD)	72.9 (7.7)	74.2 (6)	>0.50*
Gender, female, n (%)	39 (89)	20 (87)	>0.99†
Fracture type, 2-part, n (%)	27 (61)	11 (48)	>0.29‡
Fracture type, 3- and 4-part, n (%)	17 (39)	12 (52)	>0.29‡
Smoking (%)	7 (16)	3 (13)	>0.90†
Diabetes, n (%)	6 (14)	2 (9)	>0.90†
Neurological disease, n (%)	4 (19)	2 (8)	>0.96†

SD, standard deviation.
*Student's t-test.
†Fisher's exact test.
‡Chi-square test.

Table III
Distribution of full-thickness rotator cuff tears between the group with 2-part fractures and the group with 3- and 4-part fracture.

Involved tendons	2-Part fracture	3- and 4-Part fracture
Supraspinatus tear	11	4
Supraspinatus + infraspinatus tear	0	6
Supraspinatus + subscapularis tear	0	2

Numbers refer to the number of patients.

Table IV
Primary and secondary outcome measures for the intact rotator cuff group and the rotator cuff tear group at baseline, 6, and 12 months of follow-up.

Outcome measures	Intact rotator cuff group	Rotator cuff tear group	Difference between groups, mean (95% CI)	*P* value
Constant-Murley Score				
No.	41	20		
6 mo, mean (SD)	57.1 (17.5)	44.3 (16.2)	12.8 (3.5;22.2)	.008
No.	37	18		
12 mo, mean (SD)	65.7 (16.3)	53.9 (16.0)	11.8 (2.5;21.2)	.01
DASH score				
No.	44	22		
Baseline, mean (SD)	14.0 (15.9)	18.2 (14.7)	4.2 (−3.9;12.3)	.30
No.	41	21		
6 mo, mean (SD)	26.3 (18.7)	34.8 (21.9)	8.5 (−2.1;19.2)	.11
No.	39	19		
12 mo, mean (SD)	20.5 (17.2)	29.7 (19.5)	9.3 (−0.8;19.3)	.07
VAS score (in mm)				
No.	39	21		
Baseline, mean (SD)	53.2 (27.3)	65.0 (31.0)	11.8 (−3.7;27.3)	.13
No.	41	21		
6 mo, mean (SD)	15.5 (14.3)	28.1 (29.6)	12.4 (−1.8;25.3)	.09†
No.	39	19		
12 mo, mean (SD)	13.8 (19.3)	16.3 (20.3)	2.5 (−8.5;13.5)	.70
EQ-5D				
No.	44	23		
Baseline, median (IQR)	0.77 (0.29)	0.79 (0.25)		.73*
No.	40	21		
6 mo, median (IQR)	0.82 (0.34)	0.78 (0.17)		.29*
No.	39	18		
12 mo, median (IQR)	1.00 (0.23)	0.75 (0.34)		.03*
15D				
No.	41	23		
Baseline, mean (SD)	0.87 (0.09)	0.85 (0.09)	0.01 (−0.06;0.03)	.56
No.	39	21		
6 mo, mean (SD)	0.88 (0.09)	0.86 (0.10)	0.02 (−0.07;0.03)	.43
No.	37	19		
12 mo, mean (SD)	0.89 (0.08)	0.86 (0.10)	0.03 (−0.08;0.01)	.17

95% CI, 95% confidence interval; *SD*, standard deviation; *DASH*, Disability of the Arm, Shoulder and Hand; *VAS*, Visual Analog Scale; *EQ-5D*, EuroQol-5 Domain.
DASH, EQ-5D, and 15D baseline values denote to before proximal humerus fracture. Student's t-test with equal variances has been undertaken unless something else is noted.
*Mann-Whitney test.
†T-test with unequal variances.

potential of succeeding with rehabilitation after rotator cuff tear, which may explain the differences in results.

The impaired shoulder function in this study is possibly explained by the reduced muscle strength a tendon tear is expected to cause, which is likely to be reflected in the CS, where the objective strength measurement accounts for up to 25 points.[16] The fact that the impairment found on the DASH score was not clinically relevant could possibly indicate that PHF patients with a rotator cuff tear may not experience the shoulder impairment as a major physical limitation in their everyday life. Hence, the clinical relevance of the impairment is debatable. In addition, recent studies suggest that other factors such as fear of movement, lack of self-efficacy, and engagement must also be acknowledged as considerable predictors of a poor physical outcome after sustaining a PHF.[14,15]

The age-related degeneration of the rotator cuff tendons in older adults and the likelihood that some of the included PHF patients already had the full-thickness tear before the fracture trauma must be taken into consideration.[16,31] In this study, we were not able to distinguish between pre-existing degenerative tears and concurrent traumatic tears, and although we hypothesize that both types of tears have an impact on shoulder function, it must be regarded a limitation. Nevertheless, an examination of the rotator cuff tendons before planning the treatment strategy may contribute with useful information for both the responsible orthopedic surgeons and physiotherapist. As a consequence of full-thickness rotator cuff tear, a superior migration of the humeral head may occur over time leading to a condition of rotator cuff arthropathy.[25] Ultimately, these patients are likely to experience further impairment of the shoulder function and also pseudo paralysis in more severe cases.[9] Therefore, knowledge about the integrity of the rotator cuff tendon can be helpful in terms of predicting the outcome of physical function, as well as in supporting the planning of exercises that target the existing muscles, in patients with PHF. Finally, our findings are valuable in terms of choosing the best suitable surgical hardware for each patient, in cases where surgery is indicated. We suggest to apply US or magnetic resonance imaging examination of the rotator cuff tendons after PHF to obtain knowledge about potential soft-tissue damage; that along with information about the bony structures will help the surgeons and patients in the shared decision-making of the treatment strategy.

The prospective design must be considered a strength in this study, as well as the the pretrial training of the research physiotherapists we carried out, to standardize the measurements in the CS. Moreover, the physiotherapists were blinded to the results of the US of the rotator cuff tendons.

This study has several limitations that need to be taken into consideration when interpreting the results. First, we chose to classify the rotator cuff tears as either full-thickness rotator cuff tear or no tear because, if any, we expected full-thickness tears to have the highest impact. Therefore, patients with partial-thickness tear were categorized in the group of patients with an intact rotator cuff, which may have affected the scores in the intact rotator cuff group negatively. This is a potential bias toward the null hypothesis; thus, an underestimation of the impact of rotator cuff tears cannot be ruled out. Second, this study may be underpowered because we found higher SD values in our study than the ones used in the sample size calculation.

US has a high accuracy in detecting rotator cuff tears in people with no fracture and is found to be especially sensitive in detecting full-thickness tears.[27] The accuracy might not be as high in people with a sustained fracture because of the alterations of the anatomical structures. In order to ensure a high quality of the US, only experienced radiologists performed the examinations, which is also considered as a strength in this study. Magnetic resonance imaging could have been chosen as an alternative modality; however, it is time-consuming and costly compared with US.

Conclusion

In this study, we identified full-thickness rotator cuffs tear(s) in 23 out of 67 older adults with PHF. Our findings suggest that a full-thickness rotator cuff tear in older adults with PHF may be considered a prognostic factor for poorer shoulder function and HRQoL outcomes after 12 months. Knowledge about the integrity of the rotator cuff may contribute with important information, and that together with knowledge of fracture severity and other prognostic factors can support the planning of treatment.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jseint.2021.11.003.

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