Original Article

Handheld Ultrasound Does not Replace Magnetic Resonance Imaging for Diagnosis of Rotator Cuff Tears

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Purpose: The purpose of this study was to examine the reliability and validity of handheld ultrasound (HHUS) alone versus conventional ultrasound (US) or magnetic resonance imaging (MRI) for diagnosis of rotator cuff tears and versus MRI plus computed tomography (CT) for diagnosis of fatty infiltration. **Methods:** Adult patients with shoulder complaints were included in this study. HHUS of the shoulder was performed twice by an orthopedic surgeon and once by a radiologist. RCTs, tear width, retraction and FI were measured. Inter- and intrarater reliability of the HHUS was calculated using a Cohen's kappa coefficient. Criterion and concurrent validity were calculated using a Spearman's correlation coefficient. **Results:** Sixty-one patients (64 shoulders) were included in this study. Intra-rater agreement of HHUS for assessment of RCTs ($\kappa = 0.914$, supraspinatus) and FI ($\kappa = 0.844$, supraspinatus) was moderate to strong. Interrater agreement was none to minimal for the diagnosis of RCTs ($\kappa = 0.465$, supraspinatus) and FI ($\kappa = 0.346$, supraspinatus). Concurrent validity of HHUS compared to MRI was fair for diagnosis of RCTs ($r = 0.377$, supraspinatus) and fair-to-moderate FI ($r = 0.608$, supraspinatus). HHUS shows a sensitivity of 81.1% and specificity of 62.5% for diagnosis of supraspinatus tears, 60% and 93.1% for subscapularis tears, 55.6% and 88.9% for infraspinatus tears. **Conclusions:** On the basis of findings in this study, we conclude that HHUS is an aid in diagnosis of RCTs and higher degrees of FI in patients who are not obese, but it does not replace MRI as the gold standard. Further clinical studies on the application of HHUS comparing HHUS devices in larger patient populations and healthy patients are required to identify its utility in clinical practice.

Introduction

Rotator cuff tears (RCT) are a major public health issue. Incidence of RCTs increases with age and is as high as 80% in patients older than 80 years.[1-4] Furthermore, occurrence of large and massive RCTs increases with age.[1] Considering the aging of the population, it is likely that the prevalence of RCTs will increase over the following decades. In order to keep orthopaedic care accessible for this increasing patient flow over the upcoming years, the health system needs to be adapted to become more efficient and cost-effective.

Currently, magnetic resonance imaging (MRI) is considered the "gold standard" diagnostic test for RCTs, as well as fatty infiltration (FI).[5] However, MRI is a costly, not readily available and time-consuming method.[6] Ultrasound (US) allows for dynamic imaging of the rotator cuff tendons, has a high spatial resolution, and allows for instant combination of findings in physical examination with visual input.[6-8] Furthermore, when considering resource allocation, the use of US significantly reduces patient waiting time and costs compared to MRI.[8,9] However, US can only be used to replace MRI if its reliable and valid for diagnosis of RCTs and FI.

In 2010, Rutten et al. found comparable accuracy for MRI (94%) and US (94%) in diagnosing full-thickness RCTs.[10] Because of ongoing innovations in US systems, currently, handheld ultrasound (HHUS) devices are

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available. Several pilot studies on the use of HHUS for musculoskeletal pathologies showed promising results regarding its diagnostic accuracy.[11,12] A pilot study, including 10 patients with shoulder pathology, compared HHUS to US.[11] One evaluator found 7/10 diagnoses correctly, and a second evaluator found 8/10 diagnoses correctly.[11] A second study, including 100 participants with musculoskeletal pathology compared HHUS to US. Results were concordant in 65% of cases.[12]

There is a lack of data on the reliability and validity of HHUS for the assessment of rotator cuff pathology. Therefore, the purpose of this study was to examine the reliability and validity of handheld ultrasound (HHUS) alone versus conventional ultrasound (US) or magnetic resonance imaging (MRI) for diagnosis of rotator cuff tears and versus MRI plus computed tomography (CT) for diagnosis of fatty infiltration. We hypothesize that HHUS is as valid and reliable as the gold standard MRI for diagnosis of RCTs and as reliable and valid as MRI or CT for diagnosis of FI.

Methods

Medical ethical approval for this study was obtained (code METC 2020-2319). This research was approved by the Institutional Review Board (IRB) of VieCuri Medisch Centrum (code 2020_077).

This study is a retrospective cohort study conducted between April 2020 and March 2022. Medical ethical approval for this study was obtained (METC 2020-2319).

Patients were selected from a single outpatient clinic, based on available MRI and computed tomography (CT) images of the shoulder, dated between January 2020 and January 2022. Patients aged 18 years and older were included. Patients who underwent previous rotator cuff repair or arthroplasty or patients who underwent shoulder surgery between the MRI/CT and onset of the study were excluded. All patients provided written consent for participation in this study.

Data were electronically collected (Castor Web database, 2021, Castor). For each participant, baseline data were collected, consisting of age, sex, weight, height, laterality (left or right). For MRI, US, and HHUS, the following data were collected: muscle tear (SSP, supraspinatus; ISP, infraspinatus; SSC, subscapularis), tear width, and retraction. Patients of whom only CT images were available, were not included in the analysis of RCTs. Full-thickness tears were defined on the basis of greatest dimension as small (<1 cm), medium (1-3 cm), large (3-5 cm), or massive (>5 cm), as proposed by DeOrio and Cofield.[13,14] FI was assessed on MRI, CT, US, and HHUS, using the Goutallier classification.[15] A simplified version of the Goutallier classification was used to visually determine FI on ultrasound images consisting of three categories: 1) Goutallier grade 0, 2) Goutallier grade 1-2, and 3) Goutallier grade 3-4.[16,17]

All participants underwent four US examinations. Three were performed using a HHUS device; Lumify L12-4 linear array transducer (Philips Health Systems, Best, Netherlands) connected to an iPad Mini (Apple Inc., Cupertino, CA) or Samsung Galaxy Tab S8 (Samsung Electronics, Daegu, South Korea). Two of the HHUS exams were performed by a fellowship-trained orthopedic surgeon (OLH), trained specifically in musculoskeletal imaging of the shoulder, and one was performed by a fellowship-trained radiologist who specialized in musculoskeletal ultrasound (T.K.). The orthopedic surgeon saw a minimum of 3 other patients before repeating the HHUS examination to avoid bias regarding previous findings. One conventional US study was performed by a second radiologist (DI) using the EPIQ 7 device (Philips Health Systems) and eL18-4 PureWave transducer (Philips Health Systems). All US examinations were carried out, according to the guidelines by the European Society of Musculoskeletal Radiology.[18] All specialists who carried out the HHUS and US examinations were blinded to the diagnosis of the study participants. MRI of the shoulder (Oblique, sagittal, T-2 weighed, Turbo Spin Echo sequence) was performed using the MRI MAGNETOM AREA 1.5T/ MRI SOLA 1.5 T (Siemens, München, Germany). CT of the shoulder (Spiral-mode, 2.0-mm slice thickness, cranio-caudal direction) was performed using the CT SOMATOM Definition AS/ CT SOMATOM go VA20 (Siemens, München, Germany). MRI and CT images of the shoulder were assessed by 2 independent reviewers (OLH, DI). Any disagreements were resolved during a consensus meeting.

Data were analyzed using IBM SPSS Statistics Software, version 24.0. To report the frequency of each recorded variable, descriptive statistics were used. Cohen's kappa and weighted kappa (κ) were used to assess inter- and intrarater reliability of HHUS. To assess concurrent and criterion validity of HHUS, a Spearman's correlation coefficient (r) was calculated. Sensitivity and specificity of HHUS for diagnosis of SSC, SSP, and ISP tears, compared to MRI were calculated. Values of kappa and weighted kappa as measurement of agreement were categorized as no agreement ($\kappa < 0.20$), minimal ($\kappa = 0.21$-0.39), weak ($\kappa = 0.40$-0.59), moderate (0.60-0.79), strong ($\kappa = 0.80$-0.90), and almost perfect agreement ($\kappa > 0.90$).[19] The following categorical ranking was applied to Spearman's correlation coefficient: poor ($r < 0.20$), fair ($r = 0.30$-0.59), moderate ($r = 0.60$-0.79), very strong ($r = 0.80$-0.99), and perfect ($r = 1$).[20]

Results

Sixty-one patients (64 shoulders) were included in this analysis. Thirteen patients refused to participate in the US examinations due to a move abroad ($n = 2$), inability to travel to the hospital ($n = 2$), no specified

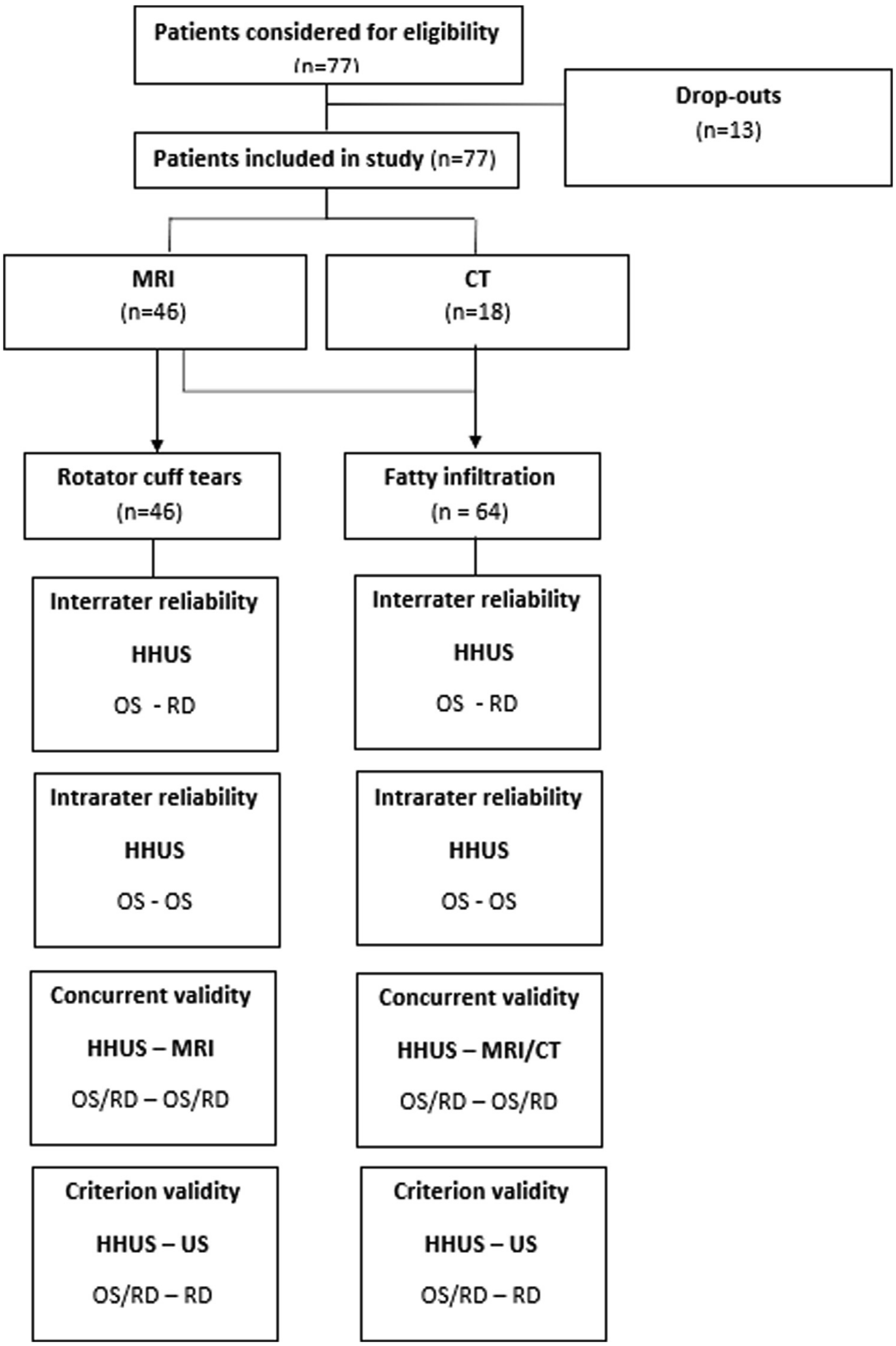

Fig 1. Flowchart of study design. CT, computed tomography; HHUS, handheld ultrasound; MRI, magnetic resonance imaging; OS, orthopaedic surgeon; RD, radiologist; US, ultrasound.

reason ($n = 9$) (Fig 1). The mean age of the participants was 64 ± 10 years. In Table 1, descriptive results are shown. Of the 61 subjects, 26 (43%) were male and 35 (57%) were female, mean body mass index (BMI) was 28 ± 4. Only a CT without intra-articular contrast was available for 18 shoulders, these were included in measurement of fatty infiltration and excluded from measurements of tear type and tear size. An MRI image was available in 46 shoulders, on which in 39 cases, an RCT was found. In 7 cases no RCT was present despite the presence of complaints of subacromial pain. Forty-one percent ($n = 19$) of all tears were isolated SSP

Table 1. Baseline Characteristics of Study Population

Characteristic	Patients ($n = 61$)
Age, mean ± SD (range)	64 ± 10 (22-89)
BMI, mean ± SD (range)	28 ± 4 (21-37)
Sex (male/female)	26 (43%)/35 (57%)
Laterality (left/right), ($n = 64$)	25 (39%)/39 (61%)
Imaging modality (CT/MRI), ($n = 64$)	18 (28%)/46 (72%)
Type of tear (isolated/multiple tendon)*	20 (51%)/19 (49%)
Isolated tears (SSP/SSC)*	19 (95%)/1 (5%)
Multiple tendon tears*	
Collin type B	10 (53%)
Collin type C	5 (26%)
Collin type D	4 (21%)
Tear size*	
SSP	
Small/medium size tears (≤ 3 cm)	19 (51%)
Large/massive size tears (>3 cm)	18 (49%)
SSC	
Small/medium size tears (≤ 3 cm)	12 (92%)
Large/massive size tears (> 3 cm)	1 (8%)

All values are presented as number (valid percent), unless indicated otherwise. BMI, body mass index; CT, computed tomography; MRI, magnetic resonance imaging; SD, standard deviation. Goutallier grades are defined as follows: Goutallier grade 0, completely normal muscle without any fatty streak; Goutallier grade 1, muscle contains some fatty streaks; Goutallier grade 2, fatty infiltration is important but there is more muscle than fat; Goutallier grade 3, equal amounts of fat and muscle; Goutallier grade 4, more fat than muscle is present.[35]

*According to the "gold standard" (MRI).

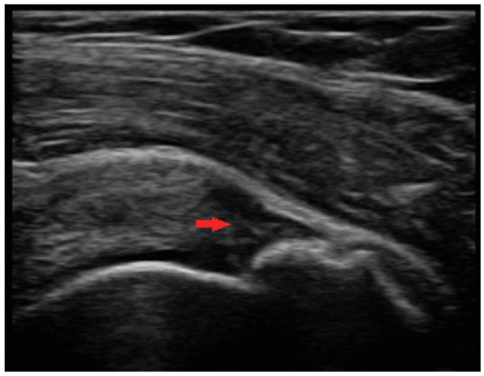

Fig 2. Handheld ultrasonography image of a small-sized supraspinatus tear, with low signal-to-noise ratio.

tears, there was one isolated SSC tear ($n = 1$). According to the classification by Collin et al., 10 (22%) of multiple tendon tears were identified as Collin Type B (SSP and SSC tear), 5 (11%) were identified as Collin type C (SSP, SSC, and ISP tear), and 4 (9%) were identified as Collin type D (SSP and ISP tear).[21] Of all SSP tears, 4 tears were partial thickness tears, and 34 tears were full-thickness tears. An example of an SSP tear on HHUS is presented in Fig 2. Of all SSC tears, 1 tear was a partial-thickness tear and 15 tears were full-thickness tears.

The interrater reliability of HHUS was weak for SSP tears ($\kappa = 0.465$), none for SSC tears ($\kappa = 0.036$), weak ($\kappa = 0.453$) for ISP FI, and minimal ($\kappa = 0.346$) for SSP FI. The intrarater reliability of HHUS was almost perfect ($\kappa = 0.914$) for SSP tears, strong ($\kappa = 0.837$) for SSC tears, moderate ($\kappa = 0.668$) for ISP FI, and strong ($\kappa = 0.844$) for SSP FI (Table 2).

The correlation between RCTs on MRI and HHUS (criterion validity) was fair for SSP tears ($r = 0.377$), SSC tears ($r = .577$), and ISP tears ($r = .444$). The criterion validity of HHUS compared to MRI/CT for measurement of FI was moderate ($r = .608$) for SSP FI and fair ($r = 0.529$) for ISP FI (Table 3).

For the diagnosis of RCTs, the correlation between the HHUS and conventional US (concurrent validity) was found to be fair for SSP tears ($r = 0.329$), SSC tears ($r = 0.370$) and ISP tears ($r = 0.589$). Correlation between HHUS and conventional US was fair for SSP FI ($r = 0.490$) and for ISP FI ($r = 0.559$) (Table 3).

For SSP tears, the sensitivity and specificity of HHUS compared to MRI was 81.1% and 62.5%, respectively (tear, $n = 37$; no tear, $n = 9$) . For diagnosis of SSC tears, the sensitivity and specificity of HHUS were 60.0% and 92.9%, respectively (tear: 16; no tear: 46) and for diagnosis of ISP tears, the sensitivity of HHUS was 55.6% and 88.9% (tear: 9; no tear: 46). Compared to MRI, HHUS diagnosed 14/19 (74%) small or medium (≤3 cm) SSP tears correctly and 16/18 (89%) large or massive (>3 cm) SSP tears correctly. Similarly, HHUS diagnosed 10/12 (83%) small or medium SSC tears correctly and 1/1 (100%) of large or massive tears correctly.

In 38 cases, a SSP tear was identified on MRI. Tear width and retraction could be measured on HHUS in 80% of the cases. In total, 15 SSC tears were identified on the MRI. In 50% of these cases, assessors were able to measure tear width and retraction. The most frequently reported cause for failed measurement of tear width and retraction was the inability to visualize both torn tendon borders in one viewing window. For measurement of SSP tear width ($r = 0.434$) and retraction ($r = 0.437$), correlation of HHUS with MRI was fair. Correlation of measurement of SSC tear width was fair ($r = 0.500$), and correlation of measurement of SSC tear retraction was very strong ($r = 0.800$). Intrarater reliability for measurement of tear width and retraction was perfect for SSC tear retraction ($r = 1.000$) and moderate for SSP tear width ($r = 0.751$) and SSP tear retraction ($r = 0.776$). For measurement of SSC tear width, correlation was fair ($r = 0.500$).

When comparison was made between the diagnostic accuracy of HHUS in obese (BMI ≥30 kg/m^2) and nonobese (BMI <30 kg/m^2) patients, accuracy of HHUS was moderate for diagnosing RCTs in nonobese patients ($r = 0.709$; SSP) and poor-to-fair accuracy for diagnosing RCTs in obese patients ($r = -.272$, SSP)

Table 2. Inter- and Intrarater Reliability of Handheld Ultrasound for Diagnosis of Rotator Cuff Tears and Fatty Infiltration

Measurement	Intrarater Correlation Cohen's kappa,* Weighted kappa**	Interrater Correlation Cohen's kappa,* Weighted kappa**
Supraspinatus tear***	0.914*	0.465*
Subscapularis tear***	0.837*	0.036*
Infraspinatus tear***	0.668*	
Supraspinatus fatty infiltration****	0.844**	0.346**
Infraspinatus fatty infiltration****	0.919**	0.453**

MRI, magnetic resonance imaging.
*Correlation is significant at the 0.05 level.
**Correlation is significant at the 0.01 level.
***CT images are not included.
****CT images are included.

Table 3. Correlation Between Handheld Ultrasound and Magnetic Resonance Imaging or Conventional Ultrasound for Diagnosis of Rotator Cuff Tears and Fatty Infiltration

Measurement	Conventional Ultrasound Spearman's Correlation Coefficient	MRI Spearman's Correlation Coefficient
Supraspinatus tear	0.329*	0.377**
Subscapularis tear	0.370**	0.577**
Infraspinatus tear	0.589**	0.444**
Supraspinatus fatty infiltration	0.490**	0.608**
Infraspinatus fatty infiltration	0.559**	0.529**

MRI, magnetic resonance imaging.
*Correlation is significant at the 0.05 level.
**Correlation is significant at the 0.01 level.

compared to MRI. This difference between groups was not observed for measurement of FI (Table 4).

Discussion

The results of this study indicate that HHUS may be an aid in the diagnostic process as a screening tool for RCTs and to detect higher degrees of FI in the nonobese patient population. Our hypothesis that HHUS is as reliable and valid as MRI for diagnosis of RCTs and as MRI/CT for diagnosis of FI was not proven. Intrarater reliability of HHUS for diagnosis of SSP and SSC tears was strong (SSP, $\kappa = 0.914$; SSC, $\kappa = 0.837$), indicating that findings can be reproduced by the same assessor. Interrater reliability for diagnosis of SSP, SSC, and ISP tears, as well as SSP and SSC FI was none to minimal, indicating that findings between assessors did not correlate well. Validity of the HHUS was fair to moderate. HHUS showed good sensitivity and specificity to diagnose RCTs compared to MRI and a better correlation with MRI for diagnosing SSP tears in nonobese patients (BMI < 30) compared to obese patients (nonobese: $r = 0.709$; obese: $r = -.272$); however, its accuracy was not sufficient to reliably estimate the exact degree of FI.

HHUS was shown to have good specificity for diagnosis of RCTs (92.9%, SSC; 88.9 ISP). This is in line with a previous study on the sensitivity and specificity of conventional ultrasound for diagnosis of RCTs, which reported a sensitivity and specificity of 84% and 89% for partial-thickness RCTs and 96% and 93% for full-thickness RCTs, compared to arthroscopic or open surgical findings.[22] A fair correlation was found between HHUS and MRI for diagnosis of RCTs. However, patients were not excluded from this study on the basis of body composition, which may have lowered the correlation. Obesity can negatively influence the quality of the images on US and the ability of the sonographer to visualize the rotator cuff. The HHUS used in this study does not have the possibility to increase the focus in deeper layers of tissue, thereby degrading the imaging quality, which reduced the validity of HHUS in obese patients.[23] Both obese and nonobese patient groups were analyzed separately, which showed that diagnosis of RCTs on HHUS in obese patients is more challenging, and findings correlate poorly with findings on MRI compared to nonobese patients. With its high specificity, HHUS could potentially be used as a screening tool for RCTs; however, the abovementioned findings suggest that this tool may only be useful in a population of nonobese patients.

Although we found strong intrarater reliability of HHUS for diagnosis of SSP, SSC, and ISP tears, the interrater reliability was minimal to weak. A study on 3D US evaluation of SSP tears reported an excellent intrarater reliability, but only fair-to-moderate interrater reliability and concluded that the reliability of 3D US depends on the level of the sonographer.[24] In our study, measurements were performed by an experienced orthopedic surgeon and radiologist. Measurements by the orthopaedic surgeon showed higher correlation with MRI. In an outpatient setting, we expect the specificity of HHUS will be even higher, as the imaging can be directly combined with findings of clinical examination, especially in nonobese patients.

We found a fair-to-moderate correlation between HHUS and MRI/CT for the classification of SSP and ISP FI, according to Goutallier et al., which is in line with a recent study.[16] Park et al. report moderate agreement when conventional US assessment of SSP and ISP FI was compared to MRI (SSP, $\kappa = 0.56$; ISP, $\kappa = 0.50$).[25] Our study included both CT and MRI images of the SSP and ISP muscle for assessment of FI. Fitzgerald et al. suggested that CT underestimates the severity of FI compared to MRI.[26] The use of both imaging modalities in the same analysis could have influenced study results. The degree of FI was graded according to a modified Goutallier grading scale, converted into a

Table 4. Correlation Between Handheld Ultrasound and Magnetic Resonance Imaging for Non-obese (BMI < 30) and Obese (BMI ≥ 30) Patients

Measurement	BMI <30 (n = 30) Spearman's Correlation Coefficient	BMI ≥30 (n = 16) Spearman's Correlation Coefficient
Supraspinatus tear	0.709*	−.277
Subscapularis tear	0.688*	0.337
Infraspinatus tear	0.707*	−.182
Supraspinatus fatty infiltration	0.547*	0.724*
Infraspinatus fatty infiltration	0.574*	0.400

BMI, body mass index.
*Correlation is significant at the 0.01 level.

three-point scale: Goutallier 0, Goutallier 1-2, and Goutallier 3-4. However, other studies report the use of a dichotomized scale: Goutallier 0-1 and Goutallier 2-4. The reason for the use of this dichotomized scale is its clinical implications. Goutallier 3-4 is predictive for higher retear rate following rotator cuff repair; thus, this dichotomized scale is more useful in clinical practice. A study comparing the dichotomized and a three-point scale reported a higher agreement of US and MRI using the dichotomized scale.[27] Although HHUS cannot be used as a replacement of MRI for diagnosis of fatty infiltration, it may be used to estimate either high or low level of fatty infiltration. This may aid in the decision-making process regarding surgery, especially in the case of elderly patients who are at high risk of complications during or after surgery.

In light of recent findings regarding the anatomy of the SSP and ISP muscle, we suggest that there is limited clinical value in the separate assessment of the ISP tendon on HHUS. The US imaging protocol by the European Society of Musculoskeletal Radiology[18] is based on the previously widely accepted concept that the ISP tendon runs parallel and posterior to the SSP tendon.[28,29] However, multiple anatomical studies have shown that the ISP tendon inserts more anteriorly and, therefore, does not run parallel to the SSP tendon and instead crosses it.[30-32] In each patient, the width of the overlapping area is slightly different; therefore, no standardized border between these two tendons can be identified on US.[30-32] In case a tear of the ISP and SSP tendon is found using the standardized US protocol, this merely indicates that the patient has a massive RCT. To assess the fatty infiltration and muscular atrophy and for the purpose of surgical treatment planning, an MRI is recommended in these cases.[29]

Finally, this study demonstrated the inability to measure tear width and retraction accurately with the HHUS device in cases of large or massive RCTs. In most cases, the inability to measure tear width by HHUS was a result of the small viewing window on which it was impossible to view both torn tendon ends in one window and, thus, impossible to measure the retraction. Additionally, in some cases, the medial torn end of the tendon retracted beneath the acromion, making it impossible to visualize it on any US device.[33]

Limitations

For performance of the HHUS, the same imaging device (transducers and image processing application) was used by both assessors. However, this device was connected to two different tablets. The difference in display image quality between the tablets could have caused a greater interrater variability in results.

Because of the relatively small sample size, not enough data were available to separately analyze partial and full-thickness tears. Studies show that the diagnostic accuracy of US for partial-thickness tears was lower (87%) than for full-thickness tears (98%).[34] The prevalence of different tear sizes in our analysis may have influenced the overall reported accuracy of HHUS.

Conclusion

On the basis of the findings in this study, we conclude that HHUS is an aid in diagnosis of RCTs and higher degrees of FI in patients who are not obese, but it does not replace MRI as the gold standard. Further clinical studies of the application of HHUS comparing HHUS devices in larger patient populations and healthy patients are required to identify its utility in clinical practice.

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