Optimizing ultrasound images for quantitative analysis in patients with fatty infiltration in rotator cuff tears

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25118

Source
NTR

Health condition

Rotator cuff tear

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Reinier Haga Orthopedisch Centrum

Intervention

Outcome measures

Primary outcome

Fatty infiltration of the supra- and infraspinatus in patients with rotator cuff tear, measured on ultrasound by using Computed Assisted Grey Scale Analysis with standard histogram function and Matlab. To reduce measurement variation we use both short- and long-axis images of the supra- and infraspinatus guided by anatomic landmarks. Using both axis we will evaluate grey scale intensities in two orthogonal directions of each rotator cuff muscle. This will give a representative impression of the amount of fat in each muscle on three

different sagittal-oblique and coronal-oblique T1 images using modified Goutallier grading system. The ultrasound, magnetic resonance imaging and consultation will be conducted within three weeks.

Secondary outcome

- Muscle Echo Intensity (ipsilateral and contralateral rotator cuff)
- Mean grey value ipsi- and contralateral (ultrasound)
- Internal architecture rotator cuff, deltoid, trapezius (ipsi- & contralateral)
- Mean modified Goutallier score and fat fraction (MRI)

Study description

Background summary

Rationale:
In rotator cuff tears (RCT) fatty infiltration grade 3-4 is generally seen as a contra-indication for rotator cuff repair1-4. Evaluation of fatty infiltration is performed by Magnetic Resonance Imaging (MRI) using the Goutallier-score. However, this is a visual score and several researchers have questioned its reliability and validity7-9;11-13. Recently several studies focused on quantitative fat fraction measurements on MRI14. An alternative technique to measure fatty infiltration is ultrasound1. Ultrasound has several advantages since it is less time consuming, has lower costs and is less invasive for the patient1. Therefore, we developed quantitative-muscle-ultrasound for measuring fatty infiltration.
In our previous study we showed that quantitative muscle ultrasound was directly linked to fat fraction on MRI and could be used as a more objective and reliable alternative to assess fatty infiltration within the supraspinatus muscle.26 Therefore, the use of quantitative ultrasound is a promising diagnostic alternative in the assessment of fatty infiltration in rotator cuff tears.
In this study we would like to optimize ultrasound settings. Advantages of this improvement are that quantitative ultrasound become more accurate and have a stronger correlation with fat fraction on MRI. Another major advantage is that this improvement could benefits patients because ultrasound is less time consuming and less invasive. Furthermore, this improvement might lower healthcare cost due to the fact that ultrasound is less expensive, less time consuming and in the future might be performed outside the hospital.

Objective:
Optimizing ultrasound quantitative skeletal muscle ultrasound as diagnostic imaging technique to evaluate fatty infiltration of the supra- and infraspinatus muscle in patients with rotator cuff tears.

Study design:
This study is a prospective cohort trial, comparing quantitative muscle ultrasound images using Computed Assisted Grey Scale Analysis1,3 with the current standard reference,

Magnetic Resonance Imaging (MRI) for the assessment of fatty infiltration in patients with RCT.

Patients will be prospectively included if they are scheduled on our outpatient clinic for ultrasound of the shoulder. Data will only be used if an MRI was made. On quantitative-muscle-ultrasound, fatty infiltration of the supraspinatus will be evaluated using computed-assisted-grey-scale-analysis with MATLAB15.

On MRI, fatty infiltration will be measured by quantitative fat fraction14 using MATLAB-software15. That way we can compare the fat fraction on MRI to the grey scale analysis on quantitative-muscle-ultrasound. Spearman' Rank correlation coefficient between fat fractions on MRI and quantitative-muscle-ultrasound are determined.

All new patients who are scheduled for ultrasound at our outpatient clinic will receive written information on the study. Furthermore, patients will be called by one of the researchers in order to explain more on the study and to make an appointment. The appointment will be made on the day of the outpatient visit for the ultrasound, just before the appointment with the orthopedic surgeon. If the patient decides to participate, the informed consent is signed. If a rotator cuff tear is suspected they will receive additional images made by the experienced sonographer during the consultation. If an MRI is necessary, these images will be used for the study. If an MRI is not necessary, the patients will we excluded from the study.

Fatty infiltration grade 3-4 is generally seen as a contra-indication for rotator cuff repair.1 Therefore, the assessment of the severity of fatty infiltration is important. The severity of fatty infiltration in the supra- and infraspinatus muscle will be assessed by evaluating muscle echogenicity by quantitative ultrasound using Computed Assisted Grey Scale Analysis1,3. The mean muscle echo intensity will be calculated using a histogram function in MATLAB® (Mathworks, Natick, Massachusetts, U.S.A.).15

The classification for the amount of fatty infiltration on magnetic resonance imaging (MRI) will be evaluated by the gold standard using the modified Goutallier grading system (see figure 1).24 However, this is a visual score and not quantitatively. In order to compare quantitative muscle ultrasound and the MRI we calculate fatty infiltration on MRI with fat fraction measurements.11,14 Fat fraction measurements can be calculated using the same technique as quantitative muscle ultrasound using MATLAB software. Then, we can compare both quantitative measurements and calculate the correlation between MRI and ultrasound.

In this study we would like to improve quantitative muscle ultrasound. Our hypothesis is that if we improve quantitative muscle ultrasound, a higher correlation between MRI and ultrasound can be found.

Study population:
Patients with rotator cuff tears who are scheduled for full examination of the shoulder, will get an ultrasound and when necessary magnetic resonance imaging in a special shoulder consultation at our institution. Patients with ultrasound as well as an MRI will be included definitively.

Main study parameters/endpoints:

Improvement of quantitative muscle ultrasound resulting in a higher correlation between MRI and ultrasound. We would like to have a spearman rank correlation coefficient of at least 0.60. This correlation coefficient correlates with a strong relationship. Fatty infiltration of the supra- and infraspinatus in patients with rotator cuff tear, measured on ultrasound by using Computed Assisted Grey Scale Analysis with standard histogram function.1 To reduce measurement variation we use both short- and long-axis images of the supra-, and infraspinatus guided by anatomic landmarks. Using both axis we will evaluate grey scale intensities in two orthogonal scanning directions of each rotator cuff muscle. This will give a representative impression of the amount of fat in each individual muscle. Fatty infiltration on magnetic resonance imaging will be evaluated by the proportion of fat in the muscle on three different sagittal-oblique and coronal-oblique T1 images using modified Goutallier grading system. The ultrasound, magnetic resonance imaging and consultation will be conducted within four weeks.

Secondary study parameters/endpoints:
- Muscle Echo Intensity (ipsilateral and contralateral rotator cuff)
- Mean grey value ipsi- and contralateral rotator cuff (ultrasound)
- Internal architecture rotator cuff, deltoid, trapezius (ipsi- & contralateral)
- Mean modified Goutallier score and fat fraction (MRI)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
There are no extra risks or burden associated with participation. Patients with RCT will already receive an ultrasound and when necessary an MRI within four weeks after the consultation day following the standard hospital procedure. To conduct this study we will use the images taken at the routine standard hospital procedure of the assessment of RCT. Only during the ultrasound examination some extra images will be obtained if informed consent is signed. The extra ultrasound data can be obtained within 5 extra minutes. The images are stored on the ultrasound machine and transported to a local secured Castor database for later analysis.
Absolute contraindications for MRI are the presence of intracerebral aneurysm clips, pacemakers, bio stimulators, implanted infusion devices, automatic defibrillators, cochlear implants and metallic (orbital) foreign bodies.

Study objective

It is hypothesised that optimizing visualization of the muscle boundries wil improve quantitative muscle ultrasound, which should increase the correlation between the outcome of quantitative muscle ultrasound and magnetic resonance imaging.

Study design

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Contacts

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Eligibility criteria

Inclusion criteria

- Patients aged 18 years and older
- Patients willing to participate
- Able to give informed consent
- Speaking Dutch language

Exclusion criteria

- Patients unwilling to participate
- Mentally retarded
- BMI > 35
- Patients who do not qualify for magnetic resonance imaging examination
- Patients with absolute contraindications for magnetic resonance imaging
- Magnetic resonance imaging/ultrasound acquired at other institution
- Artifacts/poor quality on ultrasound or magnetic resonance imaging
- Patients could not undergo ultrasound/magnetic resonance imaging (within 3 months)
- Patients who have had surgery in the investigated area

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2019
Enrollment:	25
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7778
Other	METC Zuidwest Holland : METC 19-050

Study results