The influence of active abduction on the subacromial space in patients with rotator cuff tears;vs. healthy controls

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To assess the difference in acromiohumeral (AH) distance reduction during active isometric abduction tasks (with respect to rest radiographs) between the asymptomatic and symptomatic shoulder in patients with a unilaterally diagnosed RC tear....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON38178

Source
ToetsingOnline

Brief title
iSUROC-addendum

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
rotator cuff tear, tendon tear shoulder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW,Reumafonds

Intervention

Keyword: abduction, co-contraction, proximal migration, Rotator-cuff

Outcome measures

Primary outcome

Primary outcome measures: AH reduction on radiographs acquired during isometric abduction tasks compared to rest radiographs, in both the symptomatic and asymptomatic shoulder.

ADDENDUM

- similar, but now to compare healthy subjects and rotator cuff patients

Secondary outcome

Secondary outcome measures: AH during adduction compared to rest, EMG (deltoids, pectoralis major, teres major and latissimus dorsi), Constant Shoulder score, WORC, IPQ, and a Visual Analogue Scale for pain during the experiments.

Study description

Background summary

Rotator cuff tears are a frequently diagnosed cause of shoulder complaints, and over the past years, there has been an increase in surgical treatment of rotator cuff tears. However, literature on the subjects of indication and timing of surgical treatment for rotator cuff tears remains scant, and reported results are variable. Furthermore, Magnetic Resonance Imaging (MRI) studies demonstrated that the prevalence of asymptomatic rotator cuff tears ranges up to 54% in subjects over 60 years old, making it difficult to differentiate between symptomatic and asymptomatic cuff tears, consequently complicating

diagnostic and therapeutic decision making.

Superior translation of the humeral head on a standard shoulder radiograph is indicative for rotator cuff (RC) tears. It has been reported that active abduction increases superior translation as a consequence of superiorly directed forces of the deltoids. In patients with RC pathologies, there is an excessive superior translation during abduction, due to diminished function of the RC muscles as the primary stabilizers of the glenohumeral joint. Additionally, electromyography (EMG) studies have shown arm adductor muscle co-activity during active arm abduction tasks in RC patients. Hypothetically, these adductors are activated to counteract the superiorly directed forces of the deltoid muscles.
However, current methods to determine this active superior translation are elaborate and are not applicable to assess cuff insufficiencies in clinical setting. In this project we propose to modify standard, passive, shoulder radiographs with two additional active isometric tasks (abduction and adduction) in order to develop a sensitive method to individually quantify active superior translations as a potential measure for rotator cuff dysfunction.

Patients with RC tears are the demonstrator group for general cuff diseases related with superior translation and RC insufficiency, i.e. impingement. Therefore, we will analyze this dynamic superior translation in RC patients. Our hypothesis is that a radiograph acquired during an isometric abduction task will show a detectable superior humeral head translation compared to standard AP shoulder radiographs in patients with RC tears.

ADDENDUM:
Now the introduced method has proven it is reliable and easily applicable in 20 rotator cuff tear patients and 30 impingement patients (protocol SISTIM, ABR 28090.058.09), healthy control measurements need to be obtained for further interpretation of the results in patients.

Study objective

To assess the difference in acromiohumeral (AH) distance reduction during active isometric abduction tasks (with respect to rest radiographs) between the asymptomatic and symptomatic shoulder in patients with a unilaterally diagnosed RC tear.

ADDENDUM:
Assessing subacromial space (AH) in rest, and the degree of cranialisation during abduction and adduction tasks in combination with muscle activation patterns in healthy subjects vs. rotator cuff tear patients (this protocol, ABR NL34745.058.10) and subacromial impingement patients (protocol SISTIM, ABR

28090.058.09).

Study design

Experimental validation study

Study burden and risks

Participating patients will receive standard care. The investigations for this study will take around one hour: filling out the questionnaires for 15-20 minutes, experiment for 40-45 minutes. There is no potential benefit for the individual patient. Per subject six (n=6) additional radiographs of the shoulders are acquired: 3 of the symptomatic shoulder, and 3 of the asymptomatic shoulder.

ADDENDUM
Healthy subjects: input of time will be less than 1 hour. 3 Shoulder radiographs will be acquired instead of 6. No questionnaires.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients: Present symptomatic rotator cuff tear, confirmed on MRI and/or ultrasound;ADDENDUM
Controls: no symptoms of the shoulder, no history of shoulder diseases, 35-60 y.o.

Exclusion criteria

Carcinoma
Previous shoulder surgery on the affected shouder
Patients:
Rupture of subscapular tendon on the affected shouder
Osseous pathology on the affected shouder
Frozen shoulder syndrome on the affected shouder
Subacromial infiltration with anesthetics and corticosteroids <6 weeks before intake;Controls: idem + shoulder symptoms, pace maker or other electronic implant devices.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	03-03-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	28-02-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	28-08-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL34745.058.10