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The validity of the lag signs in the diagnosis of rotator cuff dysfunction in patients with shoulder pain

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Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 16/04/2015	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0265122365

Study information

Scientific Title
The validity of the lag signs in the diagnosis of rotator cuff dysfunction in patients with shoulder pain

Study objectives
HI: There is a relationship between a positive lag sign and rotator cuff dysfunction.
Ho: There is no relationship between a positive lag sign and rotator cuff dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Shoulder pain

Interventions
It is normal that patients with shoulder pain attending an orthopaedic out-patient clinic are clinically assessed for the likelihood of having rotator cuff dysfunction. Manual tests assessing the integrity of the cuff are usually performed.

Plan of investigation: All patients returning to Mr Green's outpatient clinic at the Royal Orthopaedic Hospital following an ultrasound scan for their painful shoulder shall be invited to partake in this research. A letter and patient information sheet shall be sent to this population informing them of the research with their outpatient appointment at least 24 hours prior to their appointment.

The researcher shall attend weekly outpatient clinics at the Royal Orthopaedic Hospital and approach each patient in the above population regarding participation in the study. The researcher shall remain blind to the results of the diagnostic ultrasound and the outcome of these results shall be entered into a database by the consultant and placed in a sealed envelope with an appropriate label. If full informed consent is obtained from the patient then the three lag signs shall then be assessed.

Lag signs: Patients shall not do the three tests in the same order. This shall counterbalance any order effects (Hicks 1999).

Standardisation: All patients shall be seated for the test on an examination couch with their feet on the floor. The patient shall be advised not to reveal any results from the ultrasound scan to the examiner.

The Internal Rotation Lag Sign (IRLS): The test is performed by placing the patient's arm behind his/her back. The elbow is flexed to 90 degrees and the shoulder held at 20 degrees of elevation and 20 degrees of extension. The clinician then raises the hand passively off the back until full passive range of movement is achieved. The elbow is kept at a constant angle of 90 degrees of

flexion. The patient is then asked to maintain this position whilst the clinician releases the wrist. The sign is positive if there is a lag or an angular drop. The magnitude of the lag is recorded and graded as 0°, ~5°, r5". The IRLS is associated with increased activity of the subscapularis muscle (Greiss et al 1997). An inability to maintain this position may indicate a disruption in the subscapularis tendon.

The External Rotation Lag Sign (ERLS): The elbow is passively flexed to 90 degrees and the shoulder held at 20 degrees of elevation in the scapular plane and near maximum external rotation by the clinician. The patient is then asked to maintain the position of external rotation in elevation as the clinician releases her support of the wrist whilst maintaining the support of the elbow. This sign is graded as the IRLS. This test is used to establish the integrity of the supraspinatus tendon (Hertel 1996).

The drop sign: The shoulder is held at 90 degrees of elevation in the scapular plane and at almost full external rotation with the elbow flexed at 90 degrees. In this position the patient is asked to actively maintain this hold as the clinician releases the wrist. In this position the maintenance of external rotation is mainly the function of infraspinatus (Otis et al 1994).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The relationship between a positive lag sign and rotator cuff dysfunction

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/04/2004

Eligibility

Key inclusion criteria
Following a power calculation with the statistician (Peter Knight) it is thought that this study will need a minimum of 40 patients to make it clinically significant. Sample numbers of 40-50 have been recommended in the literature (Hicks 1999). However it is accepted that the larger the sample the greater the probability of randomness and chance operating as expected and this will reduce the chance of a sampling error (Hicks 1999).

Sample: Sample is one of convenience: patients over 18 with shoulder pain attending an outpatient clinic at the Royal Orthopaedic Hospital who have been referred for ultrasound.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Previous surgery in the last year to the limb being assessed
2. Neurological deficit on the side of pain
3. Restricted passive Range Of Motion (ROM)
4. Comprehension difficulties

Date of first enrolment
01/04/2003

Date of final enrolment
01/04/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration