The additional value of the stress radiograph and gravity stress radiograph in predicting deep deltoid ligament integrity in isolated distal fibula fractures

Published: 08-02-2018
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON44487

Source
ToetsingOnline

Brief title
WAXE-2

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
ankle fracture, supination external rotation ankle fracture (SER)

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: deep deltoid integrity, instability, isolated distal fibula fractures, stress view

Outcome measures

Primary outcome

Positive and negative predictive value of the mortise radiograph, gravity stress, and stress radiograph in predicting an instable isolated Weber B ankle fracture (with MRI as reference standard)

Secondary outcome

Inter- and intraobserver variability in determining stability of an ankle fracture on standard mortise radiograph, gravity stress and stress radiograph. Intrinsic variables are age, sex, and medical history. Based on the inital radiograph at the ER , the dislocation will be scored, together with the AO-classification and Laughe-Hansen classification.

Study description

Background summary

Supination-external rotation (Lauge-Hansen SER) Weber B-type ankle fractures are among the most common injuries seen at the Emergency Department. The decision whether to operate or treat conservatively is principally based on the stability of the ankle. The deep deltoid ligament (DDL) is, together with the medial malleolus, the main stabiliser of the ankle joint during axial load. Fibular fractures without medial injury are considered stable and most surgeons advocate conservative treatment, because nonoperative treatments have good clinical outcomes. On the other hand, a bimalleolar or a bimalleolar equivalent fracture, i.e. a fibular fracture with additional deep deltoid ligament

rupture, will be unstable due to the incompetent lateral and medial restraints of the ankle and requires operative treatment.

Accurate exclusion of medial injury in a SER ankle injury with an isolated lateral malleolus fracture is of great clinical importance, because this information confirms the choice of safe conservative management.
Widening of the medial clear space (MCS) at a mortise X-ray view is generally used to predict and indicate a DDL rupture. However, the latter might lead to surgical overtreatment of stable ankle fractures.

According to several authors, magnetic resonance imaging (MRI) is considered the reference standard for detecting DDL rupture. However, recognized disadvantages of MRI are its availability and costs. An alternative tool for MRI is the stress radiograph. In this examination, a radiograph is performed with the patient standing on his/her broken ankle. A complete deltoid rupture in the absence of a talar shift on the conventional mortise view may be detected by manifest widening of the MCS on this additional radiograph.

Study objective

The purpose of the current study is to examine the additional diagnostic value of the stress radiograph in determining deltoid ligament disruption in ankle fractures. The sensitivity and specificity of this test will be compared with findings on MRI, which is used as the reference standard.
The sensitivity and specificity of this diagnostic tool will be calculated. The value of the standard X-mortise view, compared with the stress radiograph and the gravity stress radiograph will be compared.
To be able to distinguish between a stable and instable fracture is of the main importance in deciding to operate or treat conservatively. We hope to be able to make a better distinction between these two fractures and thus a better treatment.
The hypothesis is that nowadays too many (stable) fractures are being operate (based on the current diagnostics) while MRI shows that there was no instability of the ankle.

Study design

All patients who are seen at the Emergency Room of the Haaglanden Medisch Centrum with an isolated distal fibula fracture and who meet the inclusion criteria will be asked to perform in this study. They will receive an information letter.
If they decide to take part, next tot the common diagnostics (the X-mortise view) an additional gravity stress view will be made.
Within one week, an extra MRI scan of the ankle will be made, together with an additional stress radiograph of the ankle. After these additional diagnostics tests, the doctor will make his decision of treatment.

After having included all patients; the multiple radiographs will be anonymised and will be scored by a panel of two trauma surgeons and two skeletal radiologists. They will score the radiographs independently, based on dislocation, medial clear space widening, syndesmosis aspect and the indication to operate (yes/no). These results will be compared with the results of the MRI scan. These scans will be judged by a radiology intern and a musculoskeletal radiologist. All scores are being blinded before being analysed.
To determine intra-observer variability, the radiographs are being scored after 2 months again by the four doctors who scored them at first.

Intervention

N.a.

Study burden and risks

One extra visit to the hospital, where the MRI scan and the stress radiograph will be made. This is not a very invasive burden for the patient. The stress radiograph can be painful while the patient has to stand on his broken ankle. However, this is only for a very short time and extra painkillers can be taken in advance.The time of this one extra visit will take about an hour of the patients' time.
An advantage for the patient, when they decide to participate in this study, is that they receive these extra diagnostic examinations. The decision to treat conservatively or to operate, will be made with extra focus on these investigations and they will receive the best treatment possible, with more knowledge about their fracture than patients with only conventional radiograph.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Acute isolated distal fibula fracture with a MCS <6mm and a MCSAge 18-70 years

Exclusion criteria

Medial clear space >6mm and/or MCS>SCS+2mm on standard mortise X-ray
Contra-indication for MRI
Mental retardation
No competence of Dutch language
Bi- or trimalleolar ankle fracture

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-06-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	08-02-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (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	NL63260.098.17