Influence of radiograph type and patient positioning on shortening of displaced midshaft clavicle fractures.

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

Summary

ID

NL-OMON42787

Source
ToetsingOnline

Brief title
-

Condition

- Fractures

Synonym
collarbone

Research involving
Human

Sponsors and support

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

Intervention

Keyword: clavicle, fracture, Shortening

Outcome measures

Primary outcome

Primary outcome measures are interobserver and intraobserver agreement of the

absolute and relative shortening in millimeters of the MSCF in different types

of radiographs and patient positioning.

Secondary outcome

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Study description

Background summary

Fractures of the clavicle are common, comprising up to 5% of all skeletal lesions in adults [1]. Most clavicle fractures are localized at the level of the midshaft-diaphyseal third [2]. Dislocation of the fracture elements in midshaft clavicle fractures (MSCF) occurs due to the actions of the sternocleiodomastoid muscle, which displaces the medial fragment superiorly and posteriorly, and of the deltoid and great pectoral muscles, which shift the lateral fragment inferiorly and anteriorly. These shifts cause a malaligned fracture that may result in symptomatic shortening of the clavicle [3].
In the last decade, many studies have reported that a shortened clavicle can lead to pain, loss of strength, rapid fatigue, hyperesthesia of the hand and arm, difficulty sleeping on the affected side and aesthetic complications [4]. Mean post-traumatic shortening of the fractured clavicle is approximately 1.2 cm, but a shortening of up to 3 cm has been reported [5]. Many authors have observed the degree of symptomatology and occurrence of malunion and pseudoarthrosis after MSCF is related to the extent of shortening and displacement of the bone segment [6]. It has been described that there are poorer outcomes when relative shortening of the clavicle is more than 9.7% as compared to the original length.[Giorgi BMC research notes]
In summary, shortening and displacement of MSCF have been found to be predictors of poor outcome concerning non-unions, persistent posttraumatic symptoms and cosmetics in conservatively treated MSCF. Therefore lately the tendency has been to surgically reduce and fixate MSCF if absolute shortened >

1,5/2cm or displaced more than the diameter of the clavicle*s shaft. A survey among upper extremity surgeons showed that 60% state that shortening is the most important factor in the decision for surgical versus nonsurgical treatment. [7]
However there is no standardized protocol on how to evaluate this shortening in a fractured clavicle in regards to patient positioning and X-ray views. AP, cranio-caudal and caudo-cranial views in anatomical (standing) and supine position are used in current practice. These different views will project differently due to the diverging angle of the X ray beams, the sigmoid shape of the clavicle and the mass of the arm pulling on the lateral fragment of the fractured clavicle. This will result in different measurements and various degrees of shortening and displacement and thus differences in indication for surgery.
Since shortening becomes a more important factor in deciding whether surgical intervention is indicated, the aim of this study is to investigate if the type of X-ray and patient positioning is influential on the measured shortening in the acutely fractured clavicle.

Study objective

It is hypothesized that the type of radiographs and patient positioning is influential on the measured relative and absolute shortening of the MSCF. The goal of this study is to investigate to what extent the type radiograph used and patient positioning is influential on the measured shortening. interobserver and intraobserver reliability will be calculated.

Study design

A prospective multi-center case series is conducted in the Radboud UMC Nijmegen OLVG Amsterdam, CWZ Nijmegen, Rijnstate Arnhem and the Admiraal De Ruyter hospital in Goes. Participating departments will be the ER, General Surgery, Orthopaedic Surgery and Radiology

Study burden and risks

Each patient will undergo 7 additional X-ray*s. Normally an AP and one other direction is made In this study the diagnosing AP will be fabricated as well as 8 additional which is 7 more than in standard practice. The additional dose of milliSieverts (about 0.007 mSv) constitutes negligible additional lifetime risk of fatal cancer. [10]
(http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray) Excacerbation of pain during protracted and retracted positions of the arm can be expected. By administering sufficient analgetics this adverse effect for the patient will be relieved.

Adverse Events

There is no reason to expect any serious adverse events. In case of a serious adverse event this will be reported to the VCMO by the researchers and the study will be stopped. Monitoring will be ensured by PH and AG.

Ethical Issues

Research protocol will be reviewed by the hospital*s medical ethical board (VCMO). The value of this study and possible impact on indication for surgical intervention in MSCF in relation to the additional impact on the subject is acceptable according to the researchers. This study will be executed according to the principles of the declaration of Helsinki and according to the WMO.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Korte Leidsedwarsstraat 163
Amsterdam 1017RA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Korte Leidsedwarsstraat 163
Amsterdam 1017RA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Closed unilateral clavicle fracture MSCF Robinson Classification Type 2B1
Age > 18 years
< 7 days after trauma

Exclusion criteria

Patients with multiple traumas
Intoxication or inability to follow instruction
Inability to follow instruction
Serious soft tissue damage

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2015
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL53368.091.15