Vertebral Fractures: Reliability of fracture measurements on a full spine x-ray*

Published: 22-02-2022
Last updated: 06-04-2024

Primary objective: We aim to examine whether the Cobb angle measurements are similar on a full spine x-ray compared to a targeted x-ray, following traumatic spinal injury in patients >55 years of age, after 3 and 12 months of follow-up.

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

Summary

ID

NL-OMON53646

Source
ToetsingOnline

Brief title
Measurements on Full Spine (MoFS)

Condition

- Fractures

Synonym
Spinal fracture; Spine fracture

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Het ziekenhuis zelf;de maatschap en Diakonessenhuis research grant 2021

Intervention

Keyword: post traumatic kyphosis, radiographic measurements, Spinal fractures

Outcome measures

Primary outcome

Cobb angle measured on full spine x-ray, from the superior endplate of the adjacent cranial vertebral body to the inferior endplate of the adjacent caudal body (bisegmental angle);

Cobb angle measured on targeted x-ray, from the superior endplate of the adjacent cranial vertebral body to the inferior endplate of the adjacent caudal body (bisegmental angle);

Wedge angle measured on full spine x-ray, measuring from the superior endplate to the inferior of the injured vertebra.

Wedge angle measured on targeted x-ray, measuring from the superior endplate to the inferior of the injured vertebra.

Secondary outcome

Date of trauma, duration of follow-up, type and region of fracture, (in case of multitrauma: injury severity score (ISS)).

Study description

Background summary

In recent years there has been an increasing interest in the understanding and prediction of global spinal balance in patients presenting with a vertebral fracture. Especially in the aged patient, spinal balance may be impaired by additional degenerative changes, decreased bone quality, or postural abnormalities. Age is known to play a role in Spinal Posttraumatic Deformity (SPTD). A vertebral fracture in older patients can lead to an anterior

displacement of the gravity mass and requires compensatory mechanisms from the hips, lower extremities and cervical spine in order to recentralize the center of gravity. These compensatory mechanisms, together with the unbalanced state of the spine and the associated biomechanical changes in loading pattern, are frequently accompanied by pain and physical impairment. The increased age of these patients, and thus the increased predisposition to balance problems, has led to a more frequent use of full-spine x-rays during follow-up in addition to the targeted x-rays of the thoracic or lumbar spine.

Despite the benefits of this additional imaging, patients are often twice exposed to radiation during the same follow-up moment. The radiation exposure of a an AP and lateral x-ray of the lumbar- and thoracic spine is 1,5 mSv and 1 mSv resp. The radiation exposure of a full-spine series is 2.7 mSv . In perspective, the average Dutch person is subjected to 2.9 mSv per year (of which 1.24 mSv due to medical diagnostics). To avoid double radiation exposure, it would be desirable to perform all measurements on the full spine radiograph.

To date, there has been no evidence of the reliability of measuring the Cobb angle on a full spine radiograph. The purpose of this study is to compare measurements of vertebral fractures on a focused X-ray to the same measurements on a full-spine X-ray

Study objective

Primary objective: We aim to examine whether the Cobb angle measurements are similar on a full spine x-ray compared to a targeted x-ray, following traumatic spinal injury in patients >55 years of age, after 3 and 12 months of follow-up.

Study design

This study will concern a single-center prospective design, the cohort will consist of patients (>=55 years), presenting with a spinal fracture between 02.2022 and 31-12-2022. Data will be gathered from a single hospital (Diakonessenhuis, Utrecht). Patients eligible for inclusion will receive an information letter and an informed consent letter and a full-spine x-ray will be made at 3- and 12 months of follow-up duration, in addition to the targeted X-ray.

Study burden and risks

This study is prospective in nature. We will ask patients for informed consent at presentation to the outpatient clinic. After 3- and 12 months of follow up the patients will undergo a targeted X-rays and full spine x-rays. The location of the targeted x-rays will depend on the location of the fracture in the spine. A lumbar spine x-ray will be made for a lumbar spine fracture, and a

thoracic spine x-ray will be made for a thoracic spine fracture. The cobb angles will be measured on both the full-spine and the targeted x-rays, and compared to each other.
The radiation exposure of a an AP and lateral x-ray of the lumbar- and thoracic spine is 1,5 mSv and 1 mSv resp. The radiation exposure of a full-spine series is 2.7 mSv . In perspective, the average Dutch person is subjected to 2.9 mSv per year (of which 1.24 mSv due to medical diagnostics). To avoid double radiation exposure, it would be desirable to perform all measurements on the full spine 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

In order to be eligible to participate in this study, a subject must meet all

of the following criteria:
- Adult (>=55 years at time of trauma)
- Traumatic spinal fracture of the thoracic or lumbar spine
- Treated between the date of approval from the METC, aimed at 01.02.2022 and 31-12-2022. at the Diakonessenhuis,
- ASIA C, D or E
- Capable of understanding the Dutch language and capable of filling out the questionnaires.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: - Oncological spinal fracture - ASIA A and B - Non-recovered neuro-trauma - Polytrauma with invalidity not caused by spinal fracture (ISS >15)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-03-2022
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	22-02-2022
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL80133.100.22