Ultrasound imaging of patients with scoliosis

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Primary Objective: the primary objective of this study is to investigate the accuracy and reliability of coronal curve ultrasound measurements in patients with scoliosis as well as the accuracy and reliability of ultrasound imaging to detect...

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

Summary

ID

NL-OMON48546

Source
ToetsingOnline

Brief title
Scolioscan 2

Condition

- Joint disorders

Synonym
Scoliose, spine deformity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Telefield medical imaging limited

Intervention

Keyword: Scolioscan, Scoliosis, Ultrasound

Outcome measures

Primary outcome

The main study parameter is the thoracic and lumbar Cobb angle measured by ultrasound device and to compare with the Cobb angle measured by X-rays.

Secondary outcome

Secondary, the sagittal alignment will be measured, more specifically the thoracic kyphosis and lumbar lordosis will be measured. The last parameter is the vertebral rotation.

Study description

Background summary

Scoliosis is a three-dimensional (3D) deformity of the spine and the entire trunk, involving changes in all three planes. Although officially defined by the Scoliosis Research Society as a lateral curve of more than ten degrees Cobb angle, its true 3D morphology also involves the sagittal plane (i.e. pathological lordosis) and transverse plane (i.e. increased axial rotation). The varied causes of scoliosis are broadly classified as congenital, neuromuscular, syndrome-related, idiopathic and spinal curvature due to secondary reasons. The idiopathic scoliosis can be subdivided in infantile (0-3 years of age) juvenile (3-10 years of age) and adolescent (10-18 years of age) scoliosis. The most common type, the adolescent idiopathic scoliosis (AIS), has a prevalence of 1.5-3% within the general population of children aged 10-18 years. Typically girls are affected more frequently with a sex-ratio of 5.4:1 for curves of 20° or more.

Traditionally, standing conventional radiographs (X-rays) of the entire spine are the gold standard for the assessment of scoliosis, as well as for clinical follow-up and treatment decision making. There are several disadvantages of this imaging method. First, an X-ray, typically performed in two directions (posterior-anterior and lateral), is a two-dimensional (2D) representation of a 3D spinal deformity. Considering that biomechanical factors and the 3D

orientation of the vertebrae in space were shown to play a role in scoliosis initiation and progression and are important for determining surgical strategy, this technique falls short of providing this 3D information to the surgeon. Second, to monitor the deformity and detect possible curve progression, patients with scoliosis are exposed to an ionizing radiation X-ray at least each 4 to 6 months. Previous studies have demonstrated that X-rays bring an inevitable exposure of repeated doses of ionizing radiation. Considering the frequency of X-ray imaging, the exposed organs, the young age of the patients, their susceptibility for ionizing radiation and remaining life span, this technique has been shown to increase the risk for developing malignancies. The risk for breast cancer is increased with 4.2% for scoliosis patients as compared to the general population. Furthermore, once this diagnosis is established there is 70% more mortality in these patients due to a more aggressive nature of the tumour. The overall risk for the development of a solid malignancy is 2% higher in the scoliosis group as compared to the general population. All these data are only based on X-ray imaging; in certain cases additional imaging with computed tomography (CT), which has a much higher exposure of ionizing radiation, is necessary and this will certainly increase this risk even more. Recently, Simony et al. described the incidence of cancer in the scoliosis patients cohort to be 17 times greater than the incidence of 0.25% in an age-sex matched non-scoliotic cohort. Once eventual treatment is completed, scoliosis patients are still exposed to ionizing radiation to evaluate the effect of treatment and to rule out curve deterioration, pseudarthrosis, metal failure and other complications. Additionally, some syndromes are associated with a higher risk of scoliosis, like the 22q11.2 deletion syndrome. The University Medical Center Utrecht (UMCU) harbours a specialized multidisciplinary outpatient clinic for children with 22q11.2 deletion syndrome. These patients are radiographically screened each two years from the age of six, to detect a possible curve of the spine and are exposed to the inevitable radiation as well, even without having scoliosis. Moreover, the rehabilitation specialists sees a number neuromuscular syndromes that are associated with an increased risk of scoliosis, such as Spinal Muscular Atrophy. These patients receive often spinal radiographs to assess the curve progression. Moreover, the rehabilitation specialists sees a number neuromuscular syndromes that are associated with an increased risk of scoliosis, such as Spinal Muscular Atrophy. These patients receive often spinal radiographs to assess the curve progression.

The progression of the scoliotic curve is monitored by using the Cobb angle, which measures the angle between the two most tilted vertebrae in opposite directions on standing X-rays. Radiation-free imaging like magnetic resonance imaging (MRI) is performed supine and is primarily used to rule out intraspinal anomalies (e.g. syrinx, Arnold-Chiari malformation, tethered cord). A new method is obviously needed, which is safe, non-radiating, fast, easy to use, cheap and preferably should provide 3D information. Recent advances in 3D tracked ultrasound technology may enable this. Based on a new collaboration with the CHU Sainte Justine Hospital (Montreal, Canada) it is possible to make

a 3D reconstruction out of the two 2D radiographs. This will give us the opportunity to compare the ultrasound with the radiograph with greater accuracy. Previous studies showed that ultrasound is a valid and reliable method for imaging of the scoliotic spine. However, most of these studies included only mild AIS patients without previous surgery. In one of our previous studies we also included mild AIS patients without previous surgery and observed that the severity of the deformity in AIS patients can be assessed by ultrasound imaging. However, further research is needed to determine if ultrasound can be used in a clinical setting for all scoliosis patients and patients that are referred for scoliosis (without having a scoliosis), to see whether the ultrasound imaging could is reliable and valid in detecting scoliosis.

Study objective

Primary Objective: the primary objective of this study is to investigate the accuracy and reliability of coronal curve ultrasound measurements in patients with scoliosis as well as the accuracy and reliability of ultrasound imaging to detect scoliosis (Cobb angle > 10°) in patients that are suspected of having scoliosis. The ultrasound imaging will be compared with the standard radiographic measurements obtained at the same consultation, at the first visit as well as the follow-up visits.
The measurements consist of the primary and secondary Cobb angles; the angle between the two most tilted vertebrae in the coronal plane of the lateral curve of the spine in both 2D and 3D measurements. The secondary objectives are based on the sagittal and the transverse plane; the thoracic kyphosis and lumbar lordosis and the apical vertebral rotation. All these measurements will be compared between the ultrasound and radiography. To test the intra- and interobserver variability, 20 patients will receive 3 scans at the first visit (2 by observer 1 and 1 by observer 2).

Study design

This prospective cohort study is initiated and coordinated by the Department of Orthopaedic Surgery from the UMCU, the Netherlands. The ultrasound device, Scolioscan®, is a unique ultrasound device developed for measuring the curvature of the scoliotic spine. The coordinating researcher completed the Scolioscan® training already.

Normally, spinal X-rays are made of patients with scoliosis, and patients suspected of having scoliosis during an orthopaedic consultation. These X-rays are required to diagnose a scoliosis and to monitor the possible progression of the curve. During the X-ray we will place a small belt around the waist of the patient in order to make the 3D reconstruction. The Cobb angle is used to express the scoliosis in the coronal plane. Furthermore, the thoracic kyphosis and lumbar lordosis are determined to describe the sagittal alignment. In this

study the patients are examined by ultrasound at the same day as the radiographs is taken. Each included patient will receive ultrasound examinations at certain intervals to determine the progression of the curve. These intervals coincide with the regular outpatient visits, with a maximum of four examinations in two years.

After obtaining informed consent, the patients will be examined by using the radiation-free ultrasound device (the Scolioscan®), on the same day as the radiograph is made and prior to the outpatient visit. The Scolioscan® software is able to provide a 3D image of the scoliotic spine from which can be derived the primary and secondary Cobb angles, thoracic kyphosis, lumbar lordosis and vertebral rotation. Prior to consultation, the scoliosis doctor will determine the thoracic and lumbar Cobb angle, thoracic kyphosis, lumbar lordosis and rotation on routine radiographs without knowledge of the ultrasound outcomes. Moreover, the radiographs will be anonymously extracted from PACS in order to make the 3D reconstruction with the use of the Clindexia and NewSpine3D software. So, tThe only addition to the regular procedure is the radiation-free ultrasound imaging of the spine that will be obtained at different visits for each included patient. Most X-rays are made in straight standing (or sitting) position. However, for operative planning, side bending X-rays will be made. If the X-rays are made in side bending position, the ultrasound scans will be made in side bending position as well, since the ultrasound scans are made in the same position as the X-rays. Furthermore, the intra- and interobserver reliability will be tested using 20 patients of each group at their first visit. For these measurements, the first observer will scan the patients twice and the second observer will scan the patients once. In total, these 20 patients receive three scans each at their first visit.

This study includes four groups of patients, based on the cause of the scoliosis; idiopathic, neuromuscular, congenital and syndrome-related. Five to ten patients meet the inclusion criteria each week at different outpatient clinics in the UMCU. Some of these patients are screened on scoliosis because they have some syndromes (like the 22q11.2 deletion syndrome) and are more likely to have a scoliosis. These screening programmes start at the age of six years. Therefore, the minimum inclusion age is six years. To include the required number of patients (256 patients), one year seems more than adequate. After this first year, all the patients are probably included, thereafter we will scan the patients for the second time, and eventually third and fourth time, at their regular visit.

Study burden and risks

The overall risks of the ultrasound device are the same as the regular ultrasound devices that are widely used. To make sure there are no other possible risks, our technical department (MTKF) will check the complete procedure and device.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: male or female between 6 and 18 years of age, planned to undergo an anterior-posterior and lateral radiograph as part of their visit to the outpatient orthopaedic clinic for assessment of a (possible) scoliosis.

Exclusion criteria

A potential subject who is not able to stand or sit for two minutes during the ultrasound procedure will be excluded from participation in this study. Furthermore, AIS patients that completed the previous Scolioscan study (METC number: 16-389), will be excluded. If the

previous Scolioscan study (METC number: 16-389) is completed, the patients that visit the University Medical Centre Utrecht for their follow-up, will be included in the current study. Last, patients with a pacemaker will be excluded.

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):	19-03-2018
Enrollment:	256
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound decive
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-02-2018
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	25-07-2018
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	24-01-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL62835.041.17