
Plan Overview

A Data Management Plan created using DeIC DMP

Title: Segmental instability in the degenerative lumbar spine

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Project abstract:

Degenerative changes in the lumbar spine can lead to spinal stenosis (LSS), which is a narrowing of the spinal canal. This can be complicated by spondylolisthesis (LDS) an anterior slippage of a superior vertebra relative to the inferior. The degenerative changes can have a dynamic component of instability. In these cases, the surgical treatment is debated amongst spine surgeons. Currently the trend is to choose fusion by signs of instability. The radiological diagnose of instability have been based on x-rays. But recent studies have shown that MRI can show signs of instability. These MRI proxies involves disc height, facet joint angle and effusion. Objective: To investigate whether MRI proxies for segmental instability are associated with radiological instability in patients with degenerative LSS and/or LDS L4/L5 scheduled for decompressive surgery with or without fusion? Method: Design: retrospective cohort study of patients undergoing surgery for LSS or LDS from 2010 to 2017 at Spine Center of Southern Denmark, Middelfart Hospital. Patient selection: the cohort is generated from DaneSpine national spine surgery database. Inclusion: MRI verified LSS with or without LDS, who underwent primary surgery for LSS and/or LDS at L4/L5 level, consent to participate in DaneSpine. Included ICD-10 diagnostic groups DM480 and DM431. Diagnostic imaging at Middelfart Hospital supine spine MRI and standing spine X-ray within 6 months before surgery. Exclusion: ASA group >II, malignant disease at inclusion, previous spine surgery, scoliosis cobb angle >20 Figure 1: patient flowchart. (unable to upload figures to DCC template - Patient flowchart see figure 1 in supplementary file). Data from database and digital image combined to create project database. Statistics: descriptive statistics according to data type. Logistic regression to determine association.

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Segmental instability in the degenerative lumbar spine

Data Collection

What data will you collect or create?

Data collected using existing data from database, and new data constructed from digital images. See Table 1. Data source: DaneSpine and digital imaging from EasyWiz
Study unit: patients undergoing primary lumbar spine surgery 2010-2017 due to spinal stenosis and/or spondylolisthesis at Middelfart Hospital.

Preexisting data:

Data source: DaneSpine

Provides data on CPR-number, demographics, HRQoL questionnaires and co-morbidities. Furthermore, on surgical data on diagnose, surgery type, instrumentation, spine level, complications and reoperation.

New data:

Data source: EasyWiz

Presurgery diagnostic imaging accessed and measurements made using the program software. Each CPR number found when applying the inclusion and exclusion criteria to the DaneSpine draw will be checked for MRI and X-ray in EasyWiz.

1. lumbar/spine: MRI
2. standing lumbar X-ray

How will the data be collected or created?

This is a retrospective study.

Table 1 showing time points for datacollection

| | Pre-surgery | Baseline | Surgery | 1 year | 2 year FU |
|---------------------|-------------|----------|---------|--------|-----------|
| DaneSpine - patient | | X | | X | X |
| DaneSpine -surgeon | | | X | (X) | |
| MRI | X | | | | |
| X-ray | X | | | | |

Data from Danespine exported to Excel datasheet.

Diagnostic imaging accessed using EasyWiz program. Measurements will be made in EasyWiz and measurements entered in project database and linked to DaneSpine Excel file on CPR number. Figure 2. Shows data flow, data structure and how data are combined. Project database consists of an excel file. Data connected based upon CPR number. Pseudonymized with Id number. (See supplementary file).

Documentation and Metadata

What documentation and metadata will accompany the data?

Project data:

Codebook, description of measurement protocol, participation and data flow, STATA do files.

Codebook as supplementary file

Participation and data flow see: figure 1 and 2 and table 1

Description of measurement protocol

Figures not possible to upload.

Data control:

The methods of measurements are agreed upon before initiation of measurements. Measured twice by independent researchers.

Data control by initial check of acquired data (RAW data). Before data from DaneSpine can be processed by STATA variables names will be changed and renamed not to include "Æ, Ø, Å". In order to control data, requirements regarding missing data, intervals of numerical data and values of categorical data are specified in a codebook – see supplementary file. Variables names according to codebook. Data imported to STATA and "string" variables decoded to numeric. In STATA an initial check of acquired data variable by variable. Data screened for missing data and outliers. Data exploration using codebook, tabulate etc. DO file crude_to_clean, Datacontrol. In data control variable labels will be defined and added. Generation of new variables according to codebook.

Regarding missing values: patient will not be included in analysis.

Ethics and Legal Compliance

How will you manage any ethical issues?

Legal basis of this project is GDPR directive 679 §10 article 9 paragraph.

Project reported to Region of Southern Denmark. The Data responsible authority: Region of Southern Denmark. Project responsible: Mikkel Østerheden Andersen, head of research at Center for Spine surgery and research, Spine Center of Southern Denmark, Middelfart Hospital and main supervisor.

Data processing agreement with Region of Southern Denmark and Ph.D. student and data processor Signe Forbech Elmoose with Mikkel Ø. Andersen as project responsible.

DaneSpine

Region of Southern Denmark have ownership of the data in DaneSpine. The Region of Southern Denmark is the data controller.

Patients give consent to participate in DaneSpine and that the data they provide will be used for research.

Applied and approved transfer of data from DaneSpine to this project.

Regarding digital imaging and approval of access.

Applied Research Ethics Comity but was not found to be necessary with an approval by the Comity, Id number: 20202000-22.

"Styrelsen for Patient Sikkerhed" applied for permission to transfer data from patients records to the project to be able to access digital imaging without consent from patients. According to Danish healthcare act §46

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Project data belongs to the research unit at Center for Spine surgery and Research, at Spine Center of Southern Denmark, Region of Southern Denmark.

Storage and Backup

How will the data be stored and backed up during the research?

Regarding DaneSpine data

During data collection data is continually stored and updated in Topica, hosted by Region of Southern Denmark.

Full logging of single data items. I.e. time of data entry, identity of the user entering data and full logging of all subsequent handling.

Export from Topica ensures metadata is kept as e.g. STATA codebooks

Permanent storing and storing on temporary data sets will be on secure data set will be on secure Topica.

The data are backed up by the host's IT department.

Regarding project database

A project space in SharePoint, where project manager and project coordinator have access.

Data from DaneSpine will be uploaded directly in SharePoint by administrative personnel from DaneSpine. This person is also administrative personnel at the research unit.

Data from digital imaging will be stored in DaneSpine file in SharePoint.

SharePoint administered by the Region of Southern Denmark and are backed up weekly.

Record of data processing activities: SharePoint: log on file level which requires Pseudo anonymized data.

How will you manage access and security?

The project coordinator at the research unit administers access to the project space at SharePoint.

The project space are secured by username and password

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Archived in a project folder at SharePoint administered by project coordinator at the research unit administers access.

What is the long-term preservation plan for the dataset?

Stored for 5 years.

Data Sharing

How will you share the data?

Since raw data can not be anonymized the only possibility for sharing is sharing of metadata and results. We should consider sharing metadata. By reuse the research unit should be acknowledged.

Are any restrictions on data sharing required?

See above

Responsibilities and Resources

Who will be responsible for data management?

The project manager (Ph.D. student) is responsible for the DMP in cooperation with supervisor. And after supervisor meeting the DMP will be revised if necessary.

What resources will you require to deliver your plan?

Access to

- SharePoint
- STATA