Patients' expectations before, and their experiences after spinal surgery, regarding pain, rehabilitation and quality of life.

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Background

Surgery can be an overwhelming and often a life-changing experience for patients. To mitigate this experience a patient-centered approach can be beneficial [1]. Patient-centered care is defined as providing care that is "respectful of and responsive to individual patient preferences, needs and values, and which ensures that patient values guide all clinical decisions" [1]. Patient-centeredness should be considered in discussions about the value of surgical treatment for the patient and the expectations regarding the process of postoperative rehabilitation, especially considering the patient's definition of a successful outcome [1]. The meaning of rehabilitation may vary between stakeholders involved in surgery, including patients, surgeons, anesthetists, nurses, and hospital administrators [2]. Studies addressing strategies to improve rehabilitation, such as minimally invasive surgery and enhanced recovery pathways, commonly focus on measures such as complication rates, gastrointestinal activity, physical function, and duration of hospital stay [2]. These parameters are mostly relevant to clinicians and administrators, but they do not reflect the complexity of the rehabilitation process or include the patient`s perspective and expectations.

In musculoskeletal practice, patients' expectations have been reported as a valuable predictor for treatment outcomes in patients with acute and chronic pain [3]. Patients with higher expectations regarding the treatment report better outcomes than those with lower expectations [3]. Previous studies have investigated the relationship between expectations and postoperative satisfactions in patients undergoing spinal surgery [4], and some evidence suggest patients' expectations also impact rehabilitation after surgery [5,6].

Patients undergoing spinal surgery usually suffer from moderate to severe pain during the perioperative and postoperative period [7], which is associated with developing persistent pain [8] and compromises patients' quality of life.

Lumbar disc herniation is one of the most common musculoskeletal diseases which, in some cases, can compromise patients' quality of life, and the most common operations performed on the spine [9]. A previous study has shown that persistent pain after surgery for lumbar disc herniation is

negatively associated with psychological and physical well-being, and the overall quality of life is decreased [10].

We hypothesize that interviewing patients in a semi-structured manner would give unique perspectives on what is important to patients, as opposed to what is important to researchers. Further, we hypothesize that patients' preoperative expectations for spinal surgery can affect postoperative rehabilitation. Gaining in-depth understanding of the process of recovery from the patients´ perspectives can, ultimately, guide patient-centered care and future research.

Aim

The purpose of this study is twofold:

1) to investigate how expectations predict patients' pain, rehabilitation and quality of life after spinal surgery.

2) to explore the patients' expectations before, and their experiences after, spinal surgery regarding pain, rehabilitation and quality of life.

Methods

Design

Prospective observational cohort study, where qualitative and quantitative data is collected. The study will illuminate the research question by using quantitative and qualitative approaches. No formal sample size calculation is performed since this is a prospective cohort study exploratory by nature.

Location of the study

The study will be conducted at the Department of Anesthesiology, Zealand University Hospital, Koege, from 01.09.2023 – 31.08.2024.

Participants

All patients at Zealand University Hospital, who meet the inclusion criteria, undergoing spinal

surgery during 1 year, will be invited to participate in the quantitative part of the study. We estimate that 300 patients will be eligible for the quantitative part. For the qualitative part, we will include 10 - 15 patients undergoing spinal surgery.

Inclusion criteria

Patients must meet all the following criteria to be suitable for inclusion in the study.
Patients > 18 years, undergoing elective spinal surgery at Zealand University Hospital, Koege.
Patients able to read and understand Danish.

Exclusion criteria

Patients meeting one or more of the following criteria are ineligible for inclusion in the study.
Patients with cognitive deficits, such as dementia or who are mentally disabled and cannot cooperate with the study based on the investigator`s judgement. Patients with alcohol and drug dependence based on the investigator`s judgement.

Procedure for patients who withdraw from the trial

In accordance with the Declaration of Helsinki [11], patients have the right to withdraw from the study at any time for any reason. It will be recorded in the patient's Case Report Form if a reason is given.

Data collection and analysis

For the quantitative part the following background characteristics will be collected in a CRF: sex (male/female), age (years), Body Max Index (BMI), preoperative opioid consumption (yes/no), civil status (response alternatives), job situation (response alternatives), and capable of working (yes/no). Questionnaires will be used for collection of data regarding pre-operative expectations (Treatment Expectation Questionnaire (TEX-Q) [12]), pain (Verbal rating scale (VRS)) functional level (Oswestry Disability Index (ODI) [13]) and quality of life (WHO Quality of Life – BREF (WHOQOL-BREF) [14]) and will be collected at baseline. Data regarding pain, functional level, and quality of life, will also be collected postoperatively. All questionnaires have been validated except the TEX-Q, which validation is under preparation.

The analyses will primarily focus on functional level and quality of life postoperatively as a function of preoperatively expectations. Other analyses will explore covariates as determinates of preoperative expectations and functional recovery. Data will be analyzed with multiple regression in SPSS. Results will be described with mean values and standard deviation of the mean value, or with median and inter-quartile range as appropriate. A 5% level of significance will be used. Relevant parametric or non-parametric methods will be used, depending on distribution of data.

For the qualitative part, data regarding pre-operative expectations, and their experiences 3 months post-operatively, will be collected using interviews. The interviews will be conducted using semi-structured questions, which will be designed prior to the interviews. Patients will be enrolled several days before surgery and will be interviewed during an in-person interview. The interviews will be recorded using an IPAD and in rooms suitable for asking emotional questions. The interviews will afterward be transcribed and analyzed by the investigators using inductive qualitative content analysis as described by Graneheim and Lundman [15]. The data will then be divided into meaning units, condensed meaning units, codes and themes and discussed by the authors until consensus has been obtained.

Ethical considerations

In this study, there will be no changes in the patient's treatment.
Written consent will be obtained from the participants after oral information, according to regulations of the local Research Ethics Committee and The Danish Data Protection Agency. The patients included in the study will not have an immediate benefit from participating, but in the future, the results of the study may be useful for other patients. The study will be conducted in accordance with the principles of the Declaration of Helsinki [11].

Protection of patient data

Information will be treated confidentially and in the reporting of test results, patients will be anonymous at all times and the persons responsible for this trial are bound to confidentially.
The primary investigator will create an identification list of all patients who have been given trial numbers. The list will contain patients` full name and CPR number stored in the template “Team

site SharePoint".
The IPAD used for the interviews will only be used for research purposes and will be locked away until the interviews have been transcribed. All transcribed material and results will be stored in the template "Team site SharePoint", a closed document library to store all files related to a specific project.
Data will be stored according to The Danish Data Protection Agency.

Financial situation

The primary investigator is employed at Zealand University Hospital, Koege and has no financial benefit from the study.
The investigators have no financial interest in the study.

Data registration and rules for the control of investigation procedures

The study will be conducted in accordance with the applicable rules on clinical trials involving people in respect of quality control and quality management, and will follow Good Clinical Practice.

The investigator and co-investigators at Zealand University Hospital, Koege are responsible for managing and archiving data in accordance with current regulations. The data belongs to Josephine Zachodnik.
The study will be reported to The Danish Data Protection Agency, Research Ethics Committee and Clinical Trials.gov

Publication of results

Data from this study will form the basis of at least 2 manuscripts to be submitted for publication with the following order of authors;

The quantitative study:

- Josephine Zachodnik
- Kasper Thybo
- Peter Udby
- Magnus Sandberg
- Anja Geisler

The qualitative study:

- Josephine Zachodnik
- Kasper Thybo
- Peter Udby
- Anja Geisler
- Magnus Sandberg

Other authors may be added during the work if relevant. Josephine Zachodnik will always be the first author.

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