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Patient-reported outcome measures (PROMs) following knee arthroplasty: a prospective cohort study protocol

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ABSTRACT

Introduction To evaluate the quality of clinical practice, patient-reported outcome measures (PROMs) are important as certain questions could only be answered by the patient himself. PROMs help to get a better understanding what is meaningful to a patient and directly affects daily functioning. To move beyond traditional measures, we are interested in what matters to patients and developed this project. The aim of this article is to provide the protocol for our study collecting PROMs in daily medical practice from patients who undergo knee arthroplasty.

Methods and analysis This study is a single-site, observational, prospective cohort study. We will recruit patients scheduled for a knee arthroplasty in our medical office, situated in a private clinic. After signed informed consent, patients complete self-reported questionnaires before the surgery, after 4 months, 1 year, 2 years, 3 years, 4 years and 5 years. We will use the following PROMs: Knee injury and Osteoarthritis Outcome Score, Forgotten Joint Score, EuroQol five dimensions and satisfaction. Additionally, the surgeon will complete the objective Knee Society Score. Administration of the questionnaires will be electronically or paper-based. We will assess differences between preoperative and postoperative data with paired t-test for continuous variables and Wilcoxon signed-rank test for categorical variables. To assess subgroup differences, we will use unpaired t-test for continuous variables and Mann-Whitney U test for categorical variables. To assess possible presence of bias, we will conduct sensitivity analyses.

Ethics and dissemination The study has been reviewed and approved by the local ethics committee in Basel, Switzerland. Written informed consent will be obtained from all patients. We will disseminate the results of the study through peer-reviewed journals, national and international conference presentations and presentations to relevant stakeholders through appropriate channels.

Strengths and limitations of this study

► Our results return a direct feedback from patients with knee arthroplasties, short to long term.
► The findings will help to understand why some patients with knee arthroplasties are not satisfied and can be compared with other data from registries with patient-reported outcome measures (PROMs).
► The Swiss National Joint Registry does not apply PROMs, our study helps to collect important data.
► Participants are recruited from a single private medical office consisting of a team of three subspecialised knee surgeons. The sample size may not be representative for all patients in Switzerland, but is likewise a homogeneous sample.

Patient-reported outcome measures (PROMs) are standardised measures to capture and translate the patients' perspective into objective numerical data. The Organisation for Economic Co-operation and Development (OECD) promotes people-centredness of primary care services[2] and the International Consortium for Health Outcomes Measurement is developing more standard sets to measure PROMs.[3]

PROMs help to get a better understanding of outcomes that are most meaningful to patients and have direct relevance to their everyday functioning. Patients with arthroplasties differ in what they consider important: the ability to run, kneel or squat has not the same relevance for all patients.[4] Despite high implant survival rates and good overall outcome of knee arthroplasties, up to 20% of the patients are still unsatisfied.[5]

Each year, 21 000 patients undergo total knee arthroplasty (TKA) in Switzerland.[6] The frequency of 250 per 100 000 population is the highest among the OECD countries.[6] The Swiss National Joint Registry captures implant specific outcomes of almost all TKA procedures in Switzerland, but until now the registry does not capture PROMs.[7] To move beyond traditional measures, we are

INTRODUCTION

Patient-reported outcomes are an important element to evaluate the quality and the results of clinical practice as they directly and without any interpretation report a patient's health status.[1] Certain questions, for example, regarding health-related quality of life (QoL) or functioning in daily life can only be answered by the patient himself.

Table 1	Inclusion and exclusion criteria
Inclusion	► Patients scheduled for elective partial or total knee arthroplasty. ► Age >18 years. ► Any diagnosis, any implant design.
Exclusion	► Insufficient knowledge of German, English, Italian or French to understand the consent form and the questionnaires.

interested in what matters to patients and developed this project. The aim of this article is to provide the protocol for our study collecting PROMs in daily medical practice from patients undergoing knee arthroplasty.

METHODS AND ANALYSIS

Study design, setting and recruitment

This study is a single-site, observational, prospective cohort study with a follow-up of five years. Recruitment will take place in our medical office, situated in a private clinic. Three experienced knee surgeons (TR, RK, MPA) will consecutively recruit patients scheduled for elective partial or TKA. As part of daily routine, we will ask all patients eligible to participate. The participation is voluntary and will not affect patients' further treatment. The inclusion and exclusion criteria are described in table 1.

A trained research associate (NV) will be responsible to instruct patients about the needs and goals of the project, to distribute and collect the questionnaires and to manage and analyse collected data.

Procedures and follow-up

After signed informed consent, we will ask patients to complete the self-reported questionnaires not before 3 weeks before the surgery. Postoperative, we will distribute questionnaires after 4 months, 1 year, 2 years, 3 years, 4 years and 5 years. Questionnaires are predominantly electronically administered or otherwise paper-based, whereby a trained research associate will enter the data into our database. In general, all study data will be collected and managed using Research Electronic Data Capture (REDCap), a secure web-based software hosted on a secured server placed in Switzerland. Authorised study personnel only will have access to uncoded patient data.

During the routine medical screening, surgeons will as well complete a questionnaire: before the surgery, after 4 months, 1 year and 5 years. We will collect demographic data and data concerning surgery details from patients' medical records. Independent of our study, every patient scheduled for a total knee or hip arthroplasty at our clinic, is eligible to participate in the Swiss National Joint Registry. For those patients who agreed to take part in the registry, we will have standardised data on their general state of health, previous surgeries and implant details.

Our data collection will be joint-based, rather than patient-based. Thus, patients with bilateral surgery will complete questionnaires for each knee joint. In case of an unreturned questionnaire, we will send out a reminder or call the patient. To assess external validity, we will collect anonymised information about age and sex for those patients not willing to take part in the study. A detailed summary about outcome measures and their distribution over time is outlined in table 2.

Outcome measures

For patients with knee osteoarthritis, numerous validated questionnaires are available to assess several aspects of functioning and health-related QoL. Such questionnaires typically comprise items on joint function, pain, stiffness and treatment satisfaction. We screened the literature for international guidelines,[3 8] common PROMs in other relevant studies and national arthroplasty registries[9] and followed the recommendation to combine generic and specific PROMs.[10] We tried to find a reasonable balance between the amount of PROMs applied and the burden for the patient to answer all items in order to increase our participation rate. As a result, we decided to use three validated PROMs and one validated clinician-completed questionnaire.

Objective Knee Society Score

The Knee Society Score (KSS) consists of different parts, we will only use the objective KSS.[11] Four items regarding alignment, stability and joint motion completed by the surgeon and three patient reported items on symptoms contribute to the KSS. The total score ranges from 0 to 100 points with a higher score indicating better outcome. The KSS is valid, responsive, reliable and consistent in patients with arthroplasties.[12 13]

Knee injury and Osteoarthritis Outcome Score

The Knee injury and Osteoarthritis Outcome Score (KOOS) is developed to assess the patient's opinion about their knee and associated problems.[14] The KOOS consists of 42 items divided into five subscales on pain, symptoms, activities of daily living, sports and recreational activities and QoL. Each subscale ranges from 0 to 100 points, with a higher score indicating better outcome. A total score has not been validated and is not recommended. Adequate measurement properties have been demonstrated.[15]

Forgotten Joint Score

The Forgotten Joint Score (FJS-12) measures through 12 items the new concept of patients' ability to forget the artificial joint in everyday life.[16] The total score ranges from 0 to 100 points with a higher score indication better outcome. The measurement properties have been evaluated and confirmed for patients with arthroplasties in several studies.[17–19] The FJS-12 showed less ceiling effects than the KOOS and might be more discriminating in patients with TKA.[20]

EuroQol five dimensions three levels

The three-level version of the EuroQol five dimensions (EQ-5D-3L) is one of the most widely used instruments

Table 2 Outcome measures and time of completion

Outcome measures	Instrument	Time of completion						
		Before surgery	4 months	1 year	2 years	3 years	4 years	5 years
Demographic data		x						
Patient-reported, knee specific								
Symptoms	KOOS symptoms	x	x	x	x	x	x	x
Pain	KOOS pain	x	x	x	x	x	x	x
Activities of daily living	KOOS ADL	x	x	x	x	x	x	x
Sports and recreational activities	KOOS sports	x	x	x	x	x	x	x
Knee related quality of life	KOOS QoL	x	x	x	x	x	x	x
Forgotten Joint	FJS-12	x	x	x	x	x	x	x
Satisfaction with surgery	Likert scale		x	x	x	x	x	x
Overall knee improvement	Likert scale		x	x	x	x	x	x
Surgery again	Yes/no		x	x	x	x	x	x
Patient-reported, generic								
Health-related quality of life	EQ-5D-3L	x	x	x	x	x	x	x
Clinician-completed								
Knee function	KSS	x	x	x				x
Degree of osteoarthritis	Kellgren-Lawrence Scale	x						
Satisfaction with surgery	Likert scale		x	x				x

ADL, activities of daily living; EQ-5D-3L, EuroQol five dimensions three levels; FJS-12, Forgotten Knee Joint Score; KOOS, Knee injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; QoL, quality of life.

for measuring generic health-related QoL[21 22] and is also the most commonly used generic PROM among arthroplasty registries.[23] The EQ-5D-3L captures five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) based on three levels of severity (no problems, moderate problems, extreme problems). To derive the summary index score, a value set of the general population of a country or region is required. In the absence of a value set for Switzerland, we will apply the European value set. The index score ranges from 0 to 1 with a higher value indication better health.

Additionally, a Visual Analogue Scale (EQ-VAS) records the patient's self-rated health on a vertical VAS with the endpoints 'The best health you can imagine' (100 points) and 'The worst health you can imagine' (0 points). The EuroQol five dimensions instruments have been proven to be valid, reliable and responsive in numerous conditions and populations[22]

Satisfaction

Besides the usage of validated questionnaires, it is recommended to use an extra item to measure global satisfaction. Such an item presents with a good face validity and gives the patient the opportunity to summarise his point of view.[10] We will ask patients on a five-point Likert scale how satisfied they are with the result of the surgery (very satisfied, satisfied, neutral, unsatisfied or very unsatisfied). To objectify this outcome, surgeons will answer this question as well.

We will also ask patients, if they would undergo the surgery again (yes or no) and how they rate their current overall improvement in their knee joint compared with the state before the surgery on a seven-point Likert scale (very much better, substantially better, a little better, no change, a little worse, substantially worse or very much worse). Health transition items are another type of PROMs to reflect a self-perceived change over a defined period.

Outcomes

We will calculate the total score for each outcome measure according their published algorithms. For all outcome measures, we will report end and change scores. Our primary outcome will be patients' satisfaction with the result of the surgery; whereas all other patient-reported and clinician-reported outcomes, adverse events and revision surgery will be secondary outcomes.

Sample size and study duration

The volume of knee arthroplasties at our medical office is approximately 130 arthroplasties in 120 patients per year (bilateral surgery possible). We estimate that only few patients are not eligible because of language barriers as the questionnaires are available in four languages (German, English, Italian and French). We will ask all patients eligible to participate and assume that 20% will reject. Finally, we will recruit about 100 patients per year and aim for at least a 90% follow-up rate in the first 2 years

after surgery. A small proportion (3%) will be patients with revision surgery whose data will be analysed separately from patients with primary knee arthroplasty.

The recruitment period will be five years, data collection period ten years (five years per patient), respectively. In total, we aim to collect data from 500 knee arthroplasties.

Missing data

We will regard the instructions on how to handle missing answers for each outcome measure. For each of the KOOS subscales at least half of the answers are mandatory, for the FJS-12 two-thirds are mandatory to calculate a mean score. All answers are mandatory for the EQ-5D-3L to compute the index value. We will report the frequency of missing data for each outcome measure and each follow-up.

Statistics

We will perform statistical analyses with IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp. Descriptive statistics will be presented, including means and standard deviation (SD) for all continuous variables, and frequency counts and percentages for categorical variables. As bilateral knee arthroplasties are possible, we will report joint-based data, rather than patient-based data.

The Kolmogorov-Smirnov test will be used to verify normal distribution. To assess differences between preoperative and postoperative data we will use paired t-test for continuous variables and Wilcoxon signed-rank test for categorical variables. To assess subgroup differences, we will use unpaired t-test for continuous variables and Mann-Whitney U test for categorical variables. To assess possible presence of bias we will conduct sensitivity analyses. We will perform all tests two tailed and consider $p \leq 0.05$ as statistically significant.

Burden and practical considerations

We estimated that patients need maximum 10 to 15 min and surgeons 2 to 3 min to complete the questionnaires. Questionnaires for patients are available in four different languages and administered electronically or paper-based. For a private medical office, the administrative burden and costs involved in routine collection of PROMs for knee arthroplasty patients are significant. A research associate coordinates all procedures and put the collection of PROMs into daily medical practice. Technical issues needed to be resolved to implement a database that is able to capture study data and send out questionnaires to patients and surgeons.

Ethics and dissemination

Our study is in accordance with the World Medical Association Declaration of Helsinki[24] and was approved by the local ethics committee in Basel, Switzerland (reference: 2016–01777).[25] All patients will have to sign a written informed consent. The findings of the study will be published in peer-reviewed journals and presented at national and international conferences. Moreover, we will communicate the results to relevant stakeholders like patients, clinicians, healthcare providers or policymakers through appropriate channels.

Patient and public involvement

Patients and the public were not directly involved in planning, design and development of the study. However, the results will be published and publicly available.

DISCUSSION

We hereby described the methods of our study to collect PROMs from patients undergoing knee arthroplasty. Our aim is to contribute to the implementation of PROMs collection into daily medical routine. For a private medical office, it is a burden regarding costs and time to realise such a project. However, we are interested in the real results of our patients and want to identify, and if possible to reduce, factors leading to unhappy patients after a knee arthroplasty. In addition, we want to answer the question, if different types of implants, off-the-shelf or customised individually made implants, show any differences in their outcomes.

We selected a balanced combination of validated generic und disease specific PROMs that are commonly used and likewise present in national arthroplasty registries. Beyond traditional PROMs like KOOS and EQ-5D-3L, we added the FJS-12. It comprises a relatively new and convincing concept of joint awareness and measures the ability to forget the artificial joint, while having less ceiling effects.[26] Distribution of questionnaires will predominantly be electronically. Thus, we avoid transcription errors while distribution is more efficient and less time consuming. We are optimistic, that the need for paper administration will diminish with time since also elderly get familiar with new technologies.[10]

Besides the evaluation of the patients perspective, PROMs can be used to engage patients in medical decision making.[27] Patients may have little experience participating in medical or health decisions and may not recognise the important role they play in clarifying their values and incorporating them into decisions.[28] In summary, we believe that the results of our study will be useful for all stakeholders, like clinicians, patients or policy-makers to enhance the understanding of the impact of knee osteoarthritis or knee arthroplasty on the patient.

Current study status

Study recruitment and data collection began in January 2017. In total, recruitment will last for five years and data collection for ten years (last patient last visit). As of the time of submission of the manuscript, we already recruited 310 patients. A continuation of the recruitment and study duration is conceivable and will be applied at the local ethics committee in due time.

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