Weight change and the risk of chronic pain following hip and knee arthroplasties: A nationwide registry-based cohort survey study.

Authors/Collaborators:

Saber M. Saber[1,2,3], MD, PhD Fellow; Jens Laigaard[1,3], MD, PhD Fellow; Martin Lindberg-Larsen, MD, PhD, Associate professor[4]; Søren Overgaard, MD, DMSc, Professor[1,3]

Affiliations:

1. Department of Orthopaedic Surgery and Traumatology, Copenhagen University Hospital, Bispebjerg and Frederiksberg, Copenhagen, Denmark; 2. The Parker Institute, Copenhagen University Hospital, Bispebjerg and Frederiksberg, Copenhagen, Denmark; 3. University of Copenhagen, Department of Clinical Medicine, Faculty of Health and Medical Sciences; 4. Department of Orthopaedic Surgery and Traumatology, Odense Hospital, Odense, Denmark.

INTRODUCTION

The treatment of hip and knee osteoarthritis not responding to non-surgical treatments may be surgical joint arthroplasty.[1] Though arthroplasty is considered an effective and safe treatment, unfavourable outcomes have been reported,[2] including persistent postoperative pain (PPP). The association between body weight and outcomes following total hip arthroplasty (THA) and knee arthroplasty is well documented: overweight carries higher risk of bad functional and surgical outcomes.[3-9] Also, Preoperative weight reduction reduces general health related complications following knee arthroplasty.[10] However, only few studies have investigated weight change following THA and knee arthroplasty.[11-16] Of these, some have indicated that weight change influences postsurgical outcomes.

Identification of factors that are linked to the incidence of PPP could help us to prevent this problematic outcome. The objective of this study is to investigate whether weight change is associated with the incidence of PPP following THA and knee arthroplasty across non-obese and obese and patients.

METHODS

Study design

The study is a nationwide, register-based cohort survey study. We will report the results following the CROSS checklist for standardized reporting of survey studies.[17] We will investigate the change of BMI 11-15 months after THA and knee arthroplasty and incidence of PPP by combining data from national registries and surveys.

Questionnaire

A 22-question questionnaire will be sent to the eligible candidates (see NCT05900791 and NCT05845177). The questionnaire is developed by combining domains from previously validated Patient Reported Outcome Measures (PROMs). Five questions are taken from the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain domain; seven questions from the Douleur Neuropathique 4 interview (DN4i); a numerical rating scale (NRS) question for pain in the operated joint in the last week; satisfaction; a single question for each of the following: willingness to repeat the surgery; pain frequency; pain interference with daily activities; other chronic pain conditions; patient-reported use of analgesics; weight; height and the permission to contact respondents again later. Patient reported weight and height has been recently found valid in a Danish e-survey setting.[18] A detailed description of the questionnaires and the current validation status of the domains can be found in 2 different papers.[19,20] The Danish and an English version of the questionnaire will be available in the final publication.

Sample characteristics

Patients with THA and knee arthroplasty who received their arthroplasty 11-15 months prior to the intended date of survey administration will be identified based on the NOMESCO (Nordic Medico-Statistical Committee) Classification of Surgical Procedures from the the Danish National Patient Register by using SKS-code. The codes for THA patients will be SKS-code DM16 [hip osteoarthritis] + KNFB20 or KNFB30 or KNFB40[Primary Total Hip Arthroplasty]. For total knee arthroplasty (TKA), SKS-code DM17 [knee osteoarthritis] + KNGB20, KNGB30 or KNGB40 [primary total knee arthroplasty]). For medial unicompartmental knee arthroplasty (UKA), SKS-code DM17 [knee osteoarthritis] + KNGB01 or KNGB11 [primary medial unicompartmental knee arthroplasty]. The baseline characteristics of the sample including their BMI will be gathered from the Danish Hip Arthroplasty Register (DHR) and the Danish Knee Arthroplasty Register (DKR).

Survey administration

The data of this study is pooled from 2 surveys sent to THA and knee arthroplasty patients.[19,20] Both surveys are distributed via 'Digital Post' which is linked to the unique Civil Registration number (CPR) using Research Electronic Data Capture (REDCap) software (www.r-project.org). A reminder will be sent 14 days after distribution for non-responders. A month after distribution date, a text-message will be sent to non-responder's telephone number if it is registered in the electronic patient file.

Statistical analysis

We expect to find a sample of around 6400 patients divided between hip and knee arthroplasty. Estimated response rates of 70% will leave us with 2240 patients to be analysed in each joint arthroplasty group. With an expected 15% of the sample to be weight gainers, we will be able to detect a minimum of 16.6% difference in the incidence of the outcome between gainers and non-gainers with a significance level of 0.05 with a power of 0.80.

We will report results for THA, TKA and medial UKA separately as we believe these are different patient groups. We will categorize patients into weight gainers (≥5% weight gain after arthroplasty), weight losers (≥5% weight loss) and those who maintain their weight. Descriptive statistics of the baseline characteristics of the three categories with the following variables will be presented in table 1: age, sex, BMI and surgical details (type of anaesthesia, operation length, use of local infiltration analgesia (LIA), use of cement, and surgical complications).

The primary outcome is the occurrence of PPP and will be defined as NRS pain score higher than 3 as proposed by Moore et. al.[21] Secondary outcomes include satisfaction defined as being very satisfied or

satisfied; willingness to repeat the surgery defined as answering "yes" in willingness question; frequent pain defined as experiencing pain constantly, daily or few times a week; use of analgesic; interference with daily activities, defined as answering "some", "much" and "very much"; WOMAC pain score will be reported as the mean (standard deviation [SD]). Following outcome dichotomization (except for WOMAC pain), we will employ a multivariate logistic regression model to estimate the Odds Ratio (OR) and the corresponding 95% Confidence Interval (CI) amongst gainers and losers in relation to those who maintained their weight. For WOMAC pain, we will report the mean difference (MD) and the corresponding 95% CI. We will stratify for baseline obesity status (non-obese: BMI < 30 kg/m^2, Obese: BMI ≥ 30 kg/m^2). We will run a non-adjusted analysis first, then we will adjust for age, sex and the use of cement. We will do a sensitivity analysis to see whether the effect size is different between non-morbidly obese (BMI 30-39 kg/m^2) and morbidly obese (BMI ≥ 40 kg/m^2), we will run another sensitivity analysis adjusting for patients having other chronic pain condition. Data is handled in the most recent version of R (www.r-project.org).

Table 1 (Demographics)									
	THA			TKA			Medial UKA		
Demographics	Weight gainers	Weight losers	Weight unchanged	Weight gainers	Weight losers	Weight unchanged	Weight gainers	Weight losers	Weight unchanged
Total N									
Age (mean)									
Female N (%)									
BMI (mean)									
General Anaesthesia N (%)									
Spinal Anaesthesia N (%)									
Operation time (mean)									

Use of Cement N (%)													
Local Infiltration of analgesia N (%)													
Surgical complication N (%)													

Table 2 (Risk of developing PPP)													
	Weight unchanged (Reference group)			Weight gainers					Weight losers				
	N	PPP: N (%)	OR (95% CI)	P value	N	PPP: N (%)	OR (95% CI)	Adjusted OR (95% CI)	P value	N	PPP: N (%)	OR (95% CI)	Adjusted OR (95% CI)	P value
THA													
Non-Obese			1										
Obese			1										
TKA													
Non-Obese			1										
Obese			1										
Medial UKA													
Non-Obese			1										
Obese			1										

HEALTH RESEARCH ETHICS AND GENERAL CONSIDERATIONS

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Patient and Public Involvement (PPI)

This project follows the EULAR recommendations for the inclusion of patient representatives in the contemporary scientific process.[22] A panel of patients helped in developing the questionnaire.

Conflict of interest

All will be disclosed.

Disclaimers

The views expressed in the submitted protocol are the authors' own and not an official position of the institution or funder.

Ethics

The local institutional review board approved the study, and the Danish Health Data Authority will provide contact information for potential respondents. Telephone numbers for non-respondents are found by searching the CPR number in the electronic patient files, but without accessing the patients' health data. According to Danish legislation, approval from the national ethics committee is neither required nor possible to obtain for survey studies.

Because we will link survey responses with perioperative data from the Danish Knee Arthroplasty Register, responses are not anonymous. However, only the authors will have access to confidential information and data will be anonymised as soon as possible. Until then, the data are stored pseudonymised at a logged and encrypted drive.

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