Risk of revision and other complications following knee arthroplasty in patients previously exposed to bariatric surgeries: A nationwide, register-based study

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Abstract

Background: Previous studies have investigated the outcomes of Knee Arthroplasty (KA) following Bariatric Surgery (BAS), but with substantial limitations as not stratifying for Body Mass Index (BMI) at time of KA or not addressing the type of BAS (gastric bypass, banding or sleeve). Since BMI varies greatly in patients with previous BAS, it is likely that BMI affects outcomes after KA in BAS-operated patients.

Objective: Based on the Danish national registers and databases. The objective of this study is to analyse the association between exposure to BAS prior to KA and the following outcomes: 1) the risk of revision, 2) use of antibiotics and 3) mortality. Furthermore, we want to test whether the association is modified by BMI status at the time KA surgery (i.e., non-obese, obese and morbidly obese patients).

Methods/Design: The study is a nationwide, register-based cohort study. The study will follow the reporting of studies conducted using observational routinely-collected data statement for PharmacoEpidemiology (RECORD-PE) guidelines. We will compare the risk of revision after primary KA between patients with or without prior BAS. We will stratify the for BMI (non-obese: BMI < 30 kg/m2, obese: BMI 30-39 kg/m2, morbidly obese: BMI ≥ 40 kg/m2) at time of KA and the type of KA (i.e., Total Knee Arthroplasty (TKA) or Unicondylar Knee Arthroplasty (UKA)).

Exposures and outcomes: Exposure will be defined as BAS prior to KA. Outcomes are 1) revision due to all causes; 2) revision due to infection; 3) Knee related use of antibiotics within 30- and 90 days after the index KA; 4) Antibiotic use due to other causes within 30- and 90 days after the index KA and 5) mortality rate within 2 years following the index KA. We will use BMI, year of KA, year of BAS, sex, household income, highest completed education, comedication, Elixhauser Comorbidity Measure (ECM) and the NOMESCO (Nordic Medico-Statistical Committee) Classification of Surgical Procedures for stratifying and matching.. Multiple sensitivity analyses will be performed to investigate the influence of time between BAS and KA; and the type of BAS on the outcomes.

Perspectives: The purpose of this study is to estimate the risk of complications following KA in patients with previous exposure to BAS and it is anticipated that findings from this study would potentially help shared-decision making between the surgeon and patient - weighing the risks and benefits and by that, optimise selection of the right patients.

Keywords: Knee Arthroplasty, Bariatric Surgery, Risk of Revision, Register, Osteoarthritis

INTRODUCTION

Knee Arthroplasty (KA) have been estimated to have a 15-years survival rate of around 93%.[1] The main indications for revision after knee arthroplasty are aseptic loosening, infection and pain.[2] Surgical risk factors for revision include uncemented components, implant malalignment and longer length of operation. Patient-related risk factors include obesity, male sex and younger age at time of KA.[3-8] Obese patients (BMI>30 kg/m^2) have a higher risk for revision, deep and superficial infection, wound dehiscence and readmission following KA.[5] As obesity is a major risk factor much attention has been paid to weight loss before surgery. bariatric surgery (BAS) is an efficient weight-reducing intervention and can lead to a decrease in excess weight by up to 74% through all types of bariatric surgeries.[9] The prevalence of BAS-operated patients is increasing due to the increased obesity worldwide.[10] Whether BAS previous to KA is advantageous is disputed, mainly because BAS carries possible long-term complications, which vary depending on the type of BAS.[11,12] For example, late, non-surgical complications such as nutritional deficiencies of micronutrients and vitamins (including vitamin D) may impact bone metabolism and immune capacity and hence increase the risk of revision after KA, despite the weight loss achieved by BAS.[13]

Previous studies have investigated the outcomes of KA after BAS, but with substantial limitations.[14-24] A recent RCT concluded a reduced risk of complications after KA in patients exposed to BAS. The trial was underpowered (and prematurely terminated) for important outcomes and has limited external validity due to unclear exclusion criteria and a high number of excluded patients.[16] Other limitation is the treatment of BAS as a homogenous group without stratifying for BMI at time of KA or type of BAS (gastric bypass, banding or sleeve).[17-24] For instance, various studies have reported that the Body Mass Index (BMI) of the BAS-groups at the time of knee arthroscopy (KA) falls within a broad range of 23-57 kg/m2.[21,22,24] This significant variance in BMI suggests considerable heterogeneity within this group. Furthermore, this wide range in BMI could potentially influence the outcomes reported in these studies. Moreover, some researchers did not report the registered body mass index (BMI) at the time of KA. Instead, they relied on ICD-9 codes for their data. [17-20,23] This approach results in a comparison between two groups that are fundamentally dissimilar. This is because ICD-9 codes do not accurately reflect overweight conditions, and in a US sample, only 15.1% of overweight patients were assigned relevant ICD-9 codes.[25]

Objective

The objective of this study is to analyse the association between exposure to BAS prior to KA and the following outcomes: 1) the risk of revision, 2) use of antibiotics and 3) mortality. Furthermore, we want to test whether the association is modified by BMI at the time KA surgery (i.e., non-obese, obese and morbidly

obese patients). This would help the surgeon in weighing the risks and benefits and by that, selecting the right patient for operation.

METHODS

Study design

The study is a nationwide, register-based cohort study. The study will be reported following the REporting of studies Conducted using Observational Routinely-collected Data statement for PharmacoEpidemiology (RECORD-PE) guidelines. [26] We will compare the risk of revision after primary KA in the period from 2011 and 2 years earlier to data-extraction date stratified for exposure to BAS prior to their KA. We will further stratify for BMI (non-obese: BMI < 30 kg/m^2, obese: BMI 30-39 kg/m^2, and morbidly obese: BMI ≥ 40 kg/m^2) at time of KA and the type of KA (i.e., Total Knee Arthroplasty (TKA) or Unicondylar Knee Arthroplasty (UKA)).

Setting

There are approximately 5.8 million inhabitants in Denmark, and every citizen has a unique 10-digit Civil Personal Register (CPR) number in the Danish Civil Registration System (DCRS), and by this number citizens can be cross-linked across different databases and be traced until death or immigration.

Data sources

The Danish Civil Registration System (DCRS) contains information on the CPR number, vital and migrant status, cohabiting status, and municipality of residence.[27]

The Danish Knee Arthroplasty Register (DKR) is nation-wide register that contains information on all primary knee arthroplasty procedures and revisions performed in Denmark, e.g., baseline characteristics as age, sex, BMI, at the time of KA operation. The registry started in 1997 and the reporting to the registry became mandatory since 2006. DKR is known for high degree of coverage and completeness.[28,29]

The Danish Microbiology Database (MiBa) is a national database containing data from all samples received by the Danish clinical microbiology departments from both hospitals and general practices with complete coverage since 2010. [30]

The Danish National Patient Register (DNPR) is a valuable tool for epidemiological research, providing longitudinal registration of diagnoses, treatments, and examinations derived from every hospital contact in Denmark with complete nationwide coverage since 1978. [31]

The Danish National Prescription Registry has kept information on all prescriptions for drugs dispensed by community pharmacies in Denmark since 1994 according to Anatomical Therapeutic Chemical (ATC) classification system (ATC codes). Data from the Danish National Prescription Registry does not include hospital dispensaries.[32]

The Danish Registers on Personal Income and Transfer Payments contains more than 160 variables including salaries, entrepreneurial income, taxes, public transfer payments, capital income, private pension contributions, and pay-outs. In addition, Statistics Denmark provide more detailed registers on specific income transfers, including sickness benefit, old age pension, disability pension, and cash and unemployment benefits.[33]

The Danish Population Education Register provides information on education status on Danish population, and it carries high degree of validity and coverage.[34]

Study population

We will include patients with primary/idiopathic or secondary (due to meniscus or cruciate ligament lesion) osteoarthritis (OA) who received primary KA in the period from 2011 and 2021. Patients will be identified from the DKR. Patients are followed for 2 years, until first revision, death or migration, whichever comes first.

Variables

Outcomes:

1. Revision due to any cause at two different observation periods within 1) 90 days and b) 2 years following KA. Revision surgery with debridement and/or exchange of at least one component will be based on a composite endpoint (34)
2. Revision due to infection within 1) 90 days and b) 2 years following KA: our definition of infection is adapted from the European Bone and Joint Infection Society (EBJIS) criteria [35] as at least one of the following
    A. DKR-registered revision surgery due to infection.
    B. At least 2 deep-tissue samples of phenotypically indistinguishable bacteria isolated from at least 3 deep-tissue samples
    C. One or more positive intraoperative samples from a closed fluid aspirate AND a biopsy (fluid AND tissue) of phenotypically indistinguishable bacteria isolated.
3. Antibiotic use within 30- and 90-days following KA as measure of knee related infection will be defined as the use of one of the following oral antibiotics: dicloxacillin, flucloxacillin,

phenoxymethylpenicillin, or amoxicillin as suggested by Milandt et al.[36] Other antibiotics recommended by the international consensus for treating joint infections will also be considered knee-related: oral ciprofloxacin, roxithromycin, linezolid, cefuroxime and cefalexin. [37]

4. Antibiotic use within 30- and 90-days following KA due to other causes: any oral antibiotic other than the forementioned ones.
5. Mortality registered in the DCRS by date up to 2 years following KA surgery.

Covariates

We will identify our cohort as patients, who had a BAS before the date of index arthroplasty based on the NOMESCO (Nordic Medico-Statistical Committee) Classification of Surgical Procedures from the DNPR (KJDF10 & KJDF11 [gastric bypass]; KJDF20 & KJDF21 [gastric banding]; KJDF40, KJDF41, KJDF96 & KJDF97 [gastric sleeve]). The comparator (unexposed) group will be patients without BAS before KA.

BMI category and the type of KA (TKA and UKA). will be used for stratifying into subgroups, differentiating individuals into appropriate baseline strata. For matching we will be using the following pre-KA-exposure covariates: age (years) at the year of KA, sex (male/female), household income (at the year of KA, categorized into quartiles), highest completed education (at the year of KA, categorized into 3 categories: <11, 11 to 15, and >15 years).

Comedication (at least one redeemed prescription 365 days earlier to index KA - 60 days for antibiotics): 1) Glucose-lowering due to the association between DM and surgical complications.[38,39] 2) Antithrombotic medications and 3) NSAIDs because of the possible postoperative bleeding-related complications [40] and 4) Antiresorptives due to the possible increased risk of revision.[41] The last covariate to be included in matching and adjustment is Elixhauser Comorbidity Measure (ECM) (at the year of KA, categorized into 3: 0, 1-2 and ≥ 3), ECM is validated comorbidity scoring measure that has shown highest discriminative ability for the occurrence of all categories of postoperative adverse outcomes following orthopedic surgeries.[42-44]

For sensitivity analyses we will analyse the type of BAS and the calendar year of BAS and the calendar year of KA.

Database construction and handling

We will extract data from all patients receiving KA in period from 2011 and 2023 the DKR, the dataset will be enriched with the relevant variables by cross-linking the CPR numbers from the MiBa and will be sent to

Statistics Denmark, where the baseline socioeconomic data will be supplied. The database will be then enriche with baseline health-related data from the Danish Health Data Authority (DHDA). The final database will be kept and handled inside an encrypted server belonging to Statistics denmark. Data is handled in the most recent version of R (www.r-project.org). The primary author (SMS) will be responsible for data management.

Data control and editing

In case of bilateral KA, the first one will be treated as study unit. In case of simultaneous bilateral KA, patients will be excluded.
We expect some missing values in our study and these values will be omitted, no data imputation will be used.
Extreme values for continuous variables will be tested by using plots and histograms to identify the possible entry-errors.
In case of abnormal data entries, e.g., wrong date format, it will be corrected if possible, otherwise the values will be omitted.

Statistical Methods

We will use descriptive statistics for the baseline characteristics of the two groups stratified for BMI and the type of KA. To address possible survival bias, number of deaths in the exposed and non-exposed groups will be reported.

First, we will run a non-adjusted (crude) analysis comparing outcomes between patients exposed and unexposed to BAS. Then we will perform a propensity score matched analysis, where we do exact matching based on BMI (non-obese: BMI < 30 kg/m^2, obese: BMI 30-39 kg/m^2, morbidly obese: BMI ≥ 40 kg/m^2) and the type of KA (i.e., TKA or UKA). Propensity scores will be estimated using a logistic regression model and will be based the forementioned covariates. We will use greedy match algorithm in a ratio of up to 1:5 of patients exposed to bariatric surgery and those who are not, in order to minimize the mean squared error of the estimated treatment effect in several scenarios, difference of maximum of 0.2 logit will be used in propensity score matching [45]. Following that, we will do a propensity score matched analysis with interaction term for BMI.

For dichotomous outcomes, a cox regression will be performed to report hazards ratio with the corresponding two-sided 95% confidence intervals (Cis) and a p-value of <0.05 will be considered as statistically significant.

To validate the propensity score matching, we will report the standardized differences of the means (or medians) of continuous variables or the prevalence of dichotomous baseline covariates between each set of groups by using the standardised differences. We will apply a standardized difference of ≥0.25 to indicate that there might be a meaningful imbalance in the baseline covariate.

Sensitivity analyses

We will do a sensitivity analysis to test whether the gap between BAS and KA would influence the obtained result by limiting the gap ≤12 months, 13-24 months and >24 months. To investigate whether the type of Bariatric Surgery (BAS), such as gastric banding or gastric bypass, has an impact on the outcomes, we plan to conduct a sensitivity analysis. This will involve narrowing our focus to each specific type of BAS. This particular approach has not been previously applied, and the findings could prove to be significant.

Patient and Public Involvement (PPI)

This project follows the EULAR recommendations for the inclusion of patient representatives in the contemporary scientific process.[46] This protocol was introduced to a Danish PPI. The research questions and the reported outcomes was discussed from the PPI perspectives.

HEALTH RESEARCH ETHICS AND GENERAL CONSIDERATIONS

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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

In Denmark, the Act on Processing of Personal Data does not require ethical permission or obtained consent for anonymised retrospective register studies. The Danish Data Protection Agency has approved the study with nr p-2023-14433.

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