



OBESITY AND REVISION SURGERY, MORTALITY, AND PATIENT-REPORTED OUTCOMES AFTER PRIMARY KNEE REPLACEMENT SURGERY: A REVIEW

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Abstract

Introduction: Access to Total knee replacement arthroplasty (TKA), a life-changing operation has recently been restricted based on body mass index (BMI) due to belief that high BMI may lead to poorer outcomes. Aim of the study is to investigate the associations between BMI and revision surgery, mortality, and pain/function following primary total knee arthroplasty (TKA).

Methods: In this retrospective observational cohort study, TKAs registered in the Indian Joint Registry (IJR) between 2005 to 2021 will be investigated for 90-day mortality and 10- year cumulative revision. After adjustment for age, gender, American Society of Anaesthesiologists (ASA) grade, indication for operation, year of primary TKA, and fixation type, patients with high BMI versus normal BMI will be compared with respect to revision surgery, mortality, and patient-reported outcomes after primary knee replacement surgery.

Conclusion: Association of BMI and with primary TKA as well as with the predisposition to revision TKA throws light on the need for weight reduction before primary TKA.

Keywords: TKA, surgery, BMI

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Introduction

Total knee replacement (TKR) is one of the most common orthopaedic operations and is generally considered to be both safe, cost-effective, and clinically effective in reducing symptoms of pain and functional limitation in most patients. The main reasons for performing a TKR are joint pain and/or functional limitation in combination with radiographic evidence of arthritis. The effectiveness of total knee arthroplasty (TKA) in relieving pain and improving function has been well documented [1,2]. TKA is considered a cost effective and efficacious treatment for patients with end stage knee osteoarthritis who experience severe pain, activity limitations and for whom conservative treatment is unsuccessful [3-5]. With more than 700 000 primary TKAs performed annually in the USA, estimates of TKA are projected to increase to 673 % by 2030 in the USA. The large demand for TKA is primarily related to the aging population, the obesity epidemic and technical advancement of the surgical procedure [6-8]. The longevity of implants is typically greater than 10 years with 32,700 revisions performed annually in the USA. Significant demand for primary TKA will correspond to a growing demand for revisions of TKA which are projected to increase by 601 % from 2005 to 2030 [6].

Revisions for TKA pose unique challenges as revision surgery is a more complex surgery than a primary TKA with increased complication and mortality rates. Although good results are presented, the outcomes are worse in comparison with those of primary TKA, with a higher failure rate. There are multiple variables linked to these results, and it is difficult to determinate the exact cause as it is often a multifactorial issue. These variables may be related to the quality of the index-procedure (TKA), to the revision procedure or to patient characteristics. Obesity is one of the variables contributing to this.

A more comprehensive understanding of the potential risk factors that lead to the revision of TKA will provide important knowledge for surgeons and patients. The objective of this study is to explore whether obesity is one of the factors that lead to increased risk of revision surgery following TKA.

Current need assessment

According to a market survey, the numbers of joint replacement surgeries in India are increasing every

Methodology

Total number of TKAs implanted between 2005 and 2021 will be investigated to note the proportion

year with the estimates for knee arthroplasty numbers in India to be around 2,00,000 in 2020 [9] and the hip arthroplasties are set to grow at the highest rate in the world from the period 2020–2026 [10]. Since the population curve of India is bell shaped, it is expected that many more people are going to enter their 50s and 60s in the coming decade. It has been estimated that the total joint replacement burden after a decade would be multifold as compared to what it is today [10].

There is growing evidence that some commissioners of health services in the UK are either restricting access to TKR for patients with high BMI or encouraging weight loss prior to referral for surgery [11,12]. This may be as a result of a belief that these patients are at a higher risk of complications. Surgeons may express concerns that increased load on a prosthesis increases the risk of failure due to loosening or wear or that the operation itself is more difficult, resulting in an increase in perioperative problems [13]. This is despite evidence that overall, the absolute risk of postoperative complications within the first 6 months of TKR is low in patients with a high BMI [14]. National guidance in the UK is clear that in patients with clinical osteoarthritis, while interventions to achieve weight loss are recommended, a high BMI and other patient specific factors should not be barriers to referral for joint replacement [15]. In contrast to this, there is some evidence from joint registries, observational cohort studies, and routine hospital admission data that high BMI is associated with poorer outcomes with regard to pain and function, mortality, complications, and need for revision surgery [14,16]. Whether these observed associations transfer to be clinically meaningful is as yet unclear.

Rationale

While total knee replacements (TKRs) are generally considered safe and effective, it has been suggested that patients with high body mass index (BMI) are at increased risk of poor outcomes, leading to policies restricting who is referred for surgery. Previous studies of the impact of BMI have used smaller datasets or have focused on a single outcome rather than the wider focus of our study which aimed to investigate whether patients with a raised BMI operated on within the Indian Joint Registry (IJR) had demonstrably worse outcomes following TKR.

of patients that died within 90 days, how many implants needed revising (redo surgery) after 10 years, and the changes between preoperative and 6-month postoperative Oxford Knee Score (OKS).

Patients with higher BMI (according to the World Health Organization (WHO) categories) will be compared to those with a “normal” BMI.

Study design and data source

An observational cohort study will be performed using data obtained from the Indian Joint Registry.

Data linkages, participants, and inclusion criteria

The IJR started collecting BMI data on April 1, 2005, and patients undergoing primary TKR from this date up to and including December 31, 2021 for revision and mortality outcomes will be investigated.

Data on patients with missing or implausible BMI, age or gender, unspecified TKA fixation type, TKAs performed for trauma as well as for patients without a specified identity (preventing linkage) or with an unknown indication will be excluded.

Outcomes

The outcome variables for this study are revision surgery (defined as the addition, removal, or modification of any part of the construct), mortality within 90 days of the primary operation, and patient-reported outcome assessed using the change in OKS after 6 months. The OKS is a patient-completed questionnaire that assesses knee pain and function with 12 questions, each scored from 0 to 4, completed using Likert scales, and the scores are summed to give a score from 0 (worst) to 48 (best) [17]. In cohort studies, the minimal detectable change (MDC) in OKS at the group level has been shown to be 4 points [18].

Exposure variable

The primary exposure of interest is BMI at the time of operation defined according to the World Health Organization (WHO) International Classification: <18.5 kg/m² (underweight); 18.5 to 24.99 kg/m² (normal weight); 25 to 29.99 kg/m² (overweight); 30 to 34.99 kg/m² (obese class I); 35 to 39.99 kg/m² (obese class II); and > 40 kg/m² (obese class III)

Statistical analysis

Kaplan–Meier estimates with risk tables will be plotted to explore cumulative probability of revision up to 10 years and death up to 90 days for the BMI categories. Time zero will be considered the time of the primary operation, patients will be considered to have exited the study after the first revision episode is observed, and patients will be censored upon death and administratively censored on December 31, 2021. Flexible parametric

survival models as described by Royston and Parmar will be used to investigate the association between BMI category and the risk of revision [19]. To choose a suitable scale and baseline complexity for the model, a univariable model (on the BMI category) will be fitted. The choice of scale and number of knots for baseline spline function will be assessed by inspecting the Akaike information criterion (AIC) and Bayes information criterion (BIC) statistics.

Cox proportional hazards regression models will be used to investigate 90-day mortality. Age, gender, ASA grade, indication for operation, and year of primary TKR will be adjusted. The assumption of proportionality of hazards will be assessed visually and through the use of Schoenfeld residuals. Linear regression modelling (ANCOVA) will be used to describe the association of BMI on 6-month OKS, adjusting for preoperative OKS as a covariate in the model and known available confounders. Stata 14.2 will be used for all analyses.

For survival outcomes, each knee replacement will be treated as an individual; this is possible given the nature of reporting of both primary and revisions in the IJR.

Sensitivity analysis

Further confounders will be adjusted that can be derived only from the subset of patients with linked data (Charlson comorbidity score and IMD deprivation score) to estimate revision and mortality.

Missing data

A comparison of demographic characteristics of participants with and without a recorded BMI was conducted to investigate the potential for selection bias.

Planning of analyses

The analysis will be planned prior to the start of all analyses. No data-driven changes to the analysis plan will be made. An additional sensitivity analysis with BMI as a continuous variable using splines (at WHO cutoffs) to investigate nonlinearity will be included.

Reporting of the study will be in keeping with guidance provided in the Reporting of studies Conducted using Observational Routinely-collected Data (RECORD) statement (S1 Checklist) [20]. Approval for this study was granted by the NJR research subcommittee reference. Written consent was granted by patients for inclusion of their data and its use in research within the NJR for England, Wales, Northern Ireland, and the Isle of Man.

Conclusion

Study may provide evidence to support clinically relevant worse outcomes following TKA for patients with a raised BMI. These findings give an idea whether restriction of referral for knee replacement based on BMI is necessary. Study results may highlight on the fact that even if some patients with raised BMI are at risk of poorer outcomes, the outcomes remain acceptable by contemporary standards, and the selection process of orthopaedic surgeons is effective at identifying the correct patients to operate on at a population level.

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