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The impact of BMI and smoking on risk of revision following knee and hip replacement surgery: evidence from routinely collected data

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SUMMARY

Objective: The aim of this study was to assess the association of body mass index (BMI) and smoking with risk of revision following total knee replacement (TKR) and total hip replacement (THR).
Design: Primary care data, from the Clinical Practice Research Datalink (CPRD), was linked to inpatient hospital records, from Hospital Episode Statistics Admitted Patient Care (HES APC), and covered 1997 to 2014. Parametric survival models, with BMI and smoking status included as explanatory variables, were estimated for 10-year risk of revision and mortality, and were extrapolated to estimate lifetime risk of revision.
Findings: TKR and THR cohorts included 10,260 and 10,961 individuals, respectively. For a change in BMI from 25 to 35, the 10-year risk of revision is expected change from 4.6% (3.3–6.4%) to 3.7% (2.6–5.1%) for TKR and 3.7% (2.8–5.1%) to 4.0% (2.8–5.7%) for THR for an otherwise average patient profile. Meanwhile, changing from a non-smoker to a current smoker is expected to change the risk of revision from 4.1% (3.1–5.5%) to 2.8% (1.7–4.7%) for TKR and from 3.8% (2.8–5.3%) to 2.9% (1.9–4.7%) for THR for an otherwise average patient profile. Estimates of lifetime risk were also similar for different values of BMI or smoking status.
Conclusions: Obesity and smoking do not appear to have a meaningful impact on the risk of revision following TKR and THR.
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Introduction

Total knee replacement (TKR) and total hip replacement (THR) lead, on average, to substantial improvements in pain, function, and overall quality-of-life[1,2], although between 15% and 30% of patients are dissatisfied with their outcome[3,4]. While these procedures are costly to provide, they are generally considered a cost-effective use of healthcare resources due to their associated health gains[5]. With healthcare budgets stretched, however, the provision of joint replacements has come under increased pressure.

Current guidelines from the National Institute for Health and Care Excellence (NICE) explicitly state that an individual's body mass index (BMI) or smoking status should not be a barrier to surgery referral[6]. However, in the English National Health Service (NHS), a number of clinical commissioning groups (CCGs) have restricted access to surgery on the basis of patient characteristics[7]. In 2015, 22% of CCGs had a mandatory policy for knee and replacement regarding BMI, varying in their cut-offs from a BMI of 30–40, while another 17% of CCGs had voluntary policies to encourage weight loss but not used to restrict access[8]. Meanwhile 4% of CCGs had mandatory policies requiring smoking cessation and another 3% had voluntary policies to encourage smoking cessation[8].

While such policies may be justified if they led to improved patient outcomes, there is relatively little evidence that this is the case. While higher BMI is associated with worse patient-reported outcomes after total knee replacement (TKR) and THR, this effect is small and unlikely to be clinically meaningful[9,10]. Meanwhile, smoking appears to have little effect on function after surgery[11].

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Both higher BMI and smoking have though been associated with an increased risk of systemic post-operative complications, such as venous thromboembolism and cardiac events, with individuals who are smokers and obese found to have a 50% increase in their odds of systemic complications in one study[12]. These post-operative complications are relatively rare, however, with the incidence of symptomatic venous thromboembolism between 2% and 4% and the incidence of myocardial infarction between 0.2% and 0.5%[13–15]. Consequently, any difference in absolute risks of adverse events is likely to be small. Indeed, restricting access to surgery for those with a BMI of 35 or above is expected to result in 16 patients denied a complication-free surgery per complication avoided, which is only slightly better than the 19 patients that would be denied a complication-free surgery if rationing was done randomly[16].

Alongside patient-reported outcomes after surgery and risks of post-operative complications, risk of revision, in which implant components are removed, added, or exchanged, is a key determinant of the cost-effectiveness of TKR and THR. Revision procedures are associated with significant reductions in patient-reported outcomes across all dimensions of patient quality of life[17], and substantial costs for the health system, with revisions typically costing more than primary procedures[18]. The relationship of BMI and smoking with the risk of revision is not yet well understood.

The aim of this study was to assess the association between BMI and smoking and the risk of revision following TKR and THR.

Methods

Study design

A dynamic cohort study design was used, with individuals diagnosed with arthritis who went on to receive a joint replacement included. The effect of BMI and smoking status, recorded in the year before surgery, on the 10-year risk of revision was assessed. The observed cumulative incidence of revisions and estimated hazard ratios (HRs) were compared using parametric survival models that controlled for age, sex, diagnosis, comorbidities, and socioeconomic status. The partial effect of BMI and smoking status on overall lifetime risk of revision was estimated by combining and extrapolating the estimated risks of revision and death following surgery using a state-based Markov model.

Setting

Primary care NHS records data were extracted from practices within the Clinical Practice Research Datalink (CPRD), which is a large, representative database of anonymised records from general practices[19]. These data were linked to inpatient hospital records in England, provided by Hospital Episode Statistics Admitted Patient Care (HES APC), and mortality data from the Office for National Statistics (ONS). The linked dataset covered 1997 to 2014.

Participants, data sources, and measurement

Knee-related and hip-related diagnosis cohorts were established separately to inform the analysis of TKR and THR. Individuals were included in the knee-related cohort if they had an incident (newly recorded) diagnosis of rheumatoid arthritis (RA) or knee osteoarthritis (OA). If an individual had diagnoses of both RA and knee OA, RA was taken as the index diagnosis. Similarly, individuals were included in the hip-related cohort if they had an incident diagnosis of RA or hip OA. Individuals could contribute to both the knee-related and hip-related cohorts.

For each of the diagnosis cohorts, the first occurrence of a TKR or THR following diagnosis was identified using HES APC. Individuals who received a bilateral surgery, where both the left and right joints were replaced concurrently, were excluded from the analysis. If an individual received multiple TKRs or THRs following diagnosis, only the first was included in the analysis.

RA and knee and hip OA were identified using clinical codes in the CPRD. Individuals' sex was derived from the CPRD. The date of a procedure recorded in HES APC and an individual's year of birth recorded in the CPRD were used to calculate age at surgery. Diagnostic codes (ICD-10) in HES APC were used to derive the Royal College of Surgeons Charlson score, which provides a summary measure of comorbidities[20]. RA diagnosis was excluded from the Charlson score calculation as it was accounted for separately in the analysis. Individuals' sex and socio-economic status were derived from the CPRD. Socio-economic status was measured by the patient-level index of multiple deprivation (IMD) with study participants grouped based on quintiles of IMD, with those in the 5th group the most deprived. BMI, as a continuous value and categorised as underweight or normal range (BMI $\leq$ 25), overweight (BMI >25 and $\leq$ 30), or obese (BMI >30), and smoking status (non-smoker, ex-smoker, or current smoker) were taken from the CPRD. Only values recorded within a year of surgery were included.

Study participants were followed for up to 10 years after surgery, with only 6% of study participants having additional follow-up available. In the absence of an event of interest, follow-up was censored before 10 years if a second TKR or THR was recorded or if the HES APC data linkage ended earlier. Revisions during follow-up were identified using OPCS-4 codes from HES APC and mortality was identified using ONS records.

Comparison of cumulative incidence of revision

Instances of revisions were compared between the different BMI and smoking status (non-smoker, ex-smoker, or current smoker) groups. The number of events and person years of follow-up are reported with cumulative incidence of revision also estimated.

Estimation of parametric survival models for 10-year risk of revision and mortality

Parametric survival models were used to estimate the association of BMI and smoking with 10-year cause-specific hazards of revision and mortality[21]. These parametric models required assumptions to be made about the underlying distribution of the event of interest. The approach used to choose these distributions is summarised in the Appendix.

Models were first estimated with BMI as a continuous value or smoking status included as the sole explanatory variable. They were then estimated with BMI, smoking status, age at surgery, sex, diagnosis (OA or RA), other comorbidities (measured by the Charlson score), and socioeconomic status (measured by IMD) included as explanatory variables. The merit of including an interaction between BMI and smoking status was considered for each of the survival models using the Wald Chi-squared test, comparing models with and without an interaction term. Non-linearity in age and BMI was considered by fitting restricted cubic splines for these variables and comparing the resulting model fit, using the Akaike information criterion, with that of a model assuming a linear relationship. Based on this approach, BMI was fitted as a linear term in each model.

There were missing data for three of the explanatory variables included in the analysis: IMD, BMI, and smoking status. Multiple imputation was used to account for these missing values. We assumed that the data were missing at random, i.e., the probability

of data being missing did not depend on the unobserved data, conditional on the observed data[22]. Explanatory variables and outcomes were used to estimate 50 imputed datasets. Pooled HRs for explanatory variables and corresponding 95% confidence intervals (CIs) were calculated using Rubin's rules.

Estimating the partial effect of BMI and smoking on lifetime risk of revision

A state-based Markov model combined the cause-specific models for revision and mortality. In such a model, individuals are assumed to be in a particular health state and events are represented as transitions from one state to another with transitions occurring as time progresses in increments[23]. A similar modelling approach has previously been used to estimate individuals' lifetime risk of undergoing primary joint replacement[24,25].

A cohort of individuals enter the model and are always in one of a set of discrete states, with events represented as transitions from one state to another. In this case, individuals began by having a TKR or THR and entered the model in the *unrevised* state. The time horizon for the model was lifetime (up to 100 years of age). As time passed, in yearly cycles, individuals could transition to the *revised* or *death* states. The model required estimates of two key transitions probabilities: *unrevised* to *revised* and, to account for the competing risk of mortality, *unrevised* to *death*. These probabilities were predicted using the cause-specific survival models described above.

To estimate the partial effect of BMI and smoking status on lifetime risk, the Markov model was run for representative patient profiles, varying the value of these characteristics while holding the rest at their average value (median if continuous and mode if categorical). Transition probabilities were based on the predicted survival functions from the respective survival models. As the estimated HRs were similar across multiply imputed datasets, to reduce computational time lifetime risks were estimated using only the models developed on the first imputed dataset. Parameter uncertainty was incorporated using 1,000 bootstrapped models. Cumulative incidence of revision was given by the proportion of patients who transitioned to the *revised* state over time and lifetime risk of revision was calculated using the proportion of patients who transitioned to the *revised* state over the duration of the model.

Results

Participants

The TKR and THR cohorts included 10,260 and 10,961 individuals, respectively. A study inclusion flowchart is provided in Appendix Fig. A1. The observed characteristics of the individuals in these cohorts are summarised in Table I.

Table I
Patient characteristics at time of surgery in the total knee replacement (TKR) and total hip replacement (THR) cohorts

	TKR	THR
n	10,260	10,961
Age at surgery (median [IQR])	71.0 [64.0, 77.0]	70.0 [62.0, 76.0]
Sex: Female (n (%))	5834 (56.9)	6436 (58.7)
Year of surgery (median [IQR])	2009 [2006, 2011]	2008 [2005, 2011]
Diagnosis: RA (n (%))	851 (8.3)	639 (5.8)
Charlson score (n (%))		
0	7804 (76.1)	8677 (79.2)
1+	2456 (23.9)	2284 (20.8)
IMD (n (%))		
1 (least deprived)	2330 (22.7)	2779 (25.4)
2	2487 (24.2)	2794 (25.5)
3	2383 (23.2)	2479 (22.6)
4	1930 (18.8)	1923 (17.5)
5 (most deprived)	1121 (10.9)	980 (8.9)
Missing	9 (0.1)	6 (0.1)
BMI (median [IQR])	30.3 [26.9, 34.3]	28.2 [25.0, 31.9]
BMI category (n (%))		
Normal or underweight	660 (6.4)	1075 (9.8)
Overweight	1593 (15.5)	1656 (15.1)
Obese	2526 (24.6)	1649 (15.0)
Missing	5481 (53.4)	6581 (60.0)
Smoking status (n (%))		
Non-smoker	2737 (26.7)	2543 (23.2)
Ex-smoker	2442 (23.8)	2233 (20.4)
Current smoker	486 (4.7)	714 (6.5)
Missing	4595 (44.8)	5471 (49.9)

TKR: total knee replacement; THR: total hip replacement; RA: rheumatoid arthritis; IMD: index of multiple deprivation; BMI: body mass index. The Charlson score calculation omitted diagnoses of rheumatoid arthritis as it was treated as a distinct variable in the analyses.

Cumulative incidence of revision

The 10-year cumulative incidence of revision for BMI and smoking status groups are summarised in Table II. The overall 10-year cumulative incidence of revision was 5.12 (95% CI: 4.32–6.06%) after TKR and 4.87% (4.20–5.65%) after THR. The CIs of all of the BMI groups and smoking status groups overlapped with one another, see Table II.

Cause-specific risk of revision

HRs for the 10-year risk of revision following TKR and THR are given for each BMI and smoking status group in Table III. After adjusting for other explanatory factors, BMI was not associated with a large or statistically significant difference in revision risk: HRs per unit increase in BMI were 0.99 (0.96–1.03) for TKR and 1.02 (0.99–1.06) for THR. After controlling for other explanatory factors, being a smoker was associated with a reduced revision risk relative to non-smokers, but the difference was not statistically significant: HRs were 0.71 (0.39–1.29) for TKR and 0.76 (0.44–1.32)for THR. HRs for the other explanatory factors are summarised in the Appendix Tables A1 and A2.

Predicted risk of revision

The average individual undergoing a TKR had a diagnosis of knee OA, was 71, female, was in the second highest (least deprived) IMD group, had a Charlson score of 0, BMI of 30, and was a non-smoker. Individuals with these characteristics were estimated to have a 10-year and a lifetime risk of revision after TKR of 4.1% (3.1–5.5%) and 5.3% (3.8–7.2%) respectively. Meanwhile, the average individual undergoing a THR had a diagnosis of hip OA, was 70, female, was in the second highest (least deprived) IMD group, had a Charlson score of 0, BMI of 28, and was a non-smoker. Individuals with these characteristics were estimated to have a 10-year and a lifetime risk of revision after THR of 3.8% (2.8–5.3%) and 8.2% (5.6–11.9%), respectively.

Transition probabilities for risk of revision and cumulative incidence of revision estimated for different values of BMI with other characteristics held at their average values are shown in Fig. 1. It can be seen that the transition probabilities, estimated based on the parametric survival models described previously, were similar for different values of BMI. The estimated cumulative incidences of revision, which incorporates the competing risk of mortality, were also similar. At 10 years following surgery, if BMI moved from 25 to 35 the risk of revision was expected to change from 4.6% (3.3–6.4%) to 3.7% (2.6–5.1%) for TKR and 3.7% (2.8–5.1%) to 4.0% (2.8–5.7%) for THR. For otherwise average individual, BMI changing from 25 to

Table II
Incidence of TKR and THR revisions by body mass index (BMI) and smoking status

	TKR		THR	
	Revisions/PYs	10-year cumulative incidence (%)	Revisions/PYs	10-year cumulative incidence (%)
Total	257/34153	5.12 (4.32–6.06)	248/43151	4.87 (4.20–5.65)
BMI				
Underweight or normal range (BMI ≤ 25)	24/1999	6.44 (4.25–9.76)	19/3848	3.69 (2.23–6.12)
Overweight (BMI >25 and ≤ 30)	31/5050	3.69 (2.31–5.87)	40/5759	6.43 (4.32–9.55)
Obese (BMI >30)	73/7329	7.38 (4.84–11.27)	48/5767	5.98 (4.25–8.43)
Missing	129/19775	4.58 (3.66–5.73)	141/27777	4.46 (3.68–5.39)
Smoking status				
Non-smoker	67/8657	4.68 (3.54–6.18)	54/9387	5.24 (3.75–7.34)
Ex-smoker	68/7230	5.49 (3.88–7.77)	48/7692	4.41 (3.02–6.43)
Current smoker	12/1552	4.26 (2.37–7.66)	13/2479	5.09 (2.43–10.66)
Missing	110/16715	4.90 (3.85–6.24)	133/23594	4.81 (3.98–5.81)

Revisions within 10 years of a total knee replacement (TKR) or total hip replacement (THR). PYs: person years, BMI: body mass index.

Table III
Estimated effect of BMI and smoking status on cause-specific risk of revision over 10 years following TKR and THR

	TKR		THR	
	Univariable	Multivariable	Univariable	Multivariable
BMI: per additional unit (HR (95% CI))	1.02 (0.99–1.05)	0.99 (0.96–1.03)	1.03 (1.00–1.07)	1.02 (0.99–1.06)
Smoking status (HR (95% CI))				
Non-smoker	*ref*	*ref*	*ref*	*ref*
Ex-smoker	1.20 (0.87–1.67)	1.14 (0.81–1.60)	1.07 (0.76–1.51)	1.02 (0.71–1.46)
Current smoker	0.99 (0.55–1.78)	0.71 (0.39–1.29)	0.86 (0.50–1.46)	0.76 (0.44–1.32)

Hazard ratios (HRs) associated with a one-unit increase in body mass index (BMI) and smoking status, respective to being a non-smoker, with 95% confidence intervals (CIs). Multivariable models included age, sex, diagnosis (osteoarthritis or rheumatoid arthritis), Charlson score (0 or 1+), and index of multiple deprivation group as explanatory factors. Multiple imputation was used for missing data and models were pooled using Rubin's rules.

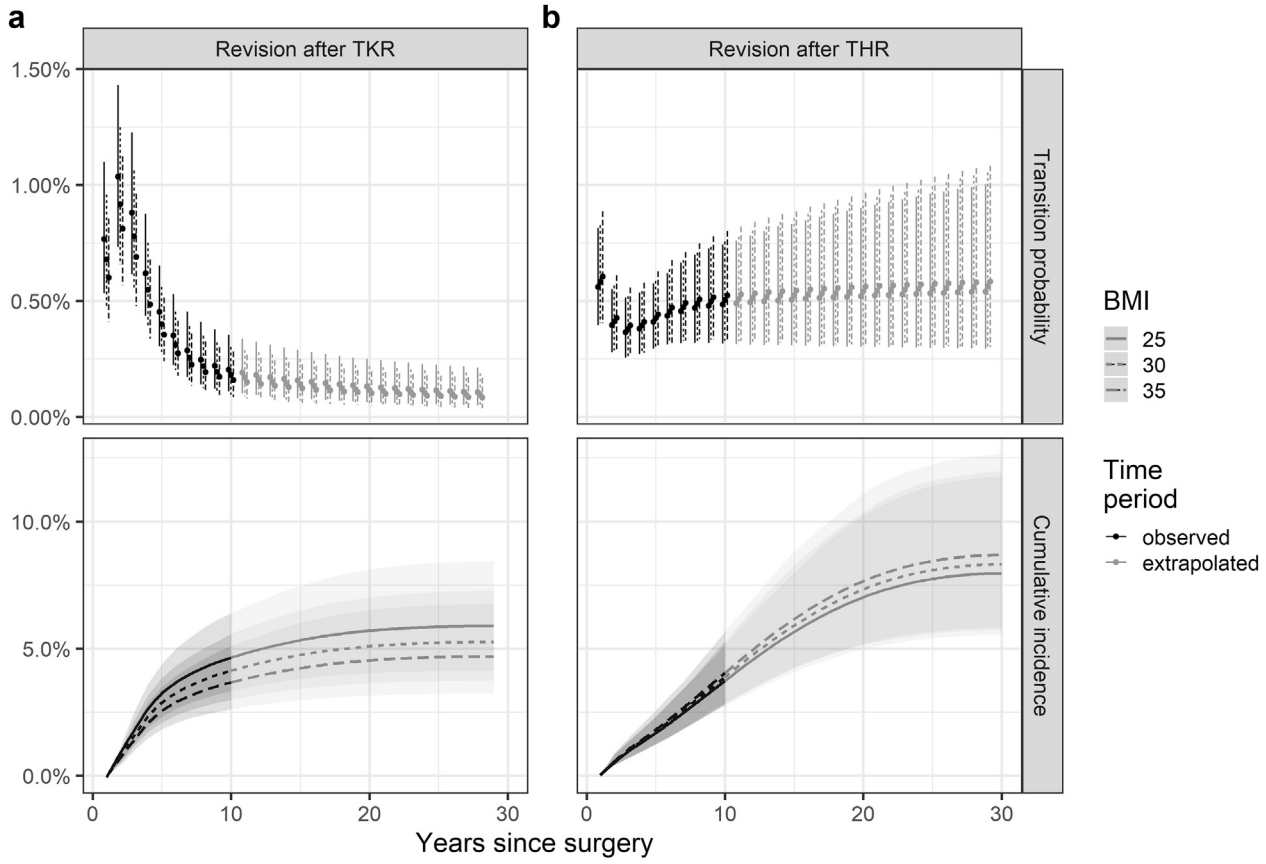

Fig. 1. Partial effect of body mass index (BMI) on transition probabilities and cumulative incidence of revision following a) total knee replacement (TKR) and b) total hip replacement (THR).

35 would be expected to change lifetime risk of revision from 5.9% (4.1–8.4%) to 4.7% (3.2–6.8%) for TKR and from 8.0% (5.5–11.8%) to 8.7% (5.8–12.7%) for THR.

Transition probabilities for risk of revision and cumulative incidence of revision estimated for each different level smoking status with other characteristics held at their average values are shown in Fig. 2. It can be seen that the transition probabilities and cumulative incidences of revision were similar for each. At 10 years following surgery, changing from a non-smoker to an ex-smoker or a current smoker was expected to change the risk of revision from 4.1% (3.1–5.5%) to 4.7% (3.4–6.6%) or 2.8% (1.7–4.7%) respectively for TKR, and from 3.8% (2.8–5.3%) to 3.8% (2.7–5.4%) or 2.9% (1.9–4.7%) for THR. For otherwise average individual, ex-smokers and current smokers had estimated lifetime risk of revision of 5.9% (4.1–8.6%) and 3.5% (2.0–6.1%)for TKR and 8.0% (5.4–11.9%) and 6.0% (3.8–10.2%) for THR.

Discussion

Key results

Obesity and smoking status had little meaningful effect on the estimated risk of revision following TKR and THR. The average individual undergoing surgery had a 10-year risk of revision of 4.1% (3.1–5.5%) after TKR and 3.8% (2.8–5.3%) after THR. At 10 years following surgery, for an otherwise average patient, if BMI moved from 25 to 35 the risk of revision was expected to change from 4.6% (3.3–6.4%) to 3.7% (2.6–5.1%) for TKR and 3.7% (2.8–5.1%) to 4.0% (2.8–5.7%) for THR. Meanwhile, changing from a non-smoker to a current smoker for an otherwise average patient was expected to change the risk of revision from 4.1% (3.1–5.5%) to 2.8% (1.7–4.7%) for TKR and from 3.8% (2.8–5.3%) to 2.9% (1.9–4.7%) for THR.

Study findings in context

Most studies have not found BMI to have a significant effect on the overall risk of revision following THR or TKR[26,27]. However, a large cohort study using primary care data found higher BMI to be associated with a small but significant increase in risk of revision, with an additional unit of BMI associated with HRs of 1.02 for both TKR and THR[28]. This previous finding agrees with the point estimate for THR and falls within the confidence interval for TKR found here.

There is also evidence that the risk of revision is particularly increased for higher levels of BMI. A meta-analysis of studies assessing the impact of obesity on risk of revision after TKR found that a BMI over 30 was associated with an increased risk of revision, relative to a BMI under 30[27]. Individuals with morbid obesity (BMI greater than or equal to 40) have previously been found to have a significantly increased risk of revision for THR[29]. The merit of incorporating a non-linear relationship between BMI and risk of revision was considered for this study. However, there was insufficient evidence to warrant its inclusion, possibly because few patients in the cohort were morbidly obese at the time of surgery.

The association between smoking status and outcomes following TKR and THR has not been studied to the same extent as other risk factors. Studies that have considered the effect of smoking on outcomes have generally not had sufficient follow-up to study the long-term risk of revision[30]. In contrast to our findings, heavy smoking was associated with an increased risk of revision after THR in one study[31].

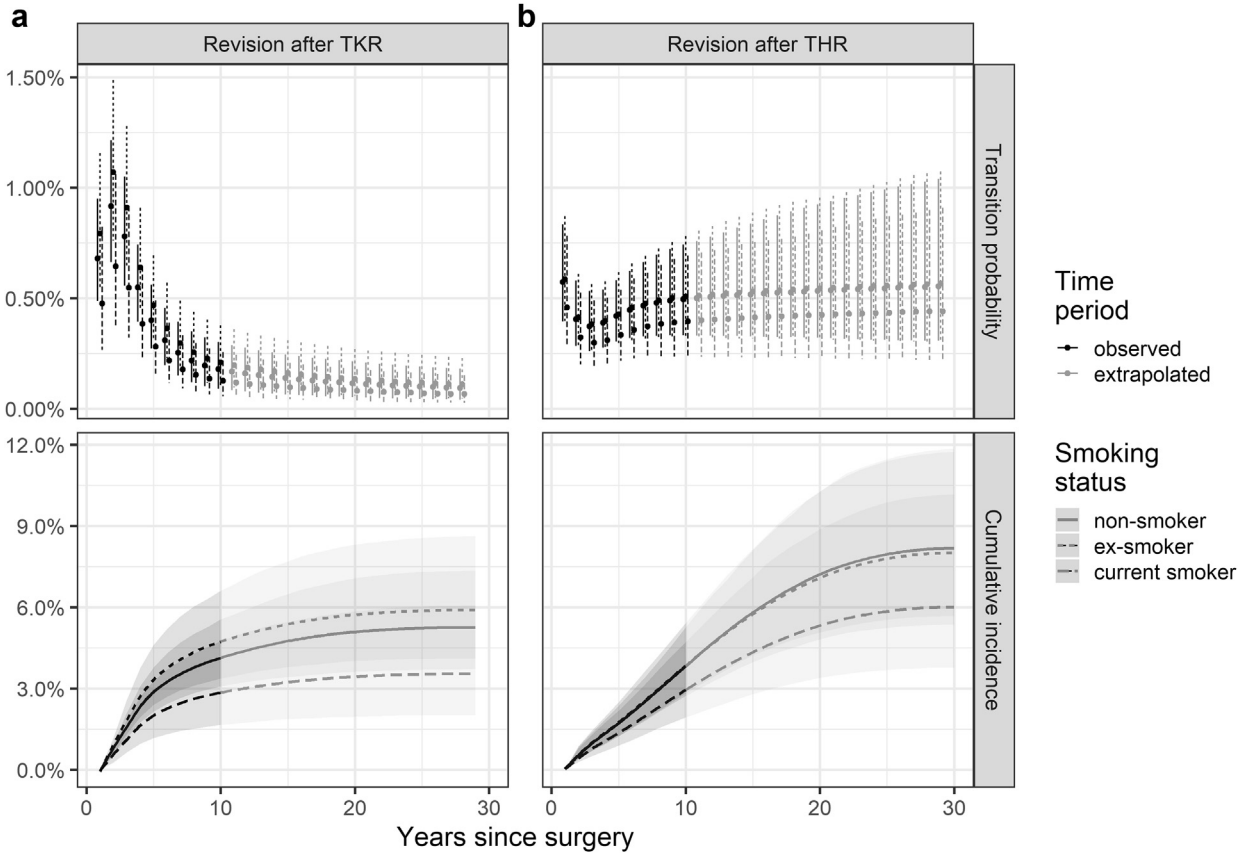

Fig. 2. Partial effect of smoking status on transition probabilities and cumulative incidence of revision following a) TKR and b) THR.

Strengths and limitations of this study

This study was informed by a large cohort derived from routinely collected data. The accuracy of the coding in such datasets is a concern, as the data are not collected primarily for research purposes. We used validated codes where possible. However, while the codes used to identify diagnoses of RA in CPRD have previously been validated[32], the codes for OA have not. As individuals identified for the study all went on to have joint replacements, we can expect a high specificity for the OA diagnosis.

BMI and smoking status are not typically collected in secondary care records. We were able to assess their effect on risk of surgery revision by linking primary and secondary healthcare records. However, BMI data were missing for 53% of the TKR cohort and 60% of the THR cohort. If data was not missing completely at random, which is likely to be the case here, using a complete case approach would have led to bias[33]. We minimised the potential bias from missing data by using multiple imputation, which produces plausible values for missing data while incorporating the uncertainty that necessarily surrounds any such estimates[22].

As this study was based on routinely collected data, we used BMI as a proxy variable for body fat. However, BMI is an indirect measure of body fat based on weight and height, and does not account for the difference between fat and non-fat mass, such as muscle[34]. The errors in measurement associated with BMI may have led to underestimating the true effect of body fat on risk of revision. Laterality was also unavailable in the data and so individuals with bilateral procedures and follow-up was censored where a second primary occurred, so that revision procedures could be linked to a primary procedure. Excluding bilateral procedures means that our results are specific to unilateral procedures and may not be generalisable to bilateral procedures, while censoring at a second knee or hip replacement resulted in a loss of power due to reduced follow-up for some individuals.

Finally, this study assessed the effect of BMI and smoking on patients' risk of revision after TKR and THR. The effects of these factors on implant failure may differ though, as implant failure does not necessarily result in revision surgery. A risk factor could reduce the risk of revision by making individuals less likely to undergo surgery due to ill-health, without necessarily having an effect on the risk of implant failure. This may explain the reduction, although non-significant, in the hazard for revision associated with being a smoker compared to non-smokers. Although their risks of implant failure may be equivalent, non-smokers are likely to be healthier, possibly leading to a lower threshold for undergoing revision surgery.

Implications for decision making

BMI and smoking appear to have little meaningful impact on patient-reported outcomes following TKR and THR[9–11]. In this study we find that these factors also have relatively little effect on lifetime risk of revision. As a result, there appears to be little justification in restricting access to surgery based on either BMI or smoking, aside from a potential benefit in terms of post-operative complications.

Author contributions

EB, CE, DWM, AS, CC, NKA, DPA, and RPV all made substantial contributions to the conception and design of the study. EB, RPV, and DPA undertook the statistical analysis. EB, RPV, and DPA drafted the manuscript, with CE, DWM, AS, CC, and NKA revising it for important intellectual content. All authors read and approved the final manuscript.

Conflict of interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: NKA has received personal fees from Freshfields Bruckhaus Deringer, Bioventus, Flexion, Merck, and Regeneron, all outside the submitted work. DPA reports grants from Amgen, Servier, and UCB Biopharma, and non-financial support from Amgen, all outside the submitted work. DWM reports grants and personal fees from Zimmer Biomet, and has a patent various patents related to Unicompartmental Knee Replacement (Zimmer Biomet) with royalties paid, all outside the submitted work.

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Ethical approval

Approval for the study was granted by the CPRD Independent Scientific Advisory Committee (protocol no. 14_126).

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.joca.2019.05.012.

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