Emulating a randomised trial of unicompartmental and total knee replacement using real world evidence

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INTRODUCTION

- 264 patients were randomly assigned unicompartmental knee replacement (UKR) and total knee replacement (TKR) in the Total or Partial Knee Arthroplasty Trial (TOPKAT).
- We emulated TOPKAT using routinely collected data.

METHODS

- Data from 5 observational health care databases covering 2005 to 2018.
- Study participants had undergone a UKR or TKR and fulfilled the inclusion criteria for TOPKAT.
- Participants were matched based on propensity scores generated using tens of thousands of baseline covariates.
- Cox models were fitted to estimate the effect of UKR relative to TKR on post-operative complications (venous thromboembolism, infection, readmission, and mortality), risk of revision, and opioid use.
- Hazard ratios were calibrated using control outcomes.

RESULTS

- 32,379 and 250,377 individuals who received UKR and TKR were matched and included in the analysis.
- UKR was consistently associated with a reduced risk of venous thromboembolism (calibrated hazard ratios (cHRs): 0.47 (0.32 to 0.71) to 0.76 (0.59 to 0.99)), although there was insufficient evidence to conclude there was a reduction in risk of infection, readmission, or mortality.
- UKR was also associated with a reduced risk of opioid use (cHRs: 0.72 (0.63 to 0.84) to 0.86 (0.78 to 0.96)), but an increased risk of revision (cHRs: 1.51 (1.24 to 1.88) to 2.16 (1.63 to 3.15)).

Study flow charts, characteristics of study participants before and after matching, propensity score distributions, and results for the primary analysis and each sensitivity analysis are detailed in an interactive web-based application at **http://data.ohdsi.org/UkaTkaSafetyEffectiveness**

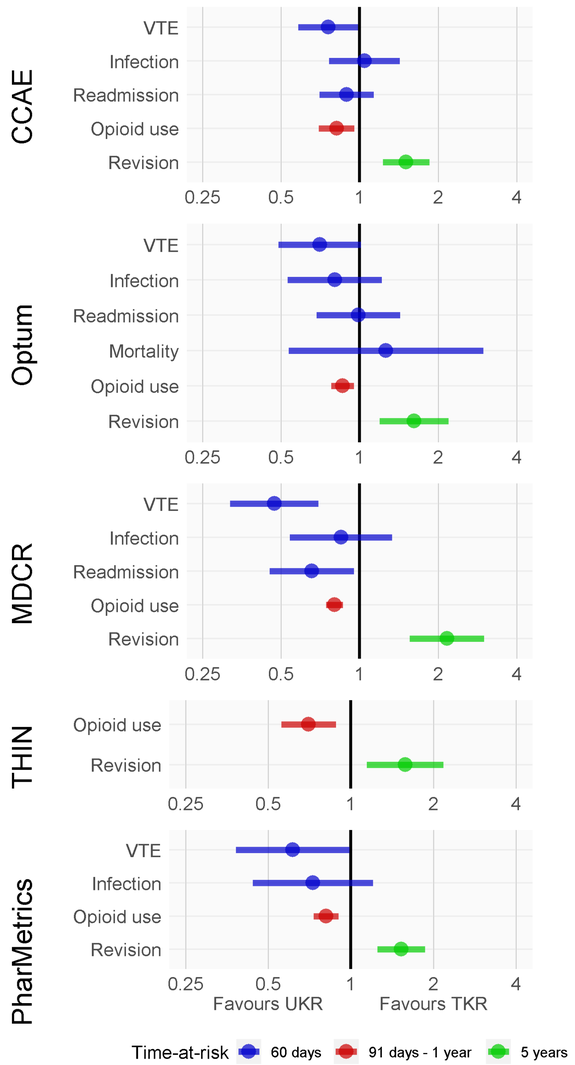

Figure 1. Calibrated hazard ratios

DISCUSSION

Key findings

- UKR was consistently found to have a decreased risk of post-operative venous thromboembolism relative to TKR, but not of other post-operative complications, such as infection and mortality.
- UKR was also consistently found to result in a lower risk of extended opioid use, but a higher risk of revision compared to TKR.

Strengths and limitations

- The use of routinely-collected data allowed for a broad assessment of the risks and benefit of UKR and TKR, with the results of this study a useful complement to those from TOPKAT.
- Not all of the inclusion criteria for TOPKAT was observable in the data and while patient characteristics were used to generate propensity scores there remains the potential risk of confounding due to unmeasured factors, such as surgeon or surgical centre characteristics.