A matched comparison of the long term outcomes of cemented and cementless total knee replacements, based on data from the national databases: An analysis from the National Joint Registry of England, Wales, Northern Ireland and Isle of Man

ABSTRACT

Background: Total knee replacement (TKR) can be implanted with or without the use of cement. It is currently unknown how cemented and cementless TKRs compare overall and in different age groups of the population in the long term.

Methods: The National Joint Registry collects information on knee replacements inserted in England, Wales, Northern Ireland and Isle of Man and was linked for multiple confounders to the National Health Service Hospital Episode Statistics database. Using propensity matched scoring techniques 44,954 cemented and cementless TKRs were compared. Regression models were used to compare the outcomes revision, two stage revision, reoperation and mortality both overall and in different age strata.

Results: The 10 year implant survival (revision endpoint) for cemented and cementless TKRs were 96.0% and 95.5% (Hazard Ratio (HR) 1.14, p=0.01). The 10 reoperation endpoint was 82.7% and 81.4% respectively (HR 1.08, p=0.001). The rates of pain were higher in cementless TKRs (0.5% vs 0.7%, p=0.002) but the rates of infection were lower (0.7% vs 0.5%, p=0.003). No significant interactions with age existed for outcomes of; revision (p=0.24), reoperation (p=0.30) or mortality (p=0.58).

Conclusions: We found that matched cemented and cementless TKRs both have 10 year implant survivals over 95%. Cementless TKRs had a higher absolute difference in revision rates (0.5%) and reoperation rates (1.3%). The rates of revision for infection were lower in the cementless group, although rates of revision for pain were higher. Age did not significantly affect the relative performances.

Level of evidence: III

INTRODUCTION

The main treatment for end stage arthritis which has failed to respond to conservative management is a total knee replacement (TKR)[1]. TKRs can be implanted with (cemented) or without the use of cement (cementless). Cemented fixation is the gold standard and forms 95% of all primary knee replacements[2]. However current cemented knee replacements have a postoperative complication rate of approximately 11%[3]. Additionally younger patients have up to twice the rates of implant failure[4-6], believed to be secondary to increased stress on the fixation interface in active patients[7]. Additional issues pertaining to cement include cement embolism, durability with cases of late component loosening and the need for complex revision surgery[8, 9].

Cementless fixation may offer a solution and has advantages including elimination of bone cement interface, no thermal necrosis from cement polymerisation and no third body wear from retained cement[10-12]. There is also evidence that cementless surgery has shorter operative times[13-15] which potentially reduces the chances of postoperative complications, morbidity and mortality[16]. There is no consensus on which fixation type is best overall and certainly not for age subgroups. The majority of studies, which compare fixation types, have been limited by small numbers or short follow up.

The aim of this study was to compare 10 year outcomes of cemented and cementless TKRs using various clinical outcomes both overall and in different age subgroups. The authors analysed data from three large datasets; (1) National Joint Registry (NJR) (2) Hospital Episodes Statistics Admitted Patient Care records (HES-APC) and (3) Office of National Statistics (ONS).

MATERIAL AND METHODS

NJR records were linked to the HES-APC database and ONS mortality data. The NJR is the world's largest arthroplasty register and reports follow up rates of over 95%[2]. HES-APC is a database of all admission episodes to an NHS hospitals in England and contains detailed information for surgical procedures and medical complications[17]. Mortality data was provided by the ONS. This study had NJR Research subcommittee and ethical approval (South Central Oxford B Research Ethics Committee, Reference: 19/SC/0292). The dataset linkage was approved by the Confidentiality Advisory Group (Reference: 19/CAG/0054).

Analyses were performed to compare the long term outcomes of cemented and cementless TKRs: revision rate, indications for revision, aseptic loosening, reoperation rate, three month HES reported complication and mortality. The cohort was divided into four age groups for subgroup analyses (1) <55 years (2) 55-64 years (3) 65-74 years (4) ≥75 years. Analysis were restricted to patients older than 18 years and hybrids were excluded.

Revision surgery was defined as any implant component removed, exchanged, or added since the primary operation. Reoperation surgery was defined as any additional surgery to the knee joint after the primary surgery and therefore included all revisions and additional operations such as manipulations under anaesthesia and arthroscopies. HES reported complications were divided into medical complications and implant complications. Medical complications were defined as a stroke, myocardial infarction, chest infection, deep vein thrombosis/pulmonary embolism (DVT/PE), urinary tract infection (UTI), acute renal failure or blood transfusion. Implant complications were defined as wound dehiscence, surgical site infection, fracture, prosthesis complications and neurovascular injury.

Statistical analysis

There were significant differences in baseline characteristics between groups (Table 1). Given the potential for factors other than fixation to affect the revision rate cemented and cementless groups were matched for multiple known confounders using propensity scores[18-25]. These included patient and surgical factors. Surgeon caseload was defined as the average number of primary knee replacements performed per year and was calculated as described previously[21, 26]. All factors in Table 1 were used for matching, apart from BMI, which had a large proportion of missing data consistent with previous studies[27-30]. Logistic regression generated a propensity score representing the probability that a patient received a cementless TKR. The algorithm used matched on the logit of the propensity score with a 0.02-SD calliper width at a 1:1 ratio. Greedy matching without replacement was utilised given this approach has been shown to have superior performance for estimating treatment effects[31]. Standardised mean differences (SMDs) were examined both before and after matching, with SMDs of 10% or more considered suggestive of covariate imbalance[32]. After matching, 44,954 knee replacements (22,477 cemented and 22,477 cementless TKRs) for analysis.

Cumulative survival was determined using the Kaplan–Meier method. The outcomes of interest were; revision surgery, reoperation and mortality. Endpoints were compared between the TKR and UKR groups, using Cox regression models, with the proportional hazards assumptions assessed in all analyses. BMI was adjusted for in the Cox models as a sensitivity analysis, but this did not influence the results. To account for clustering within the matched cohort, a robust variance estimator was used in regression models. A multi-level frailty model was tested in the regression models to control for patient clustering within surgeons. Univariable and adjusted models were also assessed. The adjusted models included

covariates with residual imbalance after matching (SMD of 10% or more). The proportional chi-square test with Yates' correction was used to compare the frequency of revisions for specific indications and three month HES reported complications between groups.

All statistical analyses were performed using Stata (Version 15.1; StataCorp, TX, USA) except propensity score matching, which was performed using R (Version 3.4.0; R Foundation for Statistical Computing, Vienna, Austria).

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RESULTS

Between 1st January 2004 and 31st December 2018 1,186,514 knee replacements were performed. From these 858,725 records were linked to the HES admitted patient care records. After removing unicompartmental knee replacements, patellofemoral replacements and missing implant types there were 784,995 TKRs for analysis. From these 683,755 knee replacements (661,269 cemented, 22,486 cementless) were not hybrids and had complete sets of data for patient and surgical factors (Figure 1). There were significant differences in baseline characteristics between the fixation groups (Table 1). The matched study group consisted of 44,954 TKRs (22,477 cemented and 22,477 cementless) and was well balanced. The mean follow-up for both groups was 7.2 years (SD 3.8).

Revision

In the cemented group there were 721 revisions at mean of 3.9 years (SD 3.2) postoperatively and in the cementless group there were 817 revisions at a mean of 3.8 years (SD 3.2) postoperatively. The 10 year implant survival using revision as the endpoint for cemented and cementless TKRs was 96.0% (CI 95.7-96.3) and 95.5% (CI 95.2-95.9). The HR was 1.14 (1.03-1.26, p=0.01) with an absolute difference in revision rate of 0.5% (Figure 2). The HRs comparing cemented and cementless TKRs by the year of primary surgery are summarised in Table 2. There was no significant interaction between revision and year of surgery (p=0.80).

The rates of revision for pain were 0.2% higher for cementless than cemented implants (p=0.002). However the rates of revision infection were 0.2% lower in the cementless group (Table 3). There were no other clinically meaningful differences between groups.

Reoperation

In the cemented group there were 3,240 reoperations at a mean of 3.1 years (SD 3.2) postoperatively. In the cementless group there 3,465 reoperations at a mean of 3.0 years (SD 3.1) postoperatively. This gave 10 year reoperation survivals of 82.7% (CI 82.1-83.3) and 81.4% (CI 80.8-82.0) respectively with an absolute difference of 1.3%. The HR was 1.08 (1.03-1.13, p=0.001) (Figure 3).

HES reported three month complications

Overall the risk of medical complications was lower for cemented TKR (3.6% vs 4.0%, p=0.03). The rates of chest infection (1.1% vs 1.3%, p=0.05) and urinary tract infection (0.88% vs 1.25%, p<0.001) were lower for the cemented group. There were no other differences (Table 4). There was no difference in the rate of implant complications between groups (1.69% vs 1.62%, p=0.54). The rates of wound dehiscence were lower in the cementless group (0.47% vs 0.25%, p<0.001). The rates of surgical site infection, fracture, prosthesis complication and neurovascular injury were not different between groups (Table 4).

Mortality

Using mortality as the endpoint in the cemented group there were 4,879 deaths at a mean of 7.0 years (SD 3.5) postoperatively. In the cementless group there were 4,916 deaths at a mean of 7.1 years (SD 3.5) postoperatively. The 10 year patient survival using mortality at the endpoint for cemented and cementless groups were 76.2% (CI 75.5-76.8) and 76.1% (CI 75.4-76.8) (Figure 4). There was no difference in patient survival between groups HR 1.00 (CI 0.96-1.04, p=0.99).

Effect of age on revision, reoperation and mortality

The numbers of TKRs in the <55 years, 55-64 years, 65-74 years and ≥75 years group were 3,219, 10,971, 17,614 and 13,150 respectively. There was no significant interaction between age and fixation on the outcomes of: revision, reoperation or mortality (p=0.24, p=0.30 and p=0.58 respectively). The 10 year survivals in each of the age groups is summarised in Tables 5-7. This suggests that age has no effect on the relative performances of cemented and cementless TKRs for the endpoints revision, reoperation or patient mortality.

Rates of aseptic loosening in different age groups

In the cementless group there were a total of 260 cases (1.2%) of loosening compared to the 231 cases (1%) in the cemented group (p=0.19). The rates of loosening were compared in each age subgroup (Table 8). The rates of aseptic loosening were higher in the 65-74 years cementless group (p=0.02). All other differences were not statistically significant. There was some evidence of an interaction (p=0.06) between age and fixation on aseptic loosening revision outcome, where in those aged under 65 there was no association of fixation on aseptic loosening revision outcome, whereas in those aged over 65 the risk of aseptic loosening was higher in the cementless group.

DISCUSSION

This is the largest study comparing the long term outcomes of cemented and cementless TKRs. All previously published comparisons have been limited by numbers or follow up. Raw data from the NJR suggests that the 10 year implant survival (revision endpoint) for cemented TKR is 96.6% and cementless is 95.8%[2]. However these values cannot be compared directly as cementless fixation tends to be used in younger patients, who are more likely to have revisions. After matching, cementless TKR had a 14% higher relative revision risk (HR 1.14), but the absolute difference was small with a 0.5% higher absolute revision rate. In terms of indications for revision; infection revision rates reduced by 0.2% in the cementless group but the revision rates for pain were 0.2% higher. Although these differences are small, they have clinical implications given the large volume of TKRs implanted globally. In cementless fixation there is concern about early loosening and peri-prosthetic fractures given the reliance of press fit fixation for primary stability[33] but this was not observed in this study.

The literature reports conflicting results with regard to implant survival and aseptic loosening of cemented and cementless TKRs. Prudhon et al.[34] in a long term study of 200 cemented and cementless TKRs found no differences in long term implant survival. However this study was underpowered. Gandhi et al's[35] meta-analysis found that cementless implants were more likely to be revised for aseptic loosening. Nam et al.[36] in a randomised controlled trial, Chen et al [37] in a systematic review and our study found no differences in aseptic loosening rates.

An important finding in our study was that the revision rate for infection decreased from 0.7% with cemented to 0.5% for cementless TKR. Gandhi et al's[35] systematic review also found the infection rate was lower following cementless TKR. It is however not clear why

the infection rate is lower with cementless components, particularly as antibiotics are routinely used in the cement. It perhaps relates to lower operation times reported for cementless compared to cemented TKR[13-15].

The rate of revision for pain was higher following cementless (0.7%) than cemented (0.5%) TKR. This could be due to early loosening not seen radiographically. Radiostereometric analysis (RSA) studies[38, 39] have shown significantly higher migration of cementless compared to cemented TKRs. Pjilis et al.[40] performed a systematic review of RSA TKR migration studies and concluded that early migration was associated with aseptic loosening. However revisions for pain are ill defined and can be caused by many reasons not related to loosening.

The absolute difference in the 10 year reoperation rate for cementless TKR was 1.3% higher than cemented TKR. We could not identify any studies comparing the reoperation rate of cemented and cementless TKRs.

Overall the rates of medical complications were slightly lower in cemented TKRs with lower rates of chest infection and UTI. There were no differences in the rates of DVT and PE which is in agreement with Gandhi et al.'s[35] systematic review. We also found no significant differences in patient mortality between cemented and cementless groups. It is unclear why the rates of wound dehiscence were lower in the cementless group by 0.2% although it may be due to shorter operative times for cementless cases[13-15].

In our study, as in previous studies[41, 42] the survival increased with increasing age. The <55 age group had higher implant survivals in the cementless group although this was not

significant. In older age groups the cemented had higher implant survivals reaching significance in the 65-74 age group. The revision rate for aseptic loosening had the same pattern. In <55 years group it was lower in cementless (HR 0.80) but in older ages cemented became more advantageous. Although the differences were only significant in one age group (65-74 years), the overall trend suggests that there is the possibly a small advantage for cementless components in the young age group (<55 years), possibly related to improved fixation. In the older age groups there is no advantage for cementless, and in those over 65 cemented appears to achieve better results.

During the study period the proportion of TKR implanted that were cementless progressively decreased from 6.5% in 2005 to 1.7% in 2018. This pattern has also been reported in Europe[43]. The reducing usage of cementless TKRs can be attributed to the early failures of cementless implants[44-47] and the long history of good results with cemented TKRs[48]. However over the last 15 years the design of cementless components has improved, with for example surface coatings to improve biological fixation[16, 44]. Zhou et al.[49] performed a meta-analysis comparing cemented and cementless TKRs studies dating between 1998 and 2015 and found no differences in implant survival at a mean follow up of 7.1 years although there were limited numbers of TKRs available for analysis. In our study the revision rate of cementless TKR implanted every year between 2004 and 2015 was higher or similar to that of cemented components (Table 2). However the revision rate of cementless components implanted in the last three years of recruitment, 2016-2018 were lower (HR=0.84, Table 2) but this did not reach significance and is limited by follow up.

The strengths of this study are that an unselected registry sample from an extended period reducing the chances of selection bias. Additionally by linking datasets various clinical

outcomes were assessed with adequate power and follow up. This is the largest study to date comparing cemented and cementless TKRs with the long term follow up. The main limitation of this study is that it is retrospective and is based on observational data. To address this limitation we propensity matched groups. Despite matching, there is potential for residual confounding and matching can reduce the generalisability of our findings. There was a substantial proportion of BMI data missing so we did not match on BMI. However, the BMI distribution between cemented and cementless groups was well balanced both before and after propensity matching. Additionally, the reasons for revision in the NJR are those recorded at the time of surgery even if this subsequently changed due to histopathology and microbiology data. Registries can underreport revisions although there is no reason to believe this would differ between the groups, and it is not possible to confirm causality in registry-based studies. Finally we did not have data on alignment, patient reported outcome measures and implant level data for this study.

In conclusion this study found that matched cemented and cementless TKRs both perform well with 10 year implant survivals over 95%. However both have ten year re-operation rates of about 20%. Cementless TKRs have higher revision and reoperation rates although the absolute differences are small. Cementless components may have slightly better results than cemented in the very young and modern designs of cementless TKR may perform better than cemented TKR which requires further study.

LIST OF FIGURES

LIST OF TABLES

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