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Risk factors for revision of polished taper-slip cemented stems for postoperative periprosthetic femoral fracture after primary total hip replacement: A registry based cohort study from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man

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Abstract

Background

Total hip replacement (THR) with a cemented polished taper-slip (PTS) femoral stem has excellent long-term results but are associated with a higher post-operative periprosthetic femoral fracture (PFF) risk compared to composite beam stems. This study aims to identify risk factors associated with PFF revision following THR with PTS stems.

Methods

299 019 primary THRs using PTS stems from the National Joint Registry (UK) were included in a retrospective cohort study with a median follow up of 5.2 (IQR, 3.1-8.2) years. Adjusted hazard ratio (HR) of PFF revision was estimated for each variable using multivariable Cox survival regression analysis.

Results

1055 of 299 019 THRs were revised for PFF at a median time of 3.1 (IQR, 1.0-6.1) years. Mean age (SD) was 72 years (9.7), 64.3% (192 365 of 299 019) participants were female and 82.6% (247,126 of 299 019) were ASA grade one or two. Variables associated with increased HR (HR, 95% Confidence interval) of PFF were: increasing age (1.02, 1.01 to 1.03, per year), intraoperative fracture (2.57, 1.42 to 4.66), ovaloid (1.96, 1.22 to 3.16) and round cross sectional shapes (9.58, 2.29 to 40.12), increasing stem offset (1.07, 1.05 to 1.09 per millimetre), increasing head size (HR 1.04, 1.01 to 1.06 per millimetre), THR performed from 2012 to 2016 (1.45, 1.18 to 1.78), cobalt chrome stem material (6.7, 3.0 to 15.4) and cobalt chrome stems with low viscosity cement (22.88, 9.90 to 52.85). Variables associated with a decreased risk of PFF revision were: female gender (0.52, 0.45 to 0.59), increasing stem length (0.97, 0.96 to 0.98 per millimetre) and a ceramic on polyethylene bearing (0.55, 95% 0.36 to 0.85).

Conclusion

Increased risk of PFF revision was associated with PTS stems which are short, high offset, used with large femoral heads, made of cobalt chrome or have ovaloid or round cross sectional shapes. Large increases in PFF risk were associated with cobalt chrome stems used with low viscosity cement. Further study is required to confirm causation.

Level of evidence

Level III: Retrospective cohort study

Introduction

The risk of postoperative periprosthetic femoral fracture (PFF) following primary total hip replacement (THR) is estimated at 3.5% and this is expected to rise in the future[1, 2]. Most patients require complex surgery which is costly and associated with substantial morbidity and mortality[3, 4]. Prevention is likely to be a more effective strategy than treatment, thus identification of modifiable risk factors which can guide surgical decision-making is crucial. Surgical technique and implant choice are the most easily modifiable risk factors for PFF. Cemented stems are considered to reduce the risk of PFF compared with cementless stems[1, 5-9]. Use of modern polished taper-slip (PTS) or 'force-closed' stems have overtaken more traditional composite beam (CB) or 'shape-closed' stems[10]. PTS stems have excellent survivorship beyond 20 years[11-13], but a higher incidence of PFF compared to CB stems[5, 8, 14-16]. PTS stem geometry and lack of cement-implant bonding may cause the femoral component to split the bone upon traumatic loading[17, 18].

Large differences in risk of PFF revision exist between PTS stem designs, but the aetiology remains unclear[14]. Biomechanical studies have shown a reduction in torque required for PFF in PTS stems which are shorter or smaller[19, 20]. PTS stems are used in conjunction with a range of cements with different mechanical properties which may affect the strength of the femoral construct[21, 22]. Accumulation of wear particles and osteolysis may also increase the risk of fracture[23, 24]. Implant design features which may predict PFF revision could be identified using large registry datasets[25]. This may develop hypotheses to reduce PFF risk which can be subsequently tested.

The aim of this study is to determine factors which are associated with revision surgery for PFF following primary THR using PTS stems using UK National Joint registry (NJR) data.

Materials and Methods

Data sources

The NJR is a population-based dataset which records data for all primary and revision THRs performed at all hospitals throughout England, Wales Northern Ireland and the Isle of Man since 2003[26] with missing data estimated at 5.8%[27]. Implant catalogue codes are recorded in the registry for each implant and were used to link implant design data on all implants (stem, cement, head, cup or shells and liners etc.).

Participants

Revisions for PFF which occurred within three months of reported intraoperative PFF were excluded to prevent miss-classification of revision which occurred as a result of intraoperative PFF rather than a new injury[25]. The formal reporting of intraoperative fractures was introduced on 01/04/2004 and THRs performed prior to this date were therefore excluded. This study analysed all primary THRs recorded in the NJR from 01/01/2004 to 30/09/2016 using a polished tapered slip (PTS) cemented femoral stem.

Variables

To reduce the confounding effect of indication, only cases performed for osteoarthritis (OA) were included. This resulted in 361 091 cases for analysis (step-wise exclusions are displayed in Figure 1). In the majority of cases, the same cement brand and viscosity was used for the acetabular and femoral components. These cases, regardless of acetabular implant fixation, were included in this analysis. Occasionally, different cement brands and viscosities were used for the acetabular and femoral components and as NJR data does not specify which cement was used for each component, these cases were excluded. A comparison of excluded patients to study patients can be seen in Appendix 1.

Patient and surgical modifiers

Patient and surgical variables were patient age (years), year of surgery (2004 to 2007, 2008 to 2011 and 2012 to 2016), gender, American Society of Anaesthesiologists group (1 and 2 versus 3 to 5), side of operation, surgical approach (posterior versus non-posterior), computer guided surgery, minimally invasive surgery, surgeon grade (consultant versus non-consultant) and surgeon-reported intraoperative fracture.

Implant modifiers

Highly cross-linked polyethylene was defined as polyethylene which had been irradiated above 50 kGy[28]. Variables included stem material (stainless steel [SS] alloy versus cobalt chrome [CoCr]) alloy, stem length (estimated to allow comparison between stem brands from medial stem length +10mm or lateral stem length -10mm), diaphyseal cross-sectional shape (ovaloid, rectangular or round), metaphyseal cross-sectional shape (flat versus vertical ridge), stem taper (double versus triple tapered), stem offset, head size, bearing combination (metal on polyethylene [MoP], metal on highly cross-linked polyethylene [MoXLP], ceramic on polyethylene [CoP], ceramic on highly cross-linked polyethylene [CoXLP] or ceramic on ceramic [CoC]) and cement viscosity (high, medium or low).

Outcomes

The primary outcome of registry analysis was implant survival to the end point of PFF revision.

Statistical analysis

Normally distributed continuous variables were expressed as means with standard deviations (SD) and non-normally distributed continuous variables were expressed as median values with interquartile range (IQR). Patient time incidence rates (PTIR) were calculated as revisions occurring per 1000 patient years. Since the dataset in this exploratory analysis was large and multiple comparisons were performed, statistical significance was set at $p < 0.01$ to reduce the risk of inappropriate false positives. Comparisons of continuous variables were performed with Welch's t-tests, and categorical variables were compared with chi-square tests. Survival was estimated using a Kaplan-Meier method. Cases were censored when the patient did not undergo revision for PFF and when patients died prior to revision for PFF. Multivariable Cox regression estimated the adjusted hazard ratio (HR) of revision with 95% confidence intervals (HR [CI 95%]) for each variable. HR estimates were adjusted for all other available variables. Assumptions of proportionality were tested numerically and upheld for all Cox regression models. Regression model discriminatory power was assessed using the concordance statistic, which is analogous to the area under the receiver operating curve (useful prognostic model between 0.6 and 0.85)[29]. To control for the effect of stem geometry, a subgroup analysis of all stems which were manufactured using both CoCr and SS with the same geometry (CPT, Zimmer Biomet, Warsaw, Indiana and CPCS, Smith and Nephew, Memphis, Tennessee) were compared as a subgroup using otherwise identical methods as described above. Analyses were completed using R (v 3.6.1, R, Vienna, Austria).

Source of Funding

None.

Results

1055 PFF revisions in 299 019 cases were recorded in the study group with an overall PTIR of 0.62 revisions per 1000 years at risk. Mean age (SD) was 72.00 (9.66), 64.3% (192 365 of 299 019) participants were female and 82.6% (247,126 of 299 019) patients were ASA grade one or two (Table 1). Median follow-up time of non-revised cases was 5.2 (IQR, 3.1-8.2) years. Minimum follow up of non-revised cases was 1.4 years. Median time to PFF revision was 3.1 (IQR, 1.0-6.1) years (Figure 2).

Implant survival to PFF revision

Kaplan-Meier unadjusted 10-year survival until revision for PFF (95% CI) was 99.3% (95% CI 99.3-99.4, number at risk = 39 173, Figure 3).

Predictors of PFF revision

The regression model performed well (concordance statistic 0.76). After adjustment for all other co-variates, variables associated with an increased risk of PFF revision were increasing age, reported intraoperative PFF, cobalt chrome stem material, increasing stem offset, ovaloid and round diaphyseal cross sectional stem shapes, increasing head size and THR performed between 2012 and 2016 (figure 4 and 5). Variables which were associated with a decreased risk of PFF revision were female sex, increasing stem length and a CoP bearing couple (figure 4 and 5).

The subgroup contained 49 840 cases (CoCr = 46 525 and SS = 3315). An identical model was used to estimate the effect of all variables on risk of PFF revision. The model performed well (concordance statistic 0.76). Median time to PFF was 8.1 (IQR, 4.0-10.0) years for SS stems and 2.7 (IQR, 0.8-5.0) years for CoCr stems. After adjustment for all other covariates, the HR of PFF revision associated with CoCr versus SS stem material was 6.7 (95% CI 3.0 to 15.4, p <0.001). To investigate the interaction between cement properties and stem material, modelling was repeated with the complete study cohort using an interaction term to classify stem material with cement viscosity (figure 6). CoCr stems were associated with a higher risk of PFF versus SS stems regardless of cement viscosity. The hazard ratio of PFF revision for CoCr stems compared to SS stems increased when used with low viscosity cement.

Discussion

Modifiable risk factors associated with an increase the risk of PFF revision include use of CoCr stem material, ovaloid and round diaphyseal cross sectional shaped stems, higher stem offsets, larger head diameter and CoCr stems, particularly when used with low viscosity cement.

The overall PFF revision incidence in this study was low and similar to previous findings[8, 14, 30]. The unadjusted incidence was comparable to PFF incidence for cementless stems in the NJR although the patient population in this study is older and possibly at higher risk of PFF revision[25].

Patient-related factors

Increasing age was associated with a significantly greater risk of PFF revision and this has been previously reported as an independent risk factor for PFF[31, 32]. Females were at a reduced risk of PFF revision which is in agreement with some results for cemented stems[5] and contradicts the findings of other results for a mixture of stem fixation methods[31, 32]. This suggests that the influence of age-related changes which reduces bone quality in female femora is less of a risk factor for PFF when using PTS stems as compared to other femoral stems. PFF risk may be reduced by the cement acting as a load sharing device which reduces point loading of the femur[12]. Male patients may be at greater risk because of larger body mass which may increase forces on the implant, thus increasing the risk of cement mantle failure and PFF. ASA is a useful surrogate marker of frailty which may infer poorer bone quality and increased risk of falling[33]. ASA has been identified as a risk factor for PFF in another study including a majority of cementless stems[32]. In this study, increasing ASA grade was not associated with an increase in risk of PFF revision, which suggests that PTS stems may provide some protection in patients with co-morbidities.

Surgical factors

Intraoperative fractures were associated with an increased risk of PFF revision, as shown previously[1]. Intraoperative PFF occur more commonly in elderly patients with osteoporotic bone who are also at increased risk of postoperative fracture following low-energy trauma[34, 35]. THRs performed between most recently were associated with an increased risk of PFF revision, in keeping with other studies, perhaps due to increasing incidence amongst older patients[15]. Increasing PFF revisions may also suggest an increase in revision surgery as a treatment but this is difficult to quantify without data regarding all treatment methods. More detailed granular data analysis of changes in PFF risk over time are required to understand why risk may change over time.

Implant-related factors

Perhaps most relevant to surgical decision-making is the impact of implant choice on PFF. CoCr stems were associated with a significantly higher risk of revision (HR 6.7 [95% CI 3.0 to 15.4, $p < 0.001$]) compared to SS stems and this observation is consistent when comparing stems from the same manufacturer with identical geometry. There was a large difference in the time to PFF revision between stem materials in the subgroup analysis, which might suggest that difference between CoCr and SS stems may be in part modified by a process of wear at the stem-cement interface. Even though CoCr alloys are harder than SS alloys, wear does occur at the stem-cement interface with CoCr PTS stems through corrosive fretting wear[36, 37] which may increase the risk of PFF revision. Risk of revision with CoCr stems increased dramatically when implanted with low viscosity cement. Low viscosity cements are reported to give poorer bone penetration, reduced tensile strength and inferior implant fixation compared to higher viscosity cements in vitro[21]. These properties may accelerate an undefined process of failure at the cement-implant interface leading to PFF revision.

Rotational force as a mechanism for PFF around a PTS stem is thought to be a major contributing factor in Vancouver type B fractures[38, 39]. Shorter PTS stems were associated with a higher risk for PFF revision which confirms findings in biomechanical models[20]. Compared to rectangular diaphyseal cross-section shape stems, circular shaped stems are associated with greater micromotion, inferior rotational stability, thinner cement mantles, and higher peak stresses within the cement mantle[40, 41]. These factors offer a theoretical basis for our observation that ovaloid and round stems were associated higher risk of PFF revision. We found that increasing offset and head size significantly increased the risk of PFF revision. Increasing femoral offset and head size results in greater torque on the femoral construct and also increases cement mantle stresses, which may predispose to PFF. Additionally, larger head sizes are associated with greater volumetric wear of polyethylene acetabular surfaces and this may result in wear-associated osteolysis[42]. However, our analysis did not show a consistent protective association of low wear bearing couples and this suggests that overall differences in PFF revision rates may not be a bearing wear related phenomenon.

Limitations

We accept certain limitations to this study. This observational study benefits from large numbers from a national registry but is unable to determine causality between risk factors and risk of revision. Confirmation of causation should be pursued using the breadth of good clinical research. In order to control for and analyse the effects of cement and implant design features, we excluded data which was not possible to interpret or was not supplied by manufacturers. The resulting dataset contains the majority of currently used constructs which makes the analysis useful for current practice but exclusions may reduce the power and scope of observations. Despite this, the large numbers in this study increase statistical power and may have led to results which are statistically significant but do not reach levels of clinical significance. As such, they should be viewed within the overall clinical context by experienced clinicians. This registry analysis estimated the risk of PFF revision and whilst this includes most cases of PFF in UK practice[43], it was likely to be an underestimate of total PFF incidence which would also include cases undergoing internal fixation or conservative management[15]. Disparities could exist in management of PFF between hospitals or between surgeons which may have substantial impact on our findings herein. Further analysis combining data on all PFFs should be performed to corroborate our findings. We excluded patients with PFF which occurred within three months of a reported intraoperative PFF to reduce confounding but a proportion of early PFFs may be due to unrecognised or unreported intraoperative fracture which propagate during the early postoperative stage[25]. This paper relies on NJR data which is a rich source of information regarding implant and practice but there is a lack of patient information which may bias the inference of results and prevent adjustment for important known and unknown patient confounding factors. Further analysis should seek to include a wider source of patient data to improve the accuracy of estimates. We were unable to analyse all the properties of implants which may be useful in predicting risk of PFF, for example, exact stem geometry, cement porosity and cement mixing technique. Future work should attempt to classify implants used to include all pertinent predictors.

Conclusion

This is the first study to evaluate detailed implant-related risk factors for revision of cemented PTS stems for PFF and it confirms that the majority of risk for PPF is attributable to modifiable factors such as surgical practice and design of PTS stem. Whilst the overall survival of PTS stems is excellent, revisions for PFF comprise of a large portion of total PFF revisions and based on our findings, we recommend that surgeons should evaluate the association between the increased risk of PFF revision and exercise prudence when using PTS stems which are short, made of cobalt chrome or have ovaloid or round diaphyseal cross sectional shapes. Caution must be applied when using high-offset stems and larger femoral heads. Elderly patients, males and those who have had an intraoperative fracture must be appropriately counselled about the increased risk of PFF. Further analysis is warranted and planned, including looking at variations in surgeon characteristics and surgical techniques as well as radiographic and biomechanical analysis that may further our understanding of risk factors associated with PFF.

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Figure legends

Figure 1. Flow chart summarising exclusion parameters. For a comparison of excluded patients to study patients please see Appendix 1.

Figure 2. Distribution of revisions for PFF in primary THR using polished tapered stems over time.

Figure 3. Kaplan-Meier survival to an endpoint of PFF revision for all study cases.

Figure 4. Forest plot displaying the effect of categorical predictors on the risk of PFF revision following THR with cemented PTS stems.

Figure 5. Effect of continuous predictors on the hazard of PFF revision.

Figure 6. Forest plot displaying the effect of stem material and cement viscosity on the risk of PFF revision following THR with cemented PST stems