STUDY PROTOCOL

Risk for second revision in patients with cemented versus non-cemented acetabular component at primary THA. A national cohort study from DHR

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Summary/Abstract

Background

Total hip arthroplasty (THA) is considered to be one of the most successful operations performed in orthopedic surgery and the treatment of choice for end-stage osteoarthritis of the hip (1). The frequency of revision surgery for total hip joint arthroplasty continues to increase worldwide (2). Generally, the longevity of revision THA is less than that of primary THA (3) . Although the optimal component fixation method in primary THA is still debated, several studies have shown increased use of the cementless technique in most parts of the world (4–6). The use of cementless technology in THA initially gained popularity as complications such as aseptic loosening and "cement disease" began to surface with the use of first-generation cement techniques (7–9). Cementless acetabular components have achieved widespread acceptance in THA as a result of their improved and reliable long-term results(10). Primary stability is achieved through press-fit fixation that requires 1–3 mm under-reaming of the acetabular cavity and forceful impaction. Studies have shown slightly higher risk of revision in uncemented acetabular components compared to those cemented (11). We believe that the differences in the fixation method during the primary operation significantly affects the surgical techniques implemented in the first revision of each group and by that influencing the risk of second revision. This was shown before in cemented vs. uncemented stem, but no study has to our knowledge reported the same concerning acetabular components (12). In previous studies comparing the risk of revision in patients undergoing THA with cemented and hybrid fixation techniques (where the cup component is non-cemented), the hybrid technique was associated with a higher risk of revision for any reason compared to the cemented technique, regardless of the patient's sex and age (11). The justification for this difference in revision rates can be the use of cement in cup fixation. This suggests that the use of cement in cup fixation may provide certain advantages, such as increased stability or longevity, which could potentially lead to a lower risk of revision compared to non-cemented cup fixation. Therefore, further research and clinical considerations are necessary to fully understand the implications of cup fixation techniques in risk of THA revision. We expect that the result from this study would help in the choice of fixation technique by shedding light on an under investigated outcome concerning the complications associated with fixation technique.

Objective

The objectives of this study are to investigate the risk of second revision of the cup alone or any component after first cup revision following cemented or non-cemented cup in the primary THA.

Methods

Study design

The current study is a nationwide register-based cohort study that utilizes prospectively collected data from the Danish Hip Arthroplasty Register (DHR) and the Danish National Patient Registry (DNPR). The study will follow the reporting of studies Conducted using Observational Routinely collected health Data (RECORD) guidelines (13). We will include patients who have undergone THA at both public and private hospitals from January, 1st ,1995, to December 31st, 2020, to ensure a minimum follow-up of 1 year. Patients will be followed from the date of the first revision and until the first of the following: Implant removal of the acetabular component, death, emigration, until the date where there is a minimum of 100 patients left in the risk set for each group, or until December 31st, 2021.

Data sources and linkage

We will use data from the DHR and the DNPR. The DHR was founded in 1995 prospectively collects data on all THAs in public and private hospitals and their subsequent revisions in Denmark. Reporting from both public and private hospitals is mandatory(14). As of 2021, the DHR has a reporting rate of 97% for primary THAs and 95% for revisions (14). The DNPR is a national administrative database that registers all hospital contacts, including discharge diagnoses (15). All Danish residents have a unique 10-digit Civil Personal Register (CPR) number in the Danish Civil Registration System (DCRS) and this number enables to cross-link inhabitants in Denmark across different databases and to be traced until death or emigration.

Study population

We will include all THAs reported to the DHR that meet the following eligibility criteria:

Inclusion criteria

- Primary osteoarthritis as the indication for the primary THA.
- Has experienced a first revision with exchange of the liner, femoral head and/or acetabular component either with or without exchange of the femoral component.
- Femoral with a size of 28mm, 32mm or 36mm after the first revision
- Surgery with the posterior approach.

Exclusion criteria

- Isolated revision of the femoral component.
- Constrained liner.
- Metal-on-metal implant.

Outcomes

The following outcomes have been defined for the current study:

Primary outcome

The risk of undergoing a second revision of the acetabular component after having first revision with exchange of the acetabular component.

Revision is defined as any surgical procedure that involves skin incision in the ipsilateral hip joint due to acetabular component failure as reported in the DHR or having one of the following NOMESCO (Nordic Medico-Statistical Committee) Classification of Surgical Procedures codes in the DNPR:

- Secondary insertion of non-cemented total hip alloplastic in hip joint (KNFC2)
- Secondary insertion of proximal component in non-cemented partial hip alloplastic (KNFC01)
- Secondary insertion of hybrid hip alloplastic in hip joint (KNFC3)
- Secondary insertion of cemented total hip alloplastic in hip joint (KNFC4)
- Secondary insertion of non-cemented proximal part alloplastic (acetabular component) in hip joint (KNFC10)
- Secondary insertion of cemented proximal part alloplastic (acetabular component) in hip joint (KNFC11)
- Secondary insertion of non-cemented proximal part alloplastic (acetabular component) in hip joint (KNFC21)
- Secondary insertion of hybrid proximal part alloplastic (acetabular component) in hip joint (KNFC31)
- Secondary insertion of cemented total alloplastic (acetabular component) in hip joint (KNFC41)
- Secondary insertion of non-cemented total alloplastic in hip joint (KNFC29)
- Secondary insertion of non- cemented both components in total alloplastic in hip joint (KNFC20)
- Secondary insertion of cemented both components in total alloplastic hip joint (KNFC40)
- Secondary insertion of cemented total alloplastic hip joint without specification (KNFC49)

Secondary outcome

1. All cause revision Defined as any surgical procedure that involves skin incision in the ipsilateral hip joint with one of the following NOMESCO codes:
   - Secondary insertion of distal component of non-cemented partial hip alloplastic (KNFC02)
   - Secondary insertion of both components of non-cemented total hip alloplastic (KNFC20)
   - Secondary insertion of distal component of non-cemented total hip alloplastic (KNFC22)
   - Secondary insertion of another component of non-cemented total hip alloplastic (KNFC23)
   - Secondary insertion of distal component of hybrid total hip alloplastic (KNFC32)
   - Secondary insertion of another component of hybrid total hip alloplastic (KNFC33)
   - Secondary insertion of distal component of cemented total hip alloplastic (KNFC42)
   - Secondary insertion of another component of cemented total hip alloplastic (KNFC43)
   - Secondary insertion of interponert prosthetic in the hip (KNFC59)
   - Secondary insertion of prosthetic join in the hip without specification (KNFC99)
   - Exploration of soft tissue in hip or thigh (KNFA0)
   - Exploration of hip joint (KNFA1)
   - Tissue or joint biopsy in hip or thigh (KNFA2)
   - Resection arthroplasty in hip joint (KNFG09)
   - Incision and revision due to infection in hip joint (KNFS19)
   - Incision and revision due to infection in hip joint with applying of drugs/medicine (KNFS49)
   - Another operation for infection in ligament, joint and bone in hip and femur (NFS99)
   - Reoperation due to ruptured wound after operation in hip or thigh (KNFW49)
   - Reoperation due to deep infection after operation in hip or thigh (KNFW69)
   - Reoperation due to deep bleeding after operation in hip or thigh (KNFW89)
   - Another reoperation after operation in hip joint or thigh (KNFW99)
   - Reoperation due to superficial infection in hip or femur (KNFW59)
   - Reoperation due to superficial bleeding in hip or femur (KNFW79)
   - Removal of total prosthetic or a part of it from hip (NFU1Y)
   - Removal of implant In relation to infection treatment in hip or femur (NFU89)
   - Removal of another implant from hip or femur (NFU99)
   - Another operation in hip or femur, not specified (NFT 99)
   - Reimplantation in femur or hip (NFP29/NFP)

All other unspecified causes indicated in the codes will be directed to the DHR for clarification on whether it is a cup or stem revision, or to specify which component is being revised.

Variables

We will gather the following variables from databases (DHR, DNPR)

DHR

- Age.
- Gender.
- Laterality of surgery.
- Indication for primary surgery
- Indication for first revision.
- Fixation technique.
- Date of surgery
- Type of surgery: primary, revision, re-revision.
- Acetabular bone loss after 1. Revision.
- Patient status: Alive, emigrated, dead.
- Surgical approach.
- Date of death
- Head size

DNPR:

NOMESCO (Nordic Medico-Statistical Committee) Classification of Surgical Procedures codes and Charlson comorbidity index.

Statistical analysis

We will stratify patients into two groups according to whether they received a cemented or an uncemented acetabular component after the first revision. We will use descriptive statistics for the baseline characteristics of the two groups. We will use mean or medians for continuous variables and the total number and percentage of the total for categorical variables. The cumulative incidence of revision will be estimated using Fine-Gray regression to model the cumulative incidence function, accounting for the competing risk of death (16). We will employ absolute risk regression function to evaluate the relative difference in the absolute risk of experiencing the outcomes of interest within the observation period and

the corresponding 95% Confidence Interval (95% CI) in patients with a cemented acetabular component compared to patients with an uncemented acetabular component (17). This will be performed using both crude and multivariable adjusted models. We will adjust for age, sex, Charlson Comorbidity Index (CCI). As it was shown that the risk revision increased over time in previous studies (18). we will also adjust for the 5-year intervals during which the primary operation was performed. P-values ≤ 0.05 will be considered statistically significant. The most recent version of R (www.r-project.org) will be used for data handling and the statistical analysis.

Table 1: Baseline characteristics at time of first revision

Parameter	First revision with cemented acetabular component	First revision with cementless acetabular component	Standardized difference of the means or prevalences
N			
Female sex, N (%)			
Age at first revision,			
Left side, N (%)			
CCI			
1-2			
3-4			
≥5			
Exchange of Femoral components N (%)			
Indication of revision N (%)			
Aseptic loosening			
Dislocation			
Infection			
Fracture			

Osteolysis/granuloma without loosening			
Components failure			
Pain			
Polyethylene wear without loosening			
Other			
Revision type N (%)			
Uncemented			
Hybrid			
Cemented			
Date of primary surgery			
1995-1999			
2000-2004			
2004-2009			
2010-2014			
2015-2019			
2020-2021			
Acetabular bone loss			
Type 1-2			
Type 3-4			
Type 5			
Unclassified			
Time until first revision			
< 1 year			
1-5 years			
> 5 years			
Head size at primary surgery			
28 mm, N (%)			
32 mm, N (%)			
36 mm, N (%)			

Table 2

Component revised	N	Number of revisions (%)	Relative Absolute risk [95% CI]	Adjusted Relative absolute risk [95%]	P value for the adjusted model
Acetabular					
Cemented					
Cementless					
All					
Cemented					
Cementless					

Table 3: Stratifying for the indication of the second revision between cemented and uncemented acetabular component

Indication of revision N (%)	Cemented acetabular component	Cementless acetabular component	Standardized difference	P value
Aseptic loosening				
Dislocation				
Infection				
Fracture				
Osteolysis/granuloma without loosening				
Components failure				
Pain				
Polyethylene wear without loosening				
Other				

Ethical considerations

This study is a part of a bigger study which was approved by the local Danish Data Protection Agency (id: P-2022-717) and carried out in compliance with The General Data Protection Regulation and the 1964 Declaration of Helsinki. Patient information is anonymized for privacy protection. All identifiers will be removed or encrypted to ensure anonymity prior to analysis. Access to data will be exclusive to authorized personnel, and all data will be secured in encrypted databases. The study results will be reported with full honesty and transparency, and any potential conflicts of interest will be transparently disclosed. Confidentiality and anonymity of data subjects will be guaranteed in all publications and presentations.

Clinical implications

A comparison was conducted to assess the risk of second revision surgery in patients who underwent cemented versus non-cemented total hip arthroplasty (THA) due to acetabular component failure. The goal was to gain new insights into the likelihood of requiring a second revision surgery specifically due to acetabular component failure in primary THA patients. This could be influenced by the type of fixation technique used, whether cemented or non-cemented. The anticipated outcome of this research is to provide valuable information that can aid in selecting the most appropriate fixation technique by addressing a lesser-known aspect of complications associated with different fixation techniques.

Reporting and trial registration

As a register-based study, this research will be reported in convenience with the Reporting of Studies Conducted using Observational Routinely-collected Data (RECORD) statement. The study protocol will be made available on a freely accessible, open access preprint archive.

Funding

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