

PhD thesis

Hip dislocation after primary Total Hip Arthroplasty – Incidence & patient reported outcome

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Abbreviations

In alphabetic order:

ASA = American Society of Anesthesiologists

BMI = Body Mass Index

CCI = Charlson Comorbidity Index

CI = Confidence Interval

CL = Constrained Liner

CPR = Central Personal Register

CT = Computed Tomography

CVR = Danish Civil Registration System

DHR = Danish Hip Arthroplasty Register

DNPR = Danish National Patient Register

DMC = Dual Mobility Cup

EQ-5D = EuroQuality of Life-5 Dimensions

HHS = Harris Hip Score

HOOS = Hip Osteoarthritis and Outcome Score

HR = Hazard Ratio

hr-QoL = health-related Quality of Life

ICD = International Classification of Diseases

OA = Osteoarthritis

PE = Polyethylene

PPV = Positive Predictive Value

PRO = Patient Reported Outcome

PROM = Patient Reported Outcome Measure

QoL = Quality of Life

RCT = Randomized Controlled Trial

REDCap = Research Electronic Data Capture

RR = Relative Risk

sd-HR = sub-distribution Hazard Rate

THA = Total Hip Arthroplasty

UCLA = University of California, Los Angeles

VAS = Visual Analog Scale

WOMAC = Western Ontario and McMaster
Universities Arthritis Index

Articles

This Ph.D. thesis is based upon the following papers:

Study I

Hermansen LL, Haubro MH, Viberg B, Overgaard S. “Patient reported outcome after hip dislocation in primary total hip arthroplasty is virtually unknown: a systematic literature review”. *Acta Orthop.* (2018) Oct 17:1-2

Study II

Hermansen LL, Viberg B, Hansen L, Overgaard S. “The ‘true’ cumulative incidence of and risk factors for hip dislocation within two years after primary total hip arthroplasty due to osteoarthritis – a nationwide population-based study from the Danish Hip Arthroplasty Register”. *J Bone Joint Surg Am.* (Accepted for publication October 2020)

Study III

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Study IV

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Study V

Hermansen LL, Viberg B, Overgaard S. “Risk factors for dislocation and re-revision after first-time revision total hip arthroplasty due to recurrent dislocation – a study from the Danish Hip Arthroplasty Register”. *J Arthroplasty* (Accepted for publication October 2020)

Dissemination

The work within this Ph.D. thesis has been presented or accepted for presentation both nationally and internationally as follows:

Oral presentations

- Danish Orthopedic Society (DOS) Congress; Copenhagen (DK), *October 2018 (Study I)*
- Danish Orthopedic Society (DOS) Congress; Vingsted (DK), *October 2019 (Study II), 2ND BEST PAPER AWARD*
- American Academy of Orthopedic Surgeons (AAOS) Congress; Orlando (FL, USA), *March 2020 (Study II, Accepted for oral presentation, Congress cancelled due to Covid-19)*
- Danish Orthopedic Society (DOS) Congress; Copenhagen (DK), *October 2020 (Study IV, Accepted for oral presentation, Congress cancelled due to Covid-19)*
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Poster presentations

- European Hip Society (EHS) Congress; Haag (NL), *September 2018 (Study I)*
- Danish Orthopedic Society (DOS) Congress; Copenhagen (DK), *October 2018 (Study I)*
- European Federation of National Association of Orthopedics and Traumatology (EFORT) Congress; Vienna (A), *June 2020 (Study II, Accepted for poster presentation, Congress cancelled due to Covid-19, Virtual EFORT Congress October 2020)*
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Summary

Total hip arthroplasties (THA) have, without doubt, made life better for millions of people worldwide who have struggled with pain, restrictions in everyday activities, and reduced quality of life (QoL) due to debilitating primary hip osteoarthritis (OA) or as a consequence of previous hip injuries. The vast majority of patients experience a satisfactory level of recovery of their daily living capacity and report excellent results. A primary THA will survive for 15 years for approximately 90% of patients and much longer still in most cases. However, serious complications may still occur. Dislocation is one of the most commonly reported complications, with a risk ranging from 0.2% to 10% after a primary THA and even higher after revision surgery. Most dislocations are managed by closed reduction of the prosthesis. Up to 50% of patients will experience recurrent dislocations, though, and many will require new surgery to restore stability. The great variation in the reported incidence rates of dislocation is partly due to significant differences in study designs, indications for surgery, surgical approaches, and follow-up periods. To date, we do not have an adequate overview of THA dislocations in Denmark and, maybe more importantly, we are simply not aware of the impact of dislocations on QoL and self-reported hip function in the years after this complication occurs. We therefore designed the following five studies in an attempt to mitigate the gaps in our current knowledge:

Study I: Our aim was to systematically review the literature for studies reporting patient-reported outcome measures (PROMs) after hip dislocation in patients with primary THA in comparison with in patients without any dislocation. We identified 3,460 unique studies using a simple and broad search query yet, of these, only two studies met the inclusion criteria.

Study II: Our aim was to report the “true” cumulative incidence of hip dislocations within two years of index surgery for all primary THAs conducted in Denmark from 2010 to 2014 due to hip OA. Secondary, we sought to analyze available patient- and surgery-related risk factors for validated dislocations. We included 31,105 primary THAs and validated 1,861 dislocations among 1,079 THAs after reviewing more than 5,000 patient files. The “true” two-year cumulative incidence of hip dislocation was 3.5% (95% confidence interval (CI): 3.3-3.7). Age, sex, American Society of Anesthesiologists (ASA)-score, head size and type, fixation method, and surgical approach were identified as independent significant risk factors for dislocation.

Study III: Our aim was to develop an algorithm designed to identify patients with dislocation in the Danish National Patient Register (DNPR) with high sensitivity, specificity, and predictive

values. The algorithm consisted of five steps, including both correct codes for dislocation and, alternatively, frequently used codes for dislocation that we validated in *Study II*. The combination of the correct diagnosis and procedure code produced a sensitivity of 63% and a positive predictive value (PPV) of 98%. After adding in alternative codes, we succeeded with increasing the sensitivity to 91%, while maintaining the PPV at 93%. The specificity was, in all steps, greater than 99%.

Study IV: Our aim was to compare QoL and hip-specific outcome measures in patients with a single or recurrent episode of THA dislocation and patients without any complications. We identified 1,010 living patients with one or more dislocations. We then matched patients with dislocation 1:2 based on age, sex, and date and hospital of primary surgery to patients without dislocation. We found that both health- and hip-related QoL were markedly and persistently reduced after THA dislocation as compared with in the control group even two to five years after the latest dislocation.

Study V: Our aim was to analyze surgery- and patient-related risk factors for both dislocation and re-revision of any cause after first-time hip revision due to dislocation. We identified 1,678 patients with a primary THA due to OA and a first-time revision due to dislocation between 1996 to 2016. After the first-time revision due to dislocation, 22.4% of these patients experienced a new dislocation and 19.8% were re-revised for any reason. We found that those patients revised with a dual mobility cup and a constrained liner exhibited a lower risk of dislocation but not so for a re-revision. The performance of a head/liner exchange was associated with a higher risk of both dislocation and subsequent re-revision as compared with a full cup revision.

In conclusion, we identified the true two-year cumulative incidence of hip dislocation after primary THA in Denmark to be 3.5%. This level is well in line with data from other countries that use the posterior approach during surgery but may be higher than outcomes of alternative approaches. We also succeeded with the creation of an acceptable algorithm that could be suitable for monitoring dislocations in a Danish quality register in the future. As we stated that the knowledge of patient-reported QoL and subjective hip function post-dislocation was merely non-existent, we have conducted the largest study to date regarding this matter. Despite the limitations inherent in the cross-sectional study design, we found that many patients suffer from the consequences of a dislocation for several years. At last, we sought to find risk factors for dislocation after both primary THA and revision procedures due to dislocation in order to increase the understanding of which patients and surgical techniques are associated with higher risks.

Dansk resumé (Danish summary)

Anvendelsen af totale hofte alloplastikker (THA) har uden tvivl gjort livet bedre for millioner af mennesker, som har kæmpet med smerter, begrænsninger i daglige aktiviteter og nedsat livskvalitet på grund af slidgigt i hoften eller følger fra tidligere hofteskader. Langt de fleste oplever en tilfredsstillende bedring i deres evne til at varetage daglige aktiviteter og rapporterer fremragende resultater. Den primære hofteprotese vil overleve 15 år hos cirka 90% af patienterne, og også længere i de fleste tilfælde. Der forekommer dog stadig alvorlige komplikationer. Hofteskred, eller luksation, er en af de mest hyppigt forekommende komplikationer, og risikoen herfor ligger mellem 0,2% til 10% efter en primær THA og endnu højere efter revisionskirurgi. De fleste luksationer kan behandles med lukket reposition af protesen. Op mod 50% vil dog opleve gentagende tilfælde af luksationer, og mange af disse patienter har brug for ny operation for at gendanne stabiliteten i hofteleddet. Den store variation i de rapporterede tilfælde af luksation skyldes delvist store forskelle i studie design, indikation for kirurgi, kirurgisk adgang og længden af opfølgningsperiode. For nuværende har vi ikke et tilstrækkeligt overblik over antallet af THA luksationer i Danmark, og - måske endnu vigtigere - vi har ikke viden omkring indvirkningen af luksationer på både patienternes livskvalitet og selvrapporteret hoftefunktion i årene efter denne komplikation. Vi designede de følgende 5 studier for at imødekomme manglerne i vores nuværende viden:

Studie I: Formålet var en systematisk gennemgang af litteraturen for at identificere samtlige studier, som har præsenteret data vedrørende patientoplevelsen efter en hofte luksation sammenlignet med patienter uden luksation. Vi fandt 3460 unikke studier ved hjælp af en enkel og bred søgestreng, men af disse opfyldte kun 2 studier inklusionskriterierne.

Studie II: Formålet var at rapportere den ”sande” kumulative forekomst af hofte luksation inden for de første 2 år efter operation for hofteslidgigt med en hofteprotese i årene 2010-2014. Sekundært ville vi undersøge for potentielle patient- og kirurgirelaterede risikofaktorer for luksation. Vi identificerede 31,105 primære hofteproteser og validerede 1,861 luksationer i 1,079 hofter efter at have gennemgået mere end 5,000 patientjournaler. Den sande 2-årige kumulative forekomst af hofte luksation var således 3,5%. Alder, køn, komorbiditet, størrelse på ledhoved og typen af artikulation, fiksationsmetode og kirurgisk adgang blev identificeret som uafhængige signifikante risikofaktorer for luksation.

Studie III: Formålet var at udvikle en algoritme designet til at identificere patienter med luksation i ved hjælp af Landspatientregistret med en høj sensitivitet, specificitet og prædiktive værdier.

Algoritmen endte med at bestå af fem trin, der indeholdt både korrekte koder for luksation suppleret med alternative, ofte anvendte koder valideret i *Studie II*. Kombinationen af den korrekt diagnose og procedurekode gav en sensitivitet på 63% og en positiv prædiktiv værdi (PPV) på 98%. Efter at have tilføjet alternative koder lykkedes det at øge sensitiviteten til 91%, mens den PPV blev holdt på 93%. Specificiteten var i alle trin større end 99%.

Studie IV: Formålet var at sammenligne livskvaliteten og den subjektive hoftefunktion hos patienter med en enkelt eller flere tilfælde af luksation med patienter uden komplikationer. Vi identificerede 1,010 nulevende patienter med en eller flere luksationer. Vi matchede patienterne med/ude luksation 1: 2 efter alder, køn, dato og hospital for den primær kirurgi. Vi fandt, at både den generelle og den hofte-relaterede livskvalitet var markant og vedvarende nedsat efter luksation af en hofteprotese sammenlignet med kontrolgruppen, selv 2-5 år efter den seneste luksation.

Studie V: Formålet var at analysere kirurgiske og patientrelaterede risikofaktorer for både luksation og yderligere revisionskirurgi af enhver årsag efter førstegangs revisionskirurgi på grund af luksation. Vi identificerede 1,678 patienter med en primær hofteprotese på grund af slidgigt og en førstegangs revision på grund af luksation foretaget mellem 1996 og 2016. Efter den første revision oplevede 22,4% en ny luksation og 19,8% blev revideret igen. Vi fandt, at patienter revideret med en bevægelig liner (dual mobility cup) eller en låsering (constrained liner) havde en lavere risiko for ny luksation, men ikke en lavere risiko for yderligere revision. Hos patienter hvor kun revision af ledhoved og liner var foretaget, så vi en højere risiko for både ny luksation og yderligere revision, sammenlignet med udskiftning af hele hofteskålen.

Som konklusion har vi identificeret den sande forekomst af luksation af hofteproteser i Danmark til 3,5% efter de første 2 år. Dette er på niveau med andre lande, der bruger den bagre adgang under operationen, men er måske højere end alternative adgange. Vi lykkedes også med at skabe en acceptabel algoritme, der kunne være egnet til at monitorere luksation i et dansk kvalitetsregister i fremtiden. Efter at vi havde fastlagt, at viden om patient-rapporteret livskvalitet og subjektiv hoftefunktion efter luksation var nærmest ikke-eksisterende, gennemførte vi den største undersøgelse til dato vedrørende dette emne. Trods svagheder ved studie designet, så bekræftede vi at mange patienter lider af konsekvenserne af en luksation i mange år. Slutteligt fandt vi risikofaktorer for luksation efter både primær og revisions kirurgi på grund af luksation, hvilket kan øge forståelsen for hvilke patienter og kirurgiske teknikker, der er forbundet med en højere risiko.

1. Background

1.1. Total hip arthroplasty and dislocation – the early results

Degeneration of the articular cartilage in the human hip joint is inevitable. The key question is rather whether it becomes clinically significant and to which degree. It is not a newly emerged condition, and the presence of hip osteoarthritis (OA) has been demonstrated in ancient European populations¹⁻³. The development of OA is often slowly progressive and the underlying cause is multifactorial^{4, 5}. As of today, most people with OA live in peace and tolerate their condition, managing it with exercise, painkillers when needed, and adaption of daily activities to their physical capabilities. However, a minority of the population eventually becomes so badly afflicted by pain, reduced mobility, and decreased quality of life (QoL) that surgical intervention becomes a necessity.

The first surgical attempts to address hip OA were recorded in the late 19th century. Early cases consisted of hip replacements of ivory⁶ or attempts to cover the degenerated femoral head with the skin or submucosa of a pig bladder⁷. Interpositional arthroplasty using glass was tried in the 1920s, while vitalium was tested in the 1930s⁶⁻⁸. Others experimented with rubber and acrylic prostheses^{9, 10}. The first metal hip prostheses showing similarities to the designs of existing models were inserted by P. Wiles in 1938¹¹ and A. Moore in 1940¹². However, the founder of the modern THA is still considered to be Sir John Charnley, who published initial results of his low-friction arthroplasty in 1961¹³.

Then, 10 years later, Charnley published a review describing his methods, including the five-year results of the first 138 THAs performed in the period of 1962 to 1963 at the Wrightington Hospital in England. He described a series of systemic and local complications following the hip surgery (Table 1), including one event of hip dislocation - corresponding to 0.7% of the study population¹⁴. Two American surgeons, following the principles of Sir John Charnley, presented the same promising

Local complications	Systemic complications
Dislocation Subluxation Superficial wound infection Deep prosthetic infection Hematoma Transient peroneal nerve palsy Trochanter bursitis	Deep venous thrombosis Pulmonary embolism Pulmonary infection Paralytic ileus Urinary retention Coronary thrombosis

Table 1. Local and systemic complications reported by J. Charnley five years after his first 138 THAs.

results in their early THA cohorts in 1970^{15, 16}. A review of the first 135 THAs performed by M. Lazansky revealed no postoperative dislocations, although two patients complained of episodes of sub-luxation though¹⁶. Lazansky ascribed his excellent results to the small study cohort and was prepared for dislocations to eventually appear with increased numbers of performed procedures. H. Amstutz reported two dislocations among 154 THAs, suggesting a promising dislocation risk of only 1.3%¹⁵. Then, in the succeeding years from 1971 to 1981, additional surgeons observed dislocation rates of 0.0% to 4.8% among THA procedure counts ranging from 60 to 6,774 THAs¹⁷⁻²⁴. Separately, Woo et al. presented a larger series of 10,500 THAs in 1983, in which 3.2% of the patients experienced a dislocation²⁵.

At the time, divergent opinions existed regarding the expected level for this complication. Charnley's early predictions suggested that, if the correct surgical techniques were applied, a rate of no more than 0.3% dislocations would persist in the future¹⁴. Lazansky's estimations were slightly more conservative but he similarly did not expect it to affect more than 2% of primary THA cases¹⁶. Moreover, some surgeons did even not consider dislocations to be a major problem since recurrent events were rarely reported²².

1.2. Local complications after THA

The possible complications listed by Charnley in the 1970s are still valid today, with a few additions¹⁴. Many of the hip-related complications observed are, fortunately, mild and often self-limiting - at least, in the surgeon's opinion. Local hematoma or wound bleeding is expected to some degree in most patients and rarely requires surgical intervention. Superficial wound infection is reported in 0.8% of patients and is typically treated with antibiotics^{26, 27}. However, a large number of patients may be treated by their general practitioner and not re-admitted to the hospital and, hence, never registered. Nerve palsy, either of the sciatic, femoral, or obturator nerve, is reported in up to 3.7% of patients depending on the surgical approach, and most patients recover completely or partially during the first postoperative years^{28, 29}. Limping may be the result of either a leg length discrepancy or related to the specific surgical approach used. Up to 25% of patients report limping as a problem after the use of the lateral approach³⁰.

Among the more serious complications, aseptic loosening predominantly appears after longer follow-up, resulting in pain, and it is currently responsible for 28% of revisions in Denmark³¹.

Apart from dislocation, other local complications feared by hip surgeons include peri-prosthetic fractures and, in particular, deep prosthetic infection. Peri-prosthetic fractures are reported in 1.5% of patients after 10 years of follow-up, increasing to 9.4% after 22 years, and comprise 17% of registered revisions in the Danish Hip Arthroplasty Register (DHR)^{31, 32}. However, many of the fractures are treated by traumatologists and are therefore not registered in the DHR. Deep infection appears in about 1% of patients after primary THA, with most cases requiring revision either via single- or two-stage procedures³³. The true number of revisions for deep infection was found to be higher than that reported in the DHR, which was explained by challenges in the registration process and lack of coupling between registers³⁴. It should be noted that it can be difficult to compare studies reporting adverse events after THA surgery since the definition of each complication may vary. To accommodate this problem, the European Hip Society recently published their proposal for a standardized list of complications including definitions for use in future research³⁵.

1.3. Dislocation – causes and definitions

In the simplest description, a THA prosthesis consists of a hollow acetabular component (the cup) and a femoral component comprising a stem, a neck, and the femoral head (Figure 1). These two components are typically constructed of various metal alloys or ceramic materials, while a



Figure 1. THA.

polyethylene (PE) liner is often applied between the articulating surfaces³⁶⁻³⁸. A dislocation of the THA is defined as the displacement of the femoral head from the cup (Figure 2). This occurs when the legs are moved to extreme positions, resulting in impingement between the acetabular rim and the femoral neck, which levers the femoral head out of the acetabular socket^{38, 39}. A combination of deep flexion, adduction, and internal rotation of the hip will result in a posterior dislocation of the femoral head.

Typically, extending and externally rotating the hip leads to the anterior

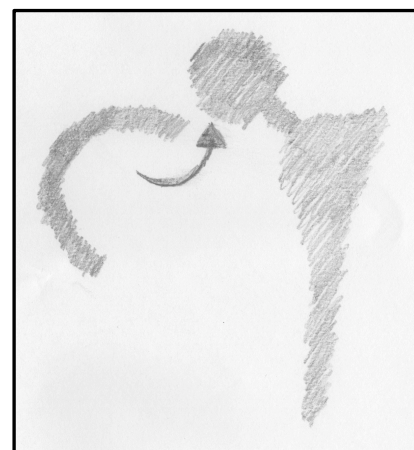


Figure 2. THA dislocation.

dislocation^{38, 40-42}. Classic mechanisms of dislocation in the prosthetic hip include falls, sitting on a low chair and

attempting to stand, crossing the legs when sitting, bending down to tie one's shoes, or when lying down and getting out of bed from lying down⁴³. Dislocation of a THA leads to the immediate onset of intense pain and an inability to stand or walk, while malalignment of the lower extremity may also be clinically visible, which, together, leaves no doubt that a major complication has occurred^{42, 44, 45}.

In contrast with the complete dislocation, some patients report the sensation of transient subluxation, where the femoral head is incompletely levered out of the acetabulum and followed by spontaneous reduction^{46, 47}. A more recent form of THA dislocation is the intra-prosthetic dislocation, which was described after the introduction of the dual mobility concept. In this case, the moving PE liner is displaced, resulting in a direct articulation between the small femoral head and the larger metallic cup. Intraprosthetic dislocation demands revision surgery, while closed reduction is not an option^{48, 49}.

1.4. Variation in the reporting methods of dislocation

The use of primary THAs continues to increase steadily worldwide^{31, 50-53}. Time has shown that Charnley's predictions of no more than 0.3% for dislocations may have been too optimistic¹⁴. Dislocation is now reported in 0.2% to 10% of patients after primary THA, and it is one of the most commonly reported indications for revision surgery⁵⁴⁻⁵⁹. The notable variation in rates among different papers is the result of the multifactorial causality of dislocation and the risk is affected by both patient-, component-, and surgery-related factors⁶⁰⁻⁶². Moreover, there are also differences in the study design and methodology including the cohort size, length of follow-up, data sources, and the choice and availability of outcome.

1.4.1. Prospective clinical studies

Some institutions report the results of a single or few surgeons using prospective designs often associated with the implementation of a new procedure. Their results vary from 0.0% to 7.0%, with follow-up between six weeks and 2.5 years⁶³⁻⁶⁷. These differences may partly be explained by deviation in the follow-up period. Moreover, the studies are typically limited by small study cohorts and, although it is a major and devastating complication for the individual patient, dislocation is a relatively rare incident, requiring large studies to reduce the susceptibility to chance. This problem is sought addressed by others joined in multicenter collaborations, reporting 2.4% dislocations

within three months after surgery^{43, 68}. Common to these prospective studies, however, is that they are time-consuming and expensive to perform, often resulting in shorter follow-up periods.

1.4.2. Arthroplasty register studies

Therefore, most studies rely on prospectively collected data from orthopedic joint replacement registries⁶⁹⁻⁷¹ (Figure 3). Several national registries have been established through the last 50 years enabling both follow-up periods of more than 20 years and cohort sizes that are not achievable in clinical studies⁷²⁻⁷⁸. Studies reporting the extent of dislocation in different subpopulations, time periods, and with varying components using these registries are numerous^{55, 79-85}. However, they are limited to report on only the THA cases with dislocation that are revised for this reason, since closed reductions are not registered within arthroplasty registries. Generally, they report rates for revision due to dislocation of 0.5% to 1.1% after 2.5 to 13.0 years of follow-up within large cohorts of up to more than 192,000 patients.

In Denmark, the registration of every primary and revision THA procedure is compulsive, securing high levels of completeness^{31, 72}. Other nations are challenged by both larger populations and geographic areas as well as more private than public health care systems. Regional arthroplasty registries^{86, 87} and registries managed by private health care organizations^{88, 89} are particularly

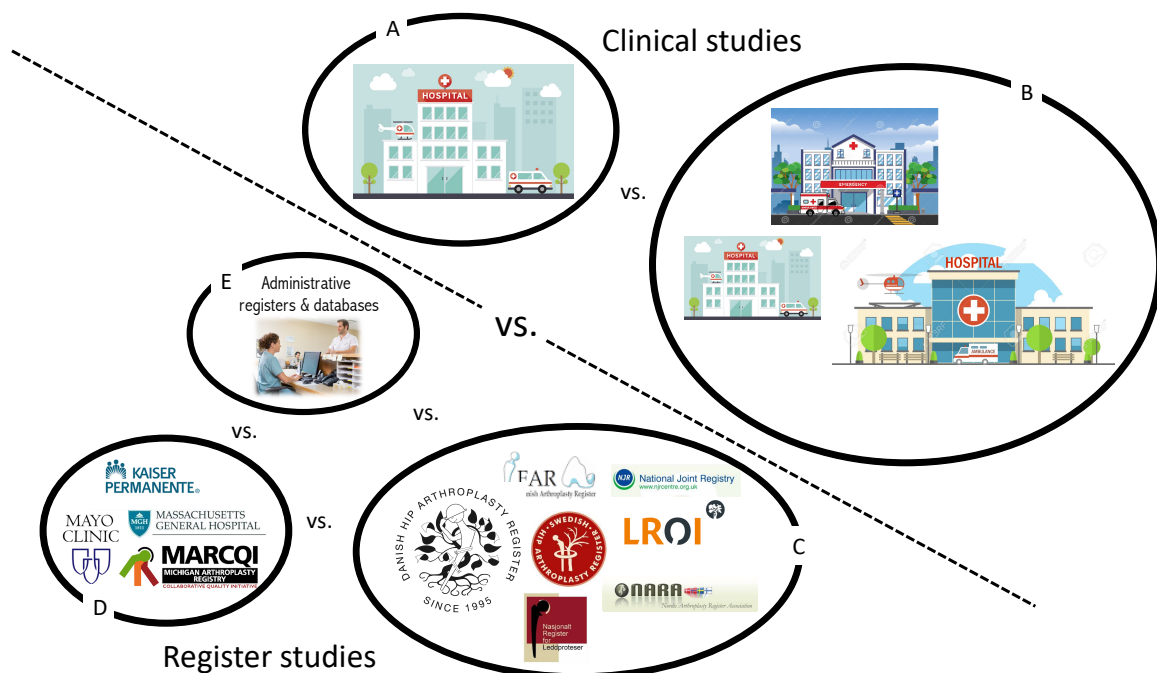


Figure 3. The extent of a complication like THA dislocations can be measured from either clinical, single- (A) or multicenter studies (B), or based on national (C), regional and private arthroplasty registries (D) or from national administrative registers and insurance databases (E).

widespread in the United States. Several studies regarding dislocation are based on these and report rates of 0.7% to 6% for dislocations with follow-up periods as long as 20 years^{25, 90, 91}. Some of these registries may also contain closed reductions, albeit only the ones performed at the participating hospitals.

1.4.3. Health administrative database studies

Another popular data source for identifying dislocations is population-based administrative patient registries. These registries contain enormous information about in- and outpatient hospital contacts, including admission and discharge times and dates, primary and secondary diagnoses, and procedure codes. The Nordic countries are, in particular, favored by a combination of government-funded universal health care and detailed, linkable patient registries covering entire nations⁹². In this context, Denmark is often described as “an epidemiologist’s dream” due to: *”1) its universal tax-funded health care system with residency-based entitlement; 2) the availability of government-maintained nationwide registries, providing longitudinal sources of routinely collected administrative, health, and clinical quality data; and 3) the unique personal identifier assigned to every Danish resident, enabling exact individual-level linkage of all records and lifelong follow-up”*⁹³. The Danish National Patient Register (DNPR)⁹⁴ alone or in combination with the DHR⁷² has formed the basis of several single- and multicenter studies reporting dislocation rates of between 0.9% to 4.4% after up to two years following index surgery^{43, 56, 95-97}. These studies capture both dislocations treated with closed reduction and those that are revised. However, only cases that are coded correctly by the treating personnel.

Other European countries have similar registries that are restricted to regional settings and often lack the opportunity of linkage due to anonymity⁹². In the absence of better alternatives, the American Medicare administrative database is frequently used to determine the number of postoperative complications including dislocations (dislocation rates of 2.0% to 4.2% after six months of follow-up)^{58, 98}. The data in this register differ from those sourced under the Nordic conditions due to being collected for payment purposes only and concerning patients older than 65 years^{92, 99, 100}.

1.4.4. Length of follow-up

Dislocations continue to occur even after several years and cumulate as the follow-up period is expanded^{101, 102}. In Charnley’s first published 10-year results, a rate of 1.6% of early dislocations occurring in the initial three weeks after surgery was noted. Surprisingly to him, an additional 1.6%

late dislocations were revealed after five to eight years among patients with no history of past instability¹⁰³. To date, there is no clear definition in the literature regarding “early” and “late” follow-up. Some studies define the three initial months as early, with 2.8% to 4.4% dislocations^{56, 104}, while others include up to two years in this category, with 0.6% to 3.9% dislocations^{58, 65, 105}. Late dislocations are considered after the first one to five years in different publications, presenting an additional of 0.8 % to 1.2% dislocations^{58, 82, 105-107}. Therefore, it is important to note the extent of follow-up when interpreting the results of dislocation.

1.5. Risk factors for dislocation

As illustrated so far, the reported burden of dislocation greatly depends on the study design as well as the specific outcomes and data sources. In addition, however, patient factors, surgical techniques, and component characteristics also influence the risk of dislocation.

1.5.1. Patient factors

1.5.1.1. Age and sex

Higher age has been identified to increase the risk of dislocation as well as the risk of revision due to dislocation in many studies, although the exact age groups vary among these studies^{43, 55, 58, 90, 95, 102}. This association might be explained by factors such as an increased risk of falling or a higher occurrence of specific comorbidities not being adjusted for. A few studies found no association between age and the risk of dislocation^{79, 91}.

Female sex has also been reported to be an independent risk factor for dislocation in some studies^{90, 102, 108}, while others suggest no difference between the sexes^{55, 95, 109}. A few studies have also found a lower risk of revision due to dislocation in females⁷⁹. However, there is no obvious reason to believe that sex itself should impact the risk of dislocation and other unknown factors could be causing residual confounding. Still, some authors have proposed increased joint laxity in women as one reason to consider¹¹⁰.

1.5.1.2. Comorbidity

Several scoring instruments for determining a patient’s comorbidity level exists. Historically, the Charlson Comorbidity Index (CCI) has been widely accepted as one of the most useful measures for this purpose^{111, 112}. The CCI is based on the International Classification of Diseases (ICD) diagnoses codes found in administrative data. Each comorbidity category has an associated weight, based on

the adjusted risk of mortality. The CCI was originally designed for predicting one-year mortality and has been updated regularly¹¹³. Malkani et al. found an increasing CCI to be associated with a higher risk of dislocation⁵⁸.

Another often-used measure for assessing the degree of comorbidity is the American Society of Anesthesiologists (ASA) score, which is a subjective assessment of a surgical patient's preoperative overall health performed by the anesthesiologist¹¹⁴. An ASA-score of one point refers to a completely healthy patient, while an ASA-score of four points describes a patient whose comorbidities are constantly a threat to their life. Among other outcomes, increasing ASA-score has been found to correlate with in-hospital death following elective THA¹¹⁵. Regarding hip dislocation, Khatod et al. reported dislocation in 1.0% of patients with an ASA-score of less than three points, while 3.3% with an ASA-score of three or more points experienced dislocation⁹¹. Similar findings have been confirmed by others^{95, 109}.

1.5.1.3. Physical condition of the patient

The impact of activity level and physical condition as measured using the patient's body mass index (BMI) is more controversial. Although the categorization of BMI in under-, normal, and overweight is not uniform, both low and high BMI values have been found to predispose patients to dislocations^{95, 116, 117}, whereas others did not reach this correlation^{43, 109}. Moreover, Fessy et al. reported a higher risk of dislocation in patients with lower levels of daily activity¹⁰⁹. The use of walking aids was not found to be associated with dislocation by Jørgensen et al.⁴³.

1.5.1.4. Primary diagnosis

Patients undergoing THA surgery make up a variegated group. According to the hip arthroplasty registries, there are more than 15 specified indications registered^{31, 53, 118}, with OA being the most common, accounting for 75% to 88%. This is followed by acute fractures, secondary arthritis due to childhood hip disease or previous fracture surgery, atraumatic necrosis of the femoral head, hip dysplasia, and inflammatory joint diseases. These patients often differ in several parameters. Patients receiving a THA following a femoral neck fracture are significantly older and possess more comorbidities than OA patients¹¹⁹. Most studies unanimously point out that OA is associated with the absolute lowest risk of dislocation, even after adjusting for age and comorbidity level. Notably, acute femoral fracture patients and patients with previous hip surgery possess a risk of dislocation that is twice that of primary OA^{25, 90, 91, 102, 109, 120}.

1.5.2. Surgical factors

1.5.2.1. *Surgical approach and capsular repair*

To gain access to the hip joint, the surgeon is forced to dissect through various parts of both static and dynamic hip stabilizers. Traditionally, three main approaches are available, but numerous variations and modifications of these original approaches exist¹²¹. The direct anterior approach was first described in the 1940s and is often highlighted due to its muscle-sparing technique^{122, 123}. The posterior approach emerged in the 1950s and is currently the most frequently used approach worldwide^{121, 123}. While no incision of the abductor muscles is needed, the posterior part of the joint capsule and the external rotator muscles must be detached to gain access, which decreases the posterior stability. Then, in the 1980s, the direct lateral approach was introduced as an alternative and it is now globally the second most popular approach^{123, 124}. The surgical approach is one of the most thoroughly researched factors for dislocation and great controversies still exist. Moreover, in the context of choosing the approach, one must keep in mind that dislocation is only one of several possible complications and the total amount of adverse events should be taken into account when considering which option is the “safest” approach^{125, 126}.

The traditional posterior approach is often mentioned as the approach leading to the highest risk of dislocation due to posterior capsular weakening. Some have confirmed this with a hazard ratio (HR) of up to 2.3 compared to the anterior approach^{90, 127, 128}, but most studies are not actually able to confirm this association^{54, 91, 109, 129-134}. In several large-cohort register studies, the use of the posterior approach resulted in significantly more revisions due to dislocation than the other approaches, but not overall revisions^{55, 79, 81, 84, 135, 136}. In contrast with the original posterior technique, the repair of the posterior wall including suturing of both the capsule and external rotators is now standard, since dislocation rates were reported to be up to 8.2 times higher without repair^{57, 127}. This may have decreased the dislocation rate and could explain why many studies do not record significant differences between the approaches nowadays. Recently, modified posterior piriformis-sparing techniques have been described, with promising low dislocation rates^{137, 138}.

1.5.2.2. *Experience of the surgeon*

The existing literature may not be sufficient to finally settle which surgical approach that possesses the safest complication profile and best outcome results¹³⁹. Some reports have indicated that each surgeon's skills and routine with their favorite access can actually have a greater impact on the outcome than the use of one particular approach^{57, 140-142}. Malkani et al. found that the risks of

early and late dislocations increased by 23% and 29%, respectively, when the patients were operated on by surgeons with a volume of five procedures or below per year as compared with higher-volume surgeons⁵⁸. Likewise, Katz et al. reported a dislocation rate of 1.5% within the first 90 postoperative days in patients treated by surgeons who performed more than 50 annual procedures as compared with that of 4.2% if the surgery was performed by a surgeon with fewer than five annual procedures¹⁴¹.

1.5.2.3. Head size and liner type

As technology has made it possible to produce thinner and more durable liners, the use of small head diameters (22/28mm) has decreased, while larger heads (32/36mm) have gained more popularity^{14, 31}. The most important theoretic advantage of the larger heads is the greater displacement distance that is required for a dislocation to happen^{143, 144} (Figure 4). Clinically, this has been confirmed by several authors^{90, 145-147}, while others report no difference^{43, 91}. Large register studies with revision due to dislocation as the endpoint have supported the theoretical benefit of larger heads^{55, 79, 85}. However, when revision for any reason is included separately as an endpoint, others report no difference^{83, 84}.

To reduce the number of dislocations, Charnley presented the elevated rim liner in the early 1970s, which could increase the stability in either the posterior or anterior direction during primary surgery if the cup had been implanted with minor malposition. Insull et al. found a reduced risk of revision due to both instability and any reason with the use of elevated liners as compared with regular liners¹⁴⁸. This was confirmed by two recent studies^{149, 150}.

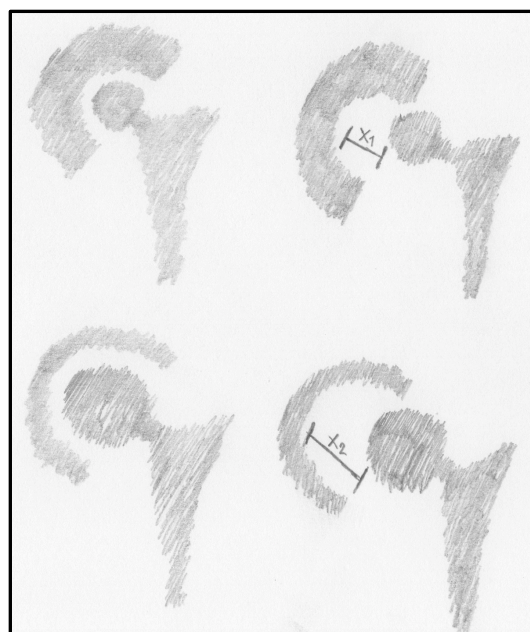


Figure 4. The jumping distance for small femoral heads (X_1) is smaller than for larger femoral heads (X_2). Theoretically, the larger head should therefore imply a lower risk of dislocation since a greater displacement of this head is required before it leaves the socket.

Another attempt to lower the dislocation rate was made with the development of dual mobility articulations in the late 1970s¹⁵¹. The mobile PE liner created an extra articulation between the liner and the metallic shell, thereby increasing the range of motion before the onset of impingement¹⁵². The dual mobility cup (DMC) quickly became popular, not only as the preferred THA type for high-risk patients but in all OA patients in some countries, with promising results¹⁵³⁻¹⁵⁶.

1.5.2.4. Component positioning and fixation

Positioning and angulation of both the cup and the stem are, obviously, of the utmost importance when considering the overall performance and kinetics of the artificial hip. Lewinnek et al. described the relationship between cup anteversion and abduction angle and the dislocation rate. They found 1.5% dislocations in patients with the cup placed in what they defined as “the safe zone” (anteversion of $15^\circ \pm 10^\circ$, abduction of $40^\circ \pm 10^\circ$), and 6.1% dislocations in cases with cup positioning outside this angulation zone²⁰. Similarly, other studies have reported findings of decreased anteversion and higher abduction angle that lead to more dislocations^{95, 109}, while others observed no such association, leading the term “safe zone” to become more controversial^{108, 157-159}. The femoral version also plays a role in the risk of dislocation and a combined version degree for both components may be the most appropriate measure¹⁶⁰. Since a proper estimation of stem ante- or retroversion requires computed tomography (CT) imaging rather than ordinary radiography, this remains, however, more poorly understood.

The use of cemented fixation in primary THA has declined in Denmark and was applied in 32% of the procedures in 2018 (7% total, 25% hybrid), while 68% were left uncemented³¹. The fixation method used differs largely worldwide¹⁶¹. Few studies to date have focused on fixation and the risk of dislocation^{109, 162-164}.

1.5.2.5. Postoperative restrictions

In the early days, patients were bedridden and splinted for several weeks^{13, 18}. Today, selected patients can be discharged just a few hours after surgery¹⁶⁵, but postoperative movement and daily life restrictions remain widely used tools for preventing dislocations. A recent paper showed that there exists significant variation between the Nordic countries as to whether hospitals apply restrictions though. In many hospitals, the restrictions have also been eased over the past five years¹⁶⁶. While Lubbeke et al. found postoperative restrictions associated with fewer dislocations¹⁶⁷, most studies discerned no such difference when changing their protocols to be less restrictive^{56, 64, 66, 168, 169}. Other studies have found that most patients remember the restrictions in detail but do not always comply with them as such affected their sleep and curtailed their daily living^{169, 170}.

1.6. Treatment of the dislocated THA

The dislocated prosthesis is usually managed with an uncomplicated closed reduction maneuver under general anesthesia including proper relaxation, resulting in open surgical reduction rarely being needed^{40, 44, 45, 171, 172}. In the absence of obvious malposition or loosening of the components, the treatment algorithm following reduction of the first hip dislocation is non-operative, frequently involving movement restrictions and braces¹⁷³. There have been many suggestions offered for the most correct conservative or surgical treatment strategy but there are still no high-quality studies available to support these¹⁷⁴. After the first hip dislocation occurs, a substantial risk of further dislocations emerges. Though a small study by Mahoney et al. reported a recurrence rate of only 10%¹⁷⁵, most studies agree that the rate is much higher and report that 39% to 62.5% of patients suffer from recurrent dislocations^{108, 176-181}. The importance of the timing of the first dislocation for the risk of experiencing multiple cases is somewhat uncertain and both early and late first-time dislocations have been associated with recurrence^{105, 108, 177, 180}.

If additional dislocations occur, revision surgery targeting the underlying issue may become necessary to restore hip stability^{173, 182}. The proportion of patients undergoing revision due to dislocation after experiencing one or more cases of dislocation varies from 16% to 51%^{105, 176-178, 181}. However, revision surgery is far from always a successful treatment and, although some studies report only 15% to 18% dislocations after revision for the same reason^{178, 181, 183}, others suggest the rate is as high as 35% to 67%^{176, 184, 185}, while re-revision may be required in 46% of the patients within 15 years¹⁸⁵.

In Denmark, 19% of all first-time revisions are currently indicated by dislocation³¹. This number is 13% in Sweden, 15% in Norway, 18% in the Netherlands, 20% in Great Britain, and 20% to 26% in Australia depending on patient age^{53, 118, 186-188}. This international variance may be explained by differences in the surgical approach, patient selection, local treatment strategies, or the use of specific components, though other factors may also play a role.

1.7. Patient-reported outcomes after THA

The original indications for THA surgery were debilitated, impaired gait function and/or severe pain and the clinical outcome assessment was purely conducted objectively by the surgeons. Nowadays, impaired QoL is a widely accepted independent indication for surgery and, as a result,

the patient experience post-surgery has been increasingly incorporated in the overall evaluation of the outcome⁷. Indeed, *the patients are the 'gold-standard' judges of their symptoms and QoL*¹⁸⁹, and the reported outcome may vary largely between health care workers and the patient themselves¹⁹⁰. In general, good to excellent PROs have gradually become the standard after primary THAs alongside improvements and refinements of both the prosthesis designs and the surgical techniques^{7, 191-195}. These outcomes reflect that most patients are spared from complications and satisfied with their results. However, a good PRO does not always tell the whole story and the patient could still be dissatisfied with the final result. Many factors may impact PROs, including the severity of symptoms, socioeconomic status, comorbidities, and pre-operative expectations¹⁹⁶⁻¹⁹⁸. Expectations vary largely between patients, and if they are not met, such will often result in low levels of satisfaction from the patient despite a well-functioning THA¹⁹⁹⁻²⁰¹.

1.8. Study motivation

Dislocation after primary THA is well-described and both the magnitude of this complication and the risk factors for both dislocation and revision due to dislocation have been extensively reported in the available literature so far. However, the present knowledge regarding both the incidence of dislocation and the accompanying risk factors for the same relies on small, prospective, and regional studies that potentially have missed patients not admitted to participating hospitals as well as being susceptible to chance. Otherwise, the numbers are based on large-cohort register studies that rely on the completeness and validity of the applied registers. Miscoded patients are not included in these datasets and the information from such registers is often not validated due to the large workload involved. To state the “true” occurrence of dislocation and report the risk factors truthfully, there is a need for a large, national study in which all dislocations are captured and also validated.

PROs after successful THA without complications are well-reported and acknowledged. In our view, however, PROs after specific complications are lacking and require attention. As surgeons, we may hypothesize that patients with one or more dislocations may end up with an inferior degree of self-reported hip function continuing to affect on the QoL even years after dislocating their hip. Or, perhaps, time heals both the expected physical and psychological wounds related to the experience of a dislocation. Either of these statements requires further scientific support.

When hip surgeons are considering a revision procedure, the patients are already being informed at that point of the considerable risk of continuous instability and dislocations afterwards since this knowledge is clear. It is less known, however, which patients and what specific surgical interventions are related to the highest post-revision dislocation rate or the highest risk of a second revision. Identifying specific risk factors is therefore essential when planning such revision procedures with the aim of avoiding further surgery.

2. Aims

The overall aim of this thesis was to compile new knowledge regarding the dislocating THA in a Danish setting, using data from patients who received their hip replacement solely due to hip OA. Separate aims for the individual studies included herein were:

Study I

- *To systematically review the literature for studies reporting PROMs after hip dislocation in patients with primary THA compared to patients without any dislocation*

Study II

- *To report the “true” cumulative incidence of hip dislocations within two years of index surgery for all the primary THAs conducted in Denmark from 2010-2014 due to hip OA*
- *Secondary, to analyze patient and component characteristics and surgical approach as potential risk factors for validated dislocations*

Study III

- *To develop an algorithm designed to identify patients with dislocation in the Danish National Patient Register with a high sensitivity, specificity, and predictive values*

Study IV

- *To compare QoL and hip specific outcome measures in patients with a single or recurrent episode of THA dislocation and patients without any complication*

Study V

- *To analyze surgical and patient-related risk factors for both dislocation and re-revision of any cause after first-time hip revision due to dislocation*

3. Methodological considerations

3.1. Study designs and limitations

It is not always easy finding the one thing that causes the other and sometimes we can get confused by data. Graphs may correlate, but causality between the variables assessed may not necessarily be present and correlations between an exposure and an outcome can be due to a third factor that affects them both (Figure 5). These hidden, third factors are called confounders, which originates from the Latin word *confundere* meaning “mixing together”²⁰². Confounding factors can be either easily accessible and amendable or unknown to date and, hence, not manageable. The golden standard study design for stating *causality* between a treatment and the outcome of interest is a prospective randomized controlled trial (RCT). The randomization process of the study cohort should automatically result in an even distribution of both known and, in particular, unknown confounders between the intervention and control groups. Thus, confounding is controlled for in the study design. However, with increasing rareness of the outcome, larger study populations are needed and a well-conducted RCT setup is far from cheap. Therefore, this kind of study is not feasible in many circumstances, both economical and ethical²⁰³.

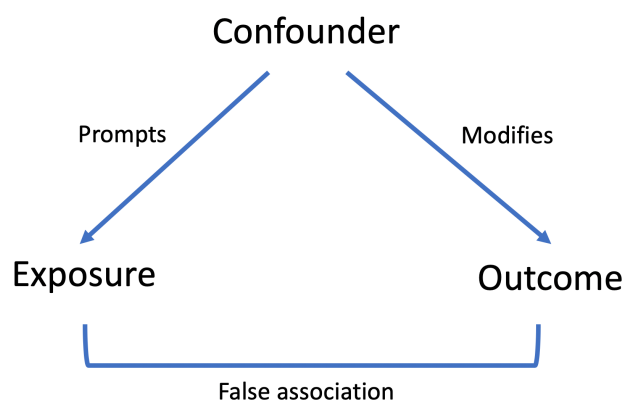


Figure 5. Well-known or unidentified confounders may affect the exposure or treatment and the measured outcome, and thereby create a false association.

3.1.1. Study II

To state the extent of dislocations after primary THA in *Study II*, the conduct of a prospective, clinical study within a specified timeframe would be appropriate. Since we were not interested in comparing two interventions, there was no need for higher quality designs like the RCT. However, a clinical design would require that we identified patients at each hospital prior to surgery, acquired their informed consent, collected all the relevant patient and surgical data, and followed them for years, which would be highly time-consuming and expensive. Instead, we took advantage of the readily available, prospectively collected data within both the DHR and the DNPR. This observational design is highly justified for the purpose of stating complications, yet also made the

study quality deeply dependent on the completeness and validity of the applied registries. It is also important to note that a register study like *Study II* will at most create an association between the chosen risk factors and the outcome. It might be a strong association, but nevertheless it will remain an association since only known and registered factors can be adjusted for as possible confounders. Therefore, the risk of residual confounding during the risk factor analysis would persist as relevant patient- and surgery-related considerations are absent in the registers. In many cases of rare outcomes, we are, unfortunately, left with this strong association and can only imply a causal connection.

3.1.2. Study IV

In *Study IV*, we included all patients alive that had been identified to have dislocations in *Study II* and chose a cross-sectional study design for assessing PROs after dislocation. Using this method, each patient is evaluated at a predetermined, specific time-point, without the possibility of tracking potential changes in the outcome of interest over time. In the context of patients with debilitating OA demanding THA surgery, it would be highly valuable to gather preoperative, baseline PRO results as well as continuous PRO follow-up data at relevant intervals (e.g., six weeks, three months, twelve months and yearly afterward). However, this information did not exist in advance for this study because PROs are not yet routinely collected for THA patients in Denmark^{31, 204}. We would, therefore, not be aware of any preoperative or immediate postoperative subjective differences among patients with and without dislocation that could bias the final scores. The only solution to this problem would be to plan and conduct our own prospective study. Based on a sample-size calculation, such an initiative would require approximately 45 patients with dislocation, where the following items are true:

- 1) the significance level α is set to 0.05 (the probability of falsely rejecting a true null hypothesis)
- 2) β is set to 0.20 (the probability of falsely accepting a false null hypothesis)
- 3) Z_α and Z_β are constants, determined from the chosen α and β level
- 4) the mean clinically relevant difference of the primary outcome score (e.g., a Hip Osteoarthritis and Outcome score (HOOS) QoL domain score) is set to 10 points
- 5) the standard deviation σ is set to 24 (based on the results from the control group without dislocation in *Study IV*)

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times \sigma^2}{d^2} = \frac{(1.96 + 0.84)^2 \times 24^2}{10^2} \approx 45 \text{ patients}$$

If we raised the power ($1 - \beta$) to 90%, the number of patients needed would increase to 61. If we applied an anticipated risk of dislocation between 2% to 5%, we should perform between 900 to 2,250 THA procedures so as to capture 45 patients with dislocation. These numbers are suggested under the assumption that all of the patients with future dislocations agree to participate and are not lost during follow-up. So, an even greater number of patients would probably be necessary. With approximately 9,000 THAs being performed yearly in Denmark due to OA³¹, such a study would not be unrealistic to conduct with the participation of all the hospitals in the Region of Southern Denmark. However, with an expected study planning period of at least one year, two years of surgery, and two to 10 years of follow-up, this was not be feasible within the time limit of this project.

3.1.3. Study V

As was the case in *Study II*, we relied on register data from the DHR in *Study V*, where we assessed potential risk factors for both new dislocations and re-revision in patients who had undergone a first-time revision procedure due to dislocation. A limitation within this study design was the risk of confounding by indication related to the first-time revision procedure that enabled patients to be included but also the potential patient selection for a re-revision. Inevitably, some patients are deemed not to be candidates for revision surgery and we cannot exclude the possibility of this having had an impact on the study results. However, conducting such a study by means other than using register data was not feasible.

3.2. Linkage of registers

In this thesis, we took advantage of the exceptional possibilities for data linkage at the individual level. Immediately after birth, in Denmark, each child is assigned a unique 10-digit personal identifier number – the Central Personal Register (CPR) number – that is based on their day, month, year, and century of birth and their sex. The introduction of a personal identifier system was made in 1924 and was handled locally for more than 40 years with no central organization. The CPR number, as we know it today, was introduced in 1968, first and foremost to ease the introduction of a central tax system but also due to an increasing need for easy access to current information on the citizens, which led to the gathering of information from the local population registers into a new common, nationwide register²⁰⁵. The CPR number is registered in every Danish health care register and quality-assessment databases and grants the possibility for unambiguous linkage between the

registers. For *Studies II* through *IV*, a common cohort was extracted from the DHR and data were added from the DNPR, the Danish Anesthesia Database, and the Danish Civil Registration System (CVR) to create the complete dataset (Figure 6). Meanwhile, a separate extraction from the DHR constituted the study cohort in *Study V*, albeit enriched using data from the DNPR.

3.2.1. The Danish Hip Arthroplasty Register

The DHR was established in 1995 and aimed to gather information on every primary and revision THA performed in Denmark in order to monitor, secure, and increase the level of quality within hip replacement surgery. The register is nationwide and the registration of procedures is

compulsory at both public and private institutions⁷². The completeness varied between 93% and 98% for primary procedures in the year 2010 to 2014²⁰⁶⁻²¹⁰, and from 83% to 93% for revisions in the years 2010 to 2016²⁰⁶⁻²¹². The reported diagnoses in the register have been validated in a few studies to date, suggesting moderate-to-high validity^{34, 213}. The DHR contains information on every relevant surgical variable, laterality, sex, age at the date of surgery, among others. Data concerning comorbidities (ASA-score) have also recently been included.

3.2.2. The Danish National Patient Register

In 1977, the DNPR was founded as a central, national hospital register that should replace the local, administrative databases in every Danish county. The register has been continuously expanded and, today, includes data on admission- and discharge times and dates, primary and secondary diagnostic codes, procedure codes, and laterality among many other variables for acute or planned in- and outpatient contacts at somatic or psychiatric hospitals⁹⁴. The register completeness tops 99% because no treatment can be provided before registration⁹². From 1977 to 2019, more than 47,000,000 hospital admissions were registered in the DNPR and the huge amount of data available makes its validation difficult. In a random sample from 1990, the Danish health authorities found high correlation between data in patient files and registration in the DNPR.

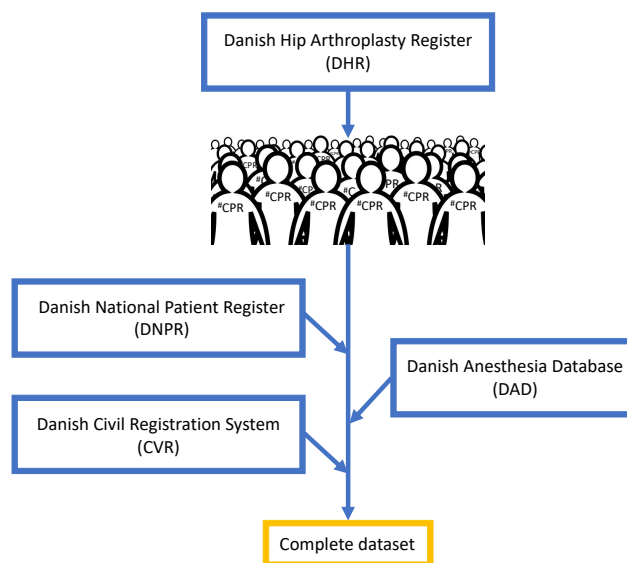


Figure 6. The unique CPR-number of every Danish citizen made it possible to link the original cohorts, extracted from the DHR, with supplemental data from additional registers, to create the complete datasets.

However, considerable variation between medical specialties became evident upon observing the lowest PPV for medical diagnoses (66%) and the highest PPV for orthopedic surgery diagnoses (83%)²¹⁴. A large review from 2015 found that the PPVs of diagnoses and treatments varied extensively from 15% to 100%⁹². Only three studies regarding orthopedics, one of which concerned traumatic hip dislocation, were identified, with PPVs ranging from 16% to 86%²¹⁵⁻²¹⁷.

3.2.3. The Danish Anesthesia Database

Patients undergoing general or regional anesthesia are registered in the Danish Anesthesia Database since its establishment in 2004. The completeness of the register is at a moderate level though (65%), partly due to the lack of national coverage^{218, 219}. However, this register contains additional patient-related variables that were not collected in the DHR between 2010 to 2014 that were relevant for the *Study II* risk factor analyses. We chose to include the available data regarding BMI and ASA-score, well aware that data would be missing for some patients, as we considered these potential confounding variables to be important.

3.2.4. The Danish Civil Registration System

The Danish CVR was created in 1968 following the assignment of the CPR number to all Danish citizens. Registration in the CVR is determined by law and the register contains information regarding name, sex, date of birth, place of birth, place of residence, vital status, and date of death. The register has never been formally validated but is considered to possess a high data validity since its data are used almost daily by many public institutions and errors are, therefore, detected and corrected quickly^{205, 220}. We extracted information on the vital status and date of death for *Studies II* through *V*, which is updated daily, and on the name and place of residency for *Study IV*.

3.3. Study population

3.3.1. Indication for surgery

We limited our cohorts in *Studies I* through *V* to include only patients with primary OA comprising about 80% of all the primary THAs conducted in Denmark every year³¹. With this decision, we aimed to unify the study population but we also created the limitation of less generalizability. The baseline characteristics and the outcome in terms of dislocation vary largely between patients with primary OA and other indications, such as acute femoral neck fractures, secondary OA due to earlier fracture, and rheumatoid arthritis, among others^{119, 120}. The lower age

limit for inclusion was set to 40 years, simply due to the rare manifestation of primary OA below this threshold²²¹⁻²²⁴.

3.3.2. Sampling method

In *Study II*, we chose to include every patient with a primary THA due to primary OA performed between 2010 and 2014. Usually, it would be deemed too huge a task to determine a mean value of an outcome based on an entire population and, in many cases, it would not be worth the effort. To lessen the workload, a random sample is often chosen. A sample mean is accompanied by a confidence interval (CI) that states in which interval the true mean is found, often with 95% certainty (Figure 7).

We did not find it attractive to perform the study using a smaller sample primarily due to the potential and maybe anticipated inconsistency in diagnoses and procedure coding inherent in everyday clinical practice. Based on our clinical experience, the reduction of dislocated THAs is performed by a broad range of medical personnel, ranging from the most experienced orthopedic hip surgeon to the more or less inexperienced, orthopedic-interested medical student, albeit with the latter typically acting under supervision. This discrepancy may increase the risk of applying wrong codes. Moreover, we included the whole country, as we considered the risk of differences in coding accuracy between both the regions and the hospitals. Finally, in order to create a truthful algorithm in *Study III*, we needed to validate all applied codes.

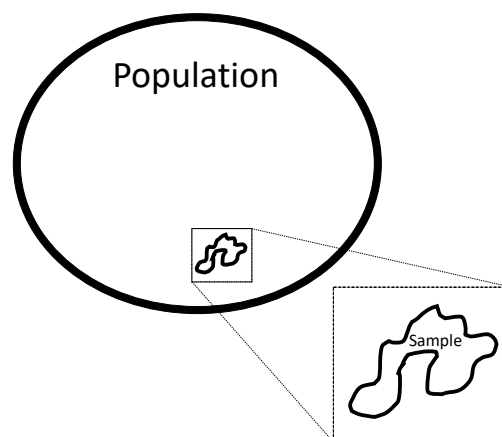


Figure 7. In order to find the mean value of an outcome an entire population, a random sample is often selected. The more the sample is representable of the population, the more the sample mean will be similar to the population mean. The 95% CI of the sample mean denotes the interval in which the true population mean is with 95% certainty.

3.4. Identifying every dislocation

The ambition of detecting every THA dislocation in *Study II* demanded a comprehensive and thorough search strategy. To find and include wrongly coded dislocations, we drafted a broad list of every hip- or dislocation-related diagnostic codes in the ICD-10 classification system and procedure

codes for every hip-related intervention (Appendix 9.6.). Every patient contact with the health care system marked with one of these codes was extracted from the DNPR, regardless of medical specialty and type of contact. These contacts were then divided into two groups; genuine dislocations and possible dislocations. Genuine dislocations were defined as contacts with a combination of the correct diagnosis (DT84.0A) and procedure code (KNFH20 – “*reduction of dislocated joint prosthesis in the hip, closed*”) under the assumption of a very low misclassification rate by this combination. All other contacts, including the two correct codes isolated, were deemed as possible dislocations and were manually reviewed to verify dislocations.

Currently, all patient files that describe hospital contacts in detail from admission to discharge are stored locally at each hospital and, apart from a few exceptions, these files can only be accessed from this particular location. The present law prohibits any researcher from visiting foreign hospitals and read the patient files. Only employees at the treating department can be granted access by the Head of Department. However, it is allowed for an employee at the treating department to open the files, make copies of the relevant material, and pass this copy on to the researcher. In both instances, though, a permission is required from the Danish Patient Safety Authority. For one-third of the contacts, copies were made and transferred. The remaining contacts were reviewed locally by a total of 12 medical students and doctors who had been thoroughly instructed about the task and who were supervised on the first day. Each hospital contact was assigned a unique record identification number and uploaded into a Research Electronic Data Capture (REDCap) database that was designed for the study. REDCap (Vanderbilt University, Nashville, TN, USA) is a browser-based software solution that can handle any kind of data retrieval task or electronic questionnaire surveys²²⁵. For each contact, the reviewer validated the dislocation, date of dislocation, laterality, number of dislocations during each admission, and date of any additional dislocations during the same admission. A potential limitation was the lack of double entry of data into the database, which could advantageously have been done for a smaller fraction of the study population.

3.5. Definition of outcomes

Dislocation of a THA was defined as the complete dissociation between the femoral head and the acetabular cup requiring medical assistance for reduction, either correctly coded or described in the patient files.

The extent of dislocations can be presented by using a range of statistical expressions. The current literature include terms such as incidence^{24, 68, 120}, cumulative incidence²²⁶, frequency^{158, 227}, risk^{43, 56, 128, 141}, cumulative risk^{90, 102, 185}, rate^{25, 160, 168, 176}, cumulative rate⁶⁷, incidence rate²²⁸, and prevalence^{104, 107, 110}, with several studies using multiple terms alternately in the same paper.

We chose the term *cumulative incidence* as the most appropriate outcome measure to describe the true occurrence of dislocations in *Study II*. An *incidence* refers to the number of patients who develop the disease or experience the specific health-related event during a period of time, relative to the total population. The incidence is often presented as an *incidence proportion*, which is equivalent to the *risk*, *frequency*, or even *rate* in many studies – in other words, the probability of developing the disease. One should be aware of that an incidence proportion may underestimate the “true” result as it ignores the patients that are lost to follow-up or excluded during the study and simulates that these patients would be free of disease for the rest of the planned follow-up period. Our follow-up period was two years and we expected low numbers of deaths, migrations, and revisions to occur during this short- to medium-term follow-up period. The term *cumulative* in the context of epidemiology refers to the risk of developing the disease within a specified period of time. Therefore, the phrase *cumulative incidence (proportion)* is applicable if every patient within the study population has been followed for the prespecified time period (i.e., if no deaths or loss to follow-up occurred).

Moreover, the incidence, presented as a proportion, is an easily understandable measure, whereas the incidence rate (*or person-time rate*), on the other hand, is more so an epidemiologic measure wherein the denominator is the time that each patient was observed, totaled for all patients. This allows for patients to enter a study at different starting points. The incidence rate also assumes that the probability of getting a dislocation remains constant during the entire study period and this is hardly the case for dislocations.

In *Study V*, we use the terms *incidence (proportion)* and *risk* to describe the probability of either a new dislocation after a first-time revision or a second revision due to any cause. These patients were not followed for the same amount of time since they are older and more likely to be excluded during the study timeline.

3.6. Adjusting for confounding factors

As mentioned, it is not always feasible to control for confounding via the study design and it is therefore often completed during the statistical analysis using different regression models. Using these models, we are attempting to make all other possible confounding factors identical except for the one variable of interest. The confounder variables are often referred to as predictors, covariables, covariates, or explanatory variables. Before making adjustments for multiple factors, one should carefully consider each variable. In theory, a confounder is a variable that influences both the exposure (the independent variable) and the outcome (the dependent variable). Moreover, the confounder must not fall within the possible causal pathway between the exposure and outcome. Adjusting for too many unnecessary confounders may mask the true effects of others, especially if the sample size is small. Furthermore, including too many risk factors will also enhance the risk of making a type-1 error.

Choosing the most appropriate regression model mainly depends upon the outcome. If the outcome is a continuous variable (e.g., blood pressure level), a multiple (or multivariable) *linear regression* approach would be suitable²²⁹. As a simple rule, one factor can be adjusted for every 10 participating patients²³⁰. In medical science, the outcome is often binary or categorical, such as mortality or another catastrophic event, and the *logistic regression model* is, hence, the most often model used. The rule for the maximum number of variables able to be included differs and depends on the number of events instead of the study sample (i.e., one variable per 10 events). In other words, if 40 out of 1,100 patients develop a disease, then four confounders can be included in the analysis²³⁰. In both linear and logistic regression models, we assume independence among the included observations (patients) and linearity between the dependent and independent variables of interest. Moreover, we assume that every patient has the same two potential outcomes when using the logistic model.

In a study, not all patients complete the intended follow-up period: some choose to withdraw from the trial, die before the event of interest, migrate, or are simply lost for unknown reasons. Therefore, the individual follow-up periods may vary largely. In this situation, the time variable becomes essential and is incorporated into the *Cox proportional-hazards regression model*, which examines how specified covariates influence the rate of a particular event from happening at a particular point in time. The patients who do not experience the defined outcome are, to use a common term, censored. These censored patients are included in the Cox regression analysis and contribute to the

calculated hazards. As was true in the logistic regression, using a ratio of 1:10 between the number of covariates and events is the rule of thumb in this context as well²³¹.

3.6.1. Study II

The three mentioned analyses are the most frequently used but far from the only ones available, as there are many more specialized alternatives also exist²³². Regarding the risk factor analysis in *Study II*, our outcome (the dependent variable) was categorical – that is, the patients either experience dislocation during the two-year follow-up period or they do not. Therefore, the risk factor analysis was conducted by a multivariable logistic regression model, in which the chosen potential risk factors were also adjusted for. With a five-year inclusion period and 9,000 annual THAs, 80% of which are due to primary OA, and the exclusion of contralateral hips, we anticipated a population of 30,000 eligible THAs. Based on the literature, this study population could be expected to experience between 600 and 1,500 dislocations with a risk of 2% to 5%. A total of 600 dislocations would allow for 60 covariates to be examined. We chose to include four patient-related risk factors (age, sex, ASA-score, and BMI) and three surgery-related (head size, fixation, and approach). These were, in our opinion, the most relevant and, importantly, the ones most readily available. All seven risk factors were analyzed as categorical variables rather than continuous ones, providing 25 cumulative subcategories, which is within a good range of the theoretical allowed maximum.

3.6.2. Study V

In *Study V*, we were interested in discerning risk factors for both dislocation after a first-time revision due to dislocation and for a re-revision of any cause. Despite the outcomes also being categorical, a logistic regression would not fit in this study. We included patients over a 20-year period from 1996 to 2016 with individual follow-up times varying from one day to 21 years. The time-to-event should therefore be incorporated into the regression analysis. As compared with in *Study II*, the revision patients were older and more likely to die during this longer study. This introduced a competing risk that would interfere with the assumption of “*independent*” censoring in a normal Cox regression analysis²³³. This assumption implies that censored patients at a certain time point are representative of the patients who are still at risk at this specific point in time^{234, 235}. However, a dead patient does not have the same risk of dislocation or re-revision as a patient still alive and included. In order to adjust for the competing risk of death, we applied a *Fine-Gray regression analysis* to calculate a sub-distribution HR (sd-HR) for each covariate. In the Cox

model, the regression coefficients represent the relative effect of the covariates on the hazard of that the outcome will occur. The sd-HR denotes the relative difference in the rate of the events among subjects who have not yet experienced the event of interest but who may have already died²³⁶. It is important to remember that, with a sd-HR, it is only approximately correct to quantify the magnitude of the effect on the incidence of the event. In many instances, only the direction of the effect of a given covariate should be discussed. However, when analyzing rare outcomes like dislocations, the sd-HR can be compared with the effect on the risk of the event²³⁶.

3.7. Overall QoL and hip specific patient-reported outcome measures

3.7.1. Generic questionnaire

As a generic questionnaire used to measure health-related QoL (hr-QoL), in *Study IV*, we chose the EQ-5D-5L. It covers five dimensions of current health status at the specific date of questionnaire completion, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The original questionnaire came with three standardized response options. In the five level version, each dimension is coupled to a five-point Likert scale that ensured increased sensitivity and reduced the ceiling effect²³⁷. An index value is calculated relative to the norm values for the relevant population (country), where an index value of 1 represents full health, that of 0 represents death, and that below 0 represents a health state worse than death. A visual analog scale (VAS), ranging from 0 to 100 points, is also included to record an individual's rating of their current hr-QoL state²³⁸. The EQ-5D is a widely used and simple tool, which increases the possibilities for comparisons.

A limitation inherent with the use of the EQ-5D questionnaire may be its lack of measuring the overall QoL. According to the World Health Organization, the definition of QoL is *“an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns”*²³⁹. Terms like “health status”, “hr-QoL”, and “functional status” are used interchangeably and often equated with the actual QoL²⁴⁰. However, there are many determinants of QoL and these factors should not be misinterpreted as being effective indicators of QoL. A person's health is an example of a determinant and the impact of this particular part on the overall QoL may vary markedly; as such, it is likely that we assign the concept of health too much importance²⁴¹. It is also important to note that a single questionnaire producing a summarized outcome will not be suitable for application in

the context of every disease. Diseases affect patients in different aspects of patient's life; hence, a low score in one domain may be hidden by higher scores in other domains and vice versa. A disease-specific QoL PROM may be more appropriate in some instances: the OsteoArthritis Knee and Hip Quality Of Life (OAKHQOL) from 2004 is one such example²⁴², although it is not presently widely used.

3.7.2. Hip-specific questionnaire

In *Study IV*, we found the HOOS questionnaire to be the most suitable and relevant for patients with hip dislocation, in particular due to the following third item of the hip-related QoL domain, which we found exceptionally important for our study: *“how much are you troubled with lack of confidence in your hip?”*²⁴³. Several other hip-specific PROMs have been developed, of which the most applied are the Harris Hip Score (HHS)²⁴⁴, Oxford Hip Score²⁴⁵, and Western Ontario and McMaster Universities Arthritis Index (WOMAC)²⁴⁶, while less common questionnaires include the Lequesne Index of Severity for Osteoarthritis of the Hip²⁴⁷, and American Academy of Orthopedic Surgeons hip and knee questionnaire²⁴⁸⁻²⁵⁰. All of these, except the HHS, are completely patient-reported yet lack a focus on hip stability. The HOOS has previously been validated for use in THA patients²⁴⁸ and a validated Danish version exists. Since we did not possess any kind of preoperative information concerning the QoL state and self-reported hip function of the included patients, we found it important to incorporate items suggesting patient satisfaction regarding their primary procedure. Obviously, this would, to some degree, require the ability to remember their preoperative state and could introduce a certain degree of recall bias.



Figure 8. Patient satisfaction was incorporated in Study IV with three separate items in order to state whether a) the patient were satisfied with the primary procedure; b) the hip function is better after the primary procedure compared to the pre-operative condition; c) the patient would undergo the same procedure once more.

4. Summary of the results

4.1. Study I

Our aim was to systematically review the literature for studies reporting PROMs after hip dislocation in patients with primary THA compared to patients without any dislocation.

The protocol was based upon the Preferred Reporting Items for Systematic reviews and Meta-Analysis Protocols (PRISMA-P) guidelines²⁵¹. In accordance with the guidelines, we registered our protocol in the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42017076125).

We identified 3,460 unique studies using a simple and broad search query. Through-out the title/abstract screening, 3,432 studies were excluded. We assessed the full text of the remaining 28 articles for eligibility, and of these, only two studies met the inclusion criteria^{252, 253}. One study reported no statistically significant differences in the reduced WOMAC and SF-12 scores between the 32 patients with dislocation and the 64 patients without dislocation. However, the group without dislocation was significantly more satisfied, postoperatively²⁵³. The second study primarily compared the anterolateral and posterior approaches. During the paper, the authors state that patients with dislocation loose approximately five points in total HHS, compared to non-dislocators²⁵².

Based on our systematic review, we concluded that knowledge of patient reported QoL and subjective hip function post-dislocation is merely non-existent.

4.2. Study II

Our aim was to report the “true” cumulative incidence of hip dislocations within two years of index surgery for all the primary THAs conducted in Denmark from 2010-2014 due to hip OA.

Secondary, we aimed to analyze available patient and component characteristics and surgical approach as potential risk factors for validated dislocations.

From the DHR, we identified 31,105 eligible primary THAs, for whom the DNPR contained 16,108 health care contacts. We reviewed more than 5,000 patient files and identified 1,861

dislocations in 1,079 THAs. The “true” two-year cumulative incidence of hip dislocation was 3.5% (95% CI 3.3-3.7). We revealed that 724 of the 1,079 THAs with at least one episode of dislocation would have been captured in the group with genuine dislocations at some point during the follow-up period, even though not all dislocations of a particular THA were correctly coded, meaning that the administrative database (DNPR) alone yielded a cumulative incidence of 2.3% (2.1-2.5).

Patients younger than 65 years had a lower risk (OR=0.70; 95% CI, 0.59-0.83) and those older than 75 years had a higher risk of dislocation (OR=1.32; 1.14-1.52) compared to patients aged 65-75 years. Patients with ASA-1 had a lower risk (OR=0.70; 0.56-0.87) and with ASA-3/4 an increased risk (OR=1.64; 1.33-2.03) compared to those with ASA-2. BMI >35 seemed to protect against dislocation (OR=0.60; 0.40-0.90). Male gender (OR=0.86; 0.75-0.98), cemented fixation (OR=0.71; 0.58-0.87) and lateral approach (OR=0.28; 0.16-0.49) were all associated with lower risk. Head size of 32 mm had a higher risk of dislocation (OR=1.27; 1.10-1.46) than 36 mm heads, while DMCs were highly protective (OR=0.13; 0.05-0.36).

After having looked in every corner of the Danish health system, we concluded the “true” cumulative incidence of hip dislocations to be 3.5%. This was 50% more than if the result had been based on registries alone. Secondary, we found age, gender, ASA-score, head size and type, fixation method and surgical approach to be independent significant factors for validated hip dislocations.

4.3. Study III

Our aim was to develop an algorithm designed to identify patients with dislocation in the DNPR with a high sensitivity, specificity, and predictive values.

We designed the algorithm using a stepwise approach by adding codes in each step, hereby continuously increasing the sensitivity while at the same time keeping the specificity and the PPV high. Based on the work in *Study II*, we identified more than 70 different diagnoses and 55 different procedure codes coupled to the hospital contacts with dislocation.

The algorithm ended up consisting of five steps. Step 1 was a combination of the correct codes (*DT840+KNFH20*) which produced a sensitivity of 63% and a PPV of 98%. We then added alternative and often applied codes (*DS730, KNFH(00;02;20;21;22)*) in three steps and ended with increasing the sensitivity to 91%, while maintaining the PPV at 93%. In the last step (*DT840 alone*),

the sensitivity increased to 95% but at the expense of an unacceptable decrease in the PPV to 82%. Specificity was in all steps greater than 99%.

We concluded that it was possible to create an algorithm identifying dislocations with acceptable sensitivity, specificity and predictive values. The algorithm has the potential to monitor dislocations after THA in Danish quality registers.

4.4. Study IV

Our aim was to compare QoL and hip specific outcome measures in patients with a single or recurrent episode of THA dislocation and patients without any complication.

Based on the work in *Study II* and the use of our algorithm from *Study III*, we identified 1,010 living patients with one or more dislocations. We matched patients with dislocation 1:2 upon age, sex, date and hospital of primary surgery to patients without dislocation. They received three PRO questionnaires (EQ-5D, HOOS, and the University of California, Los Angeles (UCLA) activity scale) and three satisfaction items. Mean follow-up was 7.2 years from index surgery and 4.9 years from the latest dislocation.

The response rate was 70.1%. Patients without dislocation reported a higher EQ-5D VAS score of 75.6 (95% CI, 74.5-76.7) compared to 67.8 (65.9-69.7) in the dislocation group, which further declined to 60.8 (57.1-64.6) in cases with revision(s). The EQ-5D-5L index mean score was 0.89 (95% CI, 0.88-0.90) for the control group, 0.78 (0.76-0.80) for the cases with dislocation without revision, and the index declined further to 0.72 (0.68-0.77) for the cases with revision(s).

Regarding hip-related QoL, patients with dislocation reported a lower HOOS-QoL domain score of 62.8 (95% CI, 60.2-65.4) compared to 82.9 (81.7-84.1) in the control group. When the case group was divided based on the number of dislocations, we found that an increasing number of dislocations was associated with lower QoL scores. The HOOS-QoL score was 53.6 (48.0-59.1) if fewer than two years had passed, whereas scores of 64.3 (59.3-69.3) and 65.6 (62.0-69.2) were reported for two to five years and more than five years follow-up since the last dislocation, respectively. The other HOOS domains were consistently 8-10 points worse after dislocation.

The mean UCLA scores for controls, cases with dislocation without revision, and cases with dislocation and subsequent revisions were 5.8 (95% CI, 5.6-5.9), 5.2 (5.0-5.4), and 4.8 (4.5-5.2) respectively.

Nearly 90% of patients without dislocation reported that the hip is “much better” than before the primary surgery, whereas only 70% of cases with dislocation report the same. Similarly, only 59% of the dislocation group reported either an “excellent” or a “very good” overall result, whereas the same number was 85% for the control group.

We concluded that both health- and hip-related QoL is markedly and persistently reduced after THA dislocation compared to a control group even two to five years after the latest dislocation. The most important aspect must be to avoid the first episode of dislocation, since the full relieving potential for this THA is never achieved.

4.5. Study V

Our aim was to analyze surgical and patient-related risk factors for both dislocation and re-revision of any cause after first-time hip revision due to dislocation.

In the DHR, we identified 1,678 patients with a primary THA due to OA and a first-time revision due to dislocation between 1996 to 2016. Risk factors were analyzed by a Fine-Gray multiple regression analysis adjusting for the competing risk of death. Results were presented as sd-HR.

After first-time revisions due to dislocation, 22.4% experienced a new dislocation and 19.8% were re-revised for any reason. Median follow-up was 5.3 years.

For new dislocations, the sd-HR was 0,36 (95% CI, 0.27-0.48) for those who had a constrained liner (CL) during revision and 0.21 (0.08-0.58) for DMCs meaning a lower risk of dislocations compared to regular liners. Changing only the head/liner increased the risk of dislocation (sd-HR=2.65; 2.05-3.42) compared to full cup revisions.

Regarding risk of re-revisions, changing only head/liner resulted in an increased risk of re-revision (sd-HR=1.73; 1.34-2.23). Patients <65 years had increased risk of re-revision compared to 65-75 years (sHR=1.36; 1.05-1.77).

We concluded that patients revised with a DMC and CL were associated with a lower risk of dislocation after a first-time revision but not re-revision, whereas only changing the head/liner was associated with higher risk of dislocation and re-revision.

5. Discussion

Every patient undergoing THA surgery is taking a risk when they choose to put themselves under the knife of an orthopedic surgeon. This is not any different than for any other surgical intervention where the skin barrier is breached. Some complications occur frequently, others rarely, several are minor events, and few are disastrous and life-changing. Disregarding that the majority of patients obtain excellent results after THA surgery, it is of the utmost importance that patients are well-informed of the potential side effects during the decision-making process. In order for us, as hip surgeons, to fulfill this important task sufficiently, there is a constant need of providing updated and reliable data. In this thesis, we have focused on a single complication following both primary and revision THA, well-aware of the fact that dislocation is just one of many potential adverse events that may appear after these procedures. The etiology of hip dislocation is indeed multifactorial and definitive conclusions based on the current knowledge are difficult to make due to the large diversity in current study designs.

5.1. The current incidence of instability

With overwhelming certainty, we have presented the cumulative incidence of dislocation experienced by the more than 30,000 patients who underwent primary THA surgery indicated by primary OA from 2010 to 2014. Obviously, we are not able to definitively state whether this risk is also valid for patients in 2020 and beyond. Implant portfolios are renewed, experienced surgeons retire and are replaced by upcoming residents, and every new patient is unique. However, the present data are based on a nationwide follow-up of five years of surgery and could reasonably be extrapolated to present-day patients. Below follows a review of previous Danish results as well as the latest publications from outside the borders of Denmark. This distinction is made due to the expected differences in the countries' medical culture; surgical techniques; component types; patient selection; and follow-up opportunities, which we claim are far better in Denmark than elsewhere.

5.1.1. Danish results

We found that 3.5% of our cohort suffered at least one episode of dislocation within the first two years after surgery. This outcome blends well among earlier results in Denmark, as the studies published during the past 10 years report 0.9% to 4.4% dislocations (Table 2). Most of the studies

Table 2 - Danish studies							
	Design	Cohort size	Diagnosis	Approach	Follow-up	Procedure for detecting dislocations	Outcome
Kristiansen et al. 1985²⁵⁴	Cohort study; data retrospectively collected	n=427	Mixed	Posterolateral	1.3 years (mean)	N/A	4.9%
Husted et al. 2010⁹⁷	Cohort/Register study; data prospectively collected	n=947	Mixed	Posterolateral	3 months	DNPR	3.5%
Jorgensen et al. 2014⁴³	Cohort/Register study; data prospectively collected	n=2,734	Mixed	Posterolateral	3 months	DNPR, verified in medical records	2.4%
Mikkelsen et al. 2014⁶⁶	Clinical cohort study; data prospectively collected	n=365	OA	Posterior	6 weeks	N/A	2.2%
Gromov et al. 2015⁵⁶	Cohort/Register study; data prospectively collected	n=1,329	Mixed	Posterolateral	3 months	DNPR	2.8%
Seagrave et al. 2017⁹⁵	Cohort/Register study; data prospectively collected	n=1,326	Mixed	Posterolateral	1.9 years (mean)	DNPR	4.4%
Rosenlund et al. 2017²⁵⁵	RCT; data prospectively collected	n=39 n=38	OA	Posterior Lateral	1 year	Medical records	2.6% 0.0%
Madsen et al. 2019⁹⁶	Clinical cohort study; data prospectively collected	n=116	Mixed (90% OA)	Posterolateral	3 months	DNPR	0.9%
Lindberg-Larsen et al. 2020¹⁶⁴	Cohort/Register study; data prospectively collected	n=8,096	OA	Posterolateral	1 month	DNPR and Patient records	1.2-1.8%
Hermansen et al. 2020²⁵⁶	Cohort/Register study; data prospectively collected	n=31,105	OA	Posterolateral Lateral	2 years	DNPR and Patient records	3.6% 1.0%

are limited to three months of follow-up only and the DNPR has been the preferred tool for detecting dislocations. In the study by Jørgensen et al.⁴³, the authors emphasize that patient files for every readmission after the primary procedure were scrutinized to avoid missing events of dislocation. In the remaining studies, with a clear statement of how dislocations are captured, it seems as though the DNPR was applied without validation using patient files^{56, 95-97}. However, it is not clear which specific codes have been applied in the DNPR search. Most likely, only the strict correct diagnosis and/or procedure codes were chosen, which implies a risk of missing patients with dislocation who were coded improperly as indicated by our results. Most of the available studies recruited their patients consecutively, regardless of the underlying diagnosis. Although the majority of patients reasonably can be assumed to suffer from primary OA, the existence of mixed-diagnoses cohorts should be kept in mind when interpreting the results as most of the alternative diagnoses are associated with higher dislocation rates.

5.1.2. International results and the surgical approach

The posterior approach has been the preferred access to the hip joint in Denmark for many decades and is chosen in 97% of procedures³¹. Although many independent factors certainly play an important roles in the dislocating THA, the surgical approach has traditionally attracted a great deal of attention. Among the most widely used approaches and their modifications, the posterior access has been known as the black sheep of approaches when considering dislocation. The detachment of the external rotator muscles and incision of the posterior capsule have been postulated to increase instability and thereby the dislocation risk significantly more so than with the corresponding anterior and lateral approaches. However, in the last few decades, the focus on improving soft-tissue repair techniques has been growing, as the lack of such repair when using the posterior approach has been found to increase the dislocation risk considerably²⁵⁷. Posterior soft-tissue repair has gradually become a standard procedure and comparisons of current dislocation rates with older results should be performed carefully with special attention paid to this matter.

A non-systematic review of international papers published during the past decade showed a risk of dislocation ranging from 0% to 3.2% after a posterior approach had been applied^{64, 67, 126, 128-131, 160, 169, 258-261} (Table 3). Meanwhile, the anterior approach has been associated with 0.4% to 2.9% dislocations^{126, 128-131, 261, 262} and the lateral approach with 0.2% to 3.0%^{128, 260, 261}. These results do not reveal that great differences exist among the three approaches concerning dislocation.

Table 3 - International studies (2010-2020)							
	Design	Cohort size	Diagnosis	Approach	Follow-up	Procedure for detecting dislocations	Outcome
Malkani et al. 2010⁵⁸	Cohort/Register study; data prospectively collected	n=39,266	Mixed	Mixed	2 years	Medicare data	3.8%
Amlie et al. 2010²⁵⁸	Cohort study; data retrospectively collected	n=2,572	OA	Posterolateral	0.5-8 years (range)	Local outpatient follow-up	2.1%
Lombardi et al. 2011¹⁴⁶	Cohort study; data retrospectively collected	n=2,020	Mixed (80% OA)	Mixed (90% direct lateral)	2.6 years (mean)	Annual patient interview	0.1%
Jameson et al. 2011²⁶³	Cohort/Register study; data prospectively collected	n=57,155	Mixed	Mixed	1.5 years	National register data	1.3%
Ho et al. 2012²⁵⁹	Cohort study; data retrospectively collected	n=421	Mixed	Posterior	1.5 years	Local administrative register and medical records	0.5%
Ji et al. 2012²⁶⁰	RCT; data prospectively collected	n=99 n=97	Mixed	Posterior Lateral	3.1 years (mean)	Local outpatient follow-up	0.0% 3.0%
De Geest et al. 2013²⁶²	Cohort study; data retrospectively collected	n=300	Mixed	Anterior	1 year	Local outpatient follow-up	0.7%
Esposito et al. 2015¹⁵⁸	Cohort/Register study; data prospectively collected	n=7,040	Mixed (94% OA)	Mixed	6 months	Patient reported questionnaire	2.1%

Table 3 (continued) - International studies (2010-2020)							
	Design	Cohort size	Diagnosis	Approach	Follow-up	Procedure for detecting dislocations	Outcome
Sheth et al. 2015²⁶¹	Cohort/Register study; data prospectively collected	No. not specified for the dislocation analysis	Mixed	Anterolateral Direct lateral Posterior Direct anterior	1 year	Regional register data	0.4% 1.8% 1.4% 0.8%
Goel et al. 2015⁹⁸	Cohort/Register study; data prospectively collected	n=51,901	N/A	N/A	6 months	Medicare data	2.8%
Fujishiro et al. 2016¹⁶⁰	Cohort/Register study; data prospectively collected	n=1,555	Mixed (88% OA)	Posterolateral	4.3 years (mean)	N/A	3.2%
Kornuijt et al. 2016⁶⁴	Clinical cohort study; data prospectively collected	n=217	Mixed (94% OA)	Posterolateral	3 months	Patient reported questionnaire	0.5%
Maratt et al. 2016¹³¹	Cohort/Register study; data prospectively collected	n=2,147 n=2,147	N/A	Posterior Anterior	3 months	Administrative and Register data	0.8% 0.8%
Cheng et al. 2016¹³⁰	RCT; data prospectively collected	n=37 n=35	OA	Posterior Anterior	3 months	Local outpatient follow-up	2.7% 2.9%
Opperer et al. 2016²⁶⁴	Cohort study; data retrospectively collected	n=1,487	Mixed	Posterolateral	1.5 years (mean)	N/A	2.6%
Allen et al. 2018¹⁶⁸	Cohort study; data retrospectively collected	n=3,224	Mixed (94% OA)	Mixed	1 year	Local administrative register	1.3%
Amado et al. 2018⁶⁷	Clinical cohort study; data prospectively collected	n=331	Mixed (75% OA)	Posterolateral	1 year	Medical records and interviews	0.9%

Table 3 (continued) - International studies (2010-2020)							
	Design	Cohort size	Diagnosis	Approach	Follow-up	Procedure for detecting dislocations	Outcome
Aggarwal et al. 2019	Cohort study; data retrospectively collected	n=1,657 n=1,329	OA	Posterior Anterior	3.7 years (mean)	Local medical records	0.8% 1.3%
Fleischmann et al. 2019¹²⁸	Cohort study; data retrospectively collected	n=2,160 n=5,465 n=8,561	Mixed	Posterolateral Anterior Lateral	2 years	Administrative and Register data, medical records, and interviews	1.7% 0.7% 0.2%
Norambuena et al. 2019¹⁸⁰	Cohort/Register study; data prospectively collected	n=21,490	Mixed	Mixed	1 year	Joint register	0.9%
Pincus et al. 2020¹²⁶	Cohort/Register study; data prospectively collected	n=2,993 n=2,993	OA	Posterior/lateral Anterior	1 year	Administrative data	0.3% 0.7%
Tetreault et al. 2020¹⁶⁹	RCT; data prospectively collected	n=594	Mixed (97% OA)	Posterior	15 weeks (mean)	Local outpatient follow-up	0.9%

However, there are large variations in the length of follow-up among the studies and the indications for surgery encompass a mixture of different diagnoses, albeit mostly OA though. In many studies, the outcomes rely on either hospital or regional register data^{126, 129, 131, 168, 180, 259, 261}, which implies that patients who are admitted elsewhere are ignored. Moreover, some studies rely on questionnaires or interviews, in which patient recall can be questioned^{164, 146, 158}, while others state planned outpatient clinical contacts as the follow-up method^{130, 169, 258, 260, 262}, which seems to be considered safe if combined with medical records. All in all, there are varying risks of missing out on relevant complications and the reported risk and incidences may not represent the true burden of dislocations. In *Study II*, we found the two-year cumulative incidence of dislocation to be 3.6% among the 29,879 THAs performed using the posterior approach, while the same number was only

1.0% using the lateral approach (n=1,226). The lateral procedures were all performed at a single institution that had used this access technique for several years.

Four large register studies, with 21,490 to 57,155 THAs included, were identified during the literature search^{58, 98, 180, 263}, but all were limited by a lack of division based on main diagnoses and, in particular, surgical approach. The four studies reported a common dislocation risk of 0.9%¹⁸⁰ to 3.8%⁵⁸ during follow-up ranging from six months⁹⁸ to two years⁵⁸. In *Study II*, our result was based on a nationwide data sample collected from every hospital. We were able to distinguish between contralateral THAs due to laterality registration, with accompanying validation using medical records. In contrast, Jameson et al.²⁶³ were limited by including only hospitals within the National Health System and these authors were not able to include emergency room contacts. The study by Norambuena et al.¹⁸⁰ included patients registered at the Mayo Clinic only, while Malkani et al.⁵⁸ and Goel et al.⁹⁸ used Medicare data, where the ability to capture complications truthfully has previously been questioned²⁶⁵. Furthermore, the lack of laterality in Medicare administrative data and other regional arthroplasty registers forced the authors to make the somewhat doubtful assumption that dislocations are related to the index hip if the complication occurs within one year of the surgery²⁶¹.

5.1.3. Time trends in dislocation incidences

Are we improving and getting better in preventing dislocations? The confident hip surgeon would say: “of course we have improved” (*personal communication*). The most appropriate answer, however, is probably: “perhaps we have”, as the interpretation of the most recent results (Tables 2 and 3) is highly complicated due to the obvious differences, particularly with the respect to the length of follow-up and methods for detecting dislocations.

In *Study II*, we showed that 3.0% of patients undergoing a THA procedure in 2010 experienced a dislocation within two years, whereas the level was a little higher at 3.5% to 3.6% for patients treated between 2011 and 2014. This is a rather narrow time span to evaluate a potential change, though. Unfortunately, there are no previous Danish studies with dislocation data up to 10 or 20 years back, with which comparisons can be made reasonably.

Using Medicare data, Goel et al. showed that the dislocation risk was relatively steady at 4% after six months in the late 1990s, whereas the risk decreased rapidly toward 2005 and remained stable at 2% during a six-year period thereafter⁹⁸.

A potential proxy measure for the change in dislocation burden is the number of revisions indicated by dislocation registered in arthroplasty registers. In Denmark, 91 patients were revised for dislocation in 2001, totaling 13.4% of all revisions²⁶⁶. Meanwhile, 18.5% of first-time revisions were indicated by dislocation in 2017 (n=195)³¹. However, these figures are almost useless in this context as early absolute numbers may suffer from lower register completeness at the time, whereas the relative numbers are directly dependent on the change in other indications for revision.

5.2. Risk factors for dislocation

Historically, the surgical approach and the diameter of the femoral head are the two modifiable factors that have attracted most attention regarding the impact on THA dislocation. The influence of the surgical approach has been discussed previously and the existing literature is still not sufficient enough to settle this battle^{13957, 140-142, 267}

Numerous other factors are related to dislocation, including many that are nonmodifiable such as age, sex, lifestyle, activity level, BMI, comorbidities, and specific illnesses, with all having different relationships and levels of dependence relative to each other. These patient-related characteristics will naturally, to a certain degree, affect the function of the chosen components and applied technique and it is not realistic to identify specific modifiable, surgery-related factors that should be avoided in every patient. Differentiated and personalized treatment plans are therefore also an obvious everyday practice applied by hip surgeons. The knowledge that forms the basis for these preoperative choices is largely based on register studies, though, from which the risk of residual confounding should always be noted.

5.2.1. Age and comorbidities

In *Study II*, we found a clear association between both age and ASA-score and the risk of dislocation. The older and sicker a patient was, the higher their risk, which persisted after adjusting for available confounders. A limitation of the different comorbidity scoring systems is that they are dependent on the registration of diagnoses within hospital settings. The ASA-score is assigned by the anesthesiologists, while the CCI is determined based on specific diagnostic codes. In Denmark, diagnoses assigned by general practitioners are not accounted for. Another limitation in the context of hip dislocation is that neuromuscular disorders like Parkinson's disease and specific conditions like alcoholism and psychosis that cause cognitive dysfunction, which may increase the dislocation

risk, are not incorporated^{104, 120, 268, 269}. Therefore, we are not able to exclude the possibility of some residual confounding of higher levels of cognitive disorders in the older age groups.

5.2.2. Head size

We found very similar dislocation rates for most head sizes as illustrated by the rates of dislocation of 3.5%, 3.3%, and 3.5% recorded when using heads measuring ≤ 28 mm, 36mm, and ≥ 40 mm heads, respectively.

The dislocation risk was higher with 32mm heads (4.1%), but the clinical significance of this minor difference may be small.

In Denmark, there has been a clear shift in head diameters over the last two decades

(Figure 9). From 2000 to 2003,

90% of patients received a

28mm head, whereas 85%

received a 32 or 36mm head from

2012 to 2017. This change was definitely facilitated by the theory of fewer dislocations with larger heads^{143, 144, 270}. In this millennium, Berry et al. confirmed the earlier results and found the

cumulative 10-year relative risk (RR) of dislocation to be 1.7 for 22mm heads as compared with 32mm heads and 1.3 for 28mm as compared with 32mm heads⁹⁰. Lombardi et al. experienced 0.8% dislocations when using heads ≤ 32 mm and 0.05% for ≥ 36 mm heads after 2.5 years of follow-up¹⁴⁶.

Cuckler et al. observed zero dislocations in more than 600 patients who received a 38mm head as compared with 2.5% dislocations when 28mm heads were applied¹⁴⁵. An identical result was found

by Peters et al.¹⁴⁷. Bistolfi et al. reported the use of 36mm heads could reduce the dislocation risk by an eightfold as compared with 28mm heads²⁷¹. In contrast, Khatod et al. could not find a difference

between 28mm and 32mm heads after one year⁹¹, while Jørgensen et al. reported similar dislocation rates for < 36 mm and ≥ 36 mm heads⁴³. Our study was performed during a rather stable period

without larger deviations in the use of head sizes. In contrast with the earlier studies, our results

excel at being based on validated dislocations. DMCs with ≤ 28 mm heads were subtracted from the 28mm head group and analyzed separately. The remaining patients may have received a 28mm

heads due to their body structure, i.e., the smaller head “fit their body” and a larger head may not

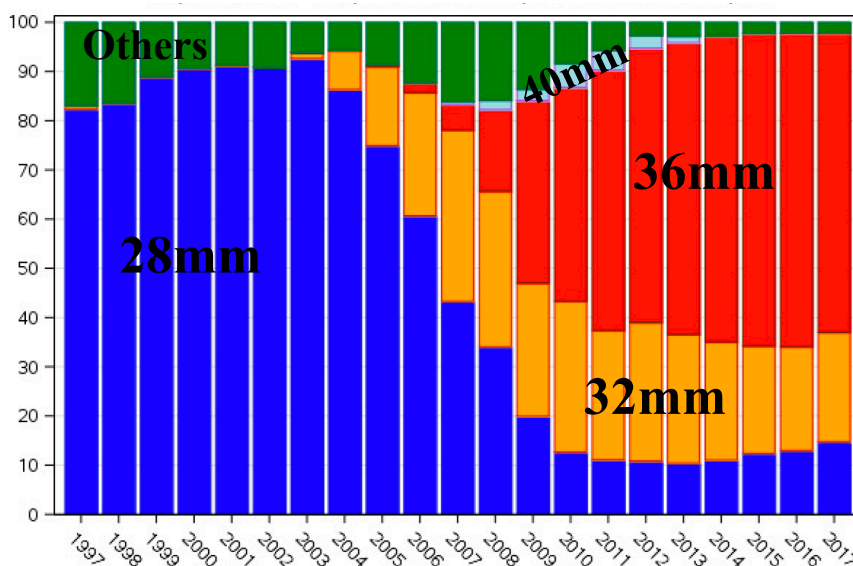


Figure 9. The development in use of different head sizes in Denmark from 1997-2017 (from the 2019 DHR annual report).

have been an option based on the acetabular conformation. This could explain the similar dislocation rates between 28mm and 36mm heads. It would have been of great interest to incorporate patients from the year 2000 and later, when nearly all patients received 28mm heads. Based on the present results, we are unable to conclude that 28mm and 36mm heads are equally safe when considering dislocations.

Although every dislocation is indisputably important, register studies presenting results of revised patients based on longer time periods are highly useful. Using the Norwegian arthroplasty register, Bystrøm et al. found the use of Exeter prostheses with 26mm heads associated with significantly more revisions due to dislocation than when using 30mm heads, with a failure rate ratio of 4.1⁵⁵. Hailer et al. reported a higher risk of revision due to dislocation in correlation with 22mm heads as compared with 28mm heads (RR=2.0) based on the Swedish arthroplasty register, while the use of 32mm and 36mm heads was not significantly lower than that of 28mm heads⁷⁹. Data from the Finnish arthroplasty register also confirmed a lower revision risk due to dislocation correlated with larger heads. The RR was 0.40 for 32mm heads, 0.41 for 36mm heads, and 0.09 for >36mm heads as compared with THAs performed with a head size of 28mm⁸⁵. However, the three studies did not present data regarding the overall revision risk^{55, 79, 85}.

This was included in a recent paper by Tsikandylakis et al., and, although 32mm heads had a lower revision risk from dislocation as compared with 28mm heads, there was no significant difference in the risk of revision due to any reason. When moving from 32 to 36mm, these authors observed a higher risk of revision for all reasons, which was not matched by a lower risk of revision due to dislocation⁸³. Similarly, Zijlstra et al. reported fewer revisions indicated by dislocation using 32mm heads instead of 22- to 28mm heads, while revisions for all other reasons were the same. Moreover, 36mm heads further reduced the risk of revision for dislocation but were associated with more revisions for any reason than 32mm heads⁸⁴. Therefore, the remaining life expectancy should also be considered, as the lower dislocation risk may be outweighed by a higher long-term revision risk due to other reasons.

5.2.3. Dual mobility cups

Evidently from *Study II*, DMCs were not yet routinely used in primary OA patients from 2010 to 2014 and are probably still considered to be mostly intended for high-risk patients who are older, suffering from neurological disorders, and with acute femoral neck fractures. We identified 725 patients with primary OA that received DMCs and only four experienced a dislocation (0.6%). The

DMC group consisted of patients of every age and ASA group, although the majority was older and from the ASA-2 group. The DMCs had been inserted at hospitals all over Denmark, although three locations made up 50% of the procedures. Based on our results, we are not able to safely state whether the DMCs have been chosen for a selected patient group and there is a risk of potential confounding by indication. However, if this was the case, the low dislocation rate becomes even more interesting.

Regarding high-risk patients, three studies found no dislocations with DMCs after short to medium follow-up¹⁵⁴⁻¹⁵⁶. A study by Prudhon et al. compared the DMCs to fixed cups and reported dislocation rates of 0.6% and 8.5%, respectively, after a mean follow-up of 13.5 years¹⁵³. A recently published review including both case-control and register studies also found lower rates of dislocation and revision due to dislocation in favor of the DMCs²⁷². Although protecting against dislocations, DMCs were, however, found to present a similar overall revision risk in a recent register study by Kreipke et al.⁸⁰.

5.2.4. Cup positioning and lumbar-pelvic anatomy

Head size, liner type, fixation, and surgical approach are all examples of variables that can, almost by free choice, be determined by the surgeon. On the contrary, positioning of the cup is far more dependent upon the skills and experience of the surgeon²⁷³. A study investigating intraoperative pelvic motion showed that there was a considerable risk of misjudging the acetabular angulation during surgery, simply due to pelvic rotation caused by the operating staff²⁷⁴. In *Study II*, we were not able to include cup positioning in the multivariable regression analysis due to the large cohort size, which is a limitation. The “safe zone” for cup orientation was defined more than 40 years ago²⁰ but, in the future, we may be directed towards more patient-dependent cup positioning as the result by Lewinnik et al. has been difficult to repeat in several studies^{108, 157-159}. There has been an increasing focus on the anatomic relationship between the lumbar spine and the pelvis in recent years and the link to THA dislocations without a clear etiology. Normally, the acetabular anteversion increases when a person moves from standing to sitting, which provides posterior support to the flexed hip²⁷⁵. This compensatory acetabular movement is impeded in patients with lumbar spine fusion, either biological or iatrogenic, which may increase their risk of dislocation^{276, 277}. Radiographic evaluation of the lower spine should perhaps be increasingly incorporated in the preoperative planning stage and, in particular, after the first dislocation episode if no other primary cause is identified.

5.3. Impact of THA dislocation on patient health and hip function

In *Study IV*, we aimed to state the impact of one or more dislocations on subjectively reported health and hip function. Our results are encumbered by some major limitations in the study design though, especially the cross-sectional strategy due to the lack of preoperative data. Also, regarding the satisfaction items, the patients were asked to compare their current hip function to the situation five to nine years ago and recall issues would be expected and obvious. However, the conditions were no different for the case patients and the study's aim was to compare patients with and without hip dislocation. Regarding the hr-QoL and hip function, patients were asked to evaluate based their current status and recall bias was therefore not a problem. A potential source of error was, also, that we did not ask the patients with poor results if it was the relevant hip that caused their inferior reporting or whether they suffered from concomitant illnesses such as lower back pain, knee OA, contralateral hip problems, or neurological disorders influencing the hip function. Due to the large study population, there is no reason to believe that patients with competing illnesses should be overrepresented in the case group.

Nevertheless, we have conducted the largest study by far to date investigating the impact of hip dislocation on hr-QoL and subjective hip function, also considering the number of dislocations and time from the latest dislocation. We found all measures to be lower among patients with dislocation as compared with in the control group and, particularly remarkable, the hip-related QoL was persistently lower after more than five years of follow-up since the latest dislocation. A THA is supposed to be the relieving choice for patients who have struggled with pain and limitations in their daily living for years due to hip OA, which consequently has affected their QoL. These individuals generally choose surgery as a last resort to improve their well-being and physical capability. Our results indicate that some patients may never recover completely from the experience of a hip dislocation.

Due to the pure qualitative outcomes and the cross-sectional design of the study, we made the decision not to perform any statistical comparisons between cases and controls. Whether or not the reported differences are to be considered significant must rely on an individual consideration supported by the CIs and minimal clinically important differences reported in other papers^{278, 279}, rather than a formal statistical calculation.

Dislocation is one of the few mechanical complications after THA for which non-surgical treatment is an option. Other complications, such as prosthetic joint infection, peri-prosthetic

fracture, or aseptic loosening after longer follow-up, are more often deemed to revision surgery and PROMs after these complications are, therefore, not comparable to our non-revised cases.

5.4. Revision of primary THAs due to dislocation

Each patient should undergo a detailed examination to identify the exact causes of dislocation. Often, multiple and simultaneous factors are identified, but sometimes there is no obvious explanation^{184, 264}. Early dislocation is typically caused by component malposition, a falling incident due to insecure gait, or just inadequate healing and a lack of capsular support. Component loosening and liner wear may be causes of dislocations several years after the primary procedure. In cases with clear malposition or loosening, a revision procedure is needed to restore stability, but most patients are guided towards a non-surgical treatment strategy¹⁷³. This conservative approach is often repeated and may continue after additional events, particularly in cases with no clear etiology. Some patients also refuse to undergo further surgery despite numerous dislocations, as they are familiar with what they have and do not know what they may achieve.

5.4.1. Timing of revision

The most appropriate timing of a hip revision is difficult to determine and should depend on the particular case, with close involvement and discussions with the patient. Our PRO results from *Study IV* could favorably be used as an integrated part of the decision-making process in future cases in doubt. We showed that the average patient with one or more dislocations did not improve much in terms of the hip-related QoL at two to five years after the latest dislocation episode. All domains in the HOOS questionnaire decreased with additional dislocations. After revision surgery, both hr-QoL and subjective hip function were reported to be lower than after dislocation without revision, though. This isolated finding does not encourage the patient to proceed with revision. However, it is important to note that the results after revision does not take into account whether the patient experienced further dislocations or not. This is an important limitation within our study and it would be of great interest and relevance to present PRO results for successful revisions only for the patients in doubt.

5.4.2. Extent of revision

There are several options on the stability palette available for the hip revision surgeon, including upsizing of the femoral head, liner change, re-positioning of the cup, soft tissue debridement

removing impinging factors, trochanteric advancement to increase abductor strength, repositioning of the stem including increasing the offset, and the use of CLs or DMCs⁵⁹. A combination of these interventions is often necessary to achieve a satisfactory result^{42, 59, 62, 173, 280}. In *Study V*, we looked at the patients who were first-time revised due to dislocations from 1996 to 2016 to find potential risk factors for both new dislocations and re-revisions. We included three surgical covariates: the head size, liner type, and the extent of revision. Using a Fine-Gray multivariable regression analysis, we found both CLs (sd-HR=0.36; 95%CI, 0.27-0.48) and DMCs (sd-HR=0.21; 0.08-0.58) to be associated with significantly fewer dislocations relative to normal liners. Exchanging the head and liner only was associated with significantly more dislocations after revision than if the cup had been revised also (sd-HR=2.65; 2.05-3.42). With the Fine-Gray analysis, it is important to note that the magnitude of the effect of a given covariate should be interpreted carefully, while the effective direction of the covariate is the more important measure²³⁶.

The protective effect of CLs and DMCs on dislocations vanished when re-revisions was set as the endpoint. However, the head/liner change was still found to be inferior in comparison with cup revision (sd-HR=1.73; 1.34-2.23). We found no significant differences among the various head sizes, but this study was also limited by a large number of unknown variables within this category. Whether or not the results would differ with the identification of these cases remains indefinite. We were not able to determine whether the head size was changed during revision surgery, as there were also many unregistered head sizes for the primary procedures. Other studies report rates of 0% to 8% for dislocations after revision due to dislocation with DMCs²⁸¹⁻²⁸³ and fewer re-revisions as compared with when using fixed cups after short- to medium-term follow-up^{284, 285}. The long-term failure rate after revision with a constrained device is reported as high as 42%^{286, 287}, while 65% of second revisions after constrained liners were reported to be indicated by recurrent dislocations^{288, 289}. A study by Lewis et al. also found a higher re-revision rate for constrained versus non-constrained first-time revisions due to dislocation²⁹⁰.

There are only a few published studies that have investigated the relationship between the extent of revision and the dislocation rate afterward and all report inferior results with head/liner exchange relative to full cup revision^{291, 292}. In contrast, to the best of our knowledge, a direct comparison of the re-revision rate between cup revision and head/liner exchange for patients revised for instability has not yet been published²⁹²⁻²⁹⁴. Notably, our results are only associations and there are some important limitations to mention. Most importantly, we adopted DHR data from immediately after

its establishment, where the completeness was lower than that presently. Also, we are not aware of the preoperative considerations of the surgeon and there is not a single operative alternative that will suit all patients. With a dislocation rate of 30% after head/liner exchange as compared with that of 14% after full cup revision, however, our results indicate that the surgeon should be absolutely confident that the cup is correctly positioned before choosing not to revise the acetabular component.

5.5. Pitfalls in the Danish method of registration

Although being the epidemiologist's dream⁹³, the Danish conditions for reliable register-based research are not without challenges. The validity of all registers is completely and exclusively dependent on the reporting of the clinical personal and the automated mechanisms that transfer local hospital coding to the central register. Based on our comprehensive review of 5,000 patient files during *Study II* and *Study III*, we are able to point out a few details that are responsible for some of the incorrect registrations of dislocation events.

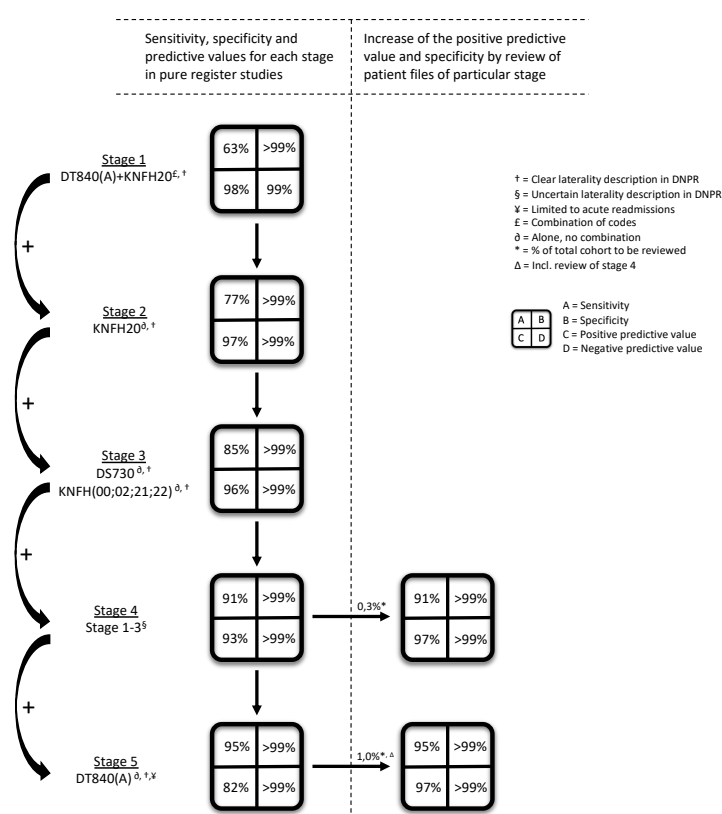
Just after admission with a suspected dislocation, a tentative diagnosis is assigned in the medical record. This is often done by newly graduated doctors or medical students who are more inexperienced with the rather complex ICD-10 coding system and hierarchy. In many circumstances, a tentative diagnosis is given prior to X-ray confirmation. When the dislocated THA has been managed, the performing surgeon adds an additional diagnostic code and a procedure code to the medical record. If the patient should suffer from other orthopedic or more medical conditions, extra codes are added during admission. Finally, it is the discharging doctors' job to summarize all the assigned codes in the discharge report, as the codes in this document are transferred to the DNPR. From our clinical experience, the codes are not always mentioned by the discharging staff and, instead, the department secretaries are forced to choose among the assigned codes during the current admission. For many of the incorrectly registered dislocations, we found that both the correct diagnosis and procedure code had actually been assigned by the operating surgeon performing the closed reduction. Therefore, we believe there is great potential for improving the DNPR validity by implementing targeted coding education of younger doctor and by increasing the focus on transferring the relevant codes to the discharge summary.

5.6. National monitoring of dislocations

Knowledge is constantly growing in most medical specialties. In orthopedics, changes in surgical techniques and the design of new implants are evolving rapidly to produce better outcomes for future patients – in most cases, successfully^{295, 296}. One could argue that advances happening so fast mean that yesterday's data become historical before we have had the time to conduct proper assessments. Arthroplasty registers are excellent for identifying components and combinations that are associated with increased revision rates. These findings are, however, not visible until after several years.

In *Study III*, we took advantage of our experiences from *Study II* and created an algorithm designed to identify dislocations with the highest possible sensitivity, specificity, and PPV. Historically, dislocations have been complicated to measure correctly. An older Swedish report by Hedlundh et al. emphasized the large differences in dislocation rate depending on how they were identified. Only half of the dislocations were found to be available in a register at the time²⁹⁷. From New Zealand, Devane et al. followed 570 THA patients for up to four years and found 1.1% of cases to be revised due to dislocation in the national joint register. A review of patient files revealed 2.5% as the true incidence of dislocations, including closed reductions²⁹⁸. Experiences from the American Medicare database published by Clair et al. outlined the difficulties in measuring adverse events, as ¹⁾re-admissions or

Flowchart "Risk of dislocation"



Flowchart description

For each step, additional codes are added to the previous step, thereby including more codes and increasing sensitivity at a cost of decreased specificity and the positive predictive value. Stage 4-5 can achieve an increase in the positive predictive value if the patient files describing the hospital contact for the specific group is reviewed and

Figure 10. Algorithm to identify dislocations based on diagnoses and procedure codes. For each step, additional codes are added to the previous step, thereby including more codes and increasing sensitivity at a cost of decreased specificity and the positive predictive value. Stage 4-5 can achieve an increase in the positive predictive value if the patient files describing the hospital contact for the specific group is reviewed and the false positives are discarded.

outpatient visits could not be linked to index admissions; ²⁾specific complications were not detected; and ³⁾the assignment of outpatient and inpatient codes allowed for duplication of complications, which may falsely elevate the true incidence²⁶⁵.

In Sweden, an instrument using administrative data to detect adverse events after surgery is already in use. A recent paper validated the instrument based on complications within 90 days of the index procedure and found a very low level of instrument sensitivity for all adverse events²⁹⁹. However, the evaluation included many minor complications. Regarding dislocations, it appears that 98.5% of identified dislocations were coded with an ICD-10 code and could be captured. Separate sensitivity, specificity, and predictive values were not presented for specific complications, such as dislocation, and it is not outlined whether the assigned codes were correct. The lack of laterality within the Swedish national patient register may also be an obstacle for complications in the extremities. In Denmark, the laterality feature in the DNPR is particularly unique and permits a distinction between contralateral hips in patients with bilateral THAs. However, if a patient with bilateral THAs dislocates the left hip and also presents with a bruised right knee, both sides (right and left) will appear in the DNPR and the laterality of the dislocation becomes uncertain. A review of the medical records is then required to determine the laterality of the dislocated hip. We believe that a sensitivity of 91% and a PPV of 93% are acceptable for monitoring THA dislocation in a national quality register and consider it feasible in the near future (Figure 10).

6. Conclusion

6.1. Study I

The systematic literature review revealed that knowledge of patient-reported QoL and subjective hip function post-dislocation was merely non-existent. The study thus confirmed the need for further focus in the area.

6.2. Study II

We found the “true” cumulative incidence of dislocations within two years after primary THA in Denmark between 2010 and 14 to be 3.5%. Age, sex, ASA-score, head size and type, fixation method, and surgical approach were independent significant factors for dislocation. We stated a high degree of wrongly registered dislocation. Therefore, comprehensive search algorithms are required to successfully identify all dislocations so that this complication can be reported accurately in national registers.

6.3. Study III

We developed an algorithm that achieved high and acceptable values for sensitivity, specificity, and prediction. We observed that surgeons in most cases coded correctly. However, the codes were not always transferred to the discharge summary.

6.4. Study IV

We found that both health- and hip-related QoL were markedly and persistently reduced among dislocation patients as compared with those among controls over several years. Therefore, the avoidance of the initial dislocation episode is important because the THA does not appear to achieve the full relieving potential.

6.5. Study V

Patients revised with DMCs and CLs were associated with a lower risk of dislocation after a first-time revision but not re-revision, whereas only changing the head/liner was associated with a higher risk of dislocation and re-revision of any cause as compared with full cup revisions. Despite the study limitations, isolated modular head/liner exchange should be re-considered in every case compared with revision of the acetabular component or, eventually, the full hip.

7. Perspectives and future research

The most important aspect must be to avoid the first episode of dislocation, as the full relieving potential is never achieved. One question to ask is how do we lower the overall risk prospectively? A solution, although somewhat controversial, could be to perform fewer primary THAs in certain high-risk patient groups. Maybe we are simply performing too many procedures currently. However, this will leave this group of patients with no other option but more painkillers and less/no daily activities. Another solution could be the increased use of DMCs in primary surgery and also a shift in surgical approach, from posterior to lateral. Although our results are only associative, they show great potential for lowering the dislocation risk.

Truthful monitoring of dislocations incorporated as a quality indicator in the DHR will enable quick detection of inferior stability with certain components. It will also facilitate comparisons between individual orthopedic departments, which is essential in the attempt to lower the total number of dislocations. We should take advantage of the high-performing departments and optimize the sharing of knowledge and experience. The most obvious example based on our results is the case of one department in Denmark using the lateral approach, while other departments may also be more successful than others in practicing a multi-disciplinary method. Before our algorithm is ready for use, we believe it should be validated in a more recent and distinct patient population. During this validation process, it would be obvious to incorporate patients with acute femoral neck fractures.

We made a huge effort to include every dislocation in our risk factor analysis but this is not feasible in every upcoming study. The burden of dislocations can be determined as either revisions due to dislocations derived from arthroplasty registries, the number of dislocations including closed reductions measured from administrative databases such as the DNPR by using our algorithm detecting 91% of all dislocations, or as the true incidence found by a review of medical records. However, is this third and latter option really necessary in a risk factor analysis? The impact of different patient- and surgery-related factors may not differ between the three endpoints. This would be an important finding to reveal in a future study as it would decrease the future workload.

Currently, the majority of patients are experiencing three or more dislocations before revision surgery is performed. Might it be possible to distinguish between patients with one dislocation only and those with recurrent events that eventually requires revision? If so, the latter group could be

guided toward revision after the first dislocation and thereby potentially be spared from years of suffering. The timing of the first dislocation might be an important factor. This remains unclear and we will proceed with studying this in a future research project.

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9. Appendices

9.1. Paper I

Annotation

Patient-reported outcome after hip dislocation in primary total hip arthroplasty is virtually unknown: a systematic literature review

Most patients have good to excellent outcomes after total hip arthroplasty (THA) due to osteoarthritis (OA). However, severe complications do still occur, and hip dislocation remains one of the most common reasons for revision surgery in the first postoperative years (Bozic et al. 2015, Singh et al. 2016). The incidence of hip dislocation after primary THA ranges from 1% to 10% (Dargel et al. 2014, Jorgensen et al. 2014, Petis et al. 2015, Zhang et al. 2015).

Implant malposition or loosening is an obvious reason for surgical intervention after hip dislocations. In cases with no clear etiology, the non-surgical treatment is often prolonged, and the effect of the dislocation on daily activities and the subjective hip symptoms become more essential. The outcome after revision surgery due to recurrent dislocations is also not encouraging, as 10–34% of the revised patients re-dislocate (Wetters et al. 2013, Jo et al. 2015, Yoshimoto et al. 2017).

In order to advise these patients properly, it is important to know the impact of 1 or recurrent dislocations on the patient's quality of life and self-experienced hip function. This will contribute to an improved decision-making process for the patients, with no obvious cause for their hip dislocation. Thus, we conducted a systematic review of studies comparing patient-reported outcomes (PROs) in patients with a primary THA due to OA with and without episodes of hip dislocation.

Method

This review is reported with respect to the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) statements (Moher et al. 2009). The protocol was based upon the Preferred Reporting Items for Systematic reviews and Meta-Analysis Protocols (PRISMA-P) guidelines (Moher et al. 2015) and registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42017076125).

We searched Pubmed, Embase, SveMed, and Cochrane databases for relevant literature from the origin of each database and up to September 1, 2017. The reference list in each of the included studies was scanned for additional eligible studies.

Studies were included in the review if the following criteria were fulfilled:

- *Study designs:* randomized controlled trials (RCT), non-randomized controlled clinical trials, prospective/retrospective cohort, and case-control studies (level of evidence 1–3).
- *Participants:* OA as a primary diagnosis.
- *Outcomes:* PRO after dislocation, either completely patient-

reported measurements or measures, where the patient part was reported separately from the clinician's evaluation.

- Studies published in English, German, and Scandinavian language.
- No "prior to revision surgery" studies were included (selected patients).

Risk of bias within cohort and case-control studies were assessed using the Critical Appraisal Skills Programme (CASP 2017) tool for relevant study designs. We performed the quality assessment of the eligible studies before data were extracted and this was carried out by 2 reviewers.

Results

We identified 3,460 unique studies using our broad search query. Throughout the title/abstract screening, 3,432 studies were excluded. We assessed full text of the remaining 28 articles for eligibility and, of these, only 2 studies (Forsythe et al. 2007, Edmunds and Boscainos 2011) met the inclusion criteria. No further studies were identified after screening the reference lists of the 2 included studies.

The study by Forsythe et al. reported no statistically significant differences in the reduced WOMAC and SF-12 scores between the 32 patients with dislocation and the 64 patients without dislocation. However, the group without dislocation was significantly more satisfied postoperatively. Edmund and Boscainos primarily compared the anterolateral and posterior approaches. The combined results from patients with or without dislocations were not presented. The authors simply concluded that patients with dislocation lose approximately 5 points in total HHS, compared with non-dislocators. 3 of these points were represented by the function score since the HHS is only partly patient reported. No statistics were performed.

A meta-analysis was not possible, since 4 different patient-reported outcome measures (PROMs) had been used in the 2 included studies. Since only 2 studies met the inclusion criteria, comparing PROs in THA patients with/without hip dislocation, we aimed to extend the scope of the present review, and also to present papers covering PROM after dislocation, without comparisons. However, we found no additional studies presenting PROMs after a dislocation episode exclusively in THA patients with OA as the primary diagnosis.

Discussion

The goal of this systematic review was to provide valuable information regarding patient experience after dislocating a

primary THA. Our review revealed that knowledge of patient-reported quality of life and subjective hip function after dislocation is merely non-existent. Efforts are ongoing to raise the use of PROMs in orthopedics from study to registry level across Europe. This will enable future prospective studies to evaluate the subjective importance of various complications (Paulsen 2014, Rolfson et al. 2016). A challenge though, is that closed reduction of prosthesis dislocation without revision is not reported in hip registries.

Presumably, quality of life must be affected and continuously decreases with recurrent events. Likewise, confidence and trust in hip function and stability is impaired. These statements need scientific support. We are planning a larger scale study to identify differences in PRO for patients with single and recurrent dislocations.

The original paper is unpublished and available on request to the corresponding author.

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“The ‘true’ cumulative incidence of and risk factors for hip dislocation within two years after primary total hip arthroplasty due to osteoarthritis – a nationwide population-based study from the Danish Hip Arthroplasty Register”

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Abstract

Background

Hip dislocation is one of the leading indications for revision and the extent of this complication is often measured by number of revisions. The exact occurrence of dislocation can be difficult to establish as closed reductions may not be captured in available registers. The purpose of this study was to identify the “true” cumulative incidence of hip dislocation (revisions and closed reductions) after primary total hip arthroplasty (THA), and the secondary aim was to find risk factors for dislocation.

Methods

From the Danish Hip Arthroplasty Register, we identified 31,105 primary THAs performed from 2010-2014 due to osteoarthritis with two years follow-up. Dislocations were identified through extraction from the Danish National Patient Register. Matching diagnosis and procedure codes were deemed correct while non-matching codes were reviewed through a comprehensive, nationwide review of patient files. Risk factors were analyzed by multiple logistic regression and presented as odds ratios (OR) with 95% confidence intervals (CI).

Results

We identified 1,861 dislocations in 1,079 THAs after review of patient files, which corresponds to a two-year cumulative incidence of 3.5% ($CI=3.3-3.7$). This was a 50% increase compared to the correctly coded dislocations captured with administrative register-data only. Patients aged <65 had a lower risk ($OR=0.70$; $CI=0.59-0.83$) and aged >75 a higher risk of dislocation ($OR=1.32$; $CI=1.14-1.52$) compared to age=65-74. Male gender ($OR=0.86$; $CI=0.75-0.98$), cemented fixation ($OR=0.71$; $CI=0.58-0.87$) and lateral approach ($OR=0.28$ $CI=0.16-0.49$) were all associated with lower risk. Head size of 32mm had a higher risk of dislocation ($OR=1.27$; $CI=1.10-1.46$) than 36mm heads, while dual mobility cups had a reduced risk ($OR=0.13$; $CI=0.05-0.36$).

Conclusion

We report the “true” cumulative incidence of dislocations within two years after primary THA in Denmark between 2010-14 to be 3.5%. Age, gender, ASA-score, head size and type, fixation method and surgical approach were independent significant factors for dislocation. Comprehensive search algorithms are needed in order to find all dislocations, so that this complication can be reported in national registers.

Introduction

Hip dislocation is a devastating complication and one of the leading indications for revision surgery after total hip arthroplasty (THA)(1-3). The term ‘revision due to dislocation’ is often how this complication is measured(4-6), as the exact occurrence of dislocations can be difficult to assess. Reasons for this include that hip dislocation treated with closed reduction may not be registered in national hip arthroplasty databases. Moreover, patients can be admitted with dislocation to other hospitals than the ones performing primary surgery, which may contribute to reduced completeness of local complication reports. Additionally, closed reduction may not always require hospital admission, and is often managed in emergency departments(7).

The risk of dislocation is reported at 0.2–10% after primary THA(8-14). The large variation may be explained by differences in study design, indication for surgery, cohort size and demography, surgical approach and technique, implant type, postoperative regime, and follow-up period(8-14). This emphasizes the need for caution when interpreting studies that compares dislocation rates. Recent studies have used administrative databases that contain the International Classification of Disease (ICD)-10 coding records in order to capture all cases of hip dislocation(7, 10, 11, 15, 16). However, this method relies on valid diagnoses and completeness of the registration, which may be questioned(17-19). Thus, in order to estimate the “true” cumulative incidence of hip dislocation following THA, a more thorough and comprehensive method is needed.

The primary objective of this study was to report the “true” cumulative incidence of hip dislocation (revisions and closed reductions) after primary THAs in the Danish population within two years of index surgery. The secondary aim was to analyze patient and component characteristics as potential risk factors for dislocation.

Materials and Methods

Study design

We designed a retrospective cohort study based on prospectively collected data to the Danish Hip Arthroplasty Register (DHR). The study followed the REporting of studies Conducted using Observational Routinely-collected Data (RECORD) guidelines(20).

Our study was nationwide and covered THAs inserted at both public and private hospitals in Denmark in the five-year period from January 1st 2010 to December 31st 2014. Since the vast

majority of dislocations appear within the first two years after primary surgery(21), we chose this as our follow-up period. Follow-up ended after two years or in the event of hip revision, death, or migration, which ever came first.

The “true cumulative incidence” includes every patient with an observed dislocation, both treated with either closed reduction or revision surgery of the dislocated hip regardless of the applied diagnosis and procedural codes at the treating hospital.

Participants

We included patients with the diagnosis ‘primary/idiopathic hip osteoarthritis (OA)’ reported to the DHR(22, 23).

We excluded patients with previous hip surgery (secondary arthritis), and also patients younger than 40 years due to the rare presence of primary OA in this age group(24-27). We excluded the second hip, if a patient underwent two primary operations in our inclusion period to avoid dependency issues(28). Primary hips with constrained liners were excluded due to the assumption of involving a very selected patient group. Metal-on-metal (MoM) THAs were still but rarely used in 2010 and 2011, after which their use was more or less abandoned in Denmark and in the rest of the world. Therefore, we excluded MoM THAs from our analysis.

Variables and Data Sources

Surgical characteristics regarding the primary procedure were extracted from the DHR, which has a completeness of 98%. Revisions and their indication were also present in the DHR (93-95% completeness)(22, 23).

Dislocations were identified from the Danish National Patient Register (DNPR), since the DHR only register revised cases. The DNPR is an administrative database that contains information on every hospital admission in Denmark (both public and private hospitals), including admission and discharge time and date, diagnosis, and operation codes with a completeness of 99.7%. Due to the unique 10-digit social security numbers for all Danish citizens, identification and cross-matching to any national register is possible. However, only correctly coded dislocations would be identified in this manner. Therefore, we conducted an additional step and reviewed all other relevant hospital contacts to recognize every instance of miscoded dislocation.

To increase the completeness of revisions, we also extracted all hip revision codes from the DNPR (see Appendix A).

Patient file review

Data from the DNPR were extracted from the day before primary surgery and up to two years postoperatively, since some patients are admitted to the hospital the day before their THA surgery. All codes assigned during the primary admission, including any postoperative complications, are coupled to the admission date.

The dataset contained all health care interactions including both orthopedic and non-orthopedic department admissions, as well as emergency room contacts coupled to a broad range of hip- or dislocation-related codes (see Appendix B).

Contacts regarding the contralateral hip, planned revision surgery, wrong diagnoses, or scheduled outpatient contacts were discarded. We also excluded contacts to private hospitals as there is no tradition of admission of patients with acute conditions in these locations in Denmark. The remaining hospital contacts were divided into two groups. We defined “genuine dislocations” as contacts assigned with both the correct diagnostic and procedure code, and the rest as “possible dislocations” (see Appendix C).

Patient files containing the possible dislocations were manually reviewed to validate the exact cause of hospital admission. If contacts with a ‘*genuine dislocation*’ had either inconsistency of laterality in the dataset or more than one operation per admission, they were reviewed to capture additional events during the same admission. The local hospitals x-ray database was used to confirm dislocations if the information in patient files was insufficient.

Risk factors

We investigated a number of possible risk factors for dislocation. Patient risk factors were age, gender, comorbidity in terms of American Society of Anesthesiologists (ASA) score and Body Mass Index (BMI). Implant- and surgical-related factors were fixation method, surgical approach, and head size; whereas patients with a dual mobility cup (DMC) reported as separate groups. BMI and ASA score were obtained from the Danish Anesthesia Database and were available for 59% of our population.

Ethics

The Danish Patient Safety Authority (3-3013-2128/1), the Danish Data Protection Agency (2008-58-0035) and head of local departments approved the storage and review of patient medical records. The study protocol was registered in Clinical Trials (Protocol-ID NCT03859791).

Statistical methods

The cumulative incidence of dislocation is presented as proportions with 95% confidence intervals (CI). Time until first dislocation is illustrated with a Kaplan-Meier failure plot. Since there were two years of follow-up for nearly all patients (with few deaths or revisions) and thus negligible competing risk, a multiple logistic regression was applied adjusting for age, gender, BMI, ASA-score, fixation, head size and approach. The most frequent group of each variable was chosen as the reference group, apart from BMI, where ‘normal weight’ according to the World Health Organization (BMI=18.5-25) was the reference. ASA category three and four were combined due to the low number of ASA-4 patients. A low number of THAs with unknown head sizes and surgical approach were found during the analysis and excluded. Results are presented with crude and adjusted odds ratios (OR) with 95% CI. We performed the statistical analysis with STATA software version 15.0.

Results

Population

According to the DHR, 32,904 patients received 36,693 THAs due to primary OA between January 1st 2010 and December 31st 2014. We excluded 5,588 THAs (Figure 1, part A). The final study cohort consisted of 31,105 THAs (Table 1), and the DNPR contained 16,108 health care contacts for these patients. The majority were discarded, leaving 1,143 genuine dislocations and 4,726 possible dislocations at 37 hospitals (Figure 1, part B). The latter were distributed across 3,808 orthopedic admissions, 808 emergency room contacts, and 110 non-orthopedic admissions.

Cumulative incidence of dislocations

In total, we identified 1,861 dislocations in 1,079 THAs. The “true” two-year cumulative incidence of hip dislocation was 3.5% (CI=3.3-3.7). A total of 41.6% (CI=38.7-44.6) of patients with dislocation experienced two or more dislocations during the two-year follow-up. The mean

time to first dislocation was 102 days ($CI=92-112$), whereas the majority (75%) of first-time dislocations occurred within the first three months (Figure 2). The cumulative incidence was lowest in THAs from 2010 but otherwise remained stable in the following four years (Table 2). 724 of the 1,079 THAs with at least one episode of dislocation would have been captured in the group with genuine dislocations at some point during the follow-up period, even though not all dislocations of a particular THA were correctly coded, meaning that the administrative database (DNPR) alone yielded a cumulative incidence of 2.3% ($CI=2.1-2.5$).

Risk factors for dislocation (Table 3)

Patients younger than 65 years had a lower risk ($OR=0.70$; $CI=0.59-0.83$) and those older than 75 years had a higher risk of dislocation ($OR=1.32$; $CI=1.14-1.52$) compared to patients aged 65-75 years. Patients with ASA-1 had a lower risk ($OR=0.70$; $CI=0.56-0.87$) and with ASA-3/4 an increased risk ($OR=1.64$; $CI=1.33-2.03$) compared to those with ASA-2. Male gender ($OR=0.86$; $CI=0.75-0.98$), cemented fixation ($OR=0.71$; $CI=0.58-0.87$) and lateral approach ($OR=0.28$; $CI=0.16-0.49$) were all associated with lower risk. Head size of 32 mm had a higher risk of dislocation ($OR=1.27$; $CI=1.10-1.46$) than 36 mm heads, while DMCs were highly protective ($OR=0.13$; $CI=0.05-0.36$). BMI >35 seemed to protect against dislocation ($OR=0.60$; $CI=0.40-0.90$).

Discussion

We report on the “true” two-year cumulative incidence of hip dislocation after primary THA based on a Danish national cohort. The study showed a cumulative incidence of 3.5% dislocations within two years after surgery in a cohort, where the majority of patients have had surgery through a posterior approach. Increasing age, female sex, higher ASA score, uncemented fixation, specific head sizes, and the posterior surgical approach were independent risk factors for dislocation.

The foundation of our study and its results are the unique registries in Denmark with high levels of completeness and possibilities for cross-linkage(22). A clear strength in this study is the comprehensive review of patient files, which complemented the administrative register-data and removed the risk of missing or including incorrect registrations of dislocation. Since our results are based on a large cohort over a five-year inclusion period and include all hospital contacts within the first two years after THA, we believe to have found the “true” occurrence of dislocation within this

patient group and timeframe. We do not believe it is likely that dislocations are treated outside hospitals and at private clinics in Denmark, although it is theoretically possible, but these cases would not change our result. We focused on a single patient group rather than mixing with other indications for surgery, such as femoral neck fractures (FNF). Patients with OA and FNF are not comparable, since the latter are significantly older and have higher comorbidity(29).

Obviously, dislocation of a THA may continue to occur after the first two years, but earlier studies have shown that the majority of dislocations happen in this time period. We did not incorporate x-rays and component positioning in our regression analysis, which is a limitation, since both cup and stem positioning can influence the result(30). A minor limitation of the DHR is its lack of patient-related data, for which we compensated by using other registers. However, BMI and ASA scores were only available for 59% of our population, since not all regions of Denmark reported to the Danish Anesthesia Database in the first years of our study period. The missing data was assigned a separate categorical variable in the analysis.

Dislocations can be measured on three levels with increasing completeness. First, as the number of revisions due to dislocations derived from arthroplasty registries such as the DHR, in which closed reductions are absent. During the first two years, 0.8% of the entire cohort were revised due to dislocation. This corresponds to 22.9% of the patients with at least one dislocation having been revised for this reason. The next level quantifies the number of all dislocations including closed reductions measured from administrative databases such as the DNPR, although incorrectly registered complications are neglected. Using this method, we found a cumulative incidence of 2.3%. Our study is now the first of its kind to report the nationwide status based on administrative registers combined with validation from patient files as the final step in identifying the “true” cumulative incidence. Earlier reports have focused on regional conditions in a single or few institutions, with results ranging from 2.8-4.9% dislocations(9, 10, 15). These results were based solely on DNPR with no clear validation, which increases the risk of missing a considerable amount of cases.

Internationally, Khatod et al. reported 1.2% dislocations with one-year follow-up from the Kaiser Permanente Total Joint Registry database for total hip arthroplasty procedures performed in Southern California(31). Woo et al. presented an incidence of dislocation at 2.2% after a mean follow-up of 3.1 years from the Mayo Clinic from 1969-1978(32). There is a potential risk of underreporting since patient files are not reviewed and if patients are referred to other hospitals. However, Woo et al. states that the latter is taken into consideration in their analysis. A Scottish

national arthroplasty register study and two American Medicare population studies reported 1.9-4.0% dislocations in OA patients based on administrative datasets without review of patient files(11, 16, 21). The limitation of register data has been shown in American settings where poor to moderate conformity with the applied codes and the actual disease or complication was identified(18, 19). A recent study found 1.4% readmissions due to dislocation after primary THA. However, an additional 50% were assumed to be treated in the emergency room and not registered as readmissions(7). Our study included readmissions to both orthopedic and non-orthopedic departments as well as emergency room visits.

To our knowledge, this is the first larger-scale paper to report risk factors for validated dislocations and not register-captured dislocations or revisions due to dislocation. An earlier study supports increasing age and ASA score as risk factors(15), while other studies report conflicting results on the effect of head size, with some reporting decreased risk with greater head diameter(33, 34) and others no effect(35). We found that patients with a 36 mm head had 0.8% lower incidence of dislocations compared to those with 32mm. THAs with 28mm and 40mm heads had similar dislocations rates to those with 36mm heads. Register studies have found a reduced risk of revision due to dislocation with larger head sizes, but not for revision of any cause(5, 14, 36). In addition, patients with DMCs had a markedly reduced dislocation risk of only 0.6% despite being used in a potentially selected high-risk group of patients. This is in accordance with a large systematic review reporting 0.9% dislocations with DMC(37). Although a lower risk of dislocation, register studies have not shown a decreased risk of overall revision(38). Moreover, elevated blood metal ion levels have been measured in approximately 10% of patients at short-term follow-up, which could lead to adverse local tissue reactions in the same way of MoM THAs. This motivate that DMCs are not used routinely and especially not in young patients but in high-risk patients balanced against the low dislocation risk(38-40)

The posterior approach has traditionally been the access of choice in Denmark and it was applied in 96% of our population. The remaining 4% were mostly done by a single institution applying the lateral approach, which was associated with a significant reduction in dislocations. The lateral or anterior approaches are more frequently used internationally and may involve a lower dislocation risk, but it could be at a cost of other complications as limping or nerve damage(41, 42).

The “true” cumulative incidence of dislocation was found to be 3.5% ($CI=3.3-3.7$). Regarding risk factors for dislocation, a head size of 36 mm had a 0.8 % lower incidence than 32 mm (3.3% vs

4.1%), whereas for patients with DMC it was reduced to 0.6%. Patients operated through the posterior approach had 3.6% dislocations and lateral 1.0%.

In perspective, our study emphasizes the need for caution in interpreting results based on registries alone, as 50% more were found by reviewing alternative codes in patient files. We believe there is a need for better algorithms in order to find all dislocations, before this complication can be reported and monitored truthfully in a national register, which is considered highly relevant. We are currently developing such an algorithm based on the results from the present study.

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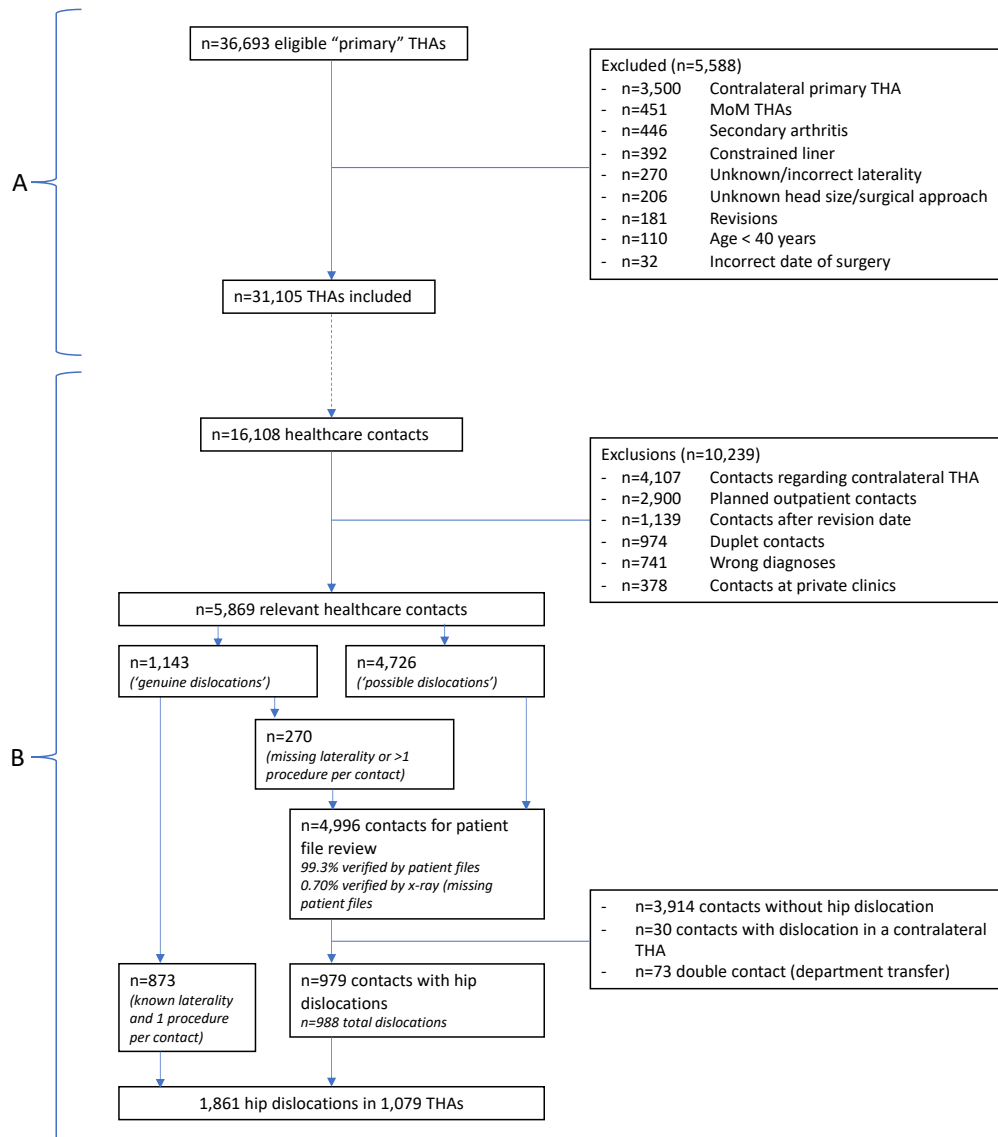
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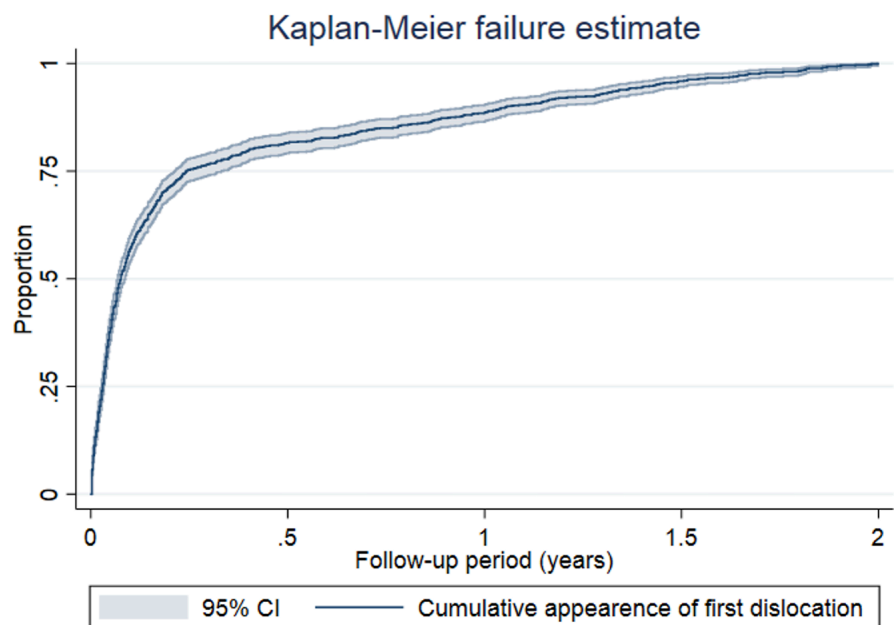
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Figure 1



“Flowchart overview of DHR (part A) and DNPR (part B) data cleaning and the following patient file review to identify the true frequency of dislocations. The dotted line indicates that 16,108 hospital contacts were found in DNPR for the 31,105 included THAs.”

Figure 2



“Occurrence of the first dislocation in the 1,079 THAs within two year follow-up period. Approximately 75% of cases occur within the first 3 months.

Table 1

	Complete study population (N=31,105) (no.)	THAs with dislocation(s) (N=1,079) (no. [%])	THAs without dislocation (N=30,026) (no. [%])
Age groups			
< 65 years	8,928	216 (20.0%)	8,712 (29.0%)
= 65 – 75 years	12,668	443 (41.1%)	12,225 (40.7%)
> 75 years	9,509	420 (38.9%)	9,089 (30.3%)
Sex			
= Male	13,705	429 (39.8%)	13,276 (44.2%)
= Female	17,400	650 (60.2%)	16,750 (55.8%)
BMI			
< 18.5	186	6 (0.6%)	180 (0.6%)
= 18.5 – 25	6,199	227 (21.0%)	5,972 (19.9%)
= 25.1 – 30	7,270	251 (23.3%)	7,019 (23.4%)
= 30.1 – 35	3,404	142 (13.2%)	3,262 (10.9%)
> 35	1,223	29 (2.7%)	1,194 (4.0%)
= Unknown	12,823	424 (39.3%)	12,399 (41.3%)
ASA score			
= 1	4,309	101 (9.4%)	4,208 (14.0%)
= 2	11,552	422 (39.1%)	11,130 (37.1%)
= 3 + 4	2,167	122 (11.3%)	2,045 (6.8%)
= Unknown	13,077	434 (40.2%)	12,643 (42.1%)
Head size			
≤ 28 mm	1,468	52 (4.8%)	1,416 (4.7%)
= 32 mm	8,563	352 (32.6%)	8,211 (27.3%)
= 36 mm	18,746	615 (57.0%)	18,131 (60.4%)
≥ 40 mm	1,603	56 (5.2%)	1,547 (5.2%)
= DMC	725	4 (0.4%)	721 (2.4%)
Fixation method			
= Cemented	3,930	133 (12.3%)	3,797 (12.6%)
= Uncemented	22,592	782 (72.5%)	21,810 (72.6%)
= Hybrid	4,583	164 (15.2%)	4,419 (14.7%)
Surgical approach			
= Posterior	29,879	1,067 (98.9%)	28,812 (96.0%)
= Lateral	1,226	12 (1.1%)	1,214 (4.0%)

“Patient demographics of all included primary THAs due to OA (n=31,105). DMC=dual mobility cups”

Table 2

	Procedures (no.)	THAs with at least one dislocation (no. [%])
2010	6,510	200 (3.1%)
2011	6,207	226 (3.6%)
2012	6,011	212 (3.5%)
2013	6,052	212 (3.5%)
2014	6,325	229 (3.6%)

“The number of yearly primary THAs due to OA and the development in dislocation rates.”

Table 3

	All patients (no.) / Dislocations (no.)	Cumulative incidence of dislocations % (CI)	OR (CI) - crude	p-values	OR (CI) - adjusted	p-values
Age groups						
< 65 years	8,928/216	2.4% (2.1-2.8)	0.68 (0.58-0.81)	p<0.005	0.70 (0.59-0.83)	p<0.005
= 65 – 75 years	12,668/443	3.5% (3.2-3.8)	1 (reference)	-	1 (reference)	-
> 75 years	9,509/420	4.4% (4.0-4.8)	1.28 (1.11-1.46)	p<0.005	1.32 (1.14-1.52)	p<0.005
Sex						
= Male	13,705/429	3.1% (2.8-3.4)	0.83 (0.74-0.94)	p=0.004	0.86 (0.75-0.98)	p=0.020
= Female	17,400/650	3.7% (3.5-4.0)	1 (reference)	-	1 (reference)	-
BMI						
< 18.5	186/6	3.2% (1.2-6.9)	0.88 (0.38-2.00)	p=0.755	0.76 (0.33-1.74)	p=0.513
= 18.5 – 25	6,199/227	3.7% (3.2-4.2)	1 (reference)	-	1 (reference)	-
= 25.1 – 30	7,270/251	3.5% (3.0-3.9)	0.94 (0.78-1.13)	p=0.513	0.97 (0.80-1.16)	p=0.716
= 30.1 – 35	3,404/142	4.2% (3.5-4.9)	1.15 (0.92-1.42)	p=0.214	1.15 (0.92-1.43)	p=0.218
> 35	1,223/29	2.4% (1.6-3.4)	0.64 (0.43-0.95)	p=0.025	0.60 (0.40-0.90)	p=0.013
= Unknown	12,823/424	3.3% (3.0-3.6)	0.90 (0.76-1.06)	p=0.207	0.90 (0.48-1.67)	p=0.773
ASA score						
= 1	4,309/101	2.3% (1.9-2.8)	0.63 (0.51-0.79)	p<0.005	0.70 (0.56-0.87)	p=0.002
= 2	11,552/422	3.7% (3.3-4.0)	1 (reference)	-	1 (reference)	-
= 3 + 4	2,167/122	5.6% (4.7-6.7)	1.57 (1.28-1.94)	p<0.005	1.64 (1.33-2.03)	p<0.005
= Unknown	13,077/434	3.3% (3.0-3.6%)	0.91 (0.79-1.04)	p=0.153	1.00 (0.54-1.85)	p=0.991
Head size						
≤28 mm	1,468/52	3.5% (2.7-4.6)	1.08 (0.81-1.44)	p=0.589	1.02 (0.76-1.37)	p=0.873
= 32 mm	8,563/352	4.1% (3.7-4.6)	1.26 (1.11-1.44)	p=0.001	1.27 (1.10-1.46)	p=0.001
= 36 mm	18,746/615	3.3% (3.0-3.5)	1 (reference)	-	1 (reference)	-
≥ 40 mm	1,603/56	3.5% (2.6-4.5)	1.07 (0.81-1.41)	p=0.647	1.22 (0.92-1.62)	p=0.168
= DMC	725/4	0.6% (0.2-1.4)	0.16 (0.06-0.44)	p<0.005	0.13 (0.05-0.36)	p<0.005
Fixation method						
= Cemented	3,930/133	3.4% (2.8-4.0)	0.98 (0.81-1.18)	p=0.807	0.71 (0.58-0.87)	p=0.001
= Uncemented	22,592/782	3.5 % (3.2-3.7)	1 (reference)	-	1 (reference)	-
= Hybrid	4,583/164	3.6% (3.1-4.2)	1.04 (0.87-1.21)	p=0.694	0.87 (0.72-1.04)	p=0.128
Surgical approach						
= Posterior	29,879/1,067	3.6% (3.4-3.8)	1 (reference)	-	1 (reference)	-
= Lateral	1,226/12	1.0% (0.5-1.7)	0.27 (0.15-0.47)	p<0.005	0.28 (0.16-0.49)	p<0.005

“Risk factors for dislocation. Odds ratio (OR) calculated by a multiple logistic regression analysis adjusted by age-group, sex, BMI, ASA-score, head size, fixation method and surgical approach.

CI=confidence interval; DMC=dual mobility cups.”

9.3. Paper III

“Development of a diagnostic algorithm identifying cases of dislocation after primary total hip arthroplasty – Based on 31,762 patients from the Danish Hip Arthroplasty Register”

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Abstract

Background and purpose

Dislocation of total hip arthroplasties (THA) is often treated with closed reduction and traditionally not registered in orthopedic registers. This study aimed to create an algorithm designed to identify cases of dislocations of THAs with high sensitivity, specificity, and positive predictive value (PPV) based on codes from the Danish National Patient Register (DNPR).

Methods

All patients (n=31,762) with primary osteoarthritis undergoing THA from January 1st 2010 to December 31st 2014 were included from the Danish Hip Arthroplasty Register (DHR). We extracted available data for every hospital contact in the DNPR during a 2-year follow-up period, then conducted a comprehensive nationwide review of 5,096 patient files to register all dislocations and applied codes.

Results

We identified 1,890 hip dislocations among 1,094 of the included 31,762 THAs. More than 70 different diagnoses and 55 procedural codes were coupled to the hospital contacts with dislocation. A combination of the correct codes produced a sensitivity of 63% and a PPV of 98%. Adding alternative and often applied codes increased the sensitivity to 91%, while the PPV was maintained at 93%. Additional steps increased sensitivity to 95% but at the expense of an unacceptable decrease in the PPV to 82%. Specificity was, in all steps, greater than 99%.

Interpretation

The developed algorithm achieved high and acceptable values for sensitivity, specificity, and predictive values. We experienced that surgeons in most cases coded correctly. However, the codes were not always transferred to the discharge summary. In perspective, this kind of algorithm may be used in Danish quality registers.

Introduction

Dislocation is a feared complication after total hip replacement. In order to prevent this and other complications of occurring, we often have to take advantage of and rely on the enormous amount of data from the many orthopedic registries in use rather than conducting large and costly clinical studies (SHAR 2017, AOANJRR 2018, DHR 2019, Varnum et al. 2019a, Varnum et al. 2019b).

However, data within these registries are not always representative of the actual occurrence of complications. Gundtoft et al. (2015) demonstrated that infections are underreported with 40%. Likewise, a recent study based on a Danish cohort and administrative registers found that the sensitivity was only 63% when patients with dislocations were identified with a combination of the correct diagnosis and procedure code, ultimately missing more than 1/3 of the patients (Hermansen et al. 2020). The treatment of choice after reduction of the first hip dislocation is nonoperative, unless there is obvious malpositioning of the inserted components causing instability. Revisions are often performed only after several dislocations (Patel et al. 2007, Devane et al. 2012, Saiz et al. 2019). Therefore, a large group of patients treated with closed reduction is never registered in arthroplasty registers and the true burden of this complication remains uncertain.

Ideally, a health care system should be able to capture all important complications that have an impact on the patient and the treatment quality. This study aimed to create an algorithm to identify dislocations of THAs with high sensitivity, specificity, and predictive values based on codes from a national health care system.

Materials and methods

Study design

We used data which was collected during a recent retrospective cohort study that used prospectively collected data from the Danish Hip Arthroplasty Register (DHR) designed to find the true frequency of hip dislocation after primary THA (Hermansen et al. 2020). We refer the reader to this paper for study details and will only report the main aspects in this article. The RECORD guidelines were followed.

Participants

We identified all patients with primary osteoarthritis (OA) who underwent a THA from January 1st 2010 to December 31st 2014 and followed each patient for 2 years after index surgery. Follow-up was ended after 2 years or before if revision surgery, emigration, or death occurred - which ever came first. We excluded THAs inserted due to other indications than primary OA. For the same reason, patients younger than 40 years of age were excluded (Duffy et al. 2001, Ellison et al. 2006). Any contralateral THA procedures during the inclusion period was also omitted to avoid dependency among observations (Ranstam et al. 2010).

Data sources and data cleaning

Dislocations together with any other type of patient contact with the Danish health care system are registered in the Danish National Patient Register (DNPR) (Lynge et al. 2011). By means of the DNPR, we were able to extract information for every hospital contact to orthopedic and non-orthopedic departments as well as outpatient emergency room contacts for each patient during the individual 2-year follow-up period. We extracted the admission and discharge date, the date of any surgical procedure, and hospital and department names for all hospital contacts that had been assigned with any primary or secondary hip or dislocation related diagnostic or procedural code (see appendix for the complete list). The DNPR completeness is over 99%, and we did not encounter any missing data regarding diagnoses and procedure codes in our population (Schmidt et al. 2015).

The diagnostic codes were extracted from the International Classification of Diseases, 10 revision (ICD-10) and procedural codes were derived from the Danish version of the Nordic Medico-Statistical Committee's (NOMESCO) Classification of Surgical Procedures (NCSP). We then established the following classification of contacts.

1. Genuine dislocations: Contacts assigned with a combination of the correct diagnostic (*DT84.0(A)*) and surgical procedure (*KNFH20*) codes.
2. Possible dislocations: Any contact not included as a genuine dislocation.

A comprehensive review of all patient files meeting criteria 2 was performed to identify every miscoded dislocation. We also reviewed 20% of the genuine

dislocation cases to validate the combination of correct codes. 5,096 patient files were manually reviewed, and all dislocations and the applied codes were registered.

Statistics

We designed the algorithm using a stepwise approach and calculated the sensitivity, specificity, the positive, and the negative predictive values for various combinations of the most frequently used codes. The steps were not pre-specified but, instead, were chosen based on the codes that had been applied nationwide from 2010 to 2016 for verified dislocations. The plan was to add codes in steps and continuously increase the sensitivity (*i.e., the proportion of true positives out of all dislocations*), while at the same time keeping the specificity (*i.e., the proportion of true negatives out of all not having a dislocation*) and the positive predictive value (PPV) (*i.e., probability that patients based on the algorithm truly have the dislocation*) high. The algorithm will identify patients with at least 1 episode of dislocation for a given period of time (*i.e., the risk of dislocation*) but it will not necessarily identify all dislocations for each patient. It is also important to note that there is a clear distinction between hospital contacts with or without denoted laterality in the DNPR. This is an important aspect in order to distinguish between contralateral THAs. Statistics was performed with STATA software version 15.0.

Ethics, funding and conflicts of interest

The Danish Patient Safety Authority (3-3013-2128/1), the Danish Data Protection Agency (2008-58-0035), and the head of local departments approved the review of patient medical records.

Several donations were kindly provided, and they all made this study feasible. The *Clara Hansens Memorial Fund* and *Appropriation Merchant Sven Hansen & Wife Ina Hansens Foundation* covered travel expenses. *The Danish Rheumatism Association*, *The A.P. Møller Foundation for the Advancement of Medical Science* and *The Orthopaedic Fund of West Jutland* covered costs for assisting personnel during the nationwide review of patient files. *The Doctor of Bramming, Grethe Marie Justesens Fund* granted statistical assistance. *The University of Southern Denmark* and *Region of Southern Denmark* each assigned a one-year Ph.D. scholarship. There are no conflicts of interest and none of the funding had any influence on the data material or reporting of the results.

Results

We identified 1,890 hip dislocations in 1,094 of the included 31,762 THAs (Figure 1), which yielded a 2-year cumulative incidence of 3.4% (95% *CI* = 3.3-3.6). More than 70 different main diagnoses and 55 different procedural codes were coupled to the hospital contacts with dislocation. The most common mistake was the application of the correct procedure code in combination with a wrong diagnosis code. Thereafter, more than 10% of all dislocations were found with codes that are intended to describe dislocation and reduction of traumatic hip dislocation of native hip joints rather than THA.

The most frequently used codes and combinations were grouped and contributed to our algorithm (Table 1). Step 1 was a combination of the correct codes (DT840+KNFH20) with known laterality resulting in a sensitivity of 63% and a PPV of 98% (Table 2). When we added the contacts with the correct procedure code alone (KFH20) and alternative and often applied codes in 2 additional steps (DS730, KNFH(21;22;00;02)), all with known laterality, we increased the sensitivity to 85%, while the PPV was 96%. Step 4 added the contacts of the above-mentioned codes from steps 1 through 3 with unknown laterality in the DNPR, which increased the sensitivity to 91% but lowered the PPV to 93%.

The only way to increase the sensitivity further was to include contacts with the correct diagnosis code alone (DT840). However, this code is often related to many other aspects of prosthesis complications and is not solely used for dislocations. Therefore, in the last step, the sensitivity increased up to 95% but at the expense of an unacceptable decrease in the PPV to 82%. Specificity was in all steps greater than 99%.

Steps 4A and 5A shows an achievable increase in the PPV at these 2 steps if the patient files for the particular step are reviewed. The results from Table 2 were combined into a flowchart (Figure 2), which states the achievable values for pure register purposes and highlights the expected burden of patient file review, which is an option in clinical studies.

Discussion

We have performed a comprehensive nationwide review and validated the applied codes for THA dislocation. We were able to improve the sensitivity by 28% without sacrificing PPV/specificity by using our approach by adding alternative and validated codes.

Accurate measurements and truthful monitoring of specific complications are important in order to decrease the risk of complications. Dislocation is a feared complication after hip replacement, leading to pain, anxiety, and reduced quality of life as well as increased costs in the health care system. Moreover, re-dislocations happens in 40% to 68% of the patients increasing the risk of reoperation (Brennan et al. 2012, Hermansen et al. 2020). In our study, an acceptable sensitivity of 91%, a specificity of more than 99%, and a PPV of 93% are achievable when combining the most frequently used codes into an algorithm. The algorithm informs about the expected sensitivity, specificity and predictive values in a stepwise approach.

Importantly, the sensitivity, specificity, and predictive values presented in the algorithm are derived from a specified cohort of primary OA patients. We have not included patients with secondary OA or femoral neck fracture patient, which is a limitation. However, there is no reason to believe that the results in other such populations would be different than those in the present study.

To our knowledge, codes for hip dislocation have never before been validated in a Danish setting. The accuracy of the DNPR for several other diseases has shown both low to moderate completeness (Nymark et al. 2003, Gundtoft et al. 2015, Jorgensen et al. 2016, Kristensen et al. 2019) and high PPV (Viborg et al. 2017), indicating great variation is introduced by coding personnel in different specialties. Internationally, there is also significant variation documented between professional hospital coders and orthopedic surgeons for both diagnoses and complications, emphasizing the need for caution when analyzing these data (Mears et al. 2002, Mont et al. 2002). There are unique possibilities for unambiguous linkage and complete follow-up of all patient contacts to the Danish health care system. Therefore, our study is based on the application of codes from the broadest range of surgeons possible. Our follow-up was not limited to readmissions at orthopedic departments, since we also reviewed all non-orthopedic readmissions and outpatient emergency room contacts.

Upon reviewing numerous patient files from admission to discharge, it is our experience that the surgeons in most cases are coding correctly. However, the codes labeled in the surgery descriptions are not transferred to the discharge summary in all occasions, which forms the basis of a patient's DNPR registration. Instead, codes used by the staff who meet the patient in the emergency department are chosen and, often, these codes are assigned by untrained and younger doctors when the diagnosis is not yet verified.

Remarkably, the sensitivity was only 63% when patients with dislocation were identified with a combination of the correct diagnosis, procedure code, and known laterality, hereby missing 1/3 of the patients (step 1). The majority of the remaining dislocations can be found using either the correct diagnosis or procedure code alone. Especially the procedure code alone is trustworthy, while the effect of the diagnosis code DT48.0(A) is far more unpredictable. The diagnosis is applied to any kind of mechanical complication, making it widely used in planned outpatient contacts. This supports the inclusion of several false-positive cases if the diagnosis alone is uncritically used in the algorithm without review of every patient case. We only included acute admissions or emergency room contacts with DT840 alone to keep the PPV as high as possible.

With this algorithm, we focused on the risk of dislocation, thus finding all patients with at least 1 dislocation and not necessarily identifying all dislocations for every patient. This is typically useful in larger register settings monitoring complications. In smaller clinical studies with closer follow-up and involvement of patient-reported outcome measures, it may be of greater importance to report all events of dislocation. Our algorithm possesses lower sensitivity for this scenario (step 4: sensitivity = 88% and PPV = 94%; step 5: sensitivity = 95% and PPV = 84%).

In the steps 1 to 3 and 5 of the algorithm, laterality is known in both DHR (laterality of the THA) and DNPR (laterality of the hospital contact) why mix in laterality of bilateral THA cases are non-existent. In step 4 we included hospital contacts with unknown or uncertain DNPR laterality to increase sensitivity. A decrease in the PPV is hereby obvious and can be managed with a review of few patient files.

The developed algorithm based on the ICD-10 and NOMESCO codes achieved a sensitivity of 91% and a PPV at 93% using register data alone, which we consider acceptable. Since the rates of missed patients with dislocation and false positivity were nearly equal, the algorithm gives a precise measure for the risk of dislocation in

this study. Higher sensitivity is possible but at the expense of drastically lowering the PPV, which is not feasible for register studies. In perspective, this algorithm is meant for incorporation in national registers for the reliable registration of dislocations and will be of major importance for monitoring this severe complication. Also, since the settings of both hip registers and coding algorithms in other Nordic countries are similar to the Danish, it would be obvious also to validate the algorithms within the Nordic Arthroplasty Register Association (NARA) collaboration.

Author contributions

LLH, BV and SO were responsible for the conception of the study; LLH was responsible for data analysis before and after review of patient files and coordinated the national review; LLH drafted the manuscript; BV and SO revised it critically.

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Supplementary data containing the appendix ((A) a list of the diagnostic ICD-10 codes and (B) the procedural NCSP codes, which were applied for in the National Patient Registry, (C) Interpretation of correct coding of a THA dislocation, and (D) Description of the review burden related to Table 2) is available in the online version of the article.

Appendix

4) A list of the diagnostic ICD-10 codes, which were applied for in the National Patient Registry data extraction to identify possible incorrectly coded dislocation cases:

DS33.3*	Dislocation of other and unspecified parts of lumbar spine and pelvis
DS70 – DS79*	Injuries to the hip and thigh
DT03.1 + DT03.3-DT03.9	Dislocations, sprains and strains involving multiple regions of lower limb(s)
DT09.2	Dislocation, sprain and strain of unspecified joint and ligament of trunk
DT12*-DT13*	Other injuries of lower limb, level unspecified
DT14.3	Dislocation, sprain and strain of unspecified body region
DT81.9	Unspecified complication of procedure
DT84.0* – DT85*	Complications of internal orthopaedic prosthetic devices, implants and grafts
DT88.9	Complication of surgical and medical care, unspecified
DT93*	Sequelae of injuries of lower limb
DT94*	Sequelae of injuries involving multiple and unspecified body regions
DT98.1-DT98.2	Sequelae of other and unspecified effects of external causes
DM15* – DM16* + DM19*	Polyarthrosis/Arthrosis of hip/Other arthrosis
DM24.3*	Pathological dislocation and subluxation of joint, not elsewhere classified
DM24.4A+B	Recurrent dislocation and subluxation of joint
DM24.9	Joint derangement, unspecified
DM25.2	Flail joint
DM25.3	Other instability of joint
DM25.5	Pain in joint

DM25.9	Joint disorder, unspecified
DM96.6* – DM96.9*	Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate/ Other postprocedural musculoskeletal disorders/ Postprocedural musculoskeletal disorder, unspecified
DZ03.9	Observation for suspected disease or condition, unspecified
DZ04.2* – DZ04.3*	Examination and observation following work accident/Examination and observation following other accident
DZ04.9*	Examination and observation for unspecified reason
DZ96.6* – DZ96.7*	Presence of orthopaedic joint implants/ Presence of other bone and tendon implants
DZ98.8	Other specified postsurgical states
(* = incl. sublevels)	

B) A list of the procedural NCSP codes, which were applied for in the National Patient Registry data extraction to identify possible incorrectly coded dislocation cases:

KNFA0* – KNFG9*	Exploratory procedures on the hip and thigh/Primary insertions of joint prosthesis in the hip joint/Secondary insertion of joint prosthesis into the hip joint/Operations on joint capsule and ligaments in the hip joint/Operations on synovia and joint surfaces of the hip joint/Resections, arthroplasty and arthrodesis of the hip joint
KNFJ0* - KNFW9*	Fracture treatments in the femur/Bone operations on the femur/Operations on muscles and tendons in the hip and thigh/Operations on fascia, tendon sheaths, ganglia and bursae in the hip and thighs/Transplantations on hip and thighs/ Replantations on hip and thighs/Amputations and other related hip and thigh surgery/Surgery for hip and thigh tumors/Operations of tendon, joint and bone infections in the hip and thigh/Different hip and thigh

	surgery/Removal of implants and external fixation equipment from hip and thigh/ Reoperations after hip and thigh surgery
KNFH0* – KNFH9*	Different joint operations in the hip
KNE*	Operations on the pelvis
KTNF*	Minor surgical procedures on hip and thighs

C) Interpretation of correct coding of a THA dislocation:

Ideally, every patient contact concerning an x-ray verified THA dislocation should be assigned with an ICD-10 diagnostic code (DT84.0A - Mechanical complication of internal joint prosthesis, hip). The contact should likewise be linked with a procedural code describing the intervention being performed. In this case reduction of the dislocated hip. The Danish version of the Nordic Medico-Statistical Committees (NOMESCO) Classification of Surgical Procedures (NCSP) is currently the standard application in Denmark. In this setting, the code KNFH2* (reduction of dislocated joint prosthesis in the hip; *either closed, arthroscopic or open) would be the most appropriate choice. There is also a laterality variable for each of the two codes. This is particular important in order to discriminate between relevant hip contacts and a contralateral hip not included in this study.

D) Description of the review burden related to Table 2:

A total of 31,762 THAs are included in our study. Here we have listed the number of contacts in group 4 and 5, and how many patient files that needs review in order to either confirm or invalidate dislocation.

Step 4A: There were 106 contacts in Group 4, and after reviewing we confirmed 70 dislocations and refuted 36.

Step 5A: There were 203 contacts in Group 5, and after reviewing we confirmed 43 dislocations and refuted 160.

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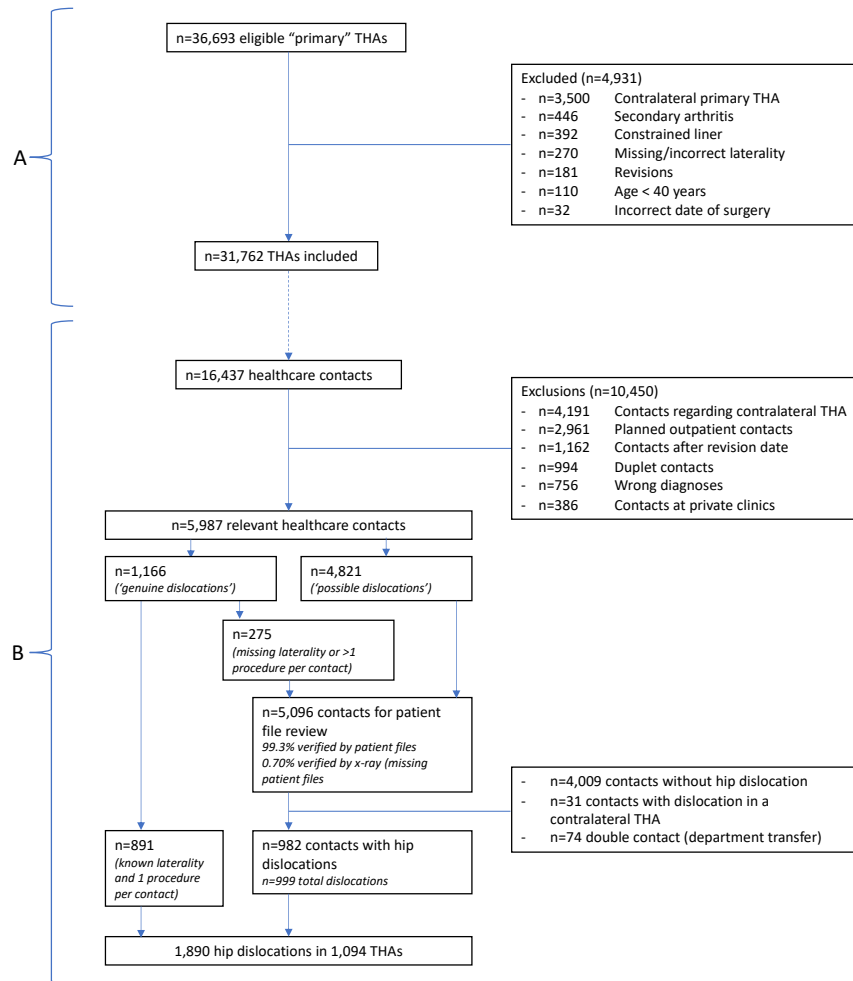
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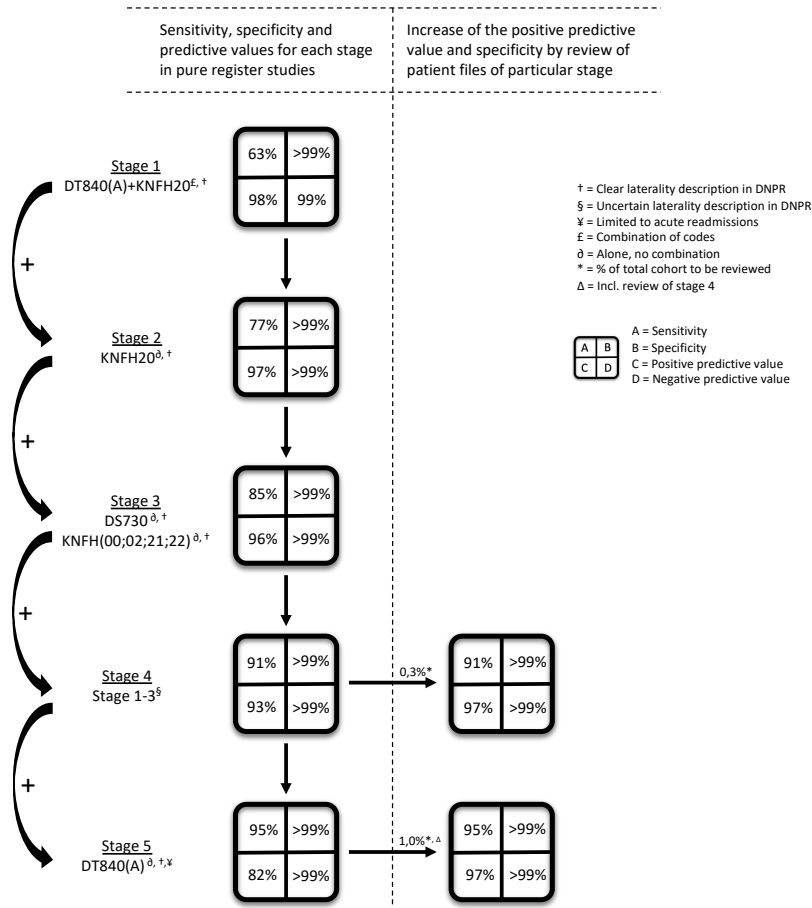
Figure 1



“Flowchart overview of DHR (part A) and DNPR (part B) data cleaning and the following patient file review to identify the true frequency of dislocations. The dotted line indicates that 16,437 hospital contacts were found in DNPR for the 31,762 included THAs.”

Figure 2

Flowchart "Risk of dislocation"



Flowchart description

For each step, additional codes are added to the previous step, thereby including more codes and increasing sensitivity at a cost of decreased specificity and the positive predictive value. Stage 4-5 can achieve an increase in the positive predictive value if the patient files describing the hospital contact for the specific group is reviewed and the false positives are discarded.

"Development of the algorithm for identifying dislocation following primary THA. Flowchart presenting sensitivity, specificity and predictive values in the attempt to identify the risk of dislocation in a pre-defined cohort of THA patients. Researchers can then decide on which level of e.g. sensitivity and positive predictive value is acceptable for their specific study design."

Table 1

	<i>Codes</i>	<i>Description</i>
Group 1	DT840(A) + KNFH20	Combination of the correct diagnosis and procedure code (with identified laterality in DNPR)
Group 2	KNFH20	The correct procedure code alone combined with any random diagnosis (with identified laterality in DNPR)
Group 3	DS730 KNFH00 KNFH02 KNFH21 KNFH22	Alternative and often used diagnose and procedure codes (with identified laterality in DNPR)
Group 4	Group 1-3	All group 1-3 cases, where laterality is uncertain in DNPR
Group 5	DT840(A)	The correct diagnoses alone combined with any random procedure code, AND limited to acute readmissions or emergency room contacts (with identified laterality in DNPR)

“Description of the 5 groups of diagnostic combinations used in the algorithm. See appendix for a detailed definition of each diagnostic and procedure code.”

Table 2

	Sensitivity % (CI)	Specificity % (CI)	Positive predictive value % (CI)	Negative predictive value % (CI)
Step 1	62.7% (59.8-65.6)	99.9% (99.9-99.9)	97.9% (96.5-98.8)	98.7% (98.6-98.8)
Step 2	77.0% (74.4-79.4)	99.9% (99.9-99.9)	96.5% (95.0-97.6)	99.2% (99.1-99.3)
Step 3	85.1% (82.9-87.2)	99.9% (99.8-99.9)	96.3% (94.9-97.4)	99.5% (99.4-99.5)
Step 4	91.3% (89.5-92.9)	99.8% (99.7-99.8)	93.3% (91.6-94.7)	99.7% (99.6-99.7)
Step 4A	91.3% (89.5-92.9)	99.9% (99.8-99.9)	96.5% (95.2-97.6)	99.7% (99.6-99.7)
Step 5	95.4% (93.9-96.5)	99.2% (99.1-99.3)	81.8% (79.4-83.7)	99.8% (99.8-99.9)
Step 5A	95.4% (93.9-96.5)	99.8% (99.8-99.9)	96.6%* (95.4-97.7)	99.8% (99.8-99.9)

*“Sensitivity, specificity and predictive values for each step of the algorithm identifying dislocations. Step 1 = Group 1 alone; Step 2 = Group 1+2 and etc. For each step an additional group is added to the previous step, thereby including more codes and increasing sensitivity at a cost of decreased specificity and the positive predictive value. The two steps marked with (A) indicates how step 4-5 can achieve an increase in the positive predictive value if the patient files for the hospital contact of the specific group is reviewed and the false positives are discarded. See appendix for examples of the review burden. *=Assumes patient file review of step 4.”*

9.4. Paper IV

“Patient reported outcome after dislocation of total hip arthroplasty – a cross-sectional matched case-control study”

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Abstract

Background

A total hip arthroplasty (THA) is a successful treatment for end-stage hip osteoarthritis for most patients. However, complications do still occur, and dislocation of the prosthesis is one of the most common, mechanical adverse events. THA dislocation may become recurrent and sometimes even require revision surgery, while others only experience a single dislocation and is successfully, in the surgeon's opinion, treated by closed reduction. However, knowledge regarding patient-reported outcomes (PRO) after patients have experienced dislocation is lacking.

Questions/Purposes

Following THA

1. Do patients with a dislocation report lower health and hip-related quality of life (QoL) than those without dislocation?
2. Do patients with a dislocation report lower patient satisfaction than patients without dislocation?
3. Does the number of dislocations, time since the latest dislocation, and revision surgery impact on hip-related QoL?
4. Do patients with a dislocation report lower activity levels than THA patients without dislocation?

Patients and Methods

We conducted a cross-sectional, matched case-control study of patients registered in the Danish Hip Arthroplasty Register, between 2010 and 2014. Dislocations were captured in the Danish National Patient Register, based on diagnosis/procedural codes and patient file reviews. Patients with dislocation were matched 1:2, according to age, sex, date, and hospital of primary surgery, to patients without dislocation. Three PRO questionnaires were applied (EQ-5D, HOOS, UCLA). Primary outcomes were health-related QoL (EQ-5D VAS score and the EQ-5D-5L mean index score), hip-related QoL (the HOOS QoL domain score), and patient satisfaction. Secondary outcomes were the remaining HOOS domain scores and the UCLA activity score. The results were compared using the mean and 95% confidence intervals (CI).

Results

We identified 1,010 living patients with dislocation. Mean follow-up was 7.2 years from index surgery and 4.9 years from the latest dislocation. Patients with dislocation reported a lower EQ-5D VAS score of 67.8 (65.9, 69.7) compared with 75.6 (74.5, 76.7) for the control group. The EQ-5D-5L mean index score was 0.89 (0.88, 0.90) for the control group, 0.78 (0.76, 0.80) for the cases

with dislocation without revision, and the index declined further to 0.72 (0.68, 0.77) for the cases with revision(s). Patients with dislocation reported a lower HOOS-QoL domain score of 62.8 (60.2, 65.4), compared with 82.9 (81.7, 84.1) for the control group. Regarding patient satisfaction, only 59% of the dislocation group reported either an “excellent” or a “very good” overall result, whereas the same number was 85% for the control group. The HOOS-QoL score decreased with additional dislocations and was 67.0 (63.8, 70.3) in patients with one dislocation, 61.4 (56.3, 66.6) after experiencing two dislocations, and 47.0 (40.4, 53.6) after more than two dislocations. Even five years after the latest dislocation, the HOOS-QoL score remained low, at 65.6 (62.0, 69.2). The other HOOS domains were consistently 8-10 points worse after dislocation. Patients with dislocation reported a mean UCLA score of 5.2 (5.0, 5.4) compared with 5.8 (5.6, 5.9) for controls with dislocation.

Conclusion

Despite the limitations within our study design, we found that both health- and hip-related QoL were markedly and persistently reduced among dislocation patients compared with those in controls, for several years. Even a single dislocation had a large impact on hip-related QoL after more than five years. Therefore, the avoidance of the initial dislocation episode is important because the THA does not appear to achieve the full relieving potential. With the large variations in dislocation rate among different patient groups, there is still a great perspective for future research in lowering the occurrence of this specific complication.

Introduction

Hip replacement is a well-described procedure for patients with debilitating hip osteoarthritis (OA), and a steady increase in the use of primary total hip arthroplasties (THA) is still reported worldwide [5, 17, 25]. Good to excellent patient- and surgeon-reported outcomes are now standard after THAs [27], but some THA patients do experience serious complications. Dislocation is observed in 0.2%-10% of the patients and represents one of the most common early complications [2, 4, 14, 18]. Dislocation leads to immediate pain and requires hospital admission, for the reduction of the dislocated hip, often under general anesthesia. After the first dislocation, recurrent dislocations are reported in up to 40%-70% of the patients, which may eventually necessitate a reoperation [3, 14]. Therefore, hip dislocations can have an immediate and negative impact on a patient's quality of life (QoL) which may potentially pursue the patient for years.

Although being a quite prevalent complication, an understanding of the patient-reported outcomes (PRO) associated with both general health-related QoL and subjective hip function remains lacking, as demonstrated in a recent systematic review [12]. This information is required when discussing indications for surgery, when advising patients after hip dislocation, and to better understand the impacts of this complication. Most likely, QoL may be affected and continuously decrease with recurrent dislocations. Likewise, confidence and trust in hip function and stability become impaired with dislocation of THAs. However, these statements require scientific support.

We aimed to compare health- and hip-related QoL and patient satisfaction among patients with single or recurrent dislocation episodes, compared with patients without complications, following primary THA due to OA, in a large-scale, cross-sectional, matched case-control study.

Patients and methods

Design

We designed a cross-sectional, matched case-control study, involving patients registered in the Danish Hip Arthroplasty Register (DHR) conducted in accordance with the STROBE guidelines and registered in Clinical Trials (NCT03860025).

Study population

We included all patients older than 40 years, who received a THA between January 1st, 2010, and December 31st, 2014, at both public and private hospitals in Denmark, to treat primary OA. Therefore, we excluded patients with acute femoral neck fractures, patients with previous hip surgeries (secondary OA), and patients younger than 40 years, as primary OA rarely occurs in younger individuals [7]. We also excluded any secondary, contralateral THA that was inserted during the inclusion period, to avoid dependency among observations [26].

We defined dislocation cases as patients with one or more THA dislocations, either with or without subsequent revision surgery. We excluded cases with revisions that were indicated by any cause other than dislocation because these patients were not included in the scope of this study. Dislocations that occurred within the initial two-year post-operative period were captured in the Danish National Patient Register (DNPR) and verified during a comprehensive review of patient files [14]. Based on these results, we created an algorithm that was designed to identify dislocations with high sensitivity (91.3%), specificity (> 99%), and positive predictive value (93.3%)[13]. This algorithm was used to identify dislocations that occurred after the end of the original two-year follow-up period, until August 1st, 2019 (Figure 1).

All patients from the original cohort [14] with no history of dislocation or revision surgery were eligible for the control group. We matched two controls without dislocation with each patient with dislocation, based on four parameters: age (± 5 years), gender, date of primary THA surgery (± 3 months), and the hospital that performed the THA.

Data sources

Primary THAs are registered in the DHR, with a completeness of 98%, whereas the completeness of reporting revisions is 93% [5, 24]. The DHR provided data regarding age, gender, and the surgical specifications of the primary THA and any following revisions.

Dislocations treated with closed reductions were extracted from the DNPR, as these are not reported to the DHR. The DNPR is an administrative database, in which all contacts with the Danish health care system are registered with diagnosis and procedure codes, including laterality. The DNPR completeness is 99.7% [28]. We extracted all diagnosis codes in the DNPR, for up to 10 years prior to the index surgery date, to calculate a Charlson Comorbidity Index (CCI). The unique Danish social security number of each Danish citizen enabled the unambiguous cross-linking of registers.

Outcome

By September 2019, our study participants received three questionnaires: a generic questionnaire that measures health-related QoL [The EuroQuality of life-5 Dimensions (EQ-5D-5L)] [9], a hip-specific questionnaire [The Hip disability and Osteoarthritis Outcome Score (HOOS)] [21], and an activity scale [The University of California Los Angeles (UCLA)] [30]. A detailed description of each questionnaire is found with supplementary data in Appendix A.

We also asked three additional questions, regarding *patient satisfaction* with the original operation, which have previously been described by The Royal College of Surgeons of England [31].

Q1 “Overall, how are the problems now in the hip on which you had surgery, compared to before your operation?” (much better/a little better/no difference/a little worse/much worse)

Q2 “How would you describe the results of your original hip operation?” (excellent/very good/good/fair/poor)”

Q3 “With the knowledge and experience you have gained after the hip operation; would you then undergo the surgery again?” (yes/no).

The questionnaires were sent using the mandatory Danish electronic mailing system (e-boks), which is coupled to the patient’s social security number. The questionnaires were electronic and were automatically returned and captured in a Research Electronic Data Capture (REDCap) database that was designed for this study. A reminder was emailed after 3 weeks. If the system registered an unsuccessful attempt to answer online, we mailed the questionnaires using regular mail to those patients. In Denmark, exemption from the electronic mailing system can be obtained

for individuals who are either mentally or physically impaired or who have no computer access. We were automatically notified regarding any study participants with exemptions, and we distributed the questionnaires through the regular mail to these patients, including a pre-paid return envelope. They received a reminder after 2 months, also by regular mail. The answers from the paper questionnaires were manually entered into the REDCap database (single-entry). Cases were able to indicate if they had never experienced a dislocation, despite our information, and controls could indicate if they had experienced a dislocation that required hospitalization and reduction.

Ethics

The Danish Patient Safety Authority (3-3013-2128) and the Danish Data Protection Agency (2008-58-0035) approved this study.

Statistics

The EQ-5D VAS scores are presented as means with 95% confidence intervals (CI). The EQ-5D-5L health states are summarized as the index value means with 95% CIs, relative to the norms established for the United Kingdom, as Danish data norms are not currently available. The HOOS results are presented for each of the five subscales, as the mean with 95% CI. A normalized score was calculated based on the mean score for each subscale, where 100 indicated no problems, and 0 indicated extreme problems. A subscale was excluded for a given patient if fewer than 50% of the items in a subscale were unanswered. This study was purely qualitative, and all results were compared descriptively using means and CIs without further analysis. We used STATA version 16.0 for statistical analysis.

Results

Participants

According to the DHR, 36,693 primary THA operations had been performed during our inclusion period, and 31,762 THA operations met our inclusion criteria (Figure 2). We identified dislocations in 1,344 THA patients, among which 282 were deceased and 52 underwent a revision for causes other than dislocation, resulting in 1,010 patients eligible for participation. This cohort included 770 patients with one or more dislocations and no revision, and 240 patients with dislocation and one or more subsequent revisions due to dislocation. We were able to match two controls for each of 1,001

cases, one control for an additional 6 cases, and no controls for the remaining 3 cases. The questionnaire response rate was 66% among the case group and 72% among the control group. After excluding those cases who denied experiencing dislocation and controls with a self-reported dislocation, 640 cases and 1422 controls were included in further analyses (Table 1). The two groups were similar in both age, gender and length of follow-up from primary surgery to the date for the receipt of questionnaires. The listed demographics for the responders were comparable to the invited cases and controls. In the case group, the mean (range) follow-up from the latest dislocation was 4.9 years (0.6, 9.7).

1. Do patients with a dislocation report lower health and hip-related quality of life (QoL) than those without dislocation?

Patients without dislocation reported a higher mean (95% CI) EQ-5D VAS score of 75.6 (74.5, 76.7) compared to 67.8 (65.9, 69.7) in the dislocation group, which further declined to 60.8 (57.1, 64.6) in cases with revision(s). The EQ-5D-5L index mean score was 0.89 (95% CI, 0.88, 0.90) for the control group, 0.78 (0.76, 0.80) for the cases with dislocation without revision, and the index declined further to 0.72 (0.68, 0.77) for the cases with revision(s). The EQ-5D-5L results, presented as health profiles with column charts, can be found in the supplementary data (Appendix B).

Subjective hip function was also affected by dislocations. A decrease of approximately 10 points was observed for four out of five HOOS domains (Pain, Symptoms, ADL, and Sport/Rec) in patients with dislocation(s) compared with scores for controls, and an additional decrease was observed in cases with dislocation and revision(s) compared with cases without revision (Table 2). Regarding hip-related QoL, patients with dislocations reported a lower mean (95% CI) HOOS-QoL domain score of 62.8 (60.2, 65.4), compared with 82.9 (81.7, 84.1) for the control group.

The third item incorporated in the HOOS-QoL domain is particularly relevant to our study cohort and it relates to the lack of hip confidence. Nearly 30% of patients with dislocation reported being either severely or extremely troubled by a lack of confidence, whereas this only applied for 5% of the controls.

2. Do patients with a dislocation report lower patient satisfaction than patients without dislocation?

Nearly 90% of patients without dislocation reported that the hip is “much better” than before the primary surgery, whereas only 70% of cases with dislocation report the same (Table 3). Similarly, only 59% of the dislocation group reported either an “excellent” or a “very good” overall result, whereas the same number was 85% for the control group. This is also reflected in the fact that only 79.5% of patients with dislocation would undergo the primary surgery again, compared with 93% of controls. 44% of patients who underwent revision surgery reported a poor result, compared with 9% of patients who experienced dislocation without revision.

3. Does the number of dislocations, time since the latest dislocation, and revision surgery impact on hip-related QoL?

When the case group was divided based on the number of dislocations, we found that patients with multiple dislocations were associated with even lower QoL scores (Table 2). We also divided the cases based on the length of follow-up from the latest dislocation. The HOOS-QoL score was 53.6 (48.0, 59.1) if fewer than two years had passed, whereas scores of 64.3 (59.3, 69.3) and 65.6 (62.0, 69.2) were reported for two to five years and more than five years follow-up since the last dislocation, respectively. The third item incorporated in the HOOS-QoL domain is particularly relevant for our study cohort and is related to the lack of confidence with the hip. Nearly 30% of patients with dislocation reports to be either severely or extremely troubled with lack of confidence while this only applies for 5% of the controls.

4. Do patients with a dislocation report lower activity levels than THA patients without dislocation?

The mean (95% CI) UCLA scores for controls, cases with dislocation without revision, and cases with dislocation and subsequent revisions were 5.8 (5.6, 5.9), 5.2 (5.0, 5.4), and 4.8 (4.5, 5.2) respectively. A value of 6 corresponds to “*Regularly participates in moderate activities*”, and a value of 5 represents “*Sometimes participates in moderate activities, such as swimming, or could do unlimited housework or shopping*” (Chart of answer distribution available in Appendix C).

Discussion

There is a clear gap in knowledge regarding PRO following hip dislocation. To our knowledge, this study on PRO in patients with primary THA represents the largest cross-sectional, matched case-control study of patients who experienced hip dislocation. A recently published systematic review identified only two studies that aimed to compare cases with dislocation with controls without complications after THA [12]. The included studies were either very small or used partly patient-reported outcomes [6, 10]. We focused solely on the patient's perspective. In the present study, the large case group examined enabled us to identify both the consequences of recurrent events and the time factor. Although our findings may have previously been empirically assumed by orthopedic surgeons, our study is the first to state and emphasize the PROs after dislocation.

Limitations

This study has some limitations. We could not obtain preoperative or immediate postoperative PRO measures, as these are not yet routinely captured in the DHR [5]. Therefore, this study was performed with a cross-sectional design. We do not know if any patient selection is overrepresented in either the case or control groups. We believe this is unlikely because all cases were included and were matched with controls according to four parameters, and that we conducted this study based on a nationwide, high-quality register. We chose not to exclude patients with a non-responding match because this would dramatically reduce the number of eligible participants, due to our 70% response rate. As expected, the responders were slightly younger and healthier than the non-responders, which was evident in both the case and control groups. With 30% non-responders, it is also a legitimate question whether the condition of these patients would change the post-dislocation scores significantly. We believe it is reasonable to assume that the non-responders are more likely to suffer from conditions like cognitive impairments, which is not captured in the CCI, or reduced function, and increased dependence on others. This patient group is likely to report lower post-dislocation scores, however, and are not likely to change our overall result [15].

Question 1

We showed that even a single dislocation after THA markedly affected the reported hip-related QoL, and that the impact persisted throughout the follow-up period. The other domains, including

health-related QoL, pain, hip-specific symptoms, ADL were all consistently lower among patients with dislocations and even lower among patients who underwent revision surgery.

The EQ-5D was chosen as a generic questionnaire, based on its widespread use, which provides excellent opportunities for comparisons. Compared with the Oxford Hip Score and the HHS, we found the HOOS questionnaire to be more relevant after dislocation, especially due to the hip-related QoL subscale. A number of papers have combined patients with different diagnoses, including patients with revision, without reporting the PRO scores for OA patients separately [1, 8, 16, 29] which is why caution is required when comparing these results for any particular patient group. We defined our cohort of interest as patients with a primary diagnosis of OA and chose to exclude patients receiving THA for other causes, since we believe they are not comparable.

Our study revealed a clear relation between dislocation and inferior PRO scores. Due to the large number of cases included over a five-year period, there is good reason to assume that the dislocation is responsible for the inferior results. Earlier studies have reported a difference of approximately 9-17 points on the HOOS questionnaire to represent the minimal clinically important difference (MICD), depending on the domain examined and the statistical method [19, 23]. In our study, this threshold has been exceeded, particularly for the HOOS-QoL domain, and is nearly exceeded for the other four domains. The reported HOOS and EQ-5D VAS scores for the control group in our study were comparable to those reported in other studies after THA [11, 22].

Dislocation is one of the few complications after THA for which non-surgical treatment is an option. Other complications, such as prosthetic joint infection, peri-prosthetic fracture, or aseptic loosening after longer follow-up, are more often deemed to revision surgery and are, therefore, not comparable to our non-revised cases.

Question 2

Expectations to a primary THA may vary largely among the patients and are highly coupled to patient satisfaction [20]. Disregard the expectations, no patient should be satisfied with any major complication. Objectively, an episode of hip dislocation is only present from the time of dislocation to the closed reduction, usually within few hours. However, even after a mean follow-up period from the latest dislocation of 4.9 years, the patients with dislocation in our study was less satisfied compared with controls, and more than 20% would not choose surgery again with their current knowledge. This lower rate of satisfaction after dislocation support the findings in the smaller study

by Forsythe et al. [10]. For those who subsequently underwent revision surgery due to dislocation, the overall result was more disappointing, and 44% reported a poor result.

Question 3

We found that even a single dislocation treated with closed reduction greatly affected hip-related QoL with a HOOS-QoL domain score of 67.0 (95% CI 63.8, 70.3) compared with controls 82.9 (81.7, 84.1). This indicates that a single dislocation experience is enough to affect the patients' trust in hip stability. With increasing number of dislocations, the HOOS QoL score decreased, and in the group with two or more dislocations it was only 47.0 (40.4-53.6). Based on our results, it seems as the impact on hip-related QoL is long-lasting. We found only a slight, not clinically relevant, improvement in the HOOS-QoL score over time among patients with dislocation, and the score remained persistently 20 points lower than that for controls, even after two years.

Question 4

The mean UCLA activity scores for the three groups (dislocation and no revision, dislocation and subsequent revision, and controls) revealed numbers that could be anticipated in a cohort of middle-aged to older patients post-THA, who are not expected to participate in high-impact sports activities. It would be fair to conclude that with mean values at 5.2 (95% CI 5.0, 5.4), 4.8 (4.5, 5.2), and 5.8 (5.6, 5.9) there were no clinically relevant difference between the groups in our study. The two case groups, in general, included higher proportions reporting lower activity levels than the control group, whereas the opposite trend can be observed for the higher activity levels (Chart in supplementary data, Appendix C).

Conclusion

Conclusively, this study has provided new and substantial information regarding the patients' experience after a hip dislocation and represents the largest national study ever conducted for this topic. Even one dislocation after a THA was associated with worse long-term self-reported outcome scores. Health- and hip-related QoL were markedly and persistently reduced, confidence regarding hip stability was lacking, and patients were less satisfied, with greater than 20% indicating that they would not choose to have a THA again if armed with their present knowledge. Therefore, the most important aspect must be to avoid the first episode of dislocation, since the full relieving potential

for this THA is never achieved, even after many years of follow-up. In perspective, this information should be incorporated with other objective aspects, when discussing indications for primary THA and when advising patients after a hip dislocation.

Author contributions

LLH, BV and SO were responsible for the conception of the study; LLH was responsible for the handling of questionnaires and data analysis; LLH drafted the manuscript; BV and SO revised the manuscript critically for important intellectual content, and all authors approved the final version to be published.

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Conflict of interest

The authors have no conflicts of interest to declare.

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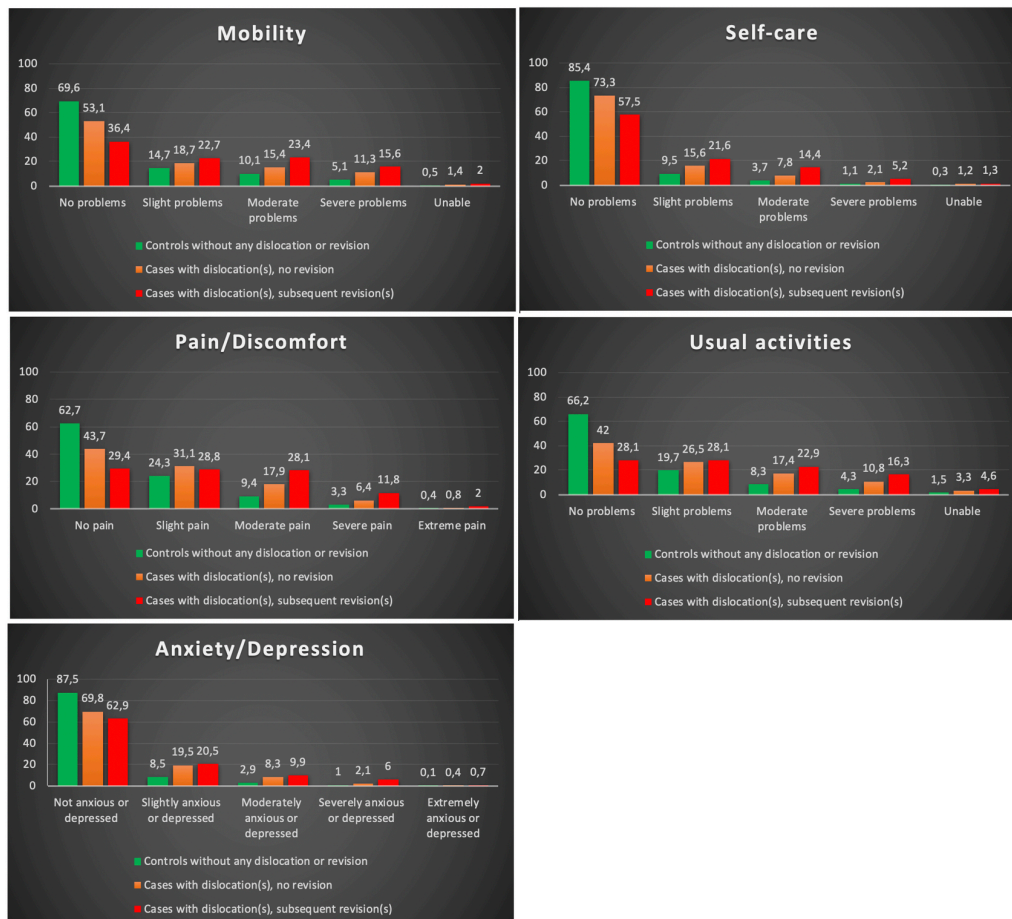
Appendix A

The EQ-5D-5L questionnaire covers five dimensions of current health status, for the specific date of questionnaire completion, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is coupled to a 5-point Likert scale. An index value is calculated relative to the normal values for the relevant population (country), where an index value of 1 represents full health, 0 represents death, and a value below 0 represents a health state worse than death. A visual analog scale (VAS), ranging from 0-100, is also included to record an individual's rating of their current health-related QoL state [9]. A Danish version was available, and approval from the EUROQOL group was obtained before use.

The HOOS questionnaire is hip-specific and consists of five domain scores, consisting of 4-17 items per subscale, for a total of 40 items. The five domains are Pain, other Symptoms, Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and hip-related QoL [21]. The third item of the hip-related QoL domain is exceptionally important for our study: "*How much are you troubled with lack of confidence in your hip?*" The last week is taken into consideration when answering the questions. Standardized answer options are provided based on a 5-point Likert scale, and each question receives a score between 0 and 4. The HOOS has been validated for THA patients, and a validated Danish version exists, that can be used free-of-charge.

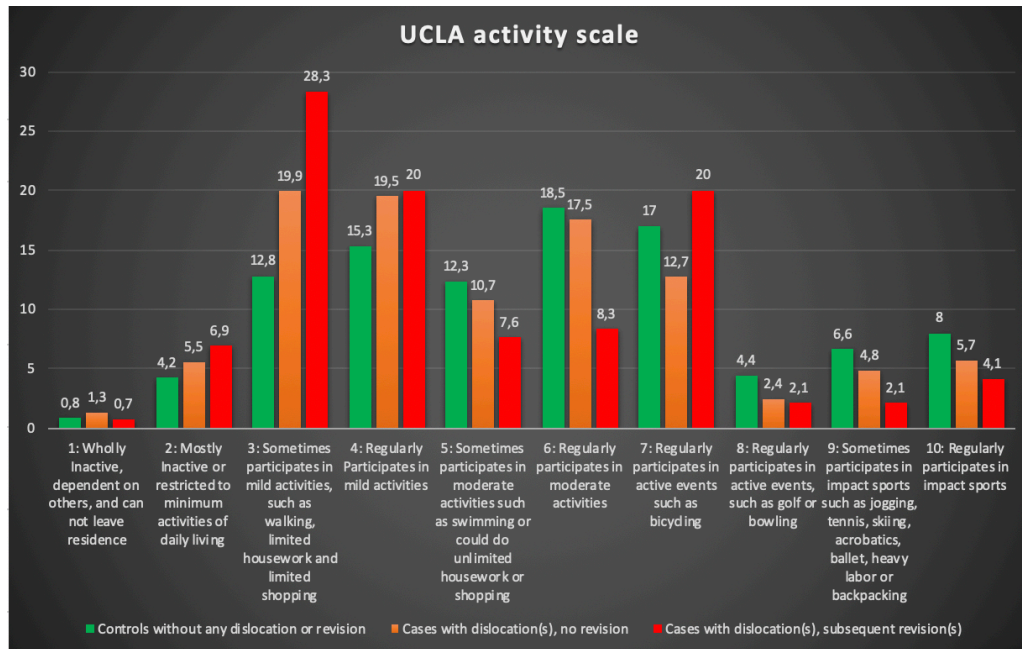
The UCLA activity scale consists of a simple rating from 1 to 10. The patient indicates the most appropriate current activity level, with 1 defined as "no physical activity, dependent on others" and 10 defined as "regular participation in impact sports." [30] The UCLA scale was found to be a reliable, feasible, and valid instrument for the assessment of activity levels in patients undergoing THA, and a Danish version exists.

Appendix B



“EQ-5D-5L scores. The diagrams present the distribution (proportions) between the five levels (No problems/Slight problems/Moderate/Severe/Unable or extreme) for each of the five domains within the EQ-5D questionnaire for controls (eligible no. = 1,399), cases with dislocation(s) (eligible no. = 482), and cases with subsequent revision(s) due to dislocation (eligible no. = 154). The cases groups are more likely to indicate problems in various degrees in every domain of the score compared to the control group.”

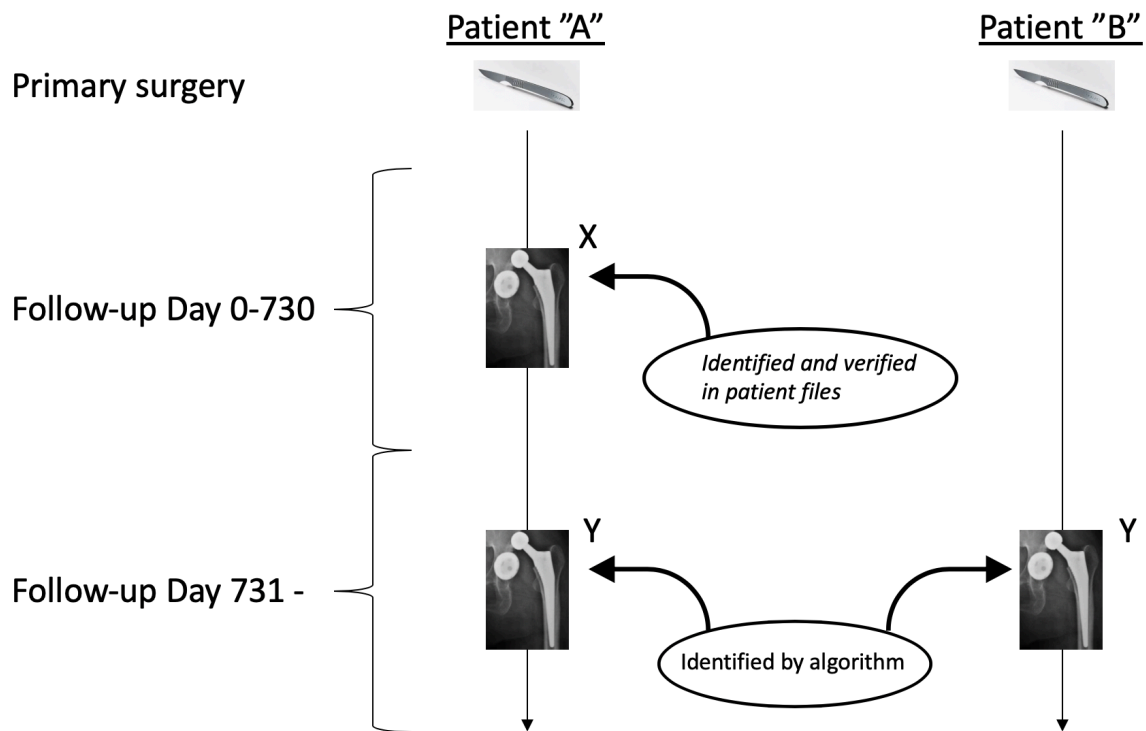
Appendix C



“UCLA activity scale. The diagram presents the proportional distribution of the UCLA activity scores for the three groups. The cases are more likely to report a lower activity level than controls. A shift is seen at level four, after which the controls are in possession of the largest proportions, except from level seven.”

Figure 1

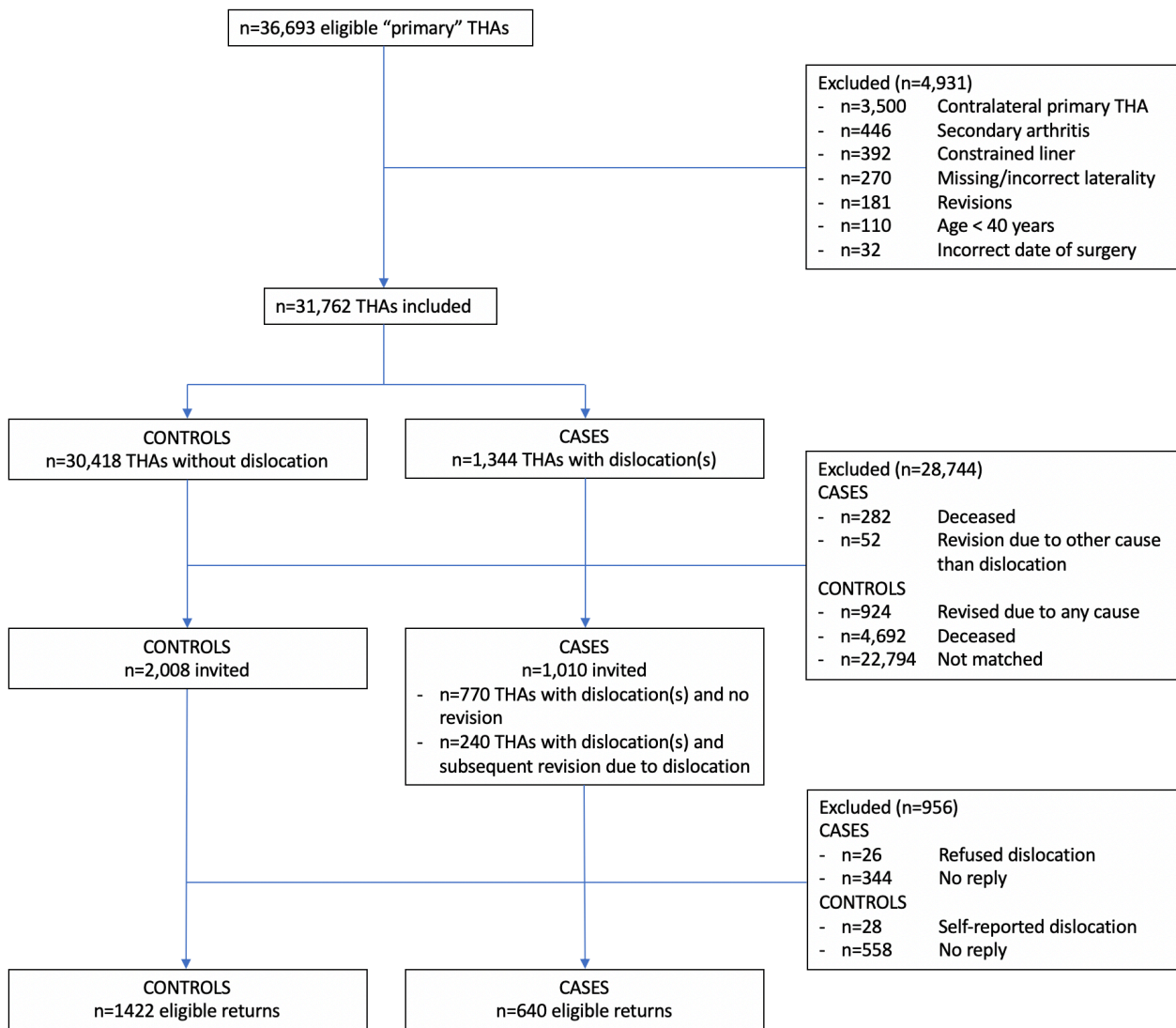
“Method for the identification of all THA dislocations”



“During the first two post-operative years, all dislocations were verified by review of patient files (Like dislocation X in patient A). After the first two years, dislocations were found by a newly developed algorithm, thereby identifying further dislocations in already known cases (Like patient A), or dislocations in patients that did not experience this within the early follow-up period (Like Patient B).”

Figure 2

“Flowchart of the inclusion/exclusion process”



“Flowchart of the selection process from DHR data retrieval to the return of questionnaires.”

Table 1

“Patient demographics for both invited and returning, eligible patients, respectively”

Invited		
	Cases (n=1,010)	Controls (n=2,008)
Age (years), mean (CI)	69.8 (69.2-70.3)	69.7 (69.4-70.1)
Gender, women (proportion)	63.6%	64%
Follow-up (years), mean (min.-max)	7.2 (4.8-9.7)	7.2 (4.8-9.7)
CCI (proportion)		
0	76.9%	81.2%
1-2	19.4%	16.7%
> 2	3.7%	2.2%
Returned, eligible		
	Cases (n=640)	Controls (n=1,422)
Age (years), mean (CI)	68.8 (68.1-69.4)	69.1 (68.7-69.5)
Gender, women (proportion)	60.2%	64.4%
Follow-up (years), mean (min.-max)	7.1 (4.8-9.7)	7.2 (4.8-9.7)
CCI (proportion)		
0	78.1%	82.5%
1-2	18.6%	15.8%
> 2	3.4%	1.7%

Table 2

“HOOS questionnaire results”

		Cases with dislocation(s), no revision			Cases with dislocation(s), subsequent revision(s)		Controls without any dislocation or revision
Invited (no.) / Returned, eligible (no.)		770/486			240/154		2,008/1,422
Pain	eligible (no.)	n=477			n=151		n=1,373
	mean (CI)	80.7 (78.8-82.6)			70.0 (66.1-74.0)		88.2 (87.3-89.1)
Symptoms	eligible (no.)	n=480			n=154		n=1,383
	mean (CI)	77.1 (75.2-79.1)			66.1 (62.1-70.1)		85.8 (84.8-86.7)
ADL	eligible (no.)	n=475			n=151		n=1,367
	mean (CI)	77.0 (74.9-79.0)			66.8 (62.7-70.9)		86.1 (85.1-87.1)
Sport/Rec	eligible (no.)	n=461			n=147		n=1,343
	mean (CI)	56.6 (53.7-59.5)			43.8 (38.8-48.8)		72.5 (71.0-74.0)
QOL	eligible (no.)	n=474			n=150		n=1,367
	mean (CI)	62.8 (60.2-65.4)			53.5 (49.0-58.0)		82.9 (81.7-84.1)
		1 dislocation (no revision)	2 dislocations (no revision)	> 2 dislocations (no revision)	Dislocation(s) and 1 revision	Dislocation(s) and > 1 revision	Controls without any dislocation or revision
Invited (no.) / Returned, eligible (no.)		459/307	160/106	125/73	197/131	43/23	2,008/1,422
Pain	eligible (no.)	n=301	n=105	n=71	n=129	n=22	n=1,373
	mean (CI)	81.9 (79.6-84.3)	80.3 (76.5-84.1)	76.3 (70.7-81.9)	71.0 (66.8-75.2)	64.3 (52.3-76.3)	88.2 (87.3-89.1)
Symptoms	eligible (no.)	n=303	n=105	n=72	n=131	n=23	n=1,383
	mean (CI)	78.3 (75.8-80.8)	77.8 (74.1-81.6)	71.4 (66.1-76.7)	67.4 (63.0-71.9)	58.5 (49.1-67.9)	85.8 (84.8-86.7)
ADL	eligible (no.)	n=298	n=105	n=72	n=130	n=21	n=1,367
	mean (CI)	78.0 (75.4-80.7)	78.6 (74.8-82.3)	70.0 (63.9-76.1)	67.6 (63.2-72.0)	61.6 (49.4-73.8)	86.1 (85.1-87.1)
Sport/Rec	eligible (no.)	n=289	n=101	n=71	n=127	n=20	n=1,343
	mean (CI)	58.7 (54.9-62.4)	56.5 (50.8-62.1)	48.5 (40.6-56.4)	44.9 (39.4-50.5)	36.6 (25.6-47.6)	72.5 (71.0-74.0)
QOL	eligible (no.)	n=298	n=105	n=71	n=128	n=22	n=1,367
	mean (CI)	67.0 (63.8-70.3)	61.4 (56.3-66.6)	47.0 (40.4-53.6)	55.0 (50.1-59.9)	44.7 (33.0-56.4)	82.9 (81.7-84.1)

Table 3

“Patient satisfaction”

	Cases with dislocation(s), no revision	Cases with dislocation(s), subsequent revision(s)	Controls without any dislocation or revision
Q1 “Overall, how are the problems now in the hip on which you had surgery, compared to before your operation?”			
Eligible (no.)	n=469	n=146	n=1358
Much better	69.5 %	56.2 %	88.8 %
A little better	13.0 %	21.2 %	5.8 %
No difference	7.7 %	6.2 %	3.2 %
A little worse	4.9 %	5.5 %	1.0 %
Much worse	4.9 %	11.0 %	1.3 %
Q2 “How would you describe the results of your original hip operation?”			
Eligible (no.)	n=471	n=145	n=1357
Excellent	27.8 %	11.7 %	58.6 %
Very good	31.6 %	13.1 %	26.7 %
Good	20.6 %	15.2 %	8.5 %
Fair	11.5 %	15.9 %	3.7 %
Poor	8.5 %	44.1 %	2.6 %
Q3 “With the knowledge and experience you have gained after the hip operation; would you then undergo the surgery again?”			
Eligible (no.)	n=464	n=145	n=1352
Yes	79.5 %	66.2 %	93.3 %
No	20.5 %	33.8 %	6.7 %

“Risk factors for dislocation and re-revision after first-time revision total hip arthroplasty due to recurrent dislocation – a study from the Danish Hip Arthroplasty Register.”

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Abstract

Background

Persistent instability after hip revision is a serious problem. Our aim was to analyze surgical and patient-related risk factors for both a new dislocation and re-revision after first-time hip revision due to dislocation.

Methods

We included patients with a primary THA due to osteoarthritis and a first-time revision due to dislocation registered in the Danish Hip Arthroplasty Register (DHR) from 1996-2016. We identified dislocations in the Danish National Patient Register and re-revisions in the DHR. Risk factors were analyzed by a multivariable regression analysis adjusting for the competing risk of death. Results are presented as sub-distribution hazard ratios (sHR).

Results

We identified 1,678 first-time revisions due to dislocation. Of these, 22.4% had a new dislocation. 19.8% were re-revised for any reason. With new dislocations treated by closed reduction as endpoint, the sHR was 0,36 (95% CI, 0.27-0.48) for those who had a constrained liner (CL) during revision and 0.21 (0.08-0.58) for dual mobility cups (DMC), thereby lowering the risk of dislocation compared to regular liners. Changing only the head/liner increased the risk of dislocation (sHR=2.65; 2.05-3.42) compared to full cup revisions. The protective effect of CLs and DMCs on dislocations vanished when re-revisions became the endpoint. The head/liner exchange was still found inferior compared to cup revision (sHR=1.73; 1.34-2.23).

Conclusion

Patients revised with DMCs and CLs were associated with a lower risk of dislocation after a first-time revision but not re-revision, whereas only changing the head/liner was associated with higher risk of dislocation and re-revision of any cause compared to cup revision.

Introduction

Instability following total hip arthroplasty (THA) is a devastating and long-lasting complication for the patient but also a major concern for the orthopedic surgeon [1]. The incidence of dislocation after primary THA ranges from 0.2% and up to 10%, and recurrence is reported in up to 60% of cases [2-8]. Unless there is a clear etiology for the instability, a non-surgical treatment plan is often advised after the first and second dislocation [9, 10]. Eventually, revision surgery might become necessary in an attempt to restore stability. Dislocation is currently responsible for 15% to 25% of performed revisions [11-16].

The outcome after revision due to recurrent dislocation is not encouraging, since 10% to 34% of revised patients experience re-dislocation [17-19], and up to 20% and 35% are re-revised within five and ten years, respectively [17]. The risk for recurrence may depend upon the extent of revision [17, 20], while the use of larger head sizes, dual mobility cups (DMCs), and constrained liners (CLs) have been advocated for as solutions to minimize the problem [17, 21-24]. To lower the risk for both re-dislocation and re-revision, it is essential to recognize specific risk factors, which are currently poorly understood [17, 25].

Thus, this study aimed to analyze both patient and surgical related risk factors concerning either dislocation treated with closed reduction or re-revision after first-time revision due to dislocation in patients treated for idiopathic osteoarthritis (OA).

Materials and Methods

Study design

The study was performed using prospectively collected data from the Danish Hip Arthroplasty Register (DHR) and followed the REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) guidelines [26]. Our study included first-time revision THA cases treated at both public and private hospitals in Denmark from January 1st 1996 to December 31st 2016. The follow-up period ended December 31st 2018 or after re-revision, death, or migration occurred, whichever came first.

Participants

Our main cohort of interest was patients with first-time revisions due to dislocation. We also included cases of revision indicated by aseptic loosening since we considered these to be the best-available ‘control’ group for comparative purposes.

We limited our study cohort to only include patients with the primary diagnosis of idiopathic hip OA, thereby excluding individuals who had undergone previous hip surgery (secondary arthritis), those with acute femoral neck fractures, and patients younger than the age of 40 years given the presence of primary OA below this age threshold is rare [27-30]. If a patient underwent a revision in the contralateral hip during our inclusion period, we excluded the second revision to avoid dependency among observations [31].

Variables and data sources

The available patient-related risk factors were age, sex, and Charlson Comorbidity Index (CCI), while the surgical risk factors of specific interest included extent of the revision, liner type, and head size.

The study cohort and associated surgical variables for both first-time revisions and re-revisions were extracted from the DHR. The DHR is a Danish nationwide arthroplasty register established in January 1995 and registration of patients from all Danish orthopedic departments is compulsory [32]. According to prior studies, the completeness of registered revisions in the DHR is 93% to 95% [13, 32]. The indication for all primary THA cases was also identified in the DHR to verify the diagnosis of primary OA in each case [33].

We calculated the CCI based on reported diagnoses registered in the Danish National Patient Register (DNPR) up to ten years prior to revision [34]. The DNPR is an administrative database that contains information about every hospital admission in Denmark (both public and private hospitals) and, due to the unique 10-digit social security number (CPR number) of all Danish citizens, unambiguous cross-matching with other registries is possible [35]. The DNPR completeness is 99.7% [36].

Outcomes

Dislocations after first-time revision were identified in the DNPR by applying an algorithm of hip- and dislocation-related codes, which was recently validated [37].

The algorithm identifies dislocations with a sensitivity of 91.3%, a specificity of more than 99%, and a positive predictive value of 93.3%.

Dislocation was defined as an episode requiring reduction assisted by a physician. We defined re-revision as any surgical intervention with implant exchange or debridement that was reported to the DHR. We excluded patients undergoing partial first-time revisions with a Girdlestone or spacer solution since these patients were predetermined to either receive no further surgery or a planned second-stage revision.

Ethics

The Danish Data Protection Agency (2008-58-0035) approved the data management and storage processes.

Statistical methods

Risk factors for dislocation and re-revision after first-time revision due to dislocation or aseptic loosening were analyzed separately by a Fine & Gray multiple regression, adjusting for age-group, sex, CCI, head size, liner type, and extent of revision. The outcome of the Fine & Gray regression analysis is a sub-distribution hazard ratio (sHR), which is comparable to a hazard ratio, but it takes the competing risk of death into account. [38, 39]. Differences in the results between the two indications for first-time revision and variations in the impact of each risk factor depending upon the endpoint (i.e., dislocation vs. re-revision) were compared descriptively. Statistical analysis was performed with Stata version 16.0 (StataCorp LLC, College Station, TX, USA).

Results

Study population

From 1996 to 2018, a total of 21,665 first-time revisions were registered in the DHR. Thereafter, we confirmed the associated primary THA procedures in the register for 9,138 of these revisions to insure an original diagnosis of primary OA. Subsequently, an additional group of 5,270 records was excluded (Figure 1), why 3,868 first-time revisions met the inclusion criteria as being revised for either dislocation or aseptic loosening.

The study cohort consisted of 55% females with a mean age of 71.7 years at the time of revision. The median follow-up period was 5.3 years (range, 1 day – 21.6 years).

Risk of dislocation after first-time revision

Patients revised due to dislocation presented the highest incidence of new dislocation at a rate of 22.4% (95% confidence interval (CI), 20.4 to 24.5) as compared with 11.3% (95% CI, 10.0 to 12.7) among those revised for aseptic loosening. The median time to dislocation following revision varied largely between the indications. THA cases revised due to dislocation re-dislocated after nearly 11 months (median, 319 days; interquartile range (IQR), 47 to 1299), whereas revisions performed after aseptic loosening dislocated earlier (median, 61 days; IQR, 20 to 460).

Risk factors for dislocation after first-time revision

Age, sex, CCI, and different head sizes were not risk factors for dislocation (Table 1). Meanwhile, patients who received a CL (sHR, 0.36; 95% CI, 0.27 to 0.48) or a DMC (sHR, 0.21; 95% CI, 0.08 to 0.58) experienced significantly fewer dislocations relative to those who received a normal liner. Most revisions for dislocation involved either a head/liner exchange only or also revision of the acetabular component. Head/liner exchange resulted in a significantly greater risk for subsequent dislocation when compared with full cup revision (sHR, 2.65; 95% CI, 2.05 to 3.42). The conduct of a total revision when the indication was aseptic loosening led to the lowest risk.

Risk factors for re-revision after first-time revision

Re-revision for any reason after first-time revision due to dislocation occurred in 19.8% (95% CI, 17.9 to 21.8) of patients (Table 2). Half of these re-revisions occurred due to re-dislocation (10.3% (95% CI, 8.9 to 11.9)). In the group of revisions for aseptic loosening, 16.2% (95% CI, 14.7 to 17.8) were re-revised for any reason and 3.5% (95% CI, 2.7 to 4.3) were re-revised due to re-dislocation.

Younger patients (aged < 65 years) possessed the highest risk of re-revision as illustrated by a sHR of 1.36 (95% CI, 1.05 to 1.77) as compared with patients aged 65 to 75 years (Table 2). Sex, CCI, and variations in head sizes did not affect the re-revision rate. There was a significantly higher risk for a re-revision after a head/liner

change only relative to if the acetabular component had been fully revised (sHR, 1.73; 95% CI, 1.34 to 2.23). CLs and DMCs were not associated with a lower risk of re-revision when compared with a normal liner. Among revisions for aseptic loosening, total revisions led to the lowest risk of re-revision.

Discussion

In this nationwide study, we reported patient and implant related risk factors for dislocation and re-revision following first-time revision due to dislocation or aseptic loosening. Separately, the use of CLs and DMCs in comparison with regular liners reduced the risk for dislocation treated with closed reduction but not for re-revision (any reason). Full acetabular component revisions were associated with the reduced risk of both dislocations and re-revisions of any cause as compared with less-invasive revisions of the head and liner only. To the best of our knowledge, a direct comparison of the re-revision rate between full cup revision and head/liner exchange in patients revised for instability has not yet been published.

There are some limitations associated with our study. Firstly, in up to 25% of cases, the head sizes and liner types were unknown. However, these missing data were not associated with a specific time period during our 20-year inclusion period. Moreover, they did not exhibit an increased risk of dislocation or re-revision, which is why we do not believe that there is any unmeasured confounding in this group. Secondly, we excluded more than 12.500 revisions with an unknown indication for the primary THA, and thereby we may have lost valuable information. However, we sought to uniform our cohort and only include first-time revision cases with a registered diagnosis of primary OA in the DHR after its establishment in 1995.

The study also has several strengths. First of all, this was a nationwide study using validated registers, thus reducing bias. Secondly, our reporting is transparent in accordance with the RECORDS guidelines. Third, in contrast with previous studies that may have underreported complications, we are able to capture cases of dislocation admitted to every national hospital due to our reliance on the nationwide patient register (DNPR). Finally, we have applied a recently published algorithm with validated codes, which minimized the risk of omitting dislocations that were mis-coded in the patient register [37].

Endpoint re-dislocation

In contrast with our study showing that 22% of patients revised for dislocation experience re-dislocations, others have reported 13.0% to 18.2% with a mean follow-up from two to five years [17-19]. We believe this discrepancy can be explained by the use of our approach, which captured all dislocations. The earlier studies do not present results for patients with primary OA only, and these percentages for OA patients alone may be lower, and the difference between our result and the previous results would, in fact, increase.

The cause of dislocations is multifactorial and any revision performed due to recurrent dislocations after a primary THA should, preferably, address the exact cause in the particular patient. This is not always an easy task since patient factors, surgical techniques, and the prosthesis itself may be involved in the pathogenesis. The time to first dislocation after the first revision varied largely among revisions due to dislocation and aseptic loosening. It was markedly longer when instability had been addressed during the revision procedure. An explanation for this outcome could be increased attention paid by the surgeon to achieving extraordinary stability in these cases. Also, the patient may exhibit a greater degree of caution for a longer period of time after surgery when they have experienced the trauma of a dislocation previously.

In 48% of patients revised for dislocation, only exchange of the head and liner were conducted. This resulted in a subsequent re-dislocation rate of 30.2%, which was significantly higher than that observed for full cup revisions (14.3%). Carter et al. reported similar results in a smaller clinical study with dislocations in 34% and 14% of patients after liner exchange and full cup revision, respectively [40], while rates as high as 55% after head/liner exchange are reported [41]. This result may be explained by that mal-positioned cups are not identified or are less prone to be revised due to their secure fixation with bony ingrowth, yet, in this context, proper tension is not being achieved, which will lead to continuous instability after revision [42]. We found that, if the revisions were conducted after aseptic loosening, there were significantly fewer dislocations following revision of both the cup and femur component as compared with after cup revision only (7.3% vs. 13.7%), which supports the results of the study by Kosashvili et al. [20]. A more accurate cup positioning and abductor tension may be easier achievable during a total revision compared with cup revision only.

The use of CLs and DMCs lowered the risk of dislocation in comparison with smaller heads ($\leq 28\text{mm}$), regular liners and unipolar cups in earlier reports [17, 18, 43]. Our findings support this, as we report dislocation rates of 4.0% and 12.9% for patients with DMCs and CLs, respectively, in comparison with that of 25.5% for patients with unipolar cups with a normal liner. Regarding head sizes, we found that heads smaller than 32mm triggered a dislocation rate of 24.6%, compared with 18.5% for 36mm – although, this is a non-significant difference.

Endpoint re-revision

In patients revised for instability, 20% were re-revised for any reason after a median follow-up of 5.3 years, corresponding to other reports of 16% undergoing re-revision after one year [25] and 23% after up to 17 years of follow-up [17].

In our study, the benefits of the use of CLs and DMCs were not present when the endpoint changed from dislocation treated with closed reduction to re-revision. Similar second-time revision rates for constrained vs. non-constrained components were also reported by Lewis et al. [23]. In contrast with our results, Mohaddes et al. found that the use of DMCs reduced the risk of a second revision compared with unipolar designs [24].

Regarding the extent of first-time revision, isolated head/liner exchange led to a higher re-revision risk as compared with following a full cup revision (23.9% vs. 15.0% (sHR, 1.73; 95% CI, 1.34 to 2.23)). This may not be surprising, since the dislocation rate was more than 30% as written above. Moreover, the surgeon may be more prone to proceed with additional surgery if the cup was not revised during the first-time revision. Earll et al. assessed cases of isolated modular head and liner exchange and observed 17.3% required re-revisions [41].

Conclusion

In conclusion, our study revealed rates of 22% for dislocations and 20% for re-revision occurring after first-time revision indicated by dislocation. The use of CLs and DMCs was associated with a reduced risk of dislocation but no change in the risk of re-revision within our follow-up period. One risk factor for both dislocation and re-revision was the conduct of isolated head/liner exchange as compared with a full cup revision.

In perspective, the surprising high risk of dislocation and re-revision stressed the importance of performing the first primary THA procedure right. High risk patients may even not be eligible for a THA. Moreover, isolated modular head/liner exchange should be re-considered in every case compared with revision of the acetabular component or, eventually, the full hip.

Funding and conflicts of interest

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Author contributions

LH, BV and SO were responsible for the conception of this study; LH was responsible for data analysis; LH drafted the manuscript; BV and SO revised the manuscript critically for important intellectual content. All authors approved the final version to be published.

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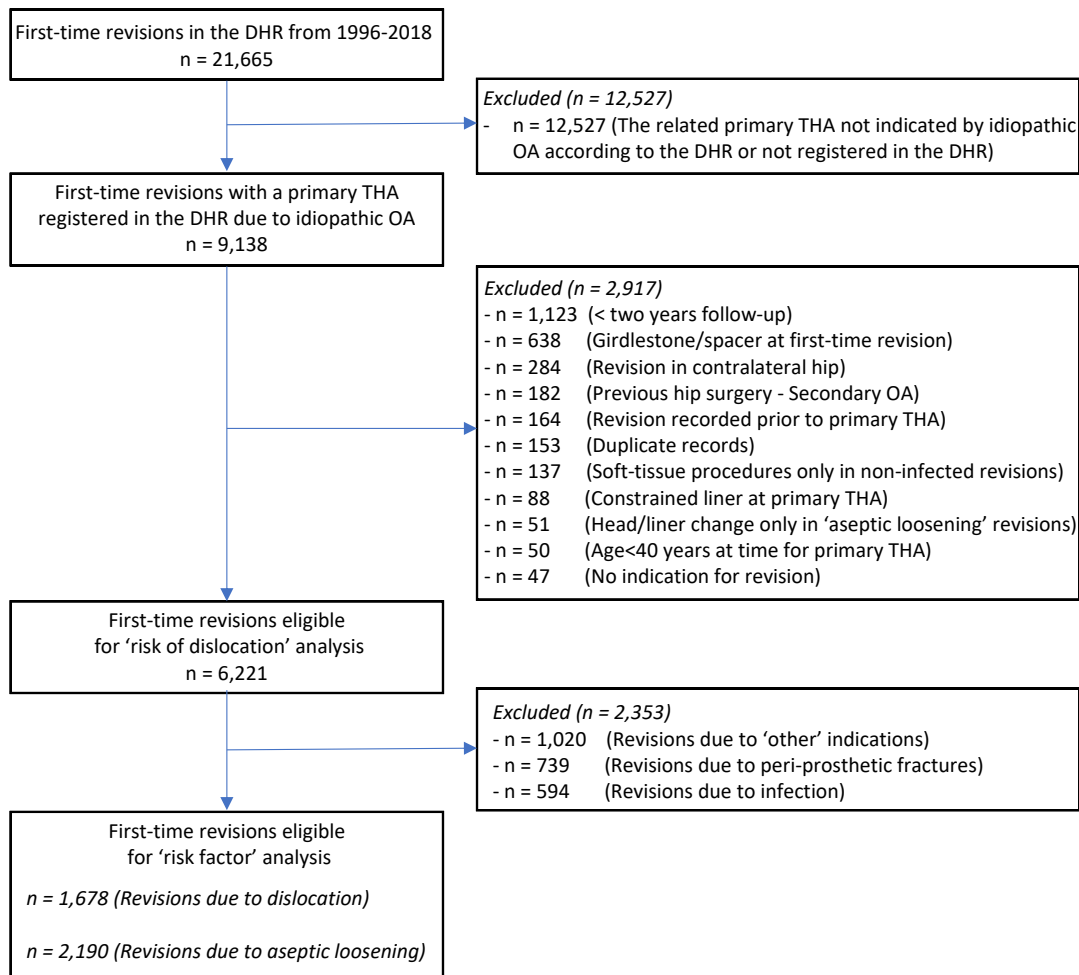
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Figure 1



“Flowchart of study participants. ‘Others’ include the less frequent reported first-time revisions indicated by either pain, liner wear without component loosening, osteolysis/granuloma without loosening, component failure (no further specification) or simply other reasons.”

Table 1

Risk factors for dislocation	Revisions due to dislocation			Revisions due to aseptic loosening		
	Patients (no.) / dislocation (no.)	Risk of dislocation, % (95% CI)	sHR (95% CI) - adjusted	Patients (no.) / dislocation (no.)	Risk of dislocation % (95% CI)	sHR (95% CI) - adjusted
Overall	1,678/376	22.4% (20.4-24.5)		2,190/248	11.3% (10.0-12.7)	
Age groups						
< 65 years	360/86	23.9% (19.6-28.6)	0.96 (0.74-1.26)	406/42	10.3% (7.6-13.7)	0.98 (0.68-1.41)
= 65 – 75 years	660/148	22.4% (19.3-25.8)	1 (reference)	777/83	10.7% (8.6-13.1)	1 (reference)
> 75 years	658/142	21.6% (18.5-24.9)	1.08 (0.86-1.37)	1,007/123	12.2% (10.3-14.4)	1.21 (0.91-1.61)
Sex						
= Male	691/162	23.4% (20.3-26.8)	1.00 (0.81-1.25)	1,003/106	10.6% (8.7-12.6)	0.96 (0.73-1.26)
= Female	987/214	21.7% (19.1-24.4)	1 (reference)	1,187/142	12.0% (10.2-13.9)	1 (reference)
CCI						
= 0	1,168/265	22.7% (20.3-25.2)	1 (reference)	1,647/179	10.9% (9.4-12.5)	1 (reference)
= 1 - 2	405/91	22.5% (18.5-26.9)	1.14 (0.89-1.46)	431/53	12.3% (9.3-15.8)	1.18 (0.87-1.61)
> 2	105/20	19.0% (12.0-27.9)	0.87 (0.55-1.38)	112/16	14.3% (8.4-22.2)	1.45 (0.85-2.48)
Head size at 1. Revision						
< 32 mm	613/151	24.6% (21.3-28.2)	1.21 (0.85-1.71)	773/96	12.4% (10.2-15.0)	1.18 (0.83-1.67)
= 32 mm	384/83	21.6% (17.6-26.1)	1.23 (0.86-1.76)	465/57	12.3% (9.4-15.6)	1.25 (0.86-1.82)
= 36 mm	286/53	18.5% (14.2-23.5)	1 (reference)	660/59	8.9% (6.9-11.4)	1 (reference)
> 36 mm	56/13	23.2% (13.0-36.4)	1.24 (0.66-2.33)	52/4	7.7% (2.1-18.5)	0.83 (0.29-2.38)
= Unknown	339/76	22.4% (18.1-27.2)	1.08 (0.73-1.60)	240/32	13.3% (9.3-18.3)	0.99 (0.62-1.60)
Liner type at 1. revision						
= Normal	632/161	25.5% (22.1-29.1)	1 (reference)	1,614/173	10.7% (9.3-12.3)	1 (reference)
= Constrained	520/67	12.9% (10.1-16.1)	0.36 (0.27-0.48)	52/2	3.8% (0.5-13.2)	0.31 (0.08-1.24)
= DMC	100/4	4.0% (1.1-9.9)	0.21 (0.08-0.58)	40/1	2.5% (0.1-13.2)	0.20 (0.03-1.47)
= Unknown	426/144	33.8% (29.3-38.5)	1.17 (0.90-1.51)	484/72	14.9% (11.8-18.4)	1.34 (0.97-1.86)
Extent of 1. revision						
= Total	92/15	16.3% (9.4-25.4)	1.15 (0.66-1.99)	655/48	7.3% (5.5-9.6)	0.49 (0.34-0.70)
= Acetabulum	699/100	14.3% (11.8-17.1)	1 (reference)	771/106	13.7% (11.4-16.4)	1 (reference)
= Femur	78/17	21.8% (13.2-32.6)	1.37 (0.80-2.35)	764/94	12.3% (10.1-14.8)	0.75 (0.54-1.04)
= Head/liner only	809/244	30.2% (27.0-33.5)	2.65 (2.05-3.42)			

“Risk factors for dislocation treated with closed reduction after revision due to either dislocation or aseptic loosening. Statistically significant differences are marked **bold**. sHR = sub-distribution hazard ratio; no. = number; CI = confidence interval.”

Table 2

Risk factors for re-revision	Revisions due to dislocation			Revisions due to aseptic loosening		
	Patients (no.) / re-revision (no.)	Risk of re-revision, % (95% CI)	sHR (95% CI) - adjusted	Patients (no.) / re-revision (no.)	Risk of re-revision, % (95% CI)	sHR (95% CI) - adjusted
Overall	1,678/332	19.8% (17.9-21.8)		2,190/355	16.2% (14.7-17.8)	
Age groups						
< 65 years	360/101	28.1% (23.5-33.0)	1.36 (1.05-1.77)	406/88	21.7% (17.8-26.0)	1.28 (0.98-1.68)
= 65 – 75 years	660/129	19.5% (16.6-22.8)	1 (reference)	777/133	17.1% (14.5-20.0)	1 (reference)
> 75 years	658/102	15.5% (12.8-18.5)	0.82 (0.63-1.08)	1,007/134	13.4% (11.3-15.6)	0.83 (0.65-1.06)
Sex						
= Male	691/142	20.5% (17.6-23.8)	0.99 (0.80-1.24)	1,003/168	16.7% (14.5-19.2)	1.04 (0.84-1.30)
= Female	987/190	19.3% (16.8-21.9)	1 (reference)	1,187/187	15.8% (13.7-18.0)	1 (reference)
CCI						
= 0	1,168/252	21.6% (19.2-24.0)	1 (reference)	1,647/275	16.7% (14.9-18.6)	1 (reference)
= 1 - 2	405/63	15.6% (12.2-19.5)	0.79 (0.60-1.05)	431/62	15.4% (11.2-18.1)	0.95 (0.72-1.25)
> 2	105/17	16.2% (9.7-24.7)	0.80 (0.48-1.33)	112/18	16.1% (9.8-24.2)	1.13 (0.69-1.86)
Head size at 1. Revision						
< 32 mm	613/132	21.4% (18.2-24.8)	1.02 (0.71-1.47)	773/153	19.8% (17.0-22.8)	1.23 (0.92-1.66)
= 32 mm	384/79	20.6% (16.6-25.0)	1.14 (0.79-1.64)	465/61	13.1% (10.2-16.5)	0.97 (0.70-1.37)
= 36 mm	286/49	17.1% (13.0-22.0)	1 (reference)	660/77	11.7% (9.3-14.4)	1 (reference)
> 36 mm	56/13	23.2% (13.0-36.4)	1.14 (0.60-2.14)	52/8	15.4% (6.9-28.1)	1.01 (0.50-2.05)
= Unknown	339/60	17.7% (13.8-22.2)	0.86 (0.57-1.29)	240/56	23.3% (18.1-29.2)	1.24 (0.86-1.79)
Liner type at 1. revision						
= Normal	632/125	19.8% (16.7-23.1)	1 (reference)	1,614/238	14.7% (13.1-16.6)	1 (reference)
= Constrained	520/89	17.1% (14.0-20.6)	0.86 (0.64-1.16)	52/7	17.1% (13.5-25.8)	0.96 (0.42-1.89)
= DMC	100/12	12.0% (6.4-20.0)	1.05 (0.56-1.94)	40/6	15.0% (5.7-29.8)	1.12 (0.48-2.64)
= Unknown	426/106	24.9% (20.8-29.3)	1.11 (0.84-1.48)	484/104	21.5% (17.9-25.4)	1.21 (0.93-1.57)
Extent of 1. revision						
= Total	92/18	19.6% (12.0-29.1)	1.37 (0.83-2.27)	655/79	12.1% (9.7-14.8)	0.58 (0.43-0.78)
= Acetabulum only	699/105	15.0% (12.5-17.9)	1 (reference)	771/149	19.3% (16.6-22.3)	1 (reference)
= Femur only	78/16	20.5% (12.2-31.2)	1.30 (0.74-2.28)	764/127	16.6% (14.1-19.5)	0.73 (0.55-0.97)
= Head/liner only	809/193	23.9% (21.0-26.9)	1.73 (1.34-2.23)			

“Risk factors for re-revision after revision due to either dislocation or aseptic loosening.

Statistically significant differences are marked **bold**. sHR = sub-distribution hazard ratio; no. = number; CI = confidence interval.”

9.6. DNPR codes used for identifying THA dislocation in Study II

a) A list of the diagnostic ICD-10 codes, which were applied for in the National Patient Registry data extraction to identify possible incorrectly coded dislocation cases:

DS33.3*	Dislocation of other and unspecified parts of lumbar spine and pelvis
DS70 – DS79*	Injuries to the hip and thigh
DT03.1 + DT03.3-DT03.9	Dislocations, sprains and strains involving multiple regions of lower limb(s)
DT09.2	Dislocation, sprain and strain of unspecified joint and ligament of trunk
DT12*-DT13*	Other injuries of lower limb, level unspecified
DT14.3	Dislocation, sprain and strain of unspecified body region
DT81.9	Unspecified complication of procedure
DT84.0* – DT85*	Complications of internal orthopaedic prosthetic devices, implants and grafts
DT88.9	Complication of surgical and medical care, unspecified
DT93*	Sequelae of injuries of lower limb
DT94*	Sequelae of injuries involving multiple and unspecified body regions
DT98.1-DT98.2	Sequelae of other and unspecified effects of external causes
DM15* – DM16* + DM19*	Polyarthrosis/Arthrosis of hip/Other arthrosis
DM24.3*	Pathological dislocation and subluxation of joint, not elsewhere classified
DM24.4A+B	Recurrent dislocation and subluxation of joint
DM24.9	Joint derangement, unspecified
DM25.2	Flail joint
DM25.3	Other instability of joint
DM25.5	Pain in joint
DM25.9	Joint disorder, unspecified
DM96.6* – DM96.9*	Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate/ Other postprocedural musculoskeletal disorders/ Postprocedural musculoskeletal disorder, unspecified
DZ03.9	Observation for suspected disease or condition, unspecified
DZ04.2* – DZ04.3*	Examination and observation following work accident/Examination and observation following other accident
DZ04.9*	Examination and observation for unspecified reason
DZ96.6* – DZ96.7*	Presence of orthopaedic joint implants/ Presence of other bone and tendon implants
DZ98.8	Other specified postsurgical states

(* = incl. sublevels)

b) A list of the procedural NCSP codes, which were applied for in the National Patient Registry data extraction to identify possible incorrectly coded dislocation cases:

KNFA0* – KNFG9*	Exploratory procedures on the hip and thigh/Primary insertions of joint prosthesis in the hip joint/Secondary insertion of joint prosthesis into the hip joint/Operations on joint capsule and ligaments in the hip joint/Operations on synovia and joint surfaces of the hip joint/Resections, arthroplasty and arthrodesis of the hip joint
KNFJ0* - KNFW9*	Fracture treatments in the femur/Bone operations on the femur/Operations on muscles and tendons in the hip and thigh/Operations on fascia, tendon sheaths, ganglia and bursae in the hip and thighs/Transplantations on hip and thighs/ Replantations on hip and thighs/Amputations and other related hip and thigh surgery/Surgery for hip and thigh tumors/Operations of tendon, joint and bone infections in the hip and thigh/Different hip and thigh surgery/Removal of implants and external fixation equipment from hip and thigh/ Reoperations after hip and thigh surgery
KNFH0* – KNFH9*	Different joint operations in the hip
KNE*	Operations on the pelvis
KTNF*	Minor surgical procedures on hip and thighs