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Patient-reported outcomes before and after total hip replacement: Are we getting better?

A registry-based study

Degree Project in Medicine

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Abstract

Total hip replacement (THR) is an effective treatment for severe degenerative hip joint disorders. During the last decades, THR-care processes have changed to optimize resource use. However, it has not been investigated if these changes may have had an impact on the patient-reported outcome measures (PROMs).

Preoperative and one-year postoperative data collected through the routine follow-up program of the Swedish Hip Arthroplasty Register between 2008 and 2015 were used for the analyses. The PROMs questionnaire comprises the EQ-5D, a visual analogue scale (VAS) on hip pain, and at follow-ups a VAS addressing satisfaction with the outcome of the THR. ANOVA trend analyses, multiple linear and logistic regression analyses were used to investigate the influence of year of surgery.

There were positive trends for all PROMs; improvement in hip pain VAS, and EQ-5D index, and satisfaction VAS. The estimated effect of years of surgery (2014-2015) was -1 unit (95% CI -1.4 - -0.7, p≤0.001) for hip pain, 0.01 (95% CI 0.004 – 0.013, p≤0.001) for EQ-5D index, and -1.7 (95% CI -2.1 - -1.3, p≤0.001) for satisfaction with years 2008-2009 set as reference. The odds ratio for improving in at least one EQ-5D dimension (without deteriorating in any other dimension) was higher during 2014-2015 compared to 2008-2009 (OR 1.07, 95% CI 1.02-1.13). The corresponding odds ratios for improvement in the pain dimension was 1.08 (95% CI 1.03 – 1.13, p=0.001). The odds ratio to worsen in self-care was 0.79 (95% CI 0.71 – 0.89, p≤0,001) and the odds ratio to worsen in usual activities was 0.85 (95% CI 0.78 – 0.93, p≤0.001).

The studied material found significant improvements to PROMs following THR in Sweden. This suggests that the last decade's changes in THR-care have been of value to patients.

Introduction

Symptomatic osteoarthritis of the hip is a common and often debilitating condition. [1] This condition is often managed by non-surgical methods but when deemed appropriate a total hip replacement (THR) can be used as treatment. [2]

To collect the data from the THR surgeries arthroplasty registries were founded. This gives the profession the opportunity to follow up on patients and study outcomes of the surgery. Outcomes include, but are not limited to, mortality and implant survival. The registries have been instrumental in following and proving the development and improvement of total hip replacement surgery regarding these clinical outcomes and implant survivorship analysis.

THR when performed as a treatment for osteoarthritis is done to improve health-related quality of life. To better reflect this patient-reported outcome measures (PROMs) were introduced to the arthroplasty registries. These PROM-questionnaires allow the patients themselves to rate their own health. The patients also rate their satisfaction with the surgery. [3]

During the last decade considerable changes have been made to the care process of THR-surgery often referred to as the "fast track surgery" concept. This concept involves optimizing patients' care including early mobilization of the patient, structured information, uniform discharge criteria, and better pain management. [4] These changes have proven to have no negative effect on readmissions or adverse events following THR. [5]

What we do not know is how these changes have affected the patients' perceived health state or their satisfaction with the procedure. A possible way to these would be to look at the PROMs over the last decade and compare them to each other.

Background

Hip replacement

Osteoarthritis (OA) of the hip is a common joint disease and affects up to 25% of the population of 85 years or older. [1] The causes for OA are multifactorial and the number of people requiring treatment are expected to rise because of an increased prevalence of risk factors. [6, 7] Symptomatic hip OA results in pain, disability, activity limitations and patients experience a decrease in health-related quality-of-life. [8, 9] If non-surgical intervention, like lifestyle changes and pain medication, does not adequately alleviate these symptoms total joint replacement is considered. [2]

Hip OA is a painful condition with adverse effects on the patients' quality of life but not a life threatening one. Because of this there are no absolute indications for THR. The patients' quality of life and possible improvement must be considered in each individual case. [9]

Outcome assessment

Traditionally outcome assessment of total hip replacement was surgeon-based. This assessment was done by assessing morbidity including the risk peri- and postoperative surgical complications such as bleeding, prosthetic joint infection, damage to anatomical structures, dislocation, anisomelia, and periprosthetic fracture and medical complications such as pneumonia, deep venous thrombosis, and pulmonary embolism. Other outcomes assessed

by the surgeon are biomechanical reconstruction, range of motion, implant survival, causes of revision, and mortality.

However, the elective nature of total hip replacement along with its goal of treating the symptoms of OA and restore functionality means that these assessments of whether the surgery was a success or not does not necessarily reflect the outcome for the patient.

There are no absolute indications for THR and the surgery is done to improve symptoms of OA. This means that the traditional outcomes might not reflect the patients' point of view. For example, would a patient with a successful implant but without improved symptoms consider the THR successful? [3, 10] To better measure the primary outcome for the patients PROMs were developed. Patients answer a survey about their own health-state which can then be used to gauge the success of the surgery.

Arthroplasty registries

Nationwide arthroplasty registries were developed in Sweden in the 1970s and has since been adopted and developed by numerous other countries. These registries collect information about the patients, the surgeries and the implants which is reported by the operating unit. [11, 12]

The registries are often run by the profession and funded by government agencies because of the powerful tools they provide to asses and evaluate arthroplasty and direct spending in the health care sector. Studies based on data from these registries provide valuable information not only because of them giving a means to evaluate real world application but because they

provided different revision rates compared to studies by financially conflicted authors. [11, 13]

The registries show that revision rates have decreased an implant survival has increased over the years. They have helped with spreading good surgical technique as well as implant choice by being able to compare internally at a unit as well as compare externally with other units. It has also proved that being conservative in using newly developed implants on a large scale could be detrimental to public health. Countries using well studied implants, over long term, have lower revision rates than those who implement newer implants without documentation for long- or mid-term status. [14, 15]

PROM-programme

PROMs were introduced in the Swedish Hip Arthroplasty Register in 2002. Patients are asked to fill in a short questionnaire with a set of questions about their condition, health-state and their satisfaction with their surgery. The questionnaires are answered pre-operatively and at one, six and ten years post-operatively. [16]

What improvements have been done in hip replacement during the last decades?

During the last decade “fast track surgery” was introduced as a concept in THR-care. In fast track surgery the clinical features are optimized in synergy with improved logistic to allow the patients to recover faster. To enable fast track surgery communication and cooperation with the patient is important as well as using well documented and efficient opioid sparing analgesia with glucocorticoids added to the pain regimen. This to enable and motivate the patient for early mobilization which is key to the fast track principle. The goal for patients and

caregivers alike is the fulfilment of functional discharge criteria allowing the patient a safe discharge. [4] The introduction of fast track surgery found no increase in readmission or adverse events. [5]

Between 1999 and 2012 the mean age of patients at the time of surgery has decreased, Body Mass Index (BMI) and comorbidities has increased. The PROMs were showing increased pain-reduction, improved general health and satisfaction with the surgery. During this time the length-of-stay at hospital was also decreased by 50%. [15]

During our literature review we found data supporting that fast track surgery did not have a negative effect traditional outcome measures as well as data hinting at improved PROMs. There were no studies investigating how the PROMs had changed over time while adjusting for confounders to find changes correlated to time. Have the changes in THR-care during the last decade had any impact on the PROMs?

Research question

How have patient-reported outcomes changed over time in the Swedish total hip replacement population?

Patients and Methods

Data sources

For his project, data from the Swedish Hip Arthroplasty Register's PROMs programme was used.

The PROMs questionnaire comprises the EQ-5D, a visual analogue scale (VAS) on hip pain and one on general health (EQ VAS), Charnley´s functional categories and at follow-ups a VAS addressing satisfaction with the outcome of the hip replacement.

The logistics of the questionnaire works as following. Pre-operatively the survey is done at the clinic and is either done by pen-and-paper or through an internet-based application. This system has been tested for validity and reliability internally and has advantages such as no missing values and decreased risk of systematic errors due to incorrect manual registration or illegible handwriting. At the one-, six- and ten-year follow ups the survey is mailed to the patient together with an instructive letter and an envelope with a stamped address to return the completed survey.

The registry has a system in place to notify the units on patients due to receive follow-up surveys to the participating clinics. Each clinic is responsible for checking the current address, sending out questionnaires and reminders and manually registering the data with the online database. After four weeks non-respondents receive a reminder to complete the survey. [16]

Patient selection

To better represent the population undergoing elective THR, those whose THR was a result of fractures or tumours, were excluded. Hip resurfacing was excluded to get better representation of THR.

Those missing the known confounders of American Society of Anesthesiologists (ASA)-score or BMI were excluded. Those with a BMI under 15 or over 50 as well as those with ASA-score 5 were excluded to limit the effect of errors in the input when registering the data.

Those deceased within the first year were excluded because they will not have any post-operative PROMS. Those re-operated on within the first year were also excluded to make sure that the answers for the post-operative PROMs were related only to the operation that was done one year before.

Finally, those missing either their pre-operative or their post-operative PROMs were excluded. The patients missing any or both of their pre- or post-operative PROMs were included in the non-respondent analysis. (See figure 1)

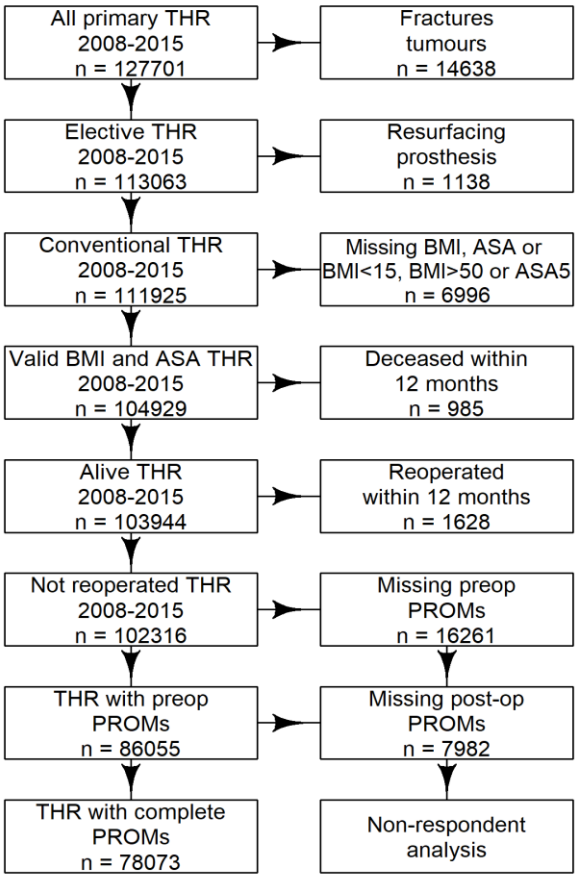


Figure 1. Patient selection flowchart

Variables

Outcome measures

In the EQ-5D patients rate their own health when it comes to mobility, self-care, usual activities, pain/discomfort, anxiety/depression. In this study these dimensions are rated on a scale of 1 to 3 where level 1 indicates no problem, level 2 indicates some problem and level 3 indicates extreme problems. These health states can be converted into a single number, the EQ-5D index by applying a formula that essentially attaches values (also called weights) to

each of the levels in each dimension. The index can be calculated by deducting the appropriate weights from 1, the value for full health (i.e. all five dimensions at level 1).

The pain VAS ranges from 0 (no pain) to 100 (worst pain imaginable) with a subscale of indicators and ordered response levels (0 to 20, no or slight pain; 20 to 40, mild pain; 40 to 60, moderate pain; 60 to 80, severe pain; 80 to 100, unbearable pain), the health state VAS (EQ-VAS) ranges from 0 (worst imaginable) to 100 (best imaginable).. The satisfaction with the outcome of the hip surgery VAS ranges from 0 (satisfied) to 100 (dissatisfied) with a subscale of indicators and ordered response levels (0 to 20, very satisfied; 20 to 40, satisfied; 40 to 60, uncertain; 60 to 80, not satisfied; 80 to 100, dissatisfied).

Other variables

Charnley´s functional categories are assessed through two questions in the PROMs questionnaire: 1) Do you have any symptoms from the other hip? and 2) Do you have problems walking because of other reasons (e.g., pain from other joints, back pain, angina, or any other medical condition impairing your walking capacity)? Category A comprises patients with unilateral hip disease, category B, patients with bilateral hip disease and category C, patients with multiple joint diseases or other major medical conditions impairing walking capacity.

Sex, age, date of surgery, ASA-score, height and weight of the patient which are recalculated into BMI, diagnosis group, uni- or bilateral hip replacement, type of fixation and type of hospital is reported by the reporting unit.

The date of surgery is categorized by the year of surgery for the trend analyses and for the regression analyses the years are grouped in pairs (2008-2009, 2010-2011, 2012-2013 and 2014-2015).

ASA-score ranges from 1 to 5 where 1 is healthy, 2 is mild systemic disease, 3 is severe systemic disease, 4 is severe systemic disease with a constant threat to life and 5 is a moribund person who is not expected to survive without the operation. [17]

BMI is calculated from weight and height and is used categorically as BMI groups in the statistical methods in this study. These are underweight (BMI < 18,5), normal (BMI 18,5 - <25), pre-obese (BMI 25 - <30), obese I (BMI 30 - <35), obese II (BMI 35 - <40) and obese III (BMI ≥ 40). [18]

The different diagnosis groups registered to the patients in this study are femoral head necrosis, inflammatory joint disease, other, primary osteoarthritis, secondary osteoarthritis and sequelae to childhood hip disease. Type of fixation is categorized as cemented, uncemented, hybrid and reverse hybrid. Type of hospital is reported as county, private, rural or university. The unit also reports if the total hip replacement is done as a bilateral one-stage or two-stage surgery or if it is a unilateral operation and if it is the first or second hip.

Statistical methods

Descriptive statistics were calculated as frequencies and percentages for categorical variables and as means and standard deviations for continuous variables. Between groups comparisons of proportions were tested using chi square and means with students t-test.

The relationships between year of surgery and the post-operative outcomes were assessed with multivariable regression using the post-operative outcome parameters of the pain VAS, EQ VAS, satisfaction VAS and EQ-5D-index as dependent variables and age, gender, Charnley category, ASA-score, BMI group, year of surgery and the corresponding pre-operative parameter as independent variables.

The EQ-5D were run as logistical regression analyses using the Paretian Classification of Health Change (PCHC) as dependent variable and age, gender, Charnley category, ASA-score, BMI group and year of surgery as covariates. In PCHC the differences between the pro-operatively and post-operatively answers in the EQ-5D are calculated on every dimension finding both the patients who have improved in each dimension as well as the patients who have worsened in each dimension. This is then calculated on all the EQ-5D dimension together finding the patients who have only improved in one dimension or more and not worsened in any, as well as the patients who have worsened in one dimension or more and not improved in any. [19] SPSS and R was used for the statistical analyses.

Trend analysis

One-way ANOVA with post hoc test was done on the pre- and post-operative hip pain VAS, EQ VAS and EQ-5D index, the differences between these as well as on the post-operative satisfaction VAS to determine if the trends are statistically significant.

Non-respondent analysis

Non-respondent analysis was done using chi-square and t-test on the patient demography to see if there has been any significant change in the demography of the non-respondents.

Ethics

This study is part of a larger research project that has been approved by etikprövningsmyndigheten in Gothenburg. Dnr 271-14.

All data used for this projected were collected by the Swedish Hip Arthroplasty Register. Registration in National Quality Registers does not require written informed consent. However, patients are informed about being registered and may actively opt-out. The information that comes with the questionnaire explains that patients' responses will be used for quality improvement work and research.

The ethical considerations relate to the handling of patient data and privacy issues. We have made the judgement that the benefits of understanding how PROMs have changed over time by far exceeds the eventual integrity harm the handling of patient data means.

Results

Demography and descriptive data

Table 1 shows statistically significant demographic differences in the population between the different years. A total of 78073 patients were included in the study, of those 33177 (42.5%) were male and 44896 (57.5%) were female. Most variables remain similar over the years, one change of note is that THRs with uncemented fixations have increased at the cost of cemented fixations.

Table 1. Patient Demography						
Variable	Level	Overall	2008-2009	2010-2011	2012-2013	2014-2015
Number		78073	17478	20054	20501	20040
Sex (%)	Male	33177 (42.5)	7294 (41.7)	8431 (42.0)	8767 (42.8)	8685 (43.3)
	Female	44896 (57.5)	10184 (58.3)	11623 (58.0)	11734 (57.2)	11355 (56.7)
Age (mean (sd))		68.26 (10.07)	68.27 (9.91)	68.05 (10.19)	68.38 (9.96)	68.33 (10.19
ASA (%)	1	19767 (25.3)	4621 (26.4)	5208 (26.0)	5085 (24.8)	4853 (24.2)
	2	47113 (60.3)	10543 (60.3)	12032 (60)	12393 (60.5)	12145 (60.6)
	3	10963 (14.0)	2269 (13.0)	2763 (13.8)	2951 (14.4)	2980 (14.9)
	4	230 (0.3)	45 (0.3)	51 (0.3)	72 (0.4)	62 (0.3)
BMI (mean (sd))		27.26 (4.36)	27.17 (4.38)	27.24 (4.38)	27.32 (4.37)	27.3 (4.33)
BMI Group (%)	Underweight	527 (0.7)	128 (0.7)	144 (0.7)	130 (0.6)	125 (0.6)
	Normal	24629 (31.5)	5671 (32.4)	6266 (31.2)	6417 (31.3)	6275 (31.3)
	Preobese	34141 (43.7)	7577 (43.4)	8810 (43.9)	9014 (44.0)	8740 (43.6)
	Obese I	14487 (18.6)	3184 (18.2)	3740 (18.6)	3774 (18.4)	3789 (18.9)
	Obese II	3596 (4.6)	752 (4.3)	907 (4.5)	973 (4.7)	964 (4.8)
	Obese III	693 (0.9)	166 (0.9)	187 (0.9)	193 (0.9)	147 (0.7)
Diagnosis (%)	Femoral head necrosis	1434 (1.8)	264 (1.5)	348 (1.7)	418 (2.0)	404 (2.0)
	Inflammatory joint disease	1024 (1.3)	295 (1.7)	294 (1.5)	224 (1.1)	211 (1.1)
	Other	43 (0.1)	7 (0.0)	19 (0.1)	10 (0.0)	7 (0.0)
	Primary OA	72417 (92.8)	16202 (92.7)	18485 (92.2)	18999 (92.7)	18731 (93.5)
	Secondary OA	1603 (2.1)	382 (2.2)	486 (2.4)	393 (1.9)	342 (1.7)
	Sequele childhood hip disease	1552 (2.0)	328 (1.9)	422 (2.1)	457 (2.2)	345 (1.7)
Uni- or bilateral	Bilateral one-stage	774 (1.0)	205 (1.2)	210 (1.0)	193 (0.9)	166 (0.8)
Surgery (%)	Bilateral two-stage	18735 (24.0)	4211 (24.1)	5045 (25.2)	5072 (24.7)	4407 (22.0)
	Unilateral first	49547 (63.5)	10076 (57.6)	12238 (61.0)	13205 (64.4)	14028 (70)
	Unilateral second	9017 (11.5)	2986 (17.1)	2561 (12.8)	2031 (9.9)	1439 (7.2)
Type of fixation (%)	Cemented	52086 (66.7)	12576 (72)	13804 (68.8)	13344 (65.1)	12362 (61.7)
	Hybrid	1753 (2.2)	214 (1.2)	311 (1.6)	464 (2.3)	764 (3.8)
	Uncemented	14163 (18.1)	2647 (15.1)	3258 (16.2)	3713 (18.1)	4545 (22.7)
	Reverse hybrid	10071 (12.9)	2041 (11.7)	2681 (13.4)	2980 (14.5)	2369 (11.8)
Type of hospital (%)	County	31248 (40.0)	7655 (43.8)	8222 (41.0)	7848 (38.3)	7523 (37.5)
	Private	16009 (20.5)	2922 (16.7))	3954 (19.7)	4475 (21.8)	4658 (23.2)
	Rural	25219 (32.3)	5796 (33.2)	6332 (31.6)	6751 (32.9)	6340 (31.6)
	University	5597 (7.2)	1105 (6.3)	1546 (7.7)	1427 (7.0)	1519 (7.6)

Table 2 shows the results for the pre-operative PROMs. We can see many similarities between the different years but patients in Charnley class A have increased.

Table 2. Pre-operative variables						
Variable	level	Overall	2008-2009	2010-2011	2012-2013	2014-2015
EQ5D3L index (mean (sd))		0.42 (0.31)	0.41 (0.32)	0.42 (0.31)	0.42 (0.31)	0.41 (0.31)
EQ mobility (%)	1	6133 (7.9)	1274 (7.3)	1595 (8.0)	1656 (8.1)	1608 (8.0)
	2	71699 (91.8)	16132 (92.3)	18402 (91.8)	18790 (91.7)	18375 (91.7)
	3	241 (0.3)	72 (0.4)	57 (0.3)	55 (0.3)	57 (0.3)
EQ selfcare (%)	1	60453 (77.4)	13469 (77.1)	15558 (77.6)	15961 (77.9)	15465 (77.2)
	2	16933 (21.7)	3849 (22.0)	4324 (21.6)	4357 (21.3)	4403 (22.0)
	3	687 (0.9)	160 (0.9)	172 (0.9)	183 (0.9)	172 (0.9)
EQ usual activity (%)	1	30545 (39.1)	6706 (38.4)	8000 (39.9)	8203 (40.0)	7636 (38.1)
	2	39781 (51.0)	8870 (50.7)	10071 (50.2)	10312 (50.3)	10528 (52.5)
	3	7747 (9.9)	1902 (10.9)	1983 (9.9)	1986 (9.7)	1876 (9.4)
EQ pain (%)	1	1178 (1.5)	258 (1.5)	352 (1.8)	285 (1.4)	283 (1.4)
	2	44374 (56.8)	9913 (56.7)	11569 (57.7)	11693 (57.0)	11199 (55.9)
	3	32521 (41.7)	7307 (41.8)	8133 (40.6)	8523 (41.6)	8558 (42.7)
EQ anxiety (%)	1	46170 (59.1)	10294 (58.9)	11861 (59.1)	12160 (59.3)	11855 (59.2)
	2	29325 (37.6)	6572 (37.6)	7511 (37.5)	7663 (37.4)	7579 (37.8)
	3	2578 (3.3)	612 (3.5)	682 (3.4)	678 (3.3)	606 (3.0)
EQ VAS (mean (sd))		56.08 (22.33)	53.92 (22.39)	54.35 (22.11)	57.65 (22.17)	58.08 (22.35)
Hip pain VAS (mean (sd))		62.89 (15.72)	62.19 (16.17)	62.37 (15.93)	63.29 (15.56)	63.63 (15.21)
Charnley (%)	A	37733 (48.3)	8115 (46.4)	9536 (47.6)	9992 (48.7)	10090 (50.3)
	B	9308 (11.9)	2043 (11.7)	2444 (12.2)	2484 (12.1)	2337 (11.7)
	C	31032 (39.7)	7320 (41.9)	8074 (40.3)	8025 (39.1)	7613 (38.0)

Table 3 shows the results for post-operative PROMs.

Table 3. Post-operative variables						
Variable	level	Overall	2008-2009	2010-2011	2012-2013	2014-2015
EQ5D3Lindex 1 year (mean (sd))		0.79 (0.23)	0.78 (0.24)	0.79 (0.24)	0.79 (0.23)	0.79 (0.23)
EQ mobility 1 year (%)	1	47491 (60.8)	10460 (59.8)	12170 (60.7)	12529 (61.7)	12332 (61.5)
	2	30493 (39.1)	7001 (40.1)	7858 (39.2)	7949 (38.8)	7685 (38.3)
	3	89 (0.1)	17 (0.1)	26 (0.1)	23 (0.1)	23 (0.1)
EQ selfcare 1 year (%)	1	72403 (92.7)	16070 (91.9)	18542 (92.5)	19080 (93.1)	18711 (93.4)
	2	5259 (6.7)	1308 (7.5)	1401 (7.0)	1322 (6.4)	1228 (6.1)
	3	411 (0.5)	100 (0.6)	111 (0.6)	99 (0.5)	101 (0.5)
EQ usual activity 1 year (%)	1	60725 (77.8)	13413 (76.7)	15542 (77.5)	16032 (78.2)	15738 (78.5)
	2	15882 (20.3)	3701 (21.2)	4144 (20.7)	4097 (20.0)	3940 (19.7)
	3	1466 (1.9)	364 (2.1)	368 (1.8)	372 (1.8)	362 (1.8)
EQ pain 1 year (%)	1	35044 (44.9)	7650 (43.8)	8851 (44.1)	9293 (45.3)	9259 (46.2)
	2	39431 (50.5)	9001 (51.5)	10266 (51.2)	10290 (50.2)	9874 (49.3)
	3	3598 (4.6)	827 (4.7)	937 (4.7)	918 (4.5)	916 (4.6)
EQ anxiety 1 year (%)	1	61396 (78.6)	13691 (78.3)	15658 (78.1)	16163 (78.8)	15884 (79.3)
	2	15546 (19.9)	3530 (20.2)	4091 (20.4)	4036 (19.7)	3889 (19.4)
	3	1131 (1.4)	257 (1.5)	305 (1.5)	302 (1.5)	267 (1.3)
EQ VAS 1 year (mean (sd))		76.67 (20.03)	76.20 (20.	76.46 (20.12)	76.95 (19.96)	76.99 (20.01)
Hip pain VAS 1 year (mean (sd))		13.20 (17.63)	13.63 (17.8)	13.54 (17.87)	13.0 (17.54)	12.67 (17.31)
Satisfaction VAS 1 year (mean (sd))		15.14 (20.21)	15.96 (20.53)	15.86 (20.88)	14.71 (19.91)	14.14 (19.5)

Table 4 demonstrates the results of the statistical analysis of variance calculated on the study population's patient demography.

Table 4. Statistical analysis of variance

Variable	p-value
Sex	0.006
Age	0.007
ASA	<0.001
BMI	0.006
BMI Group	0.37
Diagnosis	<0.001
Uni- or bilateral surgery	<0.001
Type of fixation	<0.001
Type of hospital	<0.001

Trends over time

The data gathered from the PROMs show that the mean pain reported by patients have increased from 62.1 (SD 16.1) to 63.9 (SD 15.1) pre-operatively and decreased from 13.9 (SD 18.0) to 12.7 (SD 17.5) post-operatively. The difference between pre- and post-op has increased from 48.3 (SD 22.6) to 51.2 (SD 21.7) (Figures 2, 3 and 4).

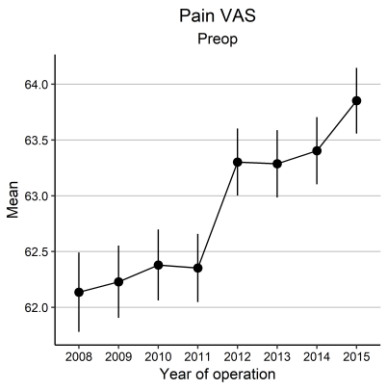


Figure 1. Pre-operative hip pain

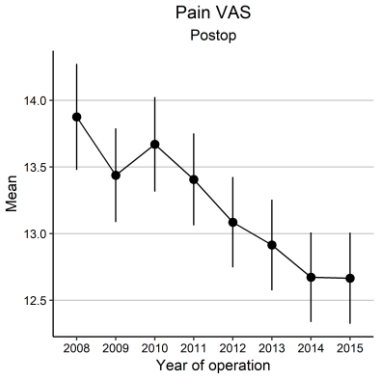


Figure 3. Post-operative hip pain

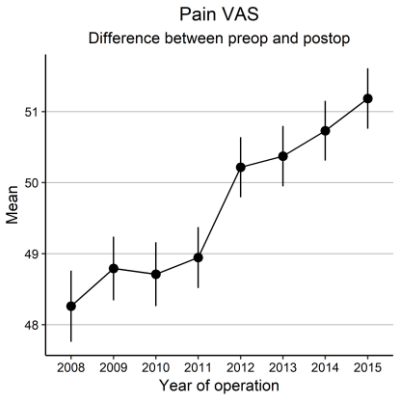


Figure 4. Difference between pre- and post-operative hip pain

The mean for the EQ VAS shows that the health reported by patients has increased from 53.8 (SD 2.5) to 58.0 (SD 22.5) pre-operatively and from 76.2 (SD 20.1) to 77.2 (SD 20.0) post-operatively. The difference between pre- and post-op has decreased from 22.4 (SD 26.7) to 19.2 (SD 25.9) (Figures 5, 6 and 7).

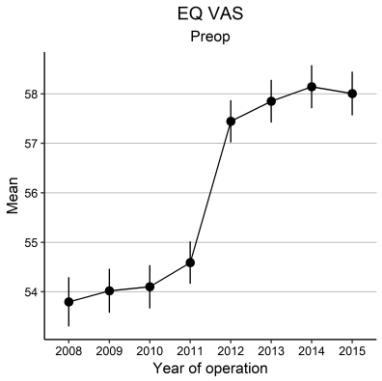


Figure 5. Pre-operative EQ VAS

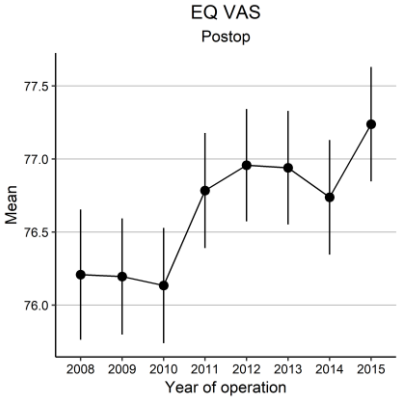


Figure 6. Post-operative EQ VAS

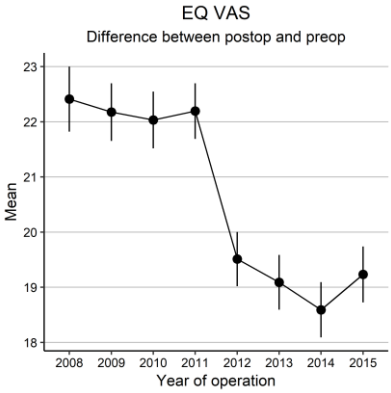


Figure 7. Difference between pre- and post-operative EQ VAS

The mean for EQ5D index has not had a clear trend towards increasing or decreasing pre-operatively but has increased post-operatively. It changed from 0.412 (SD 0.316) to 0.409 (SD 0.314) pre-operatively and from 0.782 (SD 0.237) to 0.797 (SD 0.233) post-operatively. The difference between

post- and pro-operative EQ-5D index has trended towards increasing and has changed from 0.371 (0.342) to 0.389 (SD 0.344) (Figures 8, 9 and 10).

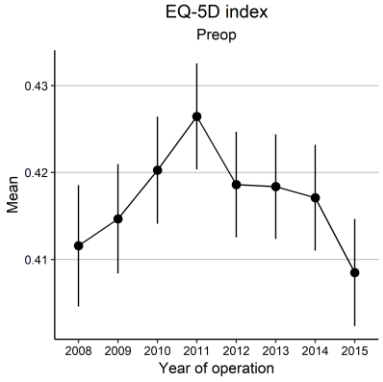


Figure 8. Pre-operative EQ-5D index

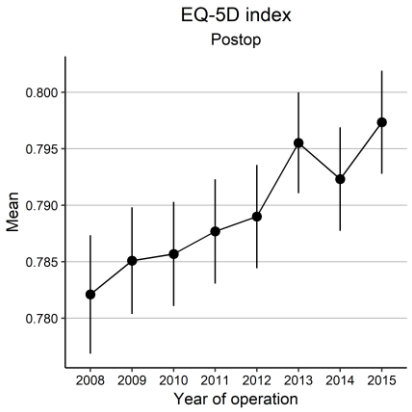


Figure 9. Post-operative EQ-5D index

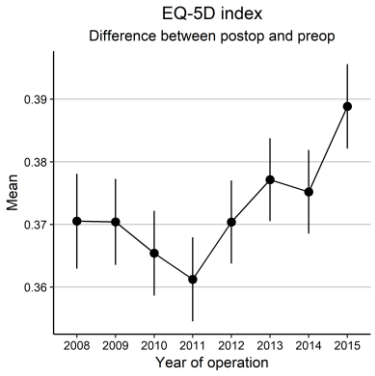


Figure 10. Difference between pre- and post-operative EQ-5D index

The mean for the satisfaction VAS has decreased from 16.1 (20.7) to 13.9 (SD 19.4) (Figure 11).

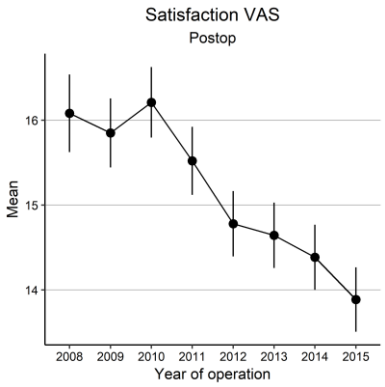


Figure 11. Satisfaction VAS

ANOVA trend analysis with post hoc test show that all trends except for pre-operative EQ5 index are significant ($p \leq 0.05$).

Multiple regression analyses

Linear regression using the post-operative outcome parameters of the pain VAS (figure 12), satisfaction VAS (figure 13), EQ-5D-index (figure 14) and EQ VAS (figure 15) and logistical regression for the Paretian Classification of Health Change for EQ-5D (figure 16-27).

Linear

The regression for the hip pain VAS shows a decrease in hip pain with -1.01 (95% CI -1.36 - -0.66, $p \leq 0.001$) when comparing 2014-2015 to the reference 2008-2009 (Figure 12).

The satisfaction VAS has decreased with -1.70 (95% CI -2.10 - -1.29, $p \leq 0.001$) when comparing 2014-2015 to the reference 2008-2009 (Figure 13).

Figure 12. Forest plot of linear regression on hip pain VAS

Figure 13. Forest plot of linear regression on satisfaction VAS

The EQ-5D index increased with 0.009 (95% CI 0.004 – 0.013, p ≤ 0.001) when comparing 2014-2015 to the reference 2008-2009 (Figure 14).

The EQ VAS showed no statistical change between 2008-2009 and 2014-2015. The beta coefficient is -0.10 (95% CI -0.26 – 0.49, p = 0.611) (Figure 15).

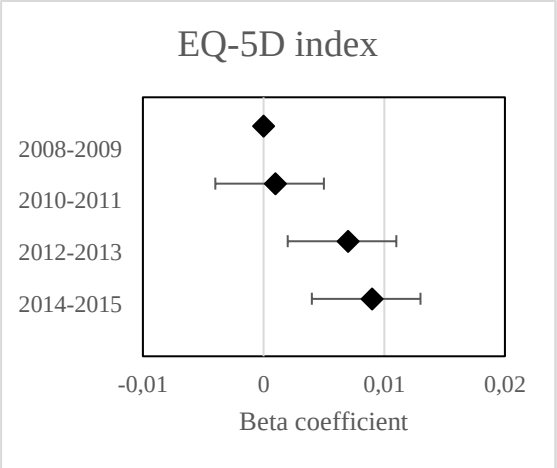


Figure 14. Forest plot of linear regression on EQ-5D index

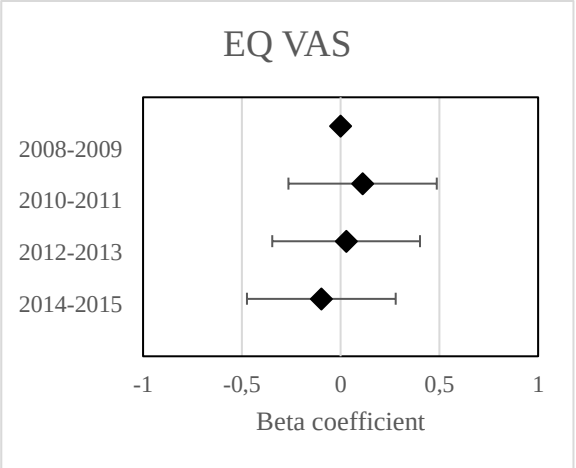


Figure 15. Forest plot of linear regression on EQ VAS

Logistic

Investigating the five dimensions and the Paretian classification using logistic regression we can see that the odds ratio for improving in at least one dimension and not getting worse in any has increased to 1.07 (95% CI 1.02 – 1.13, p = 0.005) comparing 2014-2015 to 2008-2009 (Figure 16).

The odds ratio for improving in pain increased to 1.08 (95% CI 1.03 – 1.13, p = 0.001) when comparing 2014-2015 to 2008-2009 (Figure 17).

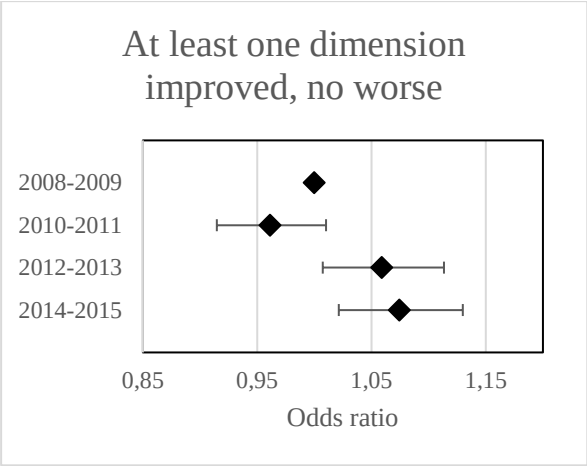


Figure 16. Forest plot of logistical regression on improved EQ-5D

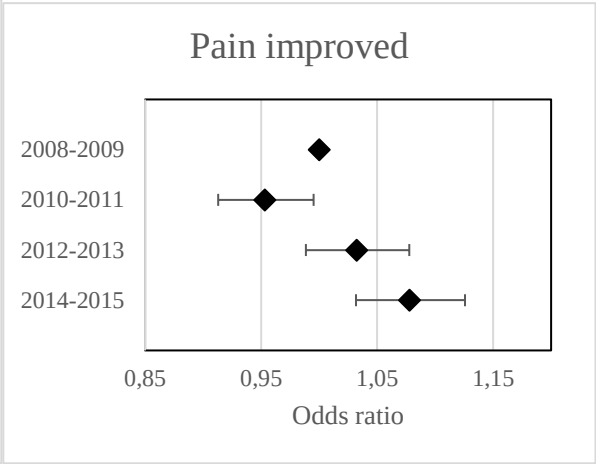


Figure 17. Forest plot of logistical regression on improved pain dimension

The odds ratio for improving mobility remains unchanged at 1.03 (95% CI 0.98 – 1.07, p = 0.243) when comparing 2014-2015 to 2008-2009 (Figure 18).

The odds ratio for improving in self-care remains unchanged at 1.03 (95% CI 0.98 – 1.09, p = 0.209) (Figure 19).

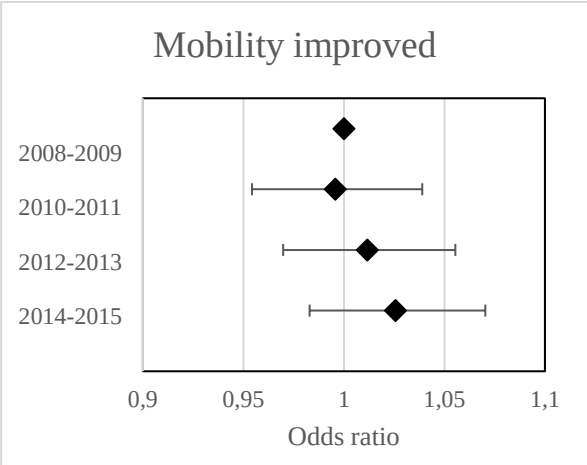


Figure 18. Forest plot of logistical regression on improved mobility dimension

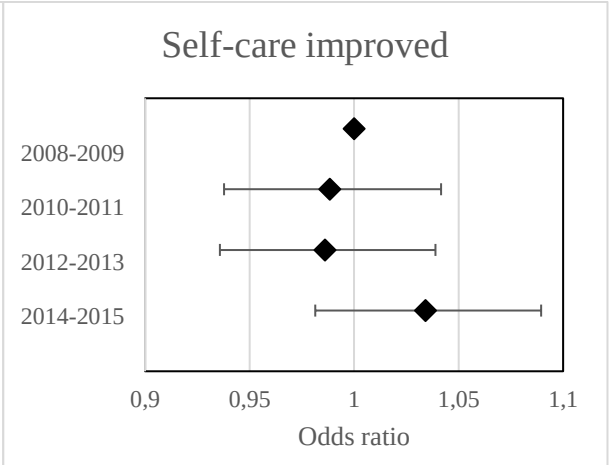


Figure 19. Forest plot of logistical regression on improved self-care dimension

The odds ratio for improving in usual activity remains unchanged at 1.02 (95% CI 0.98 – 1.06, p = 0.371) (Figure 20).

The odds ratio for improving anxiety remains unchanged at 1.03 (95% CI 0.97 – 1.08, p = 0.176) (Figure 21).

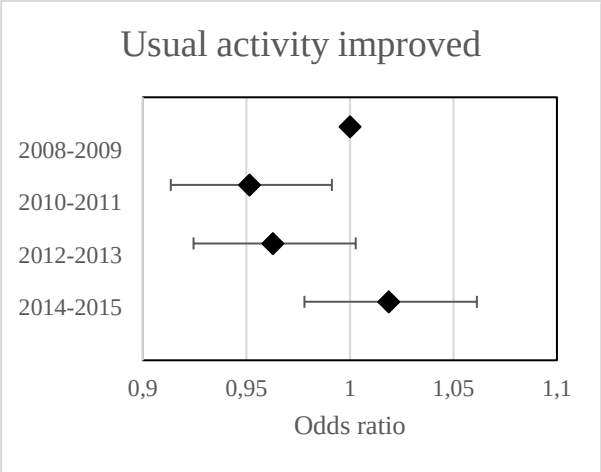


Figure 20. Forest plot of logistical regression on improved usual activity dimension

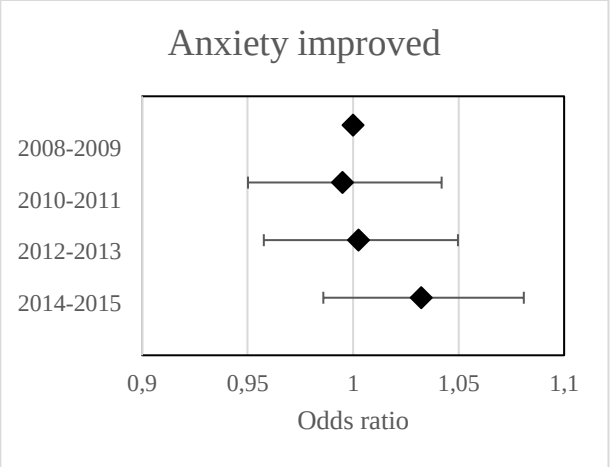


Figure 21. Forest plot of logistical regression on improved anxiety dimension

The odds ratio to worsen in at least one dimension and improve in none remains unchanged at 0.99 (95% CI 0.91 – 1.08, p = 0.787) (Figure 22).

The odds ratio to worsen in pain remains unchanged at 0.98 (95% CI 0.84 – 1.14, p = 0.795) (Figure 23).

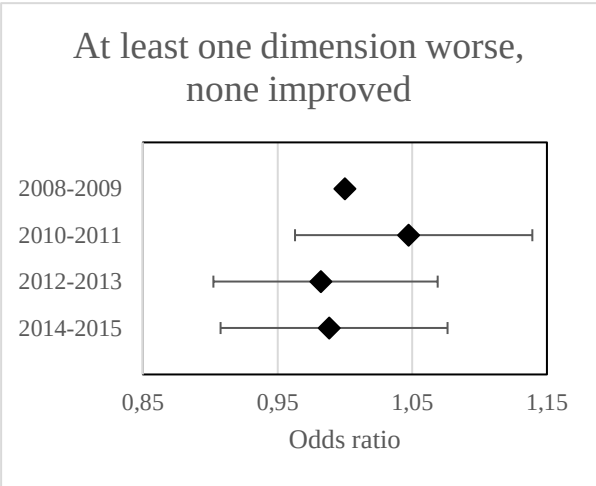


Figure 22. Forest plot of logistical regression on worsened EQ-5D

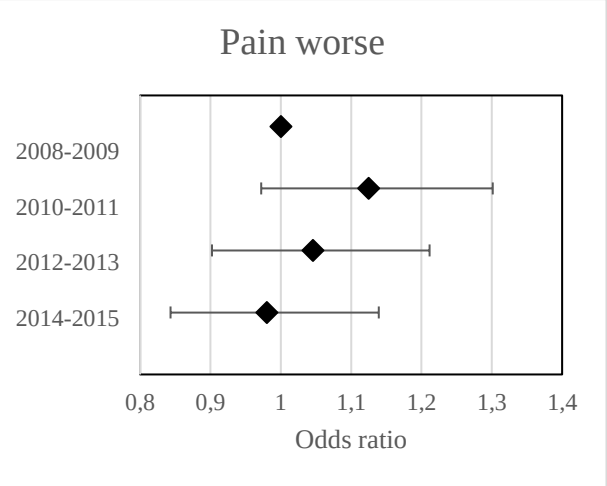
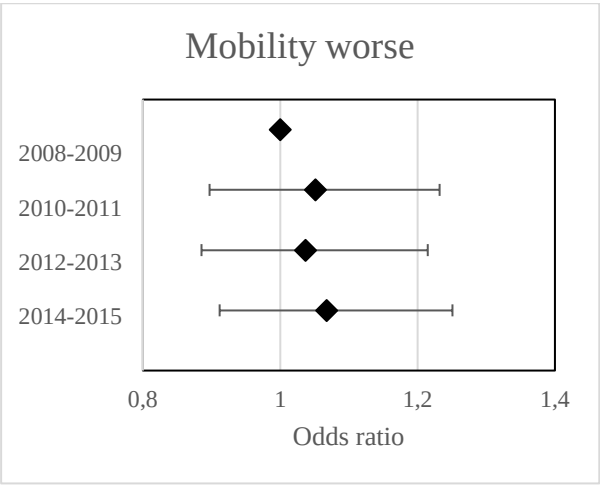


Figure 23. Forest plot of logistical regression on worsened pain dimension

The odds ratio to worsen in mobility has remained unchanged at 1.07 (95% CI 0.91 – 1.25, p = 0.416) (Figure 24).

The odds ratio to worsen I self-care has decreased to 0.79 (95% CI 0.71 – 0.89, $p \leq 0.001$) when comparing 2014-2015 to 2008-2009 (Figure 25).



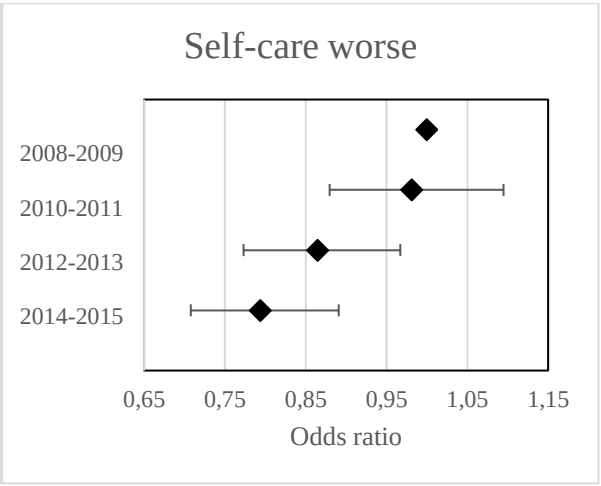
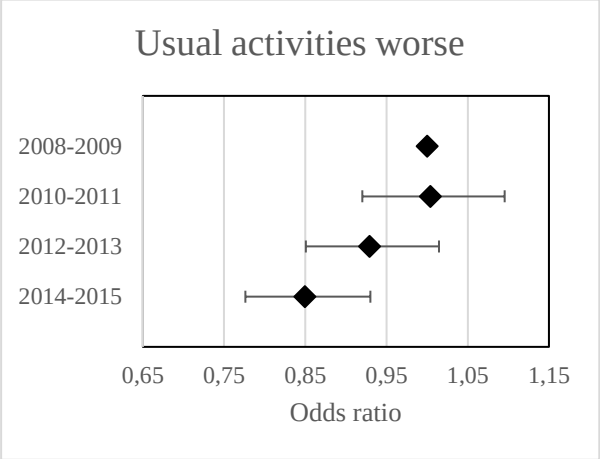


Figure 24. Forest plot of logistical regression on worsened mobility

Figure 25. Forest plot of logistical regression on worsened self-care dimension

The odds ratio to worsen in usual activities has decreased to 0.85 (95% CI 0.78 – 0.93, $p \leq 0.001$) when comparing 2014-2015 to 2008-2009 (Figure 26).

The odds ratio to worsen in anxiety remains unchanged at 1.00 (95% CI 0.92 – 1.09, $p = 0.999$) (Figure 27).



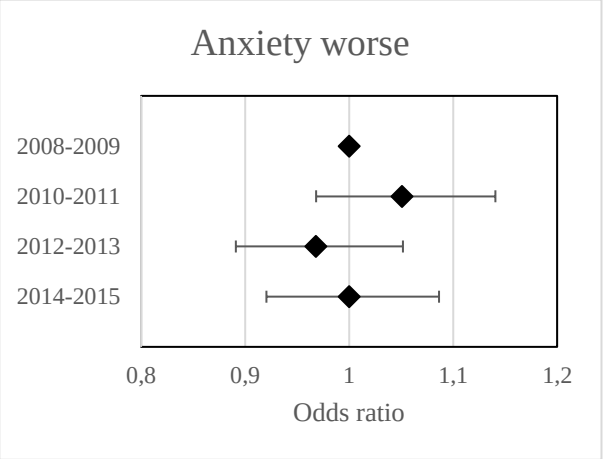


Figure 26. Forest plot of logistical regression on worsened usual activity dimension

Figure 27. Forest plot of logistical regression on worsened anxiety dimension

Non-respondent analysis

Statistically significant differences between the demographics of the different years could be found in all variables except for gender and age. There are two categories with more notable differences than the others. The first is ASA where the ASA 1 group has decreased in size in favour of ASA 2 and 3. The second is diagnosis where the number of patients diagnosed with secondary osteoarthritis decreased substantially (Table 4).

Table 5. Non-respondent demography

Variable	Level	Overall	2008-2009	2010-2011	2012-2013	2014-2015
Number		24243	4966	5674	6071	7532
Sex (%)	Male	10237 (42.2)	2062 (41.5)	2373 (41.8)	2543 (41.9)	3259 (43.3)
	Female	14006 (57.8)	2904 (58.5)	3301 (58.2)	3528 (58.1)	4273 (56.7)
Age (mean (sd))		67.06 (11.85)	67.03 (11.84)	66.94 (12.00)	67.14 (11.74)	67.11 (11.84)
ASA (%)	1	5468 (22.6)	1254 (25.3)	1274 (22.5)	1352 (22.3)	1588 (21.1)
	2	13977 (57.7)	2730 (55.0)	3302 (58.2)	3522 (58.0)	4423 (58.7)
	3	4656 (19.2)	956 (19.3)	1055 (18.6)	1166 (19.2)	1479 (19.6)
	4	142 (0.6)	26 (0.6)	43 (0.8)	31 (0.5)	42 (0.6)
BMI (mean (sd))		27.33 (4.63)	27.16 (4.63)	27.27 (4.69)	27.45 (4.66)	27.37 (4.56)
BMI Group (%)	Underweight	280 (1.2)	62 (1.2)	68 (1.2)	60 (1.0)	90 (1.2)
	Normal	7655 (31.6)	1613 (32.5)	1865 (32.9)	1870 (30.8)	2307 (30.6)
	Preobese	10105 (41.7)	2122 (42.7)	2305 (40.6)	2509 (41.3)	3169 (42.1)
	Obese I	4634 (19.1)	864 (17.4)	1076 (19.0)	1222 (20.1)	1472 (19.5)
	Obese II	1297 (5.3)	240 (4.8)	280 (4.9)	345 (5.7)	432 (5.7)
	Obese III	272 (1.1)	65 (1.3)	80 (1.4)	65 (1.1)	62 (0.8)
Diagnosis (%)	Femoral head necrosis	805 (3.3)	126 (2.5)	173 (3.0)	207 (3.4)	299 (4.0)
	Inflammatory joint disease	439 (1.8)	127 (2.6)	115 (2.0)	105 (1.7)	92 (1.2)
	Other	173 (0.8)	23 (0.4)	43 (0.7)	43 (0.7)	64 (0.8)
	Primary OA	20881 (86.1)	4021 (81.0)	4832 (85.2)	5367 (88.4)	6661 (88.4)
	Secondary OA	1298 (5.4)	523 (10.5)	355 (6.3)	188 (3.1)	232 (3.1)
	Sequele childhood hip disease	647 (2.7)	146 (2.9)	156 (2.7)	161 (2.7)	184 (2.4)
Uni- or bilateral surgery (%)	Bilateral one-stage	491 (2.0)	110 (2.2)	157 (2.8)	118 (1.9)	106 (1.4)
	Bilateral two-stage	6208 (25.6)	1247 (25.1)	1514 (26.7)	1631 (26.9)	1816 (24.1)
	Unilateral first	14784 (61.0)	2754 (55.5)	3273 (57.7)	3711 (61.1)	5046 (67.0)
	Unilateral second (first not included)	2760 (11.4)	855 (17.2)	730 (12.9)	611 (10.1)	564 (7.5)
Type of Fixation (%)	Cemented	14647 (60.4)	3185 (64.1)	3530 (62.2)	3763 (62.0)	4169 (55.4)
	Hybrid	567 (2.3)	108 (2.2)	98 (1.7)	128 (2.1)	233 (3.1)
	Uncemented	5384 (22.2)	1018 (20.5)	1173 (20.7)	1305 (21.5)	1888 (25.1)
	Reverse hybrid	3645 (15.0)	655 (13.2)	873 (15.4)	875 (14.4)	1242 (16.5)
Type of Hospital (%)	County	8757 (36.1)	1764 (35.5)	1996 (35.2)	2242 (36.9)	2755 (36.6)
	Private	5184 (21.4)	901 (18.1)	1132 (20.0)	1317 (21.7)	1834 (24.3)
	Rural	7555 (31.2)	1729 (34.8)	1895 (33.4)	1911 (31.5)	2020 (26.8)
	University	2747 (11.3)	572 (11.5)	651 (11.5)	601 (9.9)	923 (12.3)

Tale 6 demonstrates the results of the statistical analysis of variance calculated on the non-respondent patient demography.

Table 6. Statistical analysis of variance

Variable	p-value
Sex	0.17
Age	0.785
ASA	<0.001
BMI	0.006
BMI Group	<0.001
Diagnosis	<0.001

Uni- or bilateral surgery	<0.001
Type of fixation	<0.001
Type of hospital	<0.001

Discussion

Summary of study findings

The patient-reported outcomes have improved between 2008 and 2015. Patient-reported pain post-operatively has decreased, patient-reported general health has improved, satisfaction reported by patients has improved and the EQ5D index has improved post-operatively.

After adjusting for the known confounders of the patients' age, sex, Charnley category, ASA-score and BMI, time dependent improvement (2008-2009 to 2014-2015) in patient-reported hip pain and satisfaction were estimate at 1.0 and 1.7 units on a 100-degree scale, respectively, and for EQ-5D index at 0.01 units on a scale from 0 to 1.

In the analysis of the Paretian classification of the five dimension we could see changes in the chance of improving in pain, the risk of worsening in self-care and usual activities as well as the chance of improving in at least one dimension and not getting worse in any. The chance of improving in pain had increased by 8% in 2014-2015 when compared to 2008-2009. The risk of getting worse in self-care and usual activities had decreased by 21% and 15% respectively by 2014-2015 when compared to 2008-2009. The chance of improving in at least one dimension and not getting worse in any had increased by 7% by 2014-2015 when compared to 2008-2009.

No statistical significance could be found in the patient-reported general health (EQ VAS) after adjusting for confounders.

Findings in the context of previous research

This study confirms previous findings from the Swedish Hip Arthroplasty Register (SHAR) which also showed an improvement in the PROMs over time. [15] The material in this study extends the timeline of the aforementioned study and shows that the PROMs continue to improve, this even after adjusting for confounders. This suggests that the improvements found in PROMs over time are real improvements and not caused only by changes in patient demography.

Another study on the Swedish Hip Arthroplasty Register shows that the introduction did not adversely affect surgical outcomes of THR. [5] The data from this study suggest that this is true for PROMs as well.

Limitations

Differences between non-respondent demographics is a weakness of this study. While small these differences over time are still to be considered when looking at the results of this study. Notable differences are a higher proportion of secondary OA in 2008-2009 and 2010-2011 and a decrease in ASA 1 over time.

There are possibly more unknown confounders that could have an impact on the outcome measures than those adjusted for. Knowledge of such factors could improve the quality of this studies results to better reflect the true change over time.

Another point of note is that with the large study population of this study small differences in the PROMs can be statistically significant while being of low clinical relevance. However small changes in a large population could still prove to be clinically relevant. For example, the mean difference between pre- and post-operative hip pain VAS lies between 48.3 and 51.2 and the regression show that the years of surgery affects this by -1, this corresponds to 2% of the improvement caused by years of surgery. In the same way 2% of the improvements in EQ-5D index can also be explained to be caused by years of surgery.

Interpretation

The literature review found studies related to how different factors affect the PROMs [20-22] but none that studied how PROMs have changed over time.

The hip pain VAS, satisfaction VAS and the EQ-5D index have all improved significantly when adjusted for confounders. Using Paretian classification on the five dimensions of EQ-5D we could see that the odds ratio to improve in pain as well as the odds ratio to improve in at least one dimension and not get worse in any had increased. The odds ratio to worsen in usual activities and self-care had decreased.

While we cannot be certain that these improvements are a result of the changes in health care in Sweden these improvements remain after adjusting for the confounders and is correlated to the year of surgery. We can speculate that the cause are the changes made to the organization and care of patients during the last decades. What we can say is that the PROMs improve over time even with adjustments for several patient-related factors.

To improve the accuracy of the results further studies could investigate other patient-factors' relation to PROMs. Similar studies as this could investigate how factors such as type of fixation or type of hospital impacts the PROMs. Adding the PROMs six years after surgery would be a next step to understand how the long-term PROMs change over time.

Clinical significance

Decisions about how to best deliver health-care should be based on what adds value to the patient. Sweden's tradition of quality registers has been proposed to be an effective path to stimulate clinical improvement work, to implement best clinical practice, and to adhere to evidence-based methods. This study demonstrates a significant trend of improvement in patient-reported outcomes in Sweden.

This suggests that the changes made to the care of THR patients have been beneficial to the patients, or at the very least not detrimental, and that the trend possibly could continue.

Populärvetenskaplig sammanfattning på svenska:

Patientrapporterade utfall före och efter höftprotesoperation:

Blir vi bättre?

Höftproteskirurgi genomförs som behandling för svåra degenerativa tillstånd i höftleden genom att man byter ut leden mot en konstgjord led. Dessa patienter har en påverkad hälsorelaterad livskvalitet och kan ha svåra smärtor, svårt att röra sig och svårt att klara sina dagliga aktiviteter utan hjälp.

För att följa patientgruppen som helhet och på sätt kunna arbeta för att utveckla och utvärdera arbetet kring höftproteskirurgi så finns Svenska höftprotesregistret som samlar ihop data om patienterna, operationen samt uppföljning vid senar tillfällen. De utfallsmått man samlar in data om handlar om kirurgiska och medicinska komplikationer till ingreppet och sen finns det även utfallsmått där patienten själv rapporterar in om sitt hälsotillstånd, smärta, funktion och hur nöjd man är med operationen. Formuläret kallas för EQ-5D 3L och det ingår även fem dimensioner där man graderar sig i smärta/obehag, självständighet, vardagliga aktiviteter, ångest/depression och rörlighet.

Det senaste decenniet har man infört så kallad ”Fast-track”-kirurgi i höftproteskirurgi i Sverige. Detta handlar om att optimera patientens behandling, förbättra logistiken kring patienten och använda sig av utskrivningskriterier kopplat till funktion för att göra patienten utskrivningsklar tidigare efter operation.

I denna studien undersöker vi hur de patientrapporterade utfallsmåtten har förändrats mellan 2008 och 2015 för att se hur detta kan ha påverkat patientens utfall.

Inkluderade i studien är de som har kompletta svar till de patientrapporterade utfallsmåtten pre- och postoperativt ett år efter operationen. Förändringen i dessa över tid undersöktes med trendanalys samt att dessa justerades efter störfaktorer för att estimera hur mycket av förändringen som kan kopplas till operationssåret.

I studien fann vi positiva trender i de patientrapporterade utfallsmåtten. Efter att störfaktorer justerats för så kunde vi se att ca 2% av förbättringen i höftsmärta kan förklaras av operationssåret. Man kunde även se att patienterna blev mer nöjda med operationen vid senare operationssår. Förbättringen i allmän hälsa kunde inte kopplas till operationssåret.

Chansen att förbättras i minst en av dimensionerna i EQ-5D utan att försämras i någon hade en ökning med 7% som kunde kopplas till operationssår. På samma sätt ökade chansen för att förbättras i smärta med 8% samt att risken för att bli sämre i självständighet och vardagliga aktiviteter minskat med 21% respektive 15%.

Den här studien fann signifikanta förbättringar i de patientrapporterade utfallsmåtten i Svenska höftprotesregistret mellan 2008 och 2015. Detta tyder på att förändringarna som gjorts i höftproteskirurgins omhändertagande av patienter inte har påverkat patienterna negativt utan snarare varit dem till gagn.

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References

1. Murphy, L.B., et al., *One in four people may develop symptomatic hip osteoarthritis in his or her lifetime.* Osteoarthritis Cartilage, 2010. **18**(11): p. 1372-9.
2. Sinusas, K., *Osteoarthritis: diagnosis and treatment.* Am Fam Physician, 2012. **85**(1): p. 49-56.
3. Learmonth, I.D., C. Young, and C. Rorabeck, *The operation of the century: total hip replacement.* Lancet, 2007. **370**(9597): p. 1508-19.
4. Husted, H., *Fast-track hip and knee arthroplasty: clinical and organizational aspects.* Acta Orthop Suppl, 2012. **83**(346): p. 1-39.
5. Berg, U., et al., *No increase in readmissions or adverse events after implementation of fast-track program in total hip and knee replacement at 8 Swedish hospitals: An*

observational before-and-after study of 14,148 total joint replacements 2011-2015. Acta Orthop, 2018. **89**(5): p. 522-527.
6. Johnson, V.L. and D.J. Hunter, *The epidemiology of osteoarthritis.* Best Pract Res Clin Rheumatol, 2014. **28**(1): p. 5-15.
7. Palazzo, C., et al., *Risk factors and burden of osteoarthritis.* Ann Phys Rehabil Med, 2016. **59**(3): p. 134-138.
8. Quintana, J.M., et al., *Prevalence of knee and hip osteoarthritis and the appropriateness of joint replacement in an older population.* Arch Intern Med, 2008. **168**(14): p. 1576-84.
9. Quintana, J.M., et al., *Health-related quality of life and appropriateness of knee or hip joint replacement.* Arch Intern Med, 2006. **166**(2): p. 220-6.
10. Varnum, C., *Outcomes of different bearings in total hip arthroplasty - implant survival, revision causes, and patient-reported outcome.* Dan Med J, 2017. **64**(3).
11. Hughes, R.E., A. Batra, and B.R. Hallstrom, *Arthroplasty registries around the world: valuable sources of hip implant revision risk data.* Curr Rev Musculoskelet Med, 2017. **10**(2): p. 240-252.
12. Karrholm, J., *The Swedish Hip Arthroplasty Register (www.shpr.se).* Acta Orthop, 2010. **81**(1): p. 3-4.
13. Labek, G., et al., *Impact of implant developers on published outcome and reproducibility of cohort-based clinical studies in arthroplasty.* J Bone Joint Surg Am, 2011. **93 Suppl 3**: p. 55-61.
14. Herberts, P. and H. Malchau, *Long-term registration has improved the quality of hip replacement: a review of the Swedish THR Register comparing 160,000 cases.* Acta Orthop Scand, 2000. **71**(2): p. 111-21.
15. Cnudde, P., et al., *Trends in hip replacements between 1999 and 2012 in Sweden.* J Orthop Res, 2018. **36**(1): p. 432-442.
16. Rolfson, O., et al., *Patient-reported outcomes in the Swedish Hip Arthroplasty Register: results of a nationwide prospective observational study.* J Bone Joint Surg Br, 2011. **93**(7): p. 867-75.
17. Committee, A.H.o.D.E. *ASA Physical Status Classification System*. Expert Consensus Documents [Webpage] 2014 10-15 [cited 2019 04-03]; Available from: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system.
18. Organization, W.H. *Body mass index - BMI*. Health topics [Webpage] [cited 2019 04-03]; Available from: http://www.euro.who.int/en/health-topics/disease-prevention/nutrition/a-healthy-lifestyle/body-mass-index-bmi.
19. Devlin, N.J., D. Parkin, and J. Browne, *Patient-reported outcome measures in the NHS: new methods for analysing and reporting EQ-5D data.* Health Econ, 2010. **19**(8): p. 886-905.
20. Krupic, F., et al., *Poor patient-reported outcome after hip replacement, related to poor perception of perioperative information, commoner in immigrants than in non-immigrants.* Acta Orthop, 2016. **87**(3): p. 218-24.
21. Lindgren, J.V., et al., *Patient-reported outcome is influenced by surgical approach in total hip replacement: a study of the Swedish Hip Arthroplasty Register including 42,233 patients.* Bone Joint J, 2014. **96-b**(5): p. 590-6.

22. Rolfson, O., et al., *Patient-reported outcomes in cemented and uncemented total hip replacements.* Hip Int, 2016. **26**(5): p. 451-457.