Author: Hofstede, S.N.
Title: Optimization of care in orthopaedics and neurosurgery
Issue Date: 2016-09-14

Chapter 10

The influence of preoperative variables on health related quality of life, functioning and pain after total knee and hip replacement in patients with osteoarthritis: pooled analysis of existing cohorts in the Netherlands

Stefanie N Hofstede, Maaike GJ Gademan, Theo Stijnen, Rob GHH Nelissen, Perla J Marang- van de Mheen for the ARGON-OPTIMA study group

Submitted

ABSTRACT

Background

Several studies have shown contradicting results preoperative variables that predict health related quality of life (QoL), functioning and pain after total knee or hip arthroplasty (TKA/THA) possibly due to lack of power and not adjusting for confounders. The present study aims to study the independent effect of these variables on postoperative QoL, functioning and pain.

Methods

We pooled individual patient data (n=1783 TKA and n=2400 THA) from 19 cohorts with osteoarthritis (OA) patients in the Netherlands. We examined the influence of age, gender, BMI and preoperative values of QoL, functioning and pain on postoperative status and total improvement. Linear mixed models were used to estimate the effect of each preoperative variable on a particular outcome for each cohort separately. These effects were pooled across cohorts using a random effects model.

Results

For each preoperative point in QoL, the postoperative QoL increased by 0.51 points in TKA and 0.37 points in THA. Similarly, each point in preoperative functioning, resulted in a higher postoperative functioning of 0.31 (TKA) and 0.21 (THA) points on the KOOS/HOOS-ADL scale. For pain this was 0.18 (TKA) and 0.15 (THA) points higher on the KOOS/HOOS-pain scale (higher means less pain). Even though patients with better preoperative values achieved better postoperative outcomes, their improvement was smaller. Both gender and BMI influenced pain after a TKA and THA. Age and BMI influenced QoL, function and pain after a THA.

Conclusion

Patients with a better preoperative QoL, functioning and pain have better outcomes, but also less improvement. Even though the independent effects may seem small, combined results of preoperative variables may result in larger effects on postoperative outcomes. This information may help orthopaedic surgeons to estimate how much a patient and will allow them to counsel patients about the possible outcomes of a joint replacement may improve if surgery is done now versus alternative scenarios.

INTRODUCTION

Total knee or hip arthroplasty (TKA/THA) is an effective treatment for most individuals who suffer from pain and loss of function due to end stage symptomatic hip osteoarthritis (OA). In 2010, 109 and 153 patients per 100,000 persons received a TKA or THA respectively in Europe [1]. The development and progression of OA is strongly influence by age and obesity and more common in women. Parallel to the rising prevalence of knee and hip OA, due to an ageing society and obesity, surgery rates are rising as well [2-4].

TKA and THA should not be given too early since revision rates are higher in younger patients and the length of life of a prosthesis is limited [5]. On the other hand performing a surgery earlier gives more years of productive quality-adjusted life years (QALY's). However, outcomes after revision surgery are generally worse compared to primary surgery. Current practice shows that preoperative disease severity varies largely among centers and countries [6,7], suggesting differences in timing. In addition, about 10-20% of the patients is not satisfied after primary TKA/THA [8-11], possibly caused by unmet expectations of patients due to suboptimal timing of surgery.

Previous research has identified preoperative variables that influence outcomes, but these differed between studies and had opposite directions. This may be due to lack of power so that some studies did not find any effect, while other studies did not adjust for confounders. Pooling the data from available cohort studies may provide more reliable evidence on which variables influence the outcome after TKA/THA because of the larger sample size.

Therefore, the present study aims to study the independent effect of several preoperative variables for outcomes after TKA or THA by pooling individual patient data from available prospective cohorts in the Netherlands.

MATERIALS AND METHODS

The ARGON-OPTIMA (Outcome Predictors for TIMing of ArthropLasty) study is part of the ARGON program (Arthritis Research Group Orthopaedics in The Netherlands). Within this study, we pooled individual patient data from all available prospective TKA/THA cohorts in the Netherlands. All orthopaedic clinics in The Netherlands were invited to participate and submit data. We included prospective studies among patients with primary OA who underwent TKA or THA, with at least one preoperative and one postoperative measurement on functional or clinical outcomes and a follow-up of at least one year. Studies regarding metal-on-metal (MoM) prostheses were excluded, since these are not recommended in current guidelines in The Netherlands.

The assessed preoperative variables were age, gender and BMI, since these were collected in each of the included cohorts. Only few cohorts had data on smoking, degree of radiological osteoarthritis, and comorbidities. Furthermore, we examined the influence of preoperative health related quality of life (QoL), functioning and pain. We studied the effect on the absolute level of the postoperative outcome, but also on the extent of improvement to assess which patients would benefit most from change in a preoperative variable.

Since different cohorts used different questionnaires, these were standardized to compare the same domains across different questionnaires. Furthermore, multiple questionnaires were sometimes used to measure the same domain within a cohort. As each patient should be included only once for each domain, we ordered questionnaires in their ability to measure each outcome reliably, determined by a group of experts within the ARGON consortium. Only the highest rated questionnaire in each dataset was included. The following ordering was used:

Health related quality of life: 1. Physical component summary scale of the SF-36/RAND-36 (36 items), 2. Physical component summary scale of the SF-12 (12 items), 3. EQ-5D (5 items)

Functioning: 1. HOOS/ KOOS subscale ADL (17 items), 2. WOMAC subscale Physical Function (17 items), 3. HOOS-PS/KOOS-PS (5 items) 4. OHS subscale function (6 items)/ OKS subscale function (5 items) according to Harris et al. [12,13]

Pain: 1. HOOS/ KOOS subscale Pain (10 items), 2. WOMAC subscale Pain (5 items), 3. OHS subscale Pain (6 items)/ OKS subscale Pain (7 items) according to Harris et al. [12,13], VAS pain scale

Standardization was performed according to (functioning as example):

Standardized Functioning score (at each time point) =

$$\frac{\text{(functioning score (at each time point) - preoperative mean of functioning)}}{\text{preoperative SD of functioning}}$$

Some questionnaires differed in the direction of the scale e.g. on the VAS pain scale, lower scores mean less pain whereas lower scores mean more pain on the HOOS/ KOOS subscale pain. The direction of all scales were recoded so that higher scores referred to better values).

Statistical analysis

Data of TKA and THA were analyzed separately. As a first step, linear mixed models (LMM) were used to estimate the influence of each preoperative variable on each major outcome for each cohort separately, adjusted for the other variables. As determinants were included in the fixed part of the LMM: the standardized preoperative score (QoL, functioning and pain), age, sex, BMI and follow-up time. Interaction terms were fitted between the variables and follow-up time. In the LMM the patients were specified as the subjects, with an unstructured covariance matrix. This was done for each standardized postoperative outcome. In the second step, the regression coefficients from all cohorts were pooled using a random effects model to obtain one pooled estimate for each preoperative variable and outcome. Given the pooled estimates of the impact of preoperative status on postoperative status, we can also determine the total improvement (postoperative minus the preoperative status). If patients would have the same amount of improvement, 1 point higher in preoperative status would result in a postoperative status of 1 point higher. So if the increase in postoperative status is < 1 (e.g. 0.4), this means that the improvement is 0.6 points smaller for every point increase in preoperative status.

Given that preoperative scores were standardized, the pooled regression coefficient should be interpreted as the number of standard deviations that an outcome will change, per point increase in the preoperative variable. For example looking at the effect of age on postoperative functioning with a standardized regression coefficient of 0.2 and the preoperative SD of functioning is 7, this means that one year increase in age is estimated to increase the postoperative functioning by: 0.2*7. To facilitate interpretation of the pooled standardized regression coefficients of age, BMI and gender, we transformed standardized regression coefficients back to a 0-100 scale (e.g. HOOS, SF-36), using the preoperative standard deviation (SD) of the most representative study. In addition, we will illustrate the potential size of the effects by describing scenarios.

SPSS 20 was used to perform the LLM and Stata 11.1 for the meta-analyses. A p-value of 0.05 was considered significant in all analyses.

Assessment of heterogeneity

The I2 statistic was used to test for heterogeneity between cohorts. This can be interpreted as the percentage of total variability in a set of effect sizes due to between-studies variability. We considered results as heterogeneous when I2 was 50% or greater [14].

Ethical approval

The Medical Ethical Committee of the Leiden University Medical Center (CME P15.043/

SH/sh) confirmed that ethical approval for this type of study is not required under Dutch law."

Source of funding

This research project is supported by a grant (ARGON) from The Dutch Arthritis Foundation (project number BP 12-3-401). The funder had no role in the investigation.

RESULTS

Twenty hospitals submitted data and 19 cohorts from 11 hospitals were included. Of these, 8 cohorts included 1783 knee OA patients undergoing primary TKA and 11 cohorts included 2400 hip OA patients undergoing primary THA. Table 1 shows the characteristics of patients per cohort. Table 2 shows the pooled estimates of the effect of age, gender and BMI on outcomes as well as the transformed values. Most effects were small and homogeneous. For TKA, only gender and BMI were significantly associated with pain. Women had more pain postoperatively than men (3.92 points lower on a 0-100 scale, where 100 is no pain). An increase in BMI with one point, resulted in more postoperative pain (0.47 points on a 0-100 scale). For THA, age and BMI were significantly associated with QoL, functioning and pain. One year increase in age decreased postoperative functioning by 0.33 point on a 0-100 scale. Furthermore, females perceived more pain postoperatively (2 points on a 0-100 scale).

Health related quality of life

Four studies examined the effect of preoperative QoL on postoperative QoL in 760 patients after TKA. Eight studies examined this effect in 1436 patients with a THA (figure 1). A significant positive effect of preoperative QoL was found of 0.51 (95% CI 0.32 to 0.71) for patients after TKA and 0.37 (95% CI 0.21 to 0.53) after THA. This means that a patient with 1 point higher preoperative QoL on average achieves a 0.51 point (TKA) and 0.37 point (THA) higher postoperative QoL on the SF-36 scale. At the same time, if patients with a 1 point higher preoperative QoL reach a 0.51 point higher postoperative QoL after TKA, this also means that their improvement is 0.49 (0.51-1) points less. For THA this implies 0.63 (0.37-1) points less improvement postoperative. The results were heterogeneous, meaning that included studies differed with respect to the estimated effect for either TKA or THA.

Functioning

Six studies examined the effect of preoperative functioning on postoperative functioning in 1021 patients with a TKA and 10 studies examined this effect in 1271 patients with a

Table 1. Description of included TKA and THA databases

Arthroplasty	Study	n	Females (%)	Age mean (SD)	BMI mean (SD)	Follow-up
TKA	1	340	228 (67)	68.9 (9.3)	29.3 (7.6)	2 weeks, 3 months, 2-7 years
TKA	2	382	271 (71)	67.0 (9.7)	29.5 (4.7)	1 year
TKA	3	45	20 (44)	67.8 (6.5)	29.3 (5.1)	3, 6, 12 months
TKA	4	101	66 (65)	68.9 (9.1)	30.9 (5.1)	6 weeks, 6, 12 months, 5 years
TKA	5	496	274 (55)	65.9 (7.9)	27.6 (3.5)	6, 12, 24 months
TKA	6	169	120 (71)	69.8 (9.9)	29.2 (4.7)	6 weeks, 3 months, 1 year
TKA	7	41	22 (54)	62.2 (9.5)	32.0 (5.4)	3, 6 months, 4 years
TKA	8	209	127 (61)	66.4 (10.2)	29.7 (6.4)	6 weeks, 3, 6, 12 months
THA	1	498	319 (64)	65.7 (10.8)	26.9 (4.0)	2 weeks, 3 months, 2-7 years
THA	2	149	106 (71)	60.4 (6.9)	26.8 (4.2)	6 weeks, 3, 6, 12, 24 months
THA	3	398	247 (62)	66.6 (10.2)	27.2 (4.5)	1 year
THA	4	55	32 (58)	67.7 (9.7)	27.3 (3.6)	3, 6, 12 months
THA	5	73	46 (63)	65.2 (6.7)	28.0 (4.6)	6 weeks, 3, 6, 12, 24, 60 months
THA	6	26	18 (69)	62.9 (5.0)	24.5 (2.9)	6 weeks, 3, 6, 12 months
THA	7	354	228 (64)	65.9 (7.9)	26.4 (3.4)	3, 12 months
THA	8	100	58 (58)	68.7 (10.0)	28.2 (4.0)	6 weeks, 3, 12 months
THA	9	287	188 (66)	67.5 (10.6)	26.6 (4.1)	6 weeks, 3, 12 months
THA	10	73	46 (63)	66.7 (12.0)	26.5 (4.2)	3, 6, 12 months
THA	11	33	22 (67)	63.0 (11.9)	26.6 (4.3)	3, 6, 48 months
THA	12	354	257 (73)	69.0 (10.9)	28.2 (4.5)	6, 12, 24 months

THA (figure 2). We found a significant positive effect of 0.31 (95% CI 0.23 to 0.39) for TKA and 0.21 (95% CI 0.16 to 0.26) for THA. This means that a patient with a 1 point higher preoperative functioning on average achieves a 0.31 points higher postoperative functioning on the KOOS scale (TKA) and 0.21 points of the HOOS scale (THA). At the same time this means that these patients have a 0.69 and 0.79 point less improvement for TKA and THA respectively for every 1 point higher on preoperative functioning. The results were homogeneous meaning that the estimated effects did not differ between studies.

Table 2. The influence of patients characteristics on postoperative outcomes after TKA and THA

Arthroplasty	Patients characteristic	Outcome	Studies (n)	Patients (n)	Standardized regression coefficients (95% CI)	Transformed regression coefficient (0-100 scale)	I^2 (%)
TKA	Age	QoL	4	774	0.00 (-0.00, 0.01)	0.00	0.0
TKA	Age	Functioning	6	1021	-0.01 (-0.01, 0.00)	-0.18	0.0
TKA	Age	Pain	6	1102	0.01 (-0.00, 0.02)	0.16	47.0
TKA	Gender (women)	QoL	4	774	-0.05 (-0.23, 0.13)	-0.38	0.0
TKA	Gender (women)	Functioning	6	1021	-0.24 (-0.50, 0.01)	-4.12	53.6
TKA	Gender (women)	Pain	6	1102	-0.25 (-0.50, -0.01)	-3.92	50.5
TKA	BMI	QoL	4	774	-0.02 (-0.06, 0.02)	-0.23	76.1
TKA	BMI	Functioning	6	1021	-0.01 (-0.05, 0.02)	-0.18	62.5
TKA	BMI	Pain	6	1102	-0.03 (-0.05, -0.01)	-0.47	13.1
THA	Age	QoL	8	1436	-0.01 (-0.02, -0.01)	-0.08	0.0
THA	Age	Functioning	10	1271	-0.02 (-0.02, -0.01)	-0.33	0.0
THA	Age	Pain	10	1492	-0.01 (-0.01, -0.00)	-0.18	0.0
THA	Gender (women)	QoL	8	1436	-0.10 (-0.22, 0.01)	-0.78	0.0
THA	Gender (women)	Functioning	10	1271	-0.11 (-0.22, 0.01)	-1.95	10.9
THA	Gender (women)	Pain	10	1492	-0.11 (-0.21, -0.00)	-2.00	0.0
THA	BMI	QoL	8	1436	-0.03 (-0.04, -0.01)	-0.23	0.0
THA	BMI	Functioning	10	1271	-0.02 (-0.04, -0.01)	-0.35	0.0
THA	BMI	Pain	10	1492	-0.02 (-0.03, -0.00)	-0.36	0.0

Pain

Six studies examined the effect of preoperative pain on postoperative pain in 1102 TKA patients and 11 studies examined this effect in 1492 THA patients (figure 3). We found that every point increase in preoperative pain (i.e. less pain) was associated with 0.18 (95% CI 0.11 to 0.26) point increase in postoperative pain after a TKA and 0.15 (95% CI 0.08 to 0.21) after a THA. This also means that patients with less preoperative pain improve 0.82 points less after TKA and 0.85 points less after THA. The results were homogeneous meaning that the estimated effects did not differ between studies.

Combined results

Even though the independent effect of one variable may be small, the combined effect of different variables may result in clinically relevant differences. Table 3 shows some hypothetical scenarios in which several variables are combined. The first scenario is that a patient first loses some weight and reduces the BMI with 5 points to improve the

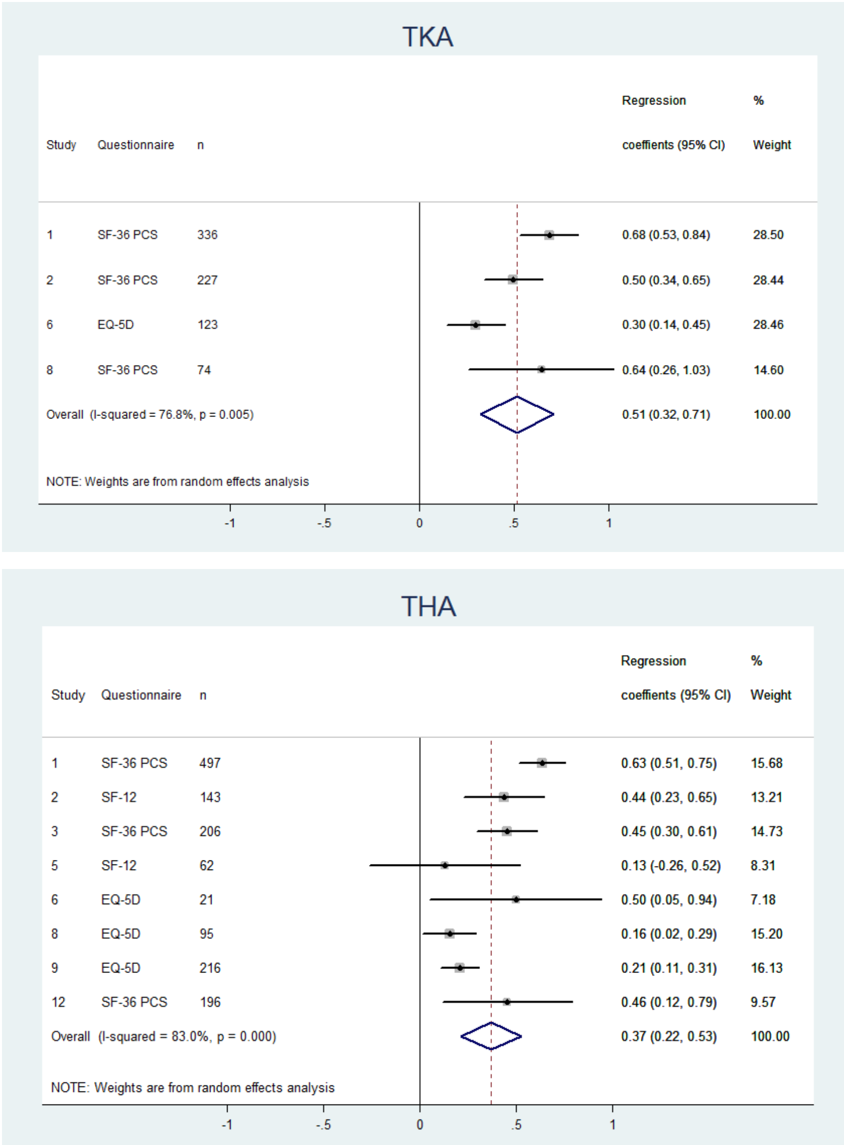

Figure 1. Forest plots - The influence of preoperative QoL on postoperative QoL after TKA (a) and THA (b)

postoperative functioning after THA. This takes some time (e.g. 5 years) and a higher age decreases the postoperative functioning. Suppose that due to the weight loss the preoperative functioning increases with 5 points (on a 0-100 scale). Taken together, this results in a 1.2 points higher postoperative outcome. The second scenario is that a surgeon thinks a patient is too young to perform a THA. If a patient receives this THA 10 years later, and during this 10 years the patient also gains weight due to an inactive

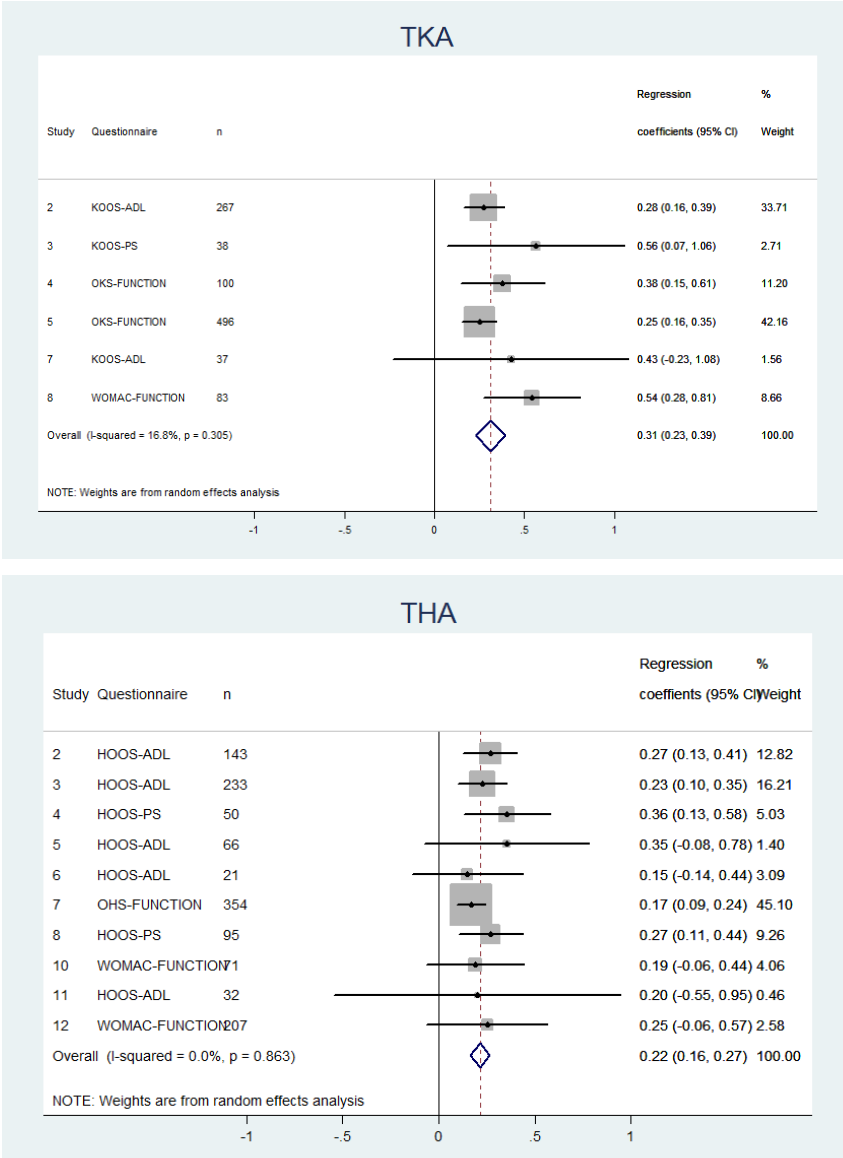

Figure 2. Forest plots - The influence of preoperative functioning on postoperative functioning after TKA (a) and THA (b)

lifestyle (e.g. 10 points of BMI) and the functioning also reduces with 10 points (on a 0-100 scale), his/her postoperative functioning will be 9 points lower compared to the situation if she/he had received THA surgery 10 years earlier. The effect of these scenarios on QoL and pain are also shown in table 3. Overall effects vary between 1.2 and 6.5 points better postoperative outcomes for scenario 1 and between 1.6 and 9 points worse postoperative outcomes for scenario 2.

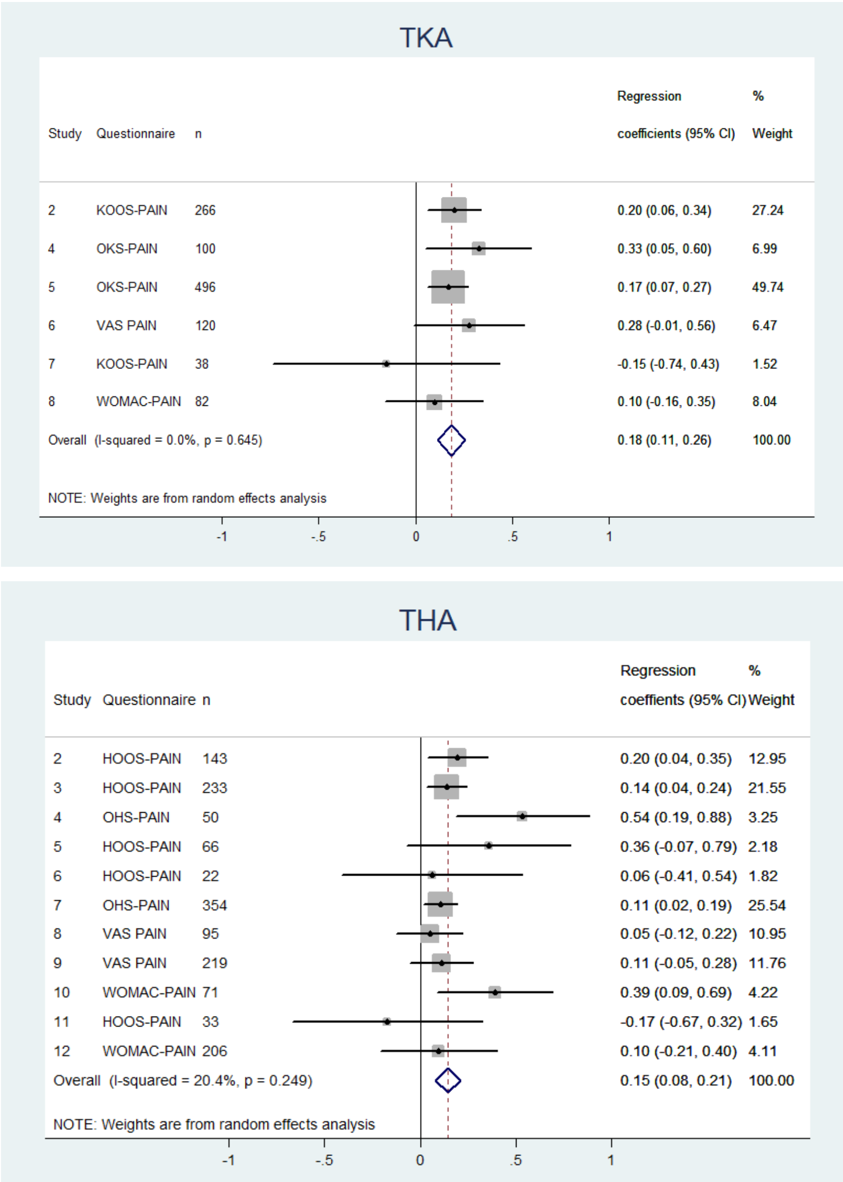

Figure 3. Forest plots - The influence of preoperative pain on postoperative pain after TKA (a) and THA (b)

Table 3. Combined data within scenarios

Scenario 1: A patient loses weight (X points) and increases preoperative status by Y points, this takes Z years

Arthroplasty	Assessed outcome	Effect of age	Effect of BMI	Effect of preoperative status	Total effect on postoperative outcome (points)[a]
X, Y, Z=5 (e.g. in 5 years BMI decreases from 30 to 25, KOOS QoL/ functioning/ pain increases from 35 to 40)					
TKA	QoL	0	0	5*0.51	2.6
	Functioning	0	0	5*0.31	1.6
	Pain	0	5*0.47	5*0.18	3.3
THA	QoL	5*-0.08	5*0.23	5*0.37	2.6
	Functioning	5*-0.33	5*0.35	5*0.22	1.2
	Pain	5*-0.18	5*0.36	5*0.15	1.7
X, Y, Z=10 (e.g. in 10 years BMI decreases from 35 to 25, KOOS QoL/ functioning/ pain increases from 35 to 45)					
TKA	QoL	0	0	10*0.51	5.1
	Functioning	0	0	10*0.31	3.1
	Pain	0	10*0.47	10*0.18	6.5
THA	QoL	10*-0.08	10*0.23	10*0.37	5.2
	Functioning	10*-0.33	10*0.35	10*0.22	2.4
	Pain	10*-0.18	10*0.36	10*0.15	3.3

Scenario 2: A patient gains weight (X points) and decreases preoperative status by Y points, this takes Z years

X, Y, Z=5 (e.g. in 5 years BMI increases from 25 to 30, HOOS QoL/ functioning/ pain decreases from 40 to 35)					
TKA	QoL	0	0	5*-0.51	-2.6
	Functioning	0	0	5*-0.31	-1.6
	Pain	0	5*-0.47	5*-0.18	-3.3
THA	QoL	5*-0.08	5*-0.23	5*-0.37	-3.4
	Functioning	5*-0.33	5*-0.35	5*-0.22	-4.5
	Pain	5*-0.18	5*-0.36	5*-0.15	-3.5
X, Y, Z=10 (e.g. in 10 years BMI increases from 25 to 35, HOOS QoL/ functioning/ pain decreases from 45 to 35)					
TKA	QoL	0	0	10*-0.51	-5.1
	Functioning	0	0	10*-0.31	-3.1
	Pain	0	10*-0.47	10*-0.18	-6.5
THA	QoL	10*-0.08	10*-0.23	10*-0.37	-6.8
	Functioning	10*-0.33	10*-0.35	10*-0.22	-9.0
	Pain	10*-0.18	10*-0.36	10*-0.15	-6.9

[a]On a 0-100 scale

DISCUSSION

The present pooled analysis of 1783 knee and 2400 hip OA patients shows that patients with a higher preoperative quality of life or functioning and less pain also have better postoperative outcomes but that they improve less. Furthermore, women and patients with a higher BMI had more postoperative pain and less improvement after both TKA and THA. Higher age and higher BMI was associated with lower postoperative QoL and functioning and more pain after a THA. However, preoperative quality of life, functioning and pain seem to be most consistently associated with outcomes after both TKA and THA.

It is important to realize that the effects found in our study are not only the effect of the surgery, but also the effect of regression to the mean (RTM). RTM occurs because values are observed with random error, such as random fluctuations in a subject [15]. This means that patients with low preoperative scores are more likely to have higher scores during the next measurement and that patients with high preoperative scores are more likely to have lower scores during the next measurement, even without surgery. This results on average in a larger “improvement” for patients with lower preoperative scores compared to patients with higher baseline scores. Although different methods have been proposed to estimate the size of the RTM effect, but no solution is available to distinguish the real change due to surgery from the change due to RTM.

Our results regarding the effect of preoperative status on outcomes are consistent with other studies that also found that patients with worse preoperative functioning had greater improvements [16-19], but did not achieve the postoperative level of those with higher preoperative functioning [20-26]. Contrary, other studies showed opposite results regarding the direction and size of the effect of age, gender and BMI. Santaguida et al. [27] performed a systematic review about patient characteristics affecting the prognosis after TKA/THA and concluded that an older age is related to worse functioning, but that age and sex do not influence postoperative pain level. We found that women had more pain after a TKA (4 points on a 100 point scale) and THA (2 points on a 100 point scale), even though this may not be a clinically relevant difference [28]. For TKA no association with age or gender and functioning was found. In addition, a previous review about prognostic variables in THA reported that preoperative functioning was most consistently associated with better outcomes [29]. In addition, another systematic review on preoperative predictors on outcomes in THA [30] concluded that only patients’ poor preoperative functioning affects the outcome after THA. This was also found for patients with a TKA [31,32]. Consistent with our finding, Lingard et al. [32] found that patients with severe pain had worse outcomes after a TKA. Other studies also identified other variables, such as radiological scores or comorbidities. A disadvantage of using multiple studies with different protocols for data acquisition was that we could not include these variables. The linear mixed model had to be the equal for each study, so that regression coefficients in each study have the same meaning. Thus the prognostic variables found in this present study are not exhaustive; there may be other variables that are also associated with the outcome.

The effect of different preoperative variables on the postoperative outcomes after TKA and THA may seem to be small on itself, but if taken together they may add up to a clinically relevant effect. However, the scenarios should be interpreted with care, because these are hypothetical examples based on observational data and cannot be interpreted causally. The overall effects of the virtual scenarios which were calculated as examples vary between 1.2 and 6.5 points better postoperative outcomes and between 1.6 and 9 points worse postoperative outcomes. These scenarios provide more insights how small differences may add up or cancel each other out. This probably explains why most effects do not reach a clinically significant difference. Usually a 10% difference (i.e. 10 points on a 0-100 scale [28]) is considered as clinically relevant, but is a 10% difference the right criterion? Postoperative TKA/THA scores increases on average by 20-40 points on a 0-100 scale (results not shown) compared to preoperative scores regardless of the preoperative status. Thus is it realistic to use a difference of 10 points to define whether it is clinically relevant to operate now or wait, based on differences in preoperative variables?

The information regarding the combined effects of preoperative variables on postoperative outcomes will support orthopaedic surgeons to estimate differences in outcome after a joint replacement for specific patient groups, i.e. poorer outcomes for patients with a worse preoperative status, but with greater postoperative improvement compared to patients with higher preoperative scores. In addition, preoperative status may decline during a long surgical delay period and thereby lead to worse postoperative outcomes if no other non-surgical treatments are started. On the other hand, it may sometimes be better to first optimize the patient’s preoperative condition or to reduce for example their BMI. The present study may support orthopaedic surgeons in their decision making by giving an estimate of the magnitude of the effect for different scenarios. Future studies should combine the results of our study with observational cohort studies among OA patients who did not have surgery yet, specific survival data from medical literature and the effects on survival of the artificial joint to assess optimal timing of surgery. This is needed to assess the long-term impact for the patient of the decision to perform surgery at a certain preoperative state of specific patient groups.

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