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ORIGINAL RESEARCH

In-Hospital Pain and Opioid Consumption After Primary Total Knee Arthroplasty Compared to Primary Total Hip Arthroplasty: Results from 7330 Patients Treated in a Fast-Track Setting

Janne Kristin Hofstad · Tina Strømdal Wik · Pål Klepstad · Kari Hanne Gjeilo · Siri Bjørgen Winther · Olav A. Foss

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ABSTRACT

***Introduction*:** Differences in in-hospital pain and consumption of opioids after primary total hip arthroplasty (THA) and knee arthroplasty (TKA) have been rarely studied in a setting where the patient course is otherwise similar. The aim of this study was to compare early pain intensity and opioid usage between patients who have undergone THA and TKA to identify potential implications for outpatient surgery.

***Methods*:** This institutional register study included 4655 patients receiving THA and 2675 patients receiving TKA. Pain at rest and during mobilization were collected once preoperatively, and postoperatively at five time-points, twice on the Day of surgery, once each on day 1 and day 2 after surgery, and at discharge, on a numeric rating scale (NRS) 0–10. Rescue opioids in oral morphine-equivalent doses (MME) were consecutively registered. Postoperative mobilization was registered twice daily.

***Results*:** Overall mean pain were 2.0 (Cl 2.0–2.0) after THA and 2.3 (Cl 2.3–2.4) after TKA at rest, and 3.3 (Cl 3.3–3.3) and 3.7 (Cl 3.7–3.8) during mobilization, respectively. Patients undergoing TKA had a transient increase in pain intensity the day after surgery, whereas patients undergoing THA had improved pain levels. Outpatient criteria for pain (NRS < 5

J. K. Hofstad (✉) · T. S. Wik · S. B. Winther · O. A. Foss
Department of Orthopaedic Surgery, St. Olavs Hospital, Trondheim, Norway
e-mail: Janne.k.hofstad@ntnu.no

T. S. Wik
e-mail: tina.stromdal.wik@stolav.no

S. B. Winther
e-mail: siri.bjorgen@ntnu.no

O. A. Foss
e-mail: olav.a.foss@stolav.no

J. K. Hofstad · K. H. Gjeilo
Department of Public Health and Nursing, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, NTNU Trondheim, Postbox 8905, 7491 Trondheim, Norway
e-mail: kari.hanne.gjeilo@ntnu.no

T. S. Wik
Department of Neuromedicine and Movement Science, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology NTNU, Trondheim, Norway

P. Klepstad
Department of Circulation and Medical Imaging, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology NTNU, Trondheim, Norway
e-mail: pal.klepstad@ntnu.no

P. Klepstad
Department of Anesthesiology and Intensive Care Medicine, St. Olavs Hospital, Trondheim, Norway

K. H. Gjeilo
Department of Cardiology, St. Olavs Hospital, Trondheim, Norway

during mobilization) were feasible for 37% of THA and 35% of TKA. Total median MME was 30.0 (0–573) after THA and 52.5 (0–390) after TKA. Patients undergoing TKA were less mobilized during hospitalization.
Conclusion: A comparable number of THA and TKA cases were eligible for same-day discharge based on outpatient discharge criteria for pain. Patients receiving TKA can expect an increase in pain intensity and opioid needs on the day after surgery.

Keywords: Fast-track; Hip arthroplasty; Knee arthroplasty; Outpatient surgery; Postoperative pain; Postoperative pain management

Key Summary Points

Postoperative pain after primary total hip arthroplasty (THA) and knee arthroplasty (TKA) has been widely investigated; however, they have rarely been compared in a setting where the patient course is otherwise similar and usually not with an emphasis on the early postoperative period.

It is important to quantify the inpatient pain levels, opioid usage, and degree of mobilization in patients undergoing THA or TKA in order to identify potential implications for a change from treatment in-hospital to outpatient surgery.

The aim of the study was to compare in-hospital pain levels and opioid usage between patients undergoing primary THA and TKA within a fast-track setting.

On the day after surgery, both opioid use and pain increased in patients receiving TKA, while they decreased in patients receiving THA.

A comparable number of THA and TKA cases were eligible for same-day discharge based on outpatient discharge criteria for pain

Pain development at the day after surgery for patients receiving TKA is novel and valuable preoperative information that should be included in the preoperative education of patients.

INTRODUCTION

Length of hospital stay (LOS) continue to shorten following fast-track primary total hip arthroplasty (THA) and knee arthroplasty (TKA) [1]. In carefully selected patients, outpatient surgery is considered to be safe and effective for patients undergoing THA and TKA [2–4]. In routine clinical settings, patient selection and strict discharge criteria are crucial for further reductions in LOS and utilization of same-day surgery, [2, 5, 6]. The most common failures to discharge on the day of surgery are pain, hypotension, and nausea [4, 7, 8]. Efforts to further reduce LOS following THA and TKA should therefore focus on the time early after surgery [4, 5, 7]. Most patients undergoing THA and TKA need opioids to treat breakthrough pain in the early postoperative period [9, 10]. Optimized pain relief is important to allow early mobilization [11, 12], and to decrease the adverse effects of opioids such as sedation, dizziness, and nausea, which all limit rapid mobilization [13–15]. Postoperative pain after THA and TKA has been widely investigated, but rarely compared in a setting where the patient course is otherwise similar and usually not with an emphasis on the early postoperative period [9, 16]. Among several criteria for outpatient surgery published by Gromov et al.[6], pain intensity is suggested to be less than 5 during mobilization and less than 3 at rest on a numeric rating scale (NRS) for pain. It is important to quantify the inpatient pain levels, opioid usage, and degree of mobilization in patients undergoing THA or TKA in order to identify potential implications for a change from treatment in-hospital to outpatient surgery. Thus, the aim of the study was to compare in-hospital pain levels and opioid usage between patients undergoing primary THA and TKA within a fast-track setting. The findings could

be used to optimize pain management and to further explore the feasibility of outpatient surgery for these patient groups.

METHODS

Design

The study had an explorative and retrospective design in which all data were prospectively recorded in an institutional registry for THA and TKA [17]. Data recorded preoperatively at the outpatient clinic and during the hospital stay were used.

Patients

All patients scheduled for primary THA or primary TKA between September 1, 2010, and February 1, 2021, were routinely screened, and all patients accepted to be included in the institutional registry. Exclusion criteria were patients scheduled for revision surgery, unicompartment knee replacement or THA after hip fracture. Each patient was included with only one surgery. Thus, for patients scheduled for subsequent primary THA and TKA, only the first arthroplasty surgery for the period was included.

The fast-track set-up included education at the preoperative out-patient clinic 2–4 weeks prior to surgery. On the day of surgery, the patients received perioperative multimodal pain treatment consisting of preoperative oral dexamethasone (16–20 mg), a non-steroidal anti-inflammatory drug (NSAID), and acetaminophen (1.5–2 g). The patients were operated under spinal anesthesia with bupivacaine 5 mg/ml (2.5–3 ml). Local anesthesia with ropivacaine (2 mg/mL) and 0.5 mL epinephrine (1 mg/ml) was administrated during surgery. After surgery, the patients received oral oxycodone (10 mg controlled release) twice a day, acetaminophen 1 g four times a day, and a NSAID twice a day. Oxycodone (5 mg immediate release) was given as rescue medicine if the numeric rating scale (NRS) for pain was 4 or more, either at rest or during mobilization. In the recovery unit, the patients were mobilized with a pulpit walker as soon as the effect of the spinal anesthesia had worn off. Thereafter, the patients were transferred to a specialized ward for multimodal rehabilitation. All the patients in this study had at least one night in hospital before discharge, and specific discharge criteria had to be fulfilled: NRS 3 or less during mobilization, the wound had to be dry, and all the patients had to manage climbing stairs with crutches while still in hospital. The patients were primarily discharged to their homes. During the study period, the multimodal pain regimen was modified for both patients receiving THA and TKA (Table 1).

Outcomes

Pain

Pain was evaluated using the NRS both at rest and during mobilization twice a day. The patients were asked a standardized question: "on a scale from 0–10, where 0 is no pain and 10 is the worst imaginable pain, can you define the pain you have right now"? Pain was registered preoperatively at rest and during mobilization. Postoperatively, pain was registered at rest and during mobilization. First, in the post-anesthesia care unit and at the arthroplasty care unit the day of surgery (Day 0), thereafter on the day after surgery (Day 1) and on the second day after surgery (Day 2), and finally on the day of discharge, with Day 1 and Day 2 referring to full calendar days.

Opioid Consumption

Opioid consumption was routinely registered by nurses throughout the hospital stay, and the rescue opioid dosages were converted to morphine milligram equivalent (MME) dosages [18].

Nausea

Postoperative nausea was routinely assessed by nurses throughout the hospital stay. First, in the post-anesthesia care unit, then in the arthroplasty care unit every day until discharge. The answers were given as yes/no.

Table 1 Changes in the multimodal pain regimen during the study period

Before 2013	
THA and TKA	Dexamethasone (16–20 mg)
	Etoricoxib (90 mg)
	Acetaminophen (1.5–2 g)
	Oxycodone (10 mg controlled release)
	Oxycodone (5 mg immediate release)
	Intraoperatively local anesthesia with ropivacaine 100–150 mL (2 mg/mL) and epinephrine 1 mg/mL)
After 2013	
THA	Dexamethasone (16–20 mg)
	Naproksen esomeprazol (500 mg/20 mg)
	Acetaminophen (1.5–2 g)
	Tapentadol (50 mg)
	Oxycodone (5 mg immediate release)
After 2013	
TKA	Dexamethasone (16–20 mg)
	Naproksen esomeprazol (500 mg/20 mg)
	Acetaminophen (1.5–2 g)
	Tapentadol (50 mg)
	Oxycodone (5 mg immediate release)
	Intraoperatively local anesthesia with ropivacaine 100–150 mL (2 mg/mL) and epinephrine 1 mg/mL)
2019 TKA	Perioperative 100 ml sodium chloride (9 mg/mL), magnesium sulfate heptahydrate (10 mmol), esketamine hydrochloride (10 mg)

THA total hip arthroplasty, *TKA* total knee arthroplasty

Mobilization

Postoperative mobilization was routinely patient-reported and recorded by nurses each morning and evening as total hours mobilized.

Statistics

Descriptive statistics have been used when presenting the results. Generalized linear mixed models were used to analyze pain at rest and pain during mobilization. Pain was modeled with 5 time-points and type of implant (THA or TKA) as fixed factors with a random subject

intercept. First, no covariates were included in the models. Second, age, sex, body mass index, side of surgery, American Society of Anesthesiologists physical (ASA) status, and pain regime were included as covariates. The inclusion of covariates was based on clinical considerations. The normality of residuals was verified with histograms. Differences in the overall pain between patients treated with THA or TKA were statistically tested without and with inclusion of covariates. A p-value < 0.05 was considered statistically significant. Longitudinal pain plots were presented as model estimates of means with 95% confidence intervals and with inclusion of covariates.

MME was compared between groups using the Mann–Whitney U-test, as the data were not normally distributed. Statistical analysis was performed with IBM SPSS, version 28 (IBM, Armonk, NY, USA). Only cases with available data were analyzed.

Ethics and Registration

All patients were informed about the institutional quality registry before inclusion, and that their data could be used for research purposes. Before inclusion, written and verbal consent were obtained from each patient. The study was conducted in accordance with the declaration of Helsinki [19], approved by the Regional Committee for Medical and Health Research Ethics (REK 290690) and complied with the General Data Protection Regulation.

RESULTS

Patients

A total of 7330 patients were included, 4655 undergoing primary THA and 2675 undergoing primary TKA (Fig. 1). Baseline data and patients' demographics are shown in Table 2.

Pain

Pain levels were similar between the THA group and the TKA group on the day of surgery. Patients in the TKA group reported higher pain intensity both at rest and during mobilization on the day after surgery until discharge (Figs. 2, 3). The overall pain, recorded at the 5 times of registration, was higher in the TKA

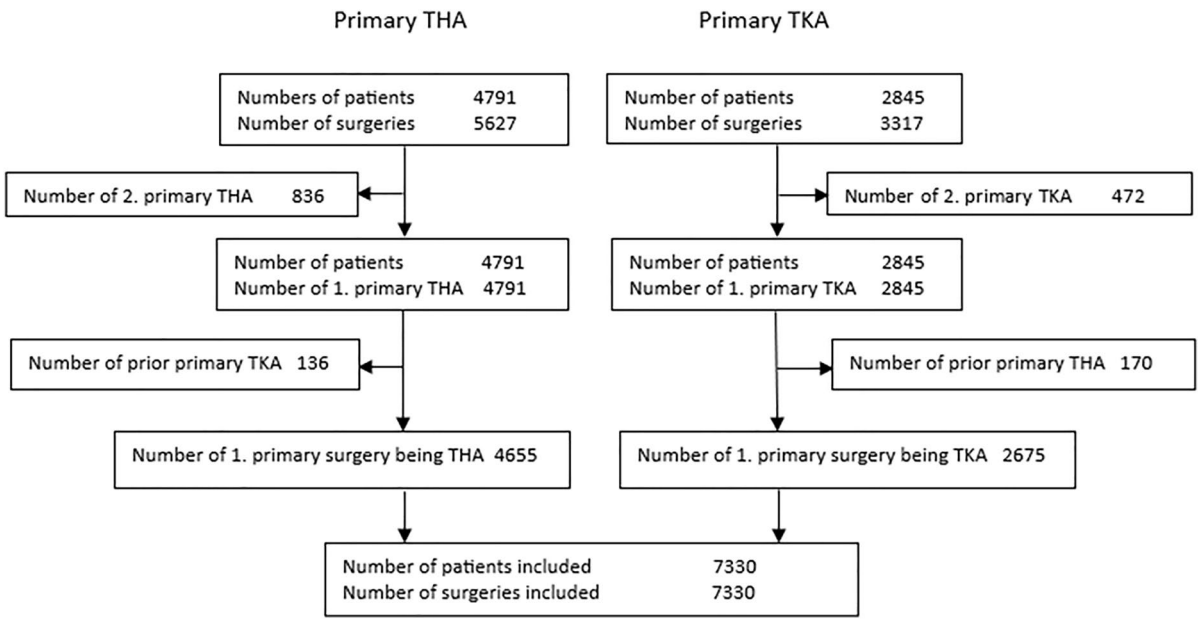

Fig. 1 Flowchart of study participants. *THA* total hip arthroplasty, *TKA* total knee arthroplasty

Table 2 Baseline data, patient's demographics, local anesthesia, and length of stay

		THA, *n* = 4655	TKA, *n* = 2675
Age, years	Mean (SD)	65.7 (13.2)	67.1 (10.3)
	Min–max	14–95	22–92
	Missing (%)	0 (0)	0 (0)
Sex			
Female	Number (%)	2984 (64.1)	1648 (61.6)
Male		1671 (35.9)	1027 (38.4)
ASA			
1	Number (%)	841 (18.1)	335 (12.5)
2		2677 (57.5)	1659 (62.0)
3		990 (21.3)	642 (24.0)
4		48 (1.0)	16 (0.6)
Missing (%)		99 (2.1)	23 (0.9)
Weight, kg	Mean (SD)	79.7 (16.1)	86.6 (16.5)
	Missing (%)	49 (1.1)	22 (0.1)
BMI	Mean (SD)	27.3 (4.7)	29.3 (4.9)
	Missing (%)	48	21
Side of surgery			
Left	Number (%)	2014 (43.3)	1203 (45.0)
Right		2583 (55.5)	1408 (52.6)
Missing (%)		58 (1.2)	64 (2.4)
LIA			
Yes	Number (%)	1562 (33.6)	2345 (87.7)
No	Number (%)	2366 (50.8)	33 (1.2)
Missing (%)		727 (15.6)	297 (11.1)
Charnley class			
A	Number (%)	1501 (32.2)	686 (25.6)
B		873 (18.0)	601 (22.5)
C		503 (10.8)	319 (11.9)
Missing (%)		1778 (38.2)	1069 (40.0)
LOS, days	Mean (SD)	2.5 (1.4)	2.7 (1.5)
	Min–Max	1–28	1–51
	Missing (%)	33 (0.7)	15 (0.6)

Table 2 continued

		THA, *n* = 4655	TKA, *n* = 2675
Preoperative, pain at rest	Mean (SD)	4.3 (2.4)	3.7 (2.5)
	Missing (%)	312 (6.7)	159 (5.9)
Preoperative, pain during mobilization	Mean (SD)	6.3 (1.9)	6.3 (1.8)
	Missing (%)	317 (6.8)	154 (5.8)
Preoperative analgesics	Yes	3471 (74.6)	1783 (66.7)
	No	897 (19.3)	588 (22.0)

Charnley comorbidity classification: *A* one joint in need of arthroplasty and no significant comorbidities, *B* two joints in need of arthroplasty and no significant comorbidities, and *C* multiple joints in need of arthroplasty and other severe comorbidities

ASA American Society of Anesthesiologist physical status classification, *BMI* Body Mass Index, *LOS* length of hospital stay, *LIA* local infiltration anesthesia, *THA* total hip arthroplasty, *TKA* total knee arthroplasty

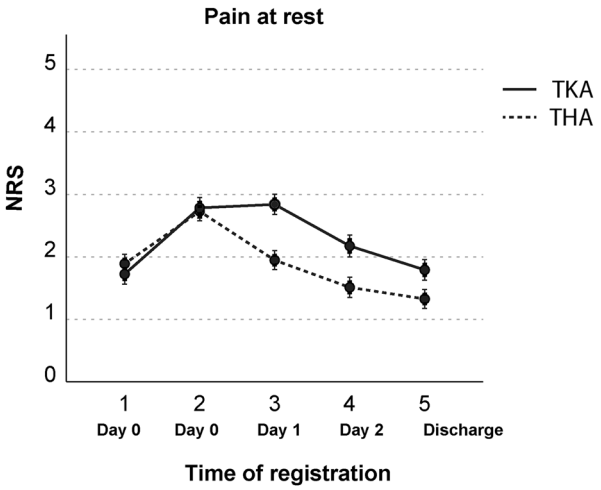

Fig. 2 Pain (NRS) 0–10, after THA and TKA at rest at five time-points: *1* in the post-anesthesia care unit on the day of surgery (*Day 0*); *2* in the arthroplasty care unit on Day 0; *3* and *4* in the arthroplasty care unit on the day after surgery (*Day 1*) and on the second day after surgery (*Day 2*), respectively; *5* at discharge. *Line plots* displays overall grand mean values with 95% confidence intervals with inclusion of covariates. *Dotted line* patients with THA, *solid line* patients with TKA. *NRS* numeric rating scale, *THA* total hip arthroplasty, *TKA* total knee arthroplasty

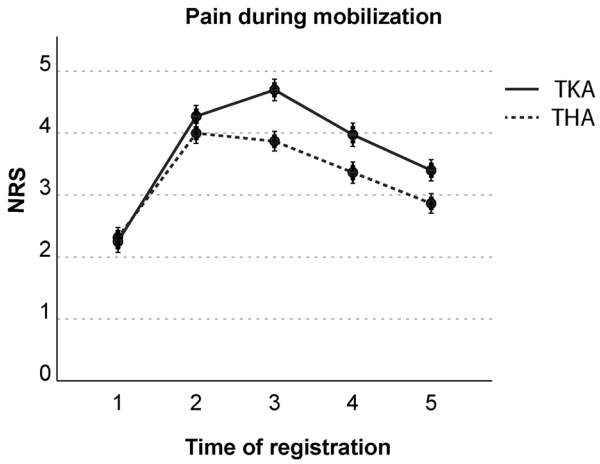

Fig. 3 Pain (NRS) 0–10 after THA and TKA during mobilization at five time-points: *1* in the post-anesthesia care unit on the day of surgery (*Day 0*); *2* in the arthroplasty care unit on Day 0; *3* and *4* in the arthroplasty care unit on the day after surgery (*Day 1*) and on the second day after surgery (*Day 2*), respectively; *5* at discharge. *Line plots* displays overall grand mean values with 95% confidence intervals with inclusion of covariates. *Dotted line* patients with THA, *solid line* patients with TKA. *NRS* numeric rating scale, *THA* total hip arthroplasty, *TKA* total knee arthroplasty

group compared to the THA group both at rest and during mobilization ($p < 0.001$) (Table 3). On the day of surgery, 35% of the TKA group and 37% of the THA group reported pain < 3 at rest and < 5 during mobilization. The day after surgery, the corresponding results were 30% for the TKA group and 52% for the THA group, respectively (Table 4). Missing pain data at discharge were 19% of THA and 19% of TKA.

Table 3 Postoperative pain analysis presented without and with inclusion of covariates

	Pain at rest			Pain during mobilization		
	Mean (95% CI)	Missing (%)	*P* value	Mean (95% CI)	Missing (%)	*P* value
Without covariates						
THA	2.0 (2.0–2.0)	101 (2.2)		3.3 (3.3–3.3)	109 (2.3)	
TKA	2.3 (2.3–2.4)	50 (1.9)		3.7 (3.7–3.8)	49 (1.8)	
Diff	− 0.3		< 0.001	− 0.4		< 0.001
With covariates						
THA	1.9 (1.8–1.9)			3.3 (3.2–3.3)		
TKA	2.3 (2.1–2.3)			3.7 (3.6–3.8)		
Diff	− 0.4		< 0.001	− 0.4		< 0.001

Covariates: age, gender, BMI (body mass index), side operated on, ASA and pain regimen

THA total hip arthroplasty, *TKA* total knee arthroplasty

Table 4 Pain at rest and the corresponding percentage of patients reporting various pain levels during mobilization on the day of surgery (*Day 0*) and the day after surgery (*Day 1*)

Pain rest (NRS <)	Pain mobile (NRS <)	THA (% of patients)		TKA (% of patients)	
		Day 0	Day 1	Day 0	Day 1
2	4	17	25	15	12
	5	18	30	18	15
	6	20	34	20	18
3	4	29	38	26	20
	5	37	52	35	30
	6	41	60	41	37
4	4	35	42	31	24
	5	52	61	47	40
	6	62	75	60	53
Missing (%)		21	17	21	16

THA total hip arthroplasty, *TKA* total knee arthroplasty

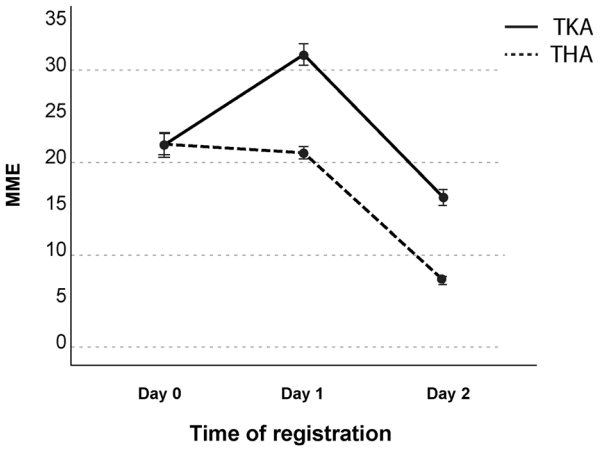

Fig. 4 Consumption of rescue opioids on the day of surgery (Day 0), on the day after surgery (*Day 1*), and on the second day after surgery (*Day 2*). *Line plots* displays the mean values of morphine milligram equivalent (MME) with 95% confidence intervals. *Dotted line* patients with THA, *solid line* patients with TKA. *THA* total hip arthroplasty, *TKA* total knee arthroplasty

Consumption of Opioids

Overall MME mean during the hospitalization period was 52.5 (22.5–99.0) in the TKA group compared to 30.0 (15.0–69.0) in the THA group ($P < 0.001$). The difference of opioid consumption between the two groups was highest the day after surgery (Fig. 4).

Nausea

The THA group reported more nausea than the TKA group immediately after surgery, whereas the TKA group reported more nausea on the day after surgery until discharge (Table 5).

Mobilization

The TKA group was less mobilized in total hours compared to the THA group on the day after surgery and until discharge (Fig. 5).

DISCUSSION

We observed that both groups of patients undergoing THA or TKA had similar pain intensities and opioid rescue need on the day of surgery. On the day after surgery, both opioid use and pain increased in patients receiving TKA, while it decreased in patients receiving THA. The pain levels were acceptable for outpatient surgery in one-third of the patients in both groups on the day of surgery. These findings support the proposition that selected patients receiving THA and TKA can be reliably discharged on the day of surgery with the current fast-track procedures.

Table 5 Postoperative nausea after THA and TKA

	1 *n* (%)	2 *n* (%)	3 *n* (%)	4 *n* (%)
THA				
Yes	296 (7.3)	428 (10.8)	437 (11.3)	302 (12.7)
No	3747 (92.7)	3532 (89.2)	3432 (88.7)	2073 (87.3)
TKA				
Yes	139 (5.9)	274 (11.6)	330 (14.4)	226 (14.5)
No	2207 (94.1)	2082 (88.4)	1955 (85.6)	1338 (85.5)

Time of registration: *1* the post-anesthesia care unit, *2* the arthroplasty care unit on the day of surgery (Day 0), *3* and *4*, the arthroplasty care unit on the day after surgery (Day 1) and on the second day after surgery (Day 2), respectively

THA total hip arthroplasty, *TKA* total knee arthroplasty

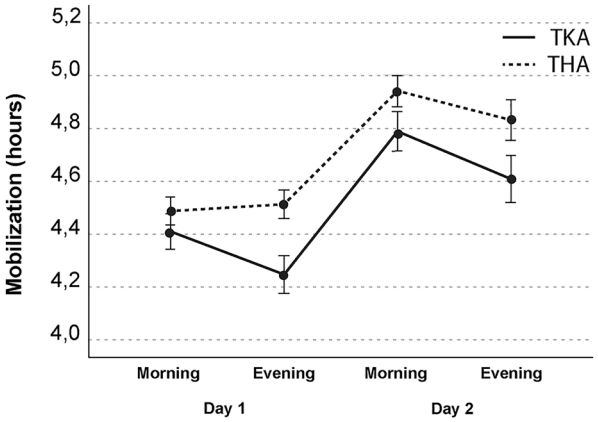

Fig. 5 Mobilization in hours on the day after surgery (*Day 1*) and on the second day after surgery (*Day 2*). *Line plots* displays mean mobilization time in hours with 95% confidence intervals. *Dotted line* patients with THA, *solid line* patients with TKA. *THA* total hip arthroplasty, *TKA* total knee arthroplasty

However, patients receiving TKA should be informed preoperatively that pain intensity may increase the day after surgery.

Gromov et al. observed that 15% of unselected patients receiving THA and TKA were feasible for same-day discharge [6]. In studies reporting successful discharge of patients undergoing THA or TKA on the day of surgery, the patients may be scheduled for same-day discharge and operations performed within specialized treatment programs with strict discharge criteria [16, 20, 21]. Our data are from everyday practice and show that approximately 35% of THA and TKA could be feasible for outpatient surgery based on specific outpatient discharge criteria for pain [6]. Before evolving outpatient surgery, the development of pain on the day after surgery should also be emphasized to provide patients with knowledge of postoperative pain management at home.

Our findings align with other studies comparing acute pain intensity for patients with THA and TKA [9, 22, 23]. In these studies, patients receiving TKA reported higher pain intensity up to 72 h after surgery. The largest of the previous studies, which included 11,693 patients, reported pain scores 24 h after surgery of 4.15 for patients with THA and 5.08 for patients with TKA, which are higher pain scores

than those reported in our study. However, this study did not distinguish between pain at rest and pain during mobilization [9]. Two other smaller studies also demonstrated corresponding differences in pain scores between patients undergoing THA and TKA [22, 23].

When evaluating postoperative pain, it is important to consider total opioid consumption. In the present study, the MME was 30 for patients receiving THA and 52.2 for patients receiving TKA. Another study reported significantly higher opioid consumption compared to our findings with MMEs of 93.76 and 147.55 following THA and TKA, respectively [9]. Total consumption of opioids in this report was calculated including both rescue opioids and scheduled opioids, which may explain the higher amount of opioids compared to our study. In addition, an opioid-sparing multimodal regimen was implemented only in the very last part of the study period [9]. In contrast to our results, Husted et al. observed that a greater proportion of patients undergoing THA required rescue opioids compared to those undergoing TKA [16]. While this study did not directly compare THA and TKA, they noted that patients receiving TKA experienced higher pain levels during the first two postoperative days. The daily use of opioids was self-reported as yes/no, which could lead to recall bias, and the patient group was carefully selected [16].

Patients undergoing TKA consumed the highest level of opioids on the day after surgery, while patients undergoing THA showed a decline in their opioid usage. In addition, patients receiving TKA reported more nausea and were less mobilized compared to patients receiving THA on the day after surgery. Similarly, Getachew et al. observed a slower progression in pain relief for patients undergoing TKA, with the worst pain intensity and highest opioid intake occurring on postoperative day 2. This peak in pain coincided with the end of the regional nerve blocks used as part of the multimodal pain regimen [24]. This illustrates the important balance between effective pain management to facilitate early mobilization, and minimizing the adverse effects associated with opioids [13], and should be especially communicated to patients undergoing TKA who are found to be eligible for outpatient surgery or early discharge.

There is an increasing awareness of preoperative patient information and shared decision-making to give patients realistic expectations [25]. The awareness of preoperative information and shared decision-making should probably also include the notion of individualized pain treatment. It is therefore important to determine if pain management in patients receiving THA and TKA is suboptimal due to modifiable factors, such as anxiety, depression, and catastrophizing, or due to expectations or organizational factors [26]. Modifiable factors should be optimized preoperatively, while non-modifiable factors such as sex and age can be useful for tailoring patients' education and individual pain management [27]. Our results on pain development on the day after surgery for patients receiving TKA are novel and have produced valuable preoperative information that should be included in the preoperative education of patients.

Limitations and strengths

During the 10 years of registration, the pain regimen was modified both for patients receiving THA and those receiving TKA, which could influence the total amount of opioid consumption and patient-reported acute pain levels. However, the modification was the same for both groups, and, after including clinically relevant covariates in the analyses, such as pain regimen, the acute pain levels and the amount of rescue opioids did not change significantly between patients undergoing THA and TKA.

The overall eligibility for outpatient surgery could not be evaluated in this study solely based on postoperative pain levels and without considering other specific discharge criteria for same-day discharge. However, pain levels and opioid use in the very early postoperative period provided valuable information before transitioning to out-patient surgery.

Studies that examine pain management following THA and TKA tend to exclude patients who are older, obese, have a high ASA score, or experience chronic use of opioids. This limits the applicability of research findings to a

broader population [28]. Thus, a strength of the present study is that all the patients scheduled for primary THA and TKA were included in the analysis regardless of, for instance, age and ASA score. Another strength that enabled a comparison between patients receiving THA and TKA, is the similarity of pre- and postoperative procedures. A further strength of our study is the large number of study participants. Register data provide a complete study population which minimizes selection bias. The data used in our study were collected over a period of 10years and the response rate was high, thus strengthening the internal validity of the study findings. The results from our study may be generalized to other THA and TKA populations in fast-track settings that receive a multimodal pain regimen. By including each patient based on just one index surgery, we eliminate potential learning effects for the patients.

CONCLUSION

Patients receiving TKA experienced more pain and consumed more rescue opioids compared to patients receiving THA. Patients scheduled for TKA should be informed preoperatively that pain intensity may increase on the day after surgery, thus modifying patients expectations and providing patients with knowledge of postoperative pain management at home. Based on pain intensity on the day of surgery, a comparable number of both THA and TKA cases were eligible for same-day discharge.

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Data availability. The dataset generated and analyzed in the present study is not publicly available because permission has not been granted from the participants or the Ethical Committee.

Declarations

Conflict of interest. Janne Kristin Hofstad, Tina Strømdal Wik, Pål Klepstad, Kari Hanne Gjeilo, Siri Bjørgen Winther and Olav Andreas Foss declare that they have no competing interests. Pål Klepstad is an Editorial Board member of Pain and Therapy. Pål Klepstad was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions.

Ethical approval. All patients were informed about the institutional quality registry before inclusion, and that their data could be used for research purposes. Before inclusion, written and verbal consent were obtained from each patient. The study was conducted in accordance with the declaration of Helsinki [19], approved by the Regional Committee for Medical and Health Research Ethics (REK 290690) and complied with the General Data Protection Regulation (GDPR).

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