Safety Aspects of Postanesthesia Care Unit Discharge without Motor Function Assessment after Spinal Anesthesia

A Randomized, Multicenter, Semiblinded, Noninferiority, Controlled Trial

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ABSTRACT

Background: Postanesthesia care unit (PACU) discharge without observation of lower limb motor function after spinal anesthesia has been suggested to significantly reduce PACU stay and enhance resource optimization and early rehabilitation but without enough data to allow clinical recommendations.

Methods: A multicenter, semiblinded, noninferiority randomized controlled trial of discharge from the PACU with or without assessment of lower limb motor function after elective total hip or knee arthroplasty under spinal anesthesia was undertaken. The primary outcome was frequency of a successful fast-track course (length of stay 4 days or less and no 30-day readmission). Noninferiority would be declared if the odds ratio (OR) for a successful fast-track course was no worse for those patients receiving no motor function assessment *versus* those patients receiving motor function assessment by OR = 0.68.

Results: A total of 1,359 patients (98.8% follow-up) were available for analysis (93% American Society of Anesthesiologists class 1 to 2). The primary outcome occurred in 92.2% and 92.0%, corresponding to no motor function assessment being noninferior to motor function assessment with OR 0.97 (95% CI, 0.70 to 1.35). Adverse events in the ward during the first 24 h occurred in 5.8% *versus* 7.4% with or without motor function assessment, respectively (OR, 0.77; 95% CI, 0.5 to 1.19, $P = 0.24$).

Conclusions: PACU discharge without assessment of lower limb motor function after spinal anesthesia for total hip or knee arthroplasty was noninferior to motor function assessment in achieving length of stay 4 days or less or 30-day readmissions. Because a nonsignificant tendency toward increased adverse events during the first 24 h in the ward was discovered, further safety data are needed in patients without assessment of lower limb motor function before PACU discharge.
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PRIMARY total hip arthroplasty (THA) and total knee arthroplasty (TKA) are performed annually in approximately 900 to 1,200 per million (THA) and 1,400 to 2,000 per million (TKA) patients in the United Kingdom and United States with a projected 6% annual increase,[1,2] representing a major demand for healthcare resources. Thus, admittance, observation, and treatments in these procedures need to be evidence based to facilitate patient recovery[3,4] and reduce costs[5] without compromising patient safety, including the time spent in the postanesthesia care unit (PACU) and ward. Spinal anesthesia may be the preferred anesthetic technique for THA/TKA, due to its reported lower morbidity compared with general anesthesia,[6,7] but it may

What We Already Know about This Topic

- Delayed recovery of lower limb function results in delays in discharging patients from the postanesthesia care unit
- The appropriateness of discharge from the postanesthesia care unit without observing the status of motor blockade has not been established

What This Article Tells Us That Is New

- A multicenter, noninferiority study involving 1,376 patients undergoing lower extremity joint replacement surgery under spinal anesthesia was conducted to determine the benefit of motor assessment
- Patients not receiving motor examination completed a fast-track course as frequently as those who were assessed

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result in prolonged PACU stay due the affected motor function of the lower limbs[8] and discharge criteria demanding motor function recovery.[9,10] A critical appraisal of criteria for PACU discharge readiness[9,10] after THA/TKA should be seen as part of the constant development of "fast track" or "enhanced recovery," where standardized evidence-based care principles have reduced length of stay (LOS) from 4 to 12 days to the current 1 to 3 days after THA and TKA without concomitant increase in morbidity, even in patients with comorbidities.[4] Similar to other major surgical procedures,[11] however, the information on the specific challenges in the PACU recovery phase after THA/TKA is sparse,[12] hindering evidence-based interventional studies to further increase recovery. In addition, information on the safety and need for observation after spinal anesthesia potentially would not only have implications for THA and TKA but also for other orthopedic, abdominal, urologic, and gynecologic procedures in which spinal anesthesia is performed, with annual rates between approximately 3,500 and 14,000 spinals per million.[13,14]

A prospective descriptive study in 163 patients on the reasons for PACU stay after THA/TKA under spinal anesthesia suggested a potential for optimization of discharge criteria, including no need for observation for motor blockade and without the occurrence of adverse events in the ward the first 24 postoperative hours.[8] Time-to-discharge readiness was reduced to a median of 15 min in comparison to the previously reported 300 to 400 min.[15] A more recent study in 45 patients undergoing TKA on the effect of low-dose spinal anesthesia (5 *vs.* 10 mg bupivacaine) on PACU discharge readiness also did not include motor function assessment and reported an approximate 10-min PACU stay. Both studies used modified versions of the widely used Aldrete discharge criteria[8,9,16]; however, neither of these studies was scaled for the detection of adverse events to assess safety or detailed systemic collection of data, including the time-incident relationship between adverse events and the spinal anesthesia, hindering evidence-based clinical recommendations for PACU stay. Understanding the type and timing of occurrence of adverse events combined with potential identification of pre-, intra-, or postoperative risk factors is crucial for identifying patients who need increased observation and early treatment in the ward. In addition, the current efforts for developing same-day THA/TKA[17–19] call for more detailed studies on recovery aspects in the PACU.

Thus, the objective was to assess the 30-day safety of PACU discharge with or without motor function assessment after spinal anesthesia for THA or TKA in a randomized, noninferiority, semiblinded controlled trial.

Materials and Methods

The study was approved by the ethics committee of the Capital Region, Hillerød, Denmark, and data handling authorities with registration at http://www.clinicaltrials.gov (NCT02134496, registered April 28, 2014, primary investigator E.K.A.) before inclusion of patients. Written informed consent was obtained from all patients participating in this Danish, five-center trial (Farsø, Gentofte, Vejle, Holstebro, and Viborg Hospitals, Denmark).

Study Information and Inclusion

Patients were eligible if scheduled for primary THA or TKA, at least 18 yr old, able to understand Danish, and scheduled for spinal anesthesia during the study-independent clinical examination preceding surgical admission at the orthopedic departments. The choice of anesthesia (spinal/general) was made by the anesthetist during consultation with the patient and reflected clinical practice.

Patients referred to the participating centers were contacted consecutively by research nurses immediately after the surgical indication had been made. If they agreed to participate, they were included by research nurses, who also assigned the randomization number in a consecutive order. Patients were excluded postinclusion if spinal anesthesia could not be performed or was contraindicated (coagulopathy, local infection, other reason), if general anesthesia was chosen by the patient (waived participation), or if the surgical procedure could not be completed without conversion to general anesthesia (failed spinal[20]), defined as the need for tracheal intubation or use of a laryngeal mask to ensure adequate oxygenation. Patients also were excluded if more than 750 ml of intraoperative bleeding occurred, although the general recommendations of the Danish Anesthesiological Society for Anesthesiology and Intensive Medicine require physician-approved discharge if intraoperative bleeding is greater than 500 ml. We only allowed PACU discharge in circulatory stable patients according to the PACU discharge criteria (table 1), and we considered this safe and again reflective of clinical practice.

Trial Protocol

Surgery was performed according to the guidelines of the participating departments. Patients were given a preoperative multimodal analgesia including acetaminophen 1 g, celecoxib 400 mg, and 125 mg methylprednisolone IV (TKA only), whereas gabapentin was given according to

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Table 1. Postanesthesia Care Unit Discharge Criteria as Recommended by the Danish Society of Anesthesia and Intensive Care Medicine

Parameter	Point	Definition
1. Sedation	0	Fully awake
	1	Asleep, aroused by verbal stimuli
	2	Asleep, aroused by physical stimuli
	3	Asleep, cannot be aroused
2. RR, min	0	Regular rate, RR > 10
	1	Snoring, 10 < RR < 30
	2	RR < 10 or RR > 30
	3	Periods of apnea or obstructive pattern
3. Spo_2, % No supplementary oxygen for 10 min	0	$Spo_2 \geq 94$
	1	$90 \leq Spo_2 < 94$
	2	$85 \leq Spo_2 < 90$
	3	$Spo_2 < 85$
4. SBP, mmHg	0	SBP ≥ 100
	1	90 ≤ SBP < 100
	2	80 ≤ SBP < 90 or SBP > 220
	3	SBP < 80
5. HR, beats/min	0	50 < HR ≤ 100
	1	100 < HR < 120
	2	40 ≤ HR ≤ 50 or 120 < HR ≤ 130
	3	HR < 40 or HR > 130
6. Pain at rest (patient evaluation)	0	No, VAS = 0
	1	Mild, VAS < 30
	2	Moderate, 30 ≤ VAS < 70
	3	Severe, VAS ≥ 70
7. Nausea (patient evaluation)	0	No, VAS = 0
	1	Mild, VAS < 30
	2	Moderate, 30 ≤ VAS < 70
	3	Severe, VAS ≥ 70
8. Motor function	0	Ability to move lower extremities freely
	1	Ability only to move feet and knee
	2	Ability only to move feet
	3	No ability to move the lower extremities
9. Uo, $ml \cdot kg^{-1} \cdot h^{-1}$	0	Uo ≥ 1.0 or no bladder catheter
	1	0.5 ≤ Uo < 1.0
	2	0 < Uo < 0.5
	3	Anuria
10. Tp, °C	0	Tp ≥ 36.0
	1	35.5 ≤ Tp < 36.0
	2	35.0 ≤ Tp < 35.5
	3	Tp < 35.0

Discharge is allowed if each one of parameter 1 to 10 is ≤1 and that cumulated score of 1 to 10 is ≤4 on two successive registrations before patient discharge from the postanesthesia care unit (by a nurse). American Society of Anesthesiologists physical status > 3 requires discharge by an anesthesiologist. Uo monitored by bladder scans. Nurse discharge with blood loss ≤750 ml was allowed. Motor function was only assessed in the control group as per protocol.

HR = heart rate; RR = respiratory rate; SBP = systolic blood pressure; Spo_2 = oxygen saturation; Tp = temperature; Uo = urine output; VAS = visual analog scale.

local guidelines. Surgery was performed with the patient under spinal anesthesia *via* the use of 0.5% isobaric bupivacaine (preferably 1.8 to 2.5 ml; *i.e.*, 9.0 to 12.5 mg) or 0.5% hyperbaric bupivacaine (preferably 1.5 to 2.0 ml; *i.e.*, 7.5 to 9.0 mg). Dosages were suggestions, with the final decision left to the anesthesiologist, again reflecting clinical practice. Toward the end of surgery, all patients undergoing TKA received infiltration of 150 ml local anesthetic in the perisurgical area[21] (148.5 ml ropivacaine 2 mg/ml + 1.5 ml epinephrine 1 mg/ml). Supplemental sedation or analgesia with propofol or remifentanil was allowed.

Randomization and Blinding

A computer-generated 1:1 random allocation sequence (control/intervention) in blocks of 50 was made for THA and TKA separately to ensure equal distribution of surgical procedures between groups with the free Internet software at http://www.sealedenvelope.com. To minimize treatment and assessment bias, a semiblinded design was chosen in which the group allocation was concealed until the patient fulfilled the discharge criteria (excluding motor function assessment), at which time the opaque, sealed randomization envelope was opened by the PACU nurse and the patient's allocation to the intervention group (immediate discharge and no motor function assessment, NMFA) or control group (discharge on usual parameters including motor function assessment, MFA) was revealed. Assessors were kept blinded to the randomization groups during the data analysis, including the evaluation of the reasons for LOS greater than 4 days or 30-day readmission.

Data Registration

Primary Outcome. LOS was drawn from the Lundbeck Foundation Centre for Fast-Track Hip and Knee Replacement database (LCDB), which is registered as a prospective research registry on patient characteristics and postoperative complications at http://www.clinicaltrials.gov (NCT01515670), and complete 30-day readmissions (and deaths) were gathered from the Danish National Patient Register (DNPR), which collects information on all hospital admissions in Denmark, including length of hospital stay.[22] The use of a LOS greater than 4 days or readmissions with overnight stay in hospital as indicator of an "unsatisfactory" fast-track procedure is a standard in the LCDB, with the cutoff of LOS less than 4 days being based on a median LOS of 3 days since 2010.[23,24] All cases of LOS greater than 4 days and readmissions are analyzed based on detailed evaluation of the discharge notes, and causes are subdivided into "surgical" and "medical."[24] For the present study only, one readmission—the most serious—per patient was included. Crosslinking between the data collected at the hospital, the LCDB, and the DNPR was done by the unique personal security number given to all Danish citizens.[22,25]

Preoperative demographics and anesthesia/surgery data were collected prospectively by interview and charts. The patients' clinical condition was assessed postoperatively before they left the operating room, when they arrived at the PACU, and every 15 min by a modified Aldrete discharge criteria

(referred to as "PACU score" in this article) as recommended by the Danish Society for Anesthesia and Intensive Medicine, to evaluate discharge readiness.[26] To summarize, the PACU score consists of 9 items (diuresis not assessed in fast-track THA/TKA) with scores ranging from 0 to 3, with "0" indicating normal values and "3" being the most severe. A single item score less than or equal to 1 and accumulated score of less than or equal to 4 on two successive registrations 15 min apart are required before discharge from PACU (table 1).

Preoperative data included age, sex, height, weight, and American Society of Anesthesiologists (ASA) physical status score[27] (table 2). Intraoperative data included THA/TKA, bleeding volume, spinal anesthesia volume, anesthesia time (spinal anesthesia to end of surgery), and surgical time (surgery start to surgery end). Postoperative data included PACU score in the operating room and every 15 min in PACU until discharge, PACU arrival time, PACU discharge time, time and reason for adverse event, type of adverse event, LOS, 30-day readmission, or death.

Adverse events in the ward were registered for the first 24 postoperative hours (0 to 24 h postspinal anesthesia) with a study-specific chart covering all major organ systems with suggestions for types of adverse events but not restricted to these (*e.g.,* cerebral: dizziness, fainting; cardiovascular: hypotension, chest pains, tachycardia, *etc.*). Adverse events were classified as all contact with the patients for medical reasons not part of the routine rounds or adverse findings during the routine rounds and registered with time and description of event (see Supplemental Digital Content 1, http://links.lww.com/ALN/B415, for details of each event). For example, pain data were not collected systematically but only when the standard regimes (supplemental opioids, nerve blockade, *etc.*) did not suffice and staff intervention was required. The primary outcome was LOS less than or equal to 4 days and no readmission/death for surgery-related factors within the first 30 postoperative days. A 30-day readmission period was chosen to detect complications that could be assumed to have occurred as a consequence of the potential earlier PACU discharge.

Secondary Outcomes. Secondary outcomes included the incidence and type of adverse event during the first day (at least 24 h) after spinal anesthesia in the ward and time from spinal anesthesia to adverse event. Realizing that events classified as cerebral (dizziness or syncope) could be the result of hypotension, we also aimed to analyze the combined occurrences of these two parameters. Other outcomes included time in PACU until discharge criteria were fulfilled (arrival in PACU to time when discharge criteria fulfilled).

Power Calculation and Sample Size. The trial was powered for comparison between the MFA and NMFA groups. Noninferiority was declared if the odds ratio (OR) for a successful fast-track course was no worse for NMFA *versus* MFA by 5% (equivalent to accepting a lower success rate of 81.7% in the NMFA *vs.* the current 86.7% in the MFA group), corresponding to OR = 0.68. The study sample-size calculation was based on analysis of the LCDB *via* use of the following definition of a successful fast-track course: LOS less than or equal to 4 days and no readmission/death for surgery-related factors within the first 30 postoperative days,[24] which occurred in 86.7% of patients in the participating centers according to the database entries as per April 2015. Thus, we expected the same frequency in the control group and

Table 2. Pre-, Intra-, and Postoperative Demographic Variables

	THA (n = 727)			TKA (n = 632)		
Variable	Motor Function Assessment (n = 358)	No Motor Function Assessment (n = 369)	*P* Value	Motor Function Assessment (n = 312)	No Motor Function Assessment (n = 320)	*P* Value†
Preoperative						
Age, yr	68 (9) [40–88]	68 (10) [22–91]	0.81	67 (10) [27–88]	68(9) [41–89]	0.84
Female, %	49.9	52.5	0.96	57.3	54.5	0.98
Height, cm	172 (9) [144–194]	171 (9) [140–199]	0.43	170 (9) [149–195]	172 (9) [141–204]	0.37
Weight, kg	80 (15) [45–130]	80 (17) [46–145]	0.81	87 (17) [48–163]	88 (18) [44–150]	0.75
BMI	27 (4) [17–45]	27 (5) [17–45]	0.68	30 (5) [18–53]	30 (5) [17–52]	0.64
ASA,* median	2 (1–2) [1–3]	2 (1–2) [1–3]	0.30	2 (1–2) [1–3]	2 (1–2) [1–4]	0.28
Intraoperative						
Spinal vol	2.5 (0.5) [1.5–4.5]	2.5 (0.5) [1.5–4.0]	0.47	2.3 (0.5) [1.5 to 4.5]	2.4 (0.5) [1.5–4.5]	0.39
Bleeding	311 (174) [80–750]	309 (164) [75–750]	0.82	123 (140) [0–700]	134 (138) [0–650]	0.84
Time (op)	0:59 (0:16) [0:38–1:47]	1:01 (0:16) [0:38–2:40]	0.78	1:09 (0:17) [0:39–2:30]	1:09 (0:17) [0:38–2:41]	0.99
Time (anesth)	1:30 (0:18) [0:56–3:22]	1:32 (0:20) [0:56–3:57]	0.87	1:40 (0:22) [1:02–4:34]	1:39 (0:18) [0:59–3:19]	0.97
Postoperative						
LOS*	2 (1–2) [1–13]	2 (1–2) [0–78]	0.67	2 (1–3) [0–32]	2 (1–3) [1–72]	0.16

Demographic variables: data are shown as mean with 95% CI and range unless otherwise stated.

*Described by median with (25th and 75th) percentiles and [range]. †Indicates motor function assessment *versus* no assessment for the respective arthroplasty type.

anesth = anesthesia; ASA = American Society of Anesthesiologists; BMI = body mass index; LOS = length of stay; op = operation; spinal vol = injected volume of 0.5% bupivacaine; THA = total hip arthroplasty; TKA = total knee arthroplasty.

designed a noninferiority study with a two-sided 95% significance level, 80% power, and a noninferiority level of 5%, resulting in a sample size of 2 × 725 patients, with an aim of 1,500 patients to adjust for loss to follow-up.

Changes to the Power Calculation after Study Start. The original power calculation was changed in April 2015 from the original 2 × 711 patients based on data from May 2014, where the primary outcome occurred in 87.5%. The change from the original 90-day follow-up was made for the study to be in accordance with relevant outcomes from our previous data.[28] The new power calculation was based on analysis of the LCDB and, as such, isolated from the study data. The new power calculation was performed because the background cohort could have changed during the period from the first power calculation due to changes in clinical protocols, *etc*. The analyst was blinded to the collected data throughout the study period. The new power analysis was not part of the protocol, nor was any stopping rule formulated.

Statistics. A noninferiority analysis was chosen to assess whether discharge criteria affected the primary outcome, and data are presented for each group and the effect size by OR and one-sided 95% CI, with a 5% significance level (chi-square test). Other data are presented with a superiority design and descriptive statistics and including mean or median and two-sided 95% CIs or percentiles and range where appropriate. Differences in the frequencies of adverse events are presented as group incidences with two-sided OR and 95% CI and *P* values with a 5% significance level, tested by chi-square test. Univariate analyses were performed for continuous data by Student's *t* test (if normally distributed as per the Kolmogorov-Smirnov test) or by nonparametric tests (Mann–Whitney U test) if not normally distributed. Data were analyzed with SPSS statistics version 22 software (IBM Corp., USA).

Results

A total of 2,317 patients were screened, 1,511 patients included in the study, and 1,376 were randomized, of whom 17 were excluded, leaving 1,359 patients for final analysis (98.8% 30 days' follow-up). Inclusion and reasons for exclusion are detailed in a CONSORT (Consolidated Standards of Reporting Trials) flowchart (fig. 1). Thus, 670 and 689 patients were analyzed from the MFA and NMFA groups, respectively, without any significant ($P > 0.28$) differences in demographics or intraoperative characteristics between groups (table 2). A total of 1,269 patients were rated as ASA I to II (93.4%), 90 (6.5%) patients as ASA III, and 1 as ASA IV (0.1%). The study took place starting from June 2014 with the last follow-up in December 2015, with an additional 4 months' confirmation of 30-day readmission causes, resulting in the final dataset being available for analysis in April 2016.

Primary Outcome

A successful fast-track course occurred in 92.2% *versus* 92.0% in the MFA and NMFA groups, respectively ($P = 0.92$). The OR comparing the occurrences NMFA and MFA was 0.97 (95% CI, 0.70 to 1.35), which did not cross the specified boundary of 0.68, establishing the noninferiority of NMFA *versus* MFA (fig. 2). In detail, LOS greater than 4 days occurred in 60 cases, corresponding to 3.6% and 5.2% ($P = 0.14$) in the MFA and NMFA groups, respectively (see Supplemental Digital Content 1, http://links.lww.com/ALN/B415). Reasons for LOS greater than 4 days were "surgically" related in 11 patients (5 control, 6 intervention), and "medically" related in 22 patients (9 control, 13 intervention), with 27 patients without chart details for LOS greater than 4 days (10 control, 17 intervention) (see Supplemental Digital Content 1, http://links.lww.com/ALN/B415). Median LOS was similar between the MFA and NMFA groups (2.0 [25th to 75th percentiles 1 and 2 days, range 0 to 32] *vs.* 2.0 days [25th to 75th percentiles 1 and 2 days, range 0 to 78], $P = 0.42$, table 2).

Readmission during the first 30 days was seen in 54 cases, occurring in 4.6% and 3.3% ($P = 0.37$) in the control and intervention groups, respectively. Reasons for readmissions were "surgically" related in 23 patients (13 control, 10 intervention) and "medically" related in 31 patients (18 control, 13 intervention) (see Supplemental Digital Content 1, http://links.lww.com/ALN/B415). There was one death due to unspecified cardiac arrest (control group) during the 30-day follow-up. Thus, 0.3% of patients had both a LOS greater than 4 days and readmission within the first 30 days. There were no significant differences in LOS or readmissions frequencies among the five participating centers ($P > 0.23$).

Secondary Outcomes

Adverse events in the ward during the first 24 h postspinal anesthesia occurred in 39 of 670 (5.8%) *versus* 51 of 689 (7.4%) patients in the MFA *versus* NMFA groups, respectively (OR, 0.77; 95% CI, 0.5 to 1.19; $P = 0.24$) (table 3). Pain resulting in the need for a physician consultation (*i.e.,* moderate/severe pain not treated sufficiently by multimodal or PRN analgesics) was the most frequent reason (40.0% of events, occurring in 2.6% of the total population) of all the 90 adverse events in the ward (fig. 3) followed by cardiovascular (16.6%) and cerebral (16.6%) causes. Combined cerebral and cardiovascular events occurred in 13 of 670 (1.9%) *versus* 17 of 689 (2.5%) of the control and intervention group, respectively (OR, 0.78; 95% CI, 0.42 to 2.65; $P = 0.44$). A total of 79.4% of the adverse events occurred more than 6 h postspinal anesthesia (fig. 4), when the majority of patients normally would have been discharged from the PACU, as 646 of 670 (96.4%) of control patients were discharged less than 6 h postspinal anesthesia. Excluding adverse events due to pain meant that 43 of 54 (79.6%) of all other events occurred more than 6 h postspinal anesthesia (see Supplemental Digital Content 2, http://links.lww.com/ALN/B416, for details on all events).

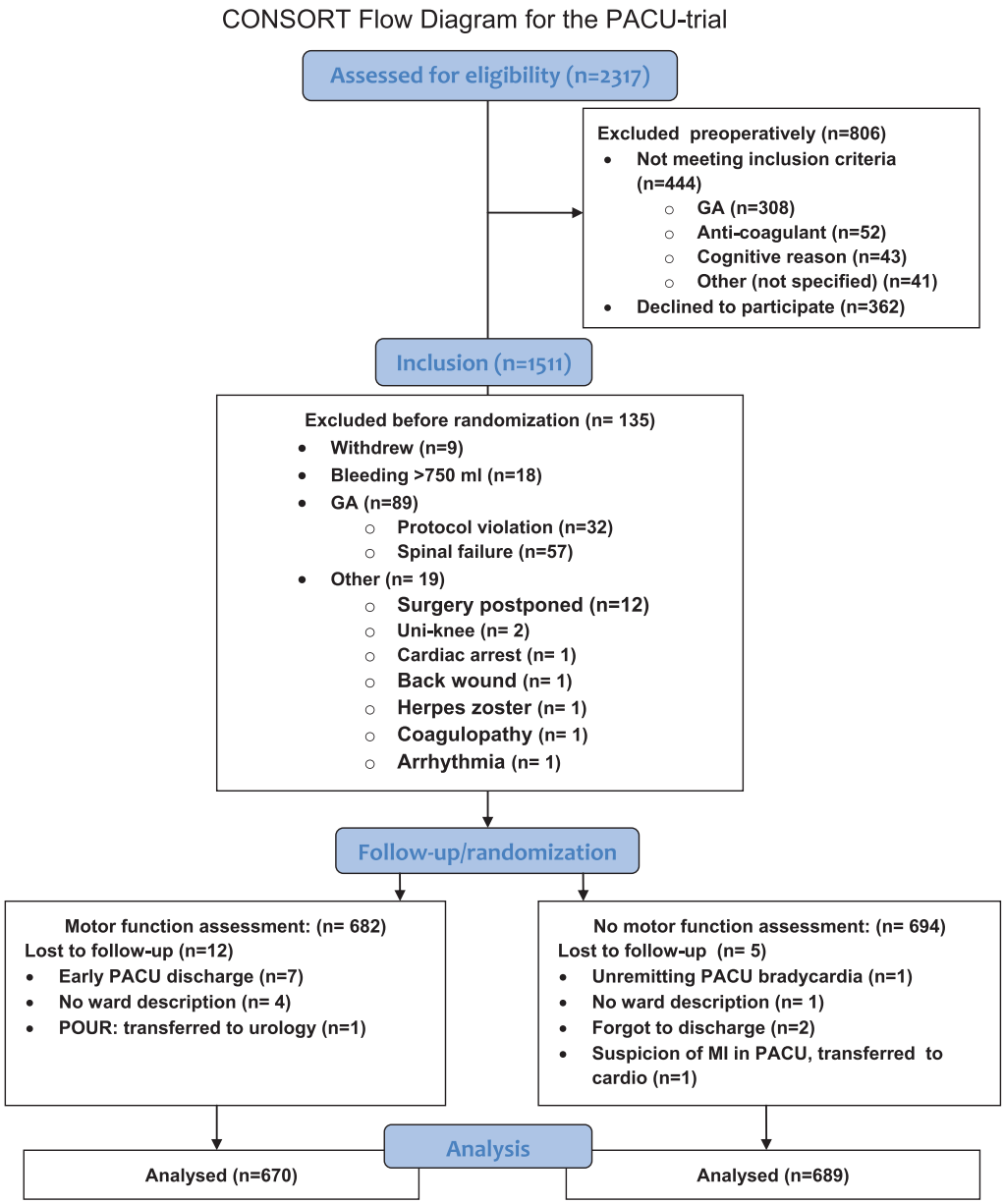


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the postanesthesia care unit (PACU) trial. GA = general anesthesia; MI = myocardial Infarction; POUR = postoperative urine retention.

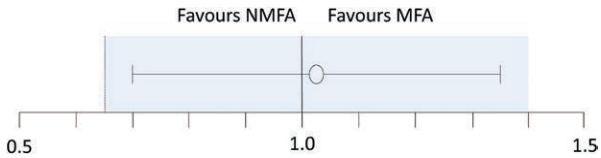


Fig. 2. Odds ratios (ORs) with 95% CI comparing the overall occurrence of a successful fast-track course after total hip arthroplasty or total knee arthroplasty under spinal anesthesia, between patients discharged after motor function assessment (MFA) or no motor function assessment (NMFA). *Vertical line* at OR = 0.68 indicates noninferiority margin. *Gray-tinted region* indicates values where NMFA would be considered noninferior to MFA.

Time in PACU was reduced significantly in the intervention group compared with the control group (mean 0:40 h; 95% CI, 0:37 to 0:42 h *vs.* 1:56 h; 95% CI, 1:51 to 2:01 h, respectively; $P < 0.001$). This was found for both surgical procedures: THA (0:30 *vs.* 2:00 h, intervention *vs.* control, respectively; $P < 0.001$) and TKA (0:35 *vs.* 1:30 h, intervention *vs.* control, respectively; $P < 0.001$). As seen in figure 5, the difference was even more pronounced in the 25% of patients with the longest PACU stay in the two groups (75th percentile THA: 2:48 *vs.* 0.49 h, and 75th percentile TKA: 2:2 *vs.* 0.45 h, control *vs.* intervention, respectively).

Patients Undergoing THA and TKA

A total of 727 patients undergoing THA and 632 patients undergoing TKA were included in the final analysis, with 53.4% and 53.6% patients undergoing THA in the control and intervention group, respectively (table 2). Patients undergoing THA and TKA were similar with respect to age, intrathecal bupivacaine volume, and ASA physical status but significantly different with regard to time in PACU, body mass index (BMI), sex, blood loss, surgery, and anesthesia time (all $P < 0.001$) (table 2; fig. 5).

For patients undergoing THA, a successful fast-track course occurred in 91.3% and 94.3% in the control and intervention groups, respectively (OR, 1.57; 95% CI, 0.89 to 2.79; $P = 0.12$). For patients undergoing TKA, a successful fast-track course occurred in 93.3% and 89.4% in the control and intervention groups, respectively (OR, 0.61; 95% CI, 0.34 to 1.07; $P = 0.08$).

Adverse events during the first 24 h after PACU discharge occurred in 7.4% *versus* 6.0% of patients undergoing THA and TKA, respectively (OR, 0.81; 95% CI, 0.52 to 1.25; $P = 0.34$). The distribution of adverse events was not significantly different between the two surgical procedures, although a trend toward increased cardiovascular and cerebral events in the THA *versus* TKA group was seen (21/727 [2.9%] *vs.* 9/632 [1.4%] of patients undergoing THA and TKA, respectively (OR, 2.06; 95% CI, 0.94 to 4.54; $P = 0.06$).

Table 3. Adverse Events in Ward during First 24 h Postspinal Anesthesia, MFA *versus* NMFA*

Adverse Event	MFA (n = 670)	NMFA (n = 689)
Cerebral	6	9
Respiratory	0	3
Circulatory	7	8
Pain	17	19
PONV	2	2
Hip/knee	1	3
Urologic/renal	2	3
Bleeding	2	2
Temperature	1	1
Miscellaneous	1	1
Total (of events, n = 90)	39 (43.3%)	51 (56.6%)
Total (of all patients, n = 1,359)	39 (5.8%)	51 (7.4%)

*Chi-square test: $P = 0.24$.

MFA = motor function assessment; NMFA = no motor function assessment; PONV = postoperative nausea and vomiting.

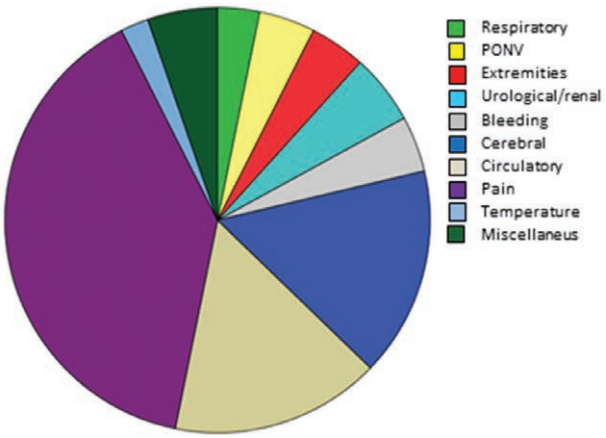


Fig. 3. Distribution of types of all 90 adverse events in the ward within the first 24 h after spinal anesthesia. PONV = postoperative nausea and vomiting.

Discussion

In this randomized, multicenter trial in an unselected patient population, we found PACU discharge after spinal anesthesia without assessment of lower limb motor function to be noninferior to motor function assessment in achieving LOS less than or equal to 4 days and/or readmission rate for the first 30 postoperative days. An increased rate (2%) of adverse events in the ward for the first 24 h was observed for patients randomized to no motor function assessment in the PACU, but the increased rate was not statistically significant in our population of 1,359 patients. Also, there were no significant differences in the occurrence of adverse events between patients undergoing THA and TKA. Finally, the trial showed that median PACU stay was reduced significantly by 1.25 h (0:40 h *vs.* 1:56 h) in the NMFA *versus* MFA group (2:00 and 1:30 h *vs.* 0:35 and 0:30 h for THA and TKA, respectively).

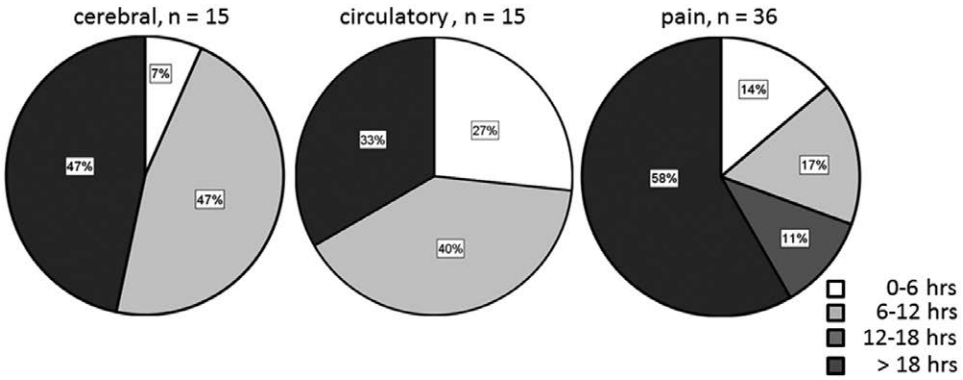
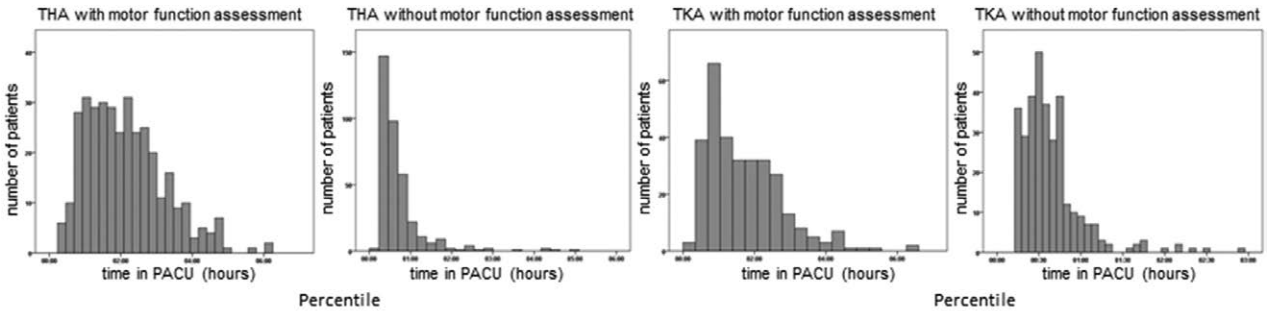


Fig. 4. Time between beginning of spinal anesthesia and occurrence of cerebral, circulatory, or pain-related adverse event in the ward in 1,359 patients undergoing operation for total hip or knee arthroplasty.



Percentile

	5th	10th	25th	50th	75th	90th	95th
MFA-group	0:43	0:50	1:15	2:00	2:48	3:40	4:15
NMFA-group	0:15	0:15	0:20	0:30	0:49	1:10	1:49

Percentile

	5th	10th	25th	50th	75th	90th	95th
MFA-group	0:30	0:40	0:52	1:30	2:20	3:01	3:40
NMFA-group	0:15	0:16	0:25	0:35	0:45	1:01	1:15

Fig. 5. Time in the postanesthesia care unit (PACU) in 1,359 patients undergoing operation for total hip arthroplasty (THA) or total knee arthroplasty (TKA) under spinal anesthesia, stratified into those discharged with (MFA) or without motor function assessment (NMFA), respectively.

The primary strength of this trial is the inclusion of unselected patients scheduled for spinal anesthesia, giving the trial result high external validity. Furthermore, we used standardized discharge criteria based on the commonly used Aldrete discharge criteria,[9,10] thus allowing for comparison with other trials. Follow-up was thorough and standardized in all patient phases during hospitalization (operating room, PACU, ward, and the LCDB) and *via* the DNPR after discharge, ensuring high data quality and a 100% follow-up of readmissions.[25] Thus, our detailed data on adverse events are gathered directly from patient records, which we consider more valid than using diagnostic codes.[29,30]

As with any clinical study, there are limitations. First, the planned spinal anesthesia was not possible to perform or was not sufficient for surgery in ~4% of patients (failed spinal anesthesia), but with a similar rate to the background literature,[20,31] and equally distributed between the two treatment groups. Second, due to the nature of the study, double blinding was not possible throughout the study; however, we aimed at minimizing bias by only revealing allocation at the time of discharge, whereas blinding assessments beyond PACU stay was not possible. Also, the relative large patient population and inclusion from five different centers is expected to have minimized any potential bias. Furthermore, during the data handling and manuscript process, treatment allocation was kept concealed to the relevant persons. Third, to identify cases in which adverse events resulted in LOS greater than 4 days or readmissions, the primary endpoint and formal power analysis was based on the definition of successful fast-track course, realizing that this may be considered an indirect measurement of serious adverse events. The safety aspect of early PACU discharge is a major issue in our study, and although not statistically significant in our population sample, we found a 2% increase in adverse events during the first 24 h in the ward. Realizing that there is no true acceptable "lower level" for serious adverse events (*e.g.*, any increased mortality), we chose to include detailed information on all adverse events occurring during the first 24 h postspinal anesthesia together with a complete 30-day follow-up from the DNPR including control over detailed pre- and intraoperative factors, to allow the readers to judge for themselves whether they will accept the outcomes in their institutions. Simply increasing the number of patients would not change the fact that some events are unacceptable no matter how frequent, and a larger sample size may result in a different frequency of adverse events; thus, we can only comment on the findings in the study population. Consequently, potentially larger studies are needed to confirm our findings. The observed increase in early adverse events, however, did not affect LOS or 30-day readmissions. Finally, because the majority of patients (~93%) were classified as ASA I to II, firm conclusions on the safety of early PACU discharge in patients with greater ASA physical statuses were not possible; however, according to the national recommendations, such patients already require physician assessment before discharge from PACU to the ward. Our data did not include specific concurrent disease data but instead included the ASA grading system of systemic diseases severity. Thus, our ~7% ASA III to IV patients is lower than other studies with up to 40 to 50% occurrence.[32,33] This finding may be explained by the lower occurrence of obese (BMI > 35, 6%) and morbidly obese patients (BMI > 40, 3%) in our cohort compared with other studies with 18% obese and 7 to 15% morbidly obese patients,[32,33] with an expected increased occurrence of associated diseases such as diabetes, cardiovascular, and pulmonary disease. Comparing the median BMI from large-scale data, however, we report our results apply to more than 70% of U.S. cases.[34] The cohort had an overall fast-track success rate of ~92%, greater than the expected 87% in the database at time of protocol planning. Without our being able to specifically explain this, several reasons are possible, including the ongoing focus in the Lundbeck database collaboration on optimization of outcomes, especially blood management and anemia,[35,36] and the exclusion of patients with preoperative potent anticoagulant treatment or an intraoperative blood loss greater than 750 ml.

Spinal anesthesia is still the preferred method of choice for THA and TKA, mainly due to the reported more favorable

morbidity profile compared with general anesthesia.[37,38] Specifically for THA and TKA, however, these recommendations are mainly based on studies that use older outdated anesthesia and analgesic techniques[6] or from large-scale database studies with potential bias from treatment stratification, calling for large-sized randomized controlled trials of spinal *versus* general anesthesia in relevant risk patients for adverse outcomes.[7,39,40]

Our trial suggests that clinically significant reductions in PACU time (hours) can be achieved by not requiring regained motor function before PACU discharge, without increasing the risk for adverse events during the first 30 postoperative days. This finding is in accordance with a previous small-scale study.[8] Apart from informing the wards of the study start, no change in observation and treatment at the wards was introduced, as it also is standard to test the lower limb strength of the patients before mobilizing them in discharges after observation for motor function because of the fact that flexion of the knee does not necessarily translate into the ability to stand or walk. In the present study population, we were able to describe when adverse events occurred stratified by type. Thus, the finding that more than 75% of events classified as cerebral or circulatory occurred more than 6 h after the spinal anesthesia and that more than 96% of patients were discharged earlier from the PACU, even in the control group, supports that most incidences were independent of the spinal anesthesia and PACU discharge time. Despite the significant reduction in PACU time, our cohort still had longer stays than reported by the two earlier studies,[8,16] which may be due to the unselected patient population, including patients with comorbidities.

Because THA and TKA are major contributors to healthcare expenditures,[1] optimal use of resources[41] and understanding the types and frequency of adverse events and potential risk factors are important for optimizing post-PACU function and allocation of resources to the wards if necessary. Our findings may not only be reserved for THA and TKA but potentially could be transferred to other orthopedic, abdominal, urologic, or gynecologic procedures with substantial impact on PACU hours and healthcare resources. Within the context of healthcare cost savings, it is important that the care burden is not shifted to the ward.[42] Although we did but not investigate this specifically in our trial, the majority of adverse events occurred more than 6 h after spinal anesthesia, when the patients normally would have been in the ward, and without significant differences between MFA and NMFA groups. Furthermore, the severity of the observed adverse events related to orthostatic intolerance, bleeding, hypotension, and respiration requires that later complications need to be explored in detail beyond the 24 h to guide ongoing efforts on the feasibility of same-day surgery[18,19] and challenges in the subacute postdischarge period.[43]

In conclusion, PACU discharge without assessment of lower limb motor function after spinal anesthesia for THA/TKA did not increase the LOS greater than 4 days or 30-day readmissions but significantly reduced time in PACU.

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Competing Interests

The authors declare no competing interests.

Reproducible Science

Full protocol available at: eske.kvanner.aasvang.01@regionh.dk. Raw data available at: eske.kvanner.aasvang.01@regionh.dk.

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