

Study protocol for discharge on day of surgery after hip and knee arthroplasty from the Center for Fast-track Hip and Knee Replacement

Martin LINDBERG-LARSEN^{1,2}, Claus VARNUM^{1,3}, Thomas JAKOBSEN^{1,4}, Mikkel Rathach ANDERSEN^{1,5}, Kim SPERLING^{1,6}, Søren OVERGAARD^{1,7}, Torben Bæk HANSEN^{1,8}, Christoffer Calov JØRGENSEN^{1,9}, Henrik KEHLET^{1,10}, and Kirill GROMOV^{1,11}



Acta Orthopaedica

¹ Center for Fast-track Hip and Knee Replacement; ² Department of Orthopaedic Surgery and traumatology, Odense University Hospital and Svendborg; ³ Department of Orthopaedic Surgery, Lillebaelt Hospital–Vejle; ⁴ Department of Orthopaedic Surgery, Aalborg University Hospital; ⁵ Department of Orthopaedic Surgery, Copenhagen University Hospital, Herlev-Gentofte; ⁶ Department of Orthopaedic Surgery, Næstved, Slagelse and Ringsted Hospitals; ⁷ Department of Orthopaedic Surgery and Traumatology, Copenhagen University Hospital, Bispebjerg; ⁸ University Clinic for Hand, Hip and Knee Surgery, Hospital Unit West Jutland and Aarhus University; ⁹ Department of Anaesthesia, Hospital of Northern Zealand, Hillerød; ¹⁰ Section of Surgical Pathophysiology, Copenhagen University Hospital, Rigshospitalet; ¹¹ Department of Orthopaedic Surgery, Hvidovre University Hospital, Denmark

Correspondence: martin.lindberg-larsen@rsyd.dk

Submitted 2022-11-25. Accepted 2023-03-04.

Background and purpose — Limited data exists on the implementation process and safety of discharge on the day of surgery after primary hip and knee arthroplasty in a multicenter setting. We report our study protocol on the investigation of the feasibility, safety, and socioeconomic aspects following discharge on day of surgery after hip and knee arthroplasty across 8 fast-track centers.

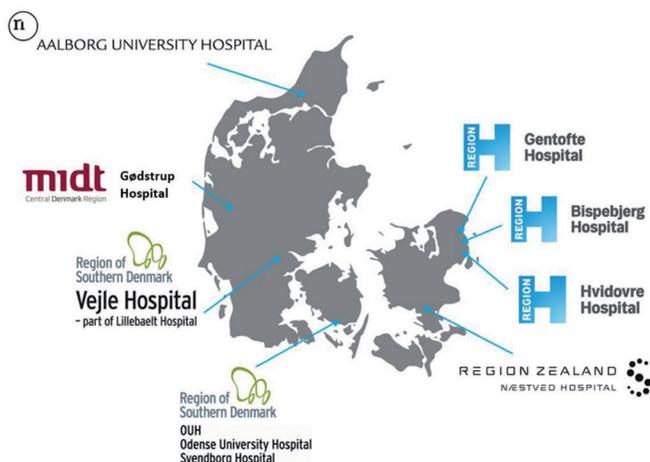
Patients and methods — This is a study protocol for a prospective cohort study on discharge on day of surgery from the Center for Fast-track Hip and Knee Replacement. The collaboration includes 8 centers covering 40% of the primary hip and knee arthroplasty procedures undertaken in Denmark. All patients scheduled for surgery are screened for eligibility using well-defined inclusion and exclusion criteria. Eligible patients fulfilling discharge criteria will be discharged on day of surgery. We expect to screen 9,000 patients annually.

Duration and outcome — Patients will be enrolled over a 3-year period from September 2022 and reporting of results will run continuously until December 2025. We shall report the proportion of eligible patients and patients discharged on day of surgery as well as limiting factors. Readmissions and complications within 30 days are recorded with real-time follow-up by research staff. Furthermore, patient-reported information on willingness to repeat discharge on day of surgery, contacts with the healthcare system, complications, and workability is registered 30 days postoperatively. EQ-5D, Oxford Knee Score, and Oxford Hip Score are completed preoperatively and after 3 months and 1 year. Finally, outcome data will be used in the development of a prediction model for successful discharge on the day of surgery.

Fast-track hip and knee arthroplasty is becoming the standard of care worldwide for selected patients. Studies have shown a reduction in perioperative morbidity and mortality (1), with a concomitant reduction in length of stay (2) and a reduction in costs (3) as functional discharge criteria are achieved earlier. Discharge on day of surgery can be seen as the ultimate goal of fast-track arthroplasty and has gained interest in an increasingly competitive financial environment (4,5). The COVID-19 pandemic has further fueled interest in discharge on day of surgery, as the number of beds available for elective surgery has been reduced, but the demands for hip and knee surgery were unchanged. This motivated shorter stay in hospital. Additionally, the need for optimal utilization of healthcare resources is evident (6,7).

Despite multiple studies showing that discharge on day of surgery after total hip arthroplasty (THA), total knee arthroplasty (TKA), and unicompartamental knee arthroplasty (UKA) may be both feasible and safe in selected patients (8–12), utilization of discharge on day of surgery remains low. Only 0.5% in the United Kingdom (13) and about 5% in Denmark (14) are discharged on the day of surgery after THA and TKA. Discharge on day of surgery after UKA is higher, at 5% in the United Kingdom (13) and 19% in Denmark (15).

There is a need for more detailed multicenter studies regarding selection criteria and patient safety (16). Thus, it is important to investigate whether discharge on day of surgery is possible without compromising patient satisfaction, functional outcome, and risk of complications. Likewise, it is important to investigate whether discharge on day of surgery is possible on a larger scale without increasing costs for the patient or the healthcare



The Centre for Fast-track Hip and Knee Arthroplasty. Participating centers from all 5 regions of Denmark.

system. Previous studies have been performed in dedicated centers, but protocols that standardize or prescribe criteria for patients for whom day of surgery discharge may be relevant and may help broader and safe adoption of this practice.

Aim

The proposed research project will determine the feasibility, safety, and socioeconomic aspects following discharge on day of surgery after primary hip and knee arthroplasty across 8 well-established fast-track centers in a socialized healthcare system in Denmark. The ambition is to increase the discharge on day of surgery after uniform multicenter introduction without compromising patient safety, satisfaction, and costs. In this perspective, we also present our current guideline for discharge on day of surgery.

Study protocol

Study design and organization

This is a study protocol for a prospective cohort study on discharge on day of surgery from the Center for Fast-track Hip and Knee Replacement, a multicenter collaboration consisting of 8 arthroplasty centers (17), covering approximately 40% of the annual hip and knee arthroplasty production in Denmark (Figure) (2). All centers follow the same guideline for discharge on day of surgery as described in this protocol. Prior to this project, only 3 (Odense University Hospital Svendborg, Lillebaelt Hospital—Vejle, Hvidovre University Hospital) of the 8 centers offered discharge on day of surgery, with up to 15% of all primary THA and TKA patients being discharged on day of surgery (10).

Center and staff education

An educational program was introduced for the 5 centers that had not implemented outpatient hip and knee arthroplasty sur-

Table 1. Inclusion and exclusion criteria for planned discharge on day of surgery

Inclusion criteria
<ul style="list-style-type: none"> • Unilateral elective primary THA, TKA, or UKA • Age 18–80
Exclusion criteria
<ul style="list-style-type: none"> • Acute myocardial infarction, cerebrovascular accident, transient ischemic attack, or coronary atherosclerotic disease within last 3 months • Unstable ischemic heart disease • Ejection fraction < 40% • Glomerular filtration rate < 60 mL/min/1.73 m² • Chronic obstructive pulmonary disease with home oxygen • Insulin-dependent diabetes mellitus • Sleep apnea requiring mechanical treatment • Clinical Frailty Scale ≥ 4 (35) • 2 or more falls within last 3 months • Body mass index < 18.5 or > 40 • Not interested in discharge on day of surgery

gery prior to study initiation. The program was cross-sectional and included education of all involved healthcare professionals at the centers and a written professional instruction. Instructions and teaching resources were available from the 3 centers with an already established outpatient program and education also included multidisciplinary visits to these centers.

Study period and number of participants

Outpatient surgery according to this protocol is implemented at the 8 participating centers from September 1, 2022. Inclusion of patients and reporting of results will run continuously until the end of 2025. We expect to screen approximately 9,000 patients and schedule about 3,000 patients for discharge on day of surgery annually.

Study participants and eligibility criteria

Patients scheduled for hip and knee arthroplasty at the 8 participating centers will be included in a database after informed consent. Inclusion and exclusion criteria for planned discharge on day of surgery are presented in Table 1. The chosen criteria were based on previous data from outpatient surgery (10,18) as well as our previous multicenter data on risk of complications after fast-track hip and knee arthroplasty (2).

Outpatient visit and preoperative phase

All patients scheduled for primary unilateral THA, TKA, or UKA at participating centers are screened for potential discharge on day of surgery according to the inclusion and exclusion criteria (Table 1). Patients fulfilling inclusion criteria will be informed about potential discharge on day of surgery. Preoperative blood samples including hemoglobin, C-reactive protein, creatinine, and electrolytes are taken, as well as blood glucose and HbA1c in diabetic patients.

Operation scheduling

If possible, patients eligible for discharge on day of surgery

are scheduled for surgery as the first patients on the operation program with intended start of surgery before 1 p.m.

Surgery and anesthesia

All patients receive high-dose glucocorticoids preoperatively (24 mg dexamethasone or 125 mg methylprednisolone) except insulin-dependent diabetic patients (19–22). 1 gram of tranexamic acid is administered intravenously during surgery in all patients and may be repeated 3–4 hours postoperatively (23,24). Patients are operated on according to a standard protocol of the individual center. Local anesthesia with minimum 150 mL ropivacaine 2 mg/mL is used in knee arthroplasties but not in hip arthroplasties (25). Both general anesthesia and spinal anesthesia may be used (26). For spinal anesthesia a relatively short-acting blockade with, e.g., ropivacaine 5 mg/mL, 3–4 mL or Marcaine 5 mg/mL 2–2.5 mL is recommended to facilitate early mobilization within 2 hours postoperatively. Peripheral nerve blocks are not used routinely (27).

Postoperative pain management and other medication

Multimodal opioid-sparing postoperative analgesics including paracetamol (1 g x 4), nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (400 mg x 3/4), or COX-2 inhibitors such as celecoxib (200 mg x 2) will be used except in cases where contraindicated. Opioids of any kind are used only as rescue treatment and opioids with depository effect are not used routinely. Medication with paracetamol and NSAIDs is initiated 1–2 hours preoperatively as premedication (28,29). Furthermore, antiemetics and laxative treatment are provided postoperatively for rescue use.

Antibiotic prophylaxis

Antibiotic prophylaxis is administered 30–60 minutes preoperatively at all sites with either cloxacillin 2 g IV or cefuroxime 1.5 g IV according to local microbiological guidelines. For knee surgery, 1 additional dose (1 g cloxacillin or 1.5 g cefuroxime) is administered within 6 hours postoperatively before discharge. For hips, a protocol for a national randomized controlled trial (ProHipQ-OA, NCT05530551) is followed comparing only preoperative prophylaxis with preoperative prophylaxis plus repeated doses 6, 12, and 18 hours postoperatively (first postoperative dose IV and the remaining doses as tablets).

Postoperative thromboprophylaxis

Postoperative thromboprophylaxis is administered once 6 to 10 hours after surgery using rivaroxaban (Xarelto 10 mg, Bayer Pharma, Berlin, Germany) or apixaban (Eliquis 5 mg, Bristol-Myers Squibb, Princeton, NJ, USA) (30).

Postoperative mobilization and discharge

All patients are intended to be mobilized < 3 hours following end of surgery with full weightbearing.

Table 2. Criteria for discharge on day of surgery

Discharge criteria
Activity level <ul style="list-style-type: none"> Steady gait with crutches No dizziness during mobilization Can use stairs, if required by participant's home environment
Postoperative nausea and vomiting (PONV) <ul style="list-style-type: none"> Minimal and efficiently treated with or without medication
EWS^a < 2 <ul style="list-style-type: none"> Patients with EWS ≥ 2 must be discussed with a doctor prior to discharge
Pain <ul style="list-style-type: none"> Numeral rating scale (NRS) [0–10, with 0 being no pain and 10 being the worst pain imaginable] <ul style="list-style-type: none"> NRS < 3 at rest NRS < 5 when walking 5 meters Or otherwise acceptable level of pain assessed by the participant regardless of NRS score
Postoperative bleeding <ul style="list-style-type: none"> Should be consistent with expected blood loss for this procedure and not require repeated dressing change
^a EWS = national implemented Early Warning Score systems based on NEWS2 from the Royal College of Physicians (36).

Patients fulfilling discharge criteria will be discharged to their own home. Discharge criteria are presented in detail in Table 2. All patients receive instruction in rehabilitation exercises before discharge.

Knee arthroplasty patients receive supervised rehabilitation 1–2 times a week for 2–3 months postoperatively in their local municipality, except for 1 center where it is only offered to selected knee patients. Hip arthroplasty patients do not routinely receive supervised rehabilitation postoperatively after discharge. The use of postoperative consultations in the outpatient clinic varies among centers.

Database

All data is collected in a REDCap database in collaboration with the Open Patient data Explorative Network (OPEN) in Odense University Hospital. Data includes patient-reported data from questionnaires filled in online or on paper according to preference. Furthermore, additional detailed data from patient files on patient comorbidities, medications, and blood samples is registered by dedicated research staff (nurses and physiotherapists) with physician back-up if necessary.

Preoperative data

Detailed patient-reported data on patient characteristics including Clinical Frailty Score, medical comorbidities, social status, workability, and living conditions is registered by the patients preoperatively with help from research staff if necessary. Furthermore, patient-reported outcomes (joint specific and generic) as well as a Pain Catastrophizing Scale are achieved through questionnaires filled in by the patients preoperatively. Preoperative medication is registered from medical charts and categorized according to indications by research

Table 3. Outcomes

<p>Feasibility</p> <ul style="list-style-type: none"> • Proportion and characteristics of patients eligible and not eligible for discharge on day of surgery • Analysis of reasons for not being eligible for discharge on day of surgery • Number and proportion of patients discharged on day of surgery (proportion both of total patients and of eligible patients) • Reasons for not fulfilling discharge criteria (analysis on total cohort and on center level) <p>Patient safety</p> <ul style="list-style-type: none"> • Readmissions and complications within 30 days with complete and real-time follow-up secured by research staff at the individual centers. Complications will be scored using the Clavien–Dindo and Comprehensive Complication Index <p>Contacts with healthcare system</p> <ul style="list-style-type: none"> • Data from a tailor-made questionnaire on all admissions, readmissions, outpatient visits, emergency room visits, and general practitioner visits within 30 days postoperatively (all contacts with the healthcare system) <p>Willingness to repeat</p> <ul style="list-style-type: none"> • Patient-reported information on willingness to repeat discharge on day of surgery if scheduled for hip and knee arthroplasty again <p>Patient-reported outcomes</p> <ul style="list-style-type: none"> • EQ-5D, Oxford Knee Score and Oxford Hip Score preoperatively and after 3 months and 1 year

staff. Data on preoperative blood samples including hemoglobin, creatinine, glomerular filtration rate, and C-reactive protein is registered by research staff. Preoperative blood samples are taken, and data is registered in the database as close to surgery as possible and maximum 2 months before.

Outcomes

Postoperative outcomes will also be registered in the database using a combination of chart review, by research staff, using the electronic healthcare records and a patient-reported questionnaire sent out 30 days postoperatively. Specific reasons for not being discharged on day of surgery are registered in patients not discharged on day of surgery despite being scheduled for it. Registration of severity of postoperative complications leading to a primary admission > 2 days or readmissions to hospital within 30 days after surgery is done using the Clavien–Dindo and Comprehensive Complication Index (31). Outcomes are listed in Table 3.

Dissemination plan

The reporting of results is planned to be divided into 4 parts:

1. Implementation of discharge on day of surgery after hip and knee arthroplasty

Main aim: to investigate the implementation process and feasibility of outpatient THA, TKA, and UKA in centers with well-established fast-track pathways in a public healthcare system.

Primary outcome: percentage of patients discharged on the day of surgery 6 months after implementation (March 1, 2023) in total and in each center, compared with baseline.

Secondary outcome: to describe barriers in the implementation process in total and on center level.

2. Safety of discharge on day of surgery after hip and knee arthroplasty in a multicenter setting

Main aim: to investigate complications and readmissions within 30 days in patients eligible for outpatient surgery discharged on day of surgery, compared with eligible patients not discharged on day of surgery in the same period, as well as baseline controls.

Primary outcome: readmission risk within 30 days after surgery.

Secondary outcomes: all postoperative complications (scored using Clavien–Dindo and Comprehensive Complication Index) and all other contacts with healthcare system including general practitioner and outpatient visits within 30 days.

3. Prediction of successful discharge on day of surgery

Main aim: development of a prediction tool for discharge on the day of surgery.

Outcomes: risk factors for unsuccessful discharge on day of surgery despite fulfilling inclusion criteria.

4. Socioeconomic analysis of discharge on day of surgery

Aim: to investigate impact on the costs per patient of implementation of discharge on day of surgery after hip and knee arthroplasty on a national level.

Estimation of costs per patient will include the costs related to the following outcomes:

- all contacts with the healthcare system within 30 days postoperatively;
- use of home nurses from the municipalities and other community health services;
- duration of sick leave related to the surgical procedure;
- patient-reported outcome (function and health status);
- patient-reported willingness to repeat discharge on day of surgery;
- changes in workflow and potential reduction in use of hospital beds.

Statistical analysis plan

In this large-scale prospective cohort study, we address multiple outcomes. For most outcomes an observational before–after research design will be used to assess the impact of discharge on day of surgery. Baseline data from the Danish National Patient Registry (32) at the participating centers from 2019 and 2020 (pre-COVID status), will be used as a baseline control in most sub-studies. Furthermore, eligible patients not discharged on day of surgery and patients not eligible for discharge on day of surgery will be used as control groups where appropriate according to outcome. Most outcomes will be presented as proportions with 95% confidence intervals. In the analysis of risk factors for unsuccessful discharge on day of surgery, a multivariable logistic regression model will be

used. Furthermore, we will use machine learning on preoperative data to develop a tool for future selection of patients best suited for discharge on day of surgery (33).

To ensure the feasibility of the study within the planned study period, preliminary power calculations for the main aims of the overall study have been performed. For discharge on day surgery, a conservative estimate is a 10-percentage point increase (from 5% to 15%). To detect this, a sample size of 266 patients in each group is needed using 90% power and 5% alpha. For risk of readmission \leq 30 days after discharge on day of surgery, 1,411 patients are needed in the study group as well as the control group to be able to detect a potential difference of 3 percentage points (from 5% to 8%) using 90% power and 5% alpha. With the expected inclusion rate, the study is very feasible and reporting on all outcomes is possible within the study period.

Patient involvement

Patients and relatives are involved in the whole research process. The posed research questions have been prepared in collaboration with the patients and relatives council at the Orthopaedic Research Unit, Odense University Hospital. The patient-reported parts (questionnaires) of the fast-track database have been tested by patients and relatives and modified. Reporting of results and status of the research project will be continuously reported on our website and accessible to participants in the study and patients in general. Finally, we have planned annual workshops with patients and relatives from different centers in order to receive their input.

Ethics, registration, funding, and disclosures

Consecutive patients are included in the database after informed consent. Ethical approval was not necessary because treatment of eligible patients using discharge on day of surgery is standard of care at the participating centers according to the described guideline. This trial is registered in Region of Southern Denmark and data processing is approved (Journal No 22/39454). The study is also registered on ClinicalTrials.gov (NCT05613439).

In 2021, the collaboration received funding from the NOVO Nordisk foundation (Grant number: NNF21SA0073760) to support the organizational setup for the entire fast-track project including dedicated research staff at all centers, data monitoring and follow-up on complications. The “discharge on day of surgery project” is part of the entire fast-track project.

The authors are members of the steering committee of the Centre of Fast-track Hip and Knee Arthroplasty and report no conflicts of interest regarding this project. HK and KG are members of the Zimmer Biomet advisory board on rapid recovery. Completed disclosure forms for this article following the ICMJE template are available on the article page, doi: 10.2340/17453674.2023.11636

Discussion

Clinical impact

Some 22,000 patients are treated with a primary hip or knee arthroplasty annually in Denmark. Mean length of hospital stay after these procedures is 1–2 days, but less than 5% are discharged on the day of surgery (14). It may be possible to increase the proportion of patients discharged on day of surgery to about 30% with continued high patient satisfaction and high patient safety. However, this requires an evidence based high-quality protocol, a well-established multicenter collaboration, and publication of the entire research process.

The planned studies on this project are clinically relevant and necessary as previous studies on the feasibility of outpatient hip and knee arthroplasty are based on data and experiences from a few dedicated centers (9-12,34). Previous large-scale register-based studies show that the use of outpatient surgery may be safe, but the use of the concept varies between centers and safety was analyzed based on procedure and diagnosis codes and not on prospectively collected data (13,15). Hence, prospective multicenter consecutive cohort studies from a public socialized healthcare system including detailed standardized information on preoperative patient characteristics and postoperative complications, costs, and patient satisfaction are needed in order to evaluate generalizability and safety of discharge on day of surgery.

Strengths and limitations

This is a pragmatic study reflecting clinical practice as it is countrywide in both university and regional hospitals, thus increasing the generalizability of the findings. There is a short distance from research to actual clinical implementation, as shown before in the center collaboration. Hence, the study should be very feasible. Finally, the standardization of postoperative complications requiring hospitalization by using the Clavien–Dindo and Comprehensive Complication Index will provide an easily comparable measure reflecting both clinician and patient perspectives on severity.

A limitation of a multicenter study may be slight differences in logistics between centers. Furthermore, adherence to study protocol and guideline may vary among centers as many individuals are involved in patient treatment at 8 centers.

Future perspective

This study will show to what extent discharge on day of surgery after hip and knee arthroplasty can be implemented across multiple centers in a socialized healthcare setting. The safety and patient-related aspects of such an implementation will be investigated and disseminated. This study will allow for improvement of patient selection for discharge on day of surgery, as patients not fulfilling the criteria for discharge on day of surgery will be identified and analyzed. The findings from the study will lead to an updated guideline for discharge on day of surgery.

Importantly, if it is possible to increase the frequency of patient discharge on day of surgery without compromising patient outcome using a well-defined guideline, this could be replicated and adapted worldwide and potentially in other parts of the healthcare system. In this way, the increasingly limited hospital resources can be used for the patients needing them most.

All authors are members of the Center for Fast-track Hip and Knee Replacement steering committee. The study protocol and guideline were planned at steering committee meetings. MLL, CV, and KG wrote the primary draft of the manuscript and led the discharge on day of surgery project within the collaboration. All authors reviewed the manuscript. MLL, KG, CV, SO, KS, MRA, TBH, and TJ are representatives from each of the 8 participating centers.

Handling co-editors: Bart Swierstra and Philippe Wagner
Acta thanks Justine Naylor and Annette W-Dahl for help with peer review of this study.

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