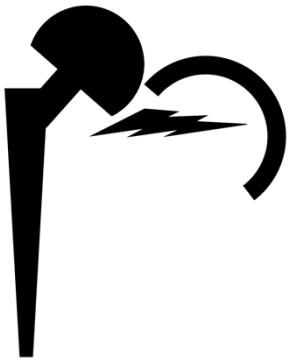
Protocol

"A **Q**uick pathway for patients with high p**R**obability of dislocat**E**d hemi- or total hip arthroplasty to minimize the time from hospital a**D**mission to red**UC**tion of the prosth**E**sis"



*the **Q-REDUCE** study*

- a prospective cohort trial

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Background:

Most patients undergo elective total hip arthroplasty (THA) due to primary osteoarthritis (OA) (80%). The remaining 20% are indicated by secondary arthritis as a consequence to earlier fracture surgery, hip dysplasia, rheumatism or tumors (1). Additionally, hip replacements are also performed in acute cases such as displaced femoral neck fractures, in which hemiarthroplasties (HA) often are preferred as opposed to THAs, depending on the surgeon's preference and skills. The patient categories differ significantly, with the acute fracture patients being older and more comorbid, thereby more fragile (2). Annually, 10,500 THAs and 2,100 HAs are implanted nationally, while the count is 2,100 THAs and 550 HAs in the Region of Southern Denmark (1, 3).

Despite being a highly successful procedure in terms of both safety and patient satisfaction, complications after hip replacements do still occur (4). One of the most common complications and reason for hip revisions is hip dislocation. After THA, it occurs in 3,5% of primary OA patients within the first two postoperative years, while the incidence is higher in other patient categories, e.g. fractures (2, 5, 6). The risk of dislocation after HA is reported between 6% - 11% (7, 8).

The dislocated prosthesis is usually managed by a simple, closed reduction maneuver under general anesthesia with or without muscle relaxation, resulting in open surgical reduction rarely being needed (9-11). Time from admission to actual reduction often includes various steps (incl. several patient transfers between emergency units, radiology departments, operating theaters) which causes an unnecessarily long period of pain for the patient. In 2015, a fast-track system was introduced at Hvidovre Hospital on a trial basis for patients highly suspected for THA/HA dislocation (12). This resulted in a significant decrease in the time from arrival to reduction and overall time of hospitalization, without resulting in more complications. The study was retrospective and did not measure how patients experienced the change in practice.

A fast-track system must be specially designed for the local departments, due to differences in the logistical options from hospital to hospital. The purpose of this study is to design a fast-track pathway for patients referred to the University Hospital of Southern Denmark, Esbjerg, with high probability of having a dislocated hip prosthesis with the primary aim to reduce the time from arrival to reduction and the total hospitalization time. Secondary aims are to

- investigate whether quicker prosthesis reduction influences on hip function and quality of life afterwards
- reduce the pain experience immediately and in the long term
- increase patient satisfaction

without changing the overall complication rate and readmission/mortality

Methods:

Trial design

The study is designed as a prospective observational cohort trial, adhering to the STROBE guidelines (13). The present protocol will be registered at *clinicaltrials.org* and submitted for publication in an international journal.

Setting

The study is conducted at the University Hospital of Southern Denmark, Esbjerg, as a collaboration between the Department of Orthopedics, Department of Anesthesiology, Department of Radiology, and Department of Emergency.

The study is planned to start September 1st, 2024, and will continue for two years. During the first year, the admitted patients will follow the current standard treatment pathway. After September 1st, 2025, a newly developed treatment pathway will be adhered to, and for the rest of the protocol, this pathway is described as the Fast-track pathway, as the expectation is that treatment strategy will shorten time to reduction.

All patients admitted with a dislocated THA or HA will be included in the study without prior informed consent. The patients are – disregard of cognitive status – admitted with a complication that requires acute treatment. After the acute treatment (reduction of the dislocated prosthesis), the patients are informed about the study and encouraged to participate in the second part of the study (see outcome section).

Participants

Inclusion criteria: All adult patients admitted to the Department of Emergency Medicine (Dept. of EM), University Hospital of Southern Denmark, Esbjerg, for suspected dislocated hip prosthesis who fulfills the following

- age > 18 years
- a history of either a THA or a HA in combination with at least one of the following terms:
  - having sustained a sudden, incorrect movement or twist in the hip joint in either a bending, sitting or supine position leading to inability to stand or walk
  - misalignment of the concerned lower extremity (typically shortened, with inward/outward rotation)

Exclusion criteria: Patients with

- recurrent dislocations during the same hospital admission (already "in the house")
- anticipated difficult airway by the attending anesthesiologist
- anticipated need for extended respiratory or hemodynamic monitoring by the attending anesthesiologist
- American Society of Anesthesiologists (ASA) score > 3
- Body Mass Index (BMI) > 40
- active drug abuse
- contraindication for Propofol or Esketamine

Intervention

Referred patients will follow either the standard pathway or a newly developed fast-track pathway, specifically designed with regard of the local logistics and structure at the Dept. of EM, University Hospital of Southern Denmark, Esbjerg.

Patient reported to the coordinating nurse at the Department of Emergency Medicine, fulfilling the inclusion criteria's, without violating exclusion criteria's	
Standard Pathway (September 2024 - August 2025)	**Fast-track Pathway** (September 2025 - August 2026)
Patient arrival through the ambulance entrance	Patient arrival through the ambulance entrance
Patient admitted to the Dept. of EM ward (Team 1 or 2), and transferred to a regular, standard patient bed	Patient is delivered directly to emergency trauma room no. 4 (located in conjunction of the ambulance entrance), and transferred to a radiolucent trauma bed
Patient is seen by the delegated nurse; vital parameters measured and registered, together with patient information	The orthopedic doctor AND the anesthesiologist on duty is notified and will arrive to the trauma room at their earliest convenience, depending on other acute activities
Patient is examined by one of three doctors on duty from the Dept. of Orthopedics, when	Patient is seen by the delegated nurse; vital parameters measured and registered, together with patient information, and X-ray is ordered

available (varying degree of education), and X-ray is ordered	
Patient is moved to the X-ray room (same floor level), (transfer to a special X-ray bearing is required) and will be returned to the bed ward	The diagnosis is verified by X-ray on site, by transportable X-ray machine, carried out by the radiology staff, *without the need for patient transfer*
Diagnosis is verified and the patient's medical files is updated	Patient's medical files is updated by the orthopedic doctor on duty (*a standard paragraph will be developed for quick documentation in the medical records*)
Patient is booked for a closed reduction maneuver in the operating theater during a short general anesthesia	The anesthesiologist on duty prepares for local sedation, following the sedation algorithm designed for this study, assisted by an anesthesiology nurse
Patient is reported to the anesthesiologists on duty for the purpose of planning and preparation for the anesthetic procedure	Closed reduction is completed, and control X-ray is conducted immediately on site, by transportable X-ray machine, carried out by the radiology staff, *without the need for patient transfer*
Patient is transferred to the operating theater, depending on other surgical activities and fasting time	Patient is transferred to the Dept. of EM ward
Closed reduction is completed during a short general anesthesia, often with simultaneous muscle relaxation. Patient is transferred back and forth to a surgical bearing to confirm reduction, using a C-arm X-ray (not useful for documentation)	Patient is seen by a physiotherapist and mobilized with/without walking aids
Patient return to the Dept. of EM bed ward	Patient is discharged with/without a planned outpatient follow-up by a hip surgeon, depending on the specific patient case
Patient is moved to the X-ray room for a control X-ray (same floor level), (transfer to a special X-ray bearing is required) and will be returned to the bed ward	
Patient is seen by a physiotherapist and mobilized with/without walking aids	

Patient is discharged with/without a planned outpatient follow-up by a hip surgeon, depending on the specific patient case	

Assumed fast-track advantages includes

- elimination of several patient transfers back and forth from the Dept. of EM bed ward to X-ray rooms and operating theater (saves ***time*** and ***hospital resources***)
- elimination of several patient transfers between different beds (reduces ***patient pain*** and ***discomfort***)
- hip reduction in sedation rather than general anesthesia disregard of fasting time,- safely administered by anesthesiologists rather than by the orthopedic (saves ***time,*** increases ***safety***)

Detailed description of standard anesthetic procedure for patients enrolled for standard pathway hip reduction (current practice)

Patients following the standard pathway and local guidelines, will receive a general anesthesia with a rapid sequence induction and intubation using Propofol 1-2 mg/kg, Alfentanil 0,2-0,3 mg/kg or Fentanyl 2-3 µg/kg and Suxamethonium 1 mg/kg. The patient is as a standard monitored with non-invasive blood pressure, saturation, pulse, 3-point ECG and end-tidal CO2. More extensive monitoring may be used if considered necessary by the attending anesthesiologist.

Detailed description of new fast-track sedation procedure for patients enrolled for fast-track hip reduction

The goal for the new fast-track sedation pathway is a short deep sedation, according to the definition of level of sedation by ASA (14). This is for optimal patient comfort and success and with very low risk of aspiration (15, 16). The patient is sedated with Propofol 0,5-1 mg/kg and/or Esketamine 0,1-0,5 mg/kg. If a repeat dose is necessary, it is with Propofol 0,2 mg/kg and/or Esketamine 0,1-0,5 mg/kg (17, 18). Before sedation an intravenous line is placed with 1 L Ringer Acetate and the patient will receive a nasal cannula with an oxygen flow of 2-5 L/min. During the sedation the patient is monitored with a non-invasive blood pressure, saturation, respiratory rate, pulse and 3-point ECG and the nurse anesthetist and anesthesiologist will continuously observe the depth of sedation and respiratory drive. After the hip reduction, the patient is observed and monitored until the sedation has worn of and there is no risk of airway obstruction.

Outcomes

The *primary* outcome is time from arrival at the emergency entrance to prosthesis reduction.

The *secondary* outcomes are:

a) total hospitalization time from arrival to discharge
b) intra-operative complications (fracture, unsuccessful reduction, aspiration, need for mask ventilation and/or intubation, others)
c) post-operative complications (cardiac, pulmonal, thrombo-embolic events, nerve damage, re-dislocation, others) during hospitalization
d) 30 days re-admission
e) 30- and 90-days mortality
f) hip-related pain measured by a 10-digit numeric rating scale (NRS)
g) patient-reported outcome (PRO) using the Hip disability and Osteoarthritis Outcome Score (HOOS), domains [1)]PAIN, [2)]OTHER SYMPTOMS, [3)]FUNCTION IN DAILY LIVING, AND [4)]HIP-RELATED QUALITY OF LIFE (19)
h) Health-related quality of life using the EQ-5D questionnaire (20)
i) patient satisfaction
j) time consumption by the involved staff (orthopedic, anesthetic, radiology staff etc.)
k) total hospital costs during admission

Every admitted patient will be included for evaluation of the primary and secondary outcomes (a-e + j-k) regardless of the patient's cognitive status. However, the remaining secondary outcomes (f-i) will require that the patient is able to understand the Danish language and cognitively able to answer the questions meaningfully. A dedicated project nurse will assist during the hospital admission if required. A patient can be included several times due to recurrent dislocations which will be accounted for during statistical analysis.

Outcome/variable time table

Pre-admission (recall past 14 days)	**Hospital admission (Day 0)**	**Day 1**	**Day 3**	**Day 7**	**Day 14**	**Day 30**	**Day 90**	**Day 180**	**Day 365**
Patient-reported outcomes									
NRS	NRS	NRS	NRS	NRS	NRS	NRS			
HOOS					HOOS		HOOS	HOOS	HOOS
EQ-5D					EQ-5D		EQ-5D	EQ-5D	EQ-5D
	Satisfaction								
Registry/Patient file outcomes									
	Time to reduction								
	Time to discharge								
	Per-operative Complications								
	Post-operative complications								
						Re-admissions			
						Mortality	Mortality		
Patient variables									
	Age								
	Sex								
	ASA-score								
	BMI								
	Specific comorbidities								
Prosthesis variables									
	Primary operation date								
	No. of previous dislocations								
	Type of prosthesis (incl. liner type)								

Information acquired from patient files: Information regarding patient-related factors (age, sex, ASA-score, BMI, and specific comorbidities) and prosthesis-related factors (primary operation date, number of previous dislocations, and type of prosthesis), as well as information regarding

30-days readmission and mortality, and 90-days mortality will be acquired from the patient files after acquired patient consent. The patient- and prosthesis-related factors will be used to control for potential confounding. The acquired patient file information is dated from admission to 90 days post-admission. The prosthesis-related information is dated to the primary operation date. We will only access patient files from patients who accept to participate, therefore 120 patients.

As the acute treatment has been performed when the patient is asked for consent, we apply for the use of the data acquired during the acute treatment of the patient, regardless of whether they choose to participate in the secondary part of the study regarding the patient-reported outcomes, in order to not prolong the study unnecessary. This includes the patient- and prosthesis-related factors, as this will be used to control for potential residual confounding.

Sample size

Study sample size are based on the primary outcome "Time from arrival at the emergency entrance to prosthesis reduction", applying a formula for RCT studies with clinically superiority design (21). The null-hypothesis dictates no difference in time from arrival at the emergency entrance to prosthesis reduction for patients following the Standard Pathway or the Fast-Track Pathway.

$$N = 2 \times \left(\frac{z_{1-\alpha} + z_{1-\beta}}{\delta - \delta_0} \right)^2 \times s^2$$

N = no. of patients in each group
Alpha-value = 0,05 (5% risk of type-1 error)
Beta-value = 0,90 (10% risk of type-2 error)
Delta-value (estimated true value between the two groups) ≈ 4 hours
$Delta_0$-value (estimated clinical acceptable difference between the two groups) ≈ 3 hours
S-value (pooled standard deviation (SD) for both groups) ≈ 2.5 hours

A review of 16 randomly selected patients that was admitted to the University of Southern Denmark, Esbjerg, with a dislocated THA from January 2018 to May 2022 revealed a mean time from arrival at the emergency entrance to prosthesis reduction at 6 hours (range 2.7 – 9.0 hours) with a standard deviation at 1.6 hours.

$$N = 2 \times \left(\frac{1{,}645 \times 1{,}28}{4 - 3} \right)^2 \times 2{,}5^2 \approx 53 \; patients \; in \; each \; group$$

Based on a review of the surgical procedures performed during the period 01.02 – 31.08.2022, we expect to admit 5-6 patients per month with a dislocated THA or HA, and we expect an attendance rate of >90% based on the primary outcome. Therefore, we will include 53 patients + 15% ≈ 60 patients in each group, due to the risk that specific comorbidities will lead to exclusion from the Fast-Track pathway by the anesthetic staff. It is thus expected that a total of 120 patients will be adhered to one of the two treatment algorithms over the course of 24 months.

Blinding

This study concerns emergency research without the possibility of informed consent prior to intervention, and the patients will not be informed regarding their participation in a scientific study on arrival. Post-reduction, the patients are encouraged to participate in the second part of the study involving patient-reported outcome measures. The patient will not be informed of whether they have been adhered to the standard or Fast-track treatment strategy and are therefore blinded regard the treatment.

The orthopedic and anesthetic staff are not informed regarding the initiation of the current study and are therefore blinded in terms of the aim. The staff will be thoroughly instructed to adhere to the Fast-track strategy at the time for pathway shift.

Patient information

After reduction of the prosthesis, the patients are admitted to the ward at the Dept. of EM, regardless of the treatment received. During the admission, the patient will be interviewed by a dedicated study-nurse and informed about the study, without revealing the allocated treatment pathway. The rooms are single-patient only, in order to secure that the information can be given undisturbed. The patients will be screened for eligibility (cognitive status, language) for participation in the secondary part of the study, and the nurse will deliver patient information including a study overview depicting the timepoints for evaluation. When recruiting the patient for the secondary part of the project, it is stated that this is a scientific trial and that the patient has the right to have a companion present during the information, The patients are encouraged to respond before discharge, typically 12-24 hours after arrival.
Up to 15-20% of patients admitted to the hospital with a dislocated THA/HA is cognitively impaired due to dementia in a degree that hinders reasonable questionnaire response. These patients require the same acute treatment as any other patient, and there is no reason for not including them in this study. Information will be given to the patient's relatives, and we will ask for their permission to include the already obtained journal data in the study.

Patent information folder is found in the appendix (in Danish).

The patients are informed that consent gives the trial manager, sponsor and sponsor's representatives as well as any supervisory authority direct access to obtain information in the patient's medical record, etc., including electronic medical records, in order to see information about the subject's health, which is necessary as part of the implementation of the research project and for control purposes, including self-control, quality control and monitoring, which they are obliged to carry out.

Statistics

Mean values with standard deviation (SD) are given for normally distributed data, while median values with interquartile range (IQR) are given for skewed data. In case of normally distributed data, two-sample t-test is used. Mann-Whitney U-test is used to compare continuous nonparametric variables and chi-square test is used to compare categorical variables. STATA version 18 will be used for all statistical analyses.

Economy

The main investigator and initiator is Lars L. Hermansen, MD, Ph.D., post.doc.

The study is conducted as a collaboration between the Department of Orthopedics, Department of Anesthesiology, Department of Radiology, and Department of Emergency Medicine, University Hospital of Southern Denmark, Esbjerg. There are no special economics involved in the study between the departments, as the study is carried out as a part of normal daily, acute activity.

Vestjysk Orthopedic Fund will be applied for covering expenses to hardware (computer, Ipad etc.)

The Region of Southern Denmark’s Research Fund will be applied for covering salary to a dedicated study nurse.
Grants are administered via an account that is subject to public audit.

There are no conflicts of interest.

Ethics

Permission to store and handle data is obtained upon application to the Region of Southern Denmark’s internal register (24/34681). The Danish Law of data protection is observed.

The regional ethics committee has been applied for permission to conduct the study under special circumstances as acute research without the possibility of obtaining informed consent from the

patient prior to intervention. The purpose and hypothesis of this study can simply not be investigated if the patients are admitted as usual and permitted time for consideration to participate or not. This group of patients suffers from a complication (a dislocated hip arthroplasty) that requires intervention (reduction of the prosthesis) as quick as possible, regardless of the patient's cognitive status. There is only one treatment to this specific complication, and thus they will all receive the same surgical intervention whether they participate in the study or not. There is no reason to believe that the patients are exposed to greater risk by the Fast-Track pathway than Standard pathway. On the contrary, it is strongly expected that the patients will be treated significantly quicker during a smooth concept, thereby reducing the period in pain. Reduction in the emergency department (Fast-track pathway) is more likely to be even safer than current practice (due to the participation of the anesthesiologists), where the emergency staff and orthopedics are responsible for sedation outside the operating theater. The regional ethics committee has responded that the study does not require their permission, and the study can be conducted as a treatment-quality study, locally approved by the Executive Board at the University Hospital of Southern Denmark.

X-ray radiation dose:

The patients will be exposed for two different X-ray systems, depending on randomization. The patients following the standard pathway is transferred to a room, where a fixed, stationary X-ray system is applied, whereas a smaller, transportable X-ray machine is used for the patients randomized to the fast-track pathway. We have made a pre-liminary measurement of the radiation dosage to compare the two interventions. The conventional, standard machine exposes the patient for 0.1258 milliSievert (mSv), whereas the number is 0.1102 mSv for the mobile device. Therefore, our new pathway do not expose the patients for higher radiation doses. The annual background radiation in Denmark is 3-5 mSv, so the radiation doses are negligible and the study is categorized as IIa and justifiable if it leads to increased knowledge and health advantages. The lifetime cancer risk in Denmark is approx. 25%. This risk increases 5% pr. Sievert. Thus, participation in the study will increase the cancer risk to 25.0001%.

Patient insurance:

The Danish Patient Insurance Scheme *(Patienterstatningsordningen)* covers all subjects who participate in health science trials in Denmark. The coverage is described in the Legislative Order No. 995 of 14 June 2018 and covers all test subjects who are harmed during an experiment in Denmark.

Presentation of results

Based on the data, a manuscript will be prepared for publication so that the results can be published in an internationally recognized journal. Positive, negative as well as inconclusive results are published in relevant national and international journals, and 2-4 publications are expected divided into orthopedic surgery and anesthesiologic measurement parameters. The results of the study will be presented at professional congresses at home and abroad.

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