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# Mortality and readmission following hip fracture surgery: a retrospective study comparing conventional and fast track clinical care

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# Mortality and readmission following hip fracture surgery: a retrospective study comparing conventional and fast track clinical care

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#### Page 250f 28

#### ABSTRACT

**Objective:** To compare the efficacies of two clinical pathways —conventional and fast-track care—in patients with hip fracture.

Design: Retrospective single-center study.

Setting: University hospital in middle Norway.

**Participants:** 1592 patients aged  $\geq$ 65 years with hip fracture (intracapsular, intertrochanteric, or subtrochanteric).

Interventions: 788 patients were treated according to conventional care from April 2008 to September 2011, and 804 patients were treated according to fast-track care from October 2011 to December 2013.

Primary and secondary outcome measures: Primary: Mortality and readmission to hospital within 12-month follow-up. Secondary: Time to surgery and length of hospital stay.

Results: We found no statistically significant differences in mortality and readmission rate between patients in the fast-track and conventional care models within 12 months after the initial hospital admission. Mean number of days to death was 303 (95 % Cl 295 - 311) for fast-track care and 296 (95 % CI 288 - 305) for conventional care. Mean number of days to first readmission was 252 (95 % CI 242 - 263) for fast-track care and 251 (95 % CI 241 - 262) for conventional care. Time to surgery and length of stay were statistically significant reduced in the fast-track care. There was no statistically significant difference in Charlson Comorbidity Index score, age, gender, and type of fracture at baseline between patients in the two pathways.

Conclusions: The change in treatment from conventional to fast-track care significantly reduced time to surgery and length of stay without any increase in mortality and readmission. The introduction of fast-track care at our hospital seems to improve the efficiency of care. Further studies should thus focus on the health economic aspects of fast-track care. In addition to obvious benefits for the patient, a standardized treatment regime can be cost effective.

# <text><text><text><text> Strengths and limitations of this study

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#### **INTRODUCTION**

Elderly patients with a hip fracture have an increased risk of mortality and comorbidity.[1-3] While a 25% mortality rate was reported at 12 months, [4] another study reported an increased mortality risk 10 years after the fracture.[5] Co-morbidity and general frailty makes these patients especially vulnerable to trauma such as a hip fracture [6].

There is no consensus regarding the most beneficial treatment factors to optimize outcomes after hip fracture surgery, but in the last 15 years, guidelines have focused on factors to optimize the care involved.[7] Early surgery is considered a key factor to reduce subsequent mortality risk.[8 9] Early mobilization may influence mortality, length of stay (LOS), and further postoperative hospitalization. [10-14] LOS may influence mortality [15] and readmissions. [7 16-18]

The incidence of hip fractures in Norway is high, like in other Scandinavian countries.[19-21] So far, the majority of patients in Norway are treated with a low surgical priority and extended hospitalization.

Fast-track care is a way of organizing clinical pathways using principles from lean methodology.[22] The key concept is standardization of all routines in the clinical pathway: priority to surgery, standardized surgical techniques, improved pain control, and early mobilization. [23 24] However, different hospitals employ different aspects of the fast-track system. [23] Fast-track care for patients with hip fracture was established at the St. Olavs Hospital, Trondheim University hospital, Norway, in 2011 and included surgical priority, early mobilization, medication reconciliation, and a standardized treatment from admission to discharge.

The aim of this study was to compare the mortality and readmission rate within 12 months after a hip fracture in patients aged ≥65 years following either conventional or fast-track clinical care.

#### **METHODS**

#### **Study design**

This was a single-center retrospective study carried out at St. Olavs Hospital, University hospital in Trondheim, Norway, primary hospital for 300 000 inhabitants in the middle of Norway that treats approximately 400 hip fractures yearly. In Norway, all hip fracture patients are treated in public hospitals.

#### **Study population**

The study included 1592 patients undergoing hip fracture surgery between April 2008 to September 2011 (conventional care) and October 2011 to December 2013 (fast-track care).

In-hospital data was obtained from our internal hip-fracture quality register, manually reviewed medical journals, and partly the Trondheim Hip Fracture Trial study.[25] Retrospective data up to 12 months after discharge was collected by manually reviewing the medical journals. Only readmissions to Trondheim University hospital were registered, because data from other hospitals were not available. Permanent residents of Norway could be identified by their 11-digit personal identification number. Patient identity and the diagnostic code were matched using hospital administrative databases. Previous medical history was collected by data extraction from these administrative databases.

#### **Inclusion and exclusion criteria**

Our inclusion criteria were as follows: patients aged ≥65 years with an intracapsular, intertrochanteric, or subtrochanteric proximal femur fracture living in the county of Trondheim at the time of fracture and undergoing surgery at the University hospital. Patients with lengthy delays for surgery due to medical reasons and those with severe medical co-morbidities or short lifetime prognosis were also included.

The total number of patients along with the detailed inclusion and exclusion criteria is presented as a flowchart (Figure 1). Sixty-one patients had a second hip fracture during the one-year follow-up. In this paper, we present and discuss only results from the first fracture.

From 2008 to 2010, the Trondheim Hip Fracture Trial was conducted at St. Olavs Hospital, Trondheim, randomizing to orthogeriatric care or orthopedic care, with the latter acting as a control group.[14] Patients with pathological fractures, short life expectancy, or living permanently in nursing homes were excluded. In the present study, we included the participants in the orthopedic care group and patients excluded in the Trondheim Hip Fracture Trial. Consequently, we included a

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randomized cohort of patients (266 of 532) first excluded in the Trondheim Hip Fracture Trial. By this, we have employed the same inclusion and exclusion criteria for all patients eligible for the present study and avoided selection bias.

#### **Comorbidity Indices**

We used the Charlson Comorbidity Index score (CCIs) to control for equality in health between the two groups.[26] The coding algorithm developed by Quan identified the comorbidities and defined the weight score, ranging from 0 to 24.[27 28] The present CCI scores were based on all ICD-10 diagnosis codes occurring in the last three years prior to and including the current episode, partly based on the standards from the Norwegian Knowledge Centre for the Health Services.[29] Both main and secondary diagnoses (ICD-10), with no limitations to the number, were registered.

Both comorbidity and age may predict probability of death. The Charlson Comorbidity-Age Index score (CCAIs) [26 30] is calculated by adding one point for each decade from the time the patient turns 50 years old to adjust for age. Both indices were employed.

#### **Study interventions**

#### **Conventional care**

Patients were at first examined by a general practitioner at the site of the injury. The patient was then transported by ambulance to the emergency unit for another examination by an orthopedic resident on call, sent to the radiology department, and subsequently back to the emergency unit. Finally (and very often after 3–4 h of waiting time), the patient was brought to the orthopedic ward. Standardized nursing routines (pain control, nutrition, fluid therapy, and prevention of pressure sores) were then initiated. Prolonged waiting time for surgery was often the result as patients with hip fractures were not prioritized for surgery. Very few treatment procedures, including surgical technique, were standardized and designed for this special patient group. Surgery was often performed between 11:00 p.m. and 8:00 a.m. There was no standardized procedure for physical therapy; patients received this postoperatively at random and often after discharge from the hospital.

#### Fast-track care

Treatment of patients with hip fractures starts at the site of injury, on arrival of the ambulance personnel. They examine the patient and directly report to the hospital with a tentative diagnosis of "hip fracture" without contacting a practitioner. Pre-operative treatment like administration of morphine, oxygen, and prevention of pressure sores is started and the patient is transported directly

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to the radiology department, all by the ambulance personnel. Standardized nursing routines (pain control, nutrition, fluid therapy, and prevention of pressure sores) are then begun. On arrival at the orthopedic ward, regional anesthesia in the form of a femoral block is established, while an orthopedic resident on call examines the patient. All patients with hip fracture are scheduled for surgery within 24 h (although not between 10:00 pm. and 8:00 am).

Whenever possible, all patients are mobilized on the first postoperative day. Ward-based pharmacists evaluate the medication lists by using the method of medication reconciliation.[31 32] Planning for discharge is started on the day of admission and is coordinated with the municipal health service. Discharge criteria in the fast-track care do not differ from the criteria in conventional care.

#### Hip fracture surgery implants

For colli femoris fractures, hip pins were mostly used until 2008/2009. After this time, a bipolar, cemented hemiprosthesis has most often been used for this fracture type.[7 33] For intertrochanteric fractures, sliding hip screws were used, and for subtrochanteric fractures, intramedullary nailing or sliding hip screws were used.

#### **Primary outcomes**

#### **Mortality**

The follow-up time was 12 months. Time to death was calculated from admission to possible event. The specific mortality rate at 30 days, 90 days, and 12-month follow-up are also reported.

#### **Readmission**

The follow-up time was 12 months. A readmission was registered as such if unplanned hospitalization occurred more than 8 h after discharge of the previous admission. Reason for readmission is based on the primary diagnosis (ICD 10). Patients undergoing surgery at our hospital but geographically belonging to other hospitals are registered as "missing" in the readmission variable. The readmission rates specific to the 30-day, 90-day, and 12-month follow-up are reported.

#### **Secondary outcomes**

#### Length of stay (LOS)

Length of stay was defined as the number of days between admission and discharge from the hospital. If the patient was treated at another or several hospital departments after the fracture, the total number of treatment days were counted.

#### Time to surgery (TTS)

Time to surgery was calculated as hours from hospital admission to surgery, as the exact time of the fracture was unknown.

#### **Statistical analysis**

Visual inspection of Q-Q plots was used to evaluate normality of data. Independent-samples *t*-test was used for normally distributed data and Mann–Whitney test for non-normally distributed data. Pearson chi-square tests were used when testing categorical data.

Kaplan–Meier survival estimates with Log-rank test were used to test for patient survival from hospital admission date up to the 12-month follow-up, as well as test for the number of days from hospital discharge to first readmission up to the 12-month follow-up.

Cox regressions were used when analyzing possible differences between treatment care. The patient's age, sex, and CCIs were a-priory selected as covariates to be included based on clinical considerations.

All analyses were performed using SPSS 22 (SPSS Inc, Chicago, IL, USA) and Stata 12 (StataCorp LP, Texas, USA).

#### **RESULTS**

Of the total 1592 patients included, 788 were treated according to conventional care and 804 patients, according to fast-track care. There were no statistically significant differences between both groups according to baseline characteristics, sex, age at admission, fracture type, CCIs, or CCAIs (Table 1).

Forty-five patients (2.8%) died during index stay: 23 persons in the conventional care (2.9%) and 22 persons in the fast-track care (2.7%) groups. Further, 411 (25.8%) patients died within the first year after admission; of these, 213 (27.0%) belonged to the conventional care group and 198 (24.6%), to the fast-track care group. Mean number of days to death was 303 (95% CI 295-311) for fast-track care and 296 (95% CI 288-305) for conventional care. Mortality data are presented in Table 2, and the Kaplan–Meier survival estimates are presented in Figure 2. The log-rank test for equality of days to death showed no statistically significant differences between both groups (p = 0.26). The effects of care, CCIs, patient's age, and sex on mortality are presented in Table 3.

There was no statistically significant difference in the number of patients readmitted or the number of readmissions within one year after discharge between the two groups (Table 2). Mean number of days to first readmission was 252 (95% CI 242-263) for fast-track care and 251 (95% CI 241-262) for conventional care. The Kaplan–Meier estimates of the number of days to first readmission are presented in Figure 3. The log-rank test for equality showed no statistically significant differences between the two groups (p = 0.89). The effect of care, CCIs, patient's age, and sex on number of days to first readmission are presented in Table 3.

LOS and TTS was statistically significant shorter for patients who received fast-track care - a mean difference of 3.4 days and 6 h, respectively. Surgery times were statistically significant shorter for patients who received conventional care compared to fast track care, mean 67.0 min (SD 38.1) and 71.1 min (SD 36.3) respectively. Use of anesthesia did not differ between the two groups (Table 4).

Use of implant, however, differed between the two groups (Table 4). There was an overall statistically significant difference in the use of osteosynthesis vs. hemi-arthroplasties (p = 0.02).

The most frequent reason for first readmission within 30 days after the index stay in the fast-track care group was postoperative wound infection (n = 17 [12.4%]) and pneumonia (n = 11 [8.0%]). In the conventional care group, pneumonia was the most frequent (n = 11 [9.5%]), followed by postoperative wound infection and cardiac disease (both n = 7 [6.0%]).

#### DISCUSSION

 We found no statistically significant difference in mortality and readmission rate for patients in the fast-track care compared to conventional care within 12 months after hospital admission. We found a statistically significant decrease of approximately 6 h in TTS and 3.4 days in LOS. Baseline patient characteristics were similar.

The reduction in TTS and LOS in the fast-track care group in our study are the result of improved treatment and rehabilitation factors: early surgery, early mobilization, planned discharge, and cooperation with the municipal help service, to arrange for rehabilitation in an institution or the patient's own home. National Institute for Health and Care Excellence (NICE) guidelines recommend an early supported discharge for care home and nursing home patients.[7] Early mobilization is of vital importance, as it is considered to be an essential part of the rehabilitation process.[34]

TTS is a commonly used parameter in most hip fracture studies. A delay in TTS is often associated with an increased mortality rate, but it is controversial whether the delay is a factual cause of increased mortality risk.[35] A Swedish study based on a nationwide cohort, however, not employing the principles of fast-track care, showed that a decrease in LOS was associated with an increased mortality rate.[15] This is not in accordance with our results, as we did not find evidence of an increase in patient mortality and readmission rates caused by a reduction in LOS.

A Danish hip fracture study found that patients following a fast-track performance had lower odds of readmission (17.4%) at 30 days; their results were associated with early mobilization, systematic pain assessment, and anti-osteoporotic medication.[36] Two Danish studies [23 37] with a similar fast-track design as ours, found that fast-track care shortens the TTS and decrease mortality, consistent with our results. While one study reported a TTS of 22 h and in-hospital mortality of 5%, with the LOS being 9 days,[23] another reported a TTS of 26.4 h, 12-month mortality rate of 23%, and LOS of 9.7 days.[37]

The TTS, mortality, and readmission rates in our fast-track care group are consistent with other studies, while our LOS is significantly shorter. This shows that the factors included in our fast-track concept are favorable: reduced TTS, immediate pain control, nutrition and fluid therapy, early mobilization, and planned discharge. Difference in outcomes may be because different hospitals implement their own fast-track model. Our hospital made a change in implant choice in 2008/2009— an increase in use of hemi prosthesis and a subsequent reduction in use of screws, in line with published recommendations.[38] This can likely explain the increase in surgery time in our fast-track

care. Use of spinal anesthesia is higher in Norway than in other countries.[23 37] There is no evidence that spinal anesthesia decreases the mortality risk or eases the recovery of the patient,[39 40] but a review found a small difference according to LOS [40].

We are yet unsure if the switch to merely day-shift surgery has an impact on outcome. One could assume a reduction in complications, though we did note a small increase in the postoperative wound infection in the fast-track group. A comparison [41] of day- and night-shift surgery did not find any higher postoperative complication rate in night-shift surgery, but the study size was small, which could have affected the result. Introduction of day-shift surgery and a reduction of TTS indicates that fast-track care at our hospital improved the efficiency of care and was beneficial to both patients and staff. We were unable to correlate whether the use of medical reconciliation by pharmacists affected the outcome by less falls and other health problems. Medication reconciliation can be a contributor to prevent new fractures from occurring and was therefore included as an element in our fast-track care.

Days to first readmission and survival rate is the same for both care models. The unfortunate factors for mortality and readmission are morbidity, older age, and male sex. In our study, the most common cause for first readmission within 30 days in the fast-track care group was wound infection, while pneumonia was the most common cause in the conventional care group.

#### Strengths and limitations

There are limitations to our study, mainly owing to its retrospective design. A randomized comparison of the two pathways was not feasible as both care models could not be run at the same time because of practical hospital considerations. There was no difference in baseline characteristics of fracture types or patient's characteristics justifying our comparisons across two time periods. Only the readmissions to our hospital were registered. Because most of the included patients geographically belonged to this hospital and had a very low geographical mobility, we assumed that most of the readmissions would be to our hospital and thus, registered. Another limitation is that the calculation of TTS is from the time of arrival of the patient at the emergency ward and not from the actual fracture time.

The strengths of the study are the high completeness of the data; prior to, in-hospital, and after surgery, and our extensive inclusion criteria, including patients from nursing homes and those with dementia and severe diagnoses.

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The core of our study was the reduction in TTS and LOS without increasing mortality and readmission rates in the fast-track care model.

Further work should focus on patients' discharge location, if the decrease in LOS could be a result of a change in the rehabilitation care, and it should explore the mortality rate beyond 12 months. Further studies should also focus on the health economic aspects.

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Contributors: OAF planned the study, wrote the statistical analysis plan, did the data analysis, made the tables and figures and revised the manuscript. LGJ planned the study and revised the manuscript. TB planned the study and revised the manuscript. KH planned the study, did the data collection and the data analysis, wrote and revised the manuscript.

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Competing interest: None.

Ethical considerations: This study was approved by the Regional Committee for Medical Research Ethics, Central Norway (2013/336/REK midt).

Data Sharing: No additional data available.

Transparency: The lead author (the manuscript's guarantor) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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#### **Table 1 Baseline patient characteristics**

		Conventional care	Fast-track care	Mean difference between groups (95% CI)	p-value
Number of p	oatients	788	804		
Gender	Female	574 (73%)	567 (71%)		0.317
	Male	214 (27%)	237 (29%)		
Fracture	S72.0	512 (65%)	502 (62%)		0.544
Code	S72.1	234 (30%)	253 (32%)		
	S72.2	42 (5%)	49 (6%)		
Age at	Mean (SD)	83. 1 (7.4)	83.1 (7.8)	0.05 (-0.70 to 0.79)	0.904
(years)	Median (range)	84 (65-104)	84 (65-102)		
Charlson Co Index score	morbidity (CCIs)				
Mean (SD) Median (range)		1.21 (1.6)	1.18 (1.6)	0.03 (-0.19 to 0.14)	0.748
		0 (0-9)	0 (0-10)		
Age Index Score (CCAIs) Mean (SD) Median (range		5.1 (1.8)	5.1 (1.9)	-0.01 (-0.19 to	0.948
		5 (2-13)	5 (2-15)	0.18)	

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#### Table 2 Mortality and readmission rates within 12 months after admission for index hip fracture

	Conventional	Fast-track care	p-value
	care		
Mortality (cum)			
Within 30 days	8.0% (63)	7.0% (56)	0.447
Within 90 days	14.6% (115)	13.2% (106)	0.518
Within 12 months	27.0% (213)	24.6% (198)	0.273
No of patients readmitted (cum)			
Within 30 days	103 (13.4%)	123 (15.7%)	0.221
Within 90 days	187 (24.4%)	196 (25.1%)	0.814
Within 12 months	319 (41.7%)	327 (41.8%)	1.000
No of readmissions (cum)			
Within 30 days	116	137	0.218
Within 90 days	238	242	1.000
Within 12 months	515	548	0.651





Table 3 Hazard ratio effects of; care, CCIs, patient's age, and sex on mortality and days to first readmission within 12-months after admission

	Hazard Ratio	95% Confid Interval	ence	p-value
Mortality		I		<u> </u>
Conventional care	1.20	0.97	1.47	0.086
CCIs	1.40	1.34	1.47	<0.001
Age	1.08	1.06	1.09	<0.001
Male sex	1.52	1.22	1.89	<0.001
Days to first readmission				·
Conventional care	1.0	0.86	1.17	0.991
CCIs	1.14	1.09	1.20	<0.001
Age	1.02	1.01	1.03	<0.001
Male sex	1.28	1.08	1.51	0.004
			4	

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Table 4 Outcome measures; time to surgery, length of stay, surgery time, anesthesia and type of implant for hip fracture surgery

		Conventional	Fast-track care	Mean difference	<b>p</b> -
		care		between groups	value
				(95%CI)	
Waiting time	Mean (SD)	31 2 (25 1)	25 2 (21 2)	-6.00 (-8.28 to -3.71)	<0.001
for surgery	iniculi (5D)	51.2 (25.1)	23.2 (21.2)	0.00 ( 0.20 to 0.71)	10.001
(h)	Median (range)	25 (0-289)	21 (1-236)		
Length of stay (days)	Mean (SD)	9.5 (8.2)	6.1 (5.6)	-3.41 (-4.10 to -2.71)	<0.001
stay (aays)	Median (range)	8 (1-120)	5 (1-50)		
Surgery time	Mean (SD)	67.0 (38.1)	71.1 (36.3)	4.15 (0.50 to 7.81)	0.026
()	Median (range)	65 (6-260)	69 (8-297)		
Anesthesia	Spinal	759 (96.3%)	773 (96.1 %)		0.225
	General	22 (2.8 %)	24 (3.0 %)		
	Other/ missing	0 (0%)/ 7 (0.9	3 (0.4 %)/ 4		
		%)	(0.5 %)		
Implant	ТНА	33 (4.2%)	36 (4.5%)		0.806
	Hemi-prosthesis	284 (36.0%)	330 (41%)		0.045
	Girdlestone	4 (0.5%)	4 (0.5%)		1.000
	Intramedullary	32 (4.1%)	34 (4.2%)		0.900
	nail				
	Sliding hip screw	272 (34.5%)	288 (35.8%)		0.600
	Hip pins	163 (20.7%)	112 (13.9%)		0.000

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# Mortality and readmission following hip fracture surgery: a retrospective study comparing conventional and fast track care

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38	20	Keywords: Comorbidity, Length of stay, Risk, Pathway, Medication Reconciliation
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24 25	ABSTRACT
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27	<b>Objective:</b> To compare the efficacies of two pathways —conventional and fast-track care—in
28	patients with hip fracture.
29	Design: Retrospective single-center study.
30	Setting: University hospital in middle Norway.
31 32	Participants: 1592 patients aged ≥65 years with hip fracture (intracapsular, intertrochanteric, or subtrochanteric).
33	Interventions: 788 patients were treated according to conventional care from April 2008 to
34	September 2011, and 804 patients were treated according to fast-track care from October 2011 to
35	December 2013.
36	Primary and secondary outcome: Primary: Mortality and readmission to hospital, within 365 days
37	follow-up. Secondary: Length of hospital stay.
38	Results: We found no statistically significant differences in mortality and readmission rate between
39	patients in the fast-track and conventional care models within 365 days after the initial hospital
40	admission. Mean number of days to death was 303 (95 % CI 295 - 311) for fast-track care and 296 (95
41	% CI 288 - 305) for conventional care. Mean number of days to first readmission was 252 (95 % CI
42	242 - 263) for fast-track care and 251 (95 % CI 241 - 262) for conventional care. Length of stay and
43	time to surgery was statistically significant shorter for patients who received fast-track care, a mean
44	difference of 3.4 days and 6 h, respectively. There was no statistically significant difference in sex,
45	type of fracture, age or Charlson Comorbidity Index score at baseline between patients in the two
46	pathways.
47	Conclusions: The change in treatment from conventional to fast-track care implied no change in
48	survival rate or days to first readmission for the two care models. The length of stay and time to
49	surgery were decreased. Further studies should thus focus on the health economic aspects of fast-
50	track care. In addition to obvious benefits for the patient, a standardized treatment regime can be
51	cost effective.

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7 8	55	Strengths and limitations of this study
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11 12	57	Wide inclusion criteria, including also the most fragile natients
13	EQ	The almost complete data set with four missing data
14	50	The almost complete data set with rew missing data
16 17	59	Retrospective design
17	60	<ul> <li>Data collected in two different periods of time</li> </ul>
19 20	61	Lacks data for dwelling after discharge
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#### **INTRODUCTION**

Elderly patients with a hip fracture have an increased risk of mortality and comorbidity.[1-3] While a 25% mortality rate was reported at 12 months, [4] another study reported an increased mortality risk 10 years after the fracture.[5] Co-morbidity and general frailty makes these patients especially vulnerable to trauma such as a hip fracture [6].

There is no consensus regarding the most beneficial treatment factors to optimize outcomes after

hip fracture surgery, but in the last 15 years, guidelines have focused on factors to optimize the care

involved.[7] Early surgery is considered a key factor to reduce subsequent mortality risk.[8 9] Early

mobilization may influence mortality, length of stay (LOS), and further postoperative

hospitalization. [10-14] LOS may influence mortality [15] and readmissions. [7 16-18]

The incidence of hip fractures in Norway is high, like in other Scandinavian countries.[19-21] So far,

the majority of patients in Norway are treated with a low surgical priority and extended

hospitalization.

Fast-track care is a way of organizing clinical pathways using principles from lean methodology.[22]

The key concept is standardization of all routines in the clinical pathway: priority to surgery,

standardized surgical techniques, improved pain control, and early mobilization. [23 24] However,

different hospitals employ different aspects of the fast-track system. [23] Fast-track care for patients

with hip fracture was established at the St. Olavs Hospital, Trondheim University hospital, Norway, in

2011 and included surgical priority, early mobilization, medication reconciliation, and a standardized

treatment from admission to discharge.

The primary aims of this study were to compare the mortality and readmission rate within 365 days after a hip fracture in patients allocated to either conventional or fast-track care. The secondary aim was length of hospital stay.

#### 89 METHODS

#### 90 Study design

This was a single-center retrospective study carried out at St. Olavs Hospital, University hospital in
Trondheim, Norway, primary hospital for 300 000 inhabitants in the middle of Norway, that treats
approximately 400 hip fractures yearly. In Norway, all hip fracture patients are treated in public
hospitals.

#### 95 Study population

The study included a total of 1592 patients undergoing hip fracture surgery between April 2008 to
September 2011 (conventional care) and October 2011 to December 2013 (fast-track care).

In-hospital data was obtained from our internal hip-fracture quality register, manually reviewed
medical records, and partly the Trondheim Hip Fracture Trial study (HFT).[25] Retrospective data up
to 365 days after discharge was collected by manually reviewing medical records. Only readmissions
to Trondheim University hospital were registered, because data from other hospitals were not
available. Permanent residents of Norway could be identified by their 11-digit personal identification
number. Patient identity was used to collect previous medical history from administrative databases
and reported deaths.

#### 105 Inclusion and exclusion criteria

- 106 Our inclusion criteria were as follows: patients aged ≥65 years, with an intracapsular,
- 107 intertrochanteric, or subtrochanteric hip fracture admitted and undergoing surgery at the University
  - 108 hospital. Patients fulfilling these criteria were included irrespective of co-morbidity, dwelling or short
- 109 life-time prognosis. For patients with more than one hip fracture in the study period, only the first
- 110 hip fracture was included. Subsequent hip fractures were excluded in the hip fracture analysis.

The eligible patient population had a bias which had its origin the HFT study conducted at our hospital from 2008 to 2010, where a selection of the healthiest patients were randomized to either orthogeriatric or conventional care [14]. Consequently, the population available for the present study became skewed, with a congestion of sicker patients. To adjust for this selection bias we randomly excluded 50% (n=266) of the sickest patients in order to re-establish a representative sample.

- 116 The total number of patients along with the detailed inclusion and exclusion criteria is presented as a
- flowchart (Figure 1). Sixty-one patients had a second hip fracture during the one-year follow-up. In
- this paper, we present and discuss only results from the first fracture. Any subsequent hip fracture
- 119 was registered as a readmission in the analysis, and was neither included in the hip fracture data nor
120 in the hip fracture analysis. Data regarding the admission were included. Thus, we excluded any

121 subsequent hip fracture but not the patient.

122 Nineteen patients geographically belonging to other hospitals underwent surgery at our hospital.

- 123 Readmission data for these were not available and registered as "missing" in the readmission
- 124 analysis.

### *Comorbidity Indices*

We used the Charlson Comorbidity Index score (CCIs) to control for equality in health between the two groups.[26] The coding algorithm developed by Quan identified the comorbidities and defined the weight score, ranging from 0 to 24.[27 28] The present CCI scores were based on all ICD-10 diagnosis codes occurring in the last three years prior to and including the current episode, partly based on the standards from the Norwegian Knowledge Centre for the Health Services.[29] Both main and secondary diagnoses (ICD-10), with no limitations to the number, were registered.
Both comorbidity and age may predict probability of death. The Charlson Comorbidity-Age Index

- score (CCAIs) [26 30] is calculated by adding one point for each decade from the time the patient
  turns 50 years old to adjust for age. Both indices were calculated.

#### 137 The pathways

#### 138 Conventional care

Patients were at first examined by a general practitioner at the site of the injury. The patient was then transported by ambulance to the emergency unit for another examination by an orthopaedic resident on call, sent to the radiology department, and subsequently back to the emergency unit. Finally (and very often after 3–4 h of waiting time), the patient was brought to the orthopaedic ward. Nursing routines (pain control, nutrition, fluid therapy, and prevention of pressure sores) were then initiated. Prolonged waiting time for surgery was often the result as patients with hip fractures were not prioritized for surgery. Very few treatment procedures were standardized and designed for this special patient group. Surgery was often performed between 11:00 p.m. and 8:00 a.m. There was no strict mobilization regimens to ensure mobilization first postoperative day.

#### 148 Fast-track care

- 149 The fast-track care were started at the site of injury, on arrival of the ambulance personnel. They
- 150 examined the patient and directly reported to the hospital with a tentative diagnosis of "hip

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151	fracture" without contacting a practitioner. Pre-operative treatment like administration of morphine
152	oxygen, and prevention of pressure sores was started. The patient was transported directly to the
153	radiology department, and further on to the orthopaedic ward, all by the ambulance personnel. On
154	arrival at the orthopaedic ward, standardized nursing routines (pain control, nutrition, fluid therapy,
155	and prevention of pressure sores) were begun. Regional anesthesia in the form of a femoral block
156	were established, while an orthopaedic resident on call examined the patient. All patients with hip
157	fracture were scheduled for surgery within 24 h (although not between 10:00 pm. and 8:00 am).
158	Preparation for discharge was started on the day of admission and thus the coordination with the
159	municipal health service had an early start. Whenever possible, all patients were mobilized on the
160	first postoperative day with a physiotherapist. Ward-based pharmacists evaluated the medication
161	lists by using the method of medication reconciliation.[31 32]
162	To summarize the differences between the two pathways: for the conventional care there was no
163	preoperatively scheduled time for surgery. The pre- and postoperative pain control and
164	postoperatively mobilization regimens were not standardized.
165	For the fast-track care there were scheduled surgery within 24 hours, early preparation of discharge
166	standardized pre- and postoperative pain control, standardized mobilization on first postoperative
167	day and medication reconciliation.
168	Both pathways had similar discharge criteria; when the orthopaedic surgeon conclude there is no
169	need for further medical assessment or treatment in the specialist health services.
170	
171	Hip fracture surgery implants
172	For intracapsular fractures, hip screws were mostly used until 2008. After this time, a bipolar,
173	cemented hemiprosthesis has most often been used for this fracture type.[7 33] For
174	intertrochanteric fractures, sliding hip screws were used, and for subtrochanteric fractures,
175	intramedullary nailing or sliding hip screws were used.
176 177	Primary outcomes
170	Mortality
179	The follow-up time was 365 days. Time to death was calculated from admission to possible event.
180	The specific mortality rate at 30 days, 90 days, and 365-days follow-up are also reported.
100	

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#### **Readmission** The follow-up time was 365 days. A readmission was registered as such if unplanned hospitalization occurred more than 8 h after discharge of the previous admission. Reason for readmission was based on the primary diagnosis (ICD 10). The readmission rates specific to the 30-day, 90-day, and 365-days follow-up are reported. Length of stay (LOS) Length of stay was defined as the number of days between admission and discharge from the hospital. If the patient was treated at another or several hospital departments after the fracture, the total number of treatment days were counted. **Secondary outcome** *Time to surgery (TTS)* Time to surgery was calculated as hours from hospital admission to surgery, as the exact time of the fracture was unknown. **Statistical analysis**

The analyses were performed using Stata 13.1 (StataCorp LP, Texas, USA). Visual inspection of Q-Q plots was used to evaluate normality of data. Independent-samples t-test was used for normally distributed data, Mann–Whitney test for non-normally distributed data and Pearson chi-square tests were used for categorical data. Independent-samples *t*-test was used to analyze surgery time.

A regression analysis was used to analyze TTS (Stata command, regress). The TTS was log

transformed in order to meet the assumptions of normally distribution. The inclusion of covariates,

care, CCSi and diagnosis was based on clinical considerations.

In the following three models, these covariates were included; care, age, sex, CCIs, LOS, diagnoses and type of implant. The inclusion was based on clinical considerations. Log transformed LOS was analyzed using a regression analysis (command, regress). Cox proportional hazards regression (command, stcox) was used to analyze patient death hazards and Competing-risks regression (command, stcrreg) to analyze the hazards of readmission. The time variable was the number of days from hospital discharge to possible death or first readmission. The follow-up time was maximum 365 days. Death was considered as the competing event when analyzing the readmission hazards. The dataset was complete when analyzing the death hazards and with 19 missing patients analyzing the readmission hazards. The Cox proportional hazards assumptions was verified (p=380) (command,

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2 3	212	estat phtest) Visual inspection of Plots of Schoenfeld residuals was used to verify the proportional
4 5	213	hazard assumptions of the Competing-risks regression. [34]
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#### RESULTS

Of the total 1592 patients included, 788 were treated according to conventional care and 804 patients, according to fast-track care. There were no statistically significant differences between both groups according to baseline characteristics, sex, fracture type, age at admission, CCIs or CCAIs (Table 1).

Forty-five patients (2.8%) died during index stay: 23 persons in the conventional care (2.9%) and 22 persons in the fast-track care (2.7%) groups. Further, 411 (25.8%) patients died within the first year after admission: of these, 213 (27.0%) belonged to the conventional care group and 198 (24.6%), to the fast-track care group. Mean number of days to death was 303 (95% Cl 295-311) for fast-track care and 296 (95% CI 288-305) for conventional care. Mortality data are presented in Table 2, and the Cox proportional hazards regression are presented in Figure 2. There were no statistical difference in death hazards between conventional or fast-track care (p=0.099). The effects of care, CCIs, patient's age, sex, LOS, type of fracture and type of implant on mortality are presented in Table 3.

There was no statistically significant difference in the number of patients readmitted or the number of readmissions within one year after discharge between the two groups (Table 2). Mean number of days to first readmission was 252 (95% CI 242-263) for fast-track care and 251 (95% CI 241-262) for conventional care. The Competing-risks regression of the number of days to first readmission are presented in Figure 3. There were no statistical difference between conventional or fast-track care (p=0.260). The effect of care, CCIs, patient's age, sex, LOS, type of fracture and type of implant on number of days to first readmission are presented in Table 3.

LOS and TTS was statistically significant shorter for patients who received fast-track care - a mean difference of 3.4 days and 6 h, respectively. Surgery times were statistically significant shorter for patients who received conventional care compared to fast-track care, mean 67.0 min (SD 38.1) and 71.1 min (SD 36.3) respectively. There was an overall statistically significant difference in the use of implants (Table 4) between the two groups (p = 0.02). Use of anesthesia did not differ between the two groups (Table 4).

The most frequent reason for first readmission within 30 days after the index stay in the fast-track care group was postoperative wound infection (n = 17 [12.4%]) and pneumonia (n = 11 [8.0%]). In the 

conventional care group, pneumonia was the most frequent (n = 11 [9.5%]), followed by

postoperative wound infection and cardiac disease (both n = 7 [6.0%]).

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4 5	248	DISCUSSION
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7 8	250	We found no statistically significant difference in mortality and readmission rate for patients in the
9	251	fast-track care compared to conventional care within 12 months after hospital admission. We found
10	252	a statistically significant decrease of approximately 6 h in TTS and 3.4 days in LOS. Baseline patient
12 13	253	characteristics were similar.
14		
15 16	254	The TTS, mortality, and readmission rates in our fast-track care group are consistent with other
17	255	studies, while our LOS is significantly shorter. Two Danish studies [23 35] with a similar fast-track
18 19	256	design as ours, found that fast-track care decrease mortality and shortens the TTS, the latter
20	257	consistent with our results. They reported a TTS of 22 h and in-hospital mortality of 5%, with the LOS
21 22	258	being 9 days,[23] and a TTS of 26.4 h, 12-month mortality rate of 23%, and LOS of 9.7 days.[35]
23 24	259	The reduction in TTS and LOS in the fast-track care group in our study are the results of improved
25 26	260	treatment and rehabilitation factors, both pre- and postoperatively. Preoperatively, standardized
27	261	pain control, nutrition and fluid therapy, nursing routines, early preparation of discharge and early
28 29	262	surgery. Postoperatively, standardized pain control, early mobilization and medication reconciliation.
30	263	The discharge is prepared on admission to avoid delay by organizational reasons. The interaction of
31 32 22	264	clinical and organizational factors can affect LOS. [36]
33 34 35	265	The reduced TTS can only partly explain the reduced LOS in the present study. But, the early surgery,
36	266	efficient pain relief, mobilization on the first postoperative day and early cooperation with the
37 38	267	municipal help service to arrange for rehabilitation in an institution or the patient's own home are
39	268	elements that can contribute to a shorter LOS. An efficient pain relief may allow an early mobilization
40 41	269	which is considered to be an essential part of the rehabilitation process.[37] National Institute for
42 43	270	Health and Care Excellence (NICE) guidelines recommend an early supported discharge for care home
44	271	and nursing home patients to ensure a systematic approach to rehabilitation.[7] A Danish hip
45 46	272	fracture study found that patients following a fast-track performance had lower odds of readmission
47	273	at 30 days (17.4%); their results were associated with early mobilization, systematic pain assessment,
40 49 50	274	and anti-osteoporotic medication.[38]
51 52	275	It is known that the Kaplan-Meier estimator may overestimate the probability of events of interest
53	276	when competing risks are present. [39] Therefore, death was included as a competing event when
54 55	277	analyzing the readmission hazards. The use of implant differed between the two groups because of
56	278	the general shift from hip screws to hemi prosthesis treating intracapsular fractures, in line with
57 58 59	279	published recommendations.[40]. Both the diagnosis and type of implants were included as

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covariates when analyzing the hazards. The effect of differences in the use of implant between thetwo groups should be minimized.

The increase in use of hemi prosthesis and a subsequent reduction in use of hip screws, can likely explain the increase in surgery time in our fast-track care. Use of spinal anesthesia is higher in Norway than in other countries.[23 35] There is no evidence that spinal anesthesia decreases the mortality risk or eases the recovery of the patient,[41 42] but a review found a small difference according to LOS [42].

We are yet unsure if the switch to merely day-shift surgery has an impact on outcome. One could assume a reduction in complications, though we did note a small increase in the postoperative wound infection in the fast-track group. A comparison [43] of day- and night-shift surgery did not find any higher postoperative complication rate in night-shift surgery, but the study size was small, which could have affected the result. Introduction of day-shift surgery and a reduction of TTS indicates that fast-track care at our hospital improved the efficiency of care and was beneficial to both patients and staff. The medication reconciliation may reduce medical side effects, such as dizziness, nausea and prevent new falls from occurring, and was therefore included as an element in our fast-track care.

The critical factors for mortality are increased CCIs, older age, and male sex, the critical factor for readmission is an increased LOS, even if the effect is small. In our study, the most common cause for first readmission within 30 days in the fast-track care group was wound infection, while pneumonia was the most common cause in the conventional care group.

Priority for surgery and a standardized treatment is beneficial for these vulnerable patients. Less
night shift surgery, less hospital beds filled and reduced length of stay without increasing serious
complications is beneficial for the health care system. We find the factors included in our fast-track
concept favorable.

#### *Strengths and limitations*

The strengths of the study are the almost complete data set, with few missing data; prior to, inhospital, and after surgery, and our extensive inclusion criteria, including patients from nursing
homes and those with dementia and severe diagnoses.

- 308 There are limitations to our study, mainly owing to its retrospective design. A randomized
- 309 comparison of the two pathways was not feasible as both care models could not be run at the same
- 310 time because of practical hospital considerations. There was no difference in baseline characteristics

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of fracture types or patient's characteristics, justifying our comparisons across two time periods. Only
the readmissions to our hospital were registered. Because most of the included patients
geographically belonged to this hospital and had a very low geographical mobility, we assumed that
most of the readmissions would be to our hospital and thus, registered. Other limitations are that the

- 315 calculation of TTS is from the time of hospital admission and not from the actual fracture time, and
- the lack of data for dwelling after discharge.

#### 317 Conclusion

- 318 The core of our study was the reduction in TTS and LOS without increasing mortality and readmission 319 rates in the fast-track care model.
- 320 Further work should focus on patients' discharge location, if the decrease in LOS could be a result of
- 321 a change in the rehabilitation care, and it should explore the mortality rate beyond 12 months.
- 322 Further studies should also focus on the health economic aspects.

#### **Table 1 Baseline patient characteristics**

### 

		Conventional care	Fast-track care	Mean difference between groups (95% CI)	p-value
Number of p	patients	788	804		
Sex	Female	574 (73%)	567 (71%)		0.317
	Male	214 (27%)	237 (29%)		
Hip fracture	Intracapsular fracture	512 (65%)	502 (62%)		0.544
	Intertrochanteric fracture	234 (30%)	253 (32%)		_
	Subtrochanteric fracture	42 (5%)	49 (6%)		
Age at admission (years)	Mean (SD) Median (range)	83. 1 (7.4) 84 (65-104)	83.1 (7.8) 84 (65-102)	0.05 (-0.70 to 0.79)	0.904
Charlson Co score (CCIs) Mean (SD) Median (rar	morbidity Index	1.21 (1.6) 0 (0-9)	1.18 (1.6) 0 (0-10)	0.03 (-0.19 to 0.14)	0.748
Charlson Comorbidity-Age Index Score (CCAIs) Mean (SD) Median (range		5.1 (1.8) 5 (2-13)	5.1 (1.9) 5 (2-15)	-0.01 (-0.19 to 0.18)	0.948

#### 329 Table 2 Mortality and readmission rates within 365 days after admission for index hip fracture

#### 

	Conventional	Fast-track care	p-value
	care		
Mortality (cum)			
Within 30 days	8.0% (63)	7.0% (56)	0.447
Within 90 days	14.6% (115)	13.2% (106)	0.518
Within 365 days	27.0% (213)	24.6% (198)	0.273
No of patients readmitted (cum)			
Within 30 days	103 (13.4%)	123 (15.7%)	0.221
Within 90 days	187 (24.4%)	196 (25.1%)	0.814
Within 365 days	319 (41.7%)	327 (41.8%)	1.000
No of readmissions (cum)			
Within 30 days	116	137	0.218
Within 90 days	238	242	1.000
Within 365 days	515	548	0.651

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<text> Table 3 Hazard ratio of mortality and number of days to first readmission within 365-days after 

	Hazard Ratio	95% Confide	ence Interval	p-value
/lortality				
Conventional care	1.19	0.97	1.45	0.099
CCIs	1.39	1.33	1.45	< 0.001
\ge	1.07	1.05	1.09	< 0.001
/lale sex	1.45	1.18	1.79	< 0.001
OS	0.99	0.98	1.01	0.299
ntracapsular fracture	1.19	0.69	2.06	0.536
ntertrochanteric fracture	1.3	0.82	2.04	0.268
ΉΑ	0.64	0.29	1.41	0.269
lemi-prosthesis	0.89	0.67	1.18	0.406
Girdlestone	3.86	1.74	8.52	0.001
ntramedullary nail	0.46	0.80	2.67	0.215
liding hip screw	0.94	0.62	1.5	0.792
Readmission		·		•
Conventional care	0.91	0.78	1.07	0.260
CCIs	1.04	0.99	1.09	0.114
Nge	1.01	0.99	1.02	0.081
/ale sex	1.19	1.00	1.41	0.049
OS	1.02	1.01	1.03	0.001
ntracapsular fracture	1.07	0.67	1.70	0.777
ntertrochanteric fracture	1.29	0.86	1.92	0.222
ΉA	0.38	0.23	0.67	< 0.001
lemi-prosthesis	0.72	0.59	0.89	0.002
Girdlestone	0.65	0.17	2.43	0.521
ntramedullary nail	0.54	0.32	0.92	0.023
liding hip screw	0.64	0.46	0.91	0.013

#### implant for hip fracture surgery

		Conventional	Fast-track care	Mean difference	p-
		care		between groups	value
				(95%CI)	
Time to	Mean (SD)	31.2 (25.1)	25.2 (21.2)	-6.00 (-8.28 to -3.71)	<0.001
surgery (h)	Median (range)	25 (0-289)	21 (1-236)		
Length of	Mean (SD)	9.5 (8.2)	6.1 (5.6)	-3.41 (-4.10 to -2.71)	< 0.001
stay (days)	Median (range)	8 (1-120)	5 (1-50)		
Surgery time	Mean (SD)	67.0 (38.1)	71.1 (36.3)	4.15 (0.50 to 7.81)	0.026
(min)	Median (range)	65 (6-260)	69 (8-297)		
Anesthesia	Spinal	759 (96.3%)	773 (96.1 %)		0.225
	General	22 (2.8 %)	24 (3.0 %)		
	Other/ missing	0 (0%)/ 7 (0.9 %)	3 (0.4 %)/ 4 (0.5 %)		
Implant	ТНА	33 (4.2%)	36 (4.5%)		0.806
	Hemi-prosthesis	284 (36.0%)	330 (41%)		0.045
	Girdlestone	4 (0.5%)	4 (0.5%)		1.000
	Intramedullary nail	32 (4.1%)	34 (4.2%)		0.900
	Sliding hip screw	272 (34.5%)	288 (35.8%)		0.600
	Hip screws	163 (20.7%)	112 (13.9%)		0.000

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the tables and figures and revised the manuscript. LGJ planned the study and revised the manuscript.	d as
TB planned the study and revised the manuscript. KH planned the study, did the data collection and	10.11
the data analysis, wrote and revised the manuscript.	136/bi Pr
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Ethical considerations: This study was approved by the Regional Committee for Medical Research	74 on yht, in
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Data Sharing: No additional data available.	ugust 2 ng for 1
Transparency: The lead author (the manuscript's guarantor) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.	2017. Downloaded from http://bmjopen.bmj.com/ on June Superieur (ABES) . uses related to text and data mining, Al training, and simi
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Flowchart describing number of included and excluded patients

142x160mm (300 x 300 DPI)



Hazards for death in respect to the number of days after admission

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72x52mm (300 x 300 DPI)



Hazards for number of days to first readmission Competing-risks analysis with death defined as a competing event

72x52mm (300 x 300 DPI)

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## **BMJ Open**

# Mortality and readmission following hip fracture surgery: a retrospective study comparing conventional and fast track care

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5	1	Mortality and readmission following hip fracture surgery: a
6	2	retrospective study comparing conventional and fast-track care
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24 25	ABSTRACT
26	<b>Objective:</b> To compare the efficacies of two pathways —conventional and fast-track care—in
27	patients with hip fracture.
28	Design: Retrospective single-center study.
29	Setting: University hospital in middle Norway.
30	Participants: 1820 patients aged $\geq$ 65 years with hip fracture (intracapsular, intertrochanteric, or
31	subtrochanteric).
32	Interventions: 788 patients were treated according to conventional care from April 2008 to
33	September 2011, and 1032 patients were treated according to fast-track care from October 2011 to
34	December 2013.
35	Primary and secondary outcome: Primary: Mortality and readmission to hospital, within 365 days
36	follow-up. Secondary: Length of stay.
37	Results: We found no statistically significant differences in mortality and readmission rate between
38	patients in the fast-track and conventional care models within 365 days after the initial hospital
39	admission. The conventional care group had a higher, no statistical significant mortality hazard ratio
40	of 1.10 (95% CI; 0.91 – 1.31, p =0.326) without and 1.16 (95% CI; 0.96 – 1.40, p =0.118) with covariate
41	adjustment. Regarding the readmission, the conventional care group subhazard ratio was 1.02 (95%
42	Cl; 0.88 – 1.18, p =0.822) without and 0.97 (95% Cl; 0.83 – 1.12, p =0.644) with adjusting for
43	covariates. Length of stay and time to surgery was statistically significant shorter for patients who
44	received fast-track care, a mean difference of 3.4 days and 6 h, respectively. There was no
45	statistically significant difference in sex, type of fracture, age or Charlson Comorbidity Index score at
46	baseline between patients in the two pathways.
47	Conclusions: There was insufficient evidence to show an impact of fast track care on mortality and
48	readmission. Length of stay and time to surgery were decreased.
49	Further studies should thus focus on the health economic aspects of fast-track care. In addition to
50	obvious benefits for the patient, a standardized treatment regime can be cost effective.
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5	54	Strengths and limitations of this study
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10	56	<ul> <li>Wide inclusion criteria, including also the most fragile patients</li> </ul>
11	57	The almost complete data set with few missing data
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13	58	Retrospective design
15	59	<ul> <li>Data collected in two different periods of time</li> </ul>
16 17	60	<ul> <li>Lacks data for dwelling before admission and after discharge</li> </ul>
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#### **INTRODUCTION**

Elderly patients, aged 50 years or older, with a hip fracture have an increased risk of mortality and comorbidity.<sup>1-3</sup> While a 25% mortality rate was reported at 12 months,<sup>4</sup> another study reported an increased mortality risk 10 years after the fracture.<sup>5</sup> Co-morbidity and general frailty makes these patients especially vulnerable to trauma such as a hip fracture <sup>6</sup>. 

There is no consensus regarding the most beneficial treatment factors to optimize outcomes after hip fracture surgery, but in the last 15 years, guidelines have focused on factors to optimize the care involved.<sup>7</sup> Early surgery is considered a key factor to reduce subsequent mortality risk.<sup>8-10</sup> Early mobilization may lessen mortality, length of stay (LOS), and further postoperative hospitalization.<sup>11-14</sup> The LOS differs between studies and the effect is not consistent, some show that prolonged LOS may increase readmissions after discharge, <sup>15 16</sup> and others find that a reduction in LOS increase mortality. 

The incidence of hip fractures in Norway is high, like in other Scandinavian countries.<sup>18-20</sup> So far, the majority of patients in Norway are treated with a low surgical priority and extended hospitalization. 

Fast-track care is a way of organizing clinical pathways using principles from lean methodology.<sup>21</sup> The key concept is standardization of all routines in the clinical pathway: priority to surgery, standardized surgical techniques, improved pain control, and early mobilization.<sup>22 23</sup> However, different hospitals employ different aspects of the fast-track system.<sup>22</sup> Fast-track care for patients with hip fracture was established at the St. Olavs Hospital, Trondheim University Hospital, Norway, in 2011 and included surgical priority, early mobilization, medication reconciliation, and a standardized treatment from admission to discharge.

The primary aims of this study were to compare the mortality and readmission rate within 365 days after a hip fracture in patients allocated to either conventional or fast-track care. The secondary aim was length of stay.

## **METHODS**

#### 90 Study design

This was a single-center retrospective study carried out at St. Olavs Hospital, University Hospital in
Trondheim, Norway, primary hospital for 300 000 inhabitants in the middle of Norway, that treats
approximately 400 hip fractures yearly. In Norway, all hip fracture patients are treated in public
hospitals.

#### 95 Study population

The study included a total of 1820 patients undergoing hip fracture surgery between April 2008 to
September 2011 (conventional care) and October 2011 to December 2013 (fast-track care).

98 In-hospital data was obtained from our internal hip-fracture quality register, manually reviewed

- 99 medical records, and partly the Trondheim Hip Fracture Trial study (HFT).<sup>14 24</sup> Retrospective data up
- 100 to 365 days after discharge was collected by manually reviewing medical records. Only readmissions
- 101 to Trondheim University Hospital were registered, because data from other hospitals were not
- 102 available. Permanent residents of Norway could be identified by their 11-digit personal identification
- 103 number. Patient identity was used to collect previous medical history from administrative databases
- 104 and reported deaths.

## 105 Inclusion and exclusion criteria

- 106 Our inclusion criteria were as follows: patients aged  $\geq$ 65 years, with an intracapsular,
  - 107 intertrochanteric, or subtrochanteric hip fracture admitted and undergoing surgery at the University
- 108 Hospital. Patients fulfilling these criteria were included irrespective of co-morbidity, dwelling or short
- 109 life-time prognosis. The study was approved by the Regional Committee of Ethics in Medical
- 110 Research and participant consent was not required.
- Only data from the patient's first hip fracture in the study period was included in the hip fracture analysis. Any subsequent hip fracture was included as a readmission along with other causes of readmission. Twenty-one patients geographically belonging to other hospitals underwent surgery at our hospital. Readmission data for these were not available and registered as "missing" in the readmission analysis.

The total number of patients along with the detailed inclusion and exclusion criteria is presented as a
flowchart (Figure 1). The HFT study was conducted at our hospital from 2008 to 2010. The present

study has wider inclusion criteria than the HFT. In the HFT the sickest patients, defined as patients with pathological fractures, a short life expectancy or living permanently in nursing homes, were excluded. If all of the sickest were considered as eligible in the present study, we would end up with a skewed population with an overrepresentation of the sickest. To adjust for this we randomly excluded 50% of the sickest patients in the time-period 2008-2010 from eligibility in order to re-establish a representative population. Neither patients in the HFT who were randomized to

comprehensive geriatric care (CGC) were eligible to our study.

**Comorbidity Indices** 

We used the Charlson Comorbidity Index score (CCIs) to control for equality in health between the two groups.<sup>25</sup> The coding algorithm developed by Quan identified the comorbidities and defined the weight score, ranging from 0 to 24.<sup>26 27</sup> The present CCI scores were based on all ICD-10 diagnosis codes occurring in the last three years prior to and including the current episode, partly based on the standards from the Norwegian Knowledge Centre for the Health Services.<sup>28</sup> Both main and secondary diagnoses (ICD-10), with no limitations to the number, were registered.

Both comorbidity and age may predict probability of death. The Charlson Comorbidity-Age Index score (CCAIs)<sup>25 29</sup> is calculated by adding one point for each decade from the time the patient turns 50 years old to adjust for age. Both indices were calculated, only the CCIs was used in the regression analysis.

The pathways

**Conventional care** 

Patients were at first examined by a general practitioner at the site of the injury. The patient was then transported by ambulance to the emergency unit for another examination by an orthopaedic resident on call, sent to the radiology department, and subsequently back to the emergency unit. Finally (and very often after 3–4 h of waiting time), the patient was brought to the orthopaedic ward. Nursing routines (pain control, nutrition, fluid therapy, and prevention of pressure sores) were then initiated. Prolonged waiting time for surgery was often the result as patients with hip fractures were not prioritized for surgery. Very few treatment procedures were standardized and designed for this special patient group. Surgery was often performed between 11:00 p.m. and 8:00 a.m. There was no strict mobilization regimens to ensure mobilization first postoperative day.

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150 **Fast-track care** 151 The fast-track care were started at the site of injury, on arrival of the ambulance personnel. They 152 examined the patient and directly reported to the hospital with a tentative diagnosis of "hip 153 fracture" without contacting a practitioner. Pre-operative treatment like administration of morphine, 154 oxygen, and prevention of pressure sores was started. The patient was transported directly to the 155 radiology department, and further on to the orthopaedic ward, all by the ambulance personnel. On arrival at the orthopaedic ward, standardized nursing routines (pain control, nutrition, fluid therapy, 156 157 and prevention of pressure sores) were begun. Regional anesthesia in the form of a femoral block 158 were established, while an orthopaedic resident on call examined the patient. All patients with hip 159 fracture were scheduled for surgery within 24 h (although not between 10:00 pm. and 8:00 am). 160 Preparation for discharge was started on the day of admission and thus the coordination with the 161 municipal health service had an early start. Whenever possible, all patients were mobilized on the 162 first postoperative day with a physiotherapist. Ward-based pharmacists evaluated the medication lists by using the method of medication reconciliation.<sup>30 31</sup> 163 164 To summarize the differences between the two pathways: for the conventional care there was no 165 preoperatively scheduled time for surgery. The pre- and postoperative pain control and

- 166 postoperatively mobilization regimens were not standardized.
  - For the fast-track care there were scheduled surgery within 24 hours, early preparation of discharge,
    standardized pre- and postoperative pain control, standardized mobilization on first postoperative
    day and medication reconciliation.
  - Both pathways had similar discharge criteria; when the orthopaedic surgeon conclude there is no
    need for further medical assessment or treatment in the specialist health services.
  - 172

#### 173 Hip fracture surgery implants

- 174 For intracapsular fractures, hip screws were mostly used until 2008. After this time, a bipolar,
- 175 cemented hemiprosthesis has most often been used for this fracture type.<sup>7 32</sup> For intertrochanteric
- 176 fractures, sliding hip screws were used, and for subtrochanteric fractures, intramedullary nailing or
- 177 sliding hip screws were used.

#### 178 **Primary outcomes**

180	Mortality
181	The follow-up time was 365 days. Time to death was calculated from admission to possible event.
182	The specific mortality rate at 30 days, 90 days, and 365-days follow-up are also reported.
183	Readmission
184	The follow-up time was 365 days. A readmission was registered as such if unplanned hospitalization
185	occurred more than 8 h after discharge of the previous admission. Reason for readmission was based
186	on the primary diagnosis (ICD 10). The readmission rates specific to the 30-day, 90-day, and 365-days
187	follow-up are reported.
188	Length of stay (LOS)
189	Length of stay was defined as the number of days between admission and discharge from the
190	hospital. If the patient was treated at another or several hospital departments after the fracture, the
191	total number of treatment days were counted.
192	Secondary outcome
193	Time to surgery (TTS)
194	Time to surgery was calculated as hours from hospital admission to surgery, as the exact time of the
195	fracture was unknown.
196	Statistical analysis
197	The analyses were performed using Stata 14 (StataCorp LP, Texas, USA). The command "Sample" was
198	used to exclude a randomized 50% portion of the sickest patients in the time period 2008-2010.
199	Visual inspection of $\Omega$ - $\Omega$ plots was used to evaluate normality of data. Independent-samples <i>t</i> -test
200	was used for normally distributed data (age). Wilcoxon rank-sum test for non-normally distributed
200	data (CCIs, CCAIs, TTS, surgery time and LOS) and Pearson chi-square tests were used for categorical
201	data (sex and type of hin fracture, anesthesia and implant)
202	
203	In the following two models, covariates were included in the analyses. The selection of covariates
204	was based on clinical considerations. Cox proportional hazards regression (command, stcox) was
205	used to analyze patient mortality hazards and Competing-risks regression (command, stcrreg) to
206	analyze the hazards of readmission. The time variable, calculating mortality hazards was the number
207	of days from hospital admission to possible death. Calculating the readmission hazards, the time
208	variable was the number of days from hospital discharge to a possible first readmission. The follow-
209	up times were maximum 365 days respectively. Death was considered as the competing event when
210	analyzing the readmission hazards. The dataset was complete when analyzing the mortality hazards

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#### **RESULTS**

Of the total 1820 patients included, 788 were treated according to conventional care and 1032
patients according to fast-track care. There were no statistically significant differences between the
groups according to baseline characteristics, sex, fracture type, age at admission, CCIs and CCAIs
(Table 1).

Fifty-one patients (2.8%) died during index stay: 23 persons in the conventional care (2.9%) and 28
persons in the fast-track care (2.7%) groups. Further, 472 patients died within the first year after
admission: 213 belonged to the conventional care group and 259 to the fast-track care group.
Mortality data are presented in Table 2, and the Cox proportional hazards regression are presented
in Figure 2.

The conventional care group had a higher, no statistical significant mortality hazard ratio of 1.10
(95% Cl; 0.91 – 1.31, p =0.326) without and 1.16 (95% Cl; 0.96 – 1.40, p =0.118) with covariate
adjustment. The effects of care, CCls, patient's age, sex, LOS, type of fracture and type of implant are
presented in Table 3.

Within 30 days after discharge 103 patients were readmitted in the conventional care group and 155
patients in the fast track care group. Further, 725 patients were readmitted within first year, 319
patients in the conventional and 406 patients in the fast track care group. Readmission data are
presented in Table 2, and the Competing risk regression are presented in Figure 3.

The Competing-risks proportional subhazards of the number of days to first readmission showed no
statistical differences between the two groups. The conventional care group subhazard ratio was
1.02 (95% Cl; 0.88 – 1.18, p =0.822) without and 0.97 (95% Cl; 0.83 – 1.12, p =0.644) with adjusting
for covariates. The effects of the covariates are presented in Table 3.

The results regarding TTS, surgery time together with types of anesthesia, implants and LOS are presented in Table 4. TTS was 6 hours longer for patients who received conventional care. The use of anesthesia did not differ between the two groups. Surgery time was 4 minutes shorter for patients who received conventional care. There was an overall statistically significant difference in the use of implants between the two groups (p = 0.02). LOS was 3.4 days shorter in the Fast track care group. 

The most frequent reason for first readmission within 30 days after the index stay in the fast-track
care group was postoperative wound infection (n = 20 [12.9%]) and pneumonia (n = 13 [8.4%]). In the

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conventional care group, pneumonia was the most frequent (n = 11 [10.7%]), followed by postoperative wound infection and cardiac disease (both n = 7 [6.8%]).		st published as 10.11
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#### **DISCUSSION**

> We found no statistically significant difference in mortality and readmission rate for patients in the fast-track care compared to conventional care within 12 months after hospital admission. We found a statistically significant decrease of approximately 6 h in TTS and 3.4 days in LOS. Baseline patient characteristics were similar.

> A Danish study compared results before and after introduction of Fast-track and fond a decrease in
>  TTS, into 26.4 h, a shorter LOS, 9.7 days, a reduction in in-hospital postoperative complications and a
>  trend toward a lower mortality, a 12-month rate of 23%, after introduction of the Fast track
>  treatment.<sup>34</sup>

The reduction in TTS and LOS in the fast-track care group in our study are the results of improved treatment and rehabilitation factors, both pre- and postoperatively. Preoperatively, standardized pain control, nutrition and fluid therapy, nursing routines, early preparation of discharge and early surgery. Postoperatively, standardized pain control, early mobilization and medication reconciliation. The discharge is prepared on admission to avoid delay by organizational reasons. The interaction of clinical and organizational factors can affect LOS.<sup>35</sup>

The reduced TTS can only partly explain the reduced LOS in the present study. But, the early surgery, efficient pain relief, mobilization on the first postoperative day and early cooperation with the municipal help service to arrange for rehabilitation in an institution or the patient's own home are elements that can contribute to a shorter LOS. National Institute for Health and Care Excellence (NICE) guidelines recommend an early supported discharge for care home and nursing home patients to ensure a systematic approach to rehabilitation.<sup>7</sup> An efficient pain relief may allow an early mobilization which is considered to be an essential part of the rehabilitation process.<sup>36</sup> A Danish hip fracture study found that patients following a fast-track performance had lower odds of readmission at 30 days (17.4%); their results were associated with early mobilization, systematic pain assessment, and anti-osteoporotic medication.<sup>37</sup> 

The use of implant differed between the two groups because of the general shift from hip screws to hemiprostheses treating intracapsular fractures, in line with published recommendations.<sup>38</sup>. Both the type of hip fracture and type of implants were included as covariates when analyzing the hazards. The effect of differences in the use of implant between the two groups should therefore be minimized.

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The increase in use of hemiprostheses and a subsequent reduction in use of hip screws, can likely
explain the increase in surgery time in our fast-track care. Use of spinal anesthesia is higher in
Norway than in other countries.<sup>22 34</sup> There is no evidence that spinal anesthesia decreases the
mortality risk or eases the recovery of the patient,<sup>39 40</sup> one study found an increase in LOS after nongeneral anesthesia, <sup>41</sup> a review found a modestly shorter LOS <sup>40</sup>.

We are yet unsure if the switch to merely day-shift surgery has an impact on outcome. One could assume a reduction in complications, though we did note a small increase in the postoperative wound infection in the fast-track group. A comparison <sup>42</sup> of day- and night-shift surgery did not find any higher postoperative complication rate in night-shift surgery, but the study size was small, which could have affected the result. Introduction of day-shift surgery and a reduction of TTS indicates that fast-track care at our hospital improved the efficiency of care and was beneficial to both patients and staff. The medication reconciliation may reduce medical side effects, such as dizziness, nausea and prevent new falls from occurring, and was therefore included as an element in our fast-track care.

The critical factors for mortality are increased CCIs, older age, and male sex, the critical factor for readmission is an increased LOS, even if the effect is small. In our study, the most common cause for first readmission within 30 days in the fast-track care group was wound infection, while pneumonia was the most common cause in the conventional care group.

Priority for surgery and a standardized treatment is beneficial for these vulnerable patients. Less
night-shift surgery, less hospital beds filled and reduced LOS without increasing serious complications
is beneficial for the health care system. We find the factors included in our fast-track concept
favorable.

#### 305 Strengths and limitations

The strengths of the study are the almost complete data set, with few missing data; prior to, inhospital, and after surgery and our extensive inclusion criteria; including all patients 65 years and older, irrespective of health status. It is known that the Kaplan-Meier estimator may overestimate the probability of events of interest when competing risks are present. Therefore, death was included as a competing event when analyzing the readmission hazards.<sup>43</sup>

- 312 There are limitations to our study, mainly owing to its retrospective design. A randomized
- 313 comparison of the two pathways was not feasible as both care models could not be run at the same

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time because of practical hospital considerations. There was no difference in baseline characteristics
of fracture types or patient's characteristics, justifying our comparisons across two time periods. Only
the readmissions to our hospital were registered. Because most of the included patients
geographically belonged to this hospital and had a very low geographical mobility, we assumed that
most of the readmissions would be to our hospital and thus, registered. Other limitations are that the
calculation of TTS is from the time of hospital admission and not from the actual fracture time, and

### *Conclusion*

322 The results was insufficient to show an impact of fast track care on mortality and readmission. The

323 core of our study was the reduction in TTS and LOS without increasing mortality and readmission

324 rates in the fast-track care model.

- 325 Further work should focus on patients' discharge location, if the decrease in LOS could be a result of
- 326 a change in the rehabilitation care, and it should explore the mortality rate beyond 12 months.

327 Further studies should also focus on the health economic aspects.

the lack of data for dwelling before admission and after discharge.
Table 1

**Baseline patient characteristics** 



			Conventional care	Fast-track care	p-valu	
Number of patien	ts		788	1032		
Sex	Female		574 (73%)	734 (71%)		
(category)	Male		214 (27%)	298 (29%)	0.419	
Hip fracture	Intracapsular	fracture	512 (65%)	646 (63%)		
(category)	Intertrochant	eric fracture	234 (30%)	325 (31%)	0.567	
	Subtrochante	ric fracture	42 (5%)	61 (6%)	-	
Age at admission		Mean (SD)	83. 1 (7.4)	83.1 (7.7)		
(years)		Median (range)	84 (65-104)	84 (65-102)	0.823	
Charlson Comorb	idity Index	Mean (SD)	1.21 (1.6)	1.14 (1.6)		
score (CCIs)		Median (range)	0 (0-9)	0 (0-10)	- 0.330	
Charlson Comorbi	dity-Age Index	Mean (SD)	5.1 (1.8)	5.0 (1.9)		
(CCAIs)		Median (range)	5 (2-13)	5 (2-15)	0.474	



#### 335 Table 2

#### 336 Mortality and readmission rates within 365 days after the index hip fracture discharge

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	Conventional	Fast-track care	p-value
	care		
Mortality (cum)			
Within 30 days	63 (8.0%)	77 (7.5%)	0.368
Within 90 days	115 (14.6%)	137 (13.3%)	0.230
Within 365 days	213 (27.0%)	259 (25.1%)	0.190
No of patients readmitted (cum)			
Within 30 days	103 (13.4%)	155 (15.5%)	0.132
Within 90 days	187 (24.4%)	244 (24.4%)	0.504
Within 365 days	319 (41.7%)	406 (40.5%)	0.338
No of readmissions (cum)			
Within 30 days	116	172	0.144
Within 90 days	238	305	0.431
Within 365 days	515	678	0.463



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5	2/11	Hazard ratio of mortality within 365 days after admission and number of days to first readmission
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	Hazard Ratio	95% Confide	ence Interval	p-value
Mortality				
Conventional care	1.16	0.96	1.40	0.118
CCIs	1.38	1.33	1.44	< 0.001
Age	1.07	1.05	1.08	< 0.001
Male sex	1.46	1.20	1.77	< 0.001
LOS	0.99	0.98	1.00	0.182
Type of fracture	1.06	0.91	1.23	0.476
Type of implant	1.03	0.97	1.09	0.401
Readmission				
Conventional care	0.97	0.83	1.12	0.644
CCIs	1.05	1.00	1.09	0.043
Age	1.01	1.00	1.02	0.020
Male sex	1.22	1.04	1.44	0.014
LOS	1.01	1.00	1.02	0.004
Type of fracture	0.91	0.81	1.04	0.192
Type of implant	1.07	1.02	1.11	0.006



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#### Table 4

#### Outcome measures; time to surgery, anesthesia type, implant type surgery time and length of stay

		Conventional care	Fast-track care	p-value	
Time to	Mean (SD)	31.2 (25.1)	25.2 (21.2)	<0.001	
surgery (h)	Median (range)	25 (0-289)	21 (1-236)	~0.001	
Anesthesia	Spinal	759 (96.3%)	773 (96.1 %)		
(category)	General	22 (2.8 %)	24 (3.0 %)	0.225	
	Other/ missing	0 (0%)/ 7 (0.9 %)	3 (0.4 %)/ 4 (0.5 %)		
Implant (category)	ТНА	33 (4.2%)	36 (4.5%)	0.806	
	Hemiprosthesis	284 (36.0%)	330 (41%)	0.045	
	Girdlestone	4 (0.5%)	4 (0.5%)	1.000	
	Intramedullary nail	32 (4.1%)	34 (4.2%)	0.900	
	Sliding hip screw	272 (34.5%)	288 (35.8%)	0.600	
	Hip screws	163 (20.7%)	112 (13.9%)	<0.001	
Surgery time (min)	Mean (SD)	67.0 (38.1)	71.1 (36.3)	0.014	
	Median (range)	65 (6-260)	69 (8-297)	0.014	
Length of stay	Mean (SD)	9.5 (8.2)	6.1 (5.5)	10.001	
(days)	Median (range)	8 (1-120)	5 (0-50)	<0.001	

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- the tables and figures and revised the manuscript. LGJ planned the study and revised the manuscript.
- TB planned the study and revised the manuscript. KH planned the study, did the data collection and
- the data analysis, wrote and revised the manuscript.
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- Competing interest: None.
- Ethical considerations: This study was approved by the Regional Committee for Medical Research
- Ethics, Central Norway (REK 2013/336, 2015/485, 2017/494, REK midt).
  - Data Sharing: No additional data available.
  - Transparency: The lead author (the manuscript's guarantor) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Page 25 of 31



Figure 1 Flowchart

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Figure 2 Cox proportional hazards regression

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Figure 3 Competing-risks regression

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STROBE Statement-checklist of items that should be included in reports of observational studies

	Item	Decommondation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		In the Title and page 2, line 28.
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
		Page 2, line 32 and line 37.
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
		Page 4, line 65.
Objectives	3	State specific objectives, including any prespecified hypotheses Page 4, line 85.
Methods		
Study design	4	Present key elements of study design early in the paper Page 5, line 91.
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment.
betting	J	exposure, follow-up, and data collection
		Page 5, line 91, line 96 and line 98.
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of
		selection of participants. Describe methods of follow-up
		Flowchart (Figure 1) and page 5, line 106.
		Case-control study—Give the eligibility criteria, and the sources and methods of
		case ascertainment and control selection. Give the rationale for the choice of cases
		<i>Cross-sectional study</i> —Give the eligibility criteria and the sources and methods of
		selection of participants
		(b) Cohort study—For matched studies, give matching criteria and number of
		exposed and unexposed
		Not relevant.
		Case-control study—For matched studies, give matching criteria and the number of
		controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
		Page 6, line 140, page 7, line 150 and page 8, line $180 - 195$ .
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there

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		Page 5, line 98 and page 6, line 128.
Bias	9	Describe any efforts to address potential sources of bias Page 5, line 111, page 6, line 122 and page 6, line 128.
Study size	10	Explain how the study size was arrived at <b>Page 5, line 96.</b>
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why <b>Page 8, line 197.</b>
Statistical methods	12	( <i>a</i> ) Describe all statistical methods, including those used to control for confounding <b>Page 8, line 199.</b>
		(b) Describe any methods used to examine subgroups and interactions Not relevant.
		(c) Explain how missing data were addressed Page 8, line 210.
		( <i>d</i> ) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <b>Page 8, line 210.</b>
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of
		sampling strategy (e) Describe any sensitivity analyses
Continued on next page		

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers notentially eligit
Participants	15	examined for eligibility, confirmed eligible included in the study completing follow-
		analysed
		Figure 1 (Flowchart) Table 2 and page 10 line 220
		rigare 1 (110) enarcy, 14010 2 una page 10, me 2201
		(b) Give reasons for non-participation at each stage
		Figure 1 (Flowchart)
		(c) Consider use of a flow diagram
		A flowchart is already included, Figure 1.
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and info
data		on exposures and potential confounders
		Table 1 and page 10, line 220.
		(b) Indicate number of participants with missing data for each variable of interest
		Page 10, line 224 and Table 4.
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
		Page 10, line 225 and Table 2.
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time
		Page 10, line 224 and Table 2.
		Case-control study—Report numbers in each exposure category, or summary measures
		exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and the
		precision (eg, 95% confidence interval). Make clear which confounders were adjusted t
		why they were included
		Page 10, line 229, page 10, line 237 and Table 3.
		(b) Report category boundaries when continuous variables were categorized
		Not relevant.
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a mea
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a mea time period
		<ul><li>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meatime period</li><li>Not relevant.</li></ul>

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivit analyses
		Not relevant.
Discussion		
Key results	18	Summarise key results with reference to study objectives
		Page 12, line 254.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or impred
		Discuss both direction and magnitude of any potential bias
		Page 13, line 306 and page 13, line 312.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, mul
		of analyses, results from similar studies, and other relevant evidence
		Page 14, line 322.
Generalisability	21	Discuss the generalisability (external validity) of the study results
		Page 13, line 306.
Other information	on	
Funding	22	Give the source of funding and the role of the funders for the present study and, if appl
rununig		for the original study on which the present article is based
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runung		Page 20, line 357.
*Give informatio	n sepa	Page 20, line 357.
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*Give informatio unexposed group: <b>Note:</b> An Explan- published exampl available on the V	n sepa s in co ation a les of t Web si	Page 20, line 357. rately for cases and controls in case-control studies and, if applicable, for exposed and hort and cross-sectional studies. and Elaboration article discusses each checklist item and gives methodological backgrour ransparent reporting. The STROBE checklist is best used in conjunction with this article tes of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at and Enidemiology at http://www.enidem.com/). Information on the STROPE Initiation