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Hip precautions not meaningful after hemiarthroplasty due to hip fracture. Cluster-randomized study of 394 patients operated with direct anterolateral approach

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ABSTRACT

Aims: We aimed to compare two treatment regimes, one with and one without postoperative precautions in hemiarthroplasty patients, in terms of dislocation rate and patient-reported outcome. Direct lateral approach was used.

Patients and Methods: 394 patients were included in a cluster-randomized study 2010−2014. Depending on which ward they were admitted to, they were allotted to free rehabilitation (non-precaution group, NPG, n = 226) or our conventional regime with precautions and mandatory assistive equipment (precaution group, PG, n = 168). Patients were followed during hospital stay, at 6 weeks (postal questionnaire), 3 month (visit) and 6 months (reading of medical records) by means of function tests, health-related quality of life (EQ-5D) and other patient-reported outcome measures (PROM).

Results: One patient in each group had dislocation(s). We found no statistically significant differences regarding in-hospital-mortality, severe adverse events, EQ5D index or other PROM. In the NPG, rehabilitation personnel had significantly shorter work effort during hospital stay ($p < 0.001$). 7 in the NPG and 13 of the PG had reoperations ($p = 0.038$), 4 and 8 had deep infections, 3 and 5 periprosthetic fractures.

Conclusion: Rehabilitation precautions are not needed for preventing dislocation when direct lateral approach is used. Without precautions, rehabilitation personnel implement significantly shorter work effort during hospital. We found no statistically significant differences regarding PROM and complications except for somewhat more reoperations in total in the precaution group.

Introduction

A majority of elderly with displaced femoral neck fractures are treated with arthroplasty, either hemiarthroplasty (HA) or total hip arthroplasty (THA) [1–3]. Dislocation is a major concern, often requiring further surgical intervention [4–6]. The surgical technique can influence the dislocation risk [4,6–11] as well as patient factors such as dementia, neurological diseases [12,13] and poor soft tissue tension [14,15]. Apart from choosing the most suitable surgical technique for each patient, several preventive postoperative measures are traditionally undertaken. The patients are often prescribed movement restrictions and mandatory use of assistive devices to reduce the risk of dislocation [16,17]. But such precautions have been associated with less satisfaction, slower return to ADL and higher costs in patients with THA [16]. Only two randomised studies have evaluated hip precautions. They did not find any effect on dislocation risk, when studying THA in osteoarthritis patients operated on with direct lateral approach [18,19]. A review paper on hip precautions in fracture patients, concluded that studies are lacking and results from studies investigating patients with elective THA due to osteoarthritis cannot be extrapolated to fracture patients, due to different patients' characteristics [20]. For HA, national guidelines state precautions to be unnecessary, based on expert opinion [21].

To the best of our knowledge, no randomised trial has been performed to investigate the influence of hip precautions on dislocation rate after HA. Therefore, we designed such a study. Our

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aim was to compare two treatment regimes, one with and one without postoperative precautions after acute fracture-related hemiarthroplasty via direct lateral approach. The primary outcome was dislocation rate, and the secondary outcome was patient-reported outcome (PROM). Our hypothesis was that restriction free rehabilitation after HA does not increase the risk of dislocation, but leads to better patient-reported outcome. In addition, we aimed to evaluate the work burden on rehab personnel, related to the use of precautions, including prescription of mandatory assistive devices.

Patients and methods

394 patients with Garden III-IV [22] femoral neck fractures treated with hemiarthroplasty participated in a cluster-randomised study during 2010–2014 at XXXXX Hospital, XXXX. Inclusion criteria was an acute displaced femoral neck fracture treated with a bipolar hemiarthroplasty inserted via a direct lateral approach in supine position [23]. All such patients were considered potential study participants and invited to the study by an occupational therapist within the first postoperative days. If a patient was not capable of making decisions, relatives were asked. Detailed information of patient recruitment and follow-up is given in Fig. 1. The study was approved by The Regional Ethical Review Board in XXXX on condition that all participants, regardless of group, or their next-in-kin gave written consent (Dnr 2009/754). Since the study was deemed to pose only minimal risk and minimal burden on the participants (one group receiving standard-of-care, the other less restraining rehabilitation, warning levels to stop the study not required), the next-in-kin consent was considered ethically acceptable. In addition, we consider recruiting patients with dementia to clinical hip fracture studies to be highly relevant. Firstly, they constitute one third of that population and, secondly, any evidence-based guidelines should be based on studies including all relevant patient groups, this group as well.

Each of four wards managing hip fracture patients were assigned either to provide the standard postoperative hip precaution regime or the non-precaution regime during the entire study period. On two of the wards, the precaution group (PG) had standard postoperative hip precautions included limited flexion of the hip to 90° (avoid reaching down to toes or bringing knee up beyond 90°) and limited adduction of the hip (avoid sleeping on side and avoid crossing legs at knees or ankles). The mandatory assistive equipment to use for at least 3 months were reacher and stocking application aid. The patients were instructed only to use elevated chair, bed and toilet in order not to flex more than 90° in the hip. For the same reason a brace over the knee was prescribed for up to 6 weeks, particularly in patients with cognitive limitations.

The non-precaution group (NPG) consisted of patients treated on the other two wards. Patients in the NPG had no restrictions on mobility, i.e. they were encouraged to move freely during the recovery phase and assistive equipment were prescribed only if needed.

Admittance of a patient to either of the wards was only determined by bed availability, i.e. the health status of the patient or any other factors did not influence placement of patients. The wards were similar with regards to treatment protocol for hip fractures and level of expertise. We recruited 168 patients to the PG and 226 patients to the NPG. The size difference is explained by variation in number of beds available for fracture patients during the study period.

The initial power analysis was based on dislocation rate as the primary outcome. When designing the trial, we had a dislocation rate of 0.5% at the department. We calculated that, in order to detect an increase of 3.5 percentage points, i.e. a clinical relevant effect, we needed 340 patients in each group ($p < 0.05$). The original plan was to additionally monitor PROM in the first 400 patients, and then dislocation rate only in the remaining 400. Due to recruitment difficulties (see Discussion), the study was closed after inclusion of approximately 400 patients.

Functional assessment was made in both groups by an occupational therapist as part of standard-of-care, usually within

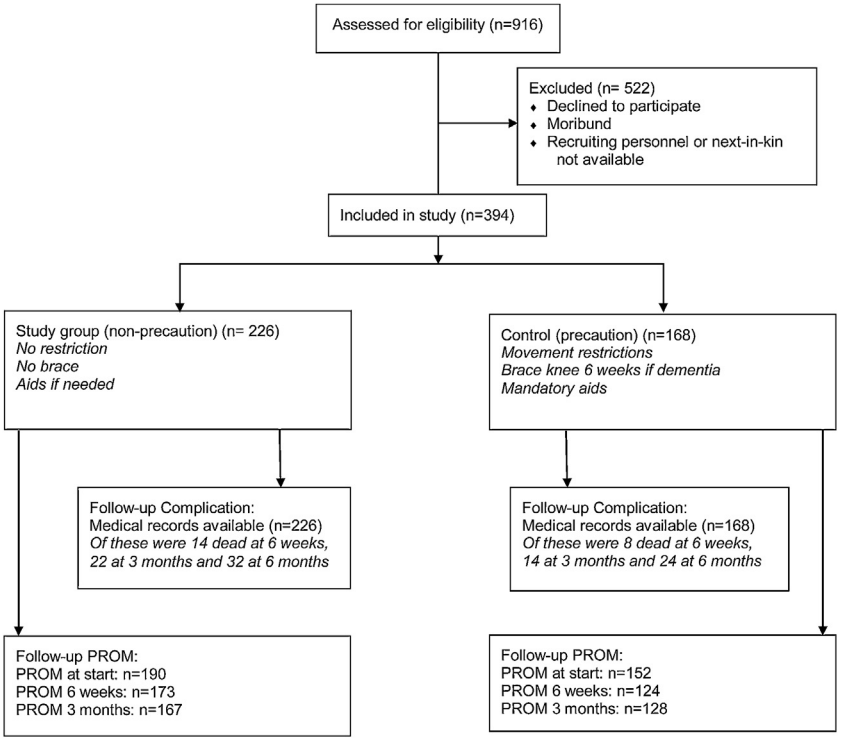

Fig. 1. Flow chart.

the first three postoperative days. The surgical procedure was a bipolar hemiarthroplasty inserted via a direct lateral approach (Hardinge) [23]. All implants were cemented, except 2 in the PG group and 5 in the NPG (1.2 and 2.2%).

During the hospital stay we registered time from admission to surgery, duration of surgery, type of implant, adversities during surgery, the experience of the surgeon, radiological evaluation, length of stay, any deaths and discharge address. The work burden of the rehabilitation personnel (occupational therapists and physiotherapists) during hospital stay was estimated by themselves as "very short", "short", "normal", "long" or "very long" work effort. No one reported "very long". "Very short" and "short" was grouped together in the analyses. The patients were followed up with postal questionnaire at 6 weeks and 3 months including EQ-5D [24] and a visual analogue scale on pain and satisfaction (0–100).

Medical records from all hospital departments (except psychiatry) were reviewed and all adverse events (death, dislocation, surgical site infection (SSI), periprosthetic fracture, deep vein thrombosis, pulmonary embolism, pneumonia, falls and new fractures, stroke and ischemic heart attack) up to 6 months postoperatively were recorded. SSI was divided in to superficial incisional SSI and deep incisional SSI and were defined according to Horan et al. [25]. The follow-up cannot consider to be blinded, as some information were gathered during the hospital stay where the group belonging of the patient was obvious.

Parallel to the study, one of the senior authors (XX) had the head of department's mandate to continuously monitor complications after hip fracture, as part of the department's quality improvement work. From this material, comparative data on dislocations was retrieved on those not included in the study.

The statistical software used was IBM SPSS Statistics 24. For description of data crosstabs were used. Nominal variables were tested by the Chi-square test and Fisher's exact test. The results were considered significant at $p < 0.05$. Uni- and multivariable linear regression models were used to investigate the association between hip precautions and patient-reported measures (EQ-5D index, Hip Pain VAS and Satisfaction VAS). The Wilson procedure with a correction for continuity was also used.

The study is registered at ClinicalTrials.gov; Identifier: NCT03468192.

Results

Patient characteristics are described in Table 1. There were no significant differences between the groups. In addition, occurrence of any alcoholic abuse was derived from medical records, but only 8 in the NPG 6 and 6 in the precaution group (PG) (5 and 3%) had information on overconsumption, which assumingly underrates the condition.

Dislocation occurred in one patient in each group, resulting in a dislocation rate of 0.4% in the NPG and 0.6% in the PG (Table 2). Using the Wilson procedure with a correction for continuity, the confidence interval for dislocation rate was -0.0229 to +0.0336 for between group differences. This implies that the difference between the two groups was less than the 3.5 percentage points (with a 95% probability) that we considered a minimal clinically important difference when designing the study.

Amongst the 550 patients *not* enrolled in the study during the study period, 9 dislocations occurred, resulting in a total dislocation rate of 11 in 944 (1.2%). Noteworthy, 4 of the dislocations in non-study population occurred within the first 48 h postoperatively, i.e., these patients dislocated before we, potentially could have, include them in the study.

Reoperations occurred in 7 of 226 (3%) in the NPG and 13 of 168 (8%) of the PG ($p = 0.038$); corresponding to a total reoperation rate of 5%. 4 and 8 had deep infections, 3 and 5 periprosthetic fractures.

Total in-hospital-mortality was 10/394 (3%), without differences between groups. Within 6 months, 71 (31%) in the NPG and 45 (27%) in the PG had severe adverse events such as death (32 and 24) and/or pneumonia (31 and 17), while thromboembolic events were uncommon (8 and 4). Stroke and ischemic heart attack were counted as severe adverse events as well (Table 3).

Regarding the work burden of the rehabilitation personnel during hospital stay, both occupational therapists and physiotherapists had significantly shorter work effort (both $p < 0.001$) (Table 4).

Regarding PROM, 190 (84%) patients in the NPG and 152 (90%) patients in the PG were able to complete different parts of the pre-fracture and follow-up questionnaire. Response rate at 3-months was 167 (74%) and 128 (76%) respectively. Mean values for pain and satisfaction after 6 weeks and 3 months were almost identical between groups (Table 5). EQ5D index scores at pre-fracture, 6 weeks and 3 months, were similar for the two groups (Table 6).

Neither univariable nor multivariable regression models could identify relationships between precaution regimen and the patient-reported outcome measures EQ-5D, pain VAS and satisfaction VAS (all $p < 0.05$) (Table 7)

Discussion

Hip precautions and mandatory use of assistive devices were not associated with the risk of dislocation after hemiarthroplasty

Table 1
Patient characteristics at inclusion.

	Non-precautions n = 226			Precautions n = 168			
	years	SD		years	SD		T-test
Mean age	85.2	7.4		83.6	7.4		0.78
	n	%	miss.	n	%	miss.	Chi-2
Female	144	64		117	70		0.22
Own home	184	82	2	148	88	0	0.11
No home care	77	35	3	70	43	5	0.09
No dementia	156	70	4	118	73	6	0.58
No neurologic disease	183	84	8	136	85	7	0.89
Need of walking aids	173	99	53	146	100	22	0.36
Able to climb stairs	102	66	71	85	75	55	0.10
Uncomplicated surgery	178	79		136	81		0.59
	hours	SD		hours	SD		T-test
Mean waiting to surgery	25	17		24	15		0.65
	minutes	SD		minutes	SD		T-test
Mean surgery time	83	27		81	29		0.20

Miss. = number of patients with missing data for the particular variable.

Table 2
Hip complications within 6 months based on reading of medical records. Fisher's Exact test is given when minimum expected count is low, i.e. few events to detect differences.

	Non-precautions n = 226		Precautions n = 168			
	n	%	n	%	Chi-2-test	Fisher
Dislocation	1	0.4	1	0.6	0.83	1
Reoperations	7	3.1	13	7.7	0.04	
Superficial wound infection	21	9.3	13	7.7	0.59	
Deep infection	4	1.8	8	4.8	0.09	
Periprosthetic fractures	3	1.3	5	3.0	0.25	0.29
Other hip complication (pain, loosening)	0	0	3	1.8	0.04	0.08

Table 3
General complications within 6 months based on reading of medical records and mortality. Fisher's Exact test is given when minimum expected count is low, i.e. few events to detect differences.

	Non-precautions n = 226		Precautions n = 168			
	n	%	n	%	Chi-2	Fisher
Deep vein thrombosis	3	1.3	1	0.6	0.47	0.64
Pulmonary embolism	5	2.2	3	1.8	0.77	1,00
Pneumonia	31	13.7	17	10.1	0.28	
Acute myocardial infarct.	9	4.0	1	0.6	0.04	0.05
Delirium	6	2.7	4	2.4	0.86	1,00
Stroke	6	2.7	2	1.2	0.31	0.48
New fall	35	15.5	22	13.1	0.51	
New fracture	15	6.6	12	7.1	0.84	
Mortality during hosp.stay	7	3.1	3	1.8	0.41	0.53
Mortality 6 months	32	14.2	24	14.3	0.97	

Table 4
Self-estimation of the work burden of the rehabilitation personnel.

	Non-precautions n = 226		Precautions n = 168	
Work effort	n	%	n	%
Physiotherapists				
Short	65	29	21	13
Normal	94	41	108	64
Long	9	4	12	7
No information	58	26	27	16
Occupational therapists				
Short	64	29	9	5
Normal	125	55	141	84
Long	7	3	9	5
No information	30	13	9	5

Table 6
EQ5D at pre-fracture, 6 weeks and 3 months.

EQ5D	Non-precautions			Precautions		
	n	Mean	SD	n	Mean	SD
Prefracture	190	0.62	0.32	152	0.58	0.34
6 weeks	173	0.44	0.32	124	0.46	0.29
3 months	167	0.52	0.31	128	0.50	0.32

due to hip fracture, when direct lateral approach is used. Our results support national guidelines such as those from the UK [21] (although these were based on experts' opinion) and two earlier randomised studies on patients with THA because of osteoarthritis [18,19]. The number of dislocation is low when direct lateral approach is used [6,8,9], which is also highlighted with our study.

Regarding health-related quality of life, pain and satisfaction, there were no statistically significant differences between the two groups. Apparently, precautions did not play such an important role for patients' well-being and in contrast to our hypothesis. In general, hemiarthroplasty patients are satisfied with the result and free of hip pain at 3 months, when the whole group is analysed. Mean EQ-5D index is low, as expected, at 6 weeks and improves, but is still lower than prefracture, at 3 months.

There were more reoperations in the group with precautions, although we find it less plausible to be due to precautions per se. There were no statistically significant differences regarding other early complications such as in-hospital-mortality, deep infections and periprosthetic fractures. One can suppose that there would be fewer adverse events if patients were able to move more freely, but complications at 6 months, with adverse events such as death, thromboembolic, stroke and ischemic heart attack, did not differ between groups.

The work load for rehabilitation personnel was significantly less during the hospital stay for the non-precaution group. We concluded that, from both a scientific and health economic point-of-view, recommending precautions is not motivated. This

Table 5
Pain and satisfaction after 6 weeks and 3 months.

	Non-precautions			Precautions		
	n	Mean	SD	n	Mean	SD
Pain 6 weeks	164	25.4	19.7	114	25.4	19.6
Pain 3 months	132	17.4	16.8	109	16.8	18.4
Satisfaction 6 weeks	164	23.7	19.1	115	24.0	20.3
Satisfaction 3 months	132	16.3	16.6	106	16.4	16.1

Table 7
Uni- and multivariable regression models. Precaution group set as reference.

	6 weeks					
	Unadjusted			Adjusted*		
	Coefficient	Lower CI	Upper CI	Coefficient	Lower CI	Upper CI
EQ-5D	−0.03	−0.11	0.06	−0.07	−0.15	0.02
Pain	2.04	−4.04	8.10	2.65	−3.70	9.01
Satisfaction VAS	1.84	−4.22	7.90	1.51	−4.56	7.58
	3 months					
	Unadjusted			Adjusted*		
	Coefficient	Lower CI	Upper CI	Coefficient	Lower CI	Upper CI
EQ-5D	0.03	−0.06	0.12	0.01	−0.80	0.01
Pain	−5.51	−13.7	2.67	−5.61	−14.02	2.80
Satisfaction VAS	−3.05	−11.34	5.24	−2.66	−10.97	5.65

*Adjusted for age, sex and where appropriate pre-operative PROM level.
CI = 95% confidence interval.

has also been put forward by others [26,27]. Time and efforts should instead be spent on rehabilitation tailored for the individual patient, aimed at restoring mobility and independence.

Reasons for dislocations are multifaceted, including surgical factors [4,6,8–11] and patient factors [12–15]. When analysing *all* our patients during the study period, we found a somewhat higher dislocation rate, compared to the group that was included in the trial. However, most of these were early, already in the perioperative phase, prior to initiation of any precautions. But 7 of these total 11 dislocations would not have been possible to avoid with precautions anyhow; 4 occurred in the perioperative phase, i.e. before both mobilisation and study inclusion interview were undertaken. 3 others were due to trauma.

Our study has some limitations; the major is the low participation rate. Our ethics review board deemed written consent necessary, also for the control group receiving standard of care. The procedure of signing the document appeared alarming for many elderly, and finding next-in-kin willing to decide on behalf of the patient when needed was difficult or at best time-consuming. Therefore, several potential participants were lost to inclusion. Difficulties to enrol geriatric hip fracture patients is a well-recognized problem, also encountered by others [28]. Recruitment difficulties also forced us to close the study prematurely. We therefore used the Wilson procedure and corrected for continuity, and found the difference between the groups to be lower than the minimal clinical difference that we anticipated, suggesting our material to be sufficient. As a clinically significant effect was not discernible in a relatively large cohort, we dare to consider our findings relevant for departments that discuss whether to abandon hip precautions or not. Actually, the traditional type of clinical trials in the field is more often than not too small, when sample size is debated based on modern statistical methods [29]. One interpretation could be that the issue should be analysed in national registers. But, to the best of our knowledge, the combination of any precautions and any dislocation is not recorded in any national hip fracture audit.

It is important to underline that our study patients were treated using a direct lateral approach and we cannot draw any conclusion if other approaches are used. As the risk of dislocation is higher after posterior approach [30], the meaningfulness of precautions in combination with that approach therefore ought to be explored.

The strength of this study is that patients were randomly allotted. Ideally, a study like this should be randomised on individual level. For practical reasons, our study had to be cluster randomized. We regarded the risk of contamination of the intervention to be high if instead individual randomization had been used and, the staff should keep in mind precautions or not for different patients in adjacent beds. Therefore, we chose a unanimous regime in each ward since the staff including physiotherapists and occupational therapists are linked to one ward.

Regarding reporting of dislocations and other complications, none of the patients were lost to follow-up. Another strength is the response rate of the PROM questionnaire, which was acceptably high for this group of frail elderly individuals.

Conclusion

Our study shows that precautions are not needed to prevent dislocation after hemiarthroplasty in hip fracture patients if direct lateral approach is used. The rehabilitation personnel would use significantly less work effort during hospital stay, if abandoning routine precautions, and time can be used for more important rehabilitative measures. We found no differences regarding patient reported outcome and complications except for somewhat more reoperations in the precaution group.

Conflict of interest

The following authors has disclosures to make. None of them report an conflict of interest regarding the current study "*Hip precautions not meaningful after hemiarthroplasty due to hip fracture*".

Kristina Åkesson: Amgen – expert and lecture fees; UCB – expert and lecture fees; Renapharma – expert advice.

Ola Rolfson: ZimmerBiomet – paid lecturer.

Cecilia Rogmark: ZimmerBiomet – paid lecturer; Swemac – paid lecturer; DePuy Johnson & Johnson – paid lecturer.

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