■ HIP

High risk of positive Trendelenburg test after using the direct lateral approach to the hip compared with the anterolateral approach

A SINGLE-CENTRE, RANDOMIZED TRIAL IN PATIENTS WITH FEMORAL NECK FRACTURE

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Aims
The aim of this randomized trial was to compare the functional outcome of two different surgical approaches to the hip in patients with a femoral neck fracture treated with a hemiarthroplasty.

Patients and Methods
A total of 150 patients who were treated between February 2014 and July 2017 were included. Patients were allocated to undergo hemiarthroplasty using either an anterolateral or a direct lateral approach, and were followed for 12 months. The mean age of the patients was 81 years (69 to 90), and 109 were women (73%). Functional outcome measures, assessed by a physiotherapist blinded to allocation, and patient-reported outcome measures (PROMs) were collected postoperatively at three and 12 months.

Results
A total of 11 patients in the direct lateral group had a positive Trendelenburg test at one year compared with one patient in the anterolateral group (11/55 (20%) *vs* 1/55 (1.8%), relative risk (RR) 11.1; p = 0.004). Patients with a positive Trendelenburg test reported significantly worse Hip Disability Osteoarthritis Outcome Scores (HOOS) compared with patients with a negative Trendelenburg test. Further outcome measures showed few statistically significant differences between the groups.

Conclusion
The direct lateral approach in patients with a femoral neck fracture appears to be associated with more positive Trendelenburg tests than the anterolateral approach, indicating a poor clinical outcome.

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Hemiarthroplasty is considered the main form of treatment for displaced femoral neck fractures.[1-3] According to annual reports from national joint registries in Norway[4] and England, Wales, Northern Ireland and the Isle of Man,[5] most surgeons prefer to undertake this procedure using the posterior approach, followed by the direct lateral approach. The posterior approach increases the risk of further surgery due to dislocation, whereas the direct lateral approach in total hip arthroplasty (THA) causes more limping.[6,7] The direct lateral approach predominates in the Scandinavian arthroplasty registries, regardless of inferior patient-reported outcomes compared with the posterior approach.[4,8] Recently, the use of minimally invasive surgical (MIS) approaches for hip arthroplasty has increased, despite relatively little evidence of superiority compared with the posterior or lateral procedures.[9] The aim of this randomized trial was to compare the outcome following the use of two approaches to the hip in patients with a femoral neck fracture with a hemiarthroplasty. The direct lateral approach was chosen because it was the preferred method of treatment in our institution (Sorlandet Hospital, Kristiansand, Norway) when inserting a hemiarthroplasty in patients with a femoral neck fracture. The anterolateral approach was chosen because our institution uses this approach for THA in patients with arthritis (moving away from the direct lateral approach due to concerns regarding gluteal insufficiency).The short-term results, including the measurements of biomarkers and their association with patient-reported functional outcome,

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Table I. Baseline and perioperative characteristics and Harris Hip Scores (HHS) of the patients

Variable	Anterolateral approach (n = 75)	Direct lateral approach (n = 75)	All (n = 150)
Mean age, yrs (SD)	81.4 (5.9)	81.3 (6.3)	81.3 (6.1)
Sex, n (%)			
Female	52 (*69*)	57 (*76*)	109 (*73*)
Male	23 (*31*)	18 (*24*)	41 (*27*)
ASA, groups I/II, n (%)	24 (*32*)	25 (*33*)	49 (*33*)
ASA, groups III/IV, n (%)	51 (*68*)	50 (*67*)	101 (*67*)
Mean BMI, kg/m^2 (SD)	23.2 (3.99)	22.5 (3.2)	22.8 (3.6)
Median stem size (IQR)	12 (11 to 13)	12 (11 to 13)	12 (11 to 13)
Mean HHS (SD)*	82.6 (15.4)	85.4 (16.3)	84 (15.8)
Mean operating time, mins (SD)	46 (10)	41 (11)	44 (11)
Mean incision length, mm (SD)	100 (15)	103 (13)	102 (14)

*Estimated prior to fall

ASA, American Society of Anesthesiologists; BMI, body mass index; IQR, interquartile range

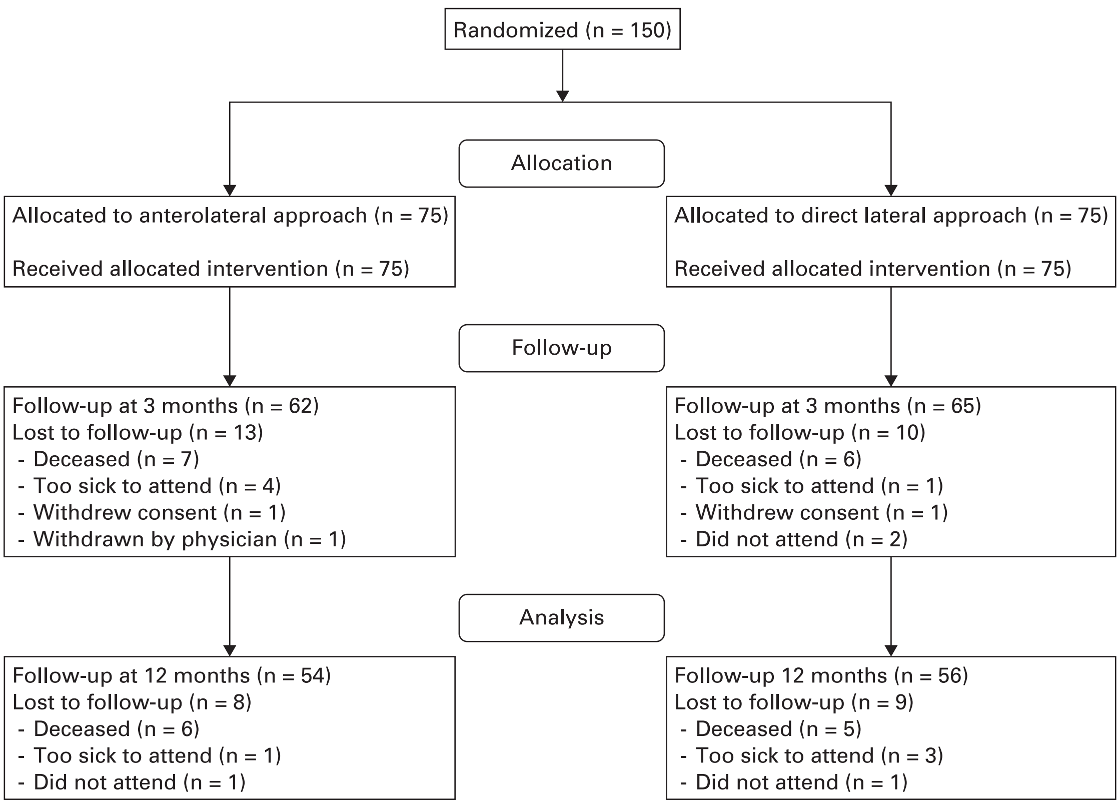

Fig. 1

Randomization and flow chart of femoral neck fracture patients during the study.

as well as the assessment of bone loss around the femoral stem, have recently been published.[10,11] We now report the outcomes 12 months postoperatively.

Patients and Methods

This was a blinded level I, prospective, randomized trial carried out at Sorlandet Hospital, Kristiansand, Norway, consisting of two parallel intervention groups (1:1 ratio) comparing different surgical approaches to the hip. The eligibility criteria were: a displaced femoral neck fracture in two radiographic planes, age between 70 and 90 years, intact cognitive function, and the ability to walk, with or without a walking aid, prior to falling. Those with a pathological fracture or local infection were excluded. The physician on duty handled the recruitment and all patients gave informed consent.

A total of 150 patients were enrolled between February 2014 and July 2017 (Fig. 1); 75 were randomized to the anterolateral group and 75 to the direct lateral group. The mean age was 81 years (69 to 90), and 109 were women (73%) (Table I). There were no major demographic differences between the groups, and the time between admission and surgery was similar.

Participants. Eligibility criteria for study participants were: a displaced femoral neck fracture in both radiological planes, aged between 70 and 90 years, intact cognitive function, and the ability to walk, with or without a walking aid, prior to falling. We did not include patients with a fracture in pathological bone, sepsis, or a local infection not eligible to be treated with a hemiarthroplasty. The physician on duty handled the recruitment and gave both verbal and written information about the trial.

A Corail cementless collared titanium alloy straight stem with a grit-blasted surface and 155 µm of hydroxyapatite coating (DePuy Orthopaedics Inc., Warsaw, Indiana) was used. It has a trapezoidal-like proximal cross-section to provide rotational stability and self-locking, and the distal part is tapered. A self-centring Bi-Polar Head was combined with an Articul/Eze 28 mm femoral head (both DePuy Synthes, West Chester, Pennsylvania). Preoperative planning was performed using Sectra Medical Systems' orthopaedic package v5.5 (Sectra AB, Linköping, Sweden).

All patients underwent surgery, performed by three consultant orthopaedic surgeons (TOU, SHU, ØHB) familiar with both approaches, within 48 hours of injury. The procedure was carried out under spinal anaesthesia and all received the same standard analgesic protocol. Prophylactic antibiotics were administered preoperatively as 2 g of cefalotin intravenously with a further three doses of 2 g over the next 24 hours. Low-dose heparin (40 mg enoxaparin) was prescribed for ten days.

The anterolateral muscle sparing approach is also known as a modified Watson–Jones approach.[12] With the patient supine, the incision is oblique, begins three fingerbreadths below the tip of the anterior superior iliac spine, and runs distally to the greater trochanter. The fascia is incised, and the plane between the tensor fasciae latae and the gluteus medius is identified. Hohmann and Cobra retractors designed especially for this type of surgery are then placed on each side of the femoral neck and the capsule incised. The direct lateral approach, with the patient in the lateral decubitus position described by Hardinge,[13] involves a slightly curved incision over the trochanter and a longitudinal incision in the fascia. The upper part of gluteus medius and minimus is separated from the greater trochanter and the capsule visualized trough placement of Hohmann retractors. For both procedures, the rest of the femoral neck was resected and femur broached according to the preoperative plan, or until rotational stability was achieved. The gluteal muscles were reinserted using osteosutures (PremiCron HR40; Aesculap AG, Tuttlingen, Germany). Drains were not used and immediate full weight-bearing was encouraged.

The primary outcomes were pain and satisfaction, assessed using a visual analogue scale (VAS). Further outcome measures included the Harris Hip Score (HHS),[14] the timed 'Up and Go' (TUG) test,[15] and the Trendelenburg test.[16] Patient-reported outcome measures (PROMs) included the Hip Disability Osteoarthritis Outcome Score (HOOS),[17] the EuroQol (EQ)-5D),[18] and the Barthel Index.[19] HHS is a clinician-based functional score validated for osteoarthritis of the hip[20] and femoral neck fracture.[21] The minimal clinically important difference (MCID) for the HHS was assumed to be approximately half of standard deviation.[22] The TUG test is a widely used functional assessment tool in geriatric patients. As suggested by Podsiadlo and Richardson,[15] the patients were arbitrarily divided into three groups based on their TUG scores (less than 20 seconds, 20 to 30 seconds, and more than 30 seconds), reflecting their physical independence. Less than 20 seconds means independence for basic transfer, while more than 30 seconds indicates a high grade of dependence. The Trendelenburg test was performed as described by Hardcastle and Nade.[16] The patient was asked to raise their foot from the ground with 30º of hip flexion. The non-stance side of the pelvis was then raised as high as possible with the examiner supporting the patient by holding their hands, if needed. Not being able to maintain the position of the raised pelvis for 30 seconds, or not being able to raise the hip of the non-stance side to above the level of the stance-side, was interpreted as a positive Trendelenberg test.[16] In cases of doubt, the patient was placed in the lateral position and the abductor mechanism was tested against manual resistance. The HHS, TUG, and Trendelenburg test were assessed by a physiotherapist masked to treatment allocation. The HOOS score is a self-reported 40-item questionnaire with five subscales to assess the opinion of the patient about the function of the hip during the previous week: symptoms, pain, limitations of activities of daily living (ADL), function in sport and recreation, and hip-related quality of life (QOL). Each subscale is scored between 0 (worst) to 100 (best).

Adverse surgical advents were also recorded. We followed the definition of prosthetic joint infection (PJI) as described by the working group of the Musculoskeletal Infection Society.[23]

Simple randomization involved the random allocation rule with a pre-specified sample size for each arm.[24] Patients were randomly assigned to undergo hemiarthroplasty using either an anterolateral or direct lateral approach. Concealed allocation was maintained, drawing a sealed and light-proof sequentially sorted envelope generated by a research secretary.[25] Blinded study personnel recorded the outcome measures, and patients were masked to the allocation of treatment.

Sample size and statistical analysis. Sample size and power calculations were based on the assumption that a difference in HHS of ten points would be clinically relevant with an expected standard deviation of 15, statistical power of 95%, and a level of significance of 5%.[1] Based on a power calculation for a two-sample Student's *t*-test, we required 60 patients in each group. A drop-out rate of 20% due to death and other causes was to be expected; we therefore planned to include a total of 150 patients. The estimated sample size would also be sufficient to detect a mean difference between the two groups of approximately half of their standard deviation, continuous and normally distributed outcome variables, including VAS, with 80% statistical power. This is often assessed as the MCID.

The groups were analyzed using the intention to treat principle. Data were assessed for normal distribution using histograms, Q–Q plots, and the Shapiro–Wilks test. The groups were compared with the independent-samples Student's *t*-test for continuous data. Categorical variables were analyzed using Pearson's chi-squared test. Non-parametric testing was performed when the normal distribution assumptions of the Student's *t*-test were not met. Binary outcomes were assessed using logistic regression or Pearson's chi-squared test. Cramer's V was used to examine the association between

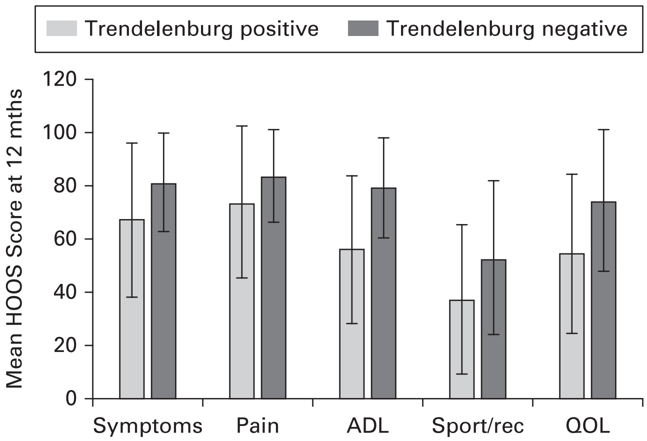

Fig. 2

Chart showing Hip Disability Osteoarthritis Outcome Score (HOOS) subscale scores at 12 months for the anterolateral and direct lateral approaches. ADL, activities of daily living; QOL, quality of life.

surgical approach and a positive Trendelenburg test. We did not perform adjustments for multiple tests. In order to assess the strength and robustness of our results, we performed several sensitivity analyses. The first set examined the impact of missing data in primary outcomes to determine whether missing data depended on the variables in the data set. Little's 'missing completely at random' test was applied, confirming that the data were missing completely at random. Statistical analysis was performed using methods of multiple imputations. A second set of sensitivity analyses was conducted to adjust for distributional assumptions, and parametric and non-parametric methods were used. A third set was undertaken in a linear regression model, with and without adjustment for baseline characteristics. A p-value of ≤ 0.05 was considered statistically significant. All analyses were conducted using IBM SPSS statistics 21 for Windows (IBM Corp., Armonk, New York).

Results

Clinical results. The mean operating time was 46 minutes (29 to 78) in the anterolateral group and 41 minutes (27 to 104) in the direct lateral approach (mean difference 4.5 minutes, 95% confidence interval (CI) 1.1 to 8.0; p = 0.009). The mean length of the incision was shorter in the anterolateral approach (100 mm (70 to 140) *vs* 103 mm (79 to 150); p = 0.22). The overall 30-day mortality was 6%, and mortality was 16% at 12 months. There was a higher risk of a positive Trendelenburg test at one year in the direct lateral group compared with the anterolateral group (11/55 (20%) *vs* 1/55 (1.8%), relative risk (RR) 11.1; p = 0.004). The degree of association expressed by Cramer's V was 0.293, indicating a low to moderate correlation between a positive Trendelenburg test and the surgical approach. There were significantly lower HOOS subscores in the Trendelenburg positive group: symptoms (mean difference 14.1, 95% CI -27.5 to; p = 0.04); ADL (mean difference 23.0, 95% CI -26.6 to -9.5; p = 0.001); and QOL (mean difference 19.6, 95% CI -38.2 to -1.0; p = 0.03) (Fig. 2). The mean HHS at 12 months in the Trendelenburg positive group was 78.5 (62 to 100) and 85.6 (34 to 100) in the Trendelenburg negative group (p = 0.08). The MCID for HHS at 12 months was 7.1 points (mean difference 7.1, 95% CI 1.0 to 15.1).

There were no significant differences between the groups for VAS pain and satisfaction at all points of follow-up. There was also no significant difference in the HHS between the groups at 12 months (mean: anterolateral, 84.4 (SD 15.4); direct lateral, 85.3 (SD 11.2); mean difference 0.89, 95% CI -6.0 to 4.1; p = 0.70). The differences fell short of the clinically improved thresholds (Table II). The results of the sensitivity analyses were similar to the findings of the primary analyses of the data set.

Adverse events. The period of surveillance for adverse events is the same as the timeframe of the randomized controlled trial. Surgical complications included PJI, intraoperative and late-periprosthetic fractures, and dislocation (Table III). Three patients (2%) developed a PJI, one in the anterolateral group and two in the direct lateral group; all were successfully revised without removal of the implant. Three patients (2%) had a minor intraoperative fracture of the calcar: two in the direct lateral group and one in the anterolateral group. Two occurred during reaming, and one was detected on postoperative radiographs. All healed without further intervention. There were three late-occurring fractures (4%) in the direct lateral group, and one (1.3%) in the anterolateral group. Two were minor trochanteric fractures requiring no further surgery; two periprosthetic fractures, one in each group, healed following surgical treatment with revision stems. No dislocations were reported. One patient in the anterolateral group had a temporary foot-drop following surgery. MRI scans showed an intramedullary spinal meningioma, which was thought to be the cause.

Discussion

In this randomized trial, the direct lateral approach was associated with a higher number of patients with a positive Trendelenburg test, reporting worse HOOS subscores compared with those with a negative Trendelenburg test. There were no statistically significant differences and no clinically important differences in VAS pain and satisfaction between the anterolateral and the direct lateral approach to the hip.

In Norway, the predominant approach when undertaking THA for arthritis is the posterior approach, possibly due to the problem of gluteal insufficiency associated with the direct lateral approach.[4,7,26] However, the direct lateral approach is the predominant approach when undertaking hemiarthroplasty for a femoral neck fracture, probably due to the greater risk of dislocation in the posterior approach.[6,27]

MIS approaches are increasingly popular for THA. These approaches offer an intermuscular plane, theoretically preserving the surrounding soft tissues and muscles with less pain and improved short-term functional outcome.[28,29] Until recently, there have been few reports of the use of MIS approaches in patients with a femoral neck fracture. To the best of our knowledge, this is the only randomized study that has evaluated abductor deficiency and the impact of the surgical approach on PROMs in patients with a hip fracture treated with a hemiarthroplasty.

Table II. Patient-reported outcome measure (PROM) scores and functional outcomes; the numbers of patients differ due to mortality and obtainment of information

PROM	Anterolateral approach	Direct lateral approach	Mean difference (95% CI)	p-value*
Harris Hip Score, n; mean (SD)				
Baseline†	74; 82.6 (15.4)	72; 85.4 (16.3)	N/A	N/A
3 mths	61; 79.1 (15.3)	61; 76.9 (13.0)	2.1 (-2.9 to 7.3)	0.396
12 mths	54; 84.4 (15.4)	56; 85.3 (11.2)	-0.89 (-6.0 to 4.1)	0.708
VAS pain score, n; mean (SD)				
24 hrs	60; 3.0 (2.2)	68; 3.5 (2.2)	-0.4 (-1.2 to 0.2)	0.216
48 hrs	58; 2.8 (2.4)	67; 3.2 (2.0)	-0.4 (-1.2 to 0.3)	0.260
3 mths	59; 1.7 (1.7)	59; 1.4 (1.3)	0.2 (-0.2 to 0.8)	0.322
12 mths	54; 1.7 (2.4)	53; 1.0 (1.2)	0.7 (0.0 to 1.4)	0.051
VAS satisfaction score, n; mean (SD)				
24 hrs	61; 2.3 (2.7)	67; 2.1 (2.0)	0.2 (-0.6 to 1.0)	0.641
48 hrs	57; 1.9 (2.4)	67; 1.5 (1.6)	0.4 (-0.2 to 1.1)	0.238
3 mths	60; 1.9 (2.3)	59; 1.8 (2.1)	0.0 (-0.7 to 0.8)	0.839
12 mths	49; 1.6 (2.6)	51; 1.1 (1.5)	0.4 (-0.3 to 1.3)	0.244
Timed Up and Go test, n; mean (SD)				
72 hrs	59; 68.2 (56.1)	62; 69.1 (54.1)	-0.8 (-20.8 to 19.3)	0.932
3 mths	60; 17.9 (11.7)	60; 17.8 (16.0)	0.1 (-4.9 to 5.2)	0.940
12 mths	52; 17.3 (14.8)	55; 14.5 (10.2)	2.8 (-2.0 to 7.7)	0.250
HOOS scores at 3 mths, n; mean (SD)				
Symptoms	58; 78.3 (30.5)	60; 78.1 (17.3)	0.1 (-6.7 to 7.1)	0.955
Pain	58; 80.7 (19.2)	59; 78.8 (17.2)	1.8 (4.8 to 8.5)	0.580
ADL	57; 71.6 (20.4)	59; 68.5 (21.6)	3.1 (-4.6 to 10.8)	0.429
Sport	57; 47.0 (29.2)	59; 36.5 (28.3)	10.4 (-0.0 to 21.0)	0.052
QOL	57; 64.4 (27.5)	59; 60.5 (24.1)	3.8 (-5.6 to 13.4)	0.421
HOOS Scores at 12 mths, n; mean (SD)				
Symptoms	48; 79.5 (19.9)	52; 80.8 (19.6)	1.2 (-9.1 to 6.5)	0.747
Pain	48; 81.4 (18.8)	51: 84.5 (18.7)	3.0 (-10.5 to 4.4)	0.421
ADL	48; 76.2 (20.6)	51; 78.0 (20.6)	1.8 (-10.0 to 6.4)	0.660
Sport	46; 51.6 (30.3)	51; 51.2 (28.2)	0.4 (-11.4 to 12.2)	0.946
QOL	48; 72.9 (29.8)	51; 72.5 (24.9)	0.3 (-10.5 to 11.3)	0.947
Barthel Index Score, n; mean (SD)				
3 mths	59; 17.5 (3.1)	59; 17.4 (3.0)	0.1 (-1.0 to 1.2)	0.858
12 mths	54; 18.8 (6.5)	54; 17.9 (3.0)	0.9 (-1.0 to 2.8)	0.377

*Independent-samples Student's *t*-test
†Harris Hip Score estimated prior to injury
CI, confidence interval; N/A, not applicable; VAS, visual analogue scale; HOOS, Hip Disability Osteoarthritis Outcome Score; ADL, activities of daily life; QOL, quality of life

Table III. Adverse events

Adverse event	Anterolateral approach (n = 75), n (%)	Direct lateral approach (n = 75), n (%)	Total (n = 150), n (%)
Dislocation	0 (*0.0*)	0 (*0.0*)	0 (*0.0*)
Prosthetic joint infection	1 (*1.3*)	2 (*2.6*)	3 (*2.0*)
Intraoperative fracture	1 (*1.3*)	2 (*2.6*)	3 (*2.0*)
Late occurring fracture	1 (*1.3*)	3 (*4.0*)	4 (*2.6*)
Nerve injury	1 (*1.3*)	0 (*0.0*)	1 (*0.6*)
Mortality within 30 days	3 (*4.0*)	6 (*8.0*)	9 (*6.0*)
Mortality within 12 mths	13 (*17.3*)	11 (*14.6*)	24 (*16.0*)

Our study has limitations. The sample size and power calculations were based on the HHS and were probably underpowered to detect smaller differences in VAS scores. However, additional statistical analysis was undertaken confirming the robustness of the results. Techniques of multiple imputation disclosed minor differences in p-values. We did not protect the type I error rate by statistical adjustment for multiplicity, reporting CIs to emphasize clinical rather than statistical significance. The HOOS subscores in the Trendelenburg positive group are of an explanatory nature and the results should be interpreted with caution. Patients were blinded in that they were not told which surgical approach was used and postoperatively the wound was covered with a large dressing. The appearance of the wound could, however, bias a patient's responses. The strengths of the trial include the randomized design and the attempted double blinding of the assessment of outcome. Patients underwent surgery within 48 hours of sustaining their fracture by three consultants who were familiar with both approaches. Blinded physiotherapists and study personnel recorded the outcome measures using recognized assessment tools. Loss to follow-up was acceptable (12%), and rates of re-operation and complications were low.[30] There were no ceiling effects for the HHS and HOOS score, and good content validity.[31,32]

Less pain and good short-term functional outcomes have been reported following the use of MIS approaches in THA. Similar results could not be confirmed in this study. Our results concur with those recently published by Parker[33] with an randomized controlled trial involving 216 patients, comparing the lateral and the posterior approach for hemiarthroplasty in patients with a femoral neck fracture. No statistically significant differences were found for any of the outcome measures. Saxer et al[34] compared the Smith-Petersen approach with a transgluteal approach, and found no statistically significant difference in the primary outcome, the TUG performance, at three weeks.

The use of the direct lateral approach in THA is associated with a limp postoperatively[35,36] and limping is associated with lower PROM scores after THA.[7,36] These findings are similar to ours. The abductor mechanism of the hip was investigated by an experienced physiotherapist performing the Trendelenburg test as described by Hardcastle and Nade.[16] The direct lateral group had significantly more patients with a positive Trendelenburg test, indicating abductor insufficiency. Patients with a positive Trendelenburg test had statistically significant worse HOOS subscores (HOOS symptoms, ADL, and QOL) compared with Trendelenburg negative patients, and some of these exceeded the proposed thresholds for MCID.[17,37] Likewise, differences in HHS between the anterolateral and the direct lateral approach came within proposed thresholds for MCID.[22,38] Three patients in our series with a positive Trendelenburg test at 12 months had a slight limp prior to injury and a persistent limp subsequently. Abductor deficiency is likely to be due to iatrogenic complications of surgery, such as rupture of the repaired gluteal insertion or damage to the superior gluteal nerve.[39-41] In this trial, we attempted to incise the gluteus medius, taking care not to go beyond the tip of the greater trochanter, and repair of the detached gluteal tendon to its insertion was performed with osteosutures. Component malpositioning regarding femoral offset and leg-length discrepancy are also believed to cause abductor deficiency.[42-44] We performed preoperative 2D planning on calibrated radiographs attempting to restore offset and leg length. Evaluation of postoperative radiographs showed adequate restoration of offset, except for one patient in whom offset was increased > 5 mm compared with the contralateral hip.

Our findings confirm that abductor deficiency associated with the direct lateral approach after THA also applies to patients with a femoral neck fracture treated with a hemiarthroplasty. The direct lateral approach appears to be associated with more positive Trendelenburg tests, reflecting a poor clinical outcome.

Take home message

- There is a high risk of a positive Trendelenburg test when using the direct lateral approach to the hip in elderly patients with a femoral neck fracture, and this is associated with a poor patient-reported outcome.

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The trial was approved by the regional ethics committee (2013/1853/REK) and registered with ClinicalTrials.gov (ClinicalTrials.gov Identifier NCT02028468). The trial was reported based on the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) Statement and in compliance with the Helsinki Declaration. Informed consent was obtained from all individual participants included in the study.

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