28.05.2019

Title:

Uncemented Hemiarthroplasty, Radiological features comparing Lateral versus Anterolateral approach: A follow-up of a randomized controlled trial.

Study Protocol

The following protocol is an extension of the project: Surgical treatment of displaced femoral neck fractures in patients between 70 and 90 years. A prospective, randomized study, comparing the lateral approach to the anterior muscle sparing approach.

Project title: Uncemented Hemiarthroplasty, Radiological features comparing Lateral versus Anterolateral approach: A follow-up of a randomized controlled trial.

Hypothesis: There is no difference in component positioning or heterotopic ossification in uncemented hemiarthroplasty operated in lateral (Hardinge) or anterolateral (modified Watson-Jones/Röttinger) approach.

The study's main objective:
To compare leg length, femoral offset, valgus/varus position, canal fill ratio and heterotopic ossification between the two approaches, and to investigate the morphology of the proximal femur with canal flare index, Dorr classification and femoral cortical thickness index. If a difference exists, we will compare the results to existing clinical findings (Harris Hips score, PROM data and Timed Up and Go test).

Background:
In Norway approximately 9,000 persons are operated every year for a fracture of the proximal femur. Of these, 38% are displaced femoral neck fractures(1). The mortality rate is approximately 25% the first year(2-5). Hemiarthroplasty is a universally accepted method for the treatment of displaced femoral neck fractures in patients over 70 years(6, 7). Several studies have compared the posterior approach to either anterior or lateral approach, and dislocation is often the primary outcome(8). Due to the risk of dislocation following the posterior approach, there is increased popularity of the muscle preserving approaches(9). Concerns about component positioning is relevant because for limited exposure(10, 11). In total hip replacement, geometrical restoration of leg length and femoral offset is important for patient satisfaction and postoperative function. These patients often perceives leg length discrepancy of 10mm(12) and a 15% reduction of offset is associated with increased frequency of gate disorders(12). A decrease in femoral offset can cause impaired function in terms of reduced abduction strength(13), induce instability(12) and a limp(14). Valgus/varus position may influence early loosening, especially in cemented stems, the reports on cementless stems is varying(15). Surgical approach is expected to effect the clinical outcome in this fragile population(8). In the current literature, lateral- and anterior approaches have comparable results. The effect of hemiarthroplasties inserted through the muscle preserving approach on femoral neck fractures is still unclear, but may be beneficial in terms of less pain and earlier mobilisation (9, 16-18).

Heterotopic ossification (HO) is a common complication following total hip arthroplasty, the incidence vary widely in the literature(19) and surgical approach is shown to affect the incidence(20). The Brooker classification is the most widely used grading system(21). For most patients the presence of HO is not clinically significant, but it may correlate with limitations in range of motion. Kocic et al found that only higher grades of HO is related to poorer clinical outcome(22). HO is possibly less common in cementless hemiarthroplasty. Corrigan et al found that the overall rates of HO in hemiarthroplasty patients did not vary with the surgical approach, but in patients who develop HO, the anterior and anterolateral approaches is associated with higher ossification rates.

Is there a difference in component positioning or heterotopic ossification in uncemented hemiarthroplasty operated in lateral (Hardinge) or anterolateral (modified Watson-Jones/Röttinger) approach?

In this study we wanted to compare the radiological features and stem positioning in two well described approaches operated by experienced surgeons. Experienced surgeons defined as having done more than 50 arthroplasties for each approach, hopefully minimizing poorer results due to longer learning curve and restricted visibility in the modified Watson-Jones approach (23).

In our study we defined leg length as the perpendicular distance between a horizontal line passing through the lower edge of the teardrop to the ipsilateral center of the femoral head(24).

Femoral offset/Global offset was defined according to Lecerf et al as the distance between the longitudinal axis of the femur to the centre of the femoral head and the distance from the centre of the femoral head to a perpendicular line passing through the medial edge of the teardrop(25).

Valgus/varus position was measured on the AP and lateral view in relation to the femoral axis.

Canal fill ratio was evaluated at the following points; 2 cm above the lower trochanter, at the tip of the lower trochanter, 2 cm and 7 cm below the tip of lesser trochanter(26).

Heterotopic ossification was classified as type 1-4 according to Brooker classification(27).

The proximal femur morphology evaluated by canal flare index(CFI)(28), Dorr classification(29) and cortical thickness index (CTI)(30). CFI defined as the ratio of the intracortical width of the femur at 20 mm proximal to the tip of lesser trochanter and isthmus at 10 cm distally. CTI defined as the ratio of cortical width minus endosteal width, to cortical width at 10 cm below the tip of lesser trochanter.

Two of the authors blinded to the surgical approach do the radiological measurement.

Primary outcome:
Leg length

Secondary outcome:
Femoral offset
Valgus/Varus position
Canal fill ratio
Heterotopic ossification
Canal flare index
Dorr classification
Cortical thickness index

Radiographic evaluation:
Included an AP view of the pelvis and lateral view of the hip. The parameters was measured on pre and post operative x-rays, and at 12 months postoperative.

Inclusion/Exclusion criteria:
In addition to the existing criteria defined in the original protocol, we excluded patients with arthroplasty, history of fracture or fracture implants in the contralateral hip.

The handling and analysis of data
The data is entered into the statistical program SPSS (SPSS Inc, Chicago, Illinois).

Sample size and and power calculation:
Based on the sample size and power calculation already done in the primary project. The sample size would be sufficient to detect a mean difference between two groups of approximately half their SD, both continuous and normally distributed outcome variables with a statistical power of 80%.

Statistical method:
Data were examined for normal distribution using histograms, Q-Q plots and the Shapiro–Wilks test. The groups were compared with the Student's independent samples t-test for continuous data, whereas categorical variables were analyzed using Pearson's chi-square test. The Student's paired samples t-test was conducted to compare changes from baseline to follow-ups. The Wilcoxon signed-rank test / Mann-Whitney U-test was performed when the normal distribution- assumptions of the Student's t-test were not met. The strength of the association between primary and secondary continuous outcomes was assessed with the Pearson correlation coefficient. Binary outcomes were assessed using logistic regression or Pearson Chi-Square test. We plan to do an intraclass correlation analysis on the measured results and a Bland-Altman plot. We plan to perform several sensitivity analysis to assess the robustness of our results and possibly do a correction for repeated measurements.

A p-value of < 0.05 was considered statistically significant. We used IBM SPSS Statistics version 25 for Windows. All statistical analysis was conducted using IBM SPSS statistics 21 for Windows (SPSS Inc., Chicago, Illinois).

Ethics
The trial was approved by the regional ethics committee Regional Committees for Medical and Health Research Ethics (REC) and registered with ClinicalTrials.gov. The trial was reported based on the guidelines of the CONSORT Statement(31) and in compliance with the Helsinki Declaration. Informed consent was obtained from all individual participants included in the study.

Publication:
Results will be published in international Orthopaedic journals with referee evaluation.

1. Gjertsen JE, Fevang JM, Matre K, Vinje T, Engesaeter LB. Clinical outcome after undisplaced femoral neck fractures. Acta orthopaedica. 2011;82(3):268-74.
2. Johnell O, Kanis JA. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2006;17(12):1726-33.
3. Johnell O, Kanis JA. An estimate of the worldwide prevalence, mortality and disability associated with hip fracture. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2004;15(11):897-902.
4. Osnes EK, Lofthus CM, Meyer HE, Falch JA, Nordsletten L, Cappelen I, et al. Consequences of hip fracture on activities of daily life and residential needs. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2004;15(7):567-74.
5. Lofthus CM, Osnes EK, Falch JA, Kaastad TS, Kristiansen IS, Nordsletten L, et al. Epidemiology of hip fractures in Oslo, Norway. Bone. 2001;29(5):413-8.
6. Baker RP, Squires B, Gargan MF, Bannister GC. Total hip arthroplasty and hemiarthroplasty in mobile, independent patients with a displaced intracapsular fracture of the femoral neck. A randomized, controlled trial. The Journal of bone and joint surgery American volume. 2006;88(12):2583-9.
7. Bhandari M, Devereaux PJ, Tornetta P, 3rd, Swiontkowski MF, Berry DJ, Haidukewych G, et al. Operative management of displaced femoral neck fractures in elderly patients. An international survey. The Journal of bone and joint surgery American volume. 2005;87(9):2122-30.
8. van der Sijp MPL, van Delft D, Krijnen P, Niggebrugge AHP, Schipper IB. Surgical Approaches and Hemiarthroplasty Outcomes for Femoral Neck Fractures: A Meta-Analysis. The Journal of arthroplasty. 2018;33(5):1617-27.e9.
9. Saxer F, Studer P, Jakob M, Suhm N, Rosenthal R, Dell-Kuster S, et al. Minimally invasive anterior muscle-sparing versus a transgluteal approach for hemiarthroplasty in femoral neck fractures-a prospective randomised controlled trial including 190 elderly patients. BMC geriatrics. 2018;18(1):222.
10. Bertin KC, Rottinger H. Anterolateral mini-incision hip replacement surgery: a modified Watson-Jones approach. Clinical orthopaedics and related research. 2004(429):248-55.
11. Innmann MM, Streit MR, Kolb J, Heiland J, Parsch D, Aldinger PR, et al. Influence of surgical approach on component positioning in primary total hip arthroplasty. BMC musculoskeletal disorders. 2015;16:180.
12. Flecher X, Ollivier M, Argenson JN. Lower limb length and offset in total hip arthroplasty. Orthopaedics & traumatology, surgery & research : OTSR. 2016;102(1 Suppl):S9-20.
13. McGrory BJ, Morrey BF, Cahalan TD, An KN, Cabanela ME. Effect of femoral offset on range of motion and abductor muscle strength after total hip arthroplasty. The Journal of bone and joint surgery British volume. 1995;77(6):865-9.
14. Asayama I, Naito M, Fujisawa M, Kambe T. Relationship between radiographic measurements of reconstructed hip joint position and the Trendelenburg sign. The Journal of arthroplasty. 2002;17(6):747-51.
15. Mukka S, Hassany HH, Sayed-Noor AS. Geometrical restoration and component positioning after hip arthroplasty for femoral neck fracture. Acta orthopaedica Belgica. 2016;82(3):557-62.
16. Renken F, Renken S, Paech A, Wenzl M, Unger A, Schulz AP. Early functional results after hemiarthroplasty for femoral neck fracture: a randomized comparison between a minimal invasive and a conventional approach. BMC musculoskeletal disorders. 2012;13:141.
17. Kunkel ST, Sabatino MJ, Kang R, Jevsevar DS, Moschetti WE. A systematic review and meta-analysis of the direct anterior approach for hemiarthroplasty for femoral neck fracture. European journal of orthopaedic surgery & traumatology : orthopedie traumatologie. 2018;28(2):217-32.

18. Schneider K, Audige L, Kuehnel SP, Helmy N. The direct anterior approach in hemiarthroplasty for displaced femoral neck fractures. International orthopaedics. 2012;36(9):1773-81.
19. Newman EA, Holst DC, Bracey DN, Russell GB, Lang JE. Incidence of heterotopic ossification in direct anterior vs posterior approach to total hip arthroplasty: a retrospective radiographic review. International orthopaedics. 2016;40(9):1967-73.
20. Corrigan CM, Greenberg SE, Sathiyakumar V, Mitchell PM, Francis A, Omar A, et al. Heterotopic ossification after hemiarthroplasty of the hip - A comparison of three common approaches. Journal of clinical orthopaedics and trauma. 2015;6(1):1-5.
21. Alijanipour P, Patel RP, Naik TU, Parvizi J. Heterotopic Ossification in Primary Total Hip Arthroplasty Using the Direct Anterior vs Direct Lateral Approach. The Journal of arthroplasty. 2017;32(4):1323-7.
22. Kocic M, Lazovic M, Mitkovic M, Djokic B. Clinical significance of the heterotopic ossification after total hip arthroplasty. Orthopedics. 2010;33(1):16.
23. Laffosse JM, Chiron P, Accadbled F, Molinier F, Tricoire JL, Puget J. Learning curve for a modified Watson-Jones minimally invasive approach in primary total hip replacement: analysis of complications and early results versus the standard-incision posterior approach. Acta orthopaedica Belgica. 2006;72(6):693-701.
24. Meermans G, Malik A, Witt J, Haddad F. Preoperative radiographic assessment of limb-length discrepancy in total hip arthroplasty. Clinical orthopaedics and related research. 2011;469(6):1677-82.
25. Lecerf G, Fessy MH, Philippot R, Massin P, Giraud F, Flecher X, et al. Femoral offset: anatomical concept, definition, assessment, implications for preoperative templating and hip arthroplasty. Orthopaedics & traumatology, surgery & research : OTSR. 2009;95(3):210-9.
26. Ishii S, Homma Y, Baba T, Ozaki Y, Matsumoto M, Kaneko K. Does the Canal Fill Ratio and Femoral Morphology of Asian Females Influence Early Radiographic Outcomes of Total Hip Arthroplasty With an Uncemented Proximally Coated, Tapered-Wedge Stem? The Journal of arthroplasty. 2016;31(7):1524-8.
27. Brooker AF, Bowerman JW, Robinson RA, Riley LH, Jr. Ectopic ossification following total hip replacement. Incidence and a method of classification. The Journal of bone and joint surgery American volume. 1973;55(8):1629-32.
28. Noble PC, Alexander JW, Lindahl LJ, Yew DT, Granberry WM, Tullos HS. The anatomic basis of femoral component design. Clinical orthopaedics and related research. 1988(235):148-65.
29. Dorr LD, Faugere MC, Mackel AM, Gruen TA, Bognar B, Malluche HH. Structural and cellular assessment of bone quality of proximal femur. Bone. 1993;14(3):231-42.
30. Nash W, Harris A. The Dorr type and cortical thickness index of the proximal femur for predicting peri-operative complications during hemiarthroplasty. Journal of orthopaedic surgery (Hong Kong). 2014;22(1):92-5.
31. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. Journal of pharmacology & pharmacotherapeutics. 2010;1(2):100-7.