

STUDY RECORD 37039_PROTOCOL

Total hip arthroplasty: direct anterior minimal invasive surgery vs Hardinge approach in obese and non-obese hip osteoarthritic patients

1. Introduction

In recent years, there has been a growing interest in the minimally invasive surgical techniques that are used for the performance of total hip arthroplasty (THA). Decreased soft tissue damage, reduced blood loss, less postoperative pain, shorter hospital-stay, improved cosmetic appearance of the incision, and quicker recovery time are all amongst the advantages of those techniques.^[1-4] Over the last decade, direct anterior minimally invasive surgery (DAMIS) has generated scientific interest because of its soft-tissue-preserving nature (intramuscular and internerve technique), combined with the relatively low risk of dislocation.^[5]

On the other hand, it is well documented that the most common cause of THA is hip osteoarthritis (OA). Epidemiological studies indicated that hip OA occurs in 88 per 100,000 people and its reported prevalence is 1.6 per 1,000 women and 0.9 per 1,000 men.^[6,7] Correspondingly, in Greece, 0.9 per 1,000 people suffer from hip OA, while its prevalence is 1.5 per 1,000 women and 0.3 per 1,000 men.^[8] The main risk factors for developing hip OA are advanced age, inherent predisposition of OA, previous hip injury, hip dysplasia and obesity. Specifically, a strong positive correlation has been found between obesity and hip OA (odds ratio ~2).^[9] In the literature, several studies indicate that obesity is associated with a higher complication rate after THA and with poorer clinical functional outcomes.^[10-12] Other studies have shown that obese patients do not differ from the non-obese in terms of postoperative outcomes.^[13-15] The data are controversial and further studies need to be performed in obese patients, especially comparative evaluations that compare minimally invasive techniques such as DAMIS with classical surgical interventions such as the Hardinge approach (HA). The HA was chosen because, compared to other classical surgical approaches used in obese patients, it offers good access to the hip joint and achieves a lower rate of dislocation by preserving the joint's posterior stabilizer muscles.^[16]

The aim of this trial is to compare DAMIS and HA in hip OA patients undergoing primary THA, with regard to pain levels, functional status and quality of life. In addition, it will investigate whether these parameters differ between obese and non-obese patients.

2. MATERIAL & METHODS

2.1 Participants

Study participations will include 120 patients (age > 50 years) with hip OA, who shall undergo THA. After recruitment they will be enrolled in four groups according to the chosen surgical approach (DAMIS vs Hardinge) and their Body Mass Index (BMI). Group A will include non-obese patients with Body Mass Index ($20 \text{ kg/m}^2 \leq \text{BMI} < 30 \text{ Kg/m}^2$), who will be operated through DAMIS. Group B will include obese patients ($\text{BMI} \geq 30 \text{ Kg/m}^2$) who will be also operated through DAMIS. Group C will be comprised of non-obese patients ($20 \text{ kg/m}^2 \leq \text{BMI} < 30 \text{ Kg/m}^2$), who will be operated through Hardinge approach while group D will be comprised by obese patients ($\text{BMI} \geq 30 \text{ Kg/m}^2$), who will be operated through Hardinge approach as well.

Exclusion criteria will be the presence of dementia, chronic respiratory disease, chronic renal failure, heart failure, neurological disorder, undergoing chemotherapy, and previous osteotomy or arthroscopy to the involved hip.^[17] In addition, after enrollment, patients will be excluded if they present postoperative complications that might prevent them from receiving the standardized postoperative physiotherapy intervention.

Upon acceptance, but prior to surgery, patients will be informed of the goals and procedures of the study. They will be then asked to give their written informed consent, in accordance with the ethical principles stated in the Declaration of Helsinki and its later amendments.^[18]

2.2 Procedures

Pain levels, functionality and quality of life will be assessed preoperatively, at the end of the 4th and at the end of the 8th postoperative week. The evaluation of pain levels will be measured with the Face Pain Scale-Revised (FPS-R).^[19] Functionality will be assessed with both the Greek version of the self-reported Modified Harris Hip Score (MHHS-Gr)^[20] and the objective physical-performance measure “Timed Up and Go” (TUG) test^[21], while quality of life will be evaluated with the Greek version of the self-reported International Hip Outcome Tool-12 items (i-HOT12-Gr)^[22]. The administration of the self-reported questionnaires and the assessment of TUG test will be carried out by the same examiner who will be blinded in respect to the group assignment.

2.3 Statistical methods

All analyses will be carried out using the statistical package SPSS v21.00 (IBM Corporation, Somers, NY, USA) by the collaborator Biostatistician. The Kolmogorov—Smirnov test will be utilized for normality analysis of the continuous variables. All tests will be two-sided, while statistical significance is set at $p < 0.05$.

Two-way ANOVA model is going to be used to examine the interaction between the “Surgical Approach” factor (DAMIS & Hardinge) and “BMI” factor (<30 & ≥ 30). In case of no statistically significant interaction, we will compare the factor “Surgical Approach” regardless of “BMI” factor and the factor “BMI” regardless of “Surgical Approach” factor.

In case of significant interaction we will then create a new factor with categories the combination of categories of “Surgical Approach” and “BMI” factors (DAMIS-BMI <30 , DAMIS-BMI ≥ 30 , Hardinge -BMI <30 , Hardinge -BMI ≥ 30) and the analysis of variables will be performed using the “One way ANOVA model”. Pairwise comparisons are going to be performed using the Bonferroni test.

References

1. Howell J R, Garbuz D S, Duncan C P. Minimally invasive hip replacement: rationale, applied anatomy, and instrumentation. *Orthop Clin North Am.* 2004; 35: 107–18.
2. Siddiqui N A, Mohandas P, Muirhead-Allwood S, Nuthall T. A review of minimally invasive hip replacement surgery – current practice and the way forward. *Curr Orthop.* 2005; 19: 247-254.
3. Sendtner E, Borowiak K, Schuster T, Woerner M, Grifka J, Renkawitz T. Tackling the learning curve: comparison between the anterior, minimally invasive (micro-hip) and the lateral, transgluteal (Bauer) approach for primary total hip replacement. *Arch Orthop Trauma Surg.* 2010; 131 (5): 597-602.
4. Bergin P F, Doppelt J D, Kephart C J, Benke M T, Graeter J H, Holmes A S, Haleen-Smith H, Tuan R S, Unger A S. Comparison of minimally invasive direct anterior versus posterior total hip arthroplasty based on inflammation and muscle damage markers. *J Bone Joint Surg (Am).* 2011 (3); 93 (15): 1392-1398.
5. Connolly KP, Kamath AF. Direct anterior total hip arthroplasty: Comparative outcomes and contemporary results. *World J Orthop.* 2016; 7(2): 94-101.
6. Oliveria SA, Felson DT, Reed JI, Cirillo PA, Walker AM. Incidence of symptomatic hand, hip, and knee osteoarthritis among patients in a health maintenance organization. *Arthritis Rheum.* 1995;38(8):1134-1141.
7. van Saase JL, van Romunde LK, Cats A, Vandenbroucke JP, Valkenburg HA. Epidemiology of osteoarthritis: Zoetermeer survey. Comparison of radiological osteoarthritis in a Dutch population with that in 10 other populations. *Ann Rheum Dis.* 1989;48(4):271-280.
8. Andrianakos AA, Kontelis LK, Karamitsos DG, Aslanidis SI, Georgountzos AI, Kaziolas GO, et al. Prevalence of symptomatic knee, hand, and hip osteoarthritis in Greece. The ESORDIG study. *J Rheumatol.* 2006;33(12):2507-2513.
9. Lieveense AM, Bierma-Zeinstra SM, Verhagen AP, van Baar ME, Verhaar JA, Koes BW: Influence of obesity on the development of osteoarthritis of the hip: a systematic review. *Rheumatology (Oxford).* 2002; 41: 1155-1162.
10. Sadr Azodi O, Adami J, Lindström D, et al. High body mass index is associated with increased risk of implant dislocation following primary total hip replacement: 2,106 patients followed for up to 8 years. *Acta Orthop.* 2008; 79:141-147.
11. Dowsey MM, Choong PF. Obesity is a major risk factor for prosthetic infection after primary hip arthroplasty. *Clin Orthop.* 2008; 466:153-158.

12. Namba RS, Paxton L, Fithian DC, Stone ML. Obesity and perioperative morbidity in total hip and total knee arthroplasty patients. *J Arthroplasty* 2005;20 (Suppl3):46-50.
13. Chan CL, Villar RN. Obesity and quality of life after primary hip arthroplasty. *J Bone Joint Surg [Br]*. 1996; 78-B:78-81.
14. Moran M, Walmsley P, Gray A, Brenkel IJ. Does body mass index affect the early outcome of primary total hip arthroplasty? *J Arthroplasty*. 2005; 20:866-869.
15. McLaughlin JR, Lee KR. The outcome of total hip replacement in obese and non- obese patients at 10- to 18-years. *J Bone Joint Surg [Br]*. 2006; 88-B:1286-1292.
16. Skutek M, Wirries N, von Lewinski G. Hip arthroplasty in obese patients: rising prevalence– standard procedures? *Orthopedic Reviews* 2016; 8:6379.
DOI:10.4081/or.2016.6379
17. Winther SB, Husby VS, Foss OA, Wik TS, Svenningsen S, et al. Muscular strength after total hip arthroplasty: What Role Does Patient Preconditioning Play? *JBJS* 2007; 89:1920.
18. World Medical Association. Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. *JAMA* 2013; 310(20):2191- 2194.
19. Von Baeyer C, Wood C, Jaaniste T. Instructions for administering the Faces Pain Scale- Revised (FPS-R) in languages other than English. (2009) Edition 6. Available at:
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjDh9D90KLfAhUPy4UKHXidCi4QFjAAegQIABAC&url=http%3A%2F%2Fwww.sfapp.org%2Fsystem%2Ffiles%2Finstructions-administering-the-faces-pain-scale.pdf&usg=AOvVaw02AivD_dxrjhJrZIVpH7uq
20. Byrd JT, Jones KS. Prospective analysis of hip arthroscopy with 2-year follow-up. *J Am Acad Orthop Surg*. 2000; 16(6):578-587.
21. Podsiadlo D, Richardson S. The timed “Up & Go”: a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc*. 1991; 39(2):142-148.
22. Griffin DR, Parsons N, Mohtadi NG, Safran MR. A Short version of the International Hip Outcome Tool(iHot-12) for use in routine clinical practice. *Arthroscopy*. 2012; 28(5):611-616.