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Original research

Non-operative management of femoroacetabular impingement: A prospective, randomized controlled clinical trial pilot study

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ABSTRACT

Objectives: To determine the efficacy of physical therapy on pain and physical function in patients with femoroacetabular impingement.
Design: Randomized, participant- and assessor blinded controlled trial pilot study.
Methods: This trial was registered at ClinicalTrials.gov (NCT01814124) and reported according to Consolidated Standards of Reporting Trials (CONSORT) requirements. Patients were randomly assigned to receive either a combination of manual therapy and supervised exercise (MTEX), plus advice and home exercise or advice and home exercise alone (Ad + HEP) over six weeks. Primary outcomes were average pain (Visual Analog Scale) and physical function (Hip Outcome Score) at week seven.
Results: Fifteen patients, mean age 33.7 (SD 9.5, 73% female) satisfied the eligibility criteria and completed week seven measurements. The between group differences for changes in pain or physical function were not significant. Both groups showed statistically significant improvements in pain: the MTEX group improved a mean of 17.6 mm and the Ad + HEP group, 18.0 mm.
Conclusions: The results of this pilot study provide preliminary evidence that symptomatic femoroacetabular impingement may be amenable to conservative treatment strategies however further full-scale randomized controlled trials are required to demonstrate this. In this small pilot study, supervised manual therapy and exercise did not result in greater improvement in pain or function compared to advice and home exercise in patients with symptomatic femoroacetabular impingement.

1. Introduction

Femoroacetabular impingement (FAI) is defined as a condition whereby morphological characteristics of the proximal femur and/or acetabulum lead to mechanical abutment during hip motion that may result in pain and decreased function. FAI is recognized as a major cause of hip pain and dysfunction and has been proposed as leading cause of labral tears in active, young adults.[1,2] Depending on its definition, current literature reports an estimated 23% to 67%[3] prevalence rate of radiographic FAI in the general population. Recently, convincing evidence has emerged to support the hypothesis that FAI may explain the etiology of hip osteoarthritis (OA) in up to 40% of patients with a prior diagnosis of idiopathic OA of the hip.[1,4,5]

Surgical techniques for treating symptomatic FAI have increased dramatically over the past decade [2,6,7] with direct costs surmounting $11,850 (USD)[8] per procedure. Despite significant improvements reported using hip outcome tools, a separate study has reported that only 55% of patients deem their current symptom state acceptable.[5] These statistics suggest the need for investigation of alternate, more cost effective treatment strategies.[5]

High quality evidence from randomized controlled trials that investigate physical therapy interventions for patients with FAI are lacking. Of the limited evidence, it has been suggested that physical therapy treatment strategies may be of benefit to patients with FAI with positive effects lasting 8–12 years.[9] These beneficial treatment effects have been attributed primarily to exercise-based programs focusing on hip and core strengthening in combination with patient education and advice.[10–12] A recent systematic review concluded that while physical therapy interventions seem to be effective, treatment regimens need to be evaluated more extensively and rigorously.[13]

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Clinical manifestations of FAI include multidirectional decreased hip range of motion and strength suggesting these impairments may be amenable to a manual therapy and exercise approach. [14,15] Manual therapy interventions have previously demonstrated effectiveness in patients with hip pain; [16–18] however, they have not been studied in patients with FAI. Manual therapy is a common practice amongst physical therapists intended to alleviate pain and modify the quality and range of motion of the target joint and soft tissue structures in patients with hip disorders.[17,19] Positive outcomes of manual therapy treatment are primarily attributed to a neurophysiological response that allows for corresponding muscle relaxation and pain reduction with no affect on bony abnormalities.[20]

Our purpose was to examine the combined effects of a six-week manual therapy and exercise (MTEX) program as compared to advice and home exercise (Ad + HEP) in decreasing pain and disability in patients with FAI. Our hypothesis was that patients who received individualized MTEX would achieve greater improvements in pain and disability compared to patients who received Ad + HEP alone.

2. Methods

This was a randomized, participant- and assessor blinded, controlled pilot study with a six week intervention and a 7-week follow up. The study was approved by the High Point University Institutional Review Board (#201207-116) and complies with the Declaration of Helsinki. All patients provided written informed consent prior to their enrollment in the study. This trial was registered at ClinicalTrials.gov (NCT01814124) reported according to Consolidated Standards of Reporting Trials (CONSORT) requirements.[21]

We recruited patients from a single surgeon practice specializing in FAI from the Department of Orthopaedic Surgery, Wake Forest Baptist Medical Center. The study sample included new and existing patients between the ages of 18 and 55 with a diagnosis of FAI that were being seen for an outpatient consultation for consideration of hip arthroscopy surgery.

A physician-led physical examination complemented by radiography was used to determine patient diagnosis and eligibility. Participants were eligible for inclusion in the study if they met the following diagnostic criteria for FAI: a finding of $\geq$2 clinical signs in combination with positive radiographic findings. Clinical signs considered positive for FAI included: reported hip pain, decreased hip flexion <95°, decreased internal rotation <10°, a positive anterior impingement test result (report of deep, anterior groin pain following combination of flexion, internal rotation, and adduction),[14] or an increased flexion, abduction, and external rotation (FABER) distance relative to the contralateral side.[22,23] All patients underwent physical examination of the hips by a single physician (AJS) at the time of the magnetic resonance imaging. The examination was done with the patient in the supine position. Radiographic findings considered positive for FAI included: presence of an alpha angle >55°; coxa profunda and acetabular overcoverage (deep center of rotation, lateral center edge angle >35°, protrusion acetabula); or acetabular retroversion demonstrated by the crossover sign.[6] Exclusion criteria were previous hip surgery; other surgical procedure of the lower limb in the prior six months; pre-existing disease state of the hip such as rheumatoid arthritis; fracture; congenital/developmental hip dysplasia; pregnancy; initiation of opioid analgesia or corticosteroid injection in the past 30 days; physical impairments unrelated to the hip preventing safe participation in exercise, manual therapy, walking or stationary cycling; advanced osteoporosis; body mass index >38; significant cardio-pulmonary disease; or stated inability to complete the proposed course of intervention and follow up.

Potential patients were contacted by telephone and scheduled for an appointment where eligibility was confirmed, written informed consent was obtained, and assessment of baseline measures was performed.

After signing informed consent, all patients provided a history, underwent a physical examination, and completed a number of self-report measures at baseline. The historical items included questions pertaining to the distribution of symptoms, description of symptoms, duration of symptoms, mechanism of injury, previous treatment of symptoms. The physical examination consisted of items routinely used in the physical therapy examination and included functional assessment, range of motion, strength testing, passive accessory motions, and provocation tests. The physical examination items were used to further determine level of irritability and tolerance to manual therapy techniques and to identify specific strength deficits. A single investigator who was blinded to the subject's treatment group administered all outcome measures.

Patients completed all outcome measures at baseline and at 7-weeks. Primary outcomes included the Hip Outcome Score (HOS) Activities of Daily Living (ADL) and Sport Subscales and the Visual Analog Scale (VAS) for pain. The HOS is a 26-item instrument (17 item ADL subscale, 9-item sports subscale) with scores ranging from 0 to 100%. A higher score represents a higher level of function. Patient data from the HOS has been reported as reliable, valid and responsive specific to this patient population[24,25] and has been identified as the best available questionnaire for assessing younger patients undergoing hip arthroscopy. The HOS subscales have high test-retest reliability (intraclass correlation coefficient [ICC] = 0.98 and 0.92 for the ADL and sports subscales, respectively)[25] The minimal detectable change (MDC) is and increase or decrease of 3 points and the minimal clinically important difference is 9 points for the ADL subscale and 6 points for the sports subscale.[25] Overall average hip pain intensity in the past 24 h was rated using a 100 mm horizontal VAS, for which 0 mm represented no pain and 100 mm, the worst possible pain. A minimal clinically important improvement is 15.3 mm.[26]

Secondary outcomes measures included the Lower Extremity Functional Scale (minimal clinically important difference, 9 points),[27] the Single Assessment Numeric Evaluation (SANE) ADL and Sport subscales,[25] global rating of change scale (GRCS) using a 15-point ordinal scale for which −7 represented a very great deal worse and +7 represented a very great deal better, the Patient Acceptable Symptom State (PASS), the deep squat, and the triple hop. The functional performance tests at baseline and seven weeks included hip flexion range of motion, hip flexion strength, deep squat, triple hop, and flexion, abduction, external rotation (FABER) flexibility (Appendix 1).

Once the baseline assessment was completed, patients were randomly assigned to MTEX or to Ad + HEP using blocked randomization with a computer random number generator. Randomization codes were sealed in consecutively numbered opaque envelopes that were opened following baseline assessment. Outcome assessors were blind to group allocation, and were not involved in providing the interventions; however, based on the nature of the interventions it was not possible to blind patients or treating therapists.

This clinical trial was designed as a pragmatic study to evaluate the overall effectiveness of manual therapy and exercise as compared to 'usual care' alone at 7 weeks. Interventions were provided at the Department of Physical Therapy, High Point University under the supervision of licensed physical therapists with clinical specialties in Orthopaedics and/or Sports (n = 3) and were trained in the study procedures by the primary investigator (AAW) who is a fellow of the American Academy of Orthopaedic Manual Physical Therapists. Participants were randomly allocated to receive MTEX or Ad + HEP. All patients received Ad + HEP as described