STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

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TITLE: EFFECTIVENESS OF A PROTOCOLIZED TREATMENT OF SPECIFIC PHYSIOTHERAPY FOR SUBJECTS SURGICALLY OPERATED BY ARTHROSCOPY FOR FEMOROACETABULAR SYNDROME

Research and Ethics Committee of General University Hospital of Elche PI 6/2019.

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STUDY PROTOCOL PLAN

1. OBJECTIVES

The objectives of our study are the following:

General:

- Determine the effectiveness of a protocolized treatment of specific physiotherapy for patients undergoing femoroacetabular syndrome by means of arthroscopy in pain, range of mobility and functionality.

Specific:

- Check how the age, level of physical activity prior to the study, sex, level of adherence to the program or body mass index of the subject influences the effectiveness of protocolized treatment of physiotherapy in patients surgically operated on femoroacetabular syndrome by arthroscopy.

2. STUDY DESIGN

An analytical, longitudinal, experimental, prospective, controlled and randomized clinical study will be conducted to analyze the cause-effect relationship of the Müller & Puig physiotherapy protocol under study in relation to the change in pain, functionality (modified Harris scale) and the range of mobility (ROM) in subjects surgically operated by Femoro-acetabular Impingement (FAI) by arthroscopy.

The study will be simple blind with blinded evaluator strategy with two parallel groups. The surgeons (recruitment) and assessors will be blinded with respect to the group belonging to the subject. The statistician will be blinded to the subjects group until the statistical analysis is completed. It is not possible to blind the physiotherapist who executes the treatment protocol or the study subjects. Subjects will be asked not to disclose their membership group or consult with the surgeon or the evaluator.

The randomization approach will be prepared by means of a randomization computer program, attributing a 1:1 ratio to the membership group. The interventionist physiotherapist will perform the randomization on the day of the first post-surgery physiotherapy session.

All participants will be informed of the purpose of the study through an information document prepared for this purpose and will be clarified any doubts that may arise. After answering as many questions as necessary, the subject must sign the informed consent document to be part of the study. The principles of the Declaration of Helsinki (2004) will

be respected at all times. The data collected will be treated confidentially by applying the current legislation on the protection of personal data (Organic Law 15/1999 of December 13, Protection of Personal Data) and / or any other applicable.

This study has been admitted by the Research and Ethics Committee of General University Hospital of Elche PI 6/2019.

3. SUBJECTS OF STUDY

The selection criteria of the sample in this study are as follows.

3.1. Inclusion criteria

a. Having suffered hip / groin pain for at least 3 months.
b. Be a patient diagnosed with femoroacetabular syndrome by an orthopedic surgeon based on symptoms, clinical signs and diagnostic imaging.
c. To have signed the informed consent.
d. Have time available to follow a 14-week physiotherapy treatment program.
e. Be programmed for hip arthroscopy.
f. Be able to speak and understand the Spanish language.
g. Be between 18 and 50 years of age.

3.2. Exclusion criteria

a. Have received physiotherapy treatment in the last three months.
b. Having previously received hip surgery.
c. Subjects with previous deformities in the femur that severely alter joint mobility such as Perthes disease, gliding of the upper femoral epiphysis or avascular necrosis, acetabular fracture, hip dislocation or fracture of the femoral neck.
d. Evidence of preexisting osteoarthritis, defined as Tonnis grade> 2
e. Subjects with previous deformities in the pelvis that severely alter joint mobility.
f. Any other cardiovascular, psychological and / or cognitive diagnosed pathology that impedes the correct understanding of the study and prevents objective study variables.
g. Subjects that are under the effects of anesthetics or muscle relaxants that mask the sensation of the patient before the techniques of the study.
h. Professional athletes.
i. Subjects in which hip arthroscopy is contraindicated.

4. INTERVENTION PROTOCOL

The intervention consists of a physiotherapy treatment protocol for post-surgical treatment of CFA under arthroscopy. This protocol is based on the existing ones to date of the various specialists in arthroscopic surgery, which propose rehabilitative actions of a general type, divided into four phases. The results of this group will be compared to those obtained in the control group that will follow the usual post-surgical general guidelines for hip interventions described by Gocen et al.

The intervention is structured in 14 weeks as described below.

Day 1 to 7:

• Isometric quadriceps contractions (4 sets of 10 repetitions twice a day)
• Isometric contractions of the vast internal (4 sets of 10 repetitions twice a day)
• Flexo-extension and ankle circumduction movements (4 sets of 10 repetitions twice a day)
• Hip flexion in supine trailing heel by stretcher (4 sets of 10 repetitions 2 times a day)
• Passive hip circumduction (2 series of 5 minutes a day)
• Ambulation with two crutches without load on the lower limb affected
• Stay in prone position (2 hours a day)
• Stay in a sitting position at 90 degrees of hip flexion (2 hours a day).
• Half-lying between 90 and 180 degrees (2 hours a day).
• Keep the hip in neutral rotation position.

Day 8 to 15:

It is added to the previous guideline:

• Patient in prone position and extension of hip with knee in full extension (4 sets of 10 repetitions once a day)
• Patient in prone position and extension of hip with knee in flexion of 45º (4 sets of 10 repetitions once a day)
• Patient in prone position and extension of hip with knee in 90º flexion (4 sets of 10 repetitions once per day)
• Patient sitting and full knee extension (4 sets of 10 repetitions once a day)

Day 16 to 21:

To the pattern of the first week we add the following:

• Patient in prone position and extension of hip with knee in full extension with resistance in ankle with elastic band of 1.5 m in length and soft resistance (4 sets of 10 repetitions once a day)

• Patient in prone position and extension of hip with knee in flexion of 45º with resistance in ankle with elastic band of 1.5 m of length and soft resistance (4 sets of 10 repetitions once a day)
• Patient in prone position and hip extension with knee in 90º flexion with resistance in the ankle with an elastic band of 1.5 m in length and soft resistance (4 sets of 10 repetitions once a day)
• Patient sitting and full knee extension with resistance in the ankle with elastic band 1.5 m long and soft resistance (4 sets of 10 repetitions once a day)

Day 22 to 30:
• Passive hip circumduction (2 series of 5 minutes once a day)
• Walking with a crutch.
• Stay in a sitting position at 90 degrees of hip flexion (2 hours a day).
• Half-lying between 90 and 180 degrees (2 hours a day).
• Keep the hip in neutral rotation position.
• Stationary bicycle with elevated saddle and with no resistance for 15 minutes.
• Patient in prone position and extension of hip with knee in full extension with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 10 repetitions once a day)
• Patient in prone position and extension of hip with knee in flexion of 45º with resistance in the ankle with an elastic band of 1.5 m of length and medium resistance (4 sets of 10 repetitions once a day)
• Patient in prone position and hip extension with knee in 90º flexion with resistance in the ankle with an elastic band of 1.5 m length and medium resistance (4 sets of 10 repetitions once a day)
• Patient in sitting position and full knee extension with resistance in the ankle with an elastic band of 1.5 m length and medium resistance (4 sets of 10 repetitions once a day)

Day 31 to 45:
• Walking with a crutch.
• Keep the hip in neutral rotation position.
• Static bike with elevated saddle and with zero resistance for 25 minutes.
• Patient in prone position and extension of hip with knee in full extension with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions once a day)

• Patient in prone position and extension of hip with knee in flexion of 45º with resistance in ankle with an elastic band of 1.5 m of length and medium resistance (4 series of 15 repetitions once a day)
• Patient in prone position and hip extension with knee in 90º flexion with resistance in the ankle with an elastic band of 1.5 m length and medium resistance (4 sets of 15 repetitions once a day)
• Patient sitting and full knee extension with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 20 repetitions once a day).

Day 46 to 60:
• Walking without crutches
• Static bike with elevated saddle and zero resistance for 25 minutes (3 times a week)
• Activity in elliptical movement machine with minimum intensity for 15 minutes (twice a week)
• Soft proprioception exercises on an unstable base (Bosu® type) with both legs for 6 sets of 20 seconds with unlocked hips and knees.
• Standing patient, hip extension with knee in full extension with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions once a day)
• Standing patient, hip extension with knee in flexion of 45º with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions once a day)
• Standing patient, hip extension with knee in 90º flexion with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions once a day)
• Patient sitting and full knee extension with resistance in the ankle with an elastic band 1.5 m long and medium resistance (4 sets of 20 repetitions once a day)

Day 61 to 75:
• Static bike with elevated saddle and with 20% resistance for 25 minutes. (3 times a week).
• Activity in elliptical movement machine with minimum intensity for 20 minutes. (3 times a week).
• Gentle proprioception exercise on an unstable base (Bosu® type) with leg affected for 6 sets of 20 seconds with unlocked hips and knees.
• Standing patient, hip extension with knee in full extension with resistance in the ankle

with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions once a day)

• Standing patient, hip extension with knee in flexion of 45º with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions once a day)

• Standing patient, hip extension with knee in 90º flexion with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions once a day)

• Patient sitting and full knee extension with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 20 repetitions once a day).

Day 76 to 97:

• Static bike with elevated saddle and with 20% resistance for 25 minutes. (3 times a week).

• Activity in elliptical movement machine with minimum intensity for 20 minutes. (3 times a week).

• Exercise of proprioception on an unstable basis (Bosu® type) with leg affected for 3 sets of 20 seconds with unlocked hips and knees and using an elastic band 1.5 m long and medium resistance in each of the four positions to adopt.

• Floating in a pool for 15 minutes (once a week)

• Standing patient, hip extension with knee in full extension with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 10 repetitions twice a day)

• Standing patient, hip extension with knee in flexion of 45º with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 10 repetitions twice a day)

• Standing patient, hip extension with knee in 90º flexion with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 10 repetitions twice a day)

• Patient sitting and full knee extension with resistance in the ankle with an elastic band of 1.5 m in length and medium resistance (4 sets of 15 repetitions twice a day).

• Basic stretching of quadriceps, hamstrings, adductor and abductor (3 times a week).

Avoid climbing stairs, ramps, squats, forced hip flexion and crossing legs in all phases.

To check the adherence to the treatment, measures based on self-report of the subject

will be used since they are the easiest to obtain and the most frequently used to measure the adherence. The measuring instrument used will be the completion of a diary design for this purpose. It will be used to monitor the performance and duration of the protocol exercises. Through the data obtained in this diary, the overall percentage of therapeutic adherence on the recommended behavior will be determined. This system acts as a reminder increasing the probability of compliance with the work plan.

5. STUDY VARIABLES

5.1. Independent variables study object

The independent variables of the project are: a) belonging to the control or intervention group; and b) time, according to the timing of presurgical and postsurgical measurements. We also recorded as independent variables the general characteristics of the sample: age, BMI, sex, hours of weekly sports activity, orthopedic surgeon who performed the intervention and compliance with the program.

5.2. Dependent variables

The dependent variables of the study are the following:

Range of Mobility (ROM).

In the present study measurements will be made by goniometry of hip joint movement ranges. The goniometry is a technique of measurement of the angles created by the intersection of the longitudinal axes of the bones at the level of the joints.

These are continuous quantitative variables, measured in degrees with a range between 0º and 180º.

a. ROM in hip flexion.
b. ROM in hip extension.
c. ROM in hip abduction.
d. ROM in hip adduction.
e. ROM in internal hip rotation.
f. ROM in external rotation of the hip.

Orthopedic tests

The FAI will be checked through the performance of the Fabere, Fadir and Ober functional tests described below.

a. FABERE TEST: The patient's hip is flexed, abducted and externally rotated by placing the external malleolus on the knee of the contralateral leg. The pelvis is

stabilized and an overpressure is applied to the inside of the knee. It is positive if the pain in the buttock or groin is reproduced. Test with inter-evaluator reliability in Kappa values (95% CI) of 0.60.

b. FADDIR TEST: Flexion, adduction and internal rotation test. The supine patient, the evaluator patiently brings the patient's hip up to 100º flexion and adduction while applying internal rotation. It is positive if pain in the groin is reproduced. Test with inter-evaluator reliability in Kappa values of 0.48.
c. OBER TEST: Patient in lateral decubitus position. The evaluator flexes the knee that is evaluated at 90º and abducts and extends the hip until it is level with the trunk. The evaluator lets the gravity bring the hip on aduction as possible. Test with inter-evaluator reliability of 0.90.

Variable intensity of pain

The Visual Analogue Scale (VAS) will be used. It is a continuous quantitative variable with a range between 0 and 10.

Evaluation functionality.

The modified Harris Scale will be used to the patient to evaluate the functionality of the hip and its interference in the activities of daily life. The patient will be evaluated with this scale prior to the surgical intervention and 14 weeks after the surgery.

6. STUDY GROUPS.

The sample will be divided into 2 groups: Intervention Group and Control Group. The postoperative physiotherapeutic treatment protocol described will be applied to the intervention group. The non-intervention group will receive the nonspecific protocol of postoperative treatment for hip rehabilitation described by Gocen et al.

7. EVALUATION.

The evaluator is the person who will perform the pre and postsurgical measurements. He will be trained in the use of the goniometer and in the performance of orthopedic tests as well as in the material to be used. It will be located in the “Evaluation Room”, with the material and conditions necessary to carry out the measurements. It will register and store the data for its later evaluation and statistical analysis.

The evaluator will be blinded with respect to the subject's belonging to the intervention or control group.

Data will be recorded at three times: before surgery, after 4 weeks and after 14 weeks of surgery. Immediate postoperative measurements will not be made, given that the clinical picture and tissue injury of the intervention could cause inaccurate results because a period of post-surgical wound stabilization has not elapsed.

These tests and measurements of variables will provide us with the degree of hip readjustment and its functionality, since they respond to the affected musculoskeletal structures both prior to the arthroscopy intervention due to the pathophysiology of the FAI, and after it for the wounds and surgical scars that are generated.

8. STUDY SEQUENCE.

A. Recruitment: it takes place before the surgery in the Traumatology clinic of Alicante Clinic (we attach authorization of the center to carry out the study) Two facultative specialists in orthopedic surgery and traumatology, transfer the information to the patient in written support about the characteristics of the study , purpose and form of follow-up, at the same time that they verify the eligibility of the subject according to the criteria of the study. Another member of the research team will independently check the eligibility of the subject in an evaluation session and will be responsible for performing the evaluations of the study variables before surgery, at 4 and 14 weeks after surgery. The evaluator will be present to resolve and clarify any doubts in this regard. After this, and with the acceptance of the patient to be part of the study, the informed consent will be signed.

B. Pre-surgery evaluation: the Harris scale questionnaire modified prior to the surgical procedure will be completed. After signing the informed consent, the pre-surgical measurement will be carried out following the following sequence:

• Assessment tests of abduction, adduction, flexion, extension, internal rotation and external rotation ROM of the hip

• Next, the Ober, Fabere and Faddir muscle tests will be performed.

• Finally, the pain will be evaluated through the Visual Analog Scale (VAS)

C. Randomization: After the presurgical evaluation and following a simple randomization process by means of a computer program, the subjects are assigned to the control or intervention group.

D. Hip arthroscopy: The study subjects will receive adequate pre- and postoperative care including health education and exercise plan for the immediate postoperative period, in addition to a follow-up visit by the traumatologist after two weeks of the intervention.

E. Intervention: The subjects of the control group follow the general postsurgical treatment protocol described by Gocen et al. The subjects of the intervention group will perform a physiotherapy session of 45 minutes each one every two weeks for a total of 7 sessions (weeks 2, 4, 6, 8, 10, 12 and 14 post surgery) following the protocol described. In addition, they will have to follow a physiotherapy exercise plan at home whose compliance they will have to register in an activity diary to check adherence to treatment.
F. Post-surgery evaluation 1: The evaluation described in section B and C is repeated 4 weeks after surgery to subjects of both groups.
G. Post-surgery evaluation 2: The evaluation described in section B and C is repeated after 14 weeks of the surgery for the subjects of both groups, and the individual study is finished.

In both groups, it will be advised to avoid stairs, ramps, squats, forced hip flexion and legs crossing in all phases. The subjects that develop a deterioration in the Modified Harris scale or in the VAS at 4 weeks after surgery compared with the pre-surgical data or those subjects that reflect complications of the surgery will be evaluated again by their corresponding traumatologist to decide whether or not to remain in the program. All complications will be documented by the principal investigator. No adverse effects are expected.

Statistical Analysis Plan (SAP)

Size Sample and Feasibility

The statistical program that we will use will be SPSS v.20. To determine the sample size, a pilot study will be conducted with the same methodology as the original study to a group of 10 subjects. These subjects will be assigned to the same group. This pilot study will provide us with the estimates of the mean and variance of the response variable, thus being able to calculate the appropriate sample size by determining a minimum power value of 80% (W> 80%) and a confidence level of 95% (p <0.05).
The pilot sample will be part of the final sample to be studied if there are no changes in the protocol or in the variables to be measured.

The FAI is an important cause of coxarthrosis. Hip osteoarthritis is a pathology of high prevalence, with important socioeconomic repercussions. In Spain, 16% of the population over 20 years of age suffers, with a clear prevalence in women.
In a retrospective radiological study, Marín et al found around 70% the presence, on radiographs performed years before the intervention, of femoral and acetabular signs suggestive of femoroacetabular shock in children under 55 years who underwent total arthroplasty. of hip. Other authors have reported values around 45% in patients pending intervention of hip prostheses with an age range between 30 and 82 years.

We consider it feasible to obtain a sample necessary for the present study (around 30 subjects per group) in view of the sample size of published articles on the effectiveness of conservative or postoperative treatment protocols for hip disorders and FAI and the high prevalence of FAI. The estimated time of obtaining the necessary sample will be around 6 months.

Descriptive analysis: A descriptive statistical analysis of all the variables will be carried out using frequency tables for the qualitative variables, and the minimum, maximum, average and standard deviation for the quantitative variables.
Inferential analysis: In relation to the inferential analysis, the statistical tests described below will be performed.

a. Normal distribution test of Kolmogorov-Smirnov to identify the distribution of the samples.
b. Levene test to check if the variances are homogeneous.

c. ANOVA test (when the sample were are normal) or Kruskal-Wallis test (when it do not comply with normality) to check the homogeneity of the characteristics of the subjects between the different groups before the intervention.
d. For the comparison of means between the results of both groups we will use the t-Student test of related samples and one-way ANOVA (when they are normal) or Mann-Whitney U test or Wilcoxon W test (when they do not meet the normal).
e. Chi square test or ANCOVA to analyze the influence of the general characteristics of the sample on the effect of the intervention.
f. For the reliability analysis of the measuring tools, Cronbach's alpha test will be used.
g. Regression analysis using the multiple linear model to study the relationship between sets of variables.

A significance index of $p < 0.05$ will be established.