SCIARPA 3/4

Prospective, non-randomized and open observational study to analyse effectiveness of orthopedic treatment in the management of three and four-parts proximal humeral fractures according to Neer´s classification.

Madrid, October 1st 2017

SUMMARY

1. Promoter

Orthopedic Surgery Service at Gregorio Marañón University Hospital

2. Clinical trial title

"Treatment of proximal humeral fractures with sling." Prospective, non-randomized and open study to evaluate the effectiveness of orthopedic treatment in the management of three and four-parts proximal humeral fractures according to Neer´s classification.

3. Principal investigators and management of your workplace

Dr. Mikel Aburto Bernardo

Orthopedic Surgery and Traumatology Service of the Gregorio Marañón University Hospital. Calle Dr. Esquerdo 28007 Madrid.

4. Centres where the test is planned

Gregorio Marañón University Hospital

5. Ethical Committee for Clinical Research evaluating the trial

CEIC of Gregorio Marañón University Hospital

6. Objectives:

1. Main:

   Evaluate the effectiveness of conservative treatment in the management of fractures in 3 and 4 fragments of the proximal humerus according to Neer classification, in patients over 75 years of age.

2. Secondary:

- Compare the results obtained with a historical surgical cohort that were treated with shoulder arthroplasty for this same pathology.
- Evaluate possible complications from orthopedic treatment.

7. Design

Unicentric, prospective, non-randomized, open clinical trial comparing the effectiveness of the orthopaedic treatment for three and four-parts proximal humeral fractures in a patient population over 75 years of age.

Two treatments for these fractures will be compared secondarily:

1. Shoulder arthroplasty
2. Conservative treatment with sling followed by physiotherapy.

Both options are accepted today for the management in this type of fractures. [1, 2]

8. Valuation variables:

1. Main:

Efficiency measured by the use of 4 valuation scales:

a. ***THE AMERICAN SHOULDER AND ELBOW SURGEONS EVALUATION SCALE (ASES)***

J Shoulder Elbow Surg 1994;3:347-352.

It includes subjective information on the part of the patient and the result of a physical examination. It is possible to get a score with a maximum of 100 points, of which 50% obtain them from the subjective perception of pain and the activities of daily life.

b***. DASHe (Disability of Arm. Shoulder and Hand)***

Spanish version of the DASH quartet. Med Clin (Barc).2006;127(12):441-7

without valuing the professional and work module.

For the final score, at least 27 of the 30 questions need to be answered. The final score is obtained by calculating the arithmetic mean of the answered questions, subtracting 1 and multiplying by 25. This calculation provides a score between 0 and 100, with the greater the disability at the highest point obtained, and considering variations with clinical significance those exceeding 10 points.

$$(\underline{\text{Sum of n answers}}) - 1 \times 25$$

c***. Constant Scale,*** *Clin. Orthop. Relate. Res 1987:160-4.*

It is the most used questionnaire for shoulder evaluation. It includes a subjective assessment of the pain presented by the patient, up to 15 points, the ability to perform daily activities, up to a maximum of 20 points, objective mobility assessment, up to 40 points, and strength through physical examination, up to 25. The maximum score is 100., considering results as excellent > 80, good 65-79, media 50-64, and bad <50.

d. **VAS (analog visual scale)** *Thong ISK, Jensen MP, Miró J, Tan G. The validity of pain intensity measures: what do the NRS, VAS, VRS, and FPS-R measure? Scand J Pain. 2018 Jan 26;18(1):99-107.*

It is defined as a one-dimensional scale for subjective assessment of pain by the patient. It consists of a straight line (usually 10 centimeters -100 millimeters-) at whose limits are the most extreme degrees of pain intensity, considering a score of 0 points for the lowest degree or absence of pain (usually referred to by the

patient as "painless") and 100 points for the highest degree (usually referred to as "the worst bearable" or "worst pain imaginable").
The final score (between 0 and 100 points) is obtained by measuring the distance in millimeters between the lower end (0-point score) and the mark the patient points along the line.

2. Secondary:

- Comparison of the results obtained on the Constant scale with a surgical historical cohort that were treated by shoulder prostheses for this same pathology.
- Complications arising from non-surgical treatment.

9. Hypothesis

NULL hypothesis : The use of ***non-surgical*** treatment for three and four-parts proximal humeral fractures in elderly people (over 75 years) does not produce a statistically significant functional improvement.

MAIN hypothesis : The use of ***non-surgical*** treatment for three and four-parts proximal humeral fractures in elderly people (over 75 years) produces a statistically significant functional improvement.

10. Population under study and total number of patients

Number of patients: The cohort to study includes of 20 patients in which we have opted for non-surgical treatment. The historical cohort consists of 20 patients undergoing shoulder replacement.

11. Study calendar

The start date of the study will be the 1st and 2nd quarter of 2017.

- Recruitment of patients: 12 months
- Follow-up period (1 year per patient): 22-24 months
- Data analysis: 3 and 12 months.

BACKGROUND AND CURRENT STATE.

Proximal limb fractures of the humerus are very common, representing 10% of all fractures, with an incidence of 6.6/1,000 people and year, with exponential increase from 40 years. [3-6]

Most of these fractures do not have displacement so they are successfully treated with brace immobilization and subsequent rehabilitation.

Fractures with displacement of the fragments require surgical management. We classify these fractures according to the number of fragments displaced in 1, 2, 3 and 4, according to the system proposed by Neer.

Displaced fractures type 3 and 4 of the Neer classification affecting older patients have been the subject of numerous studies with the aim of establishing the most appropriate treatment. [7,, 8]

Reconstruction with shoulder replacement, both inverted and anatomical, has been widely used as a treatment in these fractures; different studies have been launched to establish which of the two prosthetic models offers the best [1,, 9-13]. [14,, 15]

In older patients, where functional demand is not as demanding and where shoulder arthroplasty may cause various, conservative management can get a good clinical outcome in displaced fractures affecting the humeral neck. (17) [2, 15, 16]

JUSTIFICATION OF THE STUDY

We know the result of surgical treatment for three and four-parts proximal humeral fractures in older patients, but it was to be established if these are superior to the results obtained with conservative treatment.

OBJECTIVES

1. Main:

Compare the effectiveness of conservative treatment for the management of three and four-parts proximal humeral fractures in patients over 75 years of age.

2. Secondary:

- Compare the results obtained with a historical surgical cohort treated with shoulder prostheses for this same pathology.
- Evaluate possible complications from orthopedic treatment.

TYPE OF TEST AND DESIGN

Selection process:

Patients candidates for conservative treatment (three-week sling) will form the "cases" group and will be selected by the research team after their emergency care. They will be informed of the existence of this study and offered to participate in it; if they become part of the study, patients will receive orthopedic (non-surgical) treatment of their humeral fracture. Informed consent will then be given to the patient.

The "control" group will be formed by patients undergoing surgical treatment who will be selected from a historical cohort from a previous clinical trial. (FRALUX)

Patients who decline to be part of the study will receive the same treatment currently offered in our Traumatology Service, being able to manage their fracture either through surgical techniques (shoulder prostheses) or through immobilization and subsequent rehabilitation treatment. Assigning one treatment or another to each patient will depend on multiple clinical, radiological variables and the patient's own decision as has been made at the current time in our clinical practice.

Type of control and design

Prospective, open, non-randomized clinical trial in a patient population over 75 years of age with three and four-parts proximal humeral fractures.

Follow-up period

Each patient will have a follow-up period of one year in which they will attend:

1. Shoulder consultation (traumatology)
    a) At 3 weeks, sling removal and rehabilitation.
    b) 3 months ASES, CONSTANT, DASH and VAS
    c) 12 months ASES, CONSTANT, DASH and VAS

2. Rehabilitation consultation
    (a) At 3 weeks: rehabilitation sessions will be guidelined.
    b) At the end of rehabilitation sessions.

Selection of subjects

1. Inclusion criteria

1. Patients over 75 years of age.
2. Three and four-parts proximal humeral fractures according to Neer's classification.

2. Exclusion Criteria

1. Previous pathology that compromises functional recovery and collaboration in rehabilitative protocol (neurologycal pathology, cognitive impairment...)

2. Humerus proximal limb dislocation fractures.

3. Open fractures, with vascular or nerve injury.

4. Polytraumatized patients

Treatment description

1. Surgical treatment. These patients have undergone shoulder surgery by implanting a reverse shoulder arthroplasty. They belong to a cohort of patients who have already

been evaluated in a previous study and who underwent this surgery because they suffered a fracture in 3 or 4 fragments according to Neer's classification.

2. Conservative treatment. It consists of the use of a sling for three weeks, which will be removed twice a day to move elbow the 1st weeks and to do Codman's pendulous exercises in the 2nd and 3rd week.

3. Concomitant treatments

Patients in the non-surgical group will undergo the same rehabilitative protocol. Physical therapy will start after evaluation made by rehabilitator physician after third week.

Patients in the surgical group also began rehabilitative treatment from the third week of surgery after their visit to the rehabilitator physician.

Insurance Policy

It is considered that no insurance policy is necessary as they are two techniques that are performed in the usual surgical practice and none of them constitute a deviation from the usual clinical practice.

General and particular rules for researchers

Researchers shall strictly comply with the provisions of this protocol, fully completing the data collection sheets that will be analyzed later. The study protocol will be carried out in accordance with the guidelines of current legislation, in compliance with the standards of Good Clinical Practice and the Principles set out in the Helsinki Declaration

Security and confidentiality devices

Patient´s confidentiality will be maintained at all times, and only the investigator will be able to know the patient's personal data as well as its location in case the necessary authorities request them according to the procedures of the legislation in force.

The information disseminated and obtained by the implementation of this study is considered confidential and must be treated at all times as such. The subjects of the study will be identified only with their subject code in the study. Researchers responsible for the clinical trial, as well as a representative of the promoter or health authorities will have access to the information recorded throughout the study. In case of publication of the results of the study, the identity of the volunteers will not be revealed.

The patient may exercise his rights to the data of the study (ARCO rights, Organic Law 15/1999) before the principal investigator, Mikel Aburto Bernardo (mikelaburto@hotmail.com)

Documentation file

There will be a documentation file for all data, which will be kept in full on paper and on computer media. This file must contain the following items:

1. Approval by the CEIC of the protocol and the informed consent sheet.
2. Copy of the written consent form and protocol approved with any amendments if applicable.
3. Any correspondence with the CEIC.
4. *Curriculum vitae* of the principal investigator and the other researchers who form the research team.
5. Registration of signatures of the members of the research team.
6. List of participants' identity.
7. Copies of CRDs.

Terms of publication

All information obtained during the study will be considered confidential and belong to the promoter, who undertakes to allow the researcher to publish the results and present them in scientific meetings after their consent after the study is completed and the final analysis is carried out.

Statistical analysis

1 Sample size: Accepting an alpha risk of 5% and a beta risk of 20% in a bilateral contrast, 20 patients are required in each group to detect a difference equal to or greater than 13 units in the ASES scale score. The common standard deviation is assumed to be 15.

2 Statistical analysis: Qualitative variables shall be expressed as absolute frequencies and percentages while quantitative variables shall be presented as typical means and deviations or as medians and inter-quarterlic range depending on their normality.

Initially, the comparability of both groups will be studied to check the homogeneity of the randomization groups. Comparisons of the ASES scale and all other numeric variables between two groups will be made with student's t-test of independent measurements or Mann-Whitney test, as deemed appropriate. For repeated measurements at 3 and 12 months, the Student´s t of repeated measurements or Wilcoxon test shall be used. To study the association of categorical variables, the Pearson ji-square or Fisher exact test will be used.

Differences whose p-value associated with the contrast test is less than or equal to 0.05 shall be considered significant. Data collection will be recorded in Excel database which will then be exported and analyzed in the SPSS 18 statistical program.