Dolaren Study 2014

STUDY PROTOCOL

Randomized, controlled, open-label, to compare the analgesic efficacy of treatment programs carried out with Ozoile (Ozone topical oleic acid stabilized with vitamin E acetate) and Diclofenac, in patients with pain associated with osteoarthritis of the shoulder of moderate to severe intensity .

PROMOTOR AND COORDINATOR OF THE STUDY

“Friends of the Foundation for Research on Pain - ISAL"

territorial section of Benevento

Via Dell’ Angelo

EXPOSURE AND DISCUSSION OF THE CONCLUSIVE RESULTS OF THE STUDY DOLAREN 2014

CONDUCTED IN COLLABORATION WITH SSD PAIN THERAPY AND PALLIATIVE CARE HOSPITAL "GAETANO RUMMO" in BENEVENTO

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INTRODUCTION

The humeral scapular articulation is one of the five joints of the shoulder - the first in importance - that allows that broad movement of this anatomical region of the body. The scapular/ humeral joint (S / O) or gleno / humeral (G / O) - as is the glenoid of the scapula that articulates with the humeral head - is the main shoulder joint, one that more than any other articular segment of our skeleton allows us the sweep of the arm. The articulation works because the bone surface is covered with a protective layer which is called cartilage (white area in the figures); when it undergoes a progressive deterioration that takes place here is the pathological process that is called "osteoarthritis". The cartilage is not destroyed quickly but undergoes a gradual and steady deterioration. Patients with osteoarthritis of the shoulder classically complain of a painful and stiff shoulder, with a gradation of limited movement. The pain intensifies with the movement and stiffness increases with continuous and constant movement in time. More common in these patients is awakening from the night's sleep with intense pain. Characteristic is the "noise" heard during the movement of the arm that in this disease is fairly routine. The painful symptoms have the greatest impact on the patient to the point that even rest and / or drug treatment effectively benefits the tolerance of the disease. Our study aims to compare the analgesic efficacy of treatment programs carried out with two different drugs, Ozoile (Ozone topical oleic acid stabilized with vitamin E acetate) and Diclofenac in patients with pain associated with osteoarthritis of the shoulder, moderate to severe intensity.

MATERIALS AND METHODS

The study was conducted on 80 patients, aged between 40 and 80, of both sexes with arthrosis shoulder.

From 30/01/2014 to 30/08/2014, we selected 80 patients, 33 males and 47 females, mean age 61 years, all suffering from arthrosis shoulder that had, at the 1st visit, values of average pain felt in last 24 hours ≥ 4 measured using an NRS (numerical rating scale of pain). The observation period was 60 days for each patient and the interval evaluation was made on days 7, 15, 30, 45 and 60, after a first baseline visit. The following was considered in all the patients:

1. The level of analgesia according NRS

2. The degree of independence in activities of daily life according to the assessment scale ADL

The primary objective of the study is to compare the effectiveness of two different strategies based on two different analgesic drugs DICLOFENAC 50g and Ozoile 50 g (ozone topical oleic acid stabilized with vitamin E acetate) in patients with pain related to osteoarthritis of the shoulder.

The patients were divided into two groups of 40 units, a group was treated with 50 g DICLOFENAC, the other group with Ozoile 50 g (ozone topical oleic acid stabilized with vitamin E acetate). Patients resort to two applications per day of study directly onto the area of pain.

RESULTS

Of the 80 patients included in the study, 11 of them did not complete the course of application.

Of these 11 patients, 7 of them had to move to invasive analgesia; 2 patients needed surgery; 2 patients opted out of the study. The average value of the NRS surveys of patients treated with Ozoile is shown in table 1

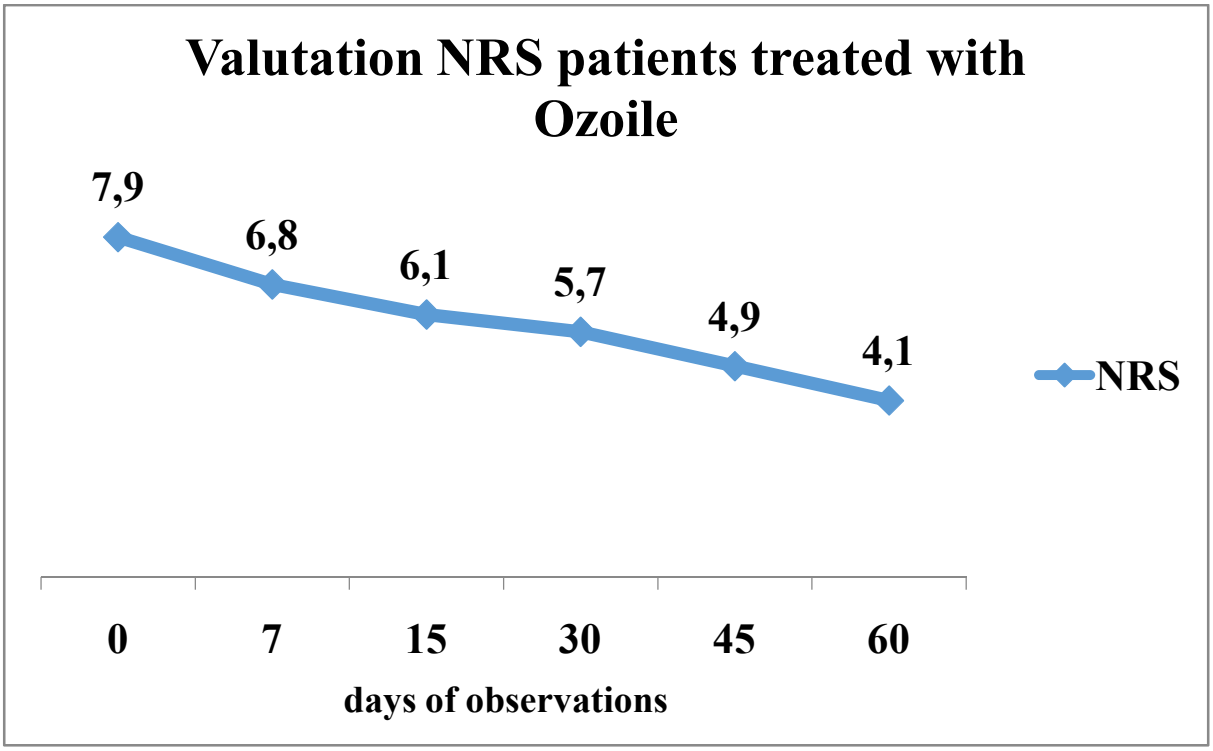


Table 1

The average value of the reliefs ADL of patients treated with Ozoile is reported in the table 2

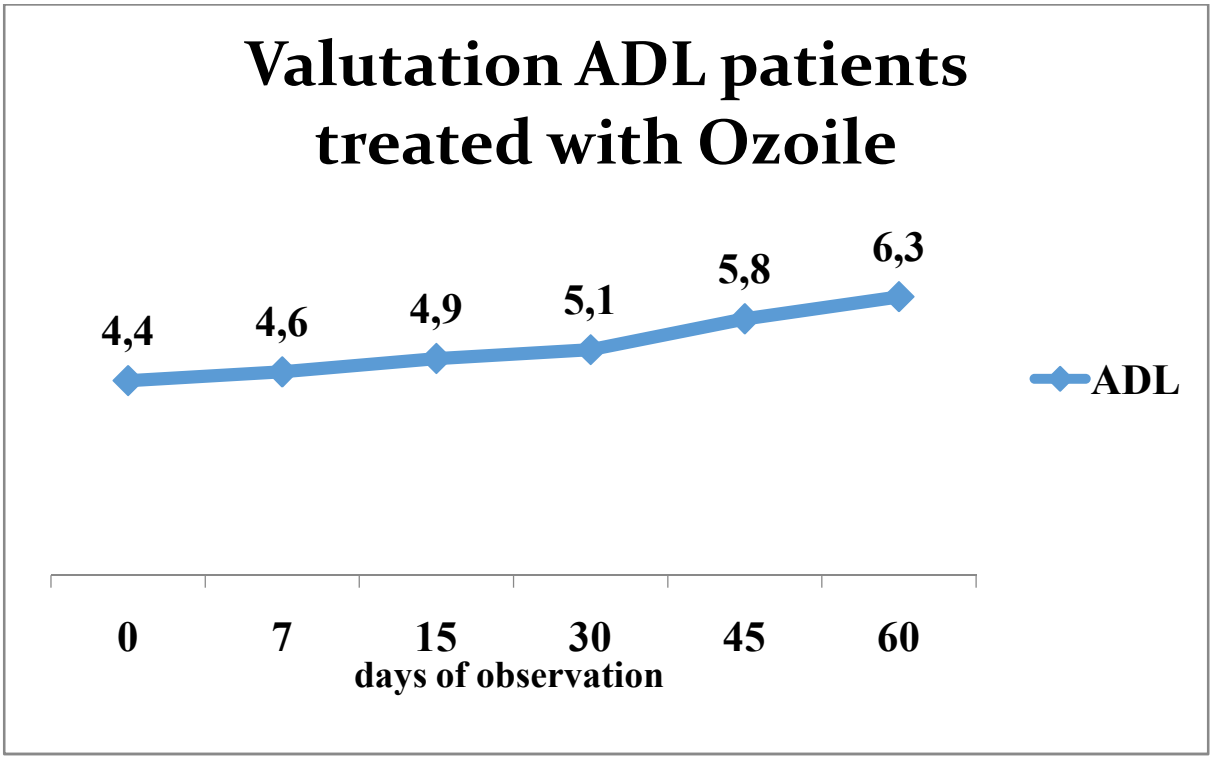


Table 2

As is evident from Table 1, the group of patients treated with Ozoile over the 60 days of observation had a reduction of the NRS score of 3.8 points on average.

As shown in Table 2, the group of patients treated with Ozoile experienced over the 60 days of observation, an increase of ADL scale score of 1.9 points on average.

The average value of the reliefs NRS of patients treated with Diclofenac is reported

in Table 3

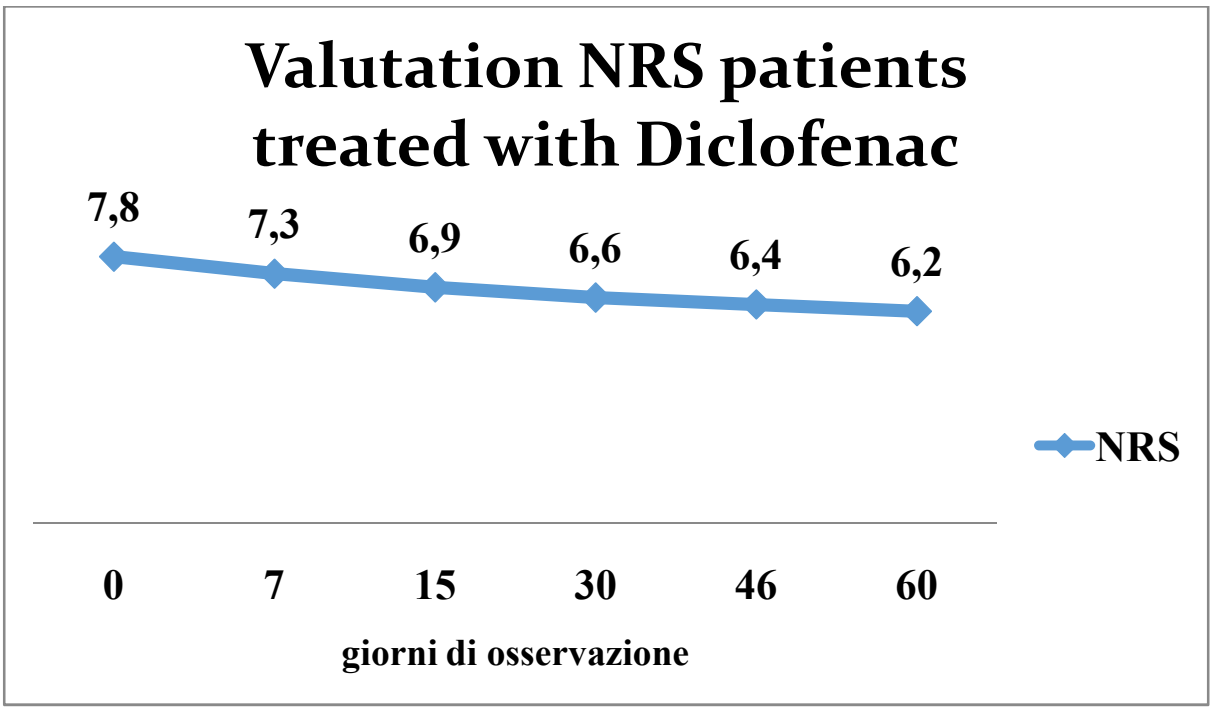


Table 3

The average value of the reliefs ADL of patients treated with Diclofenac is reported in Table 4

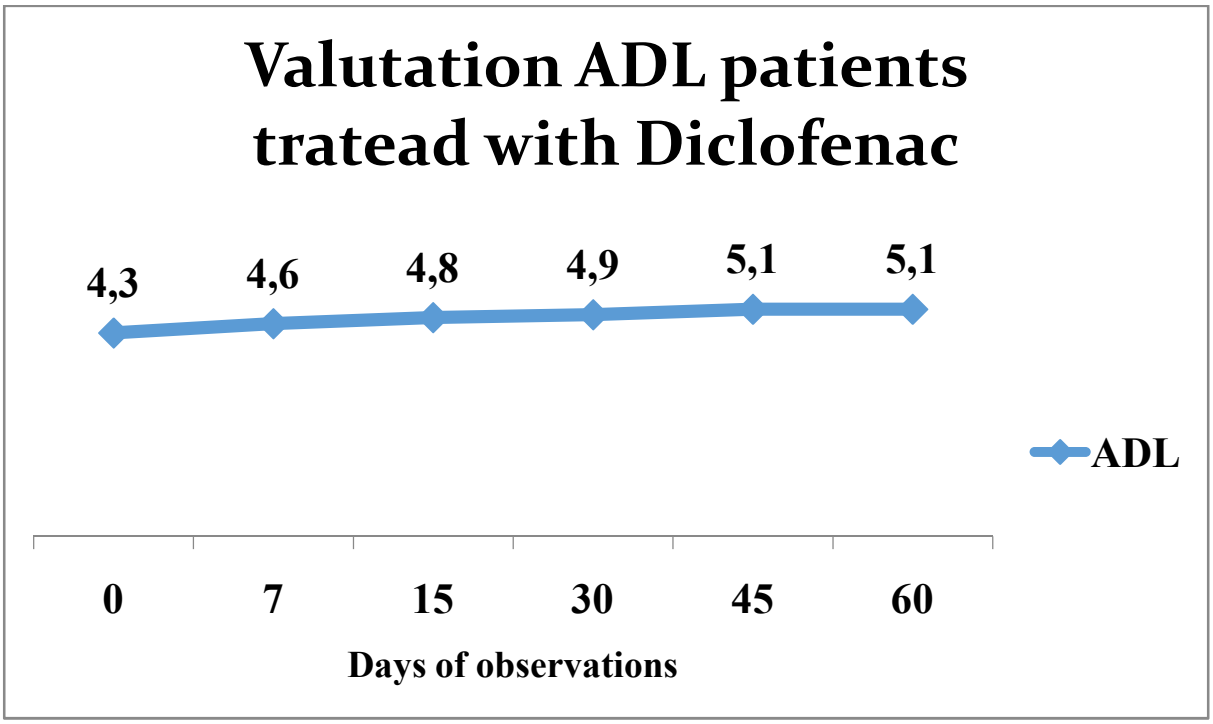


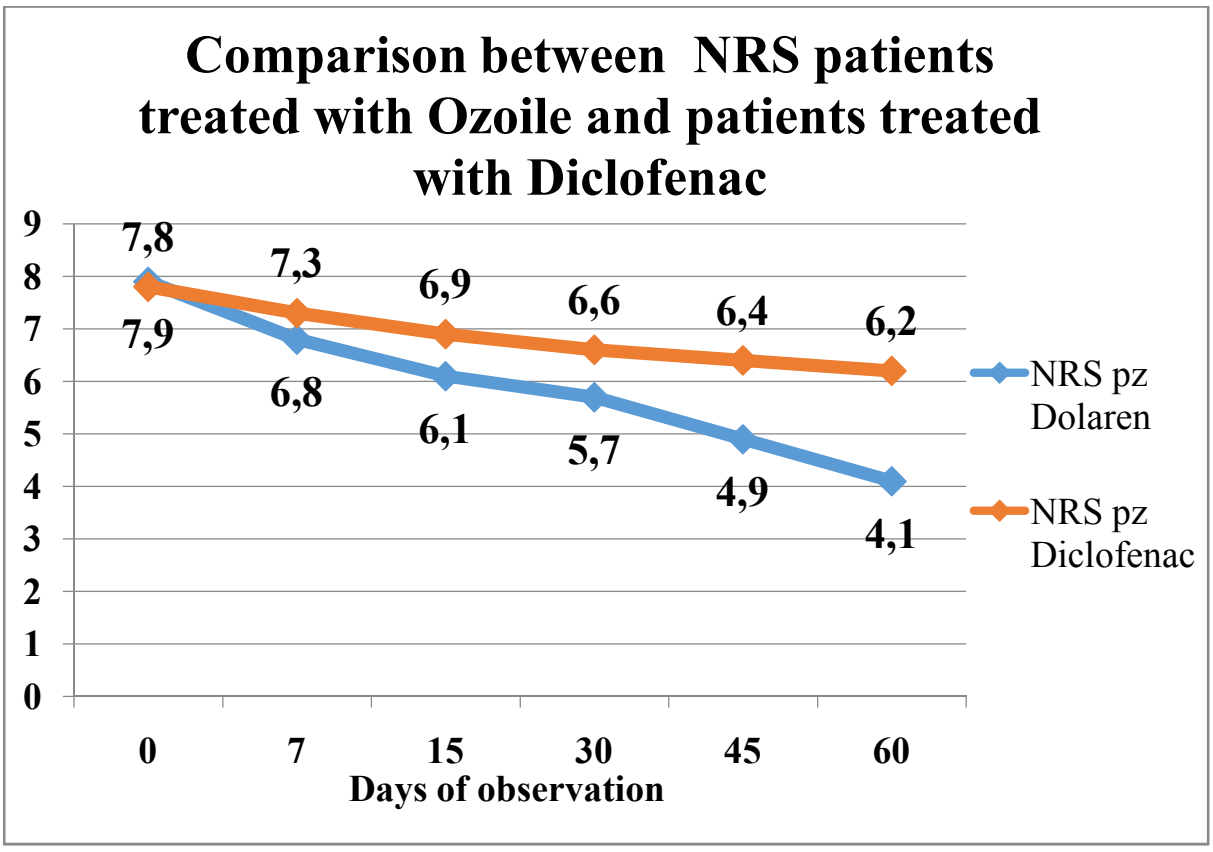
Table 4

As shown in Table 3 the group of patients treated with Diclofenac had over the 60 days of observation a reduction of the NRS score of 1.6 points on average.

As shown in Table 4, the group of patients treated with Diclofenac experienced over the 60 days of observation, an increase of ADL scale score of 0.8 points on average.

CONCLUSIONS

Our experience has shown on the basis of these data, a better analgesic efficacy of Ozoile (ozone topical oleic acid stabilized with vitamin E acetate) compared to Diclofenac. Patients in the study resorted to two applications per day of the study period. In the observation period of 60 days monitoring of pain achieved through the use of a specific rating scale of pain, the NRS (Numerical Rating Scale), allowed us to see how the group of patients treated with Ozoile felt a reduction in the average score of 3.8 compared to Diclofenac treated patients who experienced a reduction in the average score of 1.6.



In addition, our study has highlighted an even better efficiency in terms of recurrence, the functionality and performance in activities of daily living of Ozoile compared to Diclofenac. The patients in question, in the observation period were carefully monitored during 5 surveys required, with the Barthel scale or Barthel ADL Index, which is an ordinal scale used to measure the performance of a subject in the activities of life daily (ADL, activities of daily living). This rating scale allowed us to show that the group of patients treated with Ozoile experienced over the 60 days of observation, an increase in the average score of the scale equal to ADL 1.9 points, compared to patients treated with Diclofenac who over the 60 days of observation, had an increase of ADL scale score of 0.8 points on average.

