

FARMA CI

AGGIORNAMENTO CONTINUO PER LA PRATICA CLINICA

©2019 • Volume 18 • N. 2 (Estratto)

Scientific Director: **Ercole Concia** - Editorial Director: **Matteo Bassetti**

**The capsular expansion of the hip post
infiltrative therapy with Hyaluronic Acid:
extension of the previous observational,
open-label pilot study.
Integration with a psychological
approach to the infiltrative therapy**

C. Corsello¹, G. Corsello²

¹Specialist in Orthopedics and Traumatology, Aragona (AG) - Medical office "CORSELLO"

²Doctor in Psychological Sciences and Techniques, University of Palermo

Editorial Scientific Committee

ALLEGRA C.	BIANCHI PORRO G.	CONCIA E.	ESPOSITO S.	OLIVIERI D.	TODESCO S.
ALTAMURA C.	CACCIAPUOTI F.	CRINÒ L.	FERRARA P.	PUDDU P.	VAIRA D.
AMBROSIONI E.	CAMANNI F.	DAL PALÙ C.	LUISETTI M.	SCAGLIONE F.	VISCOLI C.
BASSETTI M.	CARRATÙ L.	DE GRANDIS D.	MALERBA M.	SIRTORI C.	
BELLIA V.	CARRUS P.	DI BIAGIO A.	MANCINI M.	STERNIERI E.	

FARMACI

AGGIORNAMENTO CONTINUO PER LA PRATICA CLINICA

Director Manager: Antonio Guastella

©2019 MEDIZIONI S.r.l. - Cod. 21/19
Via Monte delle Gioie, 13 - 00199 Roma
tel. 06.81153040/06.40413168 - fax. 06.40419131
medizioni@medizioni.it

Vol. 18 - n. 2/2019 - May-August
Reg. Trib. di Roma n. 238 del 23/5/2002
Four-monthly periodicity

All rights reserved.
No part can be reproduced in no way (including photocopies)
without the written permission
of the publisher.

Press: CSC Grafica Srl
Via A. Meucci, 28 - 00012 Guidonia (Roma)

Extract finished printing in September 2019

The capsular expansion of the hip post infiltrative therapy with Hyaluronic Acid: extension of the previous observational, open-label pilot study. Integration with a psychological approach to the infiltrative therapy

C. Corsello¹, G. Corsello²

¹Specialist in Orthopedics and Traumatology, Aragona (AG) - Medical office "CORSELLO"

²Doctor in Psychological Sciences and Techniques, University of Palermo

Abstract

Summary. Different aspects are debated in the intra-articular infiltrative procedure through Hyaluronic Acid (HA). These include the amount of HA to be injected and the number of infiltrations to be performed. In the treatment of osteoarthritis symptomatic hip, the HA used per via intra-articular eco-guided has demonstrated efficacy and safety. Then, the correlation between capsular expansion at baseline and post-intra-articular infiltration of HA, would allow to predict the validity of the treatment and to establish the optimal quantity of 2 ml of HA for the coxo-femoral articulation, which is 2 ml of HA at the rate of two weekly infiltrations in the first infiltrative approach. A psychological approach has been adapted to the infiltrative therapy of the hip, which involves the patient, the operator and the medical staff in order to achieve a "working alliance" that optimizes the adherence to the therapy.

Introduction. In symptomatic hip osteoarthritis, verify the use of 2 ml of linear HA with molecular weight >2.000 kDa in the amount of 2 ml per single injection, repeated one week later, for a total of two injections, verifying its effectiveness with respect to capsular expansion, using ultrasound, at baseline and after infiltration, also providing the clinical functional parameters and painful symptoms. Assess the validity and effectiveness of an original psychological approach for a patient with coxarthrosis as a candidate for infiltrative therapy.

Methods. From December 2017 to August 2018, an open-label study was conducted on 20 patients, 14 females and 6 males, aged between 27 and 90 years, with an average age of 63.8 and diagnosis of osteoarthritis, symptomatic, of the hip. Two intra-articular infiltrations, echo-guided to the hip with HA, were performed on a weekly basis for each patient. Patients who had undergone infiltrative, intra-articular hip therapy in the previous 6

months were excluded. Linear HA with a molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml) was used in the amount of 2 ml per injection. Patients were evaluated in their initial phase, i.e. at the first infiltration session, also through an ultrasound study at the baseline and at each subsequent infiltration session. None of the patients enrolled left the study. Patients were instructed to observe the recommended precautionary measures after intra-articular therapy, such as absolute rest, cryotherapy and maintaining the medication for the next 24 hours. All of the participants gave informed written consent.

Conclusions. Two weekly intra-articular hip infiltrations with 2 ml of linear HA with molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml) determine any capsular expansion of the coxo-femoral joint compared to baseline, detected using ultrasound, consistent with the functional recovery and reduction of painful symptoms in subjects with coxarthrosis. It is possible, therefore, to establish early rehabilitative treatment. Restoring capsular expansibility by means of two intra-articular infiltrations with 2 ml linear HA of molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml) would recreate the physiological intra-capsular pressure gradients and the physiological circulation of synovial fluid. The ultrasound-checked capsular expansibility data is an easily detectable and repeatable parameter and can be correlated to the functional recovery and improvement of the clinical conditions of the hip. The support of the psychologist in doctor-patient communication and in the active involvement of the patient in the infiltrative procedure for the achievement of what is known as the "working alliance" is useful and effective.

Keywords. Coxarthrosis - Hyaluronic Acid - Capsular Expansion - Echo-guided Treatment - Articular Rigidity - Working Alliance.

INTRODUCTION

In the previous article, “Hip capsular expansion after infiltrative therapy with Hyaluronic Acid, correlation with joint function: results of an observational, open-label pilot study”(C. Corsello, S. Russo, G. Corsello, *NTP Nuove Prospettive in Terapia*, Year XXVIII - no. 1/2018 - 2018 MEDIZIONI), the correlation between capsular expansibility after intra-articular infiltrative treatment with linear HA of molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml) and clinical improvement was verified. It was found that patients with severe coxarthrosis (stage IV of Kellgren and Lawrence), symptomatic and with functional limitation of the coxo-femoral joint in which it was obtained, showed a significant functional and clinical

recovery compared to baseline with a greater capsular expansion after the infiltration procedure. This observation was related to the fact of restoring expansibility by intra-articular infiltration with HA, which, by recreating the normal intra-capsular pressure gradients, would facilitate the physiological circulation of synovial fluid. The measurement of joint space (JS) and capsular expansibility after infiltrative therapy has become an essential parameter of the procedure in my clinical practice. Continuing in the enrolment of other patients and from the revision of the personal casuistry, there is more evidence to suggest that the conviction that capsular expansion (CE) after infiltrative therapy and its maintenance represent a predictive element of the success of the procedure and could represent an objective parameter of the clin-

Chart 1. Capsular Expansion Ratio - Rigidity.

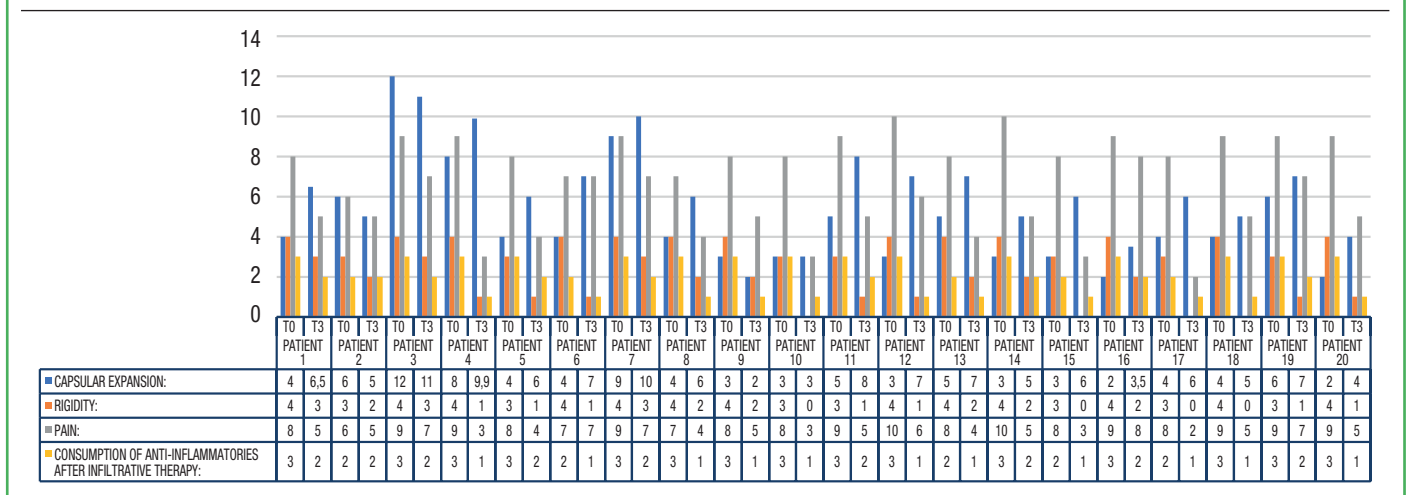
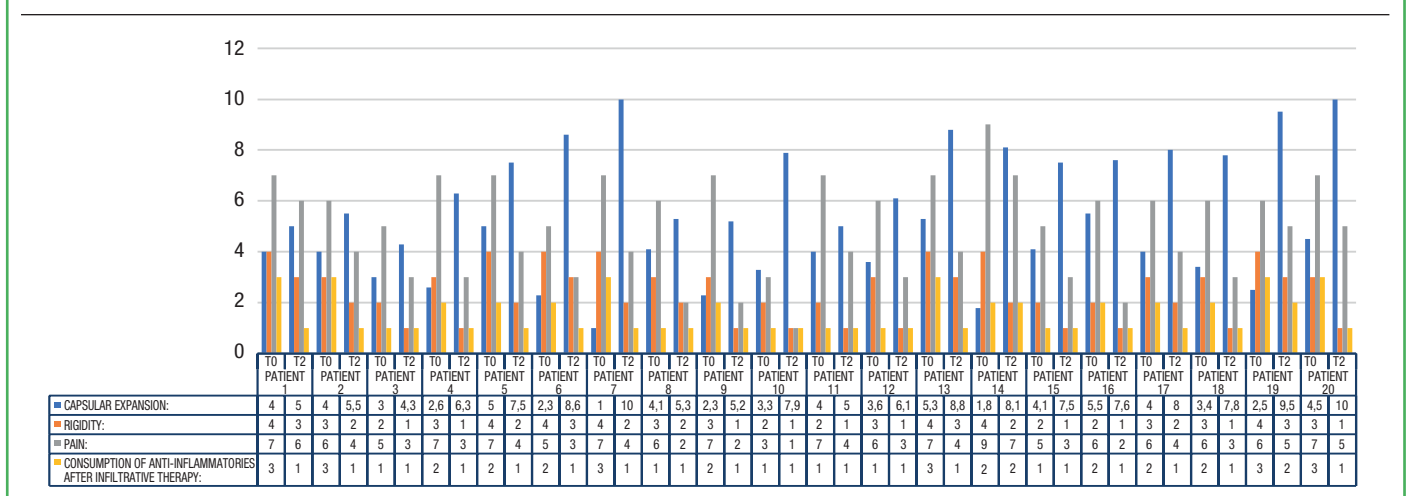


Chart 2. Capsular Expansion Ratio - Rigidity “extension study”.



ical improvement of arthritic pathology in relation, that is, to the parameters of joint rigidity and consumption of NSAIDs (Chart 1) is correct. It has been observed that an increase of one third and one half of the EC measurement compared to the baseline measurement of JS represents a numerical parameter favourable for the restoration of the physiological circulation of synovial fluid. The “beneficial condition” for the restoration of synovial fluid circulation in an arthrotic hip was observed to be an increase in the ultrasound study of the EC equal to at least 25-50% of the initial JS. This ultrasound prerogative of the so-called “responders” was obtained, on a permanent basis, after the second infiltration. The study was then continued with two weekly infiltrations (no more three) intra-articular echo-guided in hips with 2 ml of linear HA of molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml) and the results were verified (Chart 2). This represents an extension of the previous study.

MATERIALS AND METHODS

An open-label study was conducted on twenty patients with coxarthrosis (stage II - IV of Kellgren and Lawrence); the different outcome parameters chosen were determined to the twenty selected patients with symptomatic coxarthrosis, at baseline and during the study: capsular expansion, WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) score, NRS numerical scale and NSAID consumption. Two intra-articular infiltrations of HA, echo-guided in the hip, were conducted on a weekly basis. Patients who had undergone intra-articular hip infiltration therapy in the previous six months were excluded. Linear HA with molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml) was used in the amount of 2 ml per injection. Patients were initially assessed, i.e. at the first infiltration session, also by ultrasound study at baseline, and at each subsequent infiltration session. None of the patients enrolled left the study. Patients were instructed to observe the recommended precautionary measures after intra-articular therapy, absolute rest, cryotherapy and maintaining medication for the next twenty-four hours. All participants gave informed written consent. The study was conducted in accordance with good clinical practice guidelines and ethical standards for human trials. The study started in December 2017 and ended in August 2018 in Aragon (AG). An ALOKA Prosound 3500 ultrasound with 3-5 MHz convex probe and 7.5 MHz linear probe was used. The patients, who were initially undergoing ultrasound study, were examined in supine position, at baseline and with the hip in intrarotation of 15-20°. The coxo-femoral joint

is analysed through an anterior parasagittal access, laterally to the femoral vessels. The transducer is aligned with the long axis of the femoral neck, proceeding in the next distal direction and starting from the anterior superior iliac spine. Images of the coxo-femoral joints at baseline were taken in the pre-infiltration phase, with morphological evaluation of the joint and subsequent dimensional evaluation of the joint capsule.

The ultrasound study also included the acetabular lip that, once identified, is examined dynamically, to verify the known “seal” effect on the coxo-femoral joint, through passive movements of intra-extraction and abduction of the affected limb. The ultrasound effect of a normal acetabular lip is that of a “gate valve” that closes uniformly on the joint.

Disinfection of the area to be infiltrated is carried out using chlorhexidine, which is then removed by washing the area with sterile saline physiological solution. Once the infiltration surface has been defined, a sterile, adhesive and transparent dressing is applied to it. Prior to disinfection, the skin surface may be pre-treated with analgesic spray and intra-articular infiltration of HA may be preceded by infiltration of surface tissues with 1 cc of mepivacaine or lidocaine. Intra-articular infiltration is performed by inserting a 20 G spinal needle from 9 to 15 cm (depending on the patient’s morphology) using an anterior-superior approach. Using the ultrasound guide, the needle is introduced in real time until the tip touches the femoral bone plane. The preparation of HA is then injected and the intra-articular position is verified by direct ultrasound visualization of the fluid that extends on the joint capsule.

After infiltration, the CE is measured at the cervical median site (first measurement) and at the respective sides, obtaining an average of the expansion. Another measurement, with the same ultrasound findings, is made after passive flexion and subsequent extension, of the infiltrated limb at rest, reporting the average value.

PHARMACOLOGY

Hyaluronic Acid sodium salt is formed by repeated chains of disaccharide units of N-Acetyl-D-Glucosamine and sodium glucuronate and represents a fundamental component of synovial fluid, to which it confers its particular viscoelastic properties.

Information from the authorised prescription of the HA used, linear HA with molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml), shows that this is a medical device with viscoelastic properties consisting of a sterile, pyrogenic and isotonic solution of Hyaluronic Acid, purified sodium salt obtained

by fermentation and which is a substitute for synovial fluid for patients with degenerative or mechanical arthropathy. 15 mg of sodium hyaluronate are contained in 1 ml of injectable solution.

PSYCHOLOGICAL APPROACH

The patient is initially informed about the infiltration procedure but will in particular receive information about the diagnosis that has been made, the type of treatment and how it is carried out, including any changes to his/her own behaviour that may need to be made after the infiltration therapy has been carried out. As this is an invasive therapy, the patient must be aware of its risks, potential complications and side effects, as well as the possibility of implementing alternative therapies. The clinical evaluation is accompanied by objective clinical data, taken from the clinical examination, and instrumental findings, acquired at the time of diagnosis, requested later, if useful for in-depth diagnosis, or updated during treatment (e.g. ultrasound monitoring). All of this data must be included in the indication of processing and must continue to be processed. In addition to this information, the patient is given written information, which can be read at home after the examination. Consent to the treatment in written form must be obtained in accordance with Law 219 of 2017. Informed consent is signed by the patient in the presence of a family member or a person of their choice and the staff at the practice. The practitioner and staff at the practice are in turn trained and instructed on how to treat the patient by the psychologist. The effectiveness of infiltrative therapy, often used for chronic pathologies of the osteo-articular apparatus, is well known and well established. These pathologies have a considerable impact on the patient's autonomy, joint function and quality of life. For the patient, the decision about the choice of therapy and the adherence to the proposed therapy are decisive; the lack of adherence to the therapy will cause the therapy to fail with negative repercussions on the patient's state of health. It has been demonstrated that inadequate doctor-patient communication leads to poor therapeutic success and, in contrast, greater patient involvement improves success rates. The aim is to establish a "working alliance" which implies the patient's adherence to and satisfaction with medical treatment. The decision-making model adopted was that of the "sharing" of therapeutic choices (the "paternalistic" one and the "transfer of information" have been discarded): the doctor and the patient express their opinion on the different therapeutic options to reach an agreement, a joint decision on the most suitable therapy. The practitioner clearly explains

the scientific evidence on the subject, the risks and the advantages of the procedure in an understandable way, evaluating the needs and requests of the patient who will then make their own choice by implementing the Shared Decision-Making model, in our case suggested by the psychologist and applied by the practitioner.

In the specific case of infiltrative therapy for osteoarthritis of the hip, which requires different timings and a different approach compared to other joints, the sharing of the therapeutic choice was facilitated by the clear and detailed information of the state of the joint and the treatment plan in relation to the different parameters that can be used:

- degrees of range of movement and predictable improvements;
- current articular functionality (also expressed as a percentage);
- the need to preserve what is left (residual percentage);
- instrumental examination of the joint;
- commentary on the instrumental examinations;
- a series of ultrasound examinations with measurement of capsular expansibility, modifications and comparisons during therapy.

This and other information is part of the process of "empowerment" (involvement and participation of the patient) which makes an informed choice of treatment and its adherence possible, the so-called active role of the patient. This "therapeutic agreement" means that the patient has been informed of his/her pathological state and is actively involved in the implementation of his/her own treatment plan. One of the aims of the psychological approach to infiltrative therapy is to make patients "empowered", aware, informed and determined to improve their quality of life. The practitioner then has to further stimulate the involvement of the patient inviting him/her to ask questions. Our effort as practitioner and medical staff is to acquire, with the psychologist, sufficient training to increase communication with the patient, improve the knowledge of the patients and optimise their choices of therapy. As a result, a greater adherence to the therapy is obtained, the patient faces the condition better and favourable results for health and quality of life are achieved.

RESULTS

At the end of the study, patients treated with a cycle of two intra-articular infiltrations, echo-guided with linear HA with molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml), showed an improvement in hip articulation and a decrease in pain compared to baseline (Chart 3, mean values). Pain scores after treatment were significantly lower and patients did not show the need to take NSAIDs (Chart 4, mean values).

Chart 3. Mean values at baseline; cycle of two weekly infiltrations.

- CAPSULAR EXPANSION
- RIGIDITY
- PAIN
- CONSUMPTION OF ANTI-INFLAMMATORIES AFTER INFILTRATIVE THERAPY

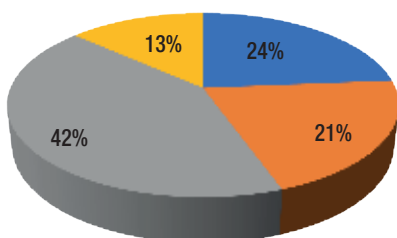


Chart 5. Mean values with a cycle of three weekly infiltrations.

- CAPSULAR EXPANSION
- RIGIDITY
- PAIN
- CONSUMPTION OF ANTI-INFLAMMATORIES AFTER INFILTRATIVE THERAPY

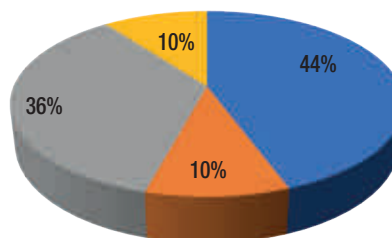


Chart 4. Mean values at the end of treatment; cycle of two weekly infiltrations.

- CAPSULAR EXPANSION
- RIGIDITY
- PAIN
- CONSUMPTION OF ANTI-INFLAMMATORIES AFTER INFILTRATIVE THERAPY

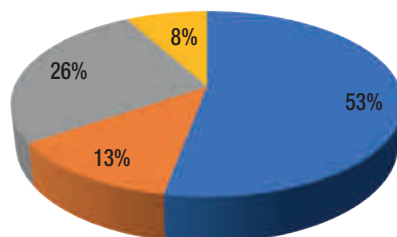
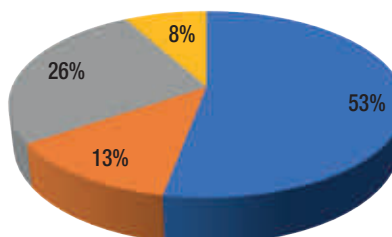


Chart 6. Mean values with a cycle of two weekly infiltrations.

- CAPSULAR EXPANSION
- RIGIDITY
- PAIN
- CONSUMPTION OF ANTI-INFLAMMATORIES AFTER INFILTRATIVE THERAPY



Articular rigidity, evaluated with WOMAC, sub simplified scale, was reduced after infiltrative therapy. The improvement of the hip joint range was significant in cases where the EC, after infiltration with HA, was greater than 25% or equal to 50% compared to the ultrasound measurement of baseline JS. Patients who started hip mobilisation early, on the basis of the positivity of expansibility, showed greater joint recovery. No adverse events were reported with the HA used.

DISCUSSION

Performing two intra-articular, echo-guided infiltrations detected by ultrasound in symptomatic hip osteoarthritis with linear HA of molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml), has a result superimposable to the infiltrative cy-

cle of three weekly infiltrations on the capsule expansibility, (Chart 5, mean cycle values 3 infiltrations per week; Chart 6, mean cycle values 2 infiltrations per week).

The extension of the study, therefore, highlights the validity of the approach with two weekly infiltrations and validates the hypothesis that the EC is an index of recovery of hip function.

Already from the first infiltration, the measurement of the EC, if compared to the basal ultrasound JS, is indicative of the state of the joint capsule and other structures related to it. The CE data can be obtained in real time during the infiltration procedure, it is reproducible and comparable. During the infiltration procedure, the expansibility data allows an immediate perception of the response of the capsule to the introduction of HA. In the next session, baseline and post-infiltration measurements, compared to baseline, show the state of expansion, mainte-

Chart 7. Comparison of 3 and 2 infiltrations.

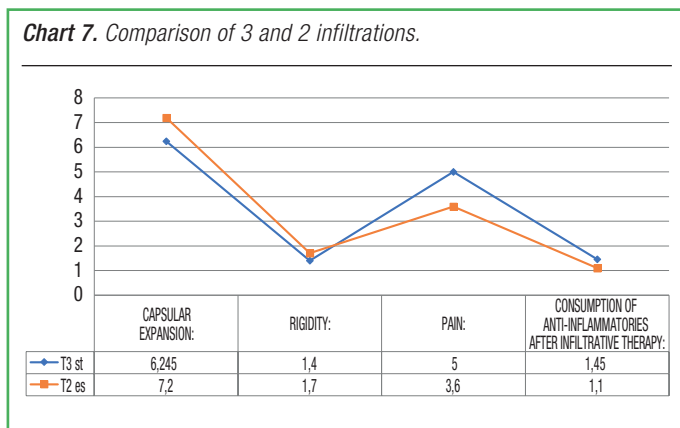
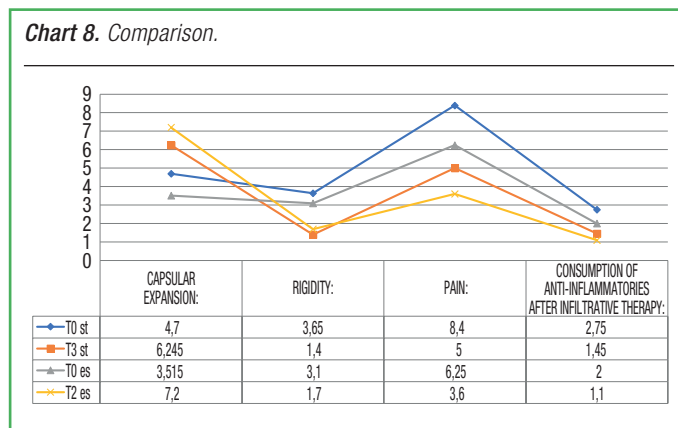


Chart 8. Comparison.



nance and possible increase. The data is always correlated to the hip joint; secondly to the pain and possible consumption of NSAIDs.

In the case studies, where an increase in post-infiltration EC compared to baseline was detected, physio-kinetic therapy using active assisted kinesis and manual hip stretching was immediately provided to reduce joint stiffness. With the reduction of rigidity, there has been a decrease in painful symptoms and, when present, the resolution of the attitude of the extra-rotation of the lower limb; all this is always closely linked to the increase in capsular expansion. The functional result, as mentioned, is enhanced by an early mobilisation of the hip (Chart 7).

Capsular expansibility depends on the condition of the capsular fibres, the integrity of the acetabular lip, the orbicular zone and the transverse acetabular ligament. The physiological mechanism of synovial fluid circulation is likely to be influenced by capsular expansion because pressure gradients are not reproducible in non-extensible cavities as is often observed in coxarthrosis. The normalization of the synovial fluid circulation allows the mobilization and the spreading of nutrients from the synovial to the articular heads carrying out the function of chondro-protection, with results expected in the medium-long term.

CONCLUSIONS

The extension of the previous pilot study on capsular expansibility during infiltrative therapy with HA in coxarthrosis was necessary, first of all, for reasons of clinical and scientific objectivity (Chart 8). Infiltration therapy with HA is practised with too much variability and instead common approaches are needed. The scientific literature on the subject is abundant and ever-increasing, but often based on a

small amount of evidence. For this reason, it would be desirable to define a treatment algorithm that can support the opinions of experts.

Continuing the treatments with linear HA with molecular weight >2.000 kDa (Syaloset® 2000 30 mg/2 ml), in the amount of 2 ml per single injection, using the same parameters and always focusing on capsular expansibility, a substantial overlap of results emerged in patients treated with two weekly infiltrations compared to those already obtained with three weekly infiltrations (three-weekly group, “first study”).

The comparison was made in the short post-infiltration period, because the parameters used are those of immediate appreciation, real-time capsular expansion (CE), joint pain and function after the procedure, reduction in the use of analgesics. The group of patients who underwent the three week procedure was used as a “control group” and the comparison was made using the same type of HA (linear with molecular weight >2.000 kDa); one less infiltrative session was provided.

Other trials and subsequent observations may however clarify whether, in the medium to long term, the capacity of visco-supplementation can be greater using three initial infiltrations.

The psychologist’s support in the infiltration procedure is very useful for the achievement of better therapeutic outcomes, for the approach with the patient and for the training of the medical staff on communicating. In the field of communication and information, the clinical and instrumental data collected at baseline and those undergoing treatment have proved to be valuable and, when compared, have allowed the patient to be aware of the outcome of the treatment immediately. The involvement in the infiltrative treatment is fully achieved by making the patient aware of his/her condition, the preservation of his/her state of health and the margins for improvement of his/her quality of life.

Bibliography

- Corsello C, Russo S, Corsello G. L'espansione capsulare dell'anca dopo terapia infiltrativa con Acido ialuronico, correlazione con la funzionalità articolare: risultati di uno studio pilota, osservazionale, in aperto. *NPT - Nuove Prospettive in Terapia* Anno XXVIII - n. 1/2018, 3-14 - 2018 MEDIZIONI.
- Renzi C, Goss C, Mosconi P. L'importanza della partecipazione dei pazienti e delle famiglie per ottimizzare l'adesione alla terapia e gli esiti di salute. *Rivista di Immunologia e Allergologia Pediatrica* 05/2009, 3-7, RIAP.
- Moja EA, Poletti P, Ministero della Salute, Direzione Generale della programmazione Sanitaria, Ufficio III, Comunicazione e performance professionale: metodi e strumenti, Il Modulo, La comunicazione medico – paziente e tra operatori sanitari. Aprile 2016.
- Prigge JC, Dietz B, Homburg C, Hoyer WD, Burton JL. Patient empowerment: A cross-disease exploration of antecedents and consequences, *Intern. J of Research in Marketing* 2015;32:375-386 ELSEVIER.
- Fuertes JN, Mislowack A, Bennett J, Laury Paul L, Gilbert TC, Fontan G, Boylan LS. The physician–patient working alliance. *Patient Education and Counseling* 2007;66:29-36 ELSEVIER.

