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KNEE OSTEOARTHRITIS COMBINATION THERAPY WITH HYALURONIC ACID, CHONDROITINE SULFATE AND GLUCOSAMINE AFTER ARTHROSCOPIC LAVAGE: LONG-TERM RESULTS

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Purpose: Purpose to study the efficiency therapy of arthroscopic lavage in combination with subsequent intra articular injection of hyaluronic acid and combined drug of chondroitin sulfate and glucosamine hydrochloride at short- and long-term outcomes.

Methods: One-hundred-forty-two patients with knee osteoarthritis (OA) were examined with accordance with the American College of Rheumatology criteria and randomized into 3 groups:

- 1. Group 1 consisted of 40 patients only after arthroscopic lavage;
- 2. Group 2 comprised 42 patients who were administered hyaluronic acid (RusVisc ®) after arthroscopic lavage;
- 3. Group 3 comprised 40 patients who were administered combined drug of chondroitin sulfate and glucosamine hydrochloride (ARTRA®) and hyaluronic acid after arthroscopic lavage.

Clinical evaluation encompassed pain while walking, resting, and moving (by a visual analogue scale), limited ability in covering 100 m (by a 5-point scale), general clinical evaluation (by a 5-point ordinal scale), the presence or absence of pain after 100-m walking, as well as resting pain (its presence or absence).

Results: The treatment effect evaluated using different indicators was comparably positive in all 3 groups within 3 months. Following 3 months of therapy, its effect remained stable and even better in Group 2 and Group 3. Groups 2 and 3 showed a particularly noticeable superiority a year later. There were excellent and good results in 88 and 91% respectively, and 47.5% in Group 1. Moreover, excellent results were observed in 51% of patients in Group 3, and in 45% in Group 2. The clinical symptoms of the disease were absent in 66% of patients in Group 3, in 58% in Group 2 and in only 15% in Group 1. Moreover, Group 1 showed worsening and 20% of the patients had no effect. This trend was also seen while evaluating the therapeutic effectiveness in different periods. Thus, after therapy, no substantial difference was found in all groups, but 3 months later this difference was as many as 0.8 scores and a year later Group 2 and Group 3 had many points in its favor (1.2 and 1.6 scores).

Conclusions: Arthroscopic lavage followed by the administration of hyaluronic acid makes it possible to prevent the negative effect of a washing liquid on the metabolism and structure of the articular cartilage. Complex therapy with hyaluronic acid and co-formulated drug of chondroitin sulfate and glucosamine hydrochloride allows to achieve a long-term effect against the major clinical symptoms (joint pain and function) affecting the quality of life. The effect depended on the magnitude of cartilage changes according to arthroscopic data and failed to be related to age and disease duration. The magnitude of cartilage changes may be a predictor of response to treatment.

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INTRA-ARTICULAR ADMINISTRATIONS OF JONEXA® IN PATIENTS WITH SYMPTOMATIC OSTEOARTHRITIS OF THE HIP. DATA FROM A MONOCENTRIC COHORT STUDY

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Purpose: Several medical devices are at now disposable for intra-articular use in patients affected by hip Osteoarthritis (OA) and several data have been produced in order to support their use. At now there are no reports on cohorts of patients undergoing intra-articular hip injections with Jonexa showing its safety and efficacy profiles in real life after commercialization. Jonexa (Hylastan SGL-80) is a sterile, colorless, non-pyrogenic

Table 1Efficacy outcome measures at each visit: VAS pain mean scores, Lequesne index mean scores, NSAID consumption mean scores

Parameters	Baseline	3 months	6 months
OA Pain VAS	7.01	3.89*	4.10*
Lequesne index	10.11	6.32*	6.11*
NSAID consumption	6,98	4.0*	4.0*

^{*} p < 0.001 when compared with baseline values.

elastoviscous fluid, with a neutral pH and osmolality compatible with synovial fluid. Hylastan SGL-80 is manufactured from hylastan, a divinyl sulfone chemically crosslinked sodium hyaluronate (HA) gel and sodium hyaluronate fluid characterized by a 80:20 gel to fluid ratio. The sodium hyaluronate used in the preparation of hylastan SGL-80 is derived from bacterial fermentation. Jonexa is commercialized in Italy since September 2010 for intra_articular use in patients affected by osteoarthritis (OA). Jonexa is expected to produce a symptom relief of at least 26 weeks when injected intra-articularly in patients affected by symptomatic OA.

This study was performed to report data on safety and efficacy profiles of Jonexa in intra-articular injections of the hip in a cohort of patients affected by hip OA from a 6 months followup monocentric study.

Methods: Adult patients suffering from hip OA grade 1 to 3 according to Kellgren and Lawrence grading were considered eligible for the study. Patients were injected with one syringe (4 ml) of Jonexa at baseline by ultrasound guidance following Migliore-Tormenta technique and were then observed by a control visit performed 3 months and 6 months after injection. The efficacy was assessed by using the Lequesne index and VAS pain score at baseline and, then, at every control visit. NSAIDs consumption was also evaluated as the number of days in the month previous to baseline visit or control visit where patient needed to assume a pain killer for knee OA. Safety was assessed by recording any adverse event during the follow up period, considering both transient pain effects and any other eventual side effects.

Results: 41 patients, 21 males and 20 females, were enrolled in the study; 11 had bilateral hip OA. All patients received one intra-articular injection of Jonexa for every hip affected by OA; a total of 52 injections was performed in this study. All patients reached the 6 months followup visit. Mean scores obtained at each visit after baseline show an improvement when compared with baseline with a statistically significant difference, p < 0,001 for every time point (Tab.1). No infectious complications were reported. 4 patients (9,75% of total patients), for a total of 5 injections (9,61% of total injections), reported a transient discomfort in the treated hip for 1-3 days after injection that regressed spontaneously or with paracetamol 1g twice or three times a day.

Conclusions: Our data suggest that beneficial effects obtained by the intra-articular injection of the hip joint may be evident at three months after first injection and seem to be maintained over six months. Further results will be obtained by the completion of this observational study.

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VISCOSUPPLEMENTATION IS NOT AN ALTERNATIVE TO HIP JOINT SURGERY IN PATIENTS WITH SEVERE HIP OSTEOARTHRITIS. RESULTS OF A "REAL LIFE" CLINICAL SURVEY IN 137 PATIENTS

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Purpose: To compare patient's satisfaction and treatment efficacy of a single hyaluronic acid (HA) intra-articular injection in patients with moderate hip osteoarthritis (OA) and in patients waiting for total hip replacement.

Methods: Multicenter standardized follow-up.137 consecutive patients treated with a single intra-articular injection of HANOX M-XL (cross-linked HA 1.5% +mannitol) for symptomatic hip OA were included in the study. Demographic data, imaging guidance (fluoroscopy or ultrasonography), pain on a 10 point Likert scale, patient's self-evaluation of efficacy, satisfaction with the treatment and tolerability were obtained. Patients were classified into two groups: Those for which the visco-supplementation was the last resort before total hip arthroplasty (THA group, N = 41) and those who would not consider surgery in the short term (Non Surgery- NS group; N = 96).

Results: The percentage of patients very satisfied/satisfied and not really satisfied/not satisfied with the treatment was 54.7% and 45.3% respectively. In satisfied patients the decrease of analgesics/NSAIDs consumption was>75% in 60.5% of cases. Efficacy was unrelated to gender, age, and guidance. It was highly correlated with both satisfaction and pain (p < 0.0001). 65.9% of the NS group patients were satisfied with the treatment versus 15.5% of those belonging to the THA group (p < 0.0001). Tolerability was very good/good in 115 patients (85.2%) and unrelated to disease severit, imaging guidance and efficacy. **Conclusions:** These data suggest that despite viscosupplementation with HANOX-M-XL is safe and efficient in moderate hip OA it is not an alternative to surgery in advanced disease.