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AB0874

FUNCTIONALITY IN OSTEOARTHRITIC GAIT IS RELATED TO TREATMENT DECISION. A MULTIFACTORIAL ANALYSIS

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Background: Osteoarthritis (OA) is a degenerative disease with complex underlying mechanisms¹⁻³. The interactions among several factors make the study of the disease very complex and often lead to different treatment, i.e. surgical or conservative, decisions for subjects clinically and radiographically similar. Recent explorations performed at the body level pointed out that macro-factors, like overweight or gait, can influence the development of the disease⁴. The number of related factors is high, and they are very likely to interact with each other. However, the literature lacks randomized and balanced studies to verify such effects of multiple factors⁵.

Objectives: The aim of this work was to develop a multifactorial analysis to explore whether and how gait functionality and dynamics can be related to treatment decision.

Methods: A multifactorial analysis of gait dynamics in OA subjects was developed. 81 OA subjects, graded 2-3 in KL, were selected based on 4 clinical factors: Gender (male – female), Age (60-67 – 68-75), BMI (25–29.9 – 30+) and Treatment (total knee replacement (TKR) – conservative treatment). Gait analysis was performed using 8 cameras BTS Smart-DX 700, 1.5 Mpixels 250 fps and 2 force plates BTS P-6000 500 Hz sampling (BTS S.p.A., Milan, Italy). Helen Hayes marker protocol with medial markers was used for the study. Each volunteer was asked to perform a minimum of 5 valid gait sequences. Functionality and dynamics parameters were measured.

Functionality: Velocity of gait and the time needed to perform a gait cycle were computed.

Dynamics: The reaction forces and torques at the ankles, knees and hips were computed through inverse dynamic analyses.

Analysis of variance was performed for the four factors described among the functionality and dynamics parameters.

Results: The multifactorial analysis showed that functionality values are more subjective to the studied factors than the dynamics ones.

Functionality seems to be directly related to the clinical treatment. Patients who selected TKR needed more time to make a step, spent more time in double stand position and walked slower ($p < 0.002$). Older subject also walked slower but this dependency seemed to vary with age (interaction between clinical treatment and age – $p < 0.02$ – Figure 1).

Figure 1 Interaction between Clinical treatment and age.

Dynamics: Forces at the joints seemed to be affected by the gender and an interaction between age and BMI ($p < 0.005$, $p < 0.02$) but not by the kind of therapy. Differently, torques were statistically related to the clinical treatment ($p < 0.007$). Age was also significant as was the interaction between age and BMI (both $p < 0.007$).

Conclusion: Reduced functionality seems to be related to the selection of therapy. In contrast to current paradigm, forces at the joints may have no role in the definition of the best therapy for OA subjects. Subjects requiring TKR do not present higher loads at the joints. However, torques seems to be related to the therapy selected. Instead of forces, kinematics and posture assessments might support rational definitions of the therapy and future multifactorial analysis should take them into consideration.

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HYBRID COOPERATIVE COMPLEXES OF SODIUM HYALURONATE + SODIUM CHONDROITIN NON-SULFATED (HA-SC) IN THE TREATMENT OF HIP OA: CLINICAL RESULTS

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Background: Hip Osteoarthritis (OA) is a widespread disease characterized by pain and functional impairment, which, particularly in the elderly, may compromise overall health and quality of life. In the last decades, Intra-articular (I.a.) injections of hyaluronic acid (HA) gained more space among the conservative treatment of OA because of their beneficial effects and positive outcomes without relevant complications. (1,2). An innovative and patented formulation containing hybrid cooperative complexes of sodium hyaluronate 2.4% + sodium chondroitin non-sulfated 1.6% of biotechnological origin (HA-SC) has been recently developed for the I.a. treatment of hip OA and evaluated in a pilot study (3).

Objectives: 1) Primary aim: Evaluation of the safety of HA-SC in the treatment of symptomatic hip OA; 2) Secondary aim: Evaluation of the efficacy of HA-SC in terms of pain reduction (VAS) and function improvement (Lequesne) of the affected hip joint.

Methods: This is a pilot, multicentric, open, prospective study. The following inclusion criteria were established: Patients (both genders) aged ≥ 40 years suffering for primary hip OA confirmed by X-Ray; Grade I-II-III according to K&L grading scale; Basal VAS pain at the target hip > 40 mm; Failure of at least two lines of conservative treatments. All patients underwent a single I.a. hip injection of a 3mL vial of HA-SC and followed-up for six months.

Results: 48 patients have been enrolled and completed the study. The treatment was generally well-tolerated, with only ten patients out of 48 (20.8%) reporting local effects mainly consisting of injection site pain and arthralgia localized in the treated area. All these patients completed the study. The treatment with HA-SC was associated with a statistically significant decrease of VAS scale from a basal value of 67.5 (mean) to 22.8 (mean, $p < 0.0001$) at the end of the observation period at six months, with a statistically significant decrease at seven days of follow-up evaluation (29.3, mean, $p < 0.0001$). The mean Lequesne's Index total score after the single injection of HA-SC decreased from a baseline value of 10.4 (mean) to 5.1 (mean, $p < 0.0001$) at six months. The decrease was marked and significant also at any of the other evaluated time point ($p < 0.0001$).

Conclusion: A single I.a. injection of the innovative formulation containing hybrid cooperative complexes of sodium hyaluronate + sodium chondroitin non-sulfated (HA-SC) showed to be well tolerated and safe in the treatment of symptomatic hip OA. A rapid and significant decrease in hip pain (VAS) and Lequesne's Index was also observed starting immediately after the I.a. injection and lasting until the end of the follow-up period. However, conservative treatment of hip OA is still challenging. This new formulation could represent a promising, long-lasting, and effective I.a. treatment.

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AB0876

THE BENEFIT AND SAFETY OF DIACEREIN IN AGED AND OBESE PATIENTS WITH SYMPTOMATIC KNEE OSTEOARTHRITIS: DATA FROM THE DISSCO CLINICAL STUDY

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Background: The DISSCO trial (6-month international, multicentre, double-blind, randomised study on the effect of diacerein vs celecoxib in symptomatic knee osteoarthritis [OA] patients) showed that diacerein had comparable efficacy to celecoxib at reducing the level of pain (WOMAC pain).

Objectives: To assess the effect of age, body mass index (BMI), and gender on the efficacy/safety profile of diacerein following 6 months of treatment.

Methods: Of the patients (n=380) that were randomised, 186 received treatment with 50mg diacerein once daily for the first month and twice daily thereafter. This study was done on the intent-to-treat population (n=183). Efficacy outcome assessments which included absolute change in WOMAC pain (score 0-50) and function (score 0-170), and VAS (score 0-10) were analysed following stratification based on age (< 65 vs ≥ 65 years old) and BMI (< 30 vs ≥ 30 kg/m²) at time of randomisation. Treatment effects on continuous efficacy outcomes were performed using covariance analysis (ANCOVA). For gastrointestinal (GI) safety outcomes, the adverse events (AEs), including diarrhoea, soft faeces, abdominal pain and dyspepsia, and the time-to-onset from baseline were stratified according to age of patients at randomisation. Treatment-related GI AEs were also assessed according to the gender. The independent variables were treatment, stratification variable, interaction between both, and the outcome measure at baseline. Comparisons between groups were carried out using Chi-square.

Results: No significant differences were found between the two age groups (<65 years old [n=105], ≥65 years old [n=78]) in the level of reduction in WOMAC pain (-10.3 ± 1.1, -8.6 ± 1.3, respectively; p=0.30), VAS (-2.3 ± 0.2, -2.2 ± 0.3, p=0.73) or improved physical function (-29.7 ± 3.7, -22.1 ± 4.2, p=0.18). The reported incidences of treatment-related GI AEs were also similar between the two age groups; more specifically for diarrhoea, incidence for patients <65 years old [n=12] 11.3% and for those ≥65 years old [n=7] 8.8% (p=0.63) with a mean time-to-onset (day 43 ± 49, 61 ± 51, respectively; p=0.11). Moreover, gender had no influence on treatment-related GI AEs (p=0.42).

In regard to treatment response of obese (n=101) vs. non-obese (n=82) patients in terms of pain reduction (WOMAC: -10.1 ± 1.2, -9.1 ± 1.1, respectively; p=0.58; VAS: -2.6 ± 0.3, -2.0 ± 0.3; p=0.15), or improved WOMAC physical function (-29.8 ± 4.2, -23.5 ± 3.8; p=0.26), there were also no significant differences.

Conclusion: In symptomatic knee OA patients, the level of effectiveness and safety profile of treatment with diacerein were found not to be influenced by age, BMI or gender.

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AB0877

CLINICAL EFFICACY AND SAFETY PROFILE OF TOPICAL ETOFENAMATE IN THE TREATMENT OF PATIENTS WITH MUSCULOSKELETAL DISORDERS: RESULTS OF A SYSTEMATIC REVIEW

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Background: Musculoskeletal disorders affect millions of people of all ages around the world [1]. Nonsteroidal anti-inflammatory drugs (NSAIDs) are, in general, the cornerstone of musculoskeletal pain management; however, systemic adverse events with oral formulations of NSAIDs are common. To address this, topical formulations of some NSAIDs have been developed. [2] Although there are many nonsteroidal anti-inflammatories, only a few are used as local therapeutics. This is because the physicochemical properties of these substances, which were originally developed for oral administration, frequently do not guarantee a satisfactory pharmaceutical formulation with satisfactory topical absorption. [3]

Objectives: The aim of this systematic review was to assess the available evidence on the efficacy and safety of the topical formulations of the NSAID etofenamate in patients with musculoskeletal disorders.

Methods: A systematic search of PubMed and Web of Science was conducted, using the key words (topical etofenamate efficacy) OR (topical etofenamate safety) OR (topical etofenamate effectiveness) to identify studies of etofenamate published from inception to November 2018. Some published manuscripts of interest known by the authors but not identified in the PubMed search were also added to ensure the review article was as comprehensive as possible.

Results: Overall, 12 studies were identified. [3-14] These studies demonstrated the ability of topical etofenamate (administered either in gel [5% or 10%], cream [10%] or lotion [10%] formulations) to improve pain and reduce inflammation in patients with musculoskeletal disorders, including blunt injuries and rheumatic diseases. Etofenamate was shown to have an overall efficacy that was superior to other topical NSAIDs, such as 1% indomethacin and 1% diclofenac, and to be as effective as topical formulations of 2.5% ketoprofen gel and 2% ketorolac gel (although ketorolac suggested a better elimination of pain at some time points). Overall, when compared to placebo, etofenamate gel 5% demonstrated significant better results in the reduction of pain symptoms (with or without combination with ultraphonophoresis). Furthermore, clinical evidence indicates that etofenamate is generally well tolerated in these indications.

Conclusion: The available clinical evidence suggests that etofenamate could be an effective therapeutic option for the management of musculoskeletal disorders, such as blunt traumas, lumbago or osteoarthritis. However, larger and well-controlled clinical trials comparing the efficacy and safety of etofenamate with other newer topical NSAIDs are warranted.

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AB0878

THE COMPARISON EFFECTS OF INTRA-ARTICULAR INJECTION OF PLATELET RICH PLASMA (PRP), PLASMA RICH IN GROWTH FACTOR (PRGF), HYALURONIC ACID (HA), AND OZONE IN KNEE OSTEOARTHRITIS: A ONE YEAR RANDOMIZED CLINICAL TRIAL

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Background: Knee osteoarthritis (OA) as a common progressive degenerative condition is one of the most important leading causes of disability and relative dependence. Worldwide prevalence of symptomatic knee OA has estimated 3.8%. It affects more than 20% of over 45-year-old population. Among the minimally invasive methods recommended for knee OA management is intra-articular injections for which a large array of products have been used. Despite all the