Treatment (total knee replacement (TKR) – conservative treatment). Gait analy-
tors: Gender (male – female), Age (60-67 – 68-75), BMI (25–29.9 – 30+) and
Methods: whether and how gait functionality and dynamics can be related to treatment decision.
Objectives: and age – p<0.02 – Figure 1).
Results:}
Position and walked slower (p<0.002). Older subject also walked slower but this
subjective to the studied factors than the dynamics ones.
Functionality
Analysis of variance was performed for the four factors described among the
dynamics parameters.

Dynamics: The reaction forces and torques at the ankles, knees and hips were
affected by the gender and an

Inclusion criteria were established: Patients (both genders) aged ≥ 40 years suf-
Affirmative side was treated for primary hip OA confirmed by X-Ray; Grade I-II-III according to K&L
Therapy function and the time needed to perform a gait cycle were

References:

Acknowledgments: MICINN Funds are acknowledged (HOLOA-DPI2016-

Disclosure of Interests: None declared

DOJ: 10.1136/annrheumdis-2020-eular.1051

AB0875 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.

References:

Figure 1 Interaction between Clinical treatment and age.
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/safety profile of diacerein following 6 months of treatment.

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=186). 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=83]) 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 61 ±51, respective; 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 pain: −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.

Disclosure of Interests: Jean-Pierre Pelletier Shareholder of: ArthroLab Inc., Jean-Pierre Pelletier Consultant of: Recently, I was a paid consultant of Bial., Speakers bureau: I have been a paid speaker for Bial., Daniele Mariotto Employee of: I’m currently an employee of BIAL pharmaceutical company, I belong to the medical affairs department of Bial.

DOI: 10.1136/annrheumdis-2020-eular.1862