Efficacy and safety of sodium hyaluronate in hip osteoarthritis. A randomized, double-blind, Lidocaine-controlled, multicenter study with a 12-months follow-up period

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Objectives

1. To evaluate the efficacy and safety of intra-articular (i.a.) injections either of sodium hyalurtonate (SH) 20mg/2.0ml (Ostenil®, TRB Chemedia AG, Germany) or lidocaine hydrochloride 20mg/2.0ml administrated 1x/week for a total of 3 injections in 2 groups of hip osteoarthritis patients.
2. To assess the long-term efficacy over a 12-months period from the 1st Ostenil injection.

Study design

- It was 6 months randomized, double-blind multicenter study carried out in 3 centers. There was follow-up period in Ostenil group (6 months).
- The study was divided into 8 visits. At the screening visit eligible patients were asked to undergo a 1 week NSAID washout period and take acetaminophen tablets (Maximum 3 gm/day).
- At baseline eligible patients were randomized at a 1:1 ration, using a randomization list generated with validated computer software to receive either Ostenil, or Lidocaine.

Patients and methods

- Patients were eligible for the study if they were between 40 and 70 years old and had hip OA according to the ACR criteria, I-III radiological stage by Kellgren/Lawrence and pain >40mm (VAS) of WOMAC A, 1 pain subscale, written informed consent.
- Exclusion criteria were accompanying knee OA of sufficient severity to interfere with hip function assessment, trauma or arthroscopic procedures in past, necrosis of the femoral head, severe concomitant diseases, hypersensitivity to hyaluronic acid, Lidocaine and Ibuprofen (resque medication), inflammatory rheumatic diseases (RA, PsA, pseudo-gout), participation in another clinical trial within 6 months prior to study start.

Evaluation of efficacy and safety

- Pain, morning stiffness, physical function and total WOMAC index (VAS, mm)
- Ibuprofen intake (number of per day tablets)
- Patients global assessment of the disease activity (VAS, mm)
- Number and severity of adverse events

Statistical analysis

- Clinical variables were analyzed by analysis of variance (ANOVA) within treatment groups, using one- and 2-way ANOVA (the ITT population)

Results

- The study included 74 patients with osteoarthritis of hip joints (OAHJ) (M:F=10:64), aged 58.6±7.7 yrs. The studied group consisted mainly of pts with the II radiological stage (65%). Median BMI was 29.7±4.5 kg/m^2. 15% of pts had BMI <25 kg/m^2. In 75% of cases bilateral OAHJ was diagnosed. During the study only one joint was analyzed ("more damaged" by the opinion of patient). Concomitant diseases not preventing to including pts into the study (mainly controlled arterial hypertension) were found in the experimental group in 77% and in the control group in 76% of pts.

Comparative assessment of Ostenil and Lidocaine efficacy parameters was done within the first 6 months, in the period on double blind study. Further on after opening the codes (in 12 months from the beginning) the after-effect was analyzed only in experimental group (Ostenil).

- It was stated, that after three injections of Ostenil into the hip joint pain reliably subsided, morning stiffness and total WOMAC index diminished.
- Assessment of pain, morning stiffness, functional activity and total WOMAC index dynamics confirmed long term, for a year, after-effect of Ostenil. The latter fact is very important as it testifies to the fact that the drug improves OAHJ prognosis.
- Cancellation of treatment due to inefficacy was required only in Lidocaine cases (5 pts). Local and/or systemic adverse events at the result of treatment were not registered.

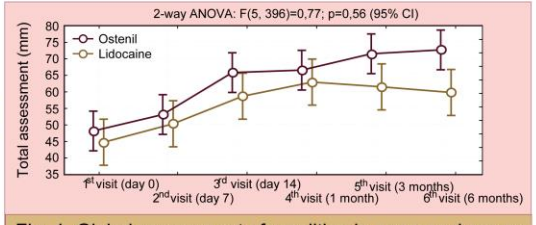

Fig. 1. Global assessment of condition in compared groups

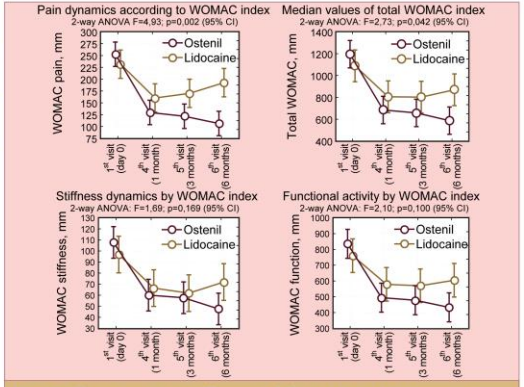

Fig. 2. Comparative efficacy of Ostenil and Lidocaine

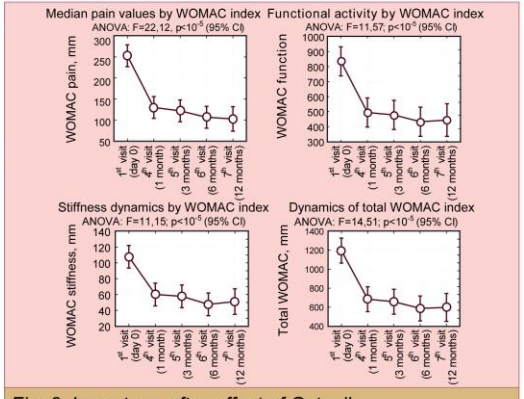

Fig. 3. Long-term after-effect of Ostenil

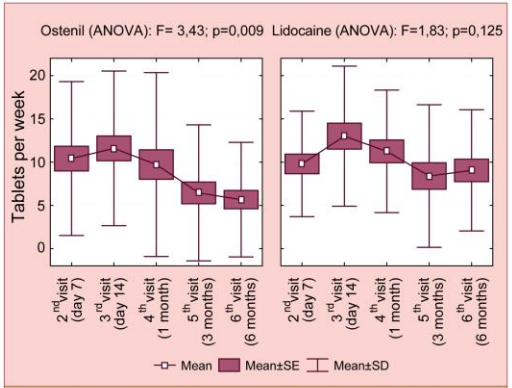

Fig. 4. Ibuprofen daily consumption in Ostenil and Lidocaine groups

Conclusion

- This is the first published double-blind Ostenil study in hip osteoarthritis patients
- Ostenil is an effective treatment for symptomatic hip osteoarthritis
- Ostenil has a long term (12 months) effect and an acceptable safety profile
- Ostenil improves the prognosis of hip osteoarthritis

References

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