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Ostenil® mini in the treatment of hallux limitus: a single-blind, randomized study

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Aim

To assess the efficacy and safety of Ostenil® mini (TRB Chemedica AG, Germany), a synovial fluid substitute containing 1.0% hyaluronan, in the treatment of osteoarthritis (OA) of the first metatarsophalangeal (FMTP) joint (Figure 1), compared with standard steroid injection.

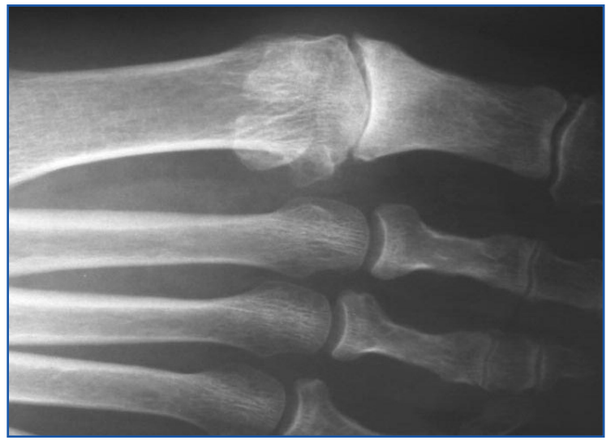

Figure 1. Radiograph showing hallux limitus.

Methods

Study site, randomization and patients

Patients (40–80 years old) with painful OA of the FMTP joint were recruited after giving written informed consent and randomized after confirmation of inclusion/exclusion criteria. Those in the Ostenil® group (OG) received one intra-articular (i.a.) injection of Ostenil® mini (1 mL), while the steroid group (SG) received one i.a. injection of 1 mL of 1% triamcinolone acetonide. Only paracetamol tablets, 500 mg, were allowed as escape medication. Patients were assessed on Days 0, 14, 28, 56 and 84 (end of study).

Data collection and primary outcome variables

Efficacy was evaluated with the following parameters: pain at the MTP joint (assessed on a 100 mm visual analogue scale) on palpation, on passive motion and on walking 20 m with standard shoes; the Hallux Metatarsophalangeal–Interphalangeal Scale of the American Orthopaedic Foot and Ankle Society (AOFAS); general evaluation of treatment by patients and physician (5-level scale); and the use of analgesics. Tolerability to treatment was assessed both by the patients and by the physician (5-level scale), and all adverse events were recorded.

Statistical methodology

SPSS for Windows (version 11.5.1) was used for data management and statistical analysis. Variables were analyzed using the Chi-squared test, the non-parametric Mann–Whitney U-test, the Wilcoxon test and the Friedman test.

Results

- A total of 37 patients (mean age: 62 years; females: 85%) (n = 40 joints) were recruited and completed the study (OG: n = 20 joints; SG: n = 20 joints).
- Pain at rest or on palpation or passive motion decreased significantly ($p < 0.01$) in both groups throughout the study compared with baseline, but there were no differences between groups ($p > 0.05$). Pain on walking 20 m decreased significantly ($p < 0.05$) more in the OG at Days 28 and 56 (Figure 2).

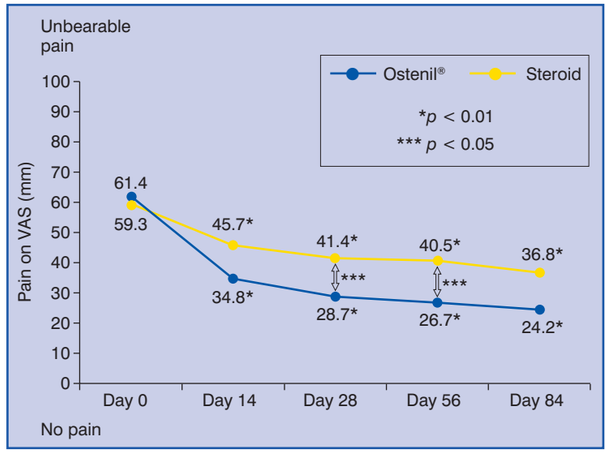

Figure 2. Change in pain upon walking 20 m with standard shoes, measured on the visual analogue scale (VAS).

- AOFAS scale evaluation showed no differences in function and alignment, but a significant reduction ($p < 0.05$) in pain and total score was observed for the OG at all visits (Figures 3 and 4).
- General evaluation of treatment by the patient showed increased patient satisfaction in both groups, but the only significant difference ($p < 0.05$) compared with Day 14 was seen at Day 56 in the OG.
- Adverse events appeared in two joints in the OG and in one joint in the SG ($p > 0.01$), and consisted of pain and/or swelling at the injection site.

Conclusion

Ostenil® mini is effective and well tolerated in decreasing pain from OA of the FMTP joint. Pain and AOFAS total score showed significant improvement with Ostenil® mini compared with steroid injection. No severe adverse reactions were observed.

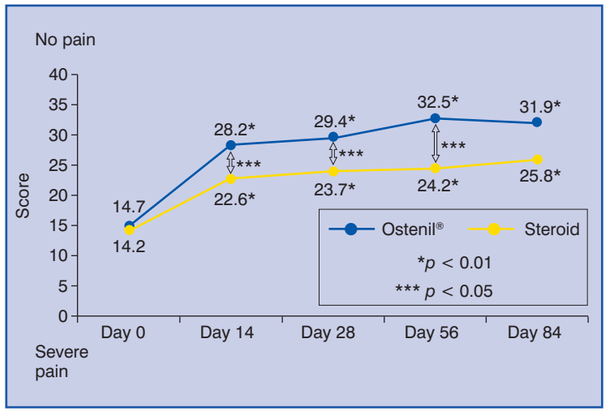

Figure 3. Change in pain on the AOFAS scale.

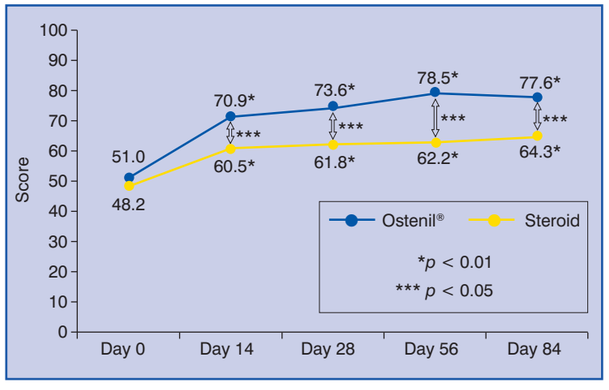

Figure 4. Change in total score on the AOFAS scale.

References

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