Efficacy and safety of viscosupplementation with HANOX-M-XL (HappyCross®) in ankle osteoarthritis. Results of a standardized follow-up

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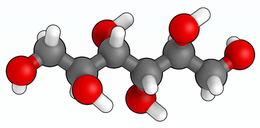
BACKGROUND

The published data suggest that viscosupplementation may be a safe and effective method in the treatment of ankle OA. However, the limited number of patients with ankle OA enrolled in clinical trials as well as the diversity of the products and dosing regimen are limiting any definitive conclusion about its safety and efficacy.

HANOX-M-XL, (LABRHA, Lyon, France) is a new viscosupplement, specifically designed to treat middle-sized joint OA. It combines a high molecular weight cross-linked sodium hyaluronate (15.5g/L) of non-animal origin and a high concentration (3.5%) of mannitol, a polyol known for its antioxidant properties by scavenging radical oxygen species (ROS).

OBJECTIVE

To obtain data on both efficacy and safety of **HANOX-M-XL**, administered through a single injection regimen in patients suffering from symptomatic ankle osteoarthritis (OA).



METHODS

Multicenter standardized follow-up.

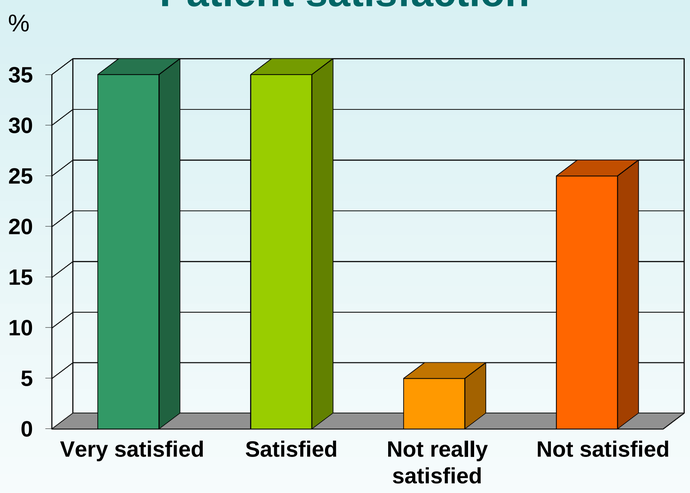
20 consecutive patients treated with a single intra-articular injection of HANOX-M-XL for symptomatic ankle OA, not responding to symptomatic treatments, were included in the survey.

Demographic data, imaging guidance, pain on a 10 point Likert scale (LS), patient's self-evaluation of efficacy, satisfaction with the treatment and tolerability were obtained.

RESULTS

Sex ratio (Male/female) was 15/5. Patients mean age (SD) was 57 (19.4) and average time of follow-up was 11.5 (4.7) weeks.
Viscosupplementation was performed under fluoroscopic guidance in 11 cases, ultrasonography (US) in 4 cases and without imaging guidance in 5 cases.

Patient satisfaction

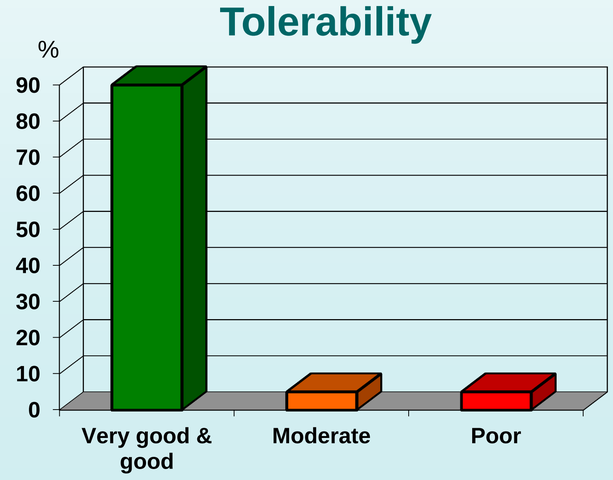


Efficacy was unrelated to sex (p=0.58), age (p=0.87), and guidance (p=0.33).
Efficacy was highly correlated with pain on LS (p<0.0001).

RESULTS

Efficacy

Tolerability



The patient who experienced high level of pain after injection was treated without imaging guidance, suggesting the treatment was not administered intra-articularly.

CONCLUSION

In ankle OA, 3 months after a single injection of **HANOX-M-XL** in the target ankle, **7 patients out of 10 were satisfied with the treatment**, without any safety concern.
These data suggest that **HANOX-M-XL** is a safe and efficient intra-articular treatment of ankle OA but large scale controlled trials are necessary to confirm these promising results.