

Efficacy and tolerance of an oral hyaluronate chondroprotector in the treatment of osteoarthritis of the knee



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Introduction

- Symptomatic Slow Acting Drugs for Osteoarthritis (**SYSADOA**) have been recommended by orthopaedic surgeons to improve the symptoms and as possible modifiers in the progression of the cartilage structural damage.
- Several studies have demonstrated that hydrolyzed collagen acts as a chondroprotector. Orally administered collagen is absorbed and distributed in joint cartilage.
- Hyaluronic acid is a glucosaminoglycan with viscoelastic and lubricant properties, widely used in cosmetic medicine and pharmacy. In humans, hyaluronic acid is synthesized by the cell membrane of all body cells, with a particularly high concentration in connective tissues, joint fluid, cartilaginous tissue, skin and vitreous body of the eye. Recent studies demonstrate wide distribution to connective tissues of orally administered hyaluronic acid.

Introduction

Objective

To study the efficacy and tolerance of the oral administration of one vial a day of a chondroprotector based on hyaluronate and hydrolyzed collagen for 90 consecutive days concerning the symptomatology of knee osteoarthritis.

Material and Methods

Study design

- Prospective, exploratory, open study
- **108 patients**
 - Affected by knee osteoarthritis (class I, II, III ACR classification).
 - Clinical history with therapeutical benefit obtained using NSAIDs.
 - Joint pain in the knee during the last 3 months.

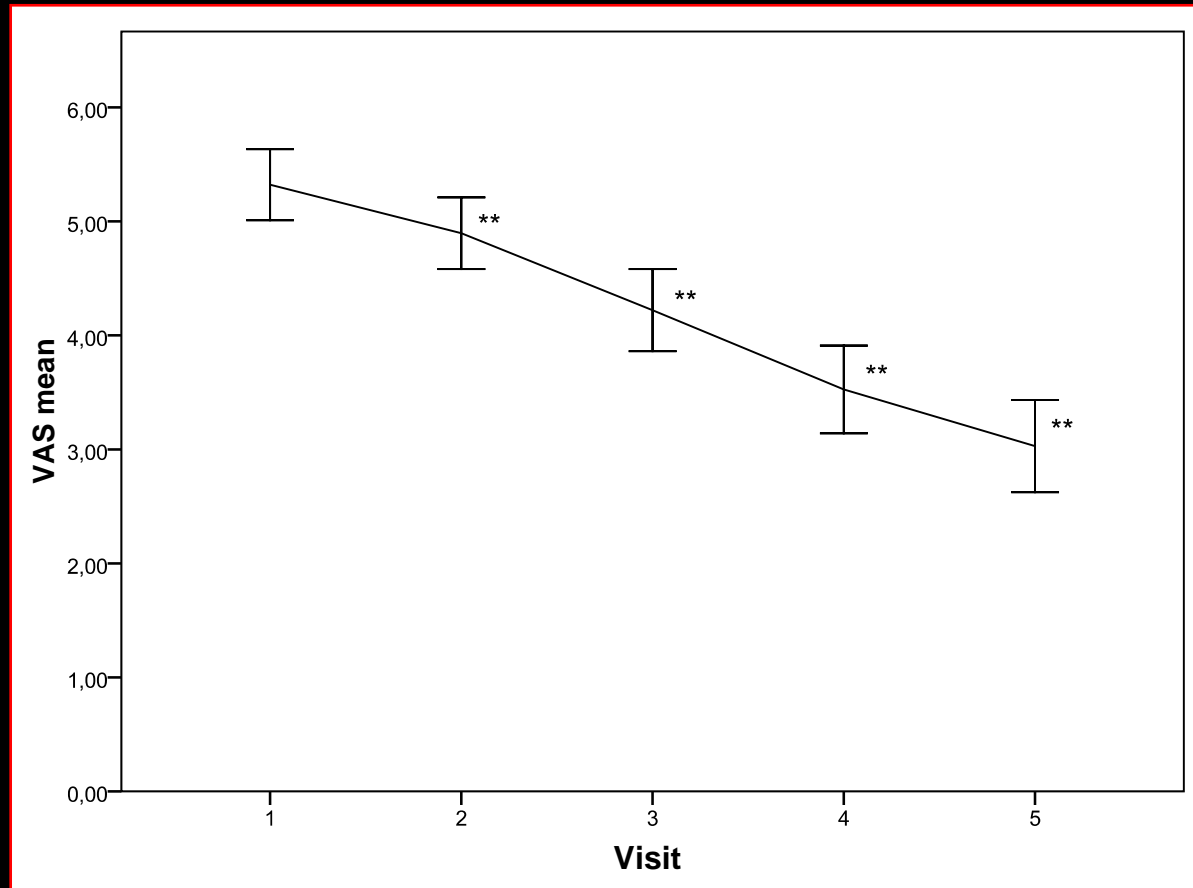
Treatment

- Oral administration of a chondroprotector based on hydrolized collagen and hyaluronate.
- Dose composition: 7g Collagen, 25mg Hyaluronic Acid, Lycopene, Quercetin and Vitamin C.
- Duration: **90 consecutive days**.

Time schedule

- Pain control of the knee (efficacy: VAS, WOMAC), safety (tolerability and adverse events).
- Assessments on days **0, 15, 30, 60** and **90**.

Results: VAS

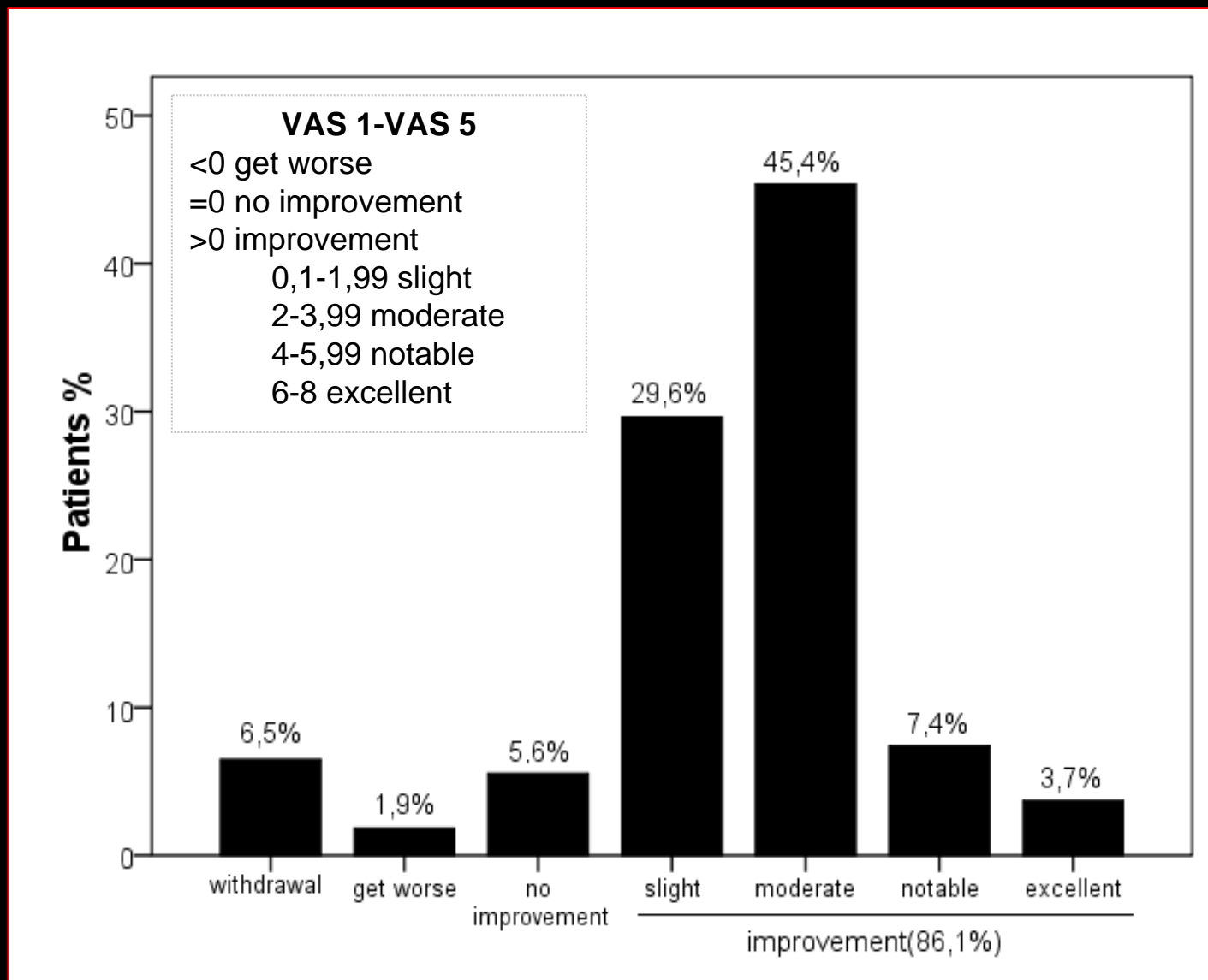


Evolution of pain (mean VAS value)

* $p < 0,05$; ** $p < 0,01$, two-by-two comparisons with respect to the first visit (Bonferroni method).

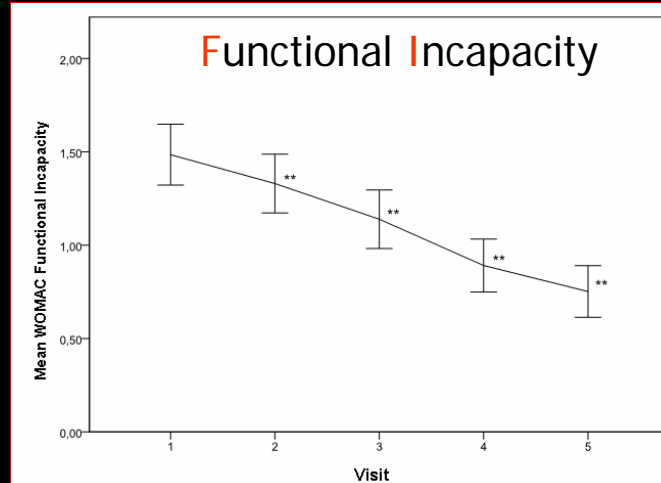
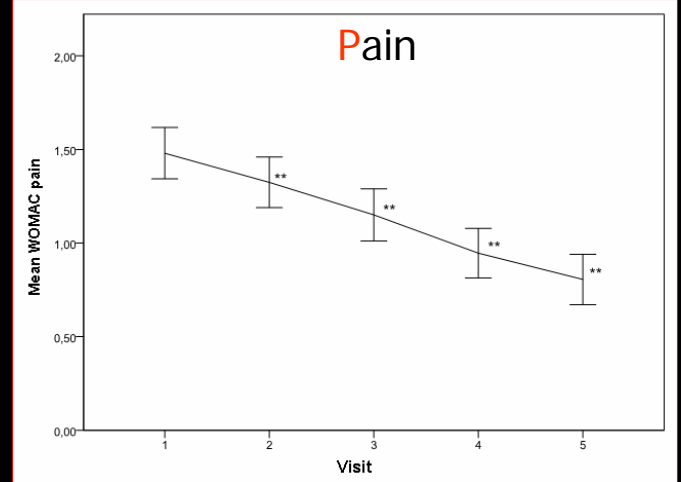
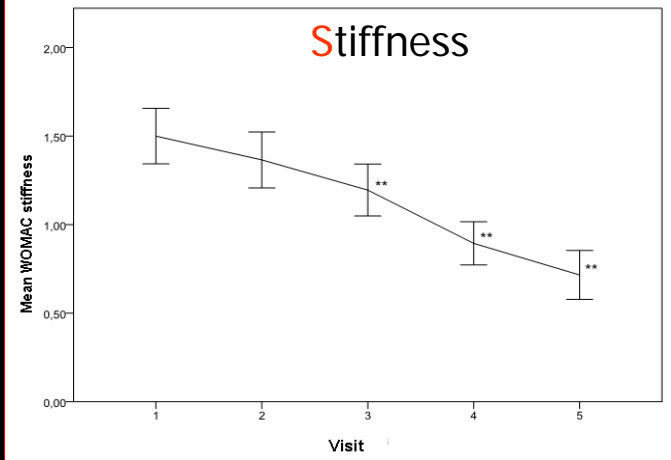
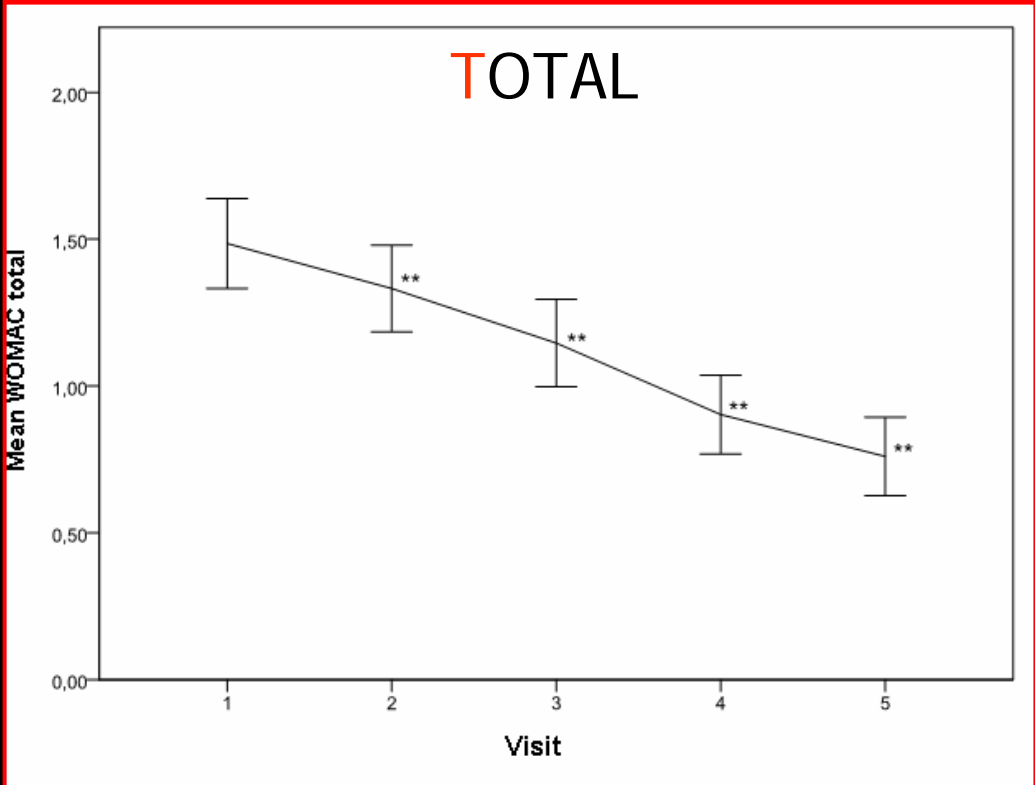
A statistically significant **reduction** in **joint pain** was showed after the second visit with respect to the baseline value.

Results: VAS



**Percentage of patients with improvement in pain
(VAS on visit 1 - VAS on visit 5)**

Results: WOMAC

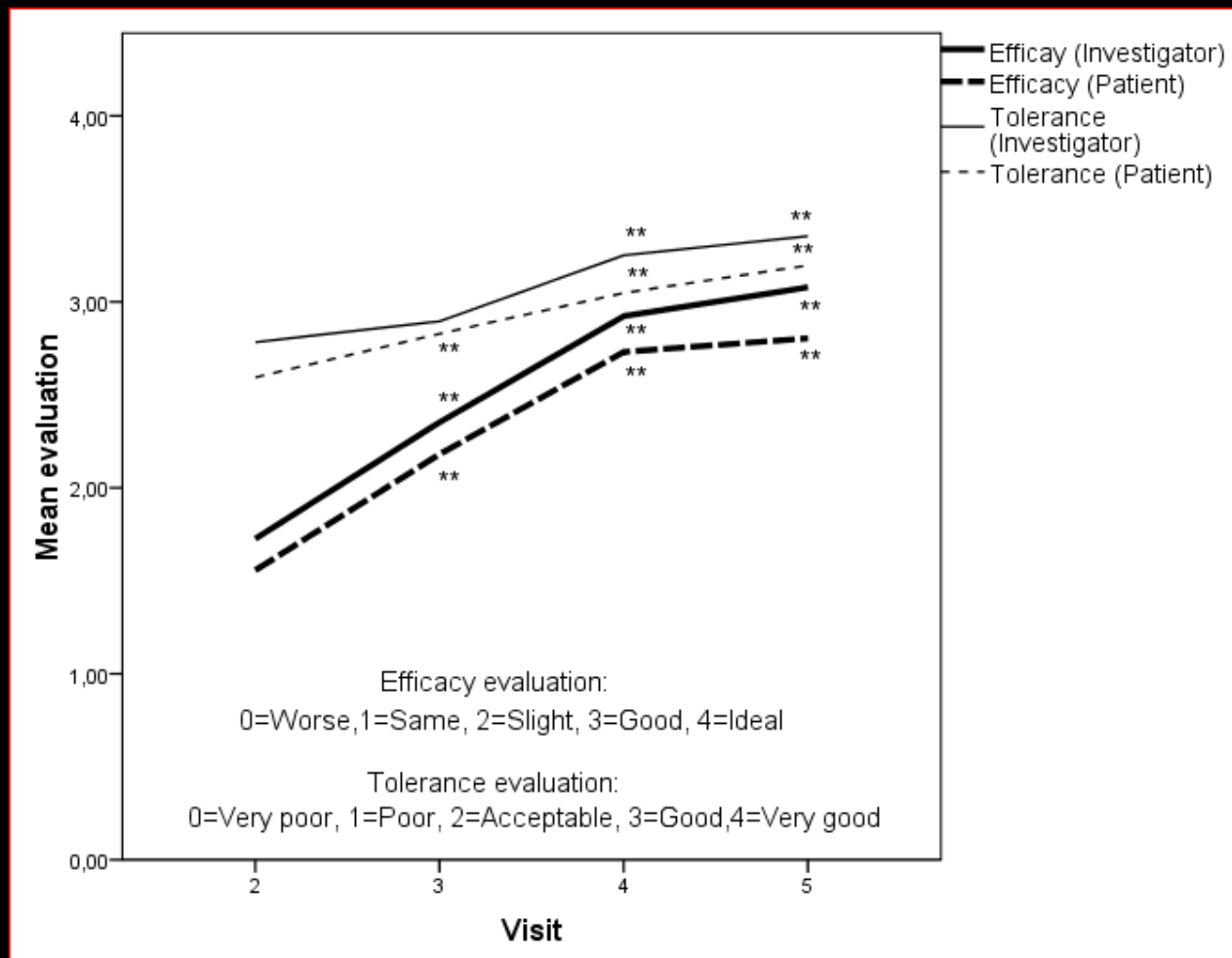


Evolution of the mean WOMAC scale value

* $p < 0,05$; ** $p < 0,01$, two-by-two comparisons with respect to the first visit (Bonferroni method)

Progressive decrease after the initial visit (statistically significant for all the parameters from the 3rd visit on).

Results: Efficacy and Tolerance



- Mean evaluation of the **efficacy**, by the investigator and the patient, **increased** with time (statistically significant).
- Excellent evaluation of tolerance.

Evolution of the mean value of the efficacy and tolerance to treatment, evaluated by the investigator and the patient

**p<0,01, two-by-two comparisons with respect to the first visit (Bonferroni method)

Conclusions

1. Oral administration of a daily supplement of hyaluronate and hydrolysed collagen during 90 consecutive days was **effective** in **reducing pain** in patients with knee osteoarthritis.
2. The mean value of all efficacy evaluations (VAS, WOMAC Scales, evaluation by the investigator and the patient) in the different visits indicates a **clear improvement** from day 15.
3. Treatment was **well tolerated** during all the study.

References

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