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EFFICACY AND SAFETY EVALUATION OF GUNA COLLAGEN MDs INJECTIONS IN KNEE OSTEOARTHRITIS – A CASE SERIES OF 30 PATIENTS

SUMMARY

Collagen is the most abundant protein (structural protein; molecular weight 300 KDa) in mammalian organisms, accounting for about 5-6% of an adult's body weight.

In this case series we have evaluated the efficacy and safety of intra-articular injections of Guna Collagen MD-Knee + Guna Collagen MD-Muscle in 30 patients (12 M, 18 F) affected by Radiological Knee Osteoarthritis (X-ray stage 2 or 3).

Patients have been administered 10 intra-articular injection with Guna Collagen MD-Knee + Guna Collagen MD-Muscle.

Evaluation was performed at baseline and then at week 8 (end of treatment) and at week 12 (4 weeks after treatment), in term of VAS pain at rest and during movement, Lequesne Index and patient and physician satisfaction.

– Intra-articular injections of Guna Collagen MDs resulted in a significant improvement of pain at rest, pain during movement and functional activity in patients with knee osteoarthritis. Guna Collagen MDs demonstrated to be safe; no side effect was reported in any patient.

KEY WORDS **KNEE OSTEOARTHRITIS, COLLAGEN INTRA-ARTICULAR INJECTION, COLLAGEN MEDICAL DEVICE, MD-KNEE, MD-MUSCLE**

INTRODUCTION

Collagen is the most abundant protein in the human body. Of the whole protein mass of higher Mammals, ¼ is composed of collagen: bones and tendons, joint capsules and muscles, ligaments and fascia, teeth and serous membranes, skin and extracellular matrix.

One of the most frequent reasons of local joint pain is the slackening of intra-articular (ligaments and articular cartilage) and extra-articular structures (ligaments, joint capsules, tendons, muscles) causing joint hypermobility (1).

– This mobility leads to further and early consumption of these systems on one hand, and on the other promotes progressive degeneration of the cartilage.

A special characteristic of Guna Collagen Medical Devices, which contain collagen and ancillary ingredients, is that they can offer an innovative approach to the treatment of painful diseases affecting the musculoskeletal system (2).

The ancillary ingredients of natural origin are combined with collagen in order to allow a better and more targeted positioning of collagen in the specific areas.

These collagen products may be used in periarticular, intra-articular, intramuscular and intradermal injections.
– Collagen provides a support which may have a positive impact in stabilizing the joint functionality, avoiding hypermobility and improving movement and pain.

Intra-articular administration of Guna Collagen Medical Devices could have a structural function: strengthening and protecting the structure of cartilage and joint capsules.
It is also supposed to provide mechanical support to the affected areas.
Strengthening these structures, Guna Collagen MDs may achieve regenerative and analgesic effects (3).
The purpose of this study is to confirm these hypothesis by evaluating the relief of localized pain or pain during movement.

MATERIALS AND METHODS

30 outpatients (12 M, 18 F) aged between 55 and 70 years, affected by **knee osteoarthritis** [X-ray stage 2 or 3, according to Kellgren-Lawrence Classification (4)] were included.

The main exclusion criteria were: inflammatory diseases, gout, and malignancy.
– Patients were administered **intra-articular** knee injections with Guna Collagen **MD-Knee** (10 amp.) + Guna Collagen **MD-Muscle** (10 amp.): 1 injection twice a week for 2 weeks, and 1 injection weekly for 6 weeks (course of treatment: 8 weeks).

Patients were evaluated before treatment (**Visit 1**), at week 8 (**Visit 2**, at the end of treatment), and at week 12 (**Visit 3**, 4 weeks after treatment) in term of pain at rest (VAS and a 5-point verbal scale) and during movement, Lequesne Algofunctional Index, assessment of efficacy by patients and physician (5).

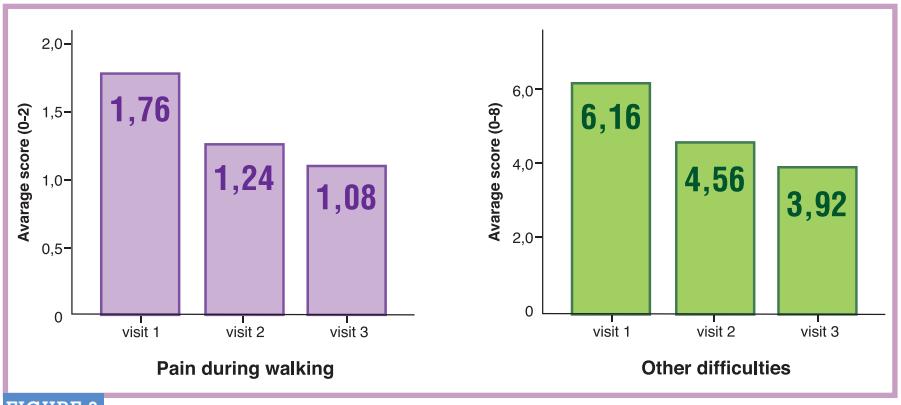

FIGURE 2

Left: Pain during walking, F (2,48) 19.750, p=0.000. Right: Other difficulties.

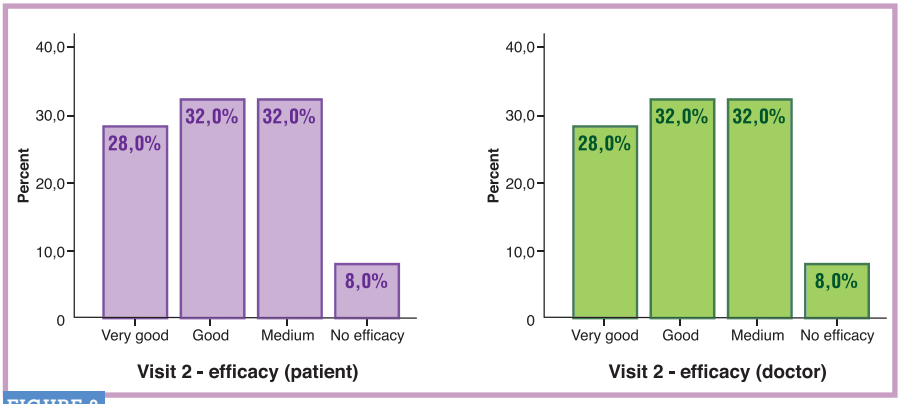

FIGURE 3

Assessment of efficacy by patients and by physicians.

RESULTS

A significant reduction of VAS pain at rest was observed at Visit 2 and Visit 3 (FIGURE 1).

– The average score for pain during movement was observed to decrease more than **twice** (2 times) at Visit 3 compared to baseline (FIGURE 1).

Pain at rest and during movement showed a statistically significant decrease after administration of the 2 Guna Collagen MDs.

The reduction continued 30 days after the end of treatment.
In terms of average score for pain during walking, at Visit 3 it was observed a reduction of 40%, compared to baseline (FIGURE 2).

At Visit 3, the average score for "other difficulties" (Lequesne Index) decreased approximately 2 times if compared to baseline (FIGURE 2). At Visit 2, the assessment of efficacy by patients and by doctors was **very good** in **28%** of cases, **good** in **32%**, **medium** in **32%** and the treatment was not considered effective in only **8%** (FIGURE 3).
At Visit 3 the percentages are even higher. The assessment of treatment efficacy at week 8 and 12 by patients and by doctors were similar. No side effects were reported during the follow-up.

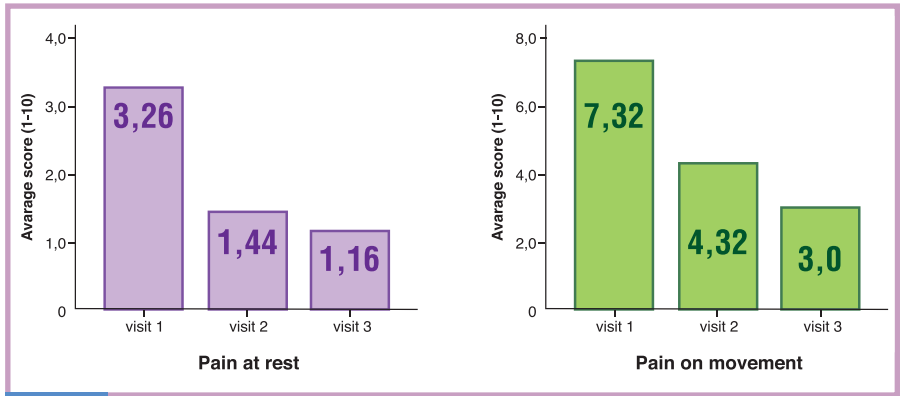

FIGURE 1

Left: Pain at rest, F (2,48) 35.871, p=0.000.
Right: Pain during movement, F (2,48) 69.630, p=0.000.

DISCUSSION

Current intra-articular treatment options for knee osteoarthritis (OA) include hya-

luronic acid (HA) and corticosteroids.

Viscosupplementation (HA) is a well-established treatment option in knee OA, and is included in the professional guidelines for treatment of the disease in this joint (6,7).

There are substantial data that exogenous HA may improve pain and function by non-mechanical, biologically-based mechanisms within the synovial and articular environment (8).

HA is comparable in efficacy with intra-articular corticosteroids, which have a faster onset of action but a shorter duration (9,10).
The conclusions of a Cochrane meta-analysis seem to be in favor of higher efficacy of HA for both pain and function; it is preferred to any other form of systemic intervention or intra-articular corticosteroids (11,12).

Despite its efficacy and safety, the use of viscosupplementation is limited by its cost, considering also the fact that most National Health Services do not reimburse such a treatment.

Also intra-articular placebo (saline solution) seems to be able to decrease pain in knee OA (13,14).

Zhang *et* Al. reported in a recent meta-analysis that IA placebo had effects above the average value of 0.51 ES (15).

Placebo in OA appeared to be effective only for all patient-related subjective outcomes such as pain, stiffness and self-reported function, but not for structural modification outcomes.

The results of this study seem to demonstrate that intra-articular administration of **Guna Collagen MDs** could be a safe and effective treatment in pain relief for patients affected by knee OA at stage 2 or 3 (Kellgren-Lawrence Classification).

– Therefore, Guna Collagen MDs might be an additional option in the intra-articular management of knee OA.

The limitation of this study is the absence of a comparative group; it would also be appropriate to carry out a comparative study firstly with placebo and then with the other products commonly used for intra-articular injections (hyaluronates, steroids, platelets rich plasma).

CONCLUSIONS

This case series suggests that intra-articular injection of Guna Collagen MDs in knee OA affects significantly pain at rest, pain during movement and functional activity.
– Due to its safety and efficacy Guna Collagen MDs may be considered an interesting and promising option for the intra-articular treatment of patients affected by intermediate knee OA. Further studies are to confirm these data. ■

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