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COLLAGEN MDs FOR CHRONIC PAIN. EFFICACY AND TOLERABILITY IN CHRONIC TREATMENT IN 124 PATIENTS

SUMMARY

Musculoskeletal disorders are the first cause of chronic pain worldwide and are the main reason of long periods of sick leave in Spain.

The objective of this study was to evaluate the efficacy and tolerability of Guna Collagen MDs (Colágeno MD, ASAC Pharma, Spain) administered via periarticular or painful trigger points injections in chronic pain treatment.

A total of 124 patients that were following an unsuccessful pharmacological, physiotherapeutic or invasive treatment (e.g. corticoid and local anaesthetics infiltration, rhizolysis, etc.) were included in the study.
– Subject to their pathology, all the 124 patients received either periarticular or trigger point injections of Collagen MDs.

Chronic pain treatment with Collagen MDs infiltrations is effective because:
1) it shows a mean EVA reduction of 3 points from the beginning to the end of the treatment;
2) pain relief is between mild and moderate in 75.3% of patients;
3) there is a reduction of pain medication needs in 24% of patients.
This reduction is especially significant in adjuvant drugs for the neuropathic component of mixed chronic pain;
4) the degree of satisfaction is between high and very high in 72.4% of patients.

Therefore, we can conclude that chronic pain treatment with Collagen MDs infiltrations is effective and offers a good safety and tolerability profile.

KEY WORDS **CHRONIC PAIN, COLLAGEN MEDICAL DEVICES, MD-LUMBAR, MD-ISCHIAL, MD-MUSCLE, MD-NEURAL**

INTRODUCTION

Musculoskeletal disorders are the first cause of chronic pain worldwide and are the main reason of long periods of sick leave in Spain.
Chronic Pain Management Units provide interventional and medical management for chronic malignant and non-malignant pain conditions.

– The main objective of the therapeutic interventions is not only to relieve pain symptoms, but also to improve the quality of life of the patients.

OBJECTIVE

To evaluate the efficacy and tolerability of **Guna Collagen MDs** (Colágeno MD, ASAC Pharma, Spain) administered via **periarticular injections** or painful trigger points in **chronic pain treatment**.

DATA AND STATISTICAL ANALYSIS

It was applied a descriptive statistical analysis with central tendency and dispersion measures for the quantitative data and total and relative frequency for the categorical data.

A parametric Student's t-test and Wilcoxon non-parametric test was applied for paired quantitative values to study the patient evolution in the different studies.
A descriptive analysis was performed: mean and standard deviation for the continuous variables and percentage for the qualitative variables.
A Student t test was used for the quantitative variables and a chi-square test for the qualitative ones. Statistical analysis was performed using a Statistical Package for the Social Sciences (SPSS) and statistical significance was considered when P value was <0.05.

OBJECT OF THE STUDY

A total of **124 patients** that were following an unsuccessful pharmacological, physiotherapeutic or invasive treatment (e.g. corticoid and local anaesthetics infiltration, rhizolysis, etc.) were included in the study.
– Subject to their pathology, all the 124 patients received either **periarticular** or **trigger point injections** of Collagen MDs.

DEMOGRAPHIC ANALYSIS

All the data from the 124 patients, 110 F (88.7%) and 14 M (11.3%), were revised.

The mean age was 67.5, (± 13.2; range 18-91).

11 (8.9%) out of 124 patients dropped out the treatment; 10 at week 6-7 due to poor efficacy, and 1 due to a bladder pre-existing neoplasm.

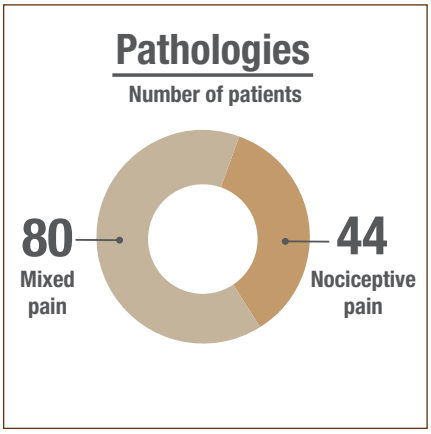


FIGURE 1

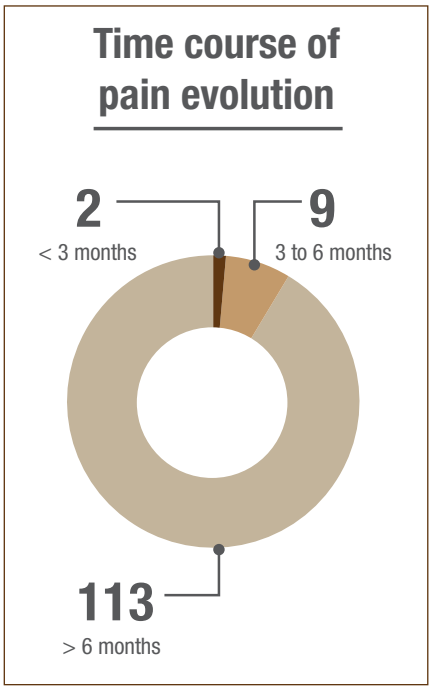


FIGURE 2

All the 113 remaining patients (91.1%) completed the study.

PAIN TYPES

Nociceptive pain accounted for 44 out of 124 patients (35.5%) and mixed pain for 80 out of 124 (64.5%) (FIGURE 1). No patient with neuropathic pain was included.

TIME COURSE OF PAIN EVOLUTION

Patients had been suffering for the following periods of time: **2** patients (1.6%) less than 3 months, **9** patients (7.3%) between 3 and 6 months, and **113** patients (91.1%) more than 6 months (FIGURE 2).

PATHOLOGIES

Patients suffered from the following pathologies:

- lumboarthrosis (42/124, equal to **34.0%**);
- cervicoarthrosis (24/124, equal to **19.6%**);
- omalgia (21/124, equal to **16.8%**);
- gonarthrosis (8/124, equal to **6.4%**);
- fibromyalgia (7/124, equal to **5.6%**);
- dorsalgia (5/124, equal to **4.0%**);
- epicondylitis (5/124, equal to **4.0%**);
- trochanteritis (4/124, equal to **3.2%**);
- hand rhyzarthrosis (3/124, equal to **2.4%**);
- ankle arthrosis (2/124, equal to **1.6%**);
- plantar fasciitis (2/124, equal to **1.6%**);
- trapezius spasm (1/124, equal to **0.8%**) (TABLE 1).

TREATMENT PROTOCOLS

Lumboarthrosis, dorsalgia and cervicoarthrosis were treated with an association of Guna Collagen **MD-Lumbar** (2 ml) + Guna Collagen **MD-Ischial** (2 ml) + Lidocaine (2%, 2 ml).
1cc was administered at each side (1.5 cm) of the medial line of the painful vertebrae after zygoapophyseal palpation.

For the other conditions a combination of Guna Collagen **MD-Muscle** (2 ml) + Guna Collagen **MD-Neural** (2 ml) + Lidocaine (2%, 2 ml) was used.
1 ml was administered via periarticular route in every painful trigger point.

EFFECTIVENESS EVALUATION

EVA was evaluated at the beginning of the treatment (T0) and controls were performed every two weeks up to week 10 or at the end of the treatment.

– It was recorded the analgesic and adjuvant medication needs for pain treatment at T0 until week 10 or at the end of the treatment.

TABLE 1

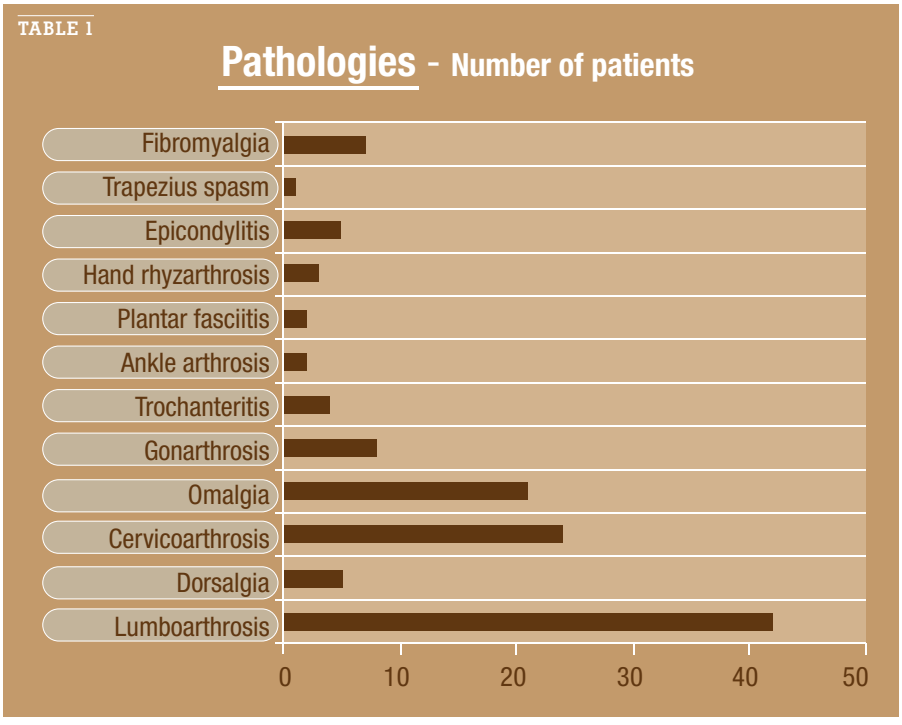
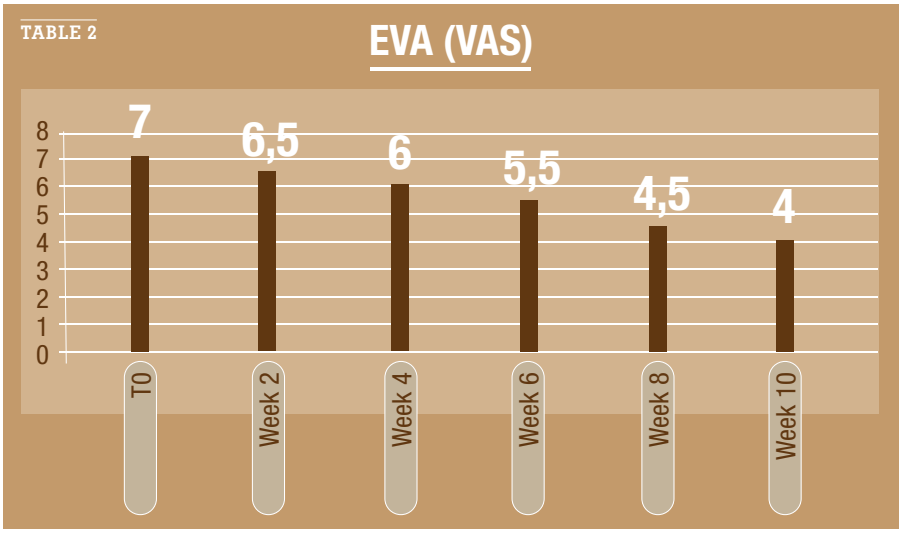


TABLE 2



Similarly, it was also recorded the need for other invasive pain management techniques that had been performed before the beginning of the treatment with Collagen MD injections.
It was assessed the degree of patient satisfaction with Collagen MD.
Moreover, it was also assessed the possible occurrence of adverse effects and possible interactions with the patient underlying conditions (e.g. Diabetes, heart disease, hypertension, etc.)

OVERALL RESULTS (EVA SCALE)

T0: EVA (VAS) **7**
Week 2: EVA **6.5** (-0.5)
Week 4: EVA **6** (-1)
Week 6: EVA **5.5** (-1.5)
Week 8: EVA **4.5** (-2.5)
Week 10: EVA **4** (-3) (TABLE 2).

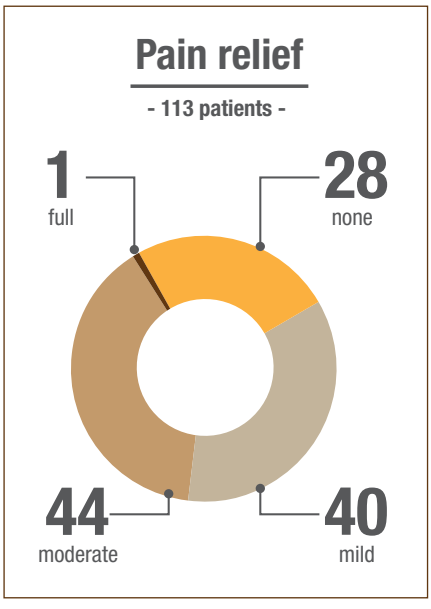
CONCLUSIONS

Mean EVA reduction could be appreciated at around week 4-6, decreasing up to 3 points at the end of the treatment (week 10), with no adverse effects or complications of other concomitant pathologies.

PAIN RELIEF

Pain relief was reported from patients at:
Week 2: WITHDRAWAL 0,
MILD in 4 **(3.2%)**,
NONE in 120 **(96.8%)**.
Week 4: WITHDRAWAL 0,
MILD in 35 **(28.2%)**,
MODERATE in 2 **(1.6%)**,
NONE in 87 **(70%)**.
Week 6: WITHDRAWAL 4 **(3.2%)**,
MILD in 61 **(49.2%)**,
MODERATE in 14 **(11.3%)**,
NONE in 45 **(36.2%)**.
Week 8: WITHDRAWAL 11 **(8.9%)**,
MILD in 51 **(41.1%)**,
MODERATE in 34 **(27.4%)**,
NONE in 28 **(22.6%)**.
Week 10: WITHDRAWAL 11 **(8.9%)**,
MILD in 40 **(32.2%)**,
MODERATE in 44 **(35.5%)**,
FULL 1 **(0.8%)**,
NONE in 28 **(22.5%)**.

FIGURE 3



CONCLUSIONS

The pain relief mostly started at **week 6**, with a mild to moderate pain relief in **60.5%** of patients. On the other hand, **22.5%** of patients reported no pain relief after 10 weeks of treatment (FIGURE 3).

PHYSIOTHERAPY AND/OR INVASIVE TREATMENTS BEFORE COLLAGEN MDs ADMINISTRATION

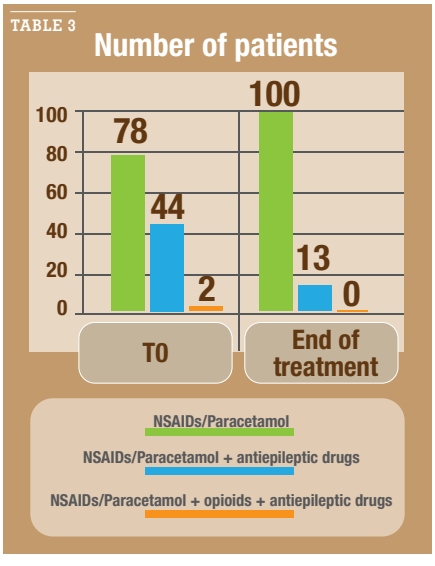
The following treatments were performed: facet infiltrations with local anaesthetics and steroids in 29 cases (23.3 %); lumbar rhizotomy by radiofrequency in 10 cases (8.1%); TENS in 12 cases (9.7%); magnetotherapy in 7 cases (5.6%); serums lidocaine (Fibromyalgia) in 6 cases (4.8%); none in 60 cases (48.4%).

NEEDS FOR ANALGESIC AND ADJUVANT MEDICATION BEFORE AND AFTER INFILTRATIONS WITH COLLAGEN MDs

At T0, medications for pain treatment in all the patients (124) were as follows:

- NSAIDs/Paracetamol in 78 cases **(62.9%)**;
- NSAIDs/Paracetamol + antiepileptic drugs in 44 cases **(35.5%)**;

TABLE 3



- NSAIDs/Paracetamol + opioids + antiepileptic drugs in 2 cases **(1.6%)**.

At the end of the treatment, medications for pain treatment in all the patients (113) were as follows:

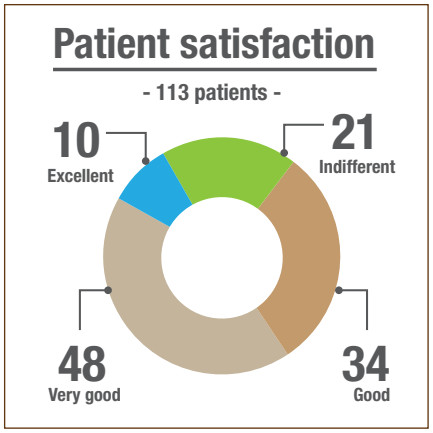
- NSAIDs/Paracetamol in 100 cases **(88.5%)**;
- NSAIDs/Paracetamol + antiepileptic drugs in 13 cases **(11.5%)**;
- NSAIDs/Paracetamol + opioids + antiepileptic drugs in 0 cases (TABLE 3).

DECREASING ANALGESIC AND COADJUVANT DRUGS DURING AND AT THE END OF TREATMENT WITH COLLAGEN INFILTRATIONS

Patients with combined pain showed a decrease of **24%** in the use of antiepileptic drugs to treat neuropathic pain.
No patients at the end of the study increased their medication.
Moreover, 2 patients were able to cease the administration of opioid drug to relief pain symptoms.
Pain was in most cases controlled with less doses of medication and only with NSAIDs combination. Paracetamol was also administered sporadically when needed.

Taking all this into account, Collagen MDs infiltrations are effective for the treatment of chronic pain as less pharmacological treatments were needed to control pain in the patients of this study.

FIGURE 4



PATIENT SATISFACTION WITH COLLAGEN MDs INFILTRATION TREATMENT

113 patients reached the end-point (10 weeks) of the study; they were asked to express their satisfaction with the treatment. They evaluated it as: **excellent** in 10 cases (**8.8%**), **very good** in 48 (**42.4%**), **good** in 34 (**30%**), **indifferent** in 21 (**18.6%**) (FIGURE 4).

CONCLUSIONS

After a 10-week treatment with Collagen MDs infiltrations, **72.4%** of patients showed a **high** or **very high** degree of satisfaction.

TOLERABILITY AND SAFETY MARGIN

No adverse effect nor complication due to other concomitant pathologies have been reported during the 10-week period of the clinical study.

CONCLUSIONS

Chronic pain treatment with Collagen MDs infiltrations is effective because:

1) it shows a mean EVA reduction of 3 points from the beginning to the end of the treatment;
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Therefore, we can conclude that chronic pain treatment with Collagen MDs infiltrations is effective with a good safety and tolerability profile. ■

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