



Promerim Efficacy: A New Revolution in Moderate Osteoarthritis Prevention. A Randomized Prospective Control Trial

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Abstract

Background: Osteocalm® is a dietary supplement approved as collagen source. The main component of Osteocalm® is Promerim®, a fish protein hydrolysate rich in type I marine collagen. Not only, but Osteocalm® has analgesic effect on joint osteoarthritis.

Method: Randomized control trial comparing Osteocalm efficacy on osteoarthritis grade 2 and 3 vs Osteocalm® combined with other anti-inflammatory using WOMAC and VAS scoring.

Results: Results were statistically significant showing that Osteocalm® on its own has analgesic effect on its own as well as combined with other anti-inflammatory.

Conclusion: Osteocalm® has an effective analgesic effect on osteoarthritis grade 2 and 3 without any other medication.

Trial registration: the trial has been registered with Lebanese Syndicate for Doctors and has been approved.

Keywords: Promerim; Osteoarthritis; Collagen; Knee pain

Introduction

Osteoarthritis (OA) is the single most important cause of locomotor disability in Western societies and is a major issue in health care systems [1,2]. It is a progressive, chronic condition leading to pain and loss of function that dramatically reduces the quality of life of patients and their ability to work. Osteoarthritis affects approximately 27 million adults in the United States, and one-third of the population over 65 years old is diagnosed with OA [3]. Osteoarthritis is a degenerative joint disease in which interleukin-1 β plays a major role in the inflammatory process. The main clinical manifestations of OA are inflammation, pain, and bone resorption. OA pain is a major cause of disability in subjects over 50 year's old [1]. Collagen hydrolysates (CHs) are peptide mixtures that are often used as nutraceuticals for OA. Administration of CH is an optional treatment of OA. Symptomatic pain relief can be obtained with analgesics such as paracetamol, or non-steroidal anti-inflammatory drugs [2]. These treatments, while generally safe when used at low doses and for short terms, can result in serious complications (gastrointestinal bleeding, renal failure, coronary heart disease) when used for long-terms or at higher doses and can obviously reduce the adherence to therapy [3,4].

Chronic inflammation and bone loss are closely related to the onset of pathophysiological events.

Traditional treatments for OA include the management of disease-related symptoms (pain, inflammation, and discomfort). Steroid and hyaluronic acid injections have also been used for treating OA with some success. Randomized controlled trials have demonstrated limited efficacy for most of these treatments [4-7]. Many patients have started using complementary and alternative medications such as dietary supplements to avoid cardiac risks and gastrointestinal problems associated with long-term traditional OA treatments [8-10]. Glucosamine, chondroitin, and methyl sulfonyl methane are commonly used as dietary supplements for treating OA-associated joint pain, either singly or in combination.

Hydrolysed gelatine products have long been used in pharmaceuticals and foods. These products are generally recognized as safe food products by regulatory agencies.

Recent studies show that the enzymatically hydrolysed collagen (collagen peptide) is absorbed and distributed to joint tissues and has analgesic and anti-inflammatory properties [2].

Protein supplementation in combination with resistance training may increase muscle mass and muscle strength in elderly subjects [3].

Promerim®, the main component of the dietary supplement Osteocalm®, is a new generation of hydrolyzed gelatin. It is extracted from highly selected resources and processed according to a specific hydrolyzation method. Promerim® contains hydrolyzed fish collagen and has been shown to be clinically effective for treating joint and connective tissue diseases, particularly pain and stiffness associated with OA, in various studies on humans. This study was conducted to evaluate the efficacy and tolerability of the oral intake of Promerim® in the elimination of acute pain and discomfort associated with knee OA [11-14].

Objective

The objective of this study was to compare on a long term the efficacy of Osteocalm® containing Promerim® on osteoarthritis vs anti-inflammatory.

Materials and Methods

Thirty patients with grade 2 and 3 osteoarthritis with pain were included in this study. There were no exclusion criteria. The patient's age ranged from 47 to 82 with the mean of 65. Out of 30, 16 patients suffered from grade 2 OA on X-ray and 14 patients grade 3. Ten patients suffered from OA in the right knee, 1 from the left and 19 from both knees. The 30 patients were randomized in two groups of 15. The first group took Osteocalm. The second group took either Osteocalm® + Arcoxia® or Osteocalm® + Diclofenac®. WOMAC and VAS were used to assess the pain and loss of function and the scores were registered by the patient with a nurse specialist on 4 different occasions : pre-test, at 2, 4 and 8 weeks. All the scorings were recorded by a third-party team hidden from the researcher themselves and with no influence. The patients were followed up closely and no patient quit during the follow up. The number of patients is statistically significant regarding the overall population as the town where the study was done is under 300 000 inhabitants.

The statistical analysis has been done by RDVC Produits Santé. A non-parametric Mann-Whitney test was applied. The parameters were divided to efficacy and the comparison of the two groups (Figure 1), randomization (Tab1) of the group (Figure 2), efficacy of Osteocalm® on its own (Figure 3) and efficacy of Osteocalm and anti-inflammatory drugs (Figure 4).

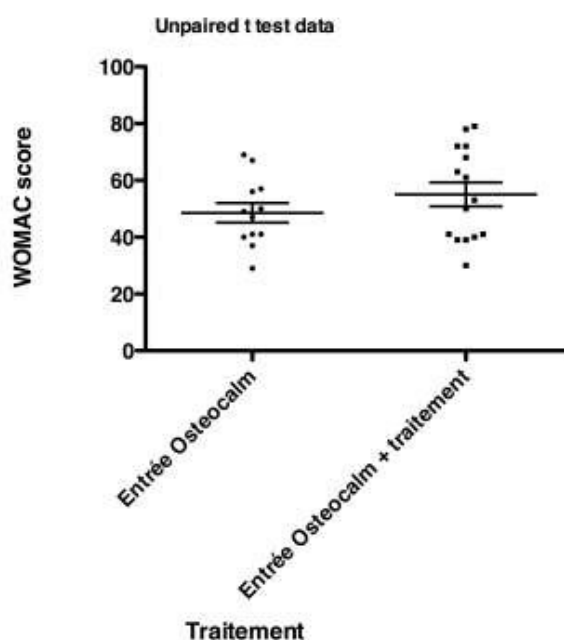


Figure 1: There is no significance between the two groups. Both Groups re well randomized and they have the same WOMAC conclusion

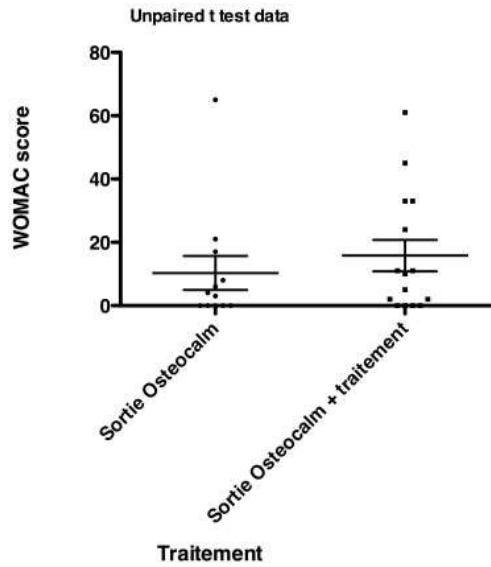


Figure 2: There is no significant difference between both treatments which means both treatments are efficient and comparable

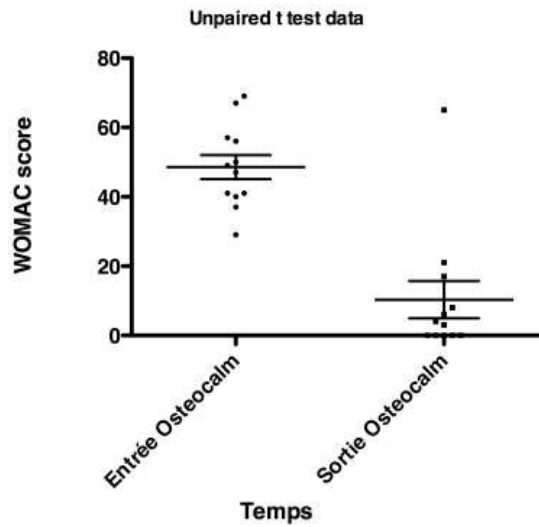


Figure 3: There is significant difference proving the efficacy of osteocalm treatment

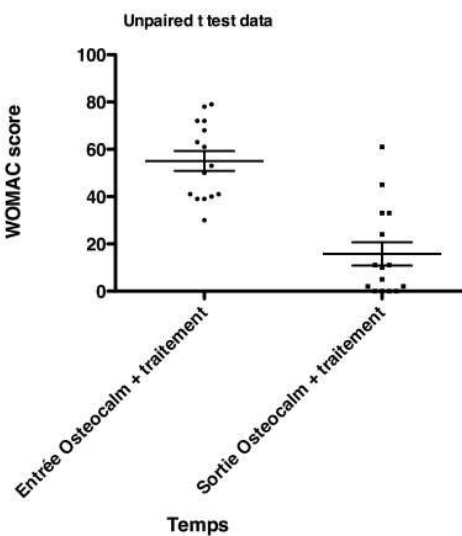


Figure 4: There is significant difference proving the efficacy of osteocalm with conventional treatment

Results

After randomization at the onset of the study, the two groups were similar with no significant difference in the WOMAC score. The two groups only differed in the adjunction of allopathic medication (Arcoxia® or Diclonerobion®).

The aim of the study was to assess the potential synergic effect of a medication along with Osteocalm®. At the end of the study, no difference was observed between the two groups.

No synergic effect was observed when the medication was added to Osteocalm®. The effect of Osteocalm® into the two groups was significant with an observed decrease of the WOMAC score by more than 70% ($p < 0.0004$).

Discussion

There are many studies discussing different food supplement from different resources. Lugo *et al.* studied thoroughly the efficacy of the undenatured type 2 collagen on osteoarthritis and found that UC-II improved knee joint symptoms in knee OA subjects and was well-tolerated [13]. Perkins *et al.* studied the effect of curcuma and found that curcuma-containing products consistently demonstrated statistically significant improvement in osteoarthritis-related endpoints [15]. In the meantime Castrogiovanni *et al.* highlighted some of many existing nutraceutical compounds that could be used as integrators in a daily diet thanks to their easy availability, such as olive oil, fish oil, and botanical extracts used as non-pharmacologic treatment [12]. On the other hand, Grover *et al.* discussed all the antioxidant and the conclusion drawn was that there is several difficulties encountered in examining this issue: poorly conducted studies, a lack of uniformity in disease definition and diagnosis, and muddling of conclusions from attempts to isolate the efficacious molecules [11]. The antioxidant supplements with most evidence for a benefit for pain relief and function in knee osteoarthritis were based on curcumin and avocado-soya bean unspesifiable. In total, there are endless studies regarding food supplement however none of the study approached Promerim®, and it will be probably the new era and revolution in the treatment as well as symptom relief for different osteoarthritis in healthy individual.

Conclusion

Osteocalm® containing Promerim® and collagen type 2 showed a good efficacy on pain management and symptoms relief in OA Grade 2 and 3. A future histological test will give a definite understanding and results.

Conflict of Interest

The author has no conflict of interest in the above studies.

Declarations

Ethics approval and consent to participate: **Not applicable**

Consent for publication: The Authors gives consent for publication.

Availability of data and material: All data and material are available upon request

Competing interests: **The authors declare no competing interests**

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Authors' contributions

BEO & RW wrote the manuscript and reviewed articles, BEO reviewed the main body of articles for the literature review and edited the manuscript.

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