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Efficacy and safety of DAIGO® Artiplus a chondroprotective agent in patients with joint pain and stiffness: a 6 months prospective study

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Key words: knee pain, osteoarthritis, chondroprotective, MirLiQ®

Introduction

A dietary supplement is a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet. Dietary supplements may be found in many forms such as tablets, capsules, soft-gels, gel-caps, liquids, or powders [1].

Some dietary supplements can help ensure to get an adequate dietary intake of essential nutrients; others may help to reduce risk of disease. Dietary supplements may therefore play a crucial role in the treatment of musculoskeletal diseases, such as osteoarthritis (OA).

OA is a type of arthritis characterized by the breakdown and eventual loss of cartilage, either due to injury or to normal wear and tear [2]. OA commonly occurs as people age and knee and hip are the most commons site of joint pain regardless of age or gender. Inflammation is a prominent mechanism leading to cartilage degeneration, and there is increasing realization that therapy must involve both cartilage protection and anti-inflammatory actions [3].

Joint pain is associated with substantial activity limitation, work disability, and reduced quality of life [4]. Conventional treatment of joint pain with non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesics is associated with gastrointestinal and cardiovascular side effects, and other adverse health effects [1]. Use of alternative supplements is reported by 47% of individuals with knee osteoarthritis [5], and well-designed human trials are needed to identify effective analgesic alternatives. In fact, certain dietary supplements can reduce pain and also improve the structural aspects of the joint and therefore slow or perhaps prevent and reverse disease progression. There have been numerous studies that assess the effects of different supplements on joint health, many of which have shown efficacy [6].

The most widely used and studied joint pain supplements include those related to chondroprotection, such as glucosamine, chondroitin, methylsulfonylmethane, collagen hydrolysates, and hyaluronic acid [7-8]. Each of these ingredients has been studied separately providing some scientific support for alleviation of joint pain, but product blends have not yet been tested in humans using a long term prospective study [8].

DAIGO® Artiplus[9] is a dietary supplement recently developed containing the following ingredients: Glucosamine, Chondroitin, Curcuma, Bromelain and MyrLiq®. Glucosamine is believed to help slow deterioration of cartilage, relieve arthritis joint pain, and improve joint mobility. Chondroitin is believed to enhance the shock-absorbing properties of collagen and block enzymes that break down cartilage. Like glucosamine, this supplement is thought to help cartilage retain water, keep joints lubricated, and possibly reverse cartilage loss [10-11].

A paper published in the prestigious Archives of Internal Medicine [12] included a comprehensive analysis of randomized, placebo-controlled clinical trials that assessed the efficacy of oral glucosamine and chondroitin on signs and symptoms associated with knee osteoarthritis. After evaluating almost 2.000 patients the authors concluded that supplementation with glucosamine and chondroitin had significant structural efficacy (joint space narrowing) and provided significant symptomatic relief as determined through several standard assessments for pain and functional outcomes. The authors wrote that it can be definitely stated that the combined oral administration of glucosamine and chondroitin decreases the symptoms of osteoarthritis.

Chondroitin is a molecule that occurs naturally in the body and a major component of cartilage, the tough, connective tissue that cushions the joints. Commercial chondroitin comes from natural sources, such as shark and bovine cartilage, or synthetic production. Chondroitin helps keep cartilage healthy by absorbing fluid (particularly water) into the connective tissue.

It may also block enzymes that break down cartilage, and it provides the building blocks for the body to produce new cartilage. A number of scientific studies suggest that chondroitin may be an effective treatment for OA, as corroborated by joint pain decrease observed in some studies upon treatment with chondroitin supplements.

Moreover, some researches in the past thought that chondroitin may actually slow progression of the disease unlike other current medical treatments for OA.

Curcuma longa has been widely known for its anti-inflammatory activity in traditional system of medicine for centuries and has been scientifically validated extensively [2]. A review revealed that a highly bioavailable form of curcumin was more effective in alleviating RA symptoms, including tenderness and swelling of joints, than the drug. Not only that, those who were taking the curcumin only, experienced the most improvement across the board. More importantly, curcumin treatment was found to be safe and not related with any adverse events.

The active ingredient curcumin present in the turmeric serves as bactericidal, anti-inflammatory, anti-viral and antioxidant agent [2]. Strong antioxidant property of curcumin eliminates free radicals and other toxic chemicals that cause damage to the healthy cell membranes and cell contents. It also blocks the metabolic pathways responsible for the generation of inflammation and pain inducing compounds like PG2. This in turn aids in regulating inflammation and pain associated with many inflammatory diseases other than arthritis. The best part is it works without causing any side effects [2].

In addition to curcumin, an analgesic effect is provided by Myrrh furanodienes contained in MyrLiq®. The pain killer activity of these compounds have been correlated to brain opioid mechanisms interactions [13].

Myrrh extracts have been also reported to play anti-inflammatory activity, being able to inhibit the frequency induced abdominal constrictions by acetic acid and formalin-induced paw edema in mice [14].

The primary purpose of this study was to assess the effects of 6 months ingestion of DAIGO® Artiplus on joint pain, stiffness, and function utilizing validated questionnaires and a 6-minute walk test in patients with mild osteoarthritis (OA).

Statistics

Data analysis was performed for the 50 subjects successfully completing the study. Data are expressed as mean ± SE. The composite scores from questionnaires were also analysed by ANOVA test. Individual answers in questionnaires and symptom log were analysed by generalized estimating equations, where each individual question (categorical variable) was the response variable. Each individual question was analysed separately. For both repeated measures ANOVA and generalized estimating equation, response variables with significant group × time interaction effect were considered to be significantly affected by the DAIGO® Artiplus and the interaction P-value was used for the categories contrast.

For symptom log variables with five time points, P-values at each time point represent independent student's t-test contrasts between scores for changes from pre-study.

Methods

Subjects

50 men and women, aged between 55 and 75 years were recruited by a phone campaign and included in this study. Inclusion criteria was the presence of a self-reported history (>3 months) of joint pain and stiffness in the knees or hip. A WOMAC pain and stiffness index score of at least 2 points was considered the minimum for inclusion.

We used a Likert 2 version of WOMAC for patient evaluation with the following score for pain and stiffness: 0=none; 1=mild; 2=moderate; 3=severe; 4=extremely.

The main exclusion criteria were: a) regular use of FANS during the previous 4 weeks; b) use of any other medications or supplements for joint pain and stiffness; c) presence of any serious medical problems; d) psychiatric disease or other condition that might interfere with self-assessment ability; e) to be able to walk for at least 6 min; f) history of allergic reactions to shellfish products; g) patients with gallstones. Written informed consent was obtained from each subject.

DAIGO® Artiplus sachet 1/daily containing curcumin and MyrLiq® was administered for 6 months. A 6m walking test was performed pre and post DAIGO® Artiplus treatment.

In Fig.1 are reported the changes in the pain scores after 6 months of DAIGO® Artiplus administration. DAIGO® Artiplus significantly ameliorate the score both in patients with mild or moderate pain ($p< 0.01$ and $P<0.05$).

The efficacy of DAIGO® Artiplus administration on joint stiffness is reported in Fig. 2. As for the pain DAIGO® Artiplus reduced the scores significantly in patients with mild or moderate stiffness ($P<0.05$ and $P=0.02$ respectively).

Discussion

There is increasing evidence that nutraceutical-based combinations of chondroprotective and/or anti-inflammatory components are effective in reducing joint pain without measurable side effects. Curcuma is widely used for the treatment of disorders associated with inflammation and was evaluated for its safety and efficacy in the treatment of painful knee osteoarthri-

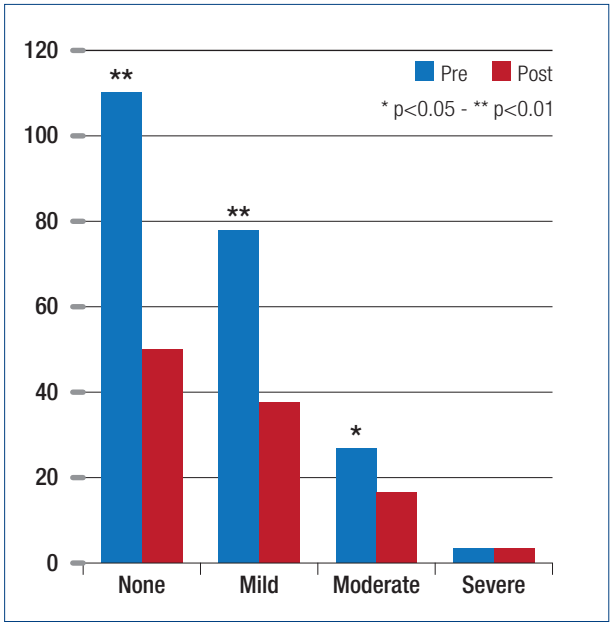

Figura 1 – Likert score (pain) after 6 month of DAIGO® Artiplus.

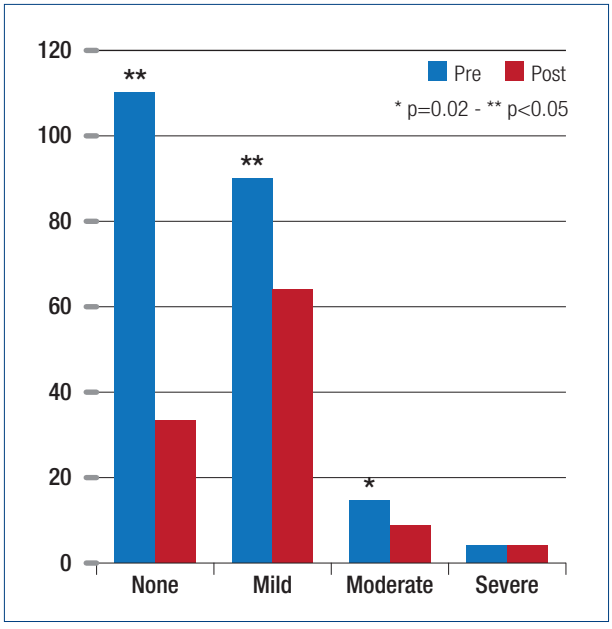

Figura 2 – Likert score (stiffness) after 6 month of DAIGO® Artiplus.

tis (OA) [15]. Myrrh extracts are known for their anti-inflammatory and analgesic activity: at the dose of 100 mg/kg exhibited prominently analgesic activity with inhibition rate of 70.57% [14]. The greatest part of previous studies testing the efficacy of dietary supplements on joint pain reduction have compared placebo to one or two of the chondroprotective components including glucosamine, chondroitin sulfate, methylsulfonylmethane, collagen hydrolysates and hyaluronic acid. This open label prospective study enrolled 50 community adults (55-75y) affected by joint pain and stiffness; the results showed how DAIGO® Artiplus is effective and safe without any adverse side effects on general metabolism and other organic functions. The primary outcomes of this study were the pain, stiffness, and function indexes of the WOMAC scores evaluated after 6 months treatment and by a 6 meters walking test. DAIGO® Artiplus for 6 months induced a significant reduction in joint pain and stiffness in subjects with mild OA as for the conclusions that has been reported in other studies using chondroprotective or anti-inflammatory dietary supplements. Finally, DAIGO® Artiplus mitigated the difficulties to performing daily activities in subjects with knee pain and stiffness. No side effects were reported in the treatment period.

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Efficacy and safety of DAIGO® Tendiplus a dietary supplement agent in patients with elbow lateral epicondylitis or Achilles tendinopathy. A pilot study

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Abstract

Background
Chronic overuse injuries such as tendinosis (including Achilles, rotator cuff, lateral and medial elbow, posterior tibial, digital flexor, and patellar) are associated with an abnormal tendon and ligament collagen.

Methods
DAIGO® Tendiplus is a dietary supplements containing type II collagen, glucosamine, chondroitin, bromelain and BosLiq®-AKBA. Forty middle age outpatients suffering from chronic mild or moderate Lateral Elbow Tendinopathy and 18 patients affected by Achilles tendinitis were enrolled in this open label pilot study lasts 24 weeks of DAIGO® Tendiplus administration.

Results
DAIGO® Tendiplus for 24 weeks induced a significant reduction in joint pain and stiffness in subjects with chronic mild or moderate lateral epicondylitis or affected by Achilles tendinitis.

Conclusions
There is increasing evidence that dietary supplement agents that contain combinations of chondro-protective and/or anti-inflammatory components are effective in reducing joint pain and stiffness without measurable side effects.

Key words: tendinitis, elbow pain, BosLiQ®, bromelain.

Introduction

Research has shown that chronic overuse injuries such as tendinosis (including Achilles, rotator cuff, lateral and medial elbow, posterior tibial, digital flexor, and patellar), as well as carpal tunnel syndrome are associated with a failed healing response in which the body's fibroblasts produce abnormal tendon and ligament collagen [1].

The composition and structure of the collagen is abnormal compared to uninjured tendon and ligament tissue. Previous studies have shown that small doses of orally administered undenatured type II collagen effectively deactivate killer T-cell attack. Lateral epicondylitis or tennis elbow is an injury involving the extensor muscles of the forearm and it is considered the most common source of lateral elbow pain[2].

Tissue samples, from the histological point of view, are characterized by collagen disorientation and disorganization; sim-

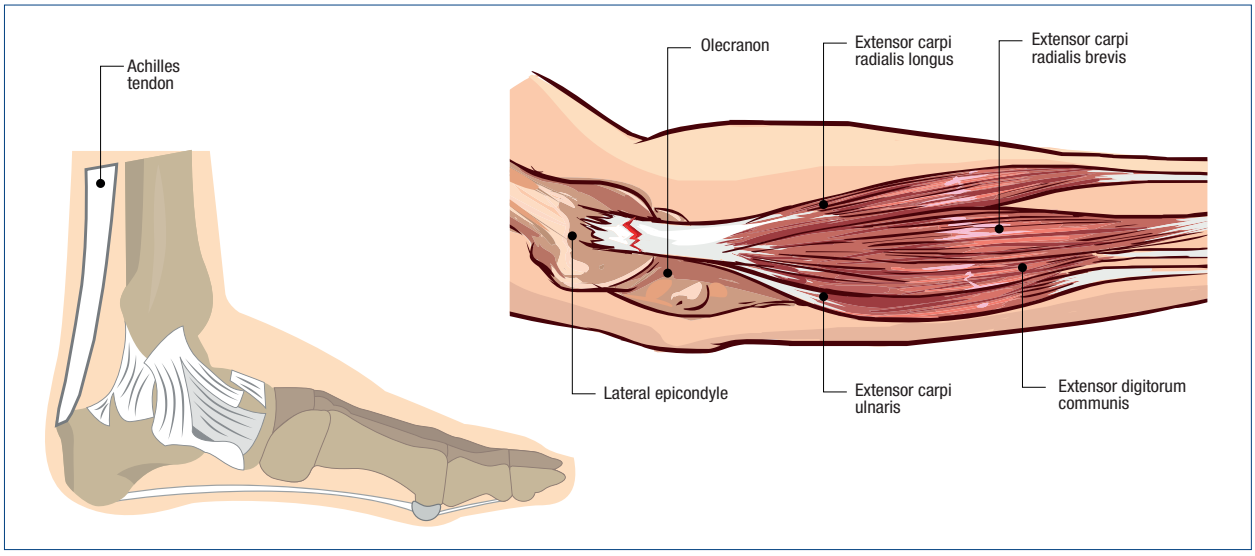

Figura 1 – Achille's and elbow tendons

ilar observations have been reported for Achilles tendinopathy, which displayed abnormal fibre structure showing an absence of type II collagen [3]. A dietary supplement is a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet.

Dietary supplements may be found in many forms such as tablets, capsules, soft-gels, gel-caps, liquids, or powders. Some dietary supplements can help ensure to get an adequate dietary intake of essential nutrients; others may help to reduce risk of disease [4]. DAIGO® Tendiplus is a dietary supplement containing type II collagen, glucosamine, chondroitin, bromelain and BosLiq®-AKBA.

Each of these ingredients has been studied separately providing some scientific support for alleviation of joint pain, but the composite product has not yet been tested in humans using a long term prospective study.

Type II collagen is the basis for articular cartilage and hyaline cartilage. It makes up 50% of all protein in cartilage and 85-90% of collagen of articular cartilage. Type II collagen does form fibrils. This fibrillar network of collagen allows cartilage to entrap the proteoglycan aggregate as well as provide tensile strength to the tissue [5].

Glucosamine and chondroitin sulfate act synergistically during the healing process, and their effects, in association, can be enhanced: whereas chondroitin sulfate intervenes at the start of the repair phase, glucosamine regulates the final stages and the stabilization of the fibrillar component. A paper published in the prestigious Archives of Internal Medicine included a comprehensive analysis of randomized, placebo-controlled clinical trials that assessed the efficacy of oral glucosamine and chondroitin on signs and symptoms associated with knee osteoarthritis [6].

After evaluating almost 2.000 patients the authors concluded that supplementation with glucosamine and chondroitin had significant structural efficacy (joint space narrowing) and provided significant symptomatic relief as determined through several standard assessments for pain and functional outcomes.

Chondroitin is a molecule that occurs naturally in the body and it is a major component of cartilage, the tough, connective tissue that cushions the joints.

Commercial chondroitin comes from natural sources, such as shark and bovine cartilage, or synthetic production. Chondroitin helps keep cartilage healthy by absorbing fluid (particularly water) into the connective tissue. It may also block enzymes that break down cartilage, and it provides the building blocks for the body to produce new cartilage [7].

BosLiq®-AKBA is a powder extract of *Boswellia sacra* obtained at low temperature that maintains all the original gum resin properties with no deterioration of the triterpene bioactive compounds 3-O-Acetyl-11-Keto-β-Boswellic Acid (AKBA),

normally occuring during the high temperatures involved in spray-drying. The pulverization is obtained at low temperatures (20-30 °C) and keeps intact the bio-active compounds which are analytically characterized and quantified by weight by using liquid chromatography coupled to tandem mass spectrometry. *Boswellia sacra* is very rich in AKBA, one of the most effective and powerful boswellic acid inhibitor of 5-lipoxygenase, the enzyme that is involved in inflammatory processes [8].

Bromelain [9] is an enzyme found in pineapple juice and in the pineapple stem. Bromelain is used for reducing swelling (inflammation), especially of the nose and sinuses, after surgery or injury. It is also used for fever, treating a bowel condition that includes swelling and ulcers (ulcerative colitis), removing dead and damaged tissue after a burn (debridement), preventing the collection of water in the lung (pulmonary edema), relaxing muscles, stimulating muscle contractions, slowing clotting, improving the absorption of antibiotics, preventing cancer, shortening labor, and helping the body get rid of fat. There is a product (Phlogenzym) for arthritis (osteoarthritis) that combines bromelain with trypsin (a protein) and rutin (a substance found in buckwheat). Bromelain used in this way seems to reduce pain and improve knee function in people with arthritis.

The primary purpose of this study was to assess the effects of 6 months ingestion of DAIGO® Tendiplus on joint pain and stiffness in subjects with chronic mild or moderate lateral epicondylitis or affected by Achilles tendinitis.

Materials and methods

Patient's eligibility criteria

Forty middle age outpatients (40-55 y) suffering from chronic (i.e., for ≥12 weeks) mild or moderate Lateral Elbow Tendinopathy and 18 patients affected by Achilles tendinitis (diagnosed using clinical and ultrasonography evaluation) were enrolled in this open label pilot study lasts 24 weeks of treatment with DAIGO® Tendiplus (1 sachet/daily) a dietary supplement containing type II collagen, glucosamine, chondroitin, bromelain and BosliQ®/AKBA.

Results were evaluated using the VAS scale (0-10 cm) for rating pain [10] and WOMAC 2 scale for rating recovery [11] of joint function (3-point objective scale: 0= none; 1=partial; 2=total) both at 24 Weeks. Clinic visit was performed before treatment and at week12 and week 24. An ultrasound and power Doppler evaluation has been performed at the beginning and at week 24. We used a Likert 2 version of WOMAC for patient evaluation, characterized by the following scores for pain and stiffness: 0=none, 1=mild, 2=moderate, 3=severe.

The main exclusion criteria were:

a) regular use of FANS during the previous 4 weeks;
b) use of any other medications or supplements for joint pain and stiffness;
c) presence of any serious medical problems;
d) psychiatric disease or other condition that might interfere with self-assessment ability.

Statistical analysis: The data are expressed as means. The composite scores were analyzed by ANOVA. A Student's independent t-test was used to evaluate comparisons between test scores. The level of significance was set at $p<0.05$.

Results

In Fig. 2 are reported the changes in the VAS pain scores after 24 weeks of DAIGO® Tendiplus administration in patients with Lateral Elbow Tendinopathy.

DAIGO® Tendiplus significantly ameliorate the score both in patients with mild or moderate pain (*$p<0.02$ and **$P=0.02$ respectevely). The same results were obtained with DAIGO® DAIGO® Tendiplus inpatients affected by Achille's Tendinitis (AT) after 24 weeks (Fig. 3). DAIGO® Tendiplus significantly ameliorate the VAS pain score both in patients with mild or moderate pain (*$p< 0.05$ and **$P=0.04$ respectevely).

Regarding the effects of DAIGO® Tendiplus on stiffness in patients with Lateral Elbow Tendinopathy, DAIGO® Tendiplus reduced significantly the stiffness score in patients affected by mild or moderate stiffness (Fig.4). ($p< 0,01$ and $p <0,05$).

Discussion

There is increasing evidence that dietary supplement agents that contain combinations of chondro-protective and/or anti-

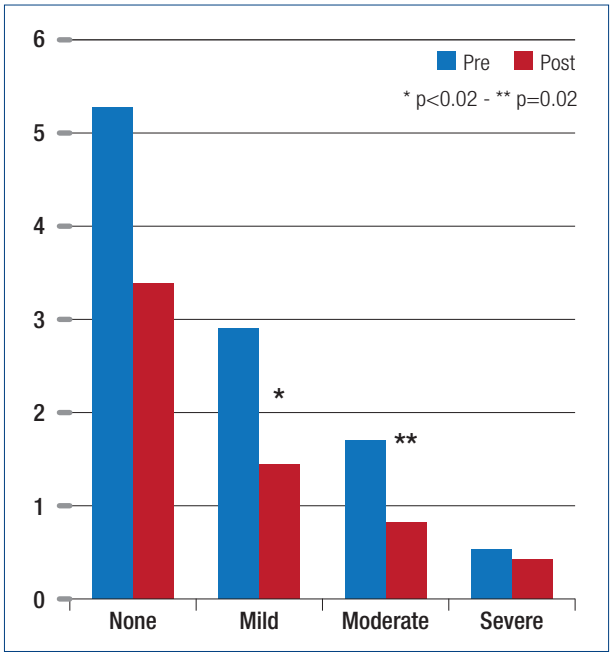

Figura 2 – VAS score in patients with Lateral Elbow Tendinopathy (LET)

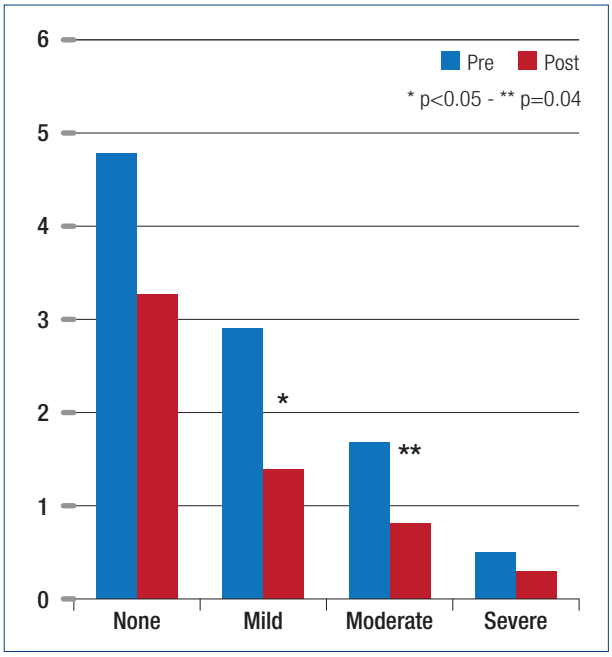

Figura 3 – VAS pain score in patients with Achille's Tendinitis (AT)

inflammatory components are effective in reducing joint pain and stiffness without measurable side effects. This pilot study enrolled 40 Middle age outpatients suffering from chronic (i.e., for ≥12 weeks) mild or moderate lateral epicondylitis and 18 patients affected by Achille's tendinitis diagnosed using clinical and ultrasonography evaluation. The primary outcomes of this study were the pain, stiffness, and function indexes of the WOMAC scores evaluated after 24 weeks of DAIGO® Tendiplus administration. DAIGO® Tendiplus for 24 weeks induced a significant reduction in joint pain and stiffness in subjects with chronic mild or moderate lateral epicondylitis or affected by Achille's tendinitis as for the conclusions that has been reported in other studies using chondroprotective and/or anti-inflammatory dietary supplements.

Conclusion

DAIGO® Tendiplus is a new dietary supplement containing type II collagen, glucosamine, chondroitin, bromelain and BosLiq®-AKBA with a good efficacy in patients affected by mild or moderate Lateral Elbow Tendinopathy or Achille's tendinitis.

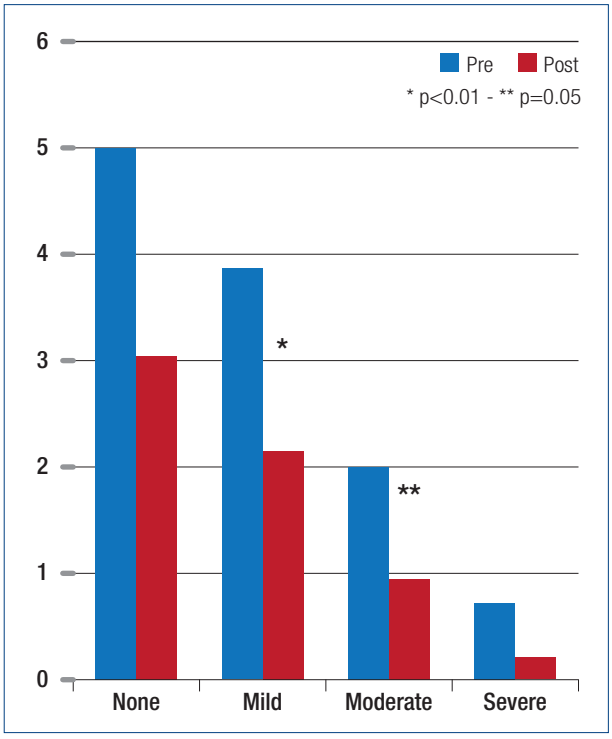

Figura 4 – Effects of DAIGO® Tendiplus on stiffness in patients with Lateral Elbow Tendinopathy (LET)

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