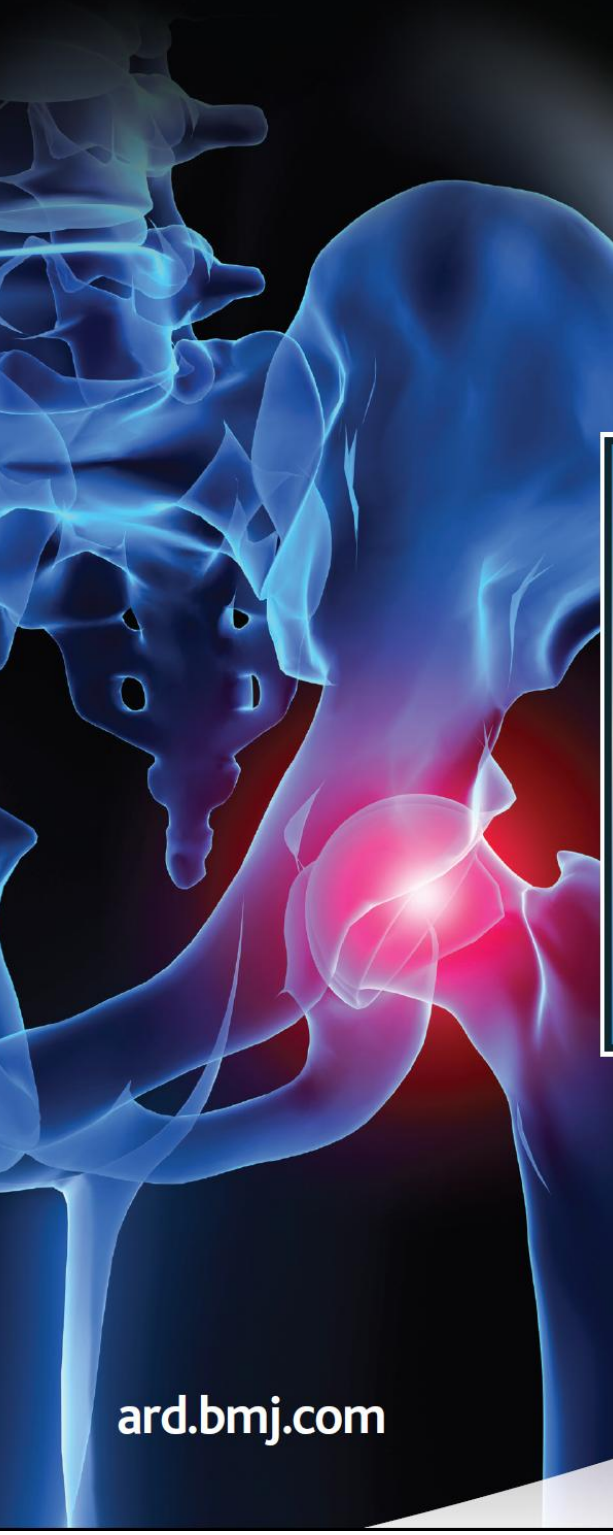
June 2014 Volume 73 Supplement 2

Annals of the Rheumatic Diseases

The EULAR Journal



Annual European Congress of RHEUMATOLOGY

EULAR 2014

France, 11–14 June 2014

Abstracts

ard.bmj.com

eular BMJ

Abstract THU0337 – Table 1

Most common TEAEs (≥5.0%)	Lower-dose submicron indomethacin 40 mg TID (n=187), n (%)	Lower-dose submicron indomethacin 40 mg BID (n=184), n (%)	Lower-dose submicron indomethacin 20 mg TID (n=183), n (%)	Celecoxib 400 mg loading dose, 200 mg BID (n=93)[a], n (%)	Placebo (n=188), n (%)
Nausea	62 (33.2)	60 (32.6)	63 (34.4)	30 (32.3)	67 (35.6)
Post-procedural edema	44 (23.5)	40 (21.7)	48 (26.2)	25 (26.9)	60 (31.9)
Headache	29 (15.5)	25 (13.6)	20 (10.9)	5 (5.4)	21 (11.2)
Dizziness	28 (15.0)	26 (14.1)	18 (9.8)	7 (7.5)	32 (17.0)
Vomiting	14 (7.5)	19 (10.3)	21 (11.5)	3 (3.2)	21 (11.2)
Post-procedural bleeding	9 (4.8)	20 (10.9)	9 (4.9)	8 (8.6)	11 (5.9)
Constipation	7 (3.7)	9 (4.9)	11 (6.0)	3 (3.2)	9 (4.8)

TEAE, adverse event; BID, twice daily; TID, 3 times daily. [a]Only study 1 had a celecoxib arm.

than commercially available drug products, Iroko Pharmaceuticals is developing investigational, lower-dose SoluMatrix® indomethacin using SoluMatrix Fine Particle Technology™, containing submicron particles of indomethacin with enhanced dissolution properties. We present safety and tolerability data from two phase 3 studies evaluating the efficacy of lower-dose submicron indomethacin in patients with acute pain following elective surgery.

Objectives: Evaluate safety of lower-dose submicron indomethacin in postsurgical patients.

Methods: Two phase 3, randomized, multicenter, double-blind studies enrolled patients 18–68 years old undergoing bunionectomy. Patients with moderate-to-severe pain (≥40 mm/100-mm Visual Analog Scale) received lower-dose submicron indomethacin (40 mg TID, n=187, or BID, n=184, or 20 mg TID, n=183), placebo (n=188), or, in 1 study, celecoxib (400 mg loading dose followed by 200 mg BID, n=93). AEs, vital signs, pain intensity, and rescue medication use were monitored for 48 hours. Treatment-emergent AEs (TEAEs) were summarized by severity and seriousness.

Results: TEAEs were similar across treatment groups. The most common TEAEs (≥5% of patients in any treatment group) were nausea, post-procedural edema, headache, dizziness, vomiting, post-procedural hemorrhage, and constipation (Table). Seven (0.8%) patients withdrew due to a TEAE, including 2 cases of urticaria and 1 case each of uvulitis, angioedema, and nausea among recipients of lower-dose submicron indomethacin, and 1 case each of pyrexia and anxiety in the placebo group. A serious TEAE, a single report of deep vein thrombosis, in the lower-dose submicron indomethacin 40 mg BID group was determined to be unrelated to the study drug.

Conclusions: Lower-dose submicron indomethacin was generally well tolerated in two phase 3 studies in patients with postsurgical pain. There were no serious CV, GI, or renal AEs associated with NSAID use. Based on available efficacy data, the investigational lower-dose submicron indomethacin represents a potentially promising lower-dose option for treating acute pain.

References:

[1] Langford RM. Clin Rheumatol. 2006;25 Suppl 1:S2-8.

Acknowledgements: The authors would like to thank Jennifer Nezzer, MS, and Daniel Solorio, whose contributions and individual efforts helped make these studies possible.

Disclosure of Interest: R. Altman Consultant for: Pfizer, Teva Pharmaceutical Industries Ltd, and Iroko Pharmaceuticals, LLC, A. Gibofsky Shareholder of: GlaxoSmithKline, Amgen, Bristol-Meyers Squibb, Pfizer, Abbvie, and Johnson & Johnson, Consultant for: Takeda, Amgen, AbbVie, Genentech, Horizon, UCB, and Iroko Pharmaceuticals, LLC, D. Parenti Employee of: Iroko Pharmaceuticals, LLC, C. Young Employee of: Iroko Pharmaceuticals, LLC

DOI: 10.1136/annrheumdis-2014-eular.5355

THU0338 A RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE EFFICACY AND SAFETY OF A DIETARY SUPPLEMENT CONTAINING MUCOPOLYSACCHARIDES, COLLAGEN TYPE I AND VITAMIN C FOR MANAGEMENT OF DIFFERENT TENDINOPATHIES

B. Hai Binh[1], P. Ramirez[2], D. Martinez-Puig[2]. *[1]Bach mai Hospital, Hanói, Viet Nam; [2]Bioiberica, S.A, Barcelona, Spain*

Background: Overuse tendon injury (tendinopathy) occurs in loaded tendons of the upper and lower limb and results in pain, decreased exercise tolerance of the tendon and a reduction in function. Characteristic changes occur in tendon structure, resulting in a tendon that is less capable of sustaining repeated tensile load.

Objectives: The aim of this study was to evaluate the efficacy and safety of a food supplement containing mucopolysaccharides, collagen type I and vitamin C on the clinical symptoms, pain and tendon structure of patients with tendinopathy of Achilles, supraspinatus, lateral epicondyle or plantar fasciitis.

Methods: Patients with clinically and sonographically diagnosed tendinopathy were randomized to receive two capsules per day of Tendoactive® (TA) (435mg of mucopolysaccharides, 75mg of collagen type I and 60mg of vitamin C) or two identical capsules of placebo (PBO) during 90 days. An oral NSAID (Mobic® 7.5 mg/day) was allowed in both groups as rescue medication for a maximum of 30 days. Patients were monitored monthly during the study period. Clinical assessments included presence/absence of clinical symptoms (swelling, burn and redness) and pain intensity using a visual analog scale (VAS). Tendon structure was characterized sonographically and presence/absence of tendinopathy was reported.

Results: A total of 60 patients were included, 30 assigned to each treatment group. Average age was 41,4±1,50 years in TA group and 40,2±0,26 years in PBO group. They were mostly women in both groups (83.3% and 86% in TA and PBO groups respectively). The percentage of patients presenting each clinical symptom was progressively reduced in both groups, reaching lower values in the TA group at each time point. Pain level assessed by VAS was comparable between groups at baseline (5,82±0,21 vs 5,71±0,23 in TA and PBO groups respectively). It was significantly reduced in both groups during the study period, but patients supplemented with TA had significantly lower pain value at 90 days (2,5±0,22 vs 3,20±0,20 in TA and PBO groups respectively; $P<0.05$). At the end of study, no patient in the TA group was diagnosed for tendinopathy according to ultrasounds assessment.

Conclusions: The overall results of this randomized, placebo-controlled study show that Tendoactive® supplementation is a safe and effective therapeutic option to improve both clinical symptoms and structural evolution of injured tendons as demonstrated in Achilles, supraspinatus, lateral elbow epicondyle and plantar fasciitis.

References:

[1] F. Nadal, T. Bové, D. Sanchís, D. Martinez-Puig. Effectiveness of treatment of tendinitis and plantar fasciitis by Tendoactive. Osteoarthritis and Cartilage 2009;17(1):S253

[2] M. Shakibaei, C. Buhrmann and A. Mobasheri. Anti-inflammatory and anti-catabolic effects of TENDOACTIVE® on human tenocytes in vitro. Histology and Histopathology 2011;26:1173-1185

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2014-eular.5477

THU0339 MANAGEMENT OF ACHILLES TENDINOPATHY IN REACTIVE VS DEGENERATIVE STAGE: A PROSPECTIVE, RANDOMIZED, CONTROLLED TRIAL EVALUATING THE EFFICACY OF A DIETARY SUPPLEMENT ASSOCIATED TO ECCENTRIC TRAINING OR PASSIVE STRETCHING

R. Balius[1,2], G. Álvarez[3], F. Baró[4], F. Jiménez[5], C. Pedret[2], M. Pujol[1], D.J. López[3], D. Martínez[4], P. Ramirez[6], D. Martinez-Puig[6]. *[1]CEARE, Barcelona; [2]Clínica CMI Diagonal, Esplugues de Llobregat; [3]AMS Centro de Ejercicio, Málaga; [4]Clínica Traumatológica, Valladolid; [5]Clínica Centro de Medicina y Deporte, Toledo; [6]Bioiberica, S.A, Barcelona, Spain*

Background: Tendinopathy is an overuse tendon injury that results in pain, decreased exercise tolerance and a reduction in function, being a major problem in sports and occupational medicine. A new pathology model has recently been proposed dividing tendinopathies into different stages according to severity, allowing rational placement of treatments at each different stage.

Objectives: The aim of this study is to evaluate the efficacy and safety of 3 different interventions: eccentric training (EC), eccentric training + Tendoactive®, a dietary supplement containing Mucopolisaccharides, type I Collagen and Vitamin C (EC+MCV), and passive stretching program + MCV (PS+MCV). It is also studied whether there is different response pattern to the mentioned treatments depending on the pathology stage.

Methods: In this randomized, controlled, multicenter trial fifty-nine patients were randomly assigned to 1 of 3 treatment groups, and classified in one of two subgroups designed according to the Cook & Purdam pathology model: reactive vs degenerative tendinopathy. Patients were evaluated at baseline, 6 and 12 weeks with the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire. Pain was evaluated at rest and during activity using a visual analog scale (VAS), and evolution of tendon structure was assessed by ultrasound.

Results: A significant improvement in VISA-A score, pain at rest and pain during activity were detected in all 3 treatment groups at 6 and 12 weeks follow-up, when compared to baseline. In patients with reactive tendinopathy the reduction on pain at rest was significantly greater in the groups supplemented with MCV than in the EC group ($P<0.05$), while the VISA-A score tended to obtain a better recovery in the EC+MCV treatment than in the EC alone ($P=0.069$). In patients with degenerative tendinopathy, a significant reduction of the bilateral thickness and neovascularization degree of the affected tendon, were detected in the PS+MCV group.

Conclusions: A dietary supplement containing mucopolisaccharides, type I collagen and vitamin C, seems to be safe and effective for management of tendinopathies, providing some additional benefit to the physical therapy. This is especially evident in early stages of the disease, when the tendon doesn't present severe matrix and vascular changes.