

Research Article

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Potential Benefits of Supplementation with Lecithin-Based Delivery Form of *Boswellia serrata* Extract and CoQ10 on Amateur Athletes for the Recovery of Acute Traumas or Chronic Musculoskeletal Disorders: A Single-Arm Pilot study

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Abstract

A pilot study aimed to evaluate potential advantages of Boswellia and Coenzyme Q10 supplementation was performed in amateur athletes for the recovery from both acute trauma and chronic musculoskeletal conditions such as chondropathy, tendinopathy and meniscopathy. Both Boswellia and Coenzyme Q10 in the present study formulated in phospholipids (Indena PhytosomeTM technology) were for the first time combined in the same dietary supplement (WellQ10TM). Administration was scheduled for seven days as two tablets two times a day, followed by further two tablets a day for two weeks in acute trauma; and for seven days as two tablets a day, followed by one tablet a day for three weeks in chronic disorders. A significant reduction of pain perception evaluated by VAS score was obtained after supplementation in both acute and chronic conditions. A reduction in recovery time in several amateur athletes with acute trauma was also observed. Boswellia serrata has already been described in Ayuverdic ancient tradition to have well-known anti-inflammatory properties, and Coenzyme Q10 is understood to have antioxidant properties in the context of oxidative stress generated by both strenuous training and sports activity versus trauma. The results achieved in the present study support the beneficial effect of the combination of the two ingredients in a unique supplement. The advantage of using the Phytosome™ delivery technique has opened new perspectives for future applications in the sports trauma recovery field.

Keywords: CoQ10; Coenzyme Q10; Boswellia; Inflammation; Oxidative stress; Sport; UbiqsomeTM; CasperomeTM; WellQ10TM; Pain

Introduction

Sports injuries are very common events in both professional and amateur athletes and treatment depends on the type and grade of lesions [1]. Supplementation with Coenzyme Q10 (CoQ10) could be helpful in physical activity, training, and sports in order to modulate the oxidative stress generated [2,3]. Indeed, it is known that during high intensity physical activity with oxygen consumption, reactive oxygen species (ROS) are highly produced to cause oxidative stress [4], which acts as the starter of adaptive processes, but at same time could be harmful when elevated. Boswellic acids of *Boswellia serrata* displayed anti-inflammatory and anti-arthritic properties [5], so the combination of both Boswellia and CoQ10 in one dietary supplement would

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exert both anti-inflammatory and antioxidant activities to support a fast recovery from sports injuries. The aim of the present study was to evaluate the health benefits of CoQ10 and *Boswellia serrata* extract formulated with the unique PhytosomeTM technology on pain relief in acute and chronic disorders of non-professional athletes.

Materials and Methods

Clinical study

Forty non-professional athletes (between 21 and 59 years old), including 20 (13 males, 7 females) with acute musculoskeletal injury (musculotendinous trauma) and 20 (12 males, 8 females) with chronic musculoskeletal discomfort (joint and tendon overload) were recruited for the study. Subjects with an acute episode (AS) had different degrees of lesions: 4 have a grade 0 lesion (oedema without fibers disruption), 4 have a grade 1 lesion (minimal fibers disruption without blood extravasation), and 12 have a grade 2 lesion (fibers disruption and blood extravasation). Subjects with chronic dysfunctions (CS) showed degenerative cartilagines (n=10) and degenerative tendon disease (n=10), according to instrumental evaluation such as nuclear magnetic resonance or ultrasound. All subjects exercised daily.

Experimental design

The Visual Analogue Scale (VAS), which allowed subjects to evaluate their pain level between 0 ("no pain") and 10 ("worst possible pain") was detected at 0, 10, and 20 day timepoints. In acute episodes, the objective ultrasound evaluation at the same timepoints was performed. Qualitative data of localized bioimpedance measurements were obtained for some AS in order to analyze muscle injury severity by examining the phase angle, expressing the relationship between the cellular component and liquids locally [6]. The frequency of daily physical activity was also monitored in CS.

Supplement and administration schedule

Subjects were supplemented with WellQ10TM (FARMAD LABORATORI FIRENZE SRL), containing: CoQ10 PhytosomeTM as 150 mg UbiqsomeTM standardized to contain 18-22% of CoQ10, Indena SpA [7], combined with 250 mg Boswellia PhytosomeTM (CasperomeTM standardized in ≥25% of triterpenoid acids by HPLC, Indena SpA) [8]. AS received two tablets (two times a day) for seven days, followed by two tablets a day for another two weeks. CS were supplemented

with two tablets a day for seven days, followed by one tablet a day for three weeks.

Statistical evaluation

Data are expressed as means \pm S.D. Every data set (acute trauma and chronic disorders as: total; chondropathy; tendinopathy) was independently analysed. Analysis of variance (one-way ANOVA for repeated measures at 0, 10 and 20 days) was performed, followed by Sidaks test for multiple comparisons. Significance was set at p<0.05.

Results

Our study was performed on non-professional athletes with characteristics summarized in table 1.

Acute traumas

Supplementation with WellQ10 in AS showed a statistically significant reduction of pain, as observed via the VAS score, at day 10 and even more at day 20 in comparison to T0 (Figure 1).

In figures 2 and 3, the objective ultrasound evaluation of two AS are shown. An example of grade 1 lesion of thigh flexors was displayed in figure 2: at time zero (Figure 2a) an area of structural disarrangement with increased Doppler signal, indicative of blood flow to the injured area, was noted. At follow-up after supplementation (Figure 2b), signs of hypervascularization were absent and the area of structural damage shows a recovery of the normal architecture of the fibers, with re-absorption of the perilesional edema.

A second example of a grade 1 lesion of thigh flexors is displayed in figure 3. Area of structural disarrangement and fluid collection with bands of fibrous septae are present at time zero (Figure 3a). After supplementation (Figure 3b), a reabsorption of the fluid component and restoration of the structural damage without detectable fibrotic areas was observed, showing a complete recovery.

For some subjects with AS, localized bioimpedance measurements were also performed. Results obtained displayed a qualitative effect on the decrease of muscle injury severity (data not shown). For localized bioimpedance, the phase angle was examined, which is a parameter that expresses the relationship between the cellular components and body fluids. After the injury, the value was reduced due to a local accumulation of liquids and/or to damage to the cellular part [6]. After WellQ10 supplementation, the value

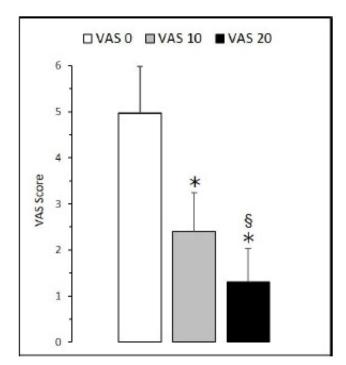
Table 1: Summary of characteristics

Disorder type	n	Gender	Age (years)	Diagnosis
Acute	7	F	24.1±3.3	Lesions of grade 0, I and II of adductor/quadriceps/triceps/hamstring
	13	М	27.4±2.7	
Chronic	8	F	39.9±9.8	Chondropathy, meniscopathy, tendinopathy
	12	M	41.8±9.8	

F=female, M=male

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Data are expressed as means \pm S.D., n=20 ANOVA: F(2.57)=94.90, P<0.0001

Sidak's test: *: P<0.0001 vs VAS 0; §: P<0.0005 vs VAS 10

Figure 1: VAS score at time 0, 10 and 20 days after supplementation in AS

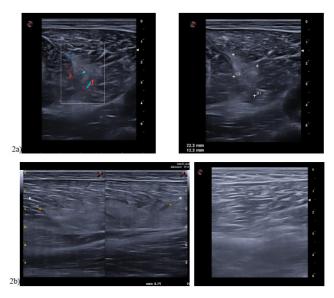


Figure 2: Objective ultrasound evaluation of an acute lesion of tight flexors before (a) and after (b) supplementation, example 1

recorded in the injured zone was compared with the value of the same contralateral district, taken as control: the recovery of the phase angle vs. control was quicker than that observed in a small group of control subjects not treated with very similar lesions (data not shown).

Chronic discomforts

WellQ10 supplementation in chronic conditions showed a statistically significant reduction of pain VAS score at day 10 and at day 20 in comparison to T0 (Figure 4).

By comparing figure 1 and figure 4, we can observe that VAS score reduction after 20 days of supplementation was greater for AS than for CS. The VAS score mean was 1.30 ± 0.73 at T20 vs 4.98 ± 1.01 at T0 for AS; while VAS score mean was 2.55 ± 0.90 at T20 vs 5.0 ± 0.83 at T0 for CS. Of

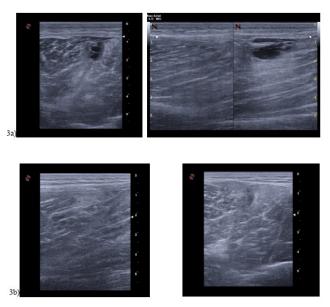
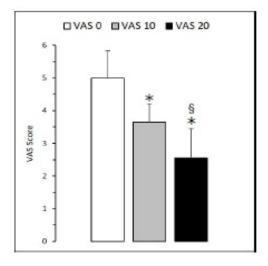


Figure 3: Objective ultrasound evaluation of an acute lesion of tight flexors before (a) and after (b) supplementation, example 2

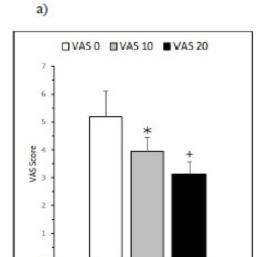


Data are expressed as means \pm S.D., n=20 ANOVA: F(2.57)=49.76, P<0.0001

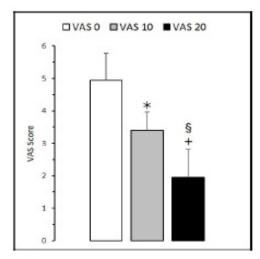
Sidak's test: *P<0.0001 vs VAS 0; §: P<0.0001 vs VAS 10

Figure 4: VAS score at time 0, 10 and 20 days after supplementation in CS





Data are expressed as means ± S.D., n=8 ANOVA: F(2.21)=20.01, p<0.0001 Sidak's test: *: P<0.005; +: P<0.0001 vs VAS 0 b)



Data are expressed as means ± S.D., n=10 ANOVA: F(2.27)=38.34, P<0.0001 Sidak's test: *: P<0.0005, +: P<0.0001 vs VAS 0; §: P<0.001 vs VAS 10

Figure 5: VAS score at time 0, 10 and 20 days after supplementation in chronic disorders as chondropathy (a) and tendinopathy (b)

note, the statistical analysis performed on CS pain subgroups (chondropathy and tendinopathy) confirmed a VAS score reduction at both the 10 and 20 day timepoints (Figure 5a, chondropathy and 5b, tendinopathy).

Discussion

Trauma due to sports activities can happen frequently in both professional or amateur athletes. Some lesions of increasing severity can occur to skeletal muscles, and therapies beyond the immediate RICE (rest, ice, compression, elevation) [9], can mainly include the use of classical NSAIDs, i.e. non-steroidal anti-inflammatory drugs. As an alternative to Standard Management, supplementation with natural substances within the time window peculiar to muscle type and individual characteristics, would be useful for two reasons: first for pain relief and second for inflammatory process modulation. Indeed, analgesic effects on the causal mechanism allows for a rapid start of the recovery phase; furthermore an improvement of the healthy inflammatory reaction together with an antioxidant activity and a contribution to a regular production of the mitochondrial energy ensures a decrease in the extent of the damage (i.e. secondary lesions) and the reduction of oedema due to the lesion [10]. In order to support that hypothesis, the present study was conducted in amateur athletes with acute trauma supplemented with the combination of Boswellia and CoQ10, both formulated with PhytosomeTM technology. In the same study, subjects having chronic musculoskeletal disorders like chondropathy, tendinopathy, or meniscopathy were also included to evaluate the potential benefits of this supplement

in chronic discomforts. The supplementation doses given to AS subjects were higher than that of CS, because it was very important in the first post-lesional phase to immediately reduce inflammatory and oxidant response, without interfering with coagulation mechanisms to avoid establishment or worsening of blood extravasation. That necessity makes it difficult, or not advisable in many cases, to use classical anti-inflammatory therapy and justifies the preferential use of natural substances such as CasperomeTM to avoid the known adverse effects discussed above. Results obtained showed a significant reduction in pain intensity already after 10 days of supplementation, and even more at the end of supplementation (20 days), evaluated by VAS score, in acute situations. Noteworthy, objective ultrasound evaluations showed amelioration of target organ tissues. In our study, also chronic, unhealthy dysfunctions were positively modulated through the supplementation. Those results are in agreement with previous studies where after four weeks, CasperomeTM supplementation was able to modulate inflammation and osteo-muscular pain in young rugby players [11]. Furthermore, an enhanced recovery from mild severity ankle sprains due to sports training was observed in healthy subjects supplemented with the same product [12]. In the context of knee osteoarthritis, benefits of anti-inflammatory supplements like Boswellia were claimed [13,14]. The importance of the antioxidant activity of CoQ10 in sport was also supported by recent previous studies [2,15], suggesting a CoQ10 protective activity against oxidative stress induced by sports and related trauma. The 30-day supplementation by CoQ10 formulated as PhytosomeTM allowed for higher plasmatic and



muscular CoQ10 levels than the control group [7,15], with a significant reduction in both inflammatory cytokines and malonyl dialdehyde plasma levels in healthy aging runners after stressful exercise. The PhytosomeTM technology applied to both Boswellia and CoQ10 represents a successful delivery system to optimize oral absorption [7,11,15,16]. For the first time, the combination of CasperomeTM and UbiqsomeTM present in a unique supplement confirmed and extended the benefits on pain perception in acute traumas and chronic musculoskeletal conditions, possibly due to complementary anti-inflammatory activity related to Boswellia and the antioxidant properties of CoQ10, especially in target tissues. The lack of a control group in the present single-arm pilot study represents the major limitation of the study, together with the lack of biochemical measures. However, ultrasound data for AS clearly showed a recovery from trauma at the tissue level, and the qualitative localized bioimpedance measurements supported the effectiveness of supplementation with WellQ10. For the first time, the present study shows the beneficial properties of two natural substances, Boswellia and CoQ10 both formulated with Phytosome™ technology in a unique, rational combination for the recovery of acute and chronic musculoskeletal disorders in amateur athletes, avoiding side effects often associated with the prolonged use of NSAIDs, and at the same time providing the injured tissues with the protection given by CoQ10. Future studies including a large number of subjects and a control group could be useful to deeply evaluate the potential benefits of this association.

Acknowledgements

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Conflict of Interest

AR, PA, GP and MM are Indena's employees; PLD and SB are employees of FARMAD LABORATORI FIRENZE.

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