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Osteoarthritis and nutraceuticals: a randomised double blind study

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Abstract
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Abstract

INTRODUCTION

Osteoarthritis is the most common degenerative, chronic and progressive rheumatic joint disease over the age of 65. Hip and knee joints are the most frequently affected, with a small incidence of vertebral and small joints; the symptoms most frequently reported by the patient with osteoarthritis is pain and functional limitation. Boswellia, Curcuma, Myrrh, β-caryophyllene and piperine have demonstrated scientific validity regarding the control of osteo-articular pain, but their association has not yet been studied in double-blind randomized studies. The purpose of study is precisely to evaluate the effectiveness of this combination of nutraceuticals in addition to the standard drug therapy of osteoarthritis.

METHODS

The study is configured as a double-blind, randomized interventional study. One-hundred and forty-four patients in our clinic suffering from osteoarthritis of hip and knee with NRS ⩾ 6 were included in the study. In a randomized manner, the patients have been assigned to a prospective group and a control group (72 patients each), homogeneous for sex, age and pathology. Patients in the prospective and control group were administered drugs as per Table 1. Patients of both groups were evaluated in a first visit (T0) and a 1-month follow-up visit (T1) with administration of the WOMAC questionnaire (96 points) and NRS (10 points). The need to resort to rescue drugs during the 30 days was also assessed. Patients who interrupted or changed therapy at time T1 were excluded from the study. The occurrence of adverse events was assessed and recorded throughout the observation period.

RESULTS

The 144 patients had at T0 values of NRS equal to 7.53 ± 1.145 and WOMAC values of 51.19 ± 13.054, at T1 the values of NRS 4.41 ± 1.787 and WOMAC 41.43 ± 12.134

79.2% of patients in the prospective group presented a reduction in the NRS value between T0 and T1 equal to 46% (expected value). In the placebo group, 65.3% of patients had a 23% reduction in NRS between T0 and T1 (expected value).

29.2% of patients in the prospective group had a reduction in WOMAC value between T0 and T1> 15 points (Expected value). 2.8% of patients in the placebo group had a reduction in WOMAC value between T0 and T1> 15 points (expected value).

54 patients used rescue drugs during the observation time and 7 patients experienced adverse events during the same period.

The results show few differences between two groups. In both groups, the expected value of reduction of pain level, was reached by almost 60% of population. Patients which take the active drug show a greater pain control. Fewer patients in prospective group than in control group needed a rescue drug to control pain during therapy of observation.

No differences between two groups were observed in term of adverse effects, which resolved spontaneously and required no additional treatment.

A greater difference between two groups of patients were observed in WOMAC questionnaire. This test investigates the disability caused by pain, with question about daily life activities. Patients in prospective

group show a marked improvement in disability.

CONCLUSIONS

This study shows that a dietary supplementation of nutraceutical products in patients affected by OA, in association with analgesic drugs, could be a valid strategy to improve pain and disability in middle term. More studies are needed to evaluate long term effect of supplementation for improvement of pain and disability and adverse effects.