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ORIGINAL ARTICLE

Clinical usefulness of oral supplementation with curcumin phytosome in patients with radiculopathy due to spondyloarthritis or discopathy

Giuseppe MAIDA

Department of Surgery, Division of Spine Surgery, S. M. Maddalena Hospital, S. M. Maddalena-Rovigo, Italy

Corresponding author: Giuseppe Maida, Department of Surgery, Division of Spine Surgery, S. M. Maddalena Hospital, S. M. Maddalena-Rovigo, Italy. E-mail: giuma@vodafone.it

ABSTRACT

BACKGROUND: The aim of this study was to explore the efficacy and safety of curcumine phytosome (Meriva®) in reducing the pain due to radiculopathy, in patients affected with spine arthritis or discopathy.
METHODS: Thirty-six patients affected with radiculopathy seen in one Italian neurosurgical outpatients facility, were enrolled to participate in an open, not controlled study, and were treated with curcumine phytosome for 100 days. Pain, motor functionality and other symptoms were assessed at baseline, 50 and 100 days.
RESULTS: There was a marked reduction in pain rating, statistically significant both at 50 and 100 days from baseline. The reduction was statistically significant, both in the intention-to-treat population and in the observed cases. A mild, not clinically significant, reduction in motor functionality was observed at day 50 but not at day 100. No adverse events were recorded.
CONCLUSIONS: This exploratory study highlights the clinical usefulness of curcumine phytosome long term treatment of pain due to radiculopathy, due from spine arthritis or discopathy.

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Key words: Curcumin - Radiculopathy - Spondylarthritis.

Osteoarthritis is a well-known major source of pain and disability worldwide. The pathogenesis of the disorder is complex and multifactorial, with genetic, biological, and biomechanical components.[1] Spinal arthritis is the mechanical breakdown of the cartilage between the aligning facet joints in the posterior portion of the spine, leading often to bone spurs or osteophytes.[2] These spurs can stiffen the spine and narrow the space where nerves are located, causing them to be compressed and leading then to radiculopathy and radicular pain. Another common cause of radicular pain is the discopathy, a degenerative process of intervertebral discs that can lead to herniation or simply to a narrowing of the spaces where nerves are located with a subsequent pressure on them.[3, 4]

The radicular pain is often deep and steady, and may also be accompanied by muscle weakness, numbness and tingling. Lumbar radiculopathy is pressure on the nerve root in the lower back, and cervical radiculopathy is pressure on the nerve root in the neck. Both kinds of compression that can cause pain with different irradiations depending on the site of the pressure.[3, 4]

Curcumin has been shown to exert signifi-

cant anti-inflammatory, antioxidant, and neuroprotective effects in the peripheral nerves.[5, 6] Recently, a pharmaceutical form of curcumin coated with phospholipids has greatly improved its oral bioavailability (~29 times greater than that of traditional curcumin).[7] Alpha-lipoic acid too has data on its utility as a supplement on the peripheral nerves functionality.[8, 9]

The key feature of this report is the clinical usefulness of 100 days oral supplementation with curcumin phytosome, with the addition of alpha-lipoic acid in part of the treatment cycles, in patients affected with cervical or lumbar radiculopathy.

Materials and methods

In the context of an exploratory study, patients of both sexes, affected with radicular pain, either from cervical or lumbar spine arthritis or due to discopathy, were planned to be enrolled.

The inclusion criteria aside from this diagnosis were the pain of intensity less than eight (0-10 Visual Analogic Scale). The age of the subjects had to be between 18 and 65 years.

Exclusion criteria were malignancies, traumatic injuries, metabolic diseases and autoreactive diseases.

All eligible patients were treated orally with curcumine phytosome for 100 days (two 50 days cycle), administered at the dose of 1000 mg *b.i.d.* (Unicur® for the first twenty days of each cycle) or at the dose of 500 mg *b.i.d.* with alpha-lipoic acid 300 mg *b.i.d.* (Axin C® for the following thirty days of each cycle).

The subjective parameters evaluated at baseline, at 50 and 100 days, were pain (0-10 Visual Analogic Scale), symptoms (paresthesia, anesthesia, and hypoesthesia evaluated with a six-point semiquantitative scale, zero being the absence of symptoms) and motor functionality (0-5 Visual Analogic Scale, 5 being the normal functioning).

Statistical analysis

Statistical analysis was performed with a repeated measures regression model, taking in account gender and diagnosis as potential confounders.

Results

Thirty-six patients (11 males, 25 females) were considered eligible and treated. The mean and median age was of 47±10.1 years. 58 % of the sample were affected with spondylarthritis and 42% with discopathy.

The main symptomatic feature was the pain, rated 6.6 of mean at baseline. Other symptoms were substantially absent (mean and median values around 0), as well as the functional impairment (functionality rated as pretty normal at baseline, with a mean of 4.9).

In Table I, the number of patients evaluated and the mean pain ratings in each assessment were summarized.

The mean pain subjective rating decreased from baseline to the 50 days assessment (P=0.002) and even further at the 100 days evaluation (P<0.001 to the baseline score), both in the intention-to-treat population (Figure 1) and in per-protocol population (Figure 2).

No differences were observed adding gender and diagnosis as covariates. No differences in other symptoms were observed at the two assessment points, but for a mild decrease in motor functionality from 4.9 to 4.4 from baseline to the 50 days evaluation (P=0.006), with a subsequent increase at the 100 days assessment (mean score 4.7) with no significant differences to the baseline.

TABLE I.—*Number of patients evaluated and pain ratings.*

	T0	T50	T100
Number of subjects evaluated	36	26	28
Pain (mean±SD)	6.6±1.1	4.7±2.8	3.4±2.4

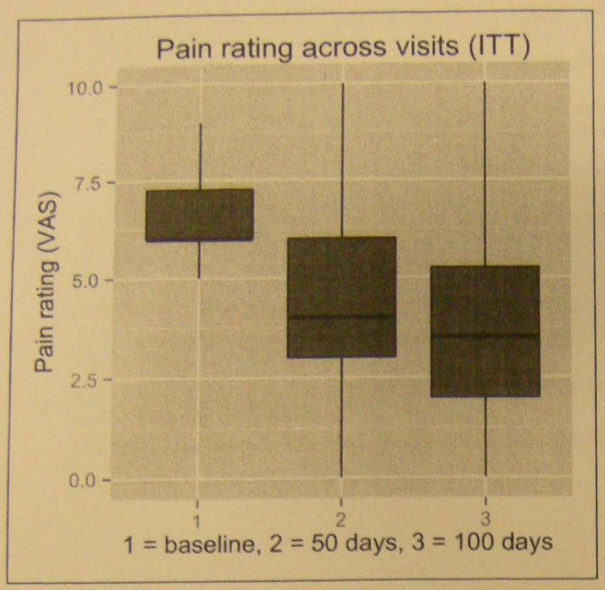

Figure 1.—Pain reduction across the assessments (intention-to-treat population).

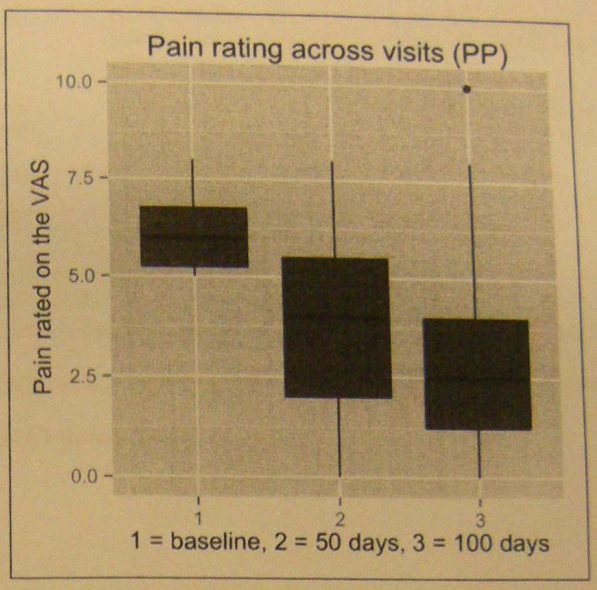

Figure 2.—Pain reduction across the assessments (per-protocol population).

Discussion

The results from the present study indicate that patients with radiculopathy, who received oral supplementation with curcumin phytosome, for a total of 100 days, have shown a statistically significant reduction in pain rating.

The reduction has been highly significant both between baseline and 50 days assessment and baseline and 100 days assessment, even accounting for multiple testing correction.

Motor functionality rating has shown a slight reduction between baseline and visit 2 but not between baseline and visit 3. Symptoms of paresthesia, anesthesia and hypoesthesia were absent at the baseline and did not emerge during subsequent assessments.

No side effects were reported, which confirm the excellent safety profile of curcumin phytosome administered either with a dietary dosage of vitamin B or with alpha-lipoic acid.

There are limitations to this study which need to be mentioned. First, the study design was monocentric, open, and not controlled. This design could be of use in an exploratory phase but a more rigorous, multicentric, randomized controlled study, sufficiently powered, need to be done to confirm curcumin phytosome efficacy in this pathology.

Another limitation is the relative heterogeneity of the primary disorder leading to radiculopathy, spine arthritis or discopathy, of the lumbar or the cervical region.

This heterogeneity could be considered a plus as for the purpose of generalizing the results, but could make the results less interpretable, even if the regression analysis did not spot confounding effects of age and diagnosis.

Conclusions

This study clearly suggests the potential usefulness of curcumin phytosome (Meriva®) in the long-term management of radicular pain. If this effect is confirmed in subsequent randomized controlled studies, the use of this product, that has an excellent safety profile, will lead to a significant improvement in the non-surgical management of radiculopathy.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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