

Acupuncture vs. placebo for chronic knee pain (osteoarthritis): an RCT

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Aims: To analyse the effectiveness of acupuncture as a complementary therapy to the pharmacologic treatment of osteoarthritis of the knee, as regards pain relief, stiffness and activity during the treatment, modification of the consumption of diclophenac, and changes in the quality of life.

Methods: Single-blind randomised controlled trial with blind evaluation and analysis by third parties. We selected outpatients who had been diagnosed with arthritis of the knee and who presented clinical-radiological and symptomatic evidence of this when the selection was made. Criteria for inclusion were established specifically, and we excluded patients who had received prior acupuncture treatment or who presented counter-indications on receiving treatment with diclophenac. The subjects were randomly assigned to one of two groups: a) experimental, with acupuncture + diclophenac; b) control group, with placebo acupuncture + diclophenac. We performed a baseline assessment, and another evaluation after the treatment had ended, using as result variables the total WOMAC (Western Ontario and McMaster Universities) Osteoarthritis Index, together with each of the following scales: pain, stiffness and physical function. Pain in the knee was evaluated by a visual analogue scale (VAS), by the weekly consumption of diclophenac and by the quality-of-life profile for the chronically ill. The two groups were compared with reference to each of the result variables, per protocol (PP), by intention to treat (ITT), by the total WOMAC index and by the pain as assessed on the VAS. The level of significance for each of the tests was set at $p < 0.05$. A multiple linear regression model was constructed for the dependent variables, incorporating the relative change in WOMAC (WOMACr) and the relative change in the pain VAS (VASr).

Results: 97 subjects were selected for the study and 88 of them completed it. The PP multivariate model for the VASr variable produced an improvement difference of 43.7% (95% CI: 29.4 – 56.0) in favour of the experimental group. This improvement, under ITT analysis, decreased to 33.4% (95% CI: 20.3 – 44.4). The relative improvement in the PP total WOMACr presented a relative decrease of 52.0%, a value that fell to 37.6% for ITT analysis.

Conclusions: The group treated with acupuncture obtained better results than did the control group in reducing pain intensity and in reducing the consumption of diclophenac; all differences were statistically significant. We discuss possible alternative types of placebo, their advantages and disadvantages, including specific and nonspecific effects.

Keywords: Osteoarthritis, Knee, Acupuncture, Placebo, Pain, Quality-of-life, Randomised controlled trial.