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File: ■ Olive (*Olea europaea*) Oil ■ Piroxicam ■ Knee Osteoarthritis

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RE: Topical Olive Oil Alleviates Pain and Improves Physical Function in Osteoarthritis Patients

Bohlooli S, Jastan M, Nakhostin-Roohi B, Mohammadi S, Baghaei Z. A pilot doubleblinded, randomized, clinical trial of topical virgin olive oil versus piroxicam gel in osteoarthritis of the knee. *J Clin Rheumatol*. March 2012;18(2):99-101.

Many people suffer from osteoarthritis (OA), with the knee being the joint most affected. Patients who do not respond well to conventional medical therapies, including topical nonsteroidal anti-inflammatory drugs (NSAIDs) and salicylates, often turn to complementary and alternative medicines. One of the traditional methods of managing knee pain in Iran, the home of these authors, is to apply topical olive (*Olea europaea*) oil. The compounds of olive oil thought to contribute to its observed health benefits include oleic acid, phenolics, and squalene,¹ while the secoiridoid derivative, (-)-oleocanthal, has been shown to have NSAID properties.² The authors conducted a pilot, prospective, comparative, randomized, double-blinded trial of topical virgin olive oil therapy versus the NSAID piroxicam gel in the treatment of knee OA.

The study was conducted in the rheumatology clinic of Imam Hospital, Ardabil University of Medical Sciences, in Ardabil, Iran, from April 2008 to April 2010. The subjects included women aged between 40 and 85 years with a diagnosis of OA of 1 or both knees according to the American College of Rheumatology criteria and with a flare of pain following prior therapy withdrawal of an oral NSAID or acetaminophen (used at least 3 days weekly during the previous month).

At the screening visit, knee pain was scored on the 20-point scale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) of pain. At that time, the subjects discontinued any current therapy for a 1-week washout period. At the baseline visit, pain was scored again. Eligible subjects had to have a pain flare and a pain subscale score of ≥ 9 on the WOMAC scale. A flare was defined as an increase in total score of at least 2 between the screening and baseline visits.

Included subjects were then randomized to apply piroxicam gel (n=36) or olive oil (n=35) for 4 weeks. They returned to the clinic on weeks 1, 2, 3, and 4 for assessment of

efficacy, safety, and compliance. The piroxicam gel (Iran Najo Co.; Tehran, Iran) contained 0.5% piroxicam in a vehicle composed of carbomer 934, ethanol, propylene glycol, hydroxypropyl, α -methyl cellulose, sodium edetate, benzyl alcohol, diisopropanolamine, and purified water. The virgin olive oil was prepared directly from fruits of olive trees grown in Gilan Province in Iran. Both were packaged in identical 60 gram tubes. The subjects were instructed to apply 1 g of the medications 3 times daily on one primary affected knee to assess efficacy; the other knee, if treated, was only evaluated for safety.

The primary outcome measure was the change in scores on the WOMAC pain subscale from baseline to weeks 1, 2, 3, and 4. The secondary outcome measure was change in physical function from baseline to final assessment in the affected knee on the 68-point WOMAC physical function subscale.

Of the 71 subjects enrolled in the study, 58 completed it. Of the 6 piroxicam and 7 olive oil dropouts, 5 were due to protocol deviations and 7 due to lack of therapeutic effect. Up to 4 acetaminophen tablets (325 mg each) daily were allowed during weeks 1-3 for residual pain. No significant group differences were found for age, weight, height, or WOMAC subscales at baseline.

The authors report that topical olive oil was superior to piroxicam gel in the WOMAC pain subscale at weeks 2, 3, and 4. The mean change on the pain subscale for olive oil was a decrease of 7.48 between weeks 0 and 4 (P<0.001). In the piroxicam group, the mean score decreased by 2.73 (P<0.001). Although pain intensity was significantly decreased from baseline in both groups between weeks 0 and 4, a more significant decrease was reported in the olive oil group (P<0.001). There were no significant differences in daily acetaminophen use between the groups.

Regarding the secondary outcome measures, the olive oil showed significant superiority to piroxicam in the WOMAC physical function subscale at weeks 2, 3, and 4. A greater mean decrease in scores from baseline on the physical function subscale was noted for subjects treated with olive oil (-23.63) compared with those in the piroxicam group (-10.97) (P<0.001). One patient reported an adverse effect: skin allergy after virgin olive oil application.

Although the composition of olive oil is complex, the component oleocanthal may be responsible for some of the beneficial effects of the olive oil on knee pain. The presence of several types of antioxidants and anti-inflammatory agents in olive oil may also be attributed to its effects.

Among the study's limitations are the small sample size, the short duration, and the fact that it was not placebo-controlled. "Further studies should be conducted to evaluate the long-term effects of virgin olive oil on knee OA in larger populations," conclude the authors.

Overall, the findings of this study suggest that treatment for knee OA with topical virgin olive oil is associated with greater improvement in all outcome measures compared to treatment with piroxicam gel. The differences increased over time in favor of the olive oil.

—Shari Henson

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