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Structural effect of avocado/soybean unsaponifiables on joint space loss in osteoarthritis of the hip.

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OBJECTIVE: To evaluate the structural effect of avocado/soybean unsaponifiables (ASU) in the treatment of patients with symptomatic osteoarthritis (OA) of the hip. **METHODS:** Patients with regular painful primary OA of the hip (European League Against Rheumatism 1980 criteria) and a joint space still $>$ or $=$ 1 mm (Kellgren grade 1 to 3, assessed by an independent observer prior to inclusion) entered a prospective, multicenter, randomized, parallel group, double-blind, placebo-controlled trial of 2 years duration. Patients had at least a 6-month history of regular pain and an algofunctional index (AFI) $>$ or $=$ 4. The primary assessment criterion was a decrease of the joint space width (JSW) on plain anteroposterior radiographs of the pelvis performed in standing position, measured at the narrowest points by 2 independent readers, previously tested and selected and blinded to both the treatment and the time sequence. Secondary criteria were standard clinical outcome measurements (AFI, pain on a visual analog scale, consumption of nonsteroidal antiinflammatory drugs and patient's and investigator's global assessments).

RESULTS: One hundred sixty-three patients were included: 102 men and 61 women (mean age 63.2 \pm 8.7 years). A total of 108 patients (72 men and 36 women; mean age 64 \pm 7.9 years) were radiologically evaluable at 23.7 \pm 2.6 months (ASU group; n = 55) and 23.7 \pm 3.2 months (placebo group; n = 53). Overall comparison of the evolution of JSW showed no difference between the ASU and placebo groups, from 2.35 \pm 0.93 to 1.87 \pm 1.10 mm and from 2.5 \pm 0.94 to 1.9 \pm 1.33 mm, respectively (intergroup P value at end point = 0.9). When patients were divided into 2 subgroups according to the median value of the baseline JSW (2.45 mm), the joint space loss in the most severely affected subgroup of patients (baseline JSW $<$ or $=$ median) was significantly greater in the placebo group than in the ASU group: from 1.69 \pm 0.58 to 0.84 \pm 0.77 mm (-0.86 \pm 0.62 mm) and from 1.66 \pm 0.42 to 1.22 \pm 0.7 mm (-0.43 \pm 0.51 mm), respectively (P $<$ 0.01). The JSW decrease was identical, with no difference in ASU and placebo groups, in the less severely affected subgroup of patients (baseline JSW $>$ median). Clinical parameters in the 2 groups did not differ significantly throughout the study. **CONCLUSION:** This pilot randomized, double-blind, placebo-controlled trial failed to demonstrate a structural effect of ASU in hip OA. However, in a post-hoc analysis, ASU significantly reduced the progression of joint space loss as compared with placebo in the subgroup of patients with advanced joint space narrowing. These results suggest that ASU could have a structural effect but require confirmation in a larger placebo-controlled study in hip OA.

Publication Types:

- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

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