ABSTRACT

OBJECTIVE
To assess the effects of the prescription formulation of glucosamine sulfate (1,500 mg administered once daily) on the symptoms of knee osteoarthritis (OA) during a 6-month treatment course.

METHODS
Three hundred eighteen patients were enrolled in this randomized, placebo-controlled, double-blind trial in which acetaminophen, the currently preferred medication for symptomatic treatment of OA, was used as a side comparator. Patients were randomly assigned to receive oral glucosamine sulfate 1,500 mg once daily (n = 106), acetaminophen 3 gm/day (n = 108), or placebo (n = 104). The primary efficacy outcome measure was the change in the Lequesne index after 6 months. Secondary parameters included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and response according to the Osteoarthritis Research Society International criteria. These outcome measures were assessed using an intent-to-treat analysis.

RESULTS
At baseline, the study patients had moderately severe OA symptoms (mean Lequesne index ~ 11 points). Glucosamine sulfate was more effective than placebo in improving the Lequesne score, with a final decrease of 3.1 points, versus 1.9 with placebo (difference -0.8 [95 % confidence interval -1.9, 0.3]) (p = 0.18). Similar results were observed for the WOMAC. There were more responders to glucosamine sulfate (39.6 %) and acetaminophen (33.3 %) than to placebo (21.2 %) (p = 0.004) and P = 0.047, respectively, versus placebo). Safety was good, and was comparable among groups.

CONCLUSION
The findings of this study indicate that glucosamine sulfate at the oral once-daily dosage of 1,500 mg is more effective than placebo in treating knee OA symptoms. Although acetaminophen also had a higher responder rate compared with placebo, it failed to show significant effects on the algofunctional indexes.