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**File: ■ Turmeric (*Curcuma longa*)
■ Boswellia (Indian Frankincense; *Boswellia serrata*)
■ Knee Osteoarthritis**

HC 101361-483

Date: October 31, 2013

RE: Turmeric and Boswellia Combination Reduces Knee Osteoarthritis Symptoms More Effectively than Celecoxib

Kizhakkedath R. Clinical evaluation of a formulation containing *Curcuma longa* and *Boswellia serrata* extracts in the management of knee osteoarthritis. *Mol Med Rep*. November 2013;8(5):1542-1548.

The degenerative joint disease osteoarthritis (OA) is physically debilitating and significantly impairs quality of life. As the cause of OA remains unknown, current medical treatment is directed towards alleviating pain and restoring movement using nonsteroidal anti-inflammatory drugs (NSAIDs). However, long term use of NSAIDs is associated with significantly increased risk of gastrointestinal, renal, and cardiovascular adverse effects. Turmeric (*Curcuma longa*) rhizome has been shown to have both anti-inflammatory and antioxidant activity. In clinical trials, boswellia (Indian frankincense; *Boswellia serrata*) gum resin has shown positive effects in treating both rheumatoid arthritis and OA. This randomized, observational trial tested the efficacy of a turmeric and boswellia (CB) combination in comparison to celecoxib (a standard NSAID) in alleviating the symptoms of knee OA.

The CB combination consisted of 350 mg of turmeric extract standardized to contain 70% curcumin, 17% demethoxycurcumin, 3.5% bisdemethoxycurcumin, and 7.5% turmeric essential oils, and 150 mg boswellia extract consisting of 75% boswellic acids and 10% 3-O-acetyl-11-keto-boswellic acid (AKBA). Although the turmeric constituent curcumin has been shown to have significant anti-inflammatory activity, oral bioavailability is very poor. A formulation providing improved curcumin bioavailability was used in this study. And while the boswellia constituent AKBA also has significant anti-inflammatory activity, the authors point out that most commercial boswellia extracts contain a relatively low concentration of AKBA (~2%). The boswellia extract used in this study was "enhanced" to contain 10% AKBA. The CB combination was provided in 500 mg capsules produced by Arjuna Natural Extracts Ltd.; Aluva, Kerala, India. No other information on the proprietary formula was provided.

In this 12-week study, conducted at Anugraha Medical Centre in Kochi, Kerala, India, 30 patients with OA were randomly assigned to receive either 500 mg of CB twice daily or

100 mg of celecoxib 2 times per day. The study included 8 clinic visits where vital signs, OA symptom scores, and physical exam results were recorded. Included patients were men and women between 18-65 years old diagnosed with moderate OA based upon radiographic evidence. Those with gross OA deformity, severe OA, severe swelling and restricted mobility, rheumatoid or reactive arthritis, other systemic diseases, malnutrition, history of alcohol or drug abuse, and breastfeeding women were excluded.

The OA symptoms scored were joint pain (no pain, mild, moderate, or severe), walking distance (greater than 1,000 m, 500-1,000 m, 100-500 m, or less than 100 m), joint tenderness (no tenderness, improved, same, or worsened), and crepitus or crackling sounds (no crepitus, mild, moderate, or severe). Knee swelling and thigh circumference were quantified using a measuring tape and range of movement was assessed in degrees using a goniometer. Joint warmth (yes, no) and gait (normal or abnormal) were also assessed. To evaluate safety, vital signs, hemogram (laboratory blood parameters), and liver and kidney function were measured at baseline, 6 weeks, and 12 weeks. The authors did not indicate whether they queried patients about possible adverse effects.

In total, 28 patients finished the study, with 1 patient from each group dropping out due to personal reasons or uncontrolled symptoms. At baseline, no significant differences were observed in age, height, weight, body mass index (BMI), temperature, blood pressure, pulse rate, or respiration between the groups. Although pain severity significantly improved from baseline to endpoint ($P < 0.05$) in both groups, no significant differences between groups were observed. However, the number of patients improved was markedly higher in the treatment group; 85.71% of patients were classified in the moderate/severe range at baseline, and at endpoint, only 21.43% of patients were in this category. In the control group, 78.57% of the patients had moderate/severe pain at baseline and 50% still had moderate/severe pain at the endpoint.

Improvement in walking distance was seen in both groups ($P < 0.05$), with 92.86% of those in the treatment group and 85.71% of those in the control group able to walk more than 1000 m at endpoint; however, there were no significant differences between groups. Also, both groups had significantly less joint tenderness at the end of the study ($P < 0.05$). In the treatment group, 85.71% had moderate/severe joint tenderness at baseline, and this decreased to 7.14% of patients at the end of the study. Patients in the control group showed a smaller improvement in joint tenderness, declining from 78.57% at baseline to 21.43% of patients after 12 weeks of treatment. Crepitus improved in both groups from baseline to endpoint ($P < 0.05$); there was also a significant beneficial effect seen in range of movement ($P < 0.05$) in both groups. Swelling, joint warmth, gait, and thigh measurements were not changed in either group. Vital signs, blood parameters, and liver and kidney function remained unchanged. No adverse effects were reported in either group.

The authors conclude that improvements in pain severity, walking distance, and joint tenderness were superior in those taking the CB supplement compared to the NSAID control medication and that CB was comparable to celecoxib in increasing range of movement and decreasing crepitus. They state, "The efficacy and tolerability of [the] CB formulation used in the current study was shown to be superior to those of celecoxib (NSAID) for treating active OA."

The authors hypothesized that the CB formulation would be as effective as celecoxib in reducing OA symptoms, and cause fewer adverse effects. While the effectiveness of the

2 treatments appeared to be comparable, no adverse effects were reported in either group. Studies with a larger sample size are needed to confirm the efficacy of CB and to detect differences in the occurrence rate of adverse effects.

—*Amy C. Keller, PhD*

The American Botanical Council has chosen not to include the original article.