

Rose Hip Reduces OA Hand Pain and Stiffness

BY PATRICE WENDLING

Chicago Bureau

CHICAGO — An herbal remedy made from a subspecies of rose hip (*Rosa canina*) significantly reduced pain in patients with osteoarthritis of the hand, compared with placebo, according to the results of a small, randomized controlled study.

The 32 patients in the study had osteoarthritis of at least one joint of the

hand and were randomized to treatment with either five capsules of 0.5 g standardized rose hip powder or identical placebo twice daily for 3 months, after which the study arms were switched and patients took the alternative treatment for an additional 3 months.

During the two treatment periods, 88% of patients taking active treatment reported a reduction in pain, compared with 36% of those taking placebo. Kaj. Winther, M.D., said in a poster presenta-

tion at the 2004 World Congress on Osteoarthritis. C-reactive protein (CRP) levels also fell with active treatment.

Dr. Winther and his and colleagues at University Hospital Rigshospitalet in Copenhagen began looking for an alternative pain medication for his elderly patients with cardiovascular disease and thrombosis who also suffered from osteoarthritis.

"Nonsteroidal, aspirin, Cox-2 [inhibitors], etc., all had their side effects, and did not go well with warfarin," Dr. Winther said at the congress, sponsored by the Osteoarthritis Research Society International.

In the current study, before and after each of the two treatment periods, patients evaluated their pain and stiffness while performing 1 of 15 different daily activities.

A 10-point scale was used to evaluate their pain, with a score of 10 being the most severe pain.

The mean age was 62 years, 28 patients were female, and all had a positive hand-grip test. Eight patients were taking NSAIDs, 16 patients regularly took acetaminophen.

Taking the mean of all 15 activity scores, pain was significantly reduced while on active treatment, compared with placebo (4.8 vs. 5.3, respectively).

Evaluation of stiffness showed a similar pattern of improvement (4.6 active treatment vs. 5.1 placebo).

The overall feeling of discomfort from the disease was significantly reduced from 5.8 at baseline to 4.6 while on active treatment, compared with 5.7 and 5.5 for the placebo group.

The treatment with LitoZin, the formulation used in the study, was associated with significant decreases in serum C-reactive protein levels below baseline levels (P value of less than .05). CRP levels fell from a range of 4-23 mg/L at baseline to a range of 3.8-16 mg/L after treatment.

LitoZin, which is manufactured by Dansk Droge Ltd., Ishøj, Denmark, and distributed in Europe, is expected to be marketed in 2005 in the United States by EuroPharma Inc., Green Bay, Wis.

Side effects were comparable with placebo, and no patients dropped out of the study, reported Dr. Winther.

Dr. Winther disclosed that he has no financial interest in the product. ■

and a one-year study of once weekly FOSAMAX® (alendronate sodium) 70 mg) the rates of discontinuation of therapy due to any clinical adverse experience were 2.7% for FOSAMAX 10 mg/day vs. 10.5% for placebo, and 6.4% for once weekly FOSAMAX 70 mg vs. 8.6% for placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in 2% of patients treated with either FOSAMAX or placebo are presented in the following table.

	Osteoporosis Studies in Men Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥2% of Patients			
	Two-Year Study		One-Year Study	
	FOSAMAX 10 mg/day (n=146)	Placebo % (n=95)	Once Weekly FOSAMAX 70 mg (n=108)	Placebo % (n=58)
Gastrointestinal				
acid regurgitation	4.1	3.2	0.0	0.0
flatulence	4.1	1.1	0.0	0.0
gastroesophageal reflux disease	0.7	3.2	2.8	0.0
diarrhea	3.4	0.0	2.8	1.7
abdominal pain	1.4	1.1	2.8	0.0
nausea	2.1	0.0	0.0	0.0

Prevention of osteoporosis in postmenopausal women

The safety of FOSAMAX tablets 5 mg/day in postmenopausal women 40-60 years of age has been evaluated in three double-blind, placebo-controlled studies involving over 1,400 patients randomized to receive FOSAMAX for either two or three years. In these studies the overall safety profiles of FOSAMAX 5 mg/day and placebo were similar. Discontinuation of therapy due to any clinical adverse experience occurred in 7.5% of 642 patients treated with FOSAMAX 5 mg/day and 7% of 648 patients treated with placebo.

In a one-year, double-blind, multicenter study, the overall safety and tolerability profiles of once weekly FOSAMAX 35 mg and FOSAMAX 5 mg daily were similar.

The adverse experiences from these studies considered by the investigators as possibly, probably, or definitely drug related in 1% of patients treated with either once weekly FOSAMAX 35 mg, FOSAMAX 5 mg/day or placebo are presented in the following table.

	Osteoporosis Prevention Studies in Postmenopausal Women Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥1% of Patients			
	Two/Three-Year Studies		One-Year Study	
	FOSAMAX 5 mg/day (n=842)	Placebo (n=848)	FOSAMAX 5 mg/day (n=361)	Once Weekly FOSAMAX 35 mg (n=362)
Gastrointestinal				
dyspepsia	1.9	1.4	2.2	1.7
abdominal pain	1.7	3.4	4.2	2.2
acid regurgitation	1.4	2.5	4.2	4.7
nausea	1.4	1.4	2.5	1.4
diarrhea	1.1	1.7	1.1	0.6
constipation	0.9	0.5	1.7	0.3
abdominal distention	0.2	0.3	1.4	1.1
Musculoskeletal				
musculoskeletal (bone, muscle or joint) pain	0.8	0.9	1.9	2.2

Concomitant use with estrogen/hormone replacement therapy

In two studies (of one and two years duration) of postmenopausal osteoporotic women (total: n=853), the safety and tolerability profile of combined treatment with FOSAMAX 10 mg once daily and estrogen + progestin (n=554) was consistent with those of the individual treatments.

Treatment of glucocorticoid-induced osteoporosis

In two, one-year, placebo-controlled, double-blind, multicenter studies in patients receiving glucocorticoid treatment, the overall safety and tolerability profiles of FOSAMAX 5 and 10 mg/day were generally similar to that of placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in 1% of patients treated with either FOSAMAX 10 mg/day (n=157), FOSAMAX 5 mg/day (n=161), or placebo (n=159), respectively, were: Gastrointestinal: abdominal pain (2.2%, 1.9%, 0.0%), acid regurgitation (2.5%, 1.9%, 1.3%), constipation (1.3%, 0.6%, 0.0%), melena (1.3%, 0.0%, 0.0%), nausea (0.6%, 1.2%, 0.6%), diarrhea (0.0%, 0.0%, 1.3%); Nervous System/Psychiatric: headache (0.6%, 0.0%, 1.3%).

The overall safety and tolerability profile in the glucocorticoid-induced osteoporosis population that continued therapy for the second year of the studies (FOSAMAX, n=147) was consistent with that observed in the first year.

Page's disease of bone

In clinical studies (osteoporosis and Page's disease), adverse experiences reported in 175 patients taking FOSAMAX 40 mg/day for 3-12 months were similar to those in postmenopausal women treated with FOSAMAX 10 mg/day. However, there was an apparent increased incidence of upper gastrointestinal adverse experiences in patients taking FOSAMAX 40 mg/day (17.7% FOSAMAX vs. 10.2% placebo). One case of esophagitis and two cases of gastritis resulted in discontinuation of treatment.

Additionally, musculoskeletal (bone, muscle or joint) pain, which has been described in patients with Page's disease treated with other bisphosphonates, was considered by the investigators as possibly, probably, or definitely drug related in approximately 6% of patients treated with FOSAMAX 40 mg/day versus approximately 1% of patients treated with placebo, but rarely resulted in discontinuation of therapy. Discontinuation of therapy due to any clinical adverse experience occurred in 6.4% of patients with Page's disease treated with FOSAMAX 40 mg/day and 2.4% of patients treated with placebo.

Laboratory Test Findings

In double-blind, multicenter, controlled studies, asymptomatic, mild, and transient decreases in serum calcium and phosphate were observed in approximately 18% and 10%, respectively, of patients taking FOSAMAX versus approximately 12% and 3% of those taking placebo. However, the incidences of decreases in serum calcium to <8.0 mg/dL (2.0 mM) and serum phosphate to <2.0 mg/dL (0.65 mM) were similar in both treatment groups.

Post-Marketing Experience

The following adverse reactions have been reported in post-marketing use:
Body as a Whole: hypersensitivity reactions including urticaria and angioedema. Transient symptoms of myalgia, malaise and rarely, fever have been reported with FOSAMAX, typically in association with initiation of treatment. Rarely, symptomatic hypocalcemia has occurred, generally in association with predisposing conditions.

Gastrointestinal: esophagitis, esophageal erosions, esophageal ulcers, rarely esophageal stricture or perforation, and oropharyngeal ulceration. Gastric or duodenal ulcers, some severe and with complications have also been reported (see WARNINGS, PRECAUTIONS, Information for Patients, and DOSAGE AND ADMINISTRATION).

Skin: rash (occasionally with photosensitivity), pruritus, rarely severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Special Senses: rarely uveitis, rarely scleritis.

For more detailed information, please read the complete Prescribing Information.

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Simple Trapeziectomy Sufficient For Thumb Osteoarthritis

BY NANCY WALSH

New York Bureau

NEW YORK — Simple trapeziectomy offers as much benefit as more complicated, combined procedures for osteoarthritis of the trapeziometacarpal joint, Timothy R.C. Davis, M.D., said at the annual meeting of the American Society for Surgery of the Hand.

Trapeziectomy has been widely performed for this condition since its use was first reported in 1949. It fell out of favor because it was perceived as having a protracted recovery, and there was a belief that the inevitable shortening of the thumb would weaken that digit.

Concerns about postoperative arthritis or instability that could lead to persistent pain led to modifications of the procedure, Dr. Davis said.

One approach was to do a tendon interposition after trapeziectomy, using the palmaris longus. A second alternative was to do the tendon interposition plus an additional ligament reconstruction, which is probably the most commonly used technique today, he said.

"But neither of these procedures has ever been demonstrated to produce better outcomes than simple excision of the trapezium," said Dr. Davis, professor of orthopaedics and accident surgery at the University of Nottingham (England).

A series of 183 thumbs in 162 women whose painful basal thumb osteoarthritis had not responded to medical therapy were

randomized to one of the three procedures.

Additional procedures such as carpal tunnel decompressions were performed as necessary. Following the surgery, each thumb was immobilized in a plaster of paris spica for 6 weeks.

Once the plaster was removed patients were encouraged to mobilize the thumb and were given physiotherapy as needed.

Subjective assessments included evaluation of pain, weakness, stiffness, and the ability to perform activities of daily living.

At 3 months about 50% of patients in all groups reported little or no pain, and by 1 year, 82% had reached this level of pain relief. "But the pain relief was not influenced by the type of operation—it was as if we had done the same operation in all the patients," Dr. Davis said.

By 1 year, 68% reported no weakness or interference with activities of daily living.

Mean thumb key pinch strength, evaluated with a pinch meter, improved significantly across all groups from 3.5 kg preoperatively to 4.6 kg at 1 year, but again the improvement was not influenced by the type of surgery performed, he said.

"In the short term at least, we concluded that palmaris longus interposition or ligament reconstruction did not improve the outcome of simple trapeziectomy with the insertion of a Kirschner wire and did not speed up recovery from the operation," Dr. Davis said.

Five-year follow-up is ongoing, but the results will have to wait until about 2007, he added. ■