

Yoga Alleviates Fibromyalgia-Related Pain, Fatigue

BY MIRIAM E. TUCKER
Senior Writer

VANCOUVER, B.C. — Yoga may be an effective adjunct to medical treatment for patients with fibromyalgia, Malinda L. Breda, Ph.D., reported at the annual meeting of the American Psychosomatic Society.

There are many reasons why yoga is an attractive treatment for fibromyalgia, which affects about 6 million Americans. Current therapies provide inadequate

symptom relief, and a recent metaanalysis concluded that optimal treatment regimens should include nonpharmacologic interventions such as exercise (Ann. Behav. Med. 1999;21:180-91).

But although conventional exercise can alleviate symptoms for some fibromyalgia patients, it actually worsens them in others, said Dr. Breda, of the California School of Professional Psychology, San Diego.

Of 38 adults who met the 1990 American College of Rheumatology criteria for

fibromyalgia, 19 were randomized to an experimental yoga group, and 19 controls were put on a waiting list. The yoga intervention consisted of 8 weeks of Classical Hatha Yoga, taught by a certified instructor who had experience with fibromyalgia patients.

The 90-minute sessions emphasized gentle poses and breath-work designed to match individual ability and were followed by relaxation/meditation exercises. Classes were conducted twice weekly, and subjects practiced at home with a video the other 5 days of each week. Class attendance was consistently high, with patients attending on average 14 of 16 sessions.

Compared with controls, significant improvements were seen in the yoga group on the Visual Analog Scale and the Pain Rating Index on Ranked values, both for pain; the Multidimensional Assessment of Fatigue scale; the Pittsburgh Sleep Quality Index; and the Fibromyal-



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gia Health Assessment Questionnaire.

The yoga group did not show significant improvements over time in disability, depression, or active coping scores. The control group showed no significant differences over time, except for worsening anxiety. ■

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=109)	Placebo % (n=58)
<i>Gastrointestinal</i>				
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
dyspepsia	3.4	0.0	2.8	1.7
diarrhea	1.4	1.1	2.8	0.0
abdominal pain	2.1	1.1	0.9	3.4
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 5.7% 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=642)	Placebo % (n=648)	FOSAMAX 5 mg/day % (n=351)	Once Weekly FOSAMAX 35 mg % (n=362)
<i>Gastrointestinal</i>				
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
<i>Musculoskeletal</i>				
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=354) 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 (3.2%; 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.

Paget's disease of bone

In clinical studies (osteoporosis and Paget'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 Paget'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 Paget'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 <4.0 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 rarely 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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Duloxetine Confirmed Effective For Fibromyalgia in Women

BY MIRIAM E. TUCKER
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VANCOUVER, B.C. — Duloxetine is a safe and effective treatment for fibromyalgia symptoms in both depressed and nondepressed women, Lesley Arnold, M.D., reported at the annual meeting of the American Psychosomatic Society.

Duloxetine (Cymbalta) is approved for the treatment of both major depression and diabetic neuropathic pain. The drug's efficacy in treating both pain and depression—which often co-occur in fibromyalgia—is probably due to its dual action as a selective serotonin and norepinephrine reuptake inhibitor, said Dr. Arnold, a psychiatrist who is director of women's health research at the University of Cincinnati.

In one of two 12-week studies funded by Lilly Research Laboratories, a total of 354 adult women who met the American College of Rheumatology's criteria for primary fibromyalgia were randomized to receive 60 mg of duloxetine once a day (118), 60 mg twice daily (116), or placebo (120).

Significant differences in the Brief Pain Inventory (BPI) average 24-hour pain score and the Fibromyalgia Impact Questionnaire (FIQ) were seen within 1 week in both the 60-mg/day and 120-mg/day duloxetine groups compared with placebo, with no significant difference between the two dosages.

In the low- and high-dose groups, 41% of patients experienced a 50% reduction in overall pain, compared with 23% of patients on placebo, Dr. Arnold reported.

Significant improvements over placebo were also seen in the FIQ total, pain, fatigue, and restfulness upon awakening scores; in the mean tender point threshold and number of tender points; in the Clinical Global Impression (CGI) and Patient Global Impression of Improvement (PGI) scores; in other BPI subscale measures of

pain severity and interference; and in several quality of life and functional measures.

This study replicated several findings from a previously-published trial of 207 fibromyalgia patients that included a small number of men. Dr. Arnold presented the findings of both trials together in a poster at the meeting.

In the earlier study, 104 patients (89% women) were randomized to 120 mg/day of duloxetine, and 103 (89% women) to placebo. Duloxetine patients improved significantly more than did placebo-treated patients on the FIQ total score, but not significantly more on the FIQ pain score (Arthritis Rheum. 2004;50:2974-84).

Duloxetine-treated patients also had significant reductions compared with placebo-treated patients in BPI scores for average pain severity and interference from pain, number of tender points, and FIQ stiffness, as well as several other fibromyalgia-specific and quality of life measures. The differences were only significant for women, but the number of men was quite small, Dr. Arnold noted.

Major depression was present in approximately 40% of the subjects in the earlier single-dose study and in about one-fourth of the subjects in the two-dose study. In both studies, there were no differences between depressed and nondepressed patients in duloxetine efficacy in alleviating pain and fibromyalgia symptoms, suggesting that these effects are not simply due to an improvement in mood, she noted.

In the first study, duloxetine was significantly more likely than placebo to be associated with side effects including constipation, dry mouth, insomnia, and a small mean increase in heart rate. These were typically mild to moderate in severity. Also in that study, anxiety was reported significantly less often with duloxetine than with placebo. ■