

# Irregular Menses Linked to Increased Heart Risk

BY MITCHEL L. ZOLER  
Philadelphia Bureau

ORLANDO — Postmenopausal women with a history of irregular menstrual cycles had a twofold increased risk of myocardial infarction and angina, compared with women with a regular menstrual history in a study with almost 700 patients.

"A history of menstrual cycling irregularity may be an important clinical marker of downstream risk, which is not immedi-

ately explained by the presence or severity of coronary artery disease risk factors or angiographic coronary artery disease," B. Delia Johnson, Ph.D., and her associates reported in a poster at the annual scientific sessions of the American Heart Association.

The analysis reported by Dr. Johnson, an epidemiologist at the University of Pittsburgh, and her coworkers included 686 postmenopausal women enrolled in the Women's Ischemia Syndrome Evaluation (WISE) study, which was funded by

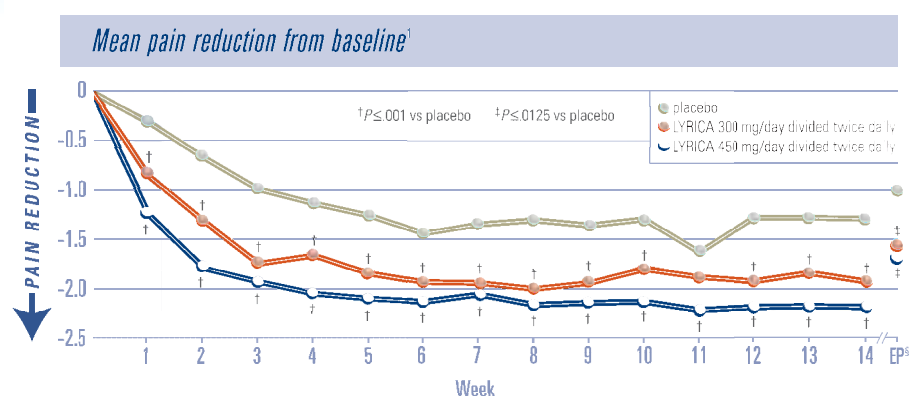
the National Heart, Lung, and Blood Institute and run at four U.S. centers. All the women in the study were scheduled to undergo coronary angiography because of clinical indications. Their average age was 62 years, and 42% of them had coronary artery disease diagnosed by their scheduled angiogram (at least one coronary artery with at least 50% stenosis). A history of abnormal menstrual cycling was reported by 19% of the women.

The rates of myocardial infarctions,

strokes, hospitalizations for angina, and total mortality were followed for an average of 5.9 years. In an analysis that adjusted for baseline differences in age, race, metabolic syndrome, severity of coronary disease, and serum level of C-reactive protein, women with a history of irregular menstrual cycles had about a 5% incidence of myocardial infarction, compared with about a 2.5% rate in women with a regular menstrual history, a statistically significant difference. ■

## t o L Y R I C A

### Rapid and powerful relief of chronic widespread pain<sup>1\*</sup>



Significant difference starting at Week 1 in some patients

Data on file<sup>1</sup>

\*Results from a 14-week, randomized, double-blind, placebo-controlled study of 745 patients to evaluate the efficacy and safety of LYRICA in Fibromyalgia. Criterion for entry into the double-blind phase was absence of a high placebo response ( $\geq 30\%$  decrease on the pain VAS) during the 1-week run-in phase. Patients received: LYRICA 300 mg/day (150 mg twice daily), 450 mg/day (225 mg twice daily), 600 mg/day (300 mg twice daily), or placebo. The primary efficacy measure was symptomatic relief of pain associated with Fibromyalgia.

Although LYRICA was also studied at 600 mg/day, there was no evidence that this dose confers additional benefit and this dose was less well tolerated. In view of the dose-dependent adverse reactions, treatment with doses above 450 mg/day is not recommended.

<sup>§</sup>End point (EP) mean pain score.

### Sustained relief of pain in a separate 6-month durability study<sup>11</sup>

<sup>11</sup>Results from a 26-week, double-blind, placebo-controlled, randomized discontinuation trial of 1051 patients designed to evaluate the time to loss of therapeutic response of LYRICA in Fibromyalgia patients. The study was comprised of 4 phases: baseline, open label, 26-week double-blind treatment, and 1-week follow-up.

#### Selected safety information:

The most common adverse reactions occurring in  $\geq 5\%$  of all LYRICA-treated patients and occurring at least twice the rate of placebo during Fibromyalgia clinical trials for patients taking LYRICA vs those taking a placebo were dizziness, somnolence, weight gain, blurred vision, dry mouth, constipation, euphoric mood, peripheral edema, balance disorder, disturbance in attention, and increased appetite.

Please see adjacent brief summary of prescribing information.

**LYRICA**<sup>®</sup>  
PREGABALIN<sup>®</sup>  
capsules