Teens' PMS Experience Mirrors That of Women

The worst symptoms among teens with PMS were identical to those reported in studies of women.

BY SHARON WORCESTER
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NEW ORLEANS — Premenstrual syndrome is common in adolescents, and symptoms are similar to those reported by women, a study suggests.

The findings debunk the "commonly accepted belief that adolescents suffer mostly from dysmenorrhea, and older women suffer mostly from PMS," Michelle D. Vichnin, M.D., said, noting that in her experience, teens do indeed suffer from PMS.

A total of 94 girls aged 13-18 years took part in the 6-month study during which they completed the Daily Symptom Report (DSR), a validated tool for measuring 17 PMS symptoms in women.

A total of 31% of the participants had self-reported and confirmed PMS; 54% had self-reported PMS, but did not meet the criteria for confirmed PMS; and 15% had no PMS, Dr. Vichnin reported during the annual meeting of the North American Society for Pediatric and Adolescent Gynecology.

Confirmed PMS was defined as a self-report of PMS along with a 50% increase in premenstrual vs. postmenstrual DSR scores, said Dr. Vichnin of the University of Pennsylvania, Philadelphia.

The worst symptoms among teens with PMS were mood swings, anxiety, irritability, food cravings, and increased appetite, swelling and/or bloating, and cramps. These symptoms are identical to those reported in studies of women with PMS, she noted.

As is also true in women, the greatest impact of these symptoms was on the home/family scale, she said.

In this study, older age and family history of PMS were significantly associated with PMS. Oral contraceptive use and dysmenorrhea were not associated with PMS.

Since these data suggest that PMS is the same condition in teens as it is in women, the next question is whether treatments shown to be effective in women would be effective in teens. Selective serotonin reuptake inhibitors (SSRIs), for example, have been shown to be quite safe and effective for PMS in women, but their use for this purpose in teens has not been well studied.

"So I would like to see a randomized placebo-controlled trial of SSRIs in adolescents with premenstrual syndrome," she said ■

Safety Review of Combination OC In Adolescents Raises No New Concerns

BY ELIZABETH MECHCATIE
Senior Writer

ROCKVILLE, MD. — No new safety concerns were raised by a review of adverse events reported during a recent 1-year period in adolescents taking a combination oral contraceptive, according to Jean Wendy Temeck, M.D., of the Food and Drug Administration's division of pediatric drug development.

The FDA's review of adverse events reported for Ortho Tri-Cyclen and Ortho Tri-Cyclen Lo, which contain norgestimate and ethinyl estradiol, was conducted between December 2003 and January 2005, the year after the FDA granted marketing exclusivity to the drug. Exclusivity is granted to a drug when companies perform pediatric studies of the product in exchange for a 6-month extension on the patent for the drugs.

Despite the fact that there were reports of some serious adverse events during this period, 'no pattern of new safety concerns' was identified.

In this case, the drug manufacturer, Ortho-McNeil Pharmaceutical Inc., which is based in Raritan, N.J., conducted a placebo-controlled study to determine whether the oral contraceptive improved bone density in adolescent girls who had been diagnosed with anorexia nervosa. The study showed no differences from placebo in increases in hip and lumbar-spine bone mineral density following 1 year of treatment.

Dr. Temek reported the findings at a meeting of the FDA's Pediatric Advisory Committee. The Best Pharmaceuticals for Children Act requires that the FDA's Office of Pediatric Therapeutics review postmarketing adverse event reports made to the FDA's MedWatch adverse event reporting system during the year after a drug receives exclusivity. These reports are then referred to the Pediatric Advisory Committee for a review.

The uses of Ortho Tri-Cyclen for female patients at 16 years of age and younger include dysfunctional uterine bleeding and acne, she said. During the postexclusivity period (Dec. 18, 2003, through Jan. 18, 2005) there were 14 unduplicated pediatric adverse event reports associated with Ortho Tri-Cyclen, including 11 serious reports and no deaths.

The 14 reports included 12 cases in adolescent girls and 2 cases involving infants that had been exposed in utero. Adverse events that were reported more than once were headaches and metrorrhagia, events that are listed in the label of Ortho Tri-Cyclen, and convulsions, an adverse event that is not in the label.

There were four hospitalizations, which included the two in utero exposures. The other two hospitalizations were in a 16-year-old patient with benign intracranial hypertension, an increase in cerebrospinal fluid pressure, and a visual field defect; and in a 14-year-old patient who had cerebral thrombosis and headache. These two patients also were using isotretinoin.

A third patient who was also on isotretinoin, as well as prednisone, was reported to have depression, dizziness, and headache, which are unlabeled events for the oral contraceptive; other symptoms included decreased interest, insomnia, and panic attack.

The labels for isotretinoin and prednisone include the possible risk of increased intracranial pressure, depression, insomnia, emotional instability, dizziness, and headache, Dr. Temeck noted.

Of the two infants who were exposed in utero, one was in a breech presentation and born prematurely, and the baby's mother also had taken penicillin, betamethasone, and alprazolam while pregnant. The second exposed infant was reported to have cerebral artery occlusion, convulsion, apnea, and developmental delay.

There were three adolescents who did report visual adverse events, which are not mentioned in the Ortho Tri-Cyclen product label: a 14-year-old patient also on oxcarbazepine who was reported to have papilledema and cluster headache; a 16-year old patient also on doxycycline and tretinoin, who experienced scotoma, blurred vision, headache and influenza-like illness; and a 16-year old patient also on isotretinoin and prednisone, who had a visual-field defect, in addition to benign intracranial hypertension and increased cerebrospinal fluid pressure. (The label for Ortho Tri-Cyclen does contain a warning of retinal thrombosis.)

The other two serious adverse events that were reported were in one 14-year-old who developed hypertension and another 14-year-old who has dysarthria and hypoesthesia—two events that are not included on the label. Convulsions also were reported in a 15-year-old who had a history of intermittent seizures.

Despite the fact that there were reports of some serious adverse events during this period, "no pattern of new safety concerns" was identified, Dr. Temeck said. Based on the presentation, the advisory panel agreed with the FDA that monitoring of adverse events for these oral contraceptives could be switched to regular monitoring. ■

Health care professionals and consumers can report any drug- or device-related adverse events to MedWatch by calling 800-332-1088, sending a fax to 800-332-0178, writing to MedWatch, Food and Drug Administration, 5600 Fishers Ln., Rockville, MD 20857-9787; or visiting www.fda.gov/medwatch.

Women Over 55 Lack HPV Risk Markers

VANCOUVER, B.C. — There's no easy way to identify older women whose risk for human papillomavirus infection is low, so physicians should continue cervical screening unless the woman has tested negative consistently for the virus, Concepcion Diaz-Arrastia, M.D., and her associates advised in a poster presentation at the 22nd International Papillomavirus Conference.

Nineteen (11%) of 176 women older than 55 years tested positive for infection with high-risk or intermediate-risk types of the human papillomavirus (HPV) in a prospective, longitudinal study, they reported at the conference, sponsored by the University of California, San Francisco.

"High-risk HPV infection is not restricted to young women," said Dr. Diaz-Arrastia of the University of Texas, Galveston, and her associates.

All the women completed a detailed medical and sexual history form and underwent a pelvic exam that included a liquid-based cervical sample and HPV test. The study found no clear social markers of risk for HPV infection in this group of older women, whose mean age was 67 years. " 'Low risk' may be more difficult to establish in this age group," the investigators concluded.

More than a third of the HPV-positive women said they had been sexually inactive for more than the past 5 years. There were no significant differences between the HPV-positive and HPV-negative women in terms of the traditional social risk factors for cervical neoplasia, including a history of first sexual activity before age 16, number of sexual partners in their lifetimes, presence of other sexually transmitted disease, history of sexual abuse, or smoking habits.

Pap smear results also did not correlate with risk for HPV infection. In the HPV-positive group, two women had atypical squamous cells of undetermined significance (ASC-US), and one woman had low-grade squamous intraepithelial lesions (LSIL). In the HPV-negative group, Pap results showed ASC-US in five women and LSIL in one woman. Stratified by race, 4% of 113 Hispanic women were HPV positive, as were 23% of 43 non-Hispanic white women and 25% of 20 African American women, the investigators reported.

—Sherry Boschert