Oral Contraceptive Builds Bones in Anorexic Teens

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LOS ANGELES — The oral contraceptive Ortho Tri-Cyclen may help teenaged girls with anorexia nervosa build bone mass as a defense against osteoporosis later in life.

Compared with placebo, it produced significantly greater increases in mean bone mineral density (BMD) of the lumbar spine during a 123-patient, double-blind, randomized trial reported at the annual meeting of the Society for Gynecologic Investigation.

This advantage was significant in 88 teenagers who completed the 13-cycle trial, but did not endure beyond 6 months in 112 girls who comprised an intent-to-treat population. Increases in hip BMD were not significantly different at 6 months or 1 year.

"Treatment of adolescent females with anorexia nervosa may improve lumbar spine but not total hip [BMD] in subjects treated for at least 12 cycles," investigator Andrew Friedman, M.D., concluded.

Dr. Friedman is senior director of clinical research at Johnson & Johnson Pharmaceutical Research and Development in Raritan, N.J., which sponsored the study.

A subsidiary, Ortho-McNeil Pharmaceutical Inc. manufactures Ortho Tri-Cyclen.

Although no other oral contraceptives were tested, Dr. Friedman acknowledged that some might offer a similar benefit for this population.

In the intent-to-treat population, average lumbar spine BMD increased 2.4% at 6 months for girls on Ortho Tri-Cyclen, but only 1% for the placebo group.

Among the subjects who completed the trial, average lumbar spine BMD increased 3.1% at 6 months and 4.5% at 1 year for those on the contraceptive.

BMD only increased 1.1% and 2.8%, respectively, in the placebo group.

All subjects received calcium and vitamin D, and both groups gained weight during the trial.

Safety data for the 123 enrollees showed adverse events to be similar for both cohorts, except for worsening of anorexia nervosa. Eleven girls on placebo and 3 on Ortho Tri-Cyclen were hospitalized for relapses.

"To treat the whole patient, [oral contraceptive] is not a substitute for counseling and other types of therapy, but it serves as an important adjunct to improve their [BMD] and maximize their peak bone mass," Dr. Friedman said in an interview.

Use of oral contraceptives for at least 12 cycles in adolescent girls with anorexia nervosa may improve lumbar spine but not total hip bone mineral density.

The study enrolled postmenarcheal patients up to age 17 years at 91 sites. Their average age was 15 years, and their mean body mass index was below 18.

Dr. Friedman said 10% had primary amenorrhea attributable to anorexia nervosa, and 90% had secondary amenorrhea. Almost all participants were white.

In the interview, he said the girls were advised to use an additional form of contraception if sexually active in case they began to menstruate during the study.

Some parents declined to allow their minor daughters to participate because the protocol called for birth control, he noted.

Another barrier to recruitment cited in his talk was the girls' concern about possible weight gain from the pill. "We had to disclose the pills had 0.4 calories per pill," he said.

As endogenous estrogen is known to help build bones in puberty, Dr. Friedman said the investigators hypothesized that estrogen in the contraceptive pill would play a similar role in these girls.

In adults, he said there is conflicting data on whether a combination of estrogen and progesterone would build bone density.

The oral contraceptive had not been previously tested in adolescents with anorexia nervosa, according to Dr. Friedman.

"I wouldn't advocate birth control pills for all anorexia nervosa subjects, but it may be appropriate for some subjects, and that is really a clinical decision," he noted during his presentation. ■

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