## **ASRM Promotes Earlier Infertility Intervention**

BY ALICIA AULT
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NEW ORLEANS — The American Society for Reproductive Medicine, in collaboration with the Society for Reproductive Endocrinology and Infertility, is revising its definition of infertility to encourage earlier evaluation of women aged over 35 years who have difficulty conceiving.

The new definition, along with a new definition of recurrent pregnancy loss, will be published in the June issue of Fertility and Sterility, Dr. Marc Fritz said at the annual meeting of the American College of Obstetricians and Gynecologists.

ASRM members requested the new definitions, in part because insurers were adhering strictly to the existing guidelines, leading to a denial of access to appropriate treatment, Dr. Fritz said in an interview.

Infertility specialists say that the changes give credence to what's been standard practice in their field. The real impact should come from the word getting out to general ob.gyns. and family physicians, Dr. Eric Surrey, medical director of the Colorado Center for Reproductive Medicine in Lonetree, said in an interview. "This message is meant for the generalist, not

the reproductive endocrinologist," Dr. Masood Khatamee of New York University said in an interview. "And it's a very, very appropriate statement," he said.

Dr. Fritz agreed that the ASRM was aiming for a broader audience. He said the ASRM will urge early evaluation and treatment of all women based on natural history and physical findings after a failure to achieve pregnancy following at least 12 months of regular unprotected intercourse. Treatment and evaluation will be warranted after 6 months for women aged over 35 years.

The ASRM also for the first time is specifically defining recurrent pregnancy loss as a disease distinct from infertility, said Dr. Fritz, professor of obstetrics and gynecology and division chief of reproductive endocrinology and infertility at the University of North Carolina at Chapel Hill. It will be defined by two or more failed pregnancies; these pregnancies must be documented by ultrasound or pathologic examination. When the cause is unknown, each pregnancy loss merits careful review to determine whether specific evaluations may be appropriate, said Dr. Fritz. After three or more losses, a thorough evaluation is warranted, he said.

Dr. Charles Miller, an infertility specialist in Chicago, said the ASRM "has thrown [its] weight behind what we in the field have done for a while."

The clear statements on both infertility and recurrent pregnancy loss may also

help convince insurance companies to cover evaluation and treatment in instances where they haven't in the past, Dr. Miller said in an interview.

Dr. Surrey agreed that the statements could

be helpful for reimbursement. For instance, insurers often consider recurrent pregnancy loss to be a form of infertility, which is inappropriate and untrue, he said in an interview.

He said he was encouraged by the statement on infertility, noting that it will heighten patient and physician awareness

that earlier evaluation is important. He said women are often told they have plenty of time to conceive. "That's not what they want to hear," he said.

The 6-month cut-off for women aged over 35 is a somewhat arbitrary figure, but

The ASRM favors early evaluation and treatment based on natural history and physical findings.

DR. FRITZ

is necessary to prompt quicker action, said Dr. Surrey. The earlier evaluations may result in more findings of no abnormalities, but at least women will be reassured that they aren't wasting their

time if they are told to spend another 6 months trying to conceive, he said.

Dr. Khatamee said he tells other physicians and medical students that a woman's age is a key deciding factor when evaluating infertility. Women over age 35 should not be told to spend a year trying to conceive, he said.



## Bisphosphonates Help After Androgen Deprivation Begun

BY SHERRY BOSCHERT
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SAN FRANCISCO — Zoledronic acid therapy increased bone mineral density in men with nonmetastatic prostate cancer even when started more than a year after initiation of androgen deprivation therapy, Dr. William R. Broderick reported at a symposium on genitourinary cancers.

The double-blind study included 93 men with nonmetastatic prostate cancer who were initiating or already on androgen deprivation therapy (ADT). The patients were randomized to receive four courses of 4 mg IV of the bisphosphonate zoledronic acid at 3-month intervals or intravenous placebo therapy on the same schedule. All patients had bone mineral density T scores at or below –2.0 at baseline. Their bone densities in the lumbar spine, hips, and femoral necks were checked at 6 and 12 months by dual-energy x-ray absorptiometry (DXA) scans.

Among 50 men who had been on ADT for less than 1 year, spinal bone mineral density increased by 6% in the 26 randomized to zoledronic acid therapy and decreased by 3% in 24 men randomized to placebo. Among 43 men who had been on ADT for 1 year or longer, spinal bone mineral density increased by 6% in the 22 randomized to zoledronic acid therapy and by 2% in 21 men randomized to placebo, Dr. Broderick said at the symposium, which was sponsored by the American Society of Clinical Oncology, the American Society for Therapeutic Radiology and Oncology, and the Society of Urologic Oncology.

Spine density results differed significantly between the zoledronic acid and placebo groups, but did not between patients stratified by their amount of time on ADT, said Dr. Broderick of the Veterans Affairs Hospital in Hines, Ill., and of Loyola University Chicago, Maywood.

The study was funded by Novartis, which markets zoledronic acid as Zometa.

Androgen deprivation therapy for prostate cancer has been associated with increased risks for osteoporosis and fracture. Previous studies have shown that initiating bisphosphonate therapy when starting ADT can delay the development of osteopenia or osteoporosis, but no studies have looked at starting bisphosphonate therapy in these patients after they've been on androgen deprivation therapy for more than a year.

"It makes sense conceptually, but we never had the data to show it. Now we do," Dr. Broderick said at his poster session. The current results also suggest that "perhaps we don't need to start bisphosphonate therapy up front in everyone," which could save some expense and avoid side effects, he added. "Perhaps we can delay bisphosphonate therapy in these patients until we are starting to see that they are becoming osteopenic."

The study was not designed to identify the best timing for starting bisphosphonate therapy in men on ADT, "but it does give us evidence that zoledronic acid works if we do start it at a later point in time" than usual, he said.

All the men in the study were started on 1,000 mg/day of supplemental calcium, 400 IU/day of vitamin D, counseling, weight-bearing exercise, and smoking cessation programs (if applicable). Demographics and other characteristics were similar between the group on androgen deprivation therapy for less than 1 year and the group with 1 or more years of ADT, except that those on ADT were significantly older—72 years, compared with 69 years.

