

Ibandronate Stops Bone Loss in Breast Ca Patients

BY MICHELE G. SULLIVAN
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SAN ANTONIO — Monthly ibandronate appears to prevent, and perhaps even reverse, bone loss in women who are taking anastrozole for estrogen receptor-positive breast cancers, Dr. J.E. Lester reported in a poster presentation at the Sixth International Meeting on Cancer-Induced Bone Disease.

While she said that further follow-up is required, her randomized placebo-controlled trial showed that after 1 year, women taking the bisphosphonate showed a significant increase in bone mineral density (BMD) at both the hip and spine, while those taking the placebo experienced a significant decrease at both sites.

Dr. Lester, of the Cancer Research Centre of Weston Park Hospital, Sheffield, England, examined ibandronate's effects in 131 postmenopausal women who had es-

trogen receptor-positive breast cancer.

The women were grouped according to baseline BMD: 68 had normal BMD (mean age 63 years), 50 were osteopenic (mean age 67 years), and 13 were osteoporotic (mean age 71 years).

All patients were taking calcium and vitamin D supplements in addition to anastrozole. Those with normal BMD continued on the supplements.

Osteopenic patients were randomized to either 150 mg oral ibandronate every 28 days (25 patients) or placebo (25 patients). All osteoporotic women received the same monthly ibandronate treatment.

Ibandronate significantly increased BMD at the hip and spine in both treated groups. At 1 year, osteopenic women had a mean increase of 2.8% at the lumbar spine and 1.4% at the hip. After 1 year, five of the previously osteopenic women were found to have normal BMD.

Women in the placebo group had a decrease of BMD at both sites (mean -2.6%

BMD Status of Patients After 1 Year

| Treatment | Normal | Osteopenia | Osteoporosis | Withdrawal |
|---------------------------------------|--------|------------|--------------|------------|
| Ibandronate for osteopenia (n = 25) | 5 | 18 | 0 | 2 |
| Placebo for osteopenia (n = 25) | 0 | 23 | 2 | 0 |
| Ibandronate for osteoporosis (n = 13) | 0 | 7 | 5 | 1 |

Source: Dr. Lester

at the lumbar spine and -2.3% at the hip).

During the blinded period, two osteopenic patients lost more than 10% of their BMD at either the spine or hip. They were withdrawn from the study and unblinded; both had been taking the placebo and both were offered open-label ibandronate.

Among the osteoporotic women, the mean increase in BMD was 2.6% at the lumbar spine and 2.6% at the hip. Seven

previously osteoporotic patients were found to be osteopenic at 1-year follow-up.

Of the 68 women with initially normal BMD who had not been treated with ibandronate, 20 were followed for 2 years.

Follow-up scans showed a mean decrease in BMD of -4% at the lumbar spine and -3% at the hip.

Despite these changes, however, none of the women who had not been treated with ibandronate developed osteoporosis. ■

PCR-Based Lymph Node Assay Is More Sensitive Than Old Intraoperative Tests

BY BRUCE JANCIN
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SAN ANTONIO — A new PCR-based assay is substantially more sensitive than current methods of intraoperative detection of breast cancer nodal metastases—and that translates into less need for second lymph node procedures, Dr. Peter W. Blumencranz said at a breast cancer symposium sponsored by the Cancer Therapy and Research Center.

"Secondary surgery on the axilla increases costs, causes time and scheduling problems, and most importantly adds to the physical and emotional burden on the patient," noted Dr. Blumencranz, medical director of comprehensive breast health services at Morton Plant Mease Health Care, Clearwater, Fla.

The GeneSearch Breast Lymph Node (BLN) assay measures expression levels of two markers of nodal metastases: mammaglobin and cytokeratin 19. The thresholds employed in the assay reliably permit identification of metastases larger than 0.2 mm (those deemed clinically significant in guidelines) while disregarding smaller ones.

Dr. Blumencranz presented data from a multicenter prospective study comparing the BLN assay's performance with the standard intraoperative tests: frozen section and touch preparation cytology.

The yardstick for comparison was permanent section hematoxylin and eosin histology, which is considered the preferred method in terms of accuracy, although results take several days. The study population consisted of breast cancer patients without clinically evident metastases who underwent sentinel lymph node biopsy—the standard of care in staging the axilla.

The BLN assay outperformed frozen section in terms of sensitivity by an absolute 10% and touch prep by an even wider margin while maintaining high specificity. (See graph, right.)

Noting other advantages of the assay, Dr. Blumencranz said that it can be performed by a technician with minimal training, and that it samples 50% of the node, compared with the

2%-5% sampled with permanent section histology. Six nodes can be sampled in a single run.

It takes 35-40 minutes from the time a surgeon removes the sentinel node for the BLN assay to yield a yes/no answer. A pathologist in the audience at the symposium argued this is an inefficient use of time, since the BLN test takes three times as long as a frozen section.

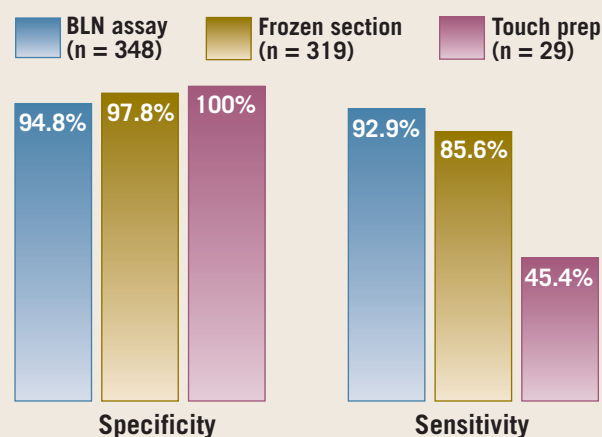
Dr. Blumencranz replied that a frozen section requires 20-25 minutes at most centers. He added that the cost of the extra 10-15 minutes in the operating room is more than offset by the savings accrued from reducing the number of reoperations needed when a sentinel node biopsy comes up positive by permanent section histology several days after a negative intraoperative frozen section or touch prep.

The comparative study was sponsored by Veridex LLC, a Johnson & Johnson company.

The BLN assay became commercially available in the European Union in November 2006, and a Food and Drug Administration advisory panel recommended its approval at that time.

Dr. Blumencranz has received research support from Veridex. ■

Head-to-Head Comparison Of Lymph Node Tests



Source: Dr. Blumencranz

Abortion-Breast Ca Tie Disproven Again

Neither spontaneous nor induced abortion appear to be related to breast cancer risk in premenopausal women, according to a retrospective study of data from the Nurses' Health Study.

"The association between abortion and breast cancer has previously been considered in numerous studies," with conflicting results, Karin B. Michels, Ph.D., of Harvard Medical School, Boston, and her associates wrote. About half of the studies of induced abortion have found an increased risk of breast cancer, while the rest have found either no association or an inverse association. Most studies of spontaneous abortion have found no link with breast cancer risk.

The investigators reviewed about a decade's worth of relevant data from the Nurses' Health Study (NHS) and reported their results in the Archives of Internal Medicine.

The NHS is an ongoing cohort study of the associations between lifestyle factors, reproductive factors, and breast cancer and other major illnesses. The first biennial NHS survey in 1989 involved more than 100,000 female registered nurses aged 25-42 years in 14 states.

Information on induced and spontaneous abortions was first obtained in 1993. Dr. Michels and her associates assessed breast cancer incidence in 105,716 of the subjects who provided that information and were followed for approximately 10 years. Of these women, 15% reported that they had had one or more induced abortions and 21% reported that they had had one or more spontaneous abortions.

A total of 1,458 newly diagnosed cases of invasive breast cancer developed during follow-up. There was no association between induced abortion and breast cancer risk. There was a suggestion of an inverse association between spontaneous abortion and risk, but that may have been because of chance, the investigators said (Arch. Intern. Med. 2007;167:814-20).

"Breast cancer cases in our study population were almost exclusively premenopausal; therefore, our results may not be generalizable to postmenopausal women," they noted.

In 2003, the summary report of a National Cancer Institute international expert panel concluded that the evidence to that date showed no link between induced abortion and breast cancer risk.

—Mary Ann Moon