VOLUME XXIV NO. 1 / JANUARY 2002

Page 27
ABSTRACT TRACKER: Age Limit for Adjuvant Therapy in Older Colon Cancer Patients

Page 41
ODAC Discusses PathVysion Assay, Camptosar, & Gliadel Wafers

Page 52
SPECIAL REPORT: Insomnia in Cancer Patients

Page 63
Agent Orange Link to AML in Vietnam Veterans' Children Remains Complex

ONCOLOGY TIMES

LIPPINCOTT WILLIAMS & WILKINS

THE INDEPENDENT NEWSPAPER FOR CANCER SPECIALISTS

AMA Decries Lack of Competition in US Health Insurance

By Peggy Eastman

WASHINGTON, DC—The American Medical Association released a new study, which it claims is the most extensive of its kind, at a news briefing here in November showing that many US markets have a few dominant health insurers who have "excessive leverage" over doctors and patients, in the AMA's words. But the Health Insurance Association of America (HIAA) said the study "creates a red herring" to get legislation passed giving doctors antitrust relief when negotiating with health plans, which the AMA favors.

The study, done with the help of consulting health economist Stephen Foreman, PhD, JD, shows that almost half of all Americans receive coverage from the 10 largest health insurers, said Donald J. Palmisano, MD, JD, AMA Secretary-Treasurer.

MAJOR FINDINGS OF THE AMA STUDY

- Almost half (19) of the **metropolitan statistical areas** —defined as populations greater than one million—have **highly concentrated HMO/PPO markets.**
- Each of the 19 HMO/PPO metropolitan statistical areas has at least **one insurer** with a **market share that is greater than 30%.**
- Some 84% of **less-populated states** have combined HMO/PPO state-level markets that are **highly concentrated.**
- **Each** of the highly concentrated state-level HMO/PPO markets includes an **insurer with a market share greater than 30%.**
- Some **62%** of the highly concentrated state-level HMO/PPO markets include an **insurer with a market share greater than 50%.**

Source: Competition in Health Insurance: A Comprehensive Study of US Markets, AMA, 11/01

Dr. Foreman said the study is the first comprehensive survey to include preferred provider organizations (PPOs) as well as health-maintenance organizations (HMOs).

The survey, which covers 46 states and 40 metropolitan areas across America, shows that in a number of markets a single insurer has a market

(continued on page 30)

Reduced-Intensity Stem Cell Transplants Open New Anticancer Possibilities

By Robert H. Carlson

Progress in reduced-intensity, nonmyeloablative stem-cell transplants (NST) in hematologic malignancies is not only good news for people with leukemia, but it may also lead to a new approach for solid tumors as well.

Unlike standard stem cell transplantation, the NST regimen is not designed to kill all cancer cells directly, but rather to use the graft to stimulate an immune response in the host.

Fewer than 500 NSTs have been performed in the US and Europe so far, said Rainer F. Storb, MD, Head of the Program in Transplantation Biology at Fred Hutchinson Cancer Research Center and Professor of Medicine at the University of Washington in Seattle, a pioneer in transplant medicine and particularly in the new field of NST.

(continued on page 21)

A Calendar of Diseases:

If It's January, It Must Be National Alzheimer's Disease Month

By Joan Klein

As the New Year begins, so does the now familiar cycle of months, weeks, and days that single out specific diseases for special recognition. In January the focus is on Alzheimer's disease, but few, if any, months go by any more without calling attention to at least one medical condition, and usually more.

Oncology and oncology-related fields are exceedingly well represented in this redrawn calendar. The idea, which was the brainchild of the American Cancer Society, began in the 1970s with Cancer Recognition Week. Grad-

(continued on page 50)

OT INSIDE

RSNA Annual Meeting

Brachytherapy Proposed as Alternative to Standard Adjuvant Radiotherapy for Non-Invasive Breast Cancer

By Peggy Peck

CHICAGO—Brachytherapy may soon become a widely available therapeutic option for early non-invasive breast cancer. That was the word from researchers presenting studies of two brachytherapy approaches—including one that features one-dose intraoperative irradiation—here at the Radiological Society of North America Annual Meeting in November.

Martin E. Keisch, MD, of Mount Sinai Medical Center in Miami Beach reported that five days of treatment with a balloon catheter device called MammoSite could deliver a total dose of 34 Gy. At that dose, he said, the five-day, twice-daily treatments can replace the standard six-week course of radiation therapy for women with early stage non-invasive breast cancer.

Likewise, Euan S. Thomson, PhD, said a single treatment with a portable electron-beam device called Intrabeam at time of surgery, "while the patient is still asleep on the table," is as effective as standard external-beam radiation treatment. Dr. Thomson, now President and CEO of the device's manufacturer, Photoelectron Corporation of Lexington, MA, helped develop Intrabeam while on staff at University College London Medical School.

Frank L. Hussey Jr., MD, of Lutheran General Hospital of Park Ridge, IL, said the interest in brachytherapy for non-invasive breast cancer is relatively recent. "These studies look encouraging, but we really need large cooperative trials to confirm the efficacy and to compare the radiobiologic effect of this treatment to external-beam treatment," he said.

Dr. Keisch said the MammoSite catheter is much more user-friendly than brachytherapy delivered with injections, because seeding requires not only careful placement of needles but also a complicated calculation of dosing.

Dr. Hussey, who was not involved in the studies, is a spokesperson for RSNA and said he uses brachytherapy to treat prostate cancer.

Dr. Keisch said the MammoSite catheter is much more user-friendly than brachytherapy delivered with injections, because seeding with injections requires not only careful placement of needles but also a complicated calculation of dosing. The steep learning curve has made some radiation oncologists reluctant to pursue brachytherapy, he explained at a press briefing. "But, MammoSite is so simple that I can train a monkey to implant it and to calculate the dose."

The deflated MammoSite is surgically implanted in the area from which the tumor has been excised. It is then inflated with saline. Twice a day, a radioactive seed attached to guide wire is advanced through the catheter into the balloon, and it "bathes the area with radiation," he noted. "Because much less tissue volume is irradiated, achieving a therapeutic dose takes much less time than standard radiotherapy. Each treatment takes about three or four minutes."

He presented results from 28 women treated with MammoSite. "We have had no single recurrence of breast cancer," he said, cautioning, however, that the results are still very early.

Most women had the device implanted under local anesthesia—although a few requested general anesthesia, he said.

Well Tolerated

While the device is implanted, the women have a small port extruding from the breast, but he said this is well tolerated. Side effects related to radiation were generally mild and included erythema, pain, and dry desquamation. "When the device is removed, it leaves a scar smaller than the tip of my pinky," Dr. Keisch said. One patient developed a post-explantation abscess that required drainage and antibiotics.

He said the device could be implanted at time of surgery but that he recommends waiting for pathology—"to be sure that you don't have nodal involvement."

Dr. Keisch said he has implanted the device as early as a few days after lumpectomy up to about eight weeks postsurgery. Waiting longer than eight weeks is not advised, because the breast begins to close up the excision site.

Although the study presented at RSNA included only 28 women, he said 43 women have now been successfully treated with MammoSite.

Dr. Thomson said his team takes a different approach, implanting Intrabeam "during surgery so we can avoid a second procedure." This device is also implanted into the excision site and delivers radiation for about 20 to 30 minutes.

"Both of these approaches reflect the growing feeling among radiation oncologists that it may be sufficient to give a localized dose rather than standard therapy," Dr. Thomson said. He presented findings from a study of 29 women who had breast-conserving surgery for lesions of 3.5 cm or smaller. The principal investigator for the study was Jeffrey Tobias, MD, Consultant Radiation Oncologist at University College London Medical School.

In the study 15 women were treated with Intrabeam and 14 with standard six-week radiation treatment. After 18 months no women in either group had a recurrence, Dr. Thomson reported.

The device is already approved by the FDA, he noted, adding that radiation oncologists at the Cleveland Clinic Foundation and New York Medical College are using the device as "a booster treatment—they irradiate at time of surgery and then follow up with standard radiation treatment."

Dr. Keisch said the maker of MammoSite—Proxima Therapeutics, Inc., of Alpharetta, GA—expects the Food and Drug Administration to approve the device early this year. He predicted that it would cost 25 to 30 percent less than standard radiation therapy. Dr. Thomson said he had no cost data on Intrabeam.

Both studies were funded by the devices' manufacturers, Proxima and Photoelectron. ■

Abstract Tracker

continued from page 27

One clear concern is that comorbidities are much more likely in older patients. His group at Mayo has developed an increasing interest in the comorbidities issue, he said, and he and Drs. Sargent and Jacobson are awaiting approval of a grant proposal for young investigators submitted to the American Cancer Society. If funded, that grant would allow conducting a study of older patients with upper gastrointestinal cancers.

The group plans to take what they have learned in colon cancer and find out whether the same lessons about chemotherapy could be applied in upper GI cancers.

In the meantime, the meta-analysis now gives clinicians an additional factor to help patients weigh their odds when deciding about adjuvant chemotherapy.

Dr. Goldberg cautioned against overgeneralizing the results of the analysis. It is important, he said, to remember that patients enrolled in the seven trials were preselected by their doctors.

"It is unlikely that people who were not very robust would have been offered the opportunity to enroll in a study like this. So what this [meta-analysis] says is that as long as you select your septuagenarians or octogenarians carefully, you can give this treatment and get benefits from it."

Most patients, he said, already do a life table analysis in their heads when told they may get a 2% difference in five-year survival with chemotherapy compared with no chemotherapy in Stage II disease. A 40-year-old patient may typically conclude that 2% is enough of a difference to go ahead with chemotherapy, while a 75-year-old may weigh the six months required for treatment and decide that a 2% difference in survival is not enough.

However, countered Dr. Sargent, a 75-year-old without cancer and in good health has a life expectancy of 10 to 12 years. "I think that sometimes people may underestimate their potential future years to gain," he said. "And, in Stage III cancer, treatment provides more on the order of a 7% increase in their survival. It really is a stage-dependent analysis." ■

Suggestions for Future Abstract Trackers?

This department follows studies from their initial presentation at scientific meetings to the subsequent publication in journal form, tracking any changes and noting situations where studies have not been published after their original presentation as an abstract. We invite readers to submit suggestions for studies for this department to report on. Please send suggestions to Abstract Tracker, Oncology Times, 345 Hudson St., 16th Fl., New York, NY 10014; fax 212-886-1209; e-mail OT@LWW.com.