

Clinical Research and New Technology

[SCREENING AND PROGNOSIS]

Contrast-Enhanced CT Can Predict the Success of Breast Conservation Therapy After Neoadjuvant Chemotherapy

Patients with malignant breast tumors classified as localized by contrast-enhanced computed tomography (CE-CT) are good candidates for breast conservation therapy (BCT) after neoadjuvant chemotherapy has been administered, according to the results of a study published in the February issue of the *Annals of Surgery*.

Sadako Akashi-Tanaka, MD, and his colleagues at the National Cancer Center Hospital in Tokyo,

Japan, noted that there was a relatively high rate of locoregional failure when BCT was used after neoadjuvant chemotherapy to downstage breast cancer. In order to determine the best candidates for BCT, the team used mammography, ultrasound, and CE-CT to evaluate 110 consecutive patients who had operable breast carcinomas of at least 3 cm in diameter at their institution. The lesions were classified as either localized or diffuse.

All candidates then received neoadjuvant chemotherapy with doxorubicin and docetaxel. The localized tumors shrank to less than 3 cm in a concentric circle. They were treated safely with lumpectomies and all the surgical specimens had negative margins. Diffuse tumors shrank into a mosaic pattern, the

smallest of which was 3.1 cm.

For more information, see *Ann Surg*. 2004;239:238-243.

Fluorescence Cystoscopy Improves Detection of Early Bladder Cancer

Fluorescence cystoscopy with hexaminolevulinate (HAL), a photosensitizing agent, is better than standard cystoscopy at detecting bladder carcinoma in situ (CIS) report researchers in the January 2004 issue of the *Journal of Urology*.

Michael Marberger, MD, and his colleagues at the University of Vienna evaluated 211 patients with symptoms suggestive of bladder cancer with both standard and HAL fluorescence cystoscopy. Each patient had 50 ml of HAL solution instilled into the bladder. The solution was left in place for about one hour, the bladder was evacuated, and both types of cystoscopy were performed.

Eighty-three of the patients had CIS. Although most of the lesions were detected with both standard and HAL cystoscopy, standard cystoscopy exclusively located two and HAL cystoscopy exclusively located 18.

For more information, see *J Urol*. 2004;171:135-138.

Computer-Aided Detection No Better Than Radiologists' Readings of Mammograms

Computer-aided detection (CAD) was not more effective than radiologists' unaided interpretations of mammography, according to a study published in the Feb. 4, 2004 issue of the *Journal of the National Cancer Institute*.

David Gur, ScD, and his colleagues at the University of Pittsburgh evaluated the results of mammogram interpretation at the Magee-Womens Hospital of the University of Pittsburgh Medical

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A woman undergoing digital mammography at the Allegheny General Hospital Breast Care Center in Pittsburgh, Pa.

PHOTOGRAPH COURTESY OF THE BREAST CARE CENTER OF ALLEGHENY GENERAL HOSPITAL, PITTSBURGH, PA.

Center between 2000 and 2002. The hospital's 24 radiologists interpreted 56,432 mammograms without the use of CAD and 59,139 mammograms using the CAD system. Recall rates (approximately 11 percent) and breast cancer detection rates (approximately 3.5 cases detected per 1,000 screening mammograms) were not statistically different between groups and were very similar among the seven radiologists who interpreted the most studies.

Study limitations include the low number of breast cancers, high intra-reader variability, inability to assess intra-reader variability, lack of adjustment for learning effect or motivation, and the use of conventional film rather than digital mammography.

For more information, see *J Natl Cancer Inst.* 2004;96:185-190.

Independent Prognostic Indicator for Overall Survival in Melanoma

TriPath Imaging, Inc., presented an independent study at the 93rd Annual Meeting of the United States and Canadian Academy of Pathology. The study demonstrated that Melastatin[®] gene expression, when measured using TriPath Imaging's Research Use Only product associated with a new chromogenic, in-situ hybridization (CISH) method, is an independent prognostic indicator for overall survival in primary and metastatic melanoma. Melastatin is a melanocyte-specific gene that has been identified as a potential prognostic biomarker of clinical outcome in patients suffering from cutaneous melanoma, a cancerous lesion of skin that accounts for nearly 75 percent of all skin cancer-related deaths.

In the study, Melastatin mRNA was detected by CISH on formalin fixed paraffin embedded tissue sections from 56 primary melanoma patients with localized disease (AJCC stage I and II) and 8 malignant melanoma patients (AJCC stage III/IV). The status of Melastatin expression as measured

using TriPath Imaging's CISH assay was correlated with known clinical outcome in these specimens. The study showed that in both primary and metastatic melanoma, loss of Melastatin was associated with reduced patient survival and was an independent prognostic factor for overall patient survival. The 5-year overall survival for complete Melastatin expression loss was 34 percent; for partial loss 50 percent; and for intact Melastatin expression 95 percent. On multivariate analysis, loss of Melastatin expression and Clark's level (tumor thickness) were independent prognostic factors.

For more information, go to www.tripathimaging.com.

[TREATMENT]

Electroporation Therapy as a Treatment for Recurrent and Second Primary Squamous Cell Carcinomas of the Head and Neck

Genetronics Biomedical has completed the Special Protocol Assessment review process with the FDA for two Phase III pivotal studies to evaluate the use of its MedPulser[®] Electroporation Therapy System as a treatment for recurrent and second primary squamous cell carcinomas of the head and neck (SCCHN). Three institutional review boards in the U.S. have approved the two protocols to date, and Genetronics has initiated patient enrollment.

Both protocols will compare Genetronics' MedPulser[®] Electroporation Therapy System to surgery in patients that have resectable recurrent or second primary SCCHN. The primary endpoint is to demonstrate that patients treated with electroporation therapy have superior preservation of function (e.g., eating, swallowing, and talking) when compared to surgery. The secondary endpoints include comparing quality of life, safety, and pharmacoeconomics. Additionally, the study aims to show local tumor control and survival outcomes that are equivalent to surgery.

The MedPulser System applies a defined electric field to the target cells that induce transient cell

membrane pores, thereby allowing previously administered therapeutic agents to easily transfer into the cell interior. In Europe, the MedPulser System, when used with the chemotherapeutic drug bleomycin, has been shown to be effective and safe for the local treatment of head and neck cancers and for cutaneous and subcutaneous cancers, as evidenced by its CE Mark certification. In the U.S., the system has demonstrated promising safety and efficacy in Phase II clinical trials, where it was used for local treatment of head and neck cancer.

For more information, go to www.genetronics.com.

New Findings on Breast-conserving Surgery

A study by a group of surgeons and physicians at The Rosenfeld Cancer Center at Abington Memorial Hospital in Abington, Pa., now indicates that women with early-stage breast cancer involving the nipple and areola can successfully undergo breast-conserving surgery. Members of the Department of Surgery and the Division of Radiation Oncology reported their findings from a 10-year study on breast conservation surgery using nipple areolar resection for central breast cancers in a recent issue of the *Archives of Surgery* (2004; 131:32-37.)

Surgeries were performed in 15 patients, ranging in age from mid-40s to late-80s. Patients with Paget disease of the nipple were included in the study. Each woman underwent breast conservation using resection of the nipple areolar complex and post-operative radiation treatment for stage 0, stage I, and stage II central breast cancers that involved the nipple, areola or both. With the breast conserving surgery, the patient maintains a sensate intact breast mound with normal peripheral contours. The women reported cosmetic results better than expected, giving them higher marks for their cosmetic results than their surgeons did. After a mean follow up of 32 months, one patient had a recurrence of cancer. She was successfully treated with a modified radical mastectomy.

For more information go to www.amb.org. 