The widespread utilization of screening mammography has led to a dramatic increase in the number of women diagnosed with DCIS. More than 54,000 women will be diagnosed this year in the United States. Clinical research has focused on optimizing control of the index lesion with minimal morbidity, and in preventing the occurrence of new primary tumors. NSABP trials B-17 and B-24 demonstrated a stepwise improvement in local and contralateral tumor control with the use of breast radiotherapy and tamoxifen in women treated with lumpectomy, although a new analysis by Allred is being presented at this meeting demonstrating that the advantage to tamoxifen was observed only in women with detectable estrogen receptors. A new NSABP study and another trial in the United Kingdom will evaluate anastrozole in postmenopausal patients with DCIS, with the hope that tumor control will be improved with fewer side effects.

NSABP B-35: TAMOXIFEN VERSUS ANASTROZOLE IN POSTMENOPAUSAL PATIENTS WITH DUCTAL CARCINOMA IN SITU — Open Protocol
Projected accrual: 3,000 patients

IBIS-2: DCIS: INTERNATIONAL, MULTI-CENTRIC STUDY OF TAMOXIFEN VERSUS ANASTROZOLE IN POSTMENOPAUSAL WOMEN WITH DUCTAL CARCINOMA IN SITU (DCIS) — Open Protocol
Projected accrual: 4,000 patients

NSABP DCIS TRIALS: CUMULATIVE INCIDENCE OF INVASIVE AND NONINVASIVE EVENTS IN THE IPSILATERAL AND CONTRALATERAL BREAST

SELECT PUBLICATIONS

As enormously successful as the Prevention Trial was in reducing the incidence of cancer by 50%, everybody understands that there must be a more effective or safer drug than tamoxifen.

That’s the driving force for us to do another DCIS trial. The ATAC trial is addressing the use of anastrozole in invasive breast cancer, but we need to ask the same question in non-invasive disease.

One can’t assume that the results of one trial can be transferred to another situation.

NSABP B-35 will replicate two arms of the ATAC trial in women with DCIS. Since these are very low-risk women, it is important to determine whether the risk-benefit ratio will justify the use of an aromatase inhibitor. The additional 50% reduction in contralateral breast cancer, associated with anastrozole in the ATAC trial, justifies the design of this trial in women with DCIS.

As a heterogeneous group of lesions, and because of that, there’s never going to be a single treatment that works for all patients — so there’s always going to be controversy about the optimal treatment. In terms of local therapy, you can do excisions of various sizes with or without radiation or you can do a mastectomy. I have a reputation for not wanting to give radiation to DCIS patients, but that’s not true. We recommend it, but not all patients. It’s relatively expensive and it’s a bit inconvenient.

Also, if you give radiation therapy for DCIS and the patient develops an invasive recurrence, radiation can’t be given again. If you don’t give radiation and there is an invasive recurrence, you can excise and irradiate.

— Melvin Silverstein, MD

NSABP B-35: TAMOXIFEN VERSUS ANASTROZOLE IN POSTMENOPAUSAL PATIENTS WITH DUCTAL CARCINOMA IN SITU — Open Protocol

Eligibility
Postmenopausal women with DCIS treated with lumpectomy. ER/PR-positive or borderline

Stratification
Age (<60 versus ≥60)

ARM 1
Tamoxifen 20 mg + placebo qd x 5 yr + XRT

ARM 2
Anastrozole 1 mg + placebo qd x 5 yr + XRT

Study Contact: Richard Margeoles, Chair
National Surgical Adjuvant Breast and Bowel Project
412-330-4650
Email: Richard.Margeoles@nshs.edu

PHASE III RANDOMIZED STUDY OF WHOLE BREAST RADIOTHERAPY VERSUS OBSERVATION WITH OR WITHOUT OPTIONAL TAMOXIFEN IN WOMEN WITH GOOD-RISK DUCTAL CARCINOMA IN SITU OF THE BREAST — Open Protocol
Projected accrual: 1,790 patients

Eligibility
DCIS ≤ 2.5 cm, no prior chemotherapy or XRT or concurrent hormone treatment (except tamoxifen)

ARM 1
Observation with optional tamoxifen qd x 5 years

ARM 2
Radiotherapy daily 5 times per week for 3.5–5.5 weeks + optional tamoxifen qd x 5 years

Study Contacts:
Barbara L Smith, Chair
412-330-4800
NCI Physician Data Query, October 2002

NSABP B-24: RADIATION THERAPY AND TAMOXIFEN FOR DCIS

Our randomized trials demonstrate that regardless of the histologic subtype and margin width, there is a clear benefit from the use of radiation therapy. There is also a clear-cut benefit from tamoxifen for both tumor recurrence and reduction in risk for contralateral breast cancers. DCIS patients are at high-risk for contralateral breast cancers, and tamoxifen reduces that risk by more than 50%.

The quest to identify patients who can avoid radiation therapy is very reasonable. The problem is that even an excellent observational series is potentially fraught with methodologic bias that can produce flawed results or conclusions.

—Lawrence Wickerham, MD

NSABP TRIALS B-17 AND B-24: RADIATION THERAPY AND TAMOXIFEN FOR DCIS

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