An Argument Against Routine Use of Radiotherapy for Ductal Carcinoma In Situ

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The major conclusion to be drawn from the extensively published University of Southern California (USC)/Van Nuys database on ductal carcinoma in situ (DCIS) is that, to the extent that DCIS can be totally excised, the ipsilateral local control rate will approach 100% with surgery alone, regardless of tumor grade or size or patient age. This conclusion, noted by Dr. Silverstein, was achieved only through prospective mammographic/pathologic correlation and a meticulous pathology protocol that required orientation, selective inking of margins, sequential sectioning and processing of the entire specimen, and prospective calculation of size and margin status.

The need for such mammographic correlation and specialized pathology practice for DCIS became apparent in initial attempts at breast conservation for that disease[1,2] and continues to be evident today.[3] Several recent consensus conferences have addressed these requirements and have mandated documentation of nuclear grade, necrosis, size, measured margins, imageguided resection, mammographic/ pathologic correlation, and processing of the entire specimen.[4-5] In the recently published United Kingdom/ Australia/New Zealand DCIS trial,[8] the researchers noted that better local control, as compared to either the National Surgical Adjuvant Breast and Bowel Project (NSABP) protocol B-17 or the European Organization for Research and Treatment of Cancer (EORTC) 10853 trial, probably reflects efforts to achieve better margins and the requirement of mammographic correlation as part of the entry criteria.

Identifying Low-Risk Subsets

Several prospective studies have corroborated the utility of the Van Nuys approach to assessing risk of recurrence among DCIS patients, confirming the ability to identify low-risk subsets.[7] I strongly advocate this practice for DCIS, and the Van Nuys Prognostic Index, in particular, for estimating a patient's risk. This algorithm is the best available at present and can be used in any practice setting. Why haven't the randomized trials conducted by the NSABP (B-17 and B-24) and EORTC been able to define similar prognostic features and establish low-risk subsets? As confirmed by several recent consensus conferences,[ 4-6] sampling of the resection, which is characteristic of these randomized trials of radiation therapy for DCIS, is not sufficient to either exclude invasion, evaluate margins, or reliably identify low-risk subsets. The protocols used in B-17 and B-24 are only slightly modified from those designed for invasive breast cancer, in which the pathologist samples the tissue and the margins. These trials did not require mammographic/ pathologic correlation, as is standard practice for mammographically detected lesions today. Such correlation is necessary to establish the likelihood of a successful resection intraoperatively and, in corollary fashion, of residual disease in the unresected breast. Although sampling is a suitable approach for palpable invasive breast cancer, it is unreliable in excluding invasive disease or margin involvement in resections for clinically occult DCIS. Consider the likelihood of detecting a 5-mm invasive focus in a standard resection of 120 cm³ (6 * 5 * 4 cm) for a DCIS sampled in 10 cassettes where 25 are required for complete processing, particularly in the absence of specimen radiography. The limitations of the conventional sampling technique used to define DCIS in these trials contribute to the high local failure rate when margins can only be estimated, and to the high rate of locoregional and distant metastatic first events when invasion cannot reasonably be excluded. The rate of metastatic first events in NSABP B-17 at 12 years of follow-up is 2%- clearly not the biology of DCIS as we know it today. The Radiation Controversy

Some trials have recently reaffirmed the efficacy of radiation therapy in all DCIS patients treated
conservatively on the basis that the requisite mammographic/pathologic correlation and tissue processing would be unavailable in the community and prohibitively expensive regardless. This ignores the recommendations of recent consensus conferences[4,6] and a growing trend in clinical practice of sequential, complete tissue processing for DCIS. Having used the sequential technique for the last 30 years, I can assure my colleagues that it does not require "hundreds of slides" or "a full day for the pathologist" to review the material. Clearly, radiation therapy is unnecessary for a substantial fraction of DCIS patients whose disease is detected mammographically and who can undergo adequate excision. The cost of the requisite mammographic/pathologic correlation and tissue processing, the latter averaging 25 blocks per case, is 29 times less than the cost of radiation therapy at 80% Medicare reimbursement rates.[6] Such meticulous mammographic/pathologic correlation permits the identification of subgroups that are unlikely to benefit from radiation therapy-as much as one-third of all patients with DCIS-as well as the subgroups that are likely to benefit. In many circumstances, this approach identifies patients whose disease is so extensive that they are unacceptable candidates for breast conservation. **Conclusions**

Randomized trials, although providing important information, are only as good as the design of the trial in the first place. The published, randomized trials-NSABP B-17 and B-24, and EORTC 10853-were designed at a time when closely correlated mammographic and pathologic data were neither available nor thought to be clinically relevant. Let us not be restricted in our understanding of DCIS by these historical trials, the current value of which is limited in today's clinical management of the disease. Incorporating new evidence better serves our patients and provides more cost-effective care.

**Disclosures:** The author(s) have no significant financial interest or other relationship with the manufacturers of any products or providers of any service mentioned in this article.

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