A series of classic randomized trials—including NSABP B-04—formed the basis for level I and II axillary node dissection becoming a standard of care for invasive breast cancer. The emergence of sentinel lymph node biopsy (SLNB) as an initial staging procedure has led to a new generation of trials evaluating the need for axillary dissection in women with both pathologically negative nodes and positive nodes. A critical, related question is the interpretation of micrometastases in both the sentinel lymph node and bone marrow. The value of treating the axilla in elderly women is also being examined, as well as the potential for treating the axilla with radiotherapy.

**Management of the Axilla**

**Phase III Prognostic Study of Sentinel Node and Bone Marrow Micrometastases in Women With Stage I or IIA Breast Cancer**

Open Protocol

**Protocol IDs:** ACOSOG-Z0019, GUMC-00152

**Projected Accrual:** 5,300 patients

**Eligibility**

Stage I or IIA breast carcinoma within 30 days of planned sentinel lymph node dissection

**Protocol**

Bilateral anterior iliac crest bone marrow aspiration to test for micrometastases + Lymphectomy + SLND

<table>
<thead>
<tr>
<th>Sentinel node</th>
<th>Protocol ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive axillary dissection</td>
<td>ACOSOG - 2001</td>
</tr>
<tr>
<td>Negative axillary dissection</td>
<td>No further surgery</td>
</tr>
</tbody>
</table>

All patients receive whole breast radiotherapy (excluding a supravacular field) 5 days a week, for a maximum of 8 weeks, and systemic adjuvant therapy as indicated.

**Patients with no sentinel node identified**

In the absence of a sentinel node, women with sentinel node metastases identified by H & E who choose not to be registered to ACOSOG-Z0011 undergo ALND.

**Study Contact:**

Armando E Giuliano, Chair. Tel: 310-829-8089

American College of Surgeons Oncology Group

Source: NCI Physician Data Query, October 2002

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**Phase III Randomized Study of Sentinel Lymph Node Dissection With or Without Conventional Axillary Dissection in Women With Clinically Negative Breast Cancer**

Open Protocol

**Protocol ID:** NSABP-B-32

**Projected Accrual:** 4,000 patients (2,000 per arm)

**Eligibility**

Clinically node-negative breast cancer

**Study Contact:**

David N Krag, Chair. Ph: 802-656-5830

American College of Surgeons Oncology Group

Source: NCI Physician Data Query, October 2002

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**Sentinel Lymph Node Biopsy for Breast Cancer: A Challenge to the Dogma**


<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Eligibility</th>
<th>Schema</th>
</tr>
</thead>
<tbody>
<tr>
<td>EORTC-10881, EORTC-10881-ANNABDS</td>
<td>T-0, SN clinically negative; Sentinel node</td>
<td>ARM 1: Complete ALND</td>
</tr>
<tr>
<td>CNR-9502, EU-9505D</td>
<td>Age 65-80; postmenopausal; stage I or II; EH-positive</td>
<td>ARM 1: Quadrantectomy with level I &amp; II ALND</td>
</tr>
<tr>
<td>EU-95013, IBCSG-10-93, NCI-PSO-0001</td>
<td>Age &lt;65; postmenopausal; stage I or II; non prior axillary clearance or biopsy allowed</td>
<td>ARM 1: Quadrantectomy without ALND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARM 2: Sentinel lymph node dissection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SLNB-axillary lymph node dissection</td>
</tr>
</tbody>
</table>

Management of the Axilla

**Rationale for Axillary Dissection**

There are three reasons to do axillary dissection: regional control, staging, and to improve survival. For staging, we have enough literature from around the world to tell us the accuracy of sentinel node biopsy. For regional control, surgery results in almost 100% control, as does radiation therapy. However, a number of randomized studies failed to show that axillary dissection improves survival. In sentinel node-positive women, the sentinel node may be enough because often it’s the only involved node. Virtually all node-positive women in this country receive adjuvant systemic therapy, and many patients are also receiving opposed tangential field radiation. In studies where patients received lumpectomy with radiation and no axillary dissection, the axillary recurrence rate was extraordinarily low. I think ACOS Z-11 is a very important, very justifiable and ethical trial. For an operation that’s been used for 100 years, it’s time to answer the question about the need for axillary dissection.

—David Krag, MD

**Clinical Trials of SLNB**

NSABP trial B-04 showed no difference in survival outcome between axillary dissection at the time of diagnosis and delayed axillary dissection if clinically positive nodes developed. Since that trial didn’t show a survival difference, it’s reasonable to expect that NSABP B-32 would. I think that’s a very open question. However, B-32 will tell us about the clinical false-negative rate when many surgeons do sentinel node biopsy, which is an important issue to inform patients about. The ACOS trial addresses the much more controversial question of whether to remove axillary nodes after the patient has been staged as node-positive. It challenges the dogma that people have had for years.

—Armando Giuliano, MD

**Accrual to Sentinel Node Trials**

In some ways, sentinel node mapping is becoming a victim of its own success. As surgeons realize that it is not a terrific technical feat to learn, and as more patients become aware of it through the Internet, it is not a terrific technical feat to learn, and as more patients become aware of it through the Internet and other sources, it will become harder and harder to find both patients and physicians willing to participate in these randomized clinical trials.

—Patrick Borgen, MD

**SELECT PUBLICATIONS**


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