Alliance A221702: ARM: Axillary Reverse Mapping - A Prospective Trial to Study Rates of Lymphedema and Regional Recurrence after Sentinel Lymph Node Biopsy and Sentinel Lymph Node Biopsy Followed by Axillary Lymph Node Dissection with and without Axillary Reverse Mapping

V. Suzanne Klimberg, MD, PhD

University of Texas Medical Branch

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Rationale

Lymph node status is a key prognostic variable, and therapeutic decisions are based on the presence or absence of breast cancer cells metastatic to the axillary lymph node(s). The results of randomized prospective clinical trials, which guide current therapy, have been based on the pathologic status of the axillary lymph nodes. Although newer markers of oncogene expression show promise with respect to the treatment of breast cancer, the status of the axillary nodes remains an important prognostic criterion and will continue to have a direct impact on clinical decisions.

When necessary, the prescribed technique for axillary lymph node dissection (ALND) has changed little over the last several decades. The principal features include removal of axillary tissue inferior to the axillary vein, medially to the medial border of the teres minor muscle, lateral to the serratus muscle, and anterior to the teres major muscle [1]. The standard teaching was that the lymphatic ran along the inferior side of the axillary vein and avoiding skeletonizing the vein would prevent lymphedema. The morbidity and risks of an ALND include the risk of general anesthesia, permanent hypesthesia and/or dysesthesia at the posterior aspect of the upper extremity (UE) [2], painful neuroma, post-operative seroma formation [3], and lymphedema of the UE [4]—the risk of which increases with greater extent of axillary node resection as well as breast surgery. [5,6] It has been reported that 82% of women experience at least one problem with their UE following ALND. Patients often have decreased mobilization of the shoulder and require physical therapy to regain full function of the upper extremity. Associated psychological distress ranges from 17% to 50% [7,8]. Depending on how it is defined, lymphedema alone has been reported to be as high as 77% [9-18] Routine use of sentinel lymph node biopsy (SLNB) has drastically reduced this risk but is still quite variable (0-13%). The wide variability with both SLNB and ALND indicate a concomitant wide variability in technique in performance of these procedures. Therefore, a modification of surgical technique that can reproducibly reduce lymphedema (LE) is necessary.

The proposed research attempts to establish the safety and efficacy of a new procedure, axillary reverse mapping (ARM), to prevent one of the major surgical side-effects of lymphadenectomy (SLNB or ALND)—lymphedema of the Upper Extremity (UE).

See protocol for references

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Objective

Primary

- To determine the occurrence of post-surgery lymphedema by conical geometric measures in clinical T1-3, N0-3, M0 breast cancer patients undergoing axillary surgery and randomized to Group 1 (no axillary reverse mapping [ARM]) versus Group II (ARM).

Secondary

- To compare between the study groups the lymphedema symptom intensity and distress as measured by the Lymphedema Symptom Intensity and Distress Survey-Arm (LSIDS-A).
- To evaluate the technical success of performance of ARM procedure: Identification of ARM lymphatics, and the ability to spare or reapproximate ARM lymphatics.
- To compare the rate of regional recurrence between patients randomized to receive ARM versus no ARM.

Exploratory

- To assess the occurrence of lymphedema as a function of radiotherapy use and targets.

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Study Schema

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

For Patients Undergoing Mastectomy

RANDOMIZE

Group I NO ARM*

1. Localize SLN**
2. Biopsy SLN
   If (+) perform ALND

Group II ARM*

1. Localize SLN**
2. Perform ARM procedure
3. Biopsy SLNIf (+) perform ALND while sparing blue ARM nodes draining upper extremity***†

* ARM: Axillary Reverse Mapping
** If sentinel lymph node (SLN) cannot be localized by radioactive isotope alone, and blue dye is injected into the breast to identify the SLN, ARM procedure cannot be performed
*** If SLN nodes are ARM nodes, remove and determine pathology. If positive, perform axillary lymph node dissection (ALND) and reapproximate afferent and efferent lymphatics of the ARM nodes.
† If ALND is performed during a separate operation, ARM procedure must be repeated.

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Study Schema

NCI Community Oncology Research Program
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For Patients Undergoing Breast Conserving Surgery (>2 Positive Nodes - Clinical or Occult*)

RANDOMIZE

Group I NO ARM*

Axillary Lymph Node Dissection (ALND)***

Group II ARM*

1. Perform ARM procedure and inject blue dye into upper extremity and radioactivity in the breast
2. 2. Perform ALND*** and reapproximate afferent and efferent lymphatics if possible

- Meaning positive by surgery but not known beforehand
- ** ARM: Axillary Reverse Mapping
- *** May be performed with or without a sentinel lymph node biopsy (SLNB)

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ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

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Treatment Plan

Patients are randomized to 1 of 2 groups.

Group I

- Patients who do not undergo ARM.
- Those in the mastectomy group may have a SLNB if the SLN is negative or a SLNB and axillary lymph node dissection (ALND) if the SLN is positive.
- Only those patients who are having BCS and do not meet Alliance Z0011 criteria will be eligible for the study and will undergo an ALND.

Group II

- Patients who undergo ARM.
- Mastectomy patients will receive radioactivity or other localization method (excluding blue dye) in the breast and will then receive subcutaneous isosulfan blue in the upper inner volar surface of the upper extremity and undergo SLNB or ALND.
- BCS patients who do not meet Alliance Z0011 criteria will receive radioactivity or other localization method (excluding blue dye) in the breast and then receive subcutaneous isosulfan blue dye in the upper inner volar surface of the upper extremity and undergo an ALND.
- Blue nodes that are also radioactive should be removed.
- An attempt should be made to reapproximate all lymphatics including the SLN afferent and efferent lymphatics and any blue lymphatics that have been transected. LYMPHA (lymphaticovenous anastomoses) is permitted when reapproximation cannot be performed.
- After completion of study, patients are followed up for 3 years.

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Eligibility Criteria

- Documentation of disease: cT1-3 patients undergoing axillary surgery.
- Prior Treatment: No prior axillary surgery except needle biopsy or concurrent SLNB
- No prior history of ipsilateral breast cancer (invasive or DCIS). LCIS and benign disease are allowed. (May have neoadjuvant chemotherapy)
- No bilateral invasive breast cancer
- No matted nodes
- No history of lymphedema of either arm
- No known allergies to make-up or blue dyes or allergies to dyes used in tattoos
- Patients must be able to speak and/or read English
- Female, not pregnant and not nursing
- Age ≥18 years.
- ECOG Performance Status 0, 1 or 2

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Contact Us

Study Chair: V. Suzanne Klimberg, MD, PhD
University of Texas Medical Branch
E-mail: Vsklimbe@utmb.edu
Phone: 501-680-0779

Statistician: Jennifer Le-Rademacher, PhD
E-mail: le-rademacher.jennifer@mayo.edu

Phone: 507-284-4402
Protocol Coordinator: Niveditha Subbiah
E-mail: niveditha@uchicago.edu
Phone: 773-702-9934

Data Manager: Aaron Steele
E-mail: steele.aaron@mayo.edu
Phone: 507-266-3551