Consent Form for Prophylactic Lymphovenous Anastomosis (LVA) During Axillary Lymph Node Dissection

CONSENT FOR PROPHYLACTIC LYMPHOVENOUS ANASTOMOSIS (LVA) DURING AXILLARY LYMPH NODE DISSECTION

PROCEDURE DESCRIPTION

You are scheduled to undergo axillary lymph node dissection (ALND) as part of your breast cancer treatment. At the same time, you are being offered prophylactic (preventive) lymphovenous anastomosis, also known as immediate lymphatic reconstruction (ILR) or the LYMPHA technique, to reduce your risk of developing arm lymphedema after surgery.[1][2][3]

During this procedure, after your surgeon removes the lymph nodes from your axilla (armpit), a specialized dye (indocyanine green or blue dye) will be injected into your arm to identify the lymphatic vessels that drain fluid from your arm. Using microsurgical techniques and an operating microscope, your surgeon will connect these small lymphatic vessels (typically 2-4 vessels) to nearby veins, creating a bypass to help maintain lymphatic drainage from your arm.[4][5][6]

This preventive procedure adds approximately 30-95 minutes to your surgery time and is performed during the same operation as your axillary lymph node dissection.[4]

There is a possibility that the length of preserved vein and the length of lymphatic channels do not reach, in which case we are unable to perform the reconstruction. This is dependent on the necessary dissection for the oncology portion, but your team will do their best to preserve structures for reconstruction.

EXPECTED BENEFITS

Based on current evidence, prophylactic LVA performed at the time of axillary dissection may provide the following benefits:

Significant reduction in lymphedema risk: Studies show that patients who undergo prophylactic LVA have a lymphedema rate of approximately 5-10% compared to 20-40% in patients who undergo standard axillary dissection alone.[1][2][3][6][7]

- The number needed to treat is approximately 3-4 patients, meaning for every 3-4 patients who undergo this procedure, one case of lymphedema is prevented.[3]

- A recent randomized controlled trial showed a cumulative lymphedema incidence of 9.5% with ILR compared to 32% without ILR.[6]

Delayed onset of lymphedema: If lymphedema does develop, it typically occurs later (approximately 543 days after surgery) compared to 389 days in patients without ILR.[8]

Reduced severity: Patients who undergo prophylactic LVA and still develop lymphedema tend to have less severe disease.[1]

Improved quality of life: Reduced symptoms of pain, tightness, and heaviness in the arm, with less impact on daily activities.[1][9]

Decreased cellulitis episodes: Lower rates of arm infections related to lymphedema.[1]

Important: This procedure reduces but does not eliminate the risk of lymphedema. You will still need to follow lymphedema prevention strategies and may require compression therapy after surgery. Results vary between individuals, and some patients may still develop lymphedema despite this preventive surgery.

RISKS AND COMPLICATIONS

Prophylactic LVA is considered safe with minimal additional risks beyond those of standard axillary dissection.[4][5]

Procedure-specific risks:

- The procedure may not be technically feasible in all patients (success rate 76-88%)[5][10]
  - Inability to identify suitable lymphatic vessels (occurs in approximately 5-10% of patients)
  - Inability to identify suitable veins for connection
  - Extensive disease in the axilla preventing safe anastomosis
- Anastomosis failure: The connections may not remain open over time
- Allergic reaction to imaging dye (indocyanine green or blue dye)
- No reduction in lymphedema risk despite the procedure

General surgical risks (same as standard axillary dissection):

- Bleeding or hematoma formation
- Infection
- Seroma (fluid collection)
- Wound healing problems

- Nerve injury causing numbness, tingling, or pain

- Shoulder stiffness or reduced range of motion

- Scarring

Important oncologic consideration: Studies show no increase in axillary recurrence rates with prophylactic LVA compared to standard axillary dissection (approximately 1% in both groups).[4][6][7]

ALTERNATIVES TO THIS PROCEDURE

Alternative options include:

1. **Standard axillary lymph node dissection without prophylactic LVA:** Proceed with lymph node removal alone and manage lymphedema if it develops

2. **Axillary reverse mapping (ARM):** A technique to identify and potentially preserve arm lymphatics during dissection, though this may not be oncologically safe in all patients[11][12]

3. **Conservative lymphedema management:** If lymphedema develops, treat it with compression therapy, manual lymphatic drainage, and exercise

4. **Delayed lymphedema surgery:** If lymphedema develops, consider therapeutic LVA or other surgical options at a later time

Your surgeon has recommended prophylactic LVA based on your individual risk factors and the current evidence supporting this approach.

FACTORS THAT MAY AFFECT SUCCESS

Certain factors may influence whether the procedure can be successfully completed or its effectiveness:

- **Body mass index (BMI):** Higher BMI may make lymphatic identification more challenging[10]

- **Smoking:** Active smoking may reduce success rates[10]

- **Extent of lymph node involvement:** Patients with extensive nodal disease may have higher rates of lymphedema despite ILR[1][13]

- **Adjuvant radiation therapy:** Radiation, particularly certain techniques, may increase lymphedema risk even with ILR[14][15]

- **Combined chemotherapy and radiation:** Patients receiving both treatments have higher lymphedema risk[15]

WHAT TO EXPECT AFTER SURGERY

- You will have the same recovery as standard axillary dissection with surgical drains in place
- You may need to wear compression garments, though requirements may be less intensive than without ILR
- You will be monitored for lymphedema development with arm measurements and/or bioimpedance testing at regular intervals
- Follow-up appointments will be scheduled at 3-month intervals for the first 1-2 years
- You should continue lymphedema prevention strategies including skin care, avoiding blood pressure measurements and blood draws in the affected arm when possible, and prompt treatment of any arm infections
- Physical therapy may be recommended to maintain shoulder range of motion

PATIENT RESPONSIBILITIES

To optimize your surgical outcome, you must:

- Follow all preoperative instructions, including fasting guidelines
- Inform your surgical team of all medications, allergies, and medical conditions
- Follow all postoperative instructions regarding wound care, drain management, and activity restrictions
- Attend all scheduled follow-up appointments for lymphedema monitoring
- Continue with recommended compression therapy and lymphedema prevention strategies
- Report any signs of infection, increased swelling, or other concerns promptly
- Maintain a healthy weight and avoid smoking
- Participate in recommended physical therapy

CONSENT

I acknowledge that:

- The nature and purpose of prophylactic lymphovenous anastomosis during axillary lymph node dissection has been explained to me
- I understand this is a preventive procedure that reduces but does not eliminate the risk of lymphedema
- I have been informed of the expected benefits and potential risks of the procedure
- I understand the procedure may not be technically feasible in all cases, and the decision to proceed will be made during surgery based on intraoperative findings
- Alternative treatment options have been discussed with me
- I have had the opportunity to ask questions and all my questions have been answered to my satisfaction
- I understand that no guarantees have been made regarding the outcome of this surgery
- I understand that this procedure does not increase my risk of cancer recurrence
- I consent to the administration of anesthesia as deemed necessary
- I consent to the use of imaging dyes (indocyanine green or blue dye) for lymphatic visualization
- I consent to photography or video recording for medical documentation purposes
- I authorize the surgical team to perform the procedure described above

  «Person_First_Middle_Last» DOB_«Person_Birth_Date»

Patient Signature: ____________________________ ***Date/Time:*** ____________

Witness Signature: ____________________________ ***Date/Time:*** ____________

Physician Signature: ____________________________ ***Date/Time:*** ____________

Physician Name (Print): ___«Doctor_First_Name» «Doctor_Last_Name» , MD___*

I certify that I have explained the nature, purpose, benefits, risks, and alternatives of the proposed procedure to the patient and have answered all questions to the best of my ability.