



Expanding Access to Immediate Lymphatic Reconstruction Through an Axillary Surgery Referral Program: A 6-Year Single-Center Experience

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ABSTRACT

Background. Recent advances in breast cancer have progressed toward less aggressive axillary surgery. However, axillary lymph node dissection (ALND) remains necessary in specific cases and can increase the risk of lymphedema. Performing ALND with immediate lymphatic reconstruction (ILR) can help lower this risk. This report outlines the implementation of an Axillary Surgery Referral Program (ASRP) to broaden access to ILR, providing insights for institutions considering similar initiatives.

Methods. A retrospective study analyzed patients referred to the ASRP at Beth Israel Deaconess Medical Center (BIDMC) between 6 January 2017 and 10 December 2022. Patients were identified from a prospective registry, with data subsequently extracted from electronic medical records. This analysis specifically centered on patients referred from external institutions to undergo ALND with ILR.

Results. The program received referrals for 131 patients from institutions across five different states. Annual referrals steadily increased over time. The primary indication for referral was residual axillary disease after neoadjuvant chemotherapy (41.2%). Among the referrals, 20 patients (15.3%) no longer required ALND due to axillary pathologic complete response to neoadjuvant therapy. Care coordination

played a crucial role in streamlining the patient care process for both efficiency and effectiveness.

Conclusion. The ASRP expands access to ILR for patients with breast cancer, the majority referred for surgical management of residual disease after chemotherapy. The program provides a model for health care institutions aiming to establish similar specialized referral services. Continued program evaluation will be instrumental in refining axillary surgery referral practices and ensuring optimal patient care.

Axillary management of patients with breast cancer has evolved significantly, resulting in less invasive surgical approaches including radiation alone, targeted axillary node dissection, and delayed sentinel lymph node biopsy.¹⁻⁴ However, cases remain for which an axillary lymph node dissection (ALND) is necessary to stage and manage axillary disease, especially when significant nodal burden, persistent disease after neoadjuvant therapy, or inflammatory breast cancer is addressed.^{5,6}

The use of ALND is associated with potential complications that can significantly affect a patient's quality of life, most notably lymphedema, which occurs in 20% to 45% of women undergoing ALND for breast cancer.^{4,7-10} To address this concern, immediate lymphatic reconstruction (ILR) through a lymphaticovenous anastomosis has emerged as a technique to reduce lymphedema risks when an ALND is necessary. Previous studies have shown a notable decrease in lymphedema rates when ILR is applied.¹¹⁻¹³ Introduced at Beth Israel Deaconess Medical Center (BIDMC) in 2016, ILR currently is performed routinely with ALND for lymphedema prevention.

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In response to the favorable outcomes associated with ILR, and recognizing its limited availability outside a few specialized centers, the Axillary Surgery Referral Program (ASRP) was initiated at BIDMC to facilitate the referral of patients from external institutions to undergo ALND with ILR. The program receives externally referred patients who have no ILR available at their local institutions.

This report details the ASRP's referral process and operational approach, highlights outcomes from its initial 6 years, and offers insights obtained from establishing a specialty referral program for axillary surgery. The goal is to provide a blueprint for health care institutions aiming to establish similar referral programs.

METHODS

Database Analysis

A retrospective review of patients referred to the ASRP at Beth Israel Deaconess Medical Center (BIDMC) during a period of 6 years, from 6 January 2017, to 10 December 2022 was conducted. The study received approval from the Institutional Review Board at BIDMC.

Patients were identified through a prospective breast surgery outcomes registry, records maintained by the ASRP nurse navigator, and a prospective lymphatic center clinical and quality improvement database. The study consisted of patients referred from outside institutions for consideration of ALND with ILR at BIDMC. Patients who had previously received breast surgery, axillary surgery, or neoadjuvant therapy were included in the study. Because the focus of the study was on the referral process, patients from within BIDMC were excluded from the analysis. Patients referred to the ASRP but who did not undergo surgery at the center for various reasons, including complete response to neoadjuvant chemotherapy (NAC), personal preference, or detection of metastatic disease, were identified but not included in the analysis.

Relevant patient data was collected from electronic medical records. These data included diagnosis, pathology findings, indication for referral, demographic information, previous breast cancer treatment, decision-making regarding ALND, and outcomes of operative intervention.

Statistical Considerations

Descriptive statistical analyses were performed using STATA BE 17.0 (StataCorp, College Station, TX, USA) to provide a comprehensive overview of the study population's sociodemographic characteristics, tumor profiles, treatment trends, and surgical outcomes. Categorical data were summarized using frequencies and percentages, whereas means were used to represent continuous data.

Axillary Surgery Referral Process

The primary objective of the ASRP is to provide ILR to patients undergoing ALND. The program is structured to streamline coordination and care for externally referred patients who have no access to the ILR procedure at their local institutions. Figure 1 provides a graphic illustration of the ASRP referral process and workflow. Further detail is provided as follows. Patients are referred to the ASRP nurse navigator, who performs the initial intake and facilitates communication between the referring institution and the ASRP surgical team. Patients typically are referred by their local surgeons and less frequently by self-initiating contact for treatment. Effective communication and coordination between the referring institution, the ASRP surgical

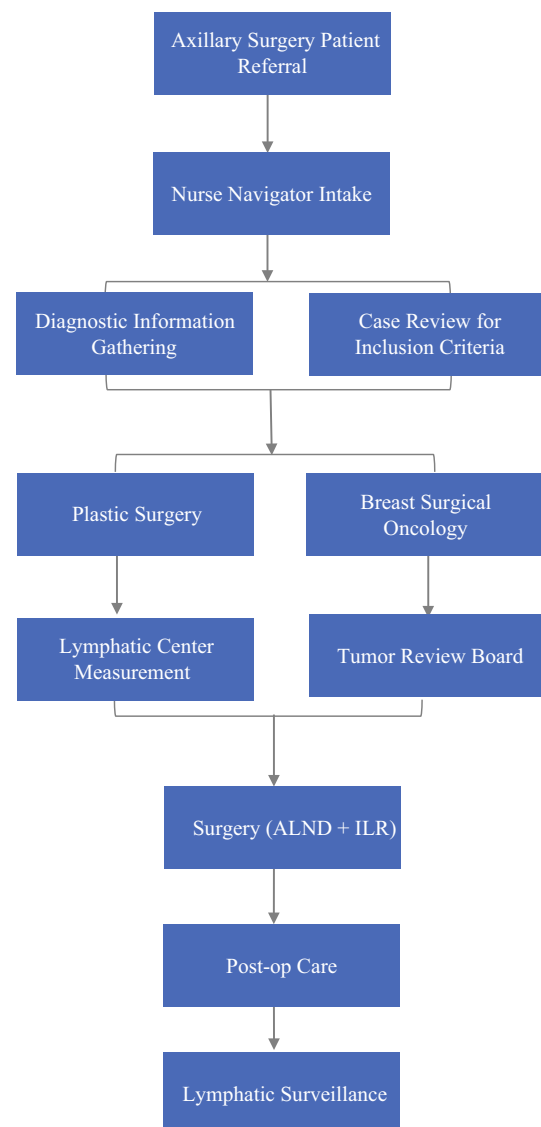


FIG. 1 Axillary surgery referral process

team, and the patient are prioritized to ensure a streamlined care process.

The nurse navigator, with internal administrative support, obtains the necessary diagnostic information and pertinent medical records from the referring institution, including imaging reports and pathology slides related to the axillary nodes. Cases are thoroughly reviewed by the breast surgical oncologist to confirm the necessity of the ALND procedure before the patient travels for consultation. Clinic appointments are then coordinated with breast surgical oncology, plastic surgery, and the Lymphatic Center's physical therapy team. Appointments are scheduled for the same day or consecutive days to reduce travel for patients.

Assessment at the Lymphatic Center includes baseline arm measurements and lymphatic mapping. Patients receive a preoperative volumetry assessment, through either circumferential measurement or perometry and bioimpedance spectroscopy/L-Dex. Patients are educated about the two procedures as well as the potential risks, benefits, and alternatives. Patients also view a video and receive a booklet about the ILR procedure.

Referred patients may be presented at the breast multidisciplinary tumor board, especially for situations in which alternatives to ALND are feasible. This includes situations in which less invasive surgical methods (e.g., targeted node dissection, reattempted sentinel lymph node biopsy [SLNB]) may be appropriate or non-surgical options such as radiation alone may be suitable.

To prevent care delays, early referrals are recommended upon confirmation of nodal metastasis. Patients with lymph node metastasis undergoing NAC are preferably seen in consultation during chemotherapy, and arrangements for surgery are made in advance. Referring institutions are advised to perform targeted node dissection or SLNB to confirm the necessity of an ALND after NAC. Surgery is typically arranged to be performed 4 to 6 weeks after chemotherapy. The program encourages all breast surgery to be performed at the referring institution by the local surgeons, with only the ALND/ILR performed at BIDMC.

Pre-authorization is pursued, but financial considerations related to insurance coverage remain an ongoing challenge. Whereas most health insurance plans cover an ALND as a recognized standard treatment procedure, ILR may be considered experimental.^{11,12} For patients whose health insurance does not cover the ILR procedure, navigation through the appeals process may be necessary, which can involve peer-to-peer reviews with insurance medical directors or an appeal letter. If the procedure still is deemed experimental and the denial is upheld, the patient is not responsible for the cost of the procedure other than any copays or deductibles he or she may have. The center is actively working on policy to establish medical necessity criteria for lymphatic surgery procedures.^{13,14}

The ALND/ILR typically is performed as an outpatient procedure. It starts with an injection protocol for lymphatic visualization involving fluorescein and isosulfan blue used at specific hand/wrist and antecubital locations. This is followed by the ALND and subsequent ILR through the same surgical exposure. If a patient has a pre-existing axillary incision from a previous procedure, such as a targeted node dissection, that incision is reused. Otherwise, a de novo axillary incision or prior mastectomy incision is used for axillary access. An axillary incision is preferred if a tissue expander is present to optimize exposure and reduce the risk of injury or infection with the expander.

During the ALND, meticulous care is taken to identify and preserve a vein suitable for lymphatic bypass, with the accessory vein as the preferred choice.¹⁵ Technical challenges may arise due to the presence of scar tissue or the prior sacrifice of superficial veins during previous axillary node-sampling procedures.

The ILR proceeds immediately after the ALND. Tributaries of the axillary vein are evaluated for adequate length and the presence of a proximal intact valve. Divided lymphatic channels are visualized under microscope, isolated, and measured using high magnification and fluorescent technology for visualization. The anastomosis is performed between the identified lymphatic channels into the selected vein. One to two channels are typically bypassed. Currently, the technique routinely uses a vein graft from the lower extremity to further facilitate the lymphatic bypass. Comprehensive details on the center's technical performance of the ILR procedure and its outcomes have been published previously.¹⁶⁻¹⁸

After surgery, information on the patient's recovery progress and subsequent pathology is provided to the referring institution. Drain care and any necessary immediate postoperative management are performed locally for patient convenience. However, the ASRP/ILR team is available to manage any complications or issues. A routine postoperative follow-up visit is arranged approximately 4 weeks after surgery with the breast surgical oncology and plastics teams at BIDMC. Whenever feasible and appropriate, tele-medicine is used to minimize the burden of travel for the patient. Patients are offered ongoing monitoring by certified lymphedema therapists at BIDMC, during which lymphedema symptoms are evaluated and both volumetry and bioimpedance measurements are retaken.

Patients followed at the center who experience signs/symptoms and measurements consistent with lymphedema initiate an intense regimen under certified lymphedema therapists that includes compression bandaging and heightened surveillance. Because the program manages referrals of patients from out of state and sometimes out of the country, some patients opt to have all monitoring and follow-up evaluation performed locally at the referring institution.

Patients also undergo any adjuvant cancer therapy and breast cancer surveillance at their home institutions.

RESULTS

During the study period from 6 January 2017 to 10 December 2022, 131 patients were referred to the ASRP at BIDMC. Patients were referred from various institutions across five U.S. states, with some referrals also coming from international locations. The median patient age was 54 years.

The predominant indications for referral to the ASRP were surgical management of residual disease after neoadjuvant chemotherapy (NAC) in 41.2% of cases ($n = 54$), positive sentinel lymph node biopsy (SLNB) warranting ALND in 33.6% of cases ($n = 44$), and diagnosis of locally advanced disease in 17.5% of cases ($n = 23$). A summary of the data on patients referred to the program is presented in Table 1.

Altogether, 111 patients (83.4%) underwent ALND with ILR. The most common tumor type was invasive ductal carcinoma (80.2%), grade 2 (54.6%), hormone receptor-positive

(HR+)/human epidermal growth factor receptor 2-negative (HER2-) (77.5%).

Before the ALND/ILR procedure, 69.4% of the patients underwent an SLNB or targeted axillary node dissection (TAD), whereas 30.6% underwent an upfront ALND without prior axillary surgery. On the average, 19 lymph nodes were removed during the ALND procedure.

The overall rate of post-surgical complications was 6.3%, which included hematoma (3.6%), cellulitis (1.8%), and seroma (0.9%). Notably, no patients experienced permanent neuromuscular nerve deficits.

The reasons for the referral of patients who did not undergo axillary surgery (15.3%, $n = 20$) were as follows: 25% ($n = 5$) achieved an axillary pathologic complete response to NAC, 15% ($n = 3$) opted to forego ALND with ILR, and 10% ($n = 2$) were found on subsequent workup to have distant metastatic disease.

An additional five patients were referred to the program for ILR with ALND but underwent alternative procedures instead. Three were referred because of unsuccessful SLNBs during partial mastectomy, and two were referred due to an upgrade from ductal carcinoma in situ to invasive carcinoma after a prior mastectomy without SLNB. In all five cases, the patients were able to undergo successful subsequent SLNB and avoid an ALND. Four of these procedures were performed through the ASRP, including one post-mastectomy SLNB, whereas the remaining post-mastectomy SLNB was performed at the referring institution based on the ASRP's recommendation.

For two patients (10%), interventions were pending, including breast surgery or systemic therapy, before ALND. Five patients (22%) were lost to follow-up evaluation after initial referral and consultation.

Throughout the duration of the study, the annual number of patients referred to the ASRP trended upward. The number of cases increased from 7 in the first 2 years to 65 in the last 2 years. The data on patients undergoing ALND and ILR are summarized in Table 2.

DISCUSSION

The ASRP at BIDMC introduces a unique approach to axillary management of breast cancer by integrating ILR and extending its scope to serve a broader range of externally referred patients. This report highlights the implementation of the ASRP and its operational framework.

The program's effectiveness is largely attributable to efficient care coordination, especially for out-of-state patients. In this regard, the nurse navigator plays a vital role in facilitating effective communication and coordination throughout the treatment process. As the primary point of contact and liaison for patients and referring physicians, the nurse navigator is responsible for performing the initial assessment,

TABLE 1 Patients referred to the axillary surgical referral program

Characteristic	<i>n</i> = 131 <i>n</i> (%)
Mean age (years)	54.43 ± 12.2
Referral states	
Maine	107 (81.7)
Massachusetts	18 (13.7)
New York	4 (3.1)
Florida	1 (0.8)
Oregon	1 (0.8)
Referred for ALND	
Performed	111 (84.7)
Omitted	20 (15.3)
Indications for referral	
Unsuccessful SLNB at home institution	3 (2.3)
Incidental IC after mastectomy	2 (1.5)
Locally advanced disease	23 (17.6)
Evaluation for residual disease after NAC	54 (41.2)
Positive SLNB (not a candidate for omission of ALND)	44 (33.6)
Other	5 (3.8)
Reasons for not performing ALND	<i>n</i> = 20
Complete response to NAC	5 (25)
Opted to omit ALND	3 (15.0)
Metastatic cancer	2 (10)
Pending further treatment at home-institution	2 (10)
Successful subsequent SLNB	3 (15)
Loss of follow-up	5 (25)

ALND, axillary lymph node dissection; SLNB, sentinel lymph node biopsy; IC, invasive carcinoma; NAC, neoadjuvant chemotherapy

TABLE 2 Patients undergoing ALND and ILR

	<i>n</i> = 111 <i>n</i> (%)
No. of cases	
2017	2
2018	5
2019	13
2020	26
2021	36
2022	29
Axillary management	
SLNB + ALND	77 (69.4)
Upfront ALND	34 (30.6)
Mean no. of nodes removed during SLNB/TAD	3.29 ± 2.24
Neoadjuvant chemotherapy	
Yes	79 (71.17)
No	32 (28.8)
Tumor histology	
Invasive carcinoma not specified	3 (2.7)
Invasive ductal carcinoma	89 (80.2)
Invasive lobular carcinoma	12 (10.8)
Mixed ductal and lobular carcinoma	2 (1.8)
Ductal carcinoma <i>in situ</i>	4 (3.6)
Inflammatory	1 (0.9)
Grade	
I	17 (15.4)
II	60 (54.6)
III	33 (30.0)
Receptor status	
HR+/HER2-	86 (77.5)
HR+/HER2+	11 (9.9)
HR-/HER2-	11 (9.9)
HR-/HER2+	3 (2.7)
Nodal evaluation on ALND	
Mean no. of nodes on ALND	18.5 ± 7.2
Patients with residual disease on ALND	63 (56.8)
Postoperative complications ^a	
Cellulitis	2 (1.8)
Hematoma	4 (3.6)
Seroma	1 (0.9)
Lymphedema after ALND with ILR ^b	<i>N</i> = 56 ^c
No	49 (87.5)
Yes	7 (12.5)

ALND, axillary lymph node dissection; ILR, immediate lymphatic reconstruction; SLNB, sentinel lymph node biopsy; TAD, targeted axillary node dissection; HR, hormone receptor (ER/PR); HER2, human epidermal growth factor receptor 2

^aEarly postoperative complications after ALND

^bAppearance of lymphedema after 1-year follow-up

^cPatients who continue with lymphedema surveillance or have shared their outside records with our institution

gathering all pertinent medical history and diagnostic information, coordinating appointments, and ensuring that all parties are consistently informed and aligned throughout the treatment process. The nurse navigator also plays a crucial role in patient education, ensuring that patients are well-informed about the procedures and process. After the surgery, the nurse navigator remains a constant touchpoint for the patients, ensuring that they are recovering well, addressing any concerns that may arise, and gathering feedback for improvement.

Many of the program's foundational elements, such as the nurse navigator, multidisciplinary tumor board, and collaboration with a plastic surgery team, are already prevalent in most breast centers. This existing infrastructure facilitates integration of a referral process for ALND/ILR. Furthermore, it provides a blueprint for other surgical programs aiming to offer specialized services to external referrals, highlighting the essential components and practices proven to be successful.

Since its inception, the annual number of referrals to the program has steadily increased. Regular outreach programs, seminars, and continuing medical education (CME) have undoubtedly played a role in growing the program, but its core strength lies in its patient-centered approach.

The program expanded ILR access for patients undergoing ALND and also guided a number of referred patients to alternative axillary treatment options including radiation alone, targeted node dissection, and post-mastectomy sentinel node dissection. The importance of reassessing nodal status after NAC and considering SLNB or TAD is evident in the cases in which patients were initially referred for an ALND but the procedure was omitted based on subsequent pathology findings from SLNB/TAD after NAC.

The majority of patients undergoing ALND were referred due to residual disease after chemotherapy. Most had receptor profiles associated with a lower likelihood of achieving an axillary pathologic complete response (PCR) after NAC. It is reasonable to assume that fewer referrals would comprise patients with tumor types more responsive to treatment, such as triple-negative breast cancer (TNBC) and HER2+ tumors, due to a higher likelihood of achieving axillary pCR and obviating the need for ALND. Interestingly, more than one third of the patients undergoing ALND, predominantly for residual disease after TAD, had no further disease found on final pathology. Ideally, a reliable method would be available for reassessment of the axilla to confirm the presence of persistent disease before an ALND is performed. Ongoing exploration into molecular imaging techniques and predictive algorithms may enable greater precision in identifying patients who truly require axillary clearance.

It is important to note that performing an ALND with ILR did not have a negative impact on the quantity of the nodes retrieved. In this study, 19 nodes were retrieved, exceeding

the commonly reported minimum quality standard of 10 lymph nodes for a complete dissection.¹⁹ This finding suggests that the quality of node clearance was not compromised when ALND was performed in conjunction with ILR.

Although the findings of the program offer pertinent insights, the study had some limitations. The retrospective nature of the analysis may have introduced inherent biases and limitations associated with data availability and accuracy. Additionally, because the study analyzed a single-center experience with specialized resources for axillary management, the findings may not be generalizable to other institutions with different resources, referral patterns, and practices. Despite these limitations, the study provided insight into the nuances of establishing a referral program for axillary surgery.

Future directions for research should include examining patient satisfaction and quality of life. Strategies to improve accessibility, such as housing and travel considerations, should also be investigated. Ongoing feedback from patients and referring institutions is actively sought to enhance the program's efficiency and patient experience.

Although the ALND/ILR procedure provides advantages in reducing lymphedema, it currently is available in only a limited number of specialized centers. As a result, it may not serve as a comprehensive solution for addressing the issue of lymphedema on a broader scale. Approaches that are more scalable and widely available will be needed to effectively reduce the morbidity associated with breast cancer-related lymphedema.

CONCLUSION

The ASRP at BIDMC demonstrates its effectiveness in facilitating appropriate referrals, providing advanced surgical techniques, and enhancing decision-making in axillary management. The role of nurse navigation and the multidisciplinary approach are vital for optimizing patient outcomes. The program serves as an example of extending the scope of a specialized surgical service and provides insights for those interested in initiating analogous programs. Ongoing efforts to refine the program and address challenges may help to further optimize the care provided to patients requiring ALND.

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