Interventional procedure overview of lymphovenous anastomosis during axillary or inguinal node dissection for preventing secondary lymphoedema

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Table 1 Abbreviations

Abbreviation	Definition
ALND	Axillary lymph node dissection
BCRL	Breast cancer-related lymphoedema
CAB	Coupler-assisted bypass
CI	Confidence interval
DLT	Decongestive lymphatic therapy
ICG	Indocyanine green (dye)
ILND	Inguinal lymph node dissection
ILR	Immediate lymphatic reconstruction
ITT	Intention to treat
LE	Lymphoedema
LVA	Lymphovenous anastomosis
LVB	Lymphovenous bypass
LYMPHA	Lymphatic microsurgical preventing healing approach
OR	Odds ratio
RCT	Randomised controlled trial
SLNB	Sentinel lymph node biopsy
S-LYMPHA	Simplified lymphatic microsurgical preventing healing approach
UEL	Upper extremity lymphoedema

Indications and current treatment

LE is the build-up of lymph fluid in a limb, causing swelling of that limb. It is a common complication after treatments for various cancers, and can be chronic and debilitating. The condition can severely damage the skin of, and cause aching in or difficulty moving the affected limb. There can also be recurrent skin infections, needing frequent antibiotic use and sometimes hospitalisation.

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There are no curative treatments but there are various treatments to help control the symptoms of LE. They aim to reduce swelling and infection while improving lymphatic flow in the body, and include:

- DLT, which comprises compression garments, manual lymphatic draining, skin care, exercise and massage done with specialist help or alone by the person with LE
- the 2 surgical techniques, liposuction and LVA.

Unmet clinical need

NHS lymphoedema services are available in various settings and mainly provided for cancer-related lymphoedema. But there is a variation in the availability of these services across different geographical locations. Patients having auxiliary lymph node dissection are at risk of developing secondary lymphoedema. By potentially reducing the need for clinic appointments for lymphoedema, treatments for associated infections, additional surgeries and hospital stays, this procedure could lead to cost savings for the healthcare system and improve patient outcomes.

What the procedure involves

This version of LVA is known as LYMPHA (lymphatic microsurgical preventative healing approach). It is done during axillary or inguinal node dissection to reduce the risk of LE developing after surgery. It involves creating a bypass from the transected lymphatics to nearby veins. Before the node dissection, a blue dye is injected to map the lymphatic circulation from the arm or thigh. During the node dissection, the surgical team inserts the cut lymphatic vessels into a small branch of the axillary or saphenous veins with the aim of restoring normal lymph flow.

The standard LYMPHA technique is done by surgeons with microvascular experience, using an operating microscope and, typically, 9-0 to 12-0 sutures. There is also a simplified technique known as S-LYMPHA, which can be done by surgeons without microsurgical training, without an operating microscope and using 7-0 sutures.

Outcome measures

The main outcomes included incidence of LE, successful completion of the preventative LVA procedure and perioperative complications.

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Evidence summary

Population and studies description

This interventional procedures overview is based on 2,121 patients from 4 systematic reviews, 1 prospective cohort study, 6 retrospective cohort studies and 1 RCT. Of these 2,121 patients, 1,164 patients had the procedure. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This overview presents 12 studies as the key evidence in table 2 and table 3, and lists 20 relevant studies in table 5.

Chun (2022) was a review and meta-analyses of 13 international studies of ILR for preventing secondary LE. It included 789 patients, 665 who had upper extremity ILR and 124 who had lower extremity ILR. Five studies were from Italy, 1 from India and 7 from the US. Ten of the studies focused on ALND for breast cancer in which 98% were women and 3 focused on ILND for malignant melanoma in which 46% were women. The mean age across the studies was 54 years and follow up ranged from 1 month to 42 months. Only 2 of 13 included studies reported control group outcomes and 5 studies were retrospective analyses. The authors highlighted many limitations of the meta-analysis. They recommended additional high-quality studies to better establish evidence-based guidelines for the procedure in different patient cohorts with comorbidities.

Cook (2022) was a review of 5 international retrospective studies on preventative ILR for BCRL. Some of these studies were included in meta-analyses. The mean age of study patients was 54 years and 249 of the 251 were women. Follow up ranged from 6 months to 48 months. The studies were limited by the small sample size, short follow up and a retrospective, non-randomised design.

Jorgensen (2017) was a systematic review of the effect of prophylactic LVA and shunts for preventing cancer-related LE. It included 12 studies in a qualitative analysis, and 4 studies in a quantitative analysis. The qualitative analysis reported outcomes for 284 patients. For 270 of these patients, the LVA procedure was feasible and completed. The studies that make up the review were international. Five focused on breast cancer, 3 on gynaecological cancers, 1 on vulvar cancer, 1 on melanoma, 1 on vulvar cancer and melanoma, and 1 on melanoma, squamous cell cancer and anal cancer. Eight of the studies were single intervention studies and 4 included a control group. But none included allocation concealment or blinding, and only 1 mentioned randomisation. The quantitative analysis included the 4 studies with control groups. These included a total of 82 patients who had prophylactic LVA and 94 patients acting as controls. The ages of study participants was not reported and follow up ranged from 3 months to 69 months. The authors reported that all the studies were highly biased.

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Markkula (2019) was a Cochrane review including 3 papers, 2 of which focused on LE prevention and 1 of which focused on LE treatment. The LE prevention studies were both RCTs and done in the same single centre in Italy. In 1, 25 of 49 patients had LVA and, in the other, 23 of 46 patients had LVA. The mean ages in the 2 relevant studies ranged from 54 to 57 years, and follow up was reported at intervals up to 24 months. The authors stated that there was an unclear or high risk of bias in multiple domains in the 2 RCTs.

Weinstein (2022) was a prospective study with 66 of 78 patients having LVA for preventing BCRL. It was done in the US and 100% of participants were women. The mean age was 53 years, and follow up was 8 months.

Ozmen (2019) was a retrospective study of a simplified approach of LYMPHA for preventing BCRL. It was done in the US and included 380 patients, 74 of whom had the LVA procedure. In all, 99% (377/380) of the patients were women, the mean age was 53 years, and follow up was 15 months.

Herremans (2021) was a retrospective study of a breast surgeon's 5-year experience with LVA for preventing BCRL in the US. It included 132 women, 76 of whom had the intervention alongside ALND and 56 of whom had ALND alone. The mean age was 56 years, and follow up was 40 months.

Ozmen (2022) was a retrospective study in the US of a simplified approach of LYMPHA for preventing BCRL. It evaluated how the procedure affected the chance of having LE. It included 194 patients, of whom 110 had LYMPHA with ALND and 84 had ALND alone. A total of 189 (97%) were women, the mean age was 50 years for the LYMPHA group and 53 years for the non-LYMPHA group, and follow up was 47 months.

Nacchiero (2022) was a retrospective study of the effect of LVA on the secondary development of LE in patients with melanoma. It was done in Italy, and 52 of 172 patients had LVA. The median age was about 54 years, 51% of the patients were men, and follow up was 6 months.

Levy (2022) was a retrospective study in the US of LYMPHA done during ALND. It included 90 women, 45 of whom had LYMPHA alongside ALND and 45 of whom had ALND alone. The mean age in the LYMPHA group was 54 years and in the ALND-alone group was 51 years. Median follow up in the LYMPHA group was 57 months and in the ALND-alone group was 63 months.

Chungsiriwattana (2022) was a retrospective study in Thailand of the effect on LE of LVA during surgery for patients with skin cancer of the lower extremities. Seven of 29 patients had LVA at the groin and 22 had wide resection of the skin cancer and ILND alone. Fifteen (52%) of the patients were women, the median age was 68 years and mean follow up was 38 months.

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Coriddi (2023) was a randomised controlled trial in the US on the efficacy of immediate lymphatic reconstruction (ILR) for decreasing the incidence of BCRL after ALND. All patients had either unilateral ALND or SLNBx with a high likelihood of ALND (for example, positive axillary lymph node biopsy). All the patients were women. The mean age was 48.5 years in the ILR group and 46.3 years in the control group. Follow up was 24 months.

Table 2 presents study details.

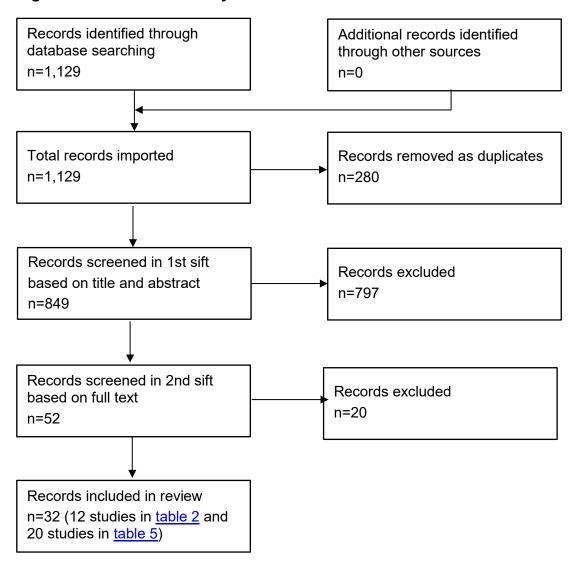**Figure 1 Flow chart of study selection**

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┌─────────────────────────────┐      ┌─────────────────────────────┐
│ Records identified through  │      │ Additional records identified│
│ database searching          │      │ through other sources       │
│ n=1,129                     │      │ n=0                         │
└─────────────────────────────┘      └─────────────────────────────┘
              │                                      │
              ▼                                      │
┌─────────────────────────────┐      ┌─────────────────────────────┐
│ Total records imported      │─────▶│ Records removed as duplicates│
│ n=1,129                     │      │ n=280                       │
└─────────────────────────────┘      └─────────────────────────────┘
              │
              ▼
┌─────────────────────────────┐      ┌─────────────────────────────┐
│ Records screened in 1st sift │─────▶│ Records excluded            │
│ based on title and abstract │      │ n=797                       │
│ n=849                       │      │                             │
└─────────────────────────────┘      └─────────────────────────────┘
              │
              ▼
┌─────────────────────────────┐      ┌─────────────────────────────┐
│ Records screened in 2nd sift │─────▶│ Records excluded            │
│ based on full text          │      │ n=20                        │
│ n=52                        │      │                             │
└─────────────────────────────┘      └─────────────────────────────┘
              │
              ▼
┌─────────────────────────────┐
│ Records included in review  │
│ n=32 (12 studies in table 2 │
│ and 20 studies in table 5)  │
└─────────────────────────────┘
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Table 2 Study details

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
1	Chun, 2022 Multiple	N=789 (upper, 99.4% female; lower, 69.4% male)	Mean age between upper/lower = 53.6 to 54.3 years	Systematic review and meta-analysis (13 studies)	ILR done to restore lymphatic drainage at the time or during the index procedure under a single anaesthesia **Exclusions:** Non-ILR interventions	ILR for preventing of upper or lower extremity LE	1 to 42 months
2	Cook, 2022 Multiple	N=251 (2:249)	Mean age = 53.8 years	Systematic review (5 studies)	Observational studies and RCTs	ILR was done concurrently with ALND for breast cancer	6 to 48 months
3	Jorgensen, 2017 Multiple	N=284	NR	Systematic review and meta-analysis (12 studies; 4 studies with control groups included in the meta-analysis)	Patients had lymphadenectomy as part of their cancer treatment Authors reported LE outcome	Prophylactic LVA for preventing (upper or lower) extremity LE	3 to 69 months
4	Markkula, 2019 Italy and Greece	N=95 (across 2 studies for preventing LE);	Mean age between studies = 47.7 to 57 years	Systematic review (3 studies)	RCTs for preventing or treating LE Pre-defined criteria for assessing LE	2/3 studies focused on preventative LVA (1 focused on	Up to 24 months

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Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
		(having preventative LVA, n=48)			Patients who had treatment for their breast cancer	treatment for LE) for UEL	
5	Weinstein, 2022 US	N=81 (0:81) (having ILR, n=66)	Mean age = 52.6 years	Prospective cohort study	Inclusion criteria mentioned but specifics not reported **Exclusions:** Preoperative ipsilateral LE Death during study period	ILR to prevent UEL	8 months
6	Ozmen, 2019 US	N=380 (3:377) (having LYMPHA, n=74)	Median age = 53 ± 11.61 years	Retrospective cohort study	Patients with breast cancer with axillary involvement having ALND	S-LYMPHA to prevent UEL	15 months
7	Herremans, 2021 US	N=132 (0:132) (having LYMPHA, n=76)	Mean age = 56.4 years	Retrospective cohort study	Patients having ALND for cT1-4N1-3M0 breast cancer	LYMPHA to prevent UEL	Mean = 40 months
8	Ozmen, 2022 US	N=194 (5:189) (having LYMPHA, n=110)	Mean age with LYMPHA = 50 ± 12 years	Retrospective cohort study	Patients with breast cancer and axillary involvement having ALND with or without S-LYMPHA	S-LYMPHA to prevent UEL	Median = 47 ± 37 months

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Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
			Mean age without LYMPHA = 53 ± 10 years		**Exclusions:** No post-op L-Dex measurements Lost to follow up		
9	Nacchiero, 2022 Italy	N=172 (having LVA, n=52) (26:26) (not having LVA, n=120) (64:56)	Median age = 53.3 to 54.8 years	Retrospective cohort study	Patients affected by melanoma of the trunk who had SLNB in the axilla or groin **Exclusions:** Presence of stage 4 melanoma or other carcinoma Compromised lymphatic drainage secondary to prior procedures	LVA to prevent upper or lower extremity LE	6 months
10	Levy, 2022 US	N=90 (0:90) (having LYMPHA, n=45)	Mean age (LYMPHA) = 54.2 ± 11 years Mean age (no LYMPHA) = 51.2 ± 12.7 years	Retrospective cohort study	Women with breast cancer who presented with axillary metastases needing ALND and possibly adjuvant radiotherapy for treatment **Exclusions:** Lympharzurin blue allergy Pregnancy	LYMPHA to prevent UEL	Median 57 to 63 months

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Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
11	Chungsiriwattana, 2022 Thailand	N=29 (14:15) (having LVA, n=7)	Median = 68 years (range 5 to 86)	Retrospective cohort study	Patients with either invasive squamous cell carcinoma or malignant melanoma skin cancer of the lower extremities with a histologically confirmed or clinically positive groin lymph node	LVA to prevent lower extremity LE	Mean = 38 months
12	Coriddi, 2023 US	N=156 (0:156) ALND with ILR=76 ALND without ILR=76	Mean age (SD) (ILR) = 48.5 years (11.3) Mean age (SD) (control) = 46.3 years (11.4)	RCT	Women with breast cancer having treatment at the Memorial Sloan Kettering Cancer Center, aged 18 to 75 years who consented to either unilateral ALND or SLNBx with a high likelihood of ALND (for example, positive axillary lymph node biopsy) **Exclusions:** Men with breast cancer, women having bilateral SLNBx or treatment for recurrent disease in the axilla, or women having treatment with SLNBx only without completion	Immediate lymphatic reconstruction (ILR) to decrease the incidence of BCRL after ALND.	24 months

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Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					of ALND or who had ALND but did not have a suitable vein or transected lymphatic channels for ILR		

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Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Jorgensen, 2017	**LE incidence:** From the pooled analysis of 4 studies with a control group, there is a 0.33 (95% CI 0.19 to 0.56) risk ratio of LE development for prophylactic LVA groups compared with the control groups (p<0.001).	**Postoperative complications** 1/12 studies reported postoperative complications. 1 case of lymphorrhoea was reported in a study of 10 LVA procedures for gynaecological cancer.
Markkula, 2019	**LE incidence:** Pooled estimate from 2 RCTs puts the risk ratio for LE development at 0.20 (95% CI 0.06 to 0.63) after LVA compared with standard care (p=0.006).	Not reported
Cook, 2022	**LE incidence:** 5.9% of patients (15/251) developed LE at a median of 10.3 months post lymphatic reconstruction. The weighted proportion of patients who acquired LE after LVA was 6.6% (95% CI 3.9 to 10.3) compared with patients without LVA, 30.5% (95% CI 4.0 to 68.1). **LVA completion:** Lymphatic reconstruction was attempted but not completed in 14.7% of patients (23/156), in 3 studies. Reasons for aborting lymphatic reconstruction included: inability to find afferent lymphatics, lack of adequate vein for LVA, or profound metastatic disease.	Not reported
Chun, 2022	**LE incidence:** The pooled LE incidence for the upper extremity subgroup was 2.7% (95% CI 1.1 to 4.4) after LVA (p=0.469).	**Postoperative complications**

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First author, date	Efficacy outcomes	Safety outcomes
	The pooled LE incidence for the <u>lower extremity</u> was 3.6% (95% CI 0.3% to 10.1%) for the 60.6% of patients followed up, on average, to 30 months after LVA (p=0.951). There were no statistically significant outcomes in relative risk of developing LE in the 2 studies that compared ILR intervention with a control group when doing a pairwise comparison.	1/3 studies for melanoma reported a wound infection
Weinstein, 2022	**LE incidence:** 4/66 (6%) patients who had LVA with ALND developed LE. 1/12 (8%) who did not have LVA developed LE. 3/5 patients with LE presented within 5 months of the operation and endorsed a rapid onset of symptoms. Statistically significant difference between LE incidence in LVA group (6%) compared with a retrospective cohort subsequently analysed at the same institution who had ALND with no LVA (44%) (p<0.0001) **LVA completion:** LVA could not be attempted in 12/78 patients. Patients were unable to have LVA after reverse lymphatic mapping because of; inability to identify afferent lymphatics (4), inadequacy of recipient veins (3), or spatial relationship incompatible with anastomosis (1).	**Postoperative complications** No LVA-associated postoperative complications were identified

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First author, date	Efficacy outcomes	Safety outcomes
	In 4 patients, lymphatics were identified, appeared intact within the field and were not disrupted for anastomosis.	
Ozmen, 2019	**LE incidence:** LE incidence was statistically significantly lower in the S-LYMPHA group compared with the non-LYMPHA group (OR=0.12, 0.03 to 0.5; p=0.001). LE incidence was 3% (2/74) in the LYMPHA group and 19% (11/87) in the non-LYMPHA group (p=0.022). In ITT analysis, the LYMPHA group experienced a 4% (3/82) LE incidence rate compared with 13% (10/79) in the non-LYMPHA group (p=0.036). LE incidence rates were equivalent (13%) between the group who didn't attempt LYMPHA and the group where LYMPHA was attempted but was unsuccessful (p=0.99). **LVA completion:** S-LYMPHA was completed in 74/82 patients (90%).	Not reported
Herremans, 2021	**LE incidence:** Statistically significantly lower LE incidence in the LYMPHA group of 13.2% (10/76) compared with 28.6% (16/56) in the ALND-alone group (p=0.045). In propensity matched analysis, the LE incidence rate was lower in the LYMPHA group (16.1%, 9/56) compared with the ALND-alone group (28.6%, 16/56) but was not a statistically significant difference (p=0.091).	Not reported

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First author, date	Efficacy outcomes	Safety outcomes
Ozmen, 2022	**LE incidence:** The LE incidence rate was statistically significantly lower in the S-LYMPHA group (16%, 18/110) than patients who had ALND alone (32%, 27/84) (p=0.01). The OR of developing LE is 0.4 (0.2 to 0.8) for patients who had S-LYMPHA than if they had had ALND alone (p=0.01). S-LYMPHA led to lower LE rates in univariate and multivariate analyses, and when looking at the outcomes from a single surgeon.	Not reported
Nacchiero, 2022	**LE incidence:** LE incidence was 4.3% (1/23) and 3.5% (1/29) in the LVA Groups 1 and 2 respectively, which was statistically significantly lower (p=0.03 and p=0.01) compared with a rate of LE development of 24.2% (29/120) in the control group. LE incidence was statistically significantly lower in LVA Groups 1 (7.7%, 1/15) and 2 (5.6%, 1/18) compared with the control group (31.9%, 22/69) for procedures at the groin (p=0.05 and p=0.02). LE incidence for procedures at the axilla was 13.7% (7/51) in the control group compared with 0 cases in either LVA group (statistical significance not calculated).	**Overall survival:** No statistically significant difference between groups who had LVA and the control group in overall survival at 3 years. **Disease-free days:** No statistically significant difference between groups who had LVA and the control group for length of disease-free period.
Levy, 2022	**LE incidence:** 31.1% (14/45) of LYMPHA patients developed LE compared with 33.3% (15/45) of the non-LYMPHA group (p>0.99).	Not reported

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First author, date	Efficacy outcomes	Safety outcomes
	No statistically significant difference between groups when focusing on obese patients (p=0.31), patients who had radiotherapy (p=0.79), or both combined (p>0.99).	
Chungsiriwattana, 2022	**LE incidence:** 42.9% (3/7) of LVA patients developed LE compared with 54.5% (12/22) in the control group (p=0.682). The LVA group had a longer median time to LE occurrence (70 compared with 17 months).	No statistically significant difference between groups in events/complications. The reported events were cancer-related, not LE-related.
Coriddi, 2023	**Cumulative incidence of BCRL:** ILR group 2.0% (95% CI, 0.16% to 9.3%) at 12 months, 9.5% (95% CI, 3.0% to 21%) at 18 months, and 9.5% (95% CI, 3.0% to 21%) at 24 months. Control group 18% (95% CI, 9.0% to 30%) at 12 months, 24% (95% CI, 12% to 37%) at 18 months, and 32% (95% CI, 17% to 47%) at 24 months.	There were no complications resulting from the ILR

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Procedure technique

Surgical technique was described in 10 studies.

A variety of agents including blue dye, ICG and fluorescein were used to visualise the lymphatic circulation. Anastomosis techniques included end-to-end, 'dunking' technique, U stitch and aborised (Chun, 2022; Weinstein, 2022). The simplified approach, or S-LYMPHA, involved using 7-0 nylon sutures without an operating microscope (Ozmen, 2019; Ozmen, 2022) as opposed to more typical approaches to LVA using 9-0, 10-0 or 11-0 sutures (Levy, 2022; Chungsiriwattana, 2022). LE measurement differed across studies. Combinations of bioimpedance, lymphoscintigraphy and other imaging, volumetry and circumferential measurements were used to assess presence of LE.

Efficacy

LE incidence

Eleven studies reported on the frequency or rate of LE incidence. Some studies reported the number of patients for whom LE developed out of a given number of patients while others gave a risk ratio or OR for LE development comparing an LVA intervention group with a control group. Four studies included some form of pooled or matched analysis for LE incidence. A few studies reported control group outcomes, and some were retrospective, potentially skewing effect size and introducing recall or selection bias.

For the meta-analysis by Chun (2022), the pooled estimate of LE incidence after LVA was 2.7% (95% CI 1.1 to 4.4, I^2=0%; 10 studies) for upper extremity indications and 3.6% (95% CI 0.3 to 10.1, I^2=0%; 3 studies) for lower extremity indications. There were no statistically significant outcomes on relative risk of developing LE in the 2 studies that compared ILR intervention with a control group when doing a pairwise comparison.

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In an RCT (Coriddi 2023), the cumulative incidence of BCRL in the ILR group was statistically significantly lower than in the control group (p=0.014). In the ILR group, the cumulative incidence of BCRL was 2.0% (95% CI, 0.16% to 9.3%) at 12 months, 9.5% (95% CI, 3.0% to 21%) at 18 months and 9.5% (95% CI, 3.0% to 21%) at 24 months. In the control group, the cumulative incidence of BCRL was 18% (95% CI, 9.0% to 30%) at 12 months, 24% (95% CI, 12% to 37%) at 18 months and 32% (95% CI, 17% to 47%) at 24 months.

The retrospective study by Cook (2022) reported a 5.9% LE incidence rate for patients who had LVA across all 5 studies. The pooled estimate for LE incidence for patients who had LVA was 6.6% (95% CI 3.9 to 10.3, I^2=0.0%; 5 studies) compared with 30.5% (95% CI 4.0 to 68.1, I^2=65.8%; 2 studies) for patients who did not have LVA.

The pooled analysis in the systematic review by Jorgensen (2017) estimated a risk ratio of 0.33 (95% CI 0.19 to 0.56) for developing LE after prophylactic LVA compared with no prophylactic LVA (p<0.001). The authors concluded that the results should be viewed with caution because the included studies were of low quality, heterogeneous and at high risk of bias.

Markkula (2019) estimated a risk ratio of 0.2 (95% CI 0.06 to 0.63) for developing LE for patients who had LVA compared with patients who did not (p=0.006) for the pooled analysis of 2 RCTs. The Cochrane reviewers stated that the certainty provided by the 2 included RCTs was low, and concluded that the evidence was not sufficient enough to support widespread adoption of the procedure.

In the retrospective analyses by Ozmen (2019 and 2022), S-LYMPHA was compared with non-S-LYMPHA. They found an OR of LE incidence of 0.12 (95% CI 0.03 to 0.50, p=0.001; Ozmen, 2019) and 0.40 (95% CI 0.2 to 0.8, p=0.01; Ozmen, 2022). Ozmen (2019) observed LE rates of 3% (2 of 74) in the LVA group and 19% (11 of 87) in the control group (p=0.022). The ITT analysis

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estimated rates of 4% in the LVA group and 13% in the control group (p=0.036). For patients in whom LVA was attempted but not successfully completed, LE incidence was 13%. This was equivalent to that in the group in which LVA was not attempted (p=0.99). Ozmen (2022) reported LE rates of 16% (18 of 110) in patients who had LVA and 32% (27 of 84) in patients who did not (p=0.01).

The matched analysis by Herremans (2021) estimated a lower LE rate of 16.1% after LVA than without LVA (28.6%) but this was not statistically significant (p=0.091).

The reported LE incidence rates ranged from 0% to 42.9% in the LVA groups across the studies. For upper extremity indications, the rate of LE incidence was reported as 0% (Nacchiero, 2022), 2.7% (Chun, 2022), 3.0% to 4.0% (Ozmen, 2019), 5.9% (Cook, 2022), 6.0% (Weinstein, 2022), 13.2% to 16.1% (Herremans, 2021), 16.0% (Ozmen, 2022) and 31.1% (Levy, 2022). For lower extremity indications, the rate of LE incidence was reported as 3.6% (Chun, 2022), 5.6% to 7.7% (Nacchiero, 2022) and 42.9% (Chungsiriwattana, 2022).

Weinstein (2022) reported an LE incidence of 6% (4 of 66) with LVA compared with 8% (1 of 12) in the control group. When compared with a retrospective cohort at the same institution, the LE incidence was estimated as 44% for patients who did not have LVA (p<0.0001).

Herremans (2021) reported LE rates of 13.2% (10 of 76) in patients who had LVA and 28.6% (16 of 56) in the control group (p=0.045).

Nacchiero (2022) reported an LE incidence of 4.3% (1 of 23) in the first LVA group, 3.5% (1 of 29) in the second LVA group and 24.2% (29 of 120) in the control group (p=0.03 and p=0.01 respectively). Results for these intervention groups and the control group were also given by axilla or groin indication. For the groin, 7.7% (1 of 15) and 5.6% (1 of 18) in the LVA groups developed LE compared with 31.9% (22 of 69) in the control group (p=0.05 and p=0.02

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respectively). For the axilla, 0% (0 of 8) and 0% (0 of 1) in the LVA groups developed LE compared with 13.7% (7 of 51) in the control group.

In the Jorgensen (2017) meta-analysis, 14.6% (12 of 82) in the LVA groups developed LE and 56.4% (53 of 94) in the control groups developed LE. Based on this, the authors suggested that the external validity of these studies was low and that the LE rates perhaps do not represent the general patient population, which it stated would usually be in the range of 20% to 40%.

In Levy (2022), the LE incidence in the LVA group was 31.1% (14 of 45) compared with 33.3% (15 of 45) in the control group, and the difference was not statistically significant (p=0.99).

Chungsiriwattana (2022) reported no statistically significant difference between groups (p=0.682). The LE incidence in the LVA group was 42.9% (3 of 7) compared with 54.5% (12 of 22) in the control group.

LVA completion

Three studies reported on the successful completion of preventative LVA.

In some studies, preventative LVA could not be attempted and in others it could be attempted but was not successfully completed. LVA was not attempted or completed in 10.0% (8 of 82; Ozmen, 2019), 14.7% (23 of 156; Cook, 2022; 3 studies) and 15.4% (12 of 78; Weinstein, 2022) of patients.

LVA could not be completed or attempted for the following reasons:

- inability to find afferent lymphatics
- lack of an adequate vein for LVA
- extensive metastatic disease
- a spatial relationship that was incompatible with anastomosis.

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Safety

Postoperative complications

Five studies reported on complications related to LVA.

One case of lymphorrhoea was reported in a study of 10 LVA procedures for gynaecological cancer (Jorgensen, 2017; 12 studies).

One patient had a wound infection in a study of melanoma with 23 patients (Chun, 2022; 3 studies).

Nacchiero (2022) included an analysis on overall survival and disease-free days, which showed that there was no statistically significant difference in overall survival at 3 years or disease-free days between the LVA and control groups.

Weinstein (2022) reported that no LVA-associated postoperative complications were identified.

Chungsiriwattana (2022) reported that there was no statistically significant difference between LVA and control groups in events or complications. The events that were reported were cancer-related and not associated with LVA or LE.

Six studies did not report complications or safety outcomes.

Anecdotal and theoretical adverse events

Expert advice was sought from consultants nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

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They listed the following anecdotal adverse events:

- development of LE

- anaphylaxis to blue dye (estimated at 1.8%) or ICG.

No theoretical adverse events were described by experts, but a unique concern was presented in Chungsiriwattana (2022). The authors expressed concerns that the tumour might be spread by reconnecting the lymphatic pathway.

Three professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the [specialist advice questionnaires for this procedure](#).

Validity and generalisability

- The 4 systematic reviews synthesised data from multiple countries. Of the 17 studies that were not systematic reviews, 11 studies were done in the US and 3 were done in Italy. None were done in the UK.

- While some of the evidence was from RCTs and prospective studies, the sample sizes were small. The 2 RCTs evaluated by Markkula (2019) included a total of 95 patients and were designated 'low certainty evidence'.

- Most of the evidence focused on BCRL, so the generalisability of this procedure for preventing lower extremity LE, as well as UEL, has limitations.

- The different ways that the presence of LE was assessed could have influenced the outcomes of individual studies.

- Most selected studies did not mention comorbidities, which may have affected results. This is because certain comorbidities affect LE incidence, for example, chronic venous insufficiency, venous leg ulcers, uterine cancer and prostate cancer.

- The average follow-up time in most studies was relatively short, limiting the evaluation of long-term effectiveness. Ozmen (2019) noted that 25% of LE

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cases will develop after 3 years and very few studies followed up to 36 months and beyond.

- The use of different diagnostic modalities for LE could have affected the quality of outcomes and risk of bias when comparing studies:
  - For example, Jorgensen (2017) stated that the studies it included diagnosed LE based on either circumference measurements or other volumetric methods. The authors stated that volumetric measurements are prone to bias, especially in the unblinded setting. They concluded that diagnosis should preferably be established as a combination of clinical and imaging evaluation.
  - The control groups in the Jorgensen (2017) meta-analysis found 56% of patients developed LE. Based on this, the authors suggested that the external validity of these studies was low, and the LE rates perhaps do not represent the general patient population, which it stated would usually be in the range of 20% to 40%.
- Levy (2022) and Chungsiriwattana (2022) reported high rates of LE in the LVA groups (although, lower than their respective comparators). Both of these studies had small sample sizes (n=90 and n=29 respectively). Levy (2022) explored potential bias, including overly broad assessment of LE. The authors remained doubtful of the long-term benefit of LVA. Chungsiriwattana (2022) did not recommend prophylactic LVA.
- Few studies report complications specific to the LVA component of this multifaceted surgery. The evidence and professional expert testimony suggests that preventative LVA does not bring additional risk of complications to the cancer-related and lymph node surgeries.
- Sample sizes varied greatly across studies, with some as low as 7 patients in the LVA group or 22 patients overall.
- No concerns around funding disclosures or conflicts of interest were identified across the studies.

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Ongoing trials include NCT04328610, NCT03941756, NCT04687956.

Related NICE guidance

Interventional procedures

NICE's interventional procedures guidance on liposuction for chronic lymphoedema (Recommendation: standard arrangements).

Medical technologies

NICE's medtech innovation briefing on L-Dex U400 for lymphoedema after breast cancer treatment

Professional societies

- British Lymphology Society
- Royal College of Surgeons of England
- Royal College of Surgeons of Edinburgh
- Royal College of Physicians and Surgeons of Glasgow
- Association of Breast Surgery
- British Association of Plastic, Reconstructive and Aesthetic Surgeons.

References

1. Jørgensen MG, Toyserkani NM, Sørensen JA (2018) The effect of prophylactic lymphovenous anastomosis and shunts for preventing cancer-related lymphedema: A systematic review and meta-analysis. Microsurgery, 38(5), 576-85

2. Markkula SP, Leung N, Allen VB et al. (2019) Surgical interventions for the prevention or treatment of lymphoedema after breast cancer treatment. Cochrane Database of Systematic Reviews, (2)

3. Cook JA, Sinha M, Lester M et al. (2022) Immediate lymphatic reconstruction to prevent breast cancer-related lymphedema: a systematic review. Advances in Wound Care, 11(7), 382-91

4. Chun MJ, Saeg F, Meade A et al. (2022) Immediate lymphatic reconstruction for prevention of secondary lymphedema: a meta-

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analysis. Journal of Plastic, Reconstructive and Aesthetic Surgery, 75(3), 1130-41

5.   Weinstein B, Le NK, Robertson E et al. (2022) Reverse lymphatic mapping and immediate microsurgical lymphatic reconstruction reduces early risk of breast cancer-related lymphedema. Plastic and Reconstructive Surgery, 149(5), 1061-9

6.   Ozmen T, Lazaro M, Zhou Y et al. (2019) Evaluation of simplified lymphatic microsurgical preventing healing approach (S-Lympha) for the prevention of breast cancer-related clinical lymphedema after axillary lymph node dissection. Annals of surgery, 270(6), 1156-60

7.   Herremans KM, Cribbin MP, Riner AN et al. (2021) Five-year breast surgeon experience in LYMPHA at time of ALND for treatment of clinical T1–4N1–3M0 breast cancer. Annals of surgical oncology, 28(10), 5775-87

8.   Ozmen T, Layton C, Friedman-Eldar O et al. (2022) Evaluation of Simplified Lymphatic Microsurgical Preventing Healing Approach (SLYMPHA) for the prevention of breast cancer-related lymphedema after axillary lymph node dissection using bioimpedance spectroscopy. European Journal of Surgical Oncology, 48(8), 1713-7

9.   Nacchiero E, Maruccia M, Robusto F et al. (2022) Prevention of Secondary Lymphedema after Complete Lymph Node Dissection in Melanoma Patients: The Role of Preventive Multiple Lymphatic–Venous Anastomosis in Observational Era. Medicina, 58(1), 117

10. Levy AS, Murphy AI, Ishtihar S et al. (2020) Lymphatic Microsurgical Preventive Healing Approach (LYMPHA) for the Primary Prevention of Lymphedema: A 4-year Follow-up Matched Cohort Study. Plastic and Reconstructive Surgery, 10-1097

11. Chungsiriwattana W, Kongkunnavat N, Kamnerdnakta S et al. (2023). Immediate inguinal lymphaticovenous anastomosis following lymphadenectomy in skin cancer of lower extremities. Asian Journal of Surgery, 46(1), 299-305

12. Coriddi M, Dayan J, Bloomfield E et al. (2023) Efficacy of Immediate Lymphatic Reconstruction to Decrease Incidence of Breast Cancer-related Lymphedema Preliminary Results of Randomized Controlled Trial. Annals of Surgery, 278 (4), 630-7

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Methods

NICE identified studies and reviews relevant to LVA during ALND or ILND for preventing secondary LE from the medical literature. The following databases were searched between the date they started to 16 November 2023: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following inclusion criteria were applied to the abstracts identified by the literature search:

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events that are not available in the published literature.
- Patients with cancer conditions needing ALND or ILND.
- Intervention or test: (preventative) LVA.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in the section on other relevant studies.

Find out more about how NICE selects the evidence for the committee.

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Table 4 literature search strategy

Databases	Date searched	Version/files
MEDLINE ALL (Ovid)	16/11/2023	1946 to November 15, 2023
EMBASE (Ovid)	16/11/2023	1974 to Nov 15, 2023,
EMBASE Conference (Ovid)	16/11/2023	1974 to 15 Nov 15, 2023
Cochrane Database of Systematic Reviews – CDSR (Cochrane Database of Systematic Reviews) (Cochrane Library)	23/11/2023	Issue 11 of 12, November 2023
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	23/11/2023	Issue 10 of 12, October 2023
International HTA (Health Technology Assessment) database (INAHTA)	23/11/2023	-

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE search strategy

1   Anastomosis, Surgical/
2   Anastomos*.tw.
3   1 or 2
4   Lymphedema/su [Surgery]
5   Lymphed*.tw.
6   4 or 5
7   3 and 6
8   (MLVA or LVA or LYMPHA).tw.
9   ((Lymphaticoven* or Lymphoven* or Lymphatic-ven*) adj4 anastomos*).tw.
10   Lymph Node Excision/
11   (Lymp* node adj4 (excision* or dissect* or ablat* or cut* or remove*)).tw.
12   ((Axill* or Inguin*) adj4 lymph node adj4 (excision* or dissect* or ablat* or cut* or remove*)).tw.
13   (ALND or INLD).tw.
14   Lymphangitis/su [Surgery]
15   Lymphangit*.tw.
16   lymphatic microsurgical preventive healing approach.tw.
17   Lymphedema/pc
18   or/7-17
19   *Breast Neoplasms/
20   *Penile neoplasm/
21   *Vulvar neoplasm/
22   *skin neoplasm/
23   *Melanoma/
24   or/19-23
25   Lymphedema/

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26   24 and 25
27   Breast Cancer Lymphedema/
28   BCRL.tw.
29   ((Breast* or penile* or vulva* or skin* or melanom*) adj4 (neoplasm* or cancer* or carcino* or adenocarcino* or tumour* or tumor* or malignan* or lump* or metast*) adj4 lymphed*).tw.
30   or/26-29
31   18 and 30
32   animals/ not Humans/
33   31 not 32
34   limit 33 to english language
35   limit 34 to ed=20230201-20231121

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Other relevant studies

Other potentially relevant studies to the IP overview that were not included in the main evidence summary (tables 2 and 3) are listed in table 5.

Table 5 additional studies identified

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Boccardo F, Casabona F, DeCian F et al. (2014) Lymphatic microsurgical preventing healing approach (LYMPHA) for primary surgical prevention of breast cancer-related lymphedema: Over 4 years follow-up. Microsurgery, 34(6), 421-424	N=78 (Had LYMPHA, n=74) Follow up = 4 years	4.05% LE incidence after LYMPHA compared with referenced rates of LE after SLNB of 6-13%, and axillary dissection alone of 13-65%.	Included in systematic reviews.
Feldman S, Bansil H, Ascherman J et al. (2015) Single institution experience with lymphatic microsurgical preventive healing approach (LYMPHA) for the primary prevention of lymphedema. Annals of surgical oncology, 22, 3296-3301	N=37 Median follow up = 6 months	12.5% LE incidence rate in a high-risk cohort of patients	Included in systematic reviews.
Boccardo F, Valenzano M, Costantini S et al. (2016) LYMPHA technique to prevent secondary lower limb lymphedema. Annals of surgical oncology, 23, 3558-3563	N=27 (n=11 with vulvar cancer, n=16 with melanoma)	6.25% (transient) LE incidence in the melanoma group (n=16) and 9% permanent LE incidence in the vulvar cancer group (n=11).	Included in systematic reviews.
Agrawal J, Mehta S, Goel A et al. (2018) Lymphatic Microsurgical	N=35	5.7% (transient) LE incidence	Other studies included with

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Preventing Healing Approach (LYMPHA) for Prevention of Breast Cancer-Related Lymphedema—a Preliminary Report. Indian Journal of Surgical Oncology, 9(3), 369-373			greater sample sizes.
Schwarz GS, Grobmyer SR, Djohan RS et al. (2019) Axillary reverse mapping and lymphaticovenous bypass: Lymphedema prevention through enhanced lymphatic visualization and restoration of flow. Journal of Surgical Oncology, 120(2), 160-167	N=60 (Had LVA, n=58) Median follow up= 11.8 months	3.4% LE incidence	Included in systematic reviews.
Johnson AR, Kimball S, Epstein S et al. (2019) Lymphedema incidence after axillary lymph node dissection: quantifying the impact of radiation and the lymphatic microsurgical preventive healing approach. Annals of Plastic Surgery, 82(4S), S234-S241	N=1,419 (Had LYMPHA, n=48) Median follow up = 25.7 months	Pooled estimate of LE incidence was 2.1% with LYMPHA compared with 14.1% in the control group (p=0.029).	Included in systematic reviews.
Cakmakoglu C, Kwiecien GJ, Schwarz GS et al. (2020) Lymphaticovenous bypass for immediate lymphatic reconstruction in locoregional advanced melanoma patients. Journal of Reconstructive Microsurgery, 36(04), 247-252	N=22 Follow up = up to 12 months	4.5% LE incidence	Other studies included with greater sample sizes.
Johnson AR, Fleishman A, Granoff MD et al. (2021) Evaluating the impact of immediate	N=97 (Had ILR, n=32)	12.5% transient and 3.1%	Included in systematic reviews.

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lymphatic reconstruction for the surgical prevention of lymphedema. Plastic and reconstructive surgery, 147(3), 373e-381e	Median follow up = 11.4 months	permanent LE incidence	
Cook JA, Sasor SR, Loewenstein SN et al. (2021) Immediate lymphatic reconstruction after axillary lymphadenectomy: a single-institution early experience. Annals of Surgical Oncology, 28, 1381-1387	N=33 Mean follow up = 9 months	9.1% transient and 6.1% permanent LE incidence	Other studies included with greater sample sizes.
Katz LM, Connolly EP, Choi JC (2022) Lymphatic Bypass in Patients Receiving Regional Nodal Radiation. International Journal of Radiation Oncology, Biology, Physics, 114(3), e32	N=54 (Had LYMPHA, n=27)	25.9% LE incidence in both LYMPHA and control groups.	Other studies included with greater sample sizes.
Wolfs, J AGN; de Joode, L GEH; van der Hulst, R RWJ; et al (2020) Correlation between patency and clinical improvement after lymphaticovenous anastomosis (LVA) in breast cancer-related lymphedema: 12-month follow-up. Breast cancer research and treatment; 179 (1); 131-138.	Case series N=25 patients had LVA procedure	LVA showed an acceptable patency and positive correlation between a patent anastomosis and clinical improvement after 12 months. Further research with a larger study population is needed to determine whether outcomes or patient characteristics statistically significantly correlate with a patent anastomosis after LVA operation.	Larger studies included in evidence summary.
Donahue, P.M.C., MacKenzie, A., Filipovic, A. *et al.* Advances in the prevention and treatment of breast	Review	Progress in prevention and treatment of BCRL continues, needing advances in early diagnosis, patient	Review

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cancer-related lymphedema. *Breast Cancer Res Treat* 200, 1–14 (2023).		education, expert consensus and novel treatments designed for lymphatic rehabilitation.	
Granoff, MD; Fleishman, A; Shillue, K et al. (2023) A 4-Year Institutional Experience of Immediate Lymphatic Reconstruction. Plastic and Reconstructive Surgery 152(5):p 773e-778e, November 2023.	Retrospective review N= 186 patients with unilateral node-positive breast cancer had axillary nodal surgery and ILR. Median follow up was 17 months	90 patients had successful ILR. The overall rate of lymphoedema was 9%. The authors' findings support that ILR at the time of ALND is an effective procedure that reduces the risk of BCRL in a high-risk patient population.	Larger studies included in evidence summary.
Lin, Ying-Sheng; Kuan, Chen-Hsiang; Tsai, Li-Wei; et al. (2023) The effect of immediate lymphatic reconstruction on the post-operative drain output after axillary lymph node dissection for breast cancer: A retrospective comparative study. Microsurgery; 43 (6); 555-562.	Retrospective comparative study N=76 patients with breast cancer (44 having ALND and ILR and 32 ALND alone).	The ILR group had statistically significantly less drainage amount than non-ILR group (39.3 ± 2.6 versus 48.3 ± 3.7, *p* = .046). For patients with breast cancer patients having ALND, the immediate lymphatic reconstruction can reduce the postoperative drainage amount from the operative wound.	Larger studies included in evidence summary.
Deban, M.; McKinnon, JG, Temple-Oberle, C. (2023) Mitigating Breast-Cancer-Related Lymphedema—A Calgary Program for Immediate Lymphatic Reconstruction (ILR) Curr. Oncol. 2023, 30(2), 1546-1559.	Review	Describes essential aspects of the elaboration of an ILR program. The Calgary experience is reviewed with specific focus on team building, technique, operating room logistics and patient follow up, all viewed through research and education lenses.	Review

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Haravu, P.N., Shakir, A., Jackson, K. *et al.* (2023) Establishment and Feasibility of an Immediate Lymphatic Reconstruction Program in a Community Health System. *Ann Surg Oncol* 31, 672–680.	Retrospective review N=90 patients had ALND with ILR compared with historical records for all patients who had ALND without ILR.	ILR was successful in 69 (76.7%). Patients with successful versus aborted ILR had lower lymphoedema rates (10.9% versus 66.7%, p < 0.01) and improved Disability of the Arm, Shoulder, and Hand (DASH) scores (8.7 versus 19.8, p = 0.25), and lower lymphoedema rates than the historical benchmark (10.9% versus 50.2%, p < 0.01). Among patients with successful ILR, older patients were more likely to develop lymphoedema (p < 0.05). Successful ILR after ALND statistically significantly reduced the lymphoedema rate when compared with aborted ILR and institution's historical benchmark. Our experience supports the efficacy of ILR and highlights the feasibility of ILR within a community health system.	Larger studies included in evidence summary.
Spoer, D.L.; Berger, L.E.; Towfighi, PN et al. (2023) Lymphovenous Coupler-Assisted Bypass (CAB) for Immediate Lymphatic Reconstruction. Journal of Reconstructive Microsurgery; DOI: 10.1055/a-2181-7559	Retrospective review N=63 immediate lymphatic reconstruction after ALND using CAB (n=24) or standard' end-to-end suturing technique, n=39	At a median follow up of 14.7 months, 9.1% (1/11) of individuals having CAB developed lymphoedema. These rates were similar to those seen after standard bypass at 4.8% (1/21), although within a statistically significantly shorter follow-up duration (standard 7.8 versus.	Comparative study of different techniques.

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		CAB 14.7 months, p=0.0170).	
Toshinskiy, S.G., Bailey, E.A. & Schwarz, G.S.(2023) Immediate Lymphatic Reconstruction in Breast Cancer Treatment: Clinical Trials and State of the Evidence. *Curr Breast Cancer Rep* 15, 310–315.	Review	ILR continues to be a promising surgical technique to reduce the risk of BCRL after ALND. Ongoing evaluation is needed to characterise the extent of protective effect conferred by ILR.	Review

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