

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Lymphovenous anastomosis during axillary or inguinal node dissection for preventing secondary lymphoedema

Lymph is a fluid that is carried around the body by a system of small vessels. Surgical removal (dissection) of lymph nodes (also called lymph glands), for example, during surgery for cancer of the breast (axillary nodes) or vulva (inguinal nodes), can lead to a build-up of lymph under the skin (lymphoedema). In this procedure, some of the lymphatic vessels around where the lymph nodes have been removed are diverted to nearby veins (lymphovenous anastomosis). This helps the lymph flow normally and not build up. The procedure is done when the lymph nodes are removed. The aim is to prevent lymphoedema and the symptoms it causes.

NICE is looking at lymphovenous anastomosis at the time of axillary/inguinal node dissection for the prevention of secondary lymphoedema.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 16 August 2023

Target date for publication of guidance: February 2024

1 Draft recommendations

1.1 For people with breast cancer, lymphovenous anastomosis during axillary dissection for preventing secondary lymphoedema should only be used with special arrangements for clinical governance, consent, and audit or research. Find out [what special arrangements mean on the NICE interventional procedures guidance page](#).

1.2 Clinicians wanting to do lymphovenous anastomosis during axillary node dissection for preventing secondary lymphoedema in people with breast cancer should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on [shared decision making](#), including [NICE's information for the public](#).
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

- 1.4 For auditing the outcomes of this procedure, the main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).
- 1.5 Patient selection should be done by a multidisciplinary team experienced in managing the condition.
- 1.6 The procedure should only be done by a multidisciplinary team experienced with it, including a surgeon with specific training in microvascular surgery.
- 1.7 For people with other cancers, lymphovenous anastomosis during axillary or inguinal node dissection for preventing secondary lymphoedema should be used only in research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.8 Further research should report details of:
- patient selection
 - quality of life
 - longer-term outcomes for lymphoedema incidence in different conditions
 - limb volume
 - safety outcomes (including survival and metastatic cancer).

Why the committee made these recommendations

Evidence from clinical trials and observational studies suggests that the procedure reduces the risk of lymphoedema after axillary node dissection in people with breast cancer. It also suggests that there are no major safety concerns. While there are some limitations in the evidence, including a lack of quality-of-life data and long-term follow up, overall, it is considered adequate.

The evidence for the procedure's efficacy in other cancers (that is, lower limb cancers and malignant melanoma) is more limited. Also, there are some safety concerns about the risk of the cancer spreading after lymphatic vessels around the dissected lymph nodes have been rediverted to nearby veins.

2 The condition, current treatments and procedure

The condition

2.1 Lymphoedema 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, and cause aching in or difficulty moving the affected limb. There can also be recurrent skin infections, needing frequent antibiotic use and sometimes hospitalisation.

Current treatments

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

- decongestive lymphatic therapy, which comprises compression garments, manual lymphatic draining, skin care, exercise and massage done with specialist help or alone by the person with lymphoedema
- the 2 surgical techniques, liposuction and lymphovenous anastomosis.

The procedure

2.3 This version of lymphovenous anastomosis is done during axillary or inguinal node dissection to reduce the risk of lymphoedema

developing after surgery. This procedure, also known as LYMPHA (lymphatic microsurgical preventive healing approach), 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.

- 2.4 The standard LYMPHA technique is done by surgeons with microvascular experience, using an operating microscope and, typically, 9-0 to 12-0 sutures.
- 2.5 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.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 1 prospective study and 6 retrospective cohort studies. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional expert and the committee considered the key efficacy outcomes to be: a reduction in secondary lymphoedema and technical success of lymphovenous anastomosis.

3.3 The professional expert and the committee considered the key safety outcomes to be: pain, bleeding, infection, overall survival and disease-free survival.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 Current treatments for lymphoedema, such as manual lymphatic drainage and compression garments, are often uncomfortable, time-consuming and need to be lifelong. This procedure has the potential to improve a person's quality of life and could have other benefits such as reduced hospitalisation.

3.6 There has been limited uptake of the procedure in the UK. The clinical expert explained that this is mainly because it needs to be done with specialist equipment by microsurgery-trained surgeons. There is a simplified version of the procedure (S-LYMPHA) that can be done by the operating breast surgeon (without microsurgical training) and does not need specialist equipment. But most of the evidence is for LYMPHA and not S-LYMPHA.

3.7 The clinical expert explained that lymphatic reconstruction may potentially increase the risk of metastatic disease. They advised that this a theoretical concern for when the procedure is done for lower limb (non-central) cancers such as malignant melanomas and that more safety evidence is needed.

3.8 There is evidence that about 25% of people will develop lymphoedema 3 years after LYMPHA. The clinical expert advised that studies with 5 year follow up are needed to better establish the safety and efficacy of the procedure.

3.9 Patient consent should include that additional operating time is needed for this procedure, and that it is still possible that lymphoedema may develop.

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