NICE National Institute for Health and Care Excellence

NICE guidance

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

Interventional procedures guidance
Published: 16 April 2024

www.nice.org.uk/guidance/ipg785

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

Breast cancer

1.1 Lymphovenous anastomosis during axillary dissection for preventing secondary lymphoedema in adults with breast cancer can be used in the NHS while more evidence is generated. It can only be used with special arrangements for clinical governance, consent, and audit or research.

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 Patient selection should be done by a multidisciplinary team experienced in managing the condition.

1.5 This procedure should only be done by a multidisciplinary team experienced in it, including a surgeon with specific training in microvascular surgery.

Other cancers

1.6 More research is needed on lymphovenous anastomosis during axillary or inguinal node dissection for preventing secondary lymphoedema for other cancers in adults.

1.7 This procedure should only be done as part of a formal research study, and a research ethics committee needs to have approved its use.

More research

1.8 More research is needed on:

- 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. So, it can be used with special arrangements for breast cancer.

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. So, it should be used only in research for other cancers.

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 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 12 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 1 randomised controlled trial, 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 lymphatic microsurgical preventive healing approach (LYMPHA) 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 if the procedure is done for lower limb (non-central) cancers such as malignant melanomas, and that more safety evidence is needed.

3.8 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.

ISBN: 978-1-4731-5887-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation