Guideline

Early and locally advanced breast cancer: diagnosis and management

Draft for consultation, September 2024

This guideline covers diagnosing and managing early and locally advanced breast cancer. It aims to help healthcare professionals offer the right treatments to people, taking into account the person's individual preferences.

This guideline will update NICE guideline NG101 (published July 2018).

Who is it for?

- Healthcare professionals
- Commissioners and providers of breast cancer services
- People with early and locally advanced breast cancer, their families and carers

What does it include?

- new and updated recommendations on lymphoedema
- the rationale and impact section that explains why the committee made the 2024 recommendations and how they might affect services.

Information about how the guideline was developed is on the guideline's webpage. This includes the evidence reviews, the scope, details of the committee and any declarations of interest.

New and updated recommendations

We have reviewed the evidence on lymphoedema risk factors, early identification, and prevention and lymphoedema management. You are invited to comment on these new and updated recommendations only. These are marked as **[2009, amended 2024]**, **[2018, amended 2024]** and **[2024]**.

Please note the recommendation numbers given in this document may not reflect their final position in the published guideline.

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1 *Lymphoedema: early identification and prevention*

1.1.1 Inform people having breast cancer treatment about their risk of developing lymphoedema after treatment. Before treatment starts, give them information in a suitable format to take away and refer to. This should include:

- information on:
  - risk reduction strategies, such as maintaining a healthy body weight, ways to reduce their risk of infection, and advice on skincare (for example, use of moisturiser and sunscreen), movement and exercise
  - early signs and symptoms, such as signs or sensations of swelling, or signs of infection
  - awareness of skin changes, such as changes in skin colour and appearance of rashes
  - how to self-monitor and identify these signs and symptoms
  - how to collect baseline measurements such as limb volume.

- that there is no consistent evidence of increased risk of lymphoedema associated with air travel, travel to hot countries, manicures, hot tub use or sports injuries
- that there is no consistent evidence of increased risk of lymphoedema associated with medical procedures (for example, blood tests, injections, intravenous medicines and blood pressure measurement) on the treated side. The decision to perform medical procedures using the arm on the treated side should be based on clinical judgement and the person's preferences, depending on clinical need and the possibility of alternatives. **[2018, amended 2024]**

1.1.2 Ensure people who have, or who are at risk of breast-cancer-related lymphoedema, are aware that:

- exercise may improve their overall quality of life, and
- there is no indication that exercise causes, or worsens lymphoedema. **[2024]**

1.1.3 Do not offer compression therapy to people who are at risk of breast-cancer-related lymphoedema. **[2024]**

Surgery for prevention

1.1.4 For advice on the use of lymphovenous anastomosis during surgery, see the NICE interventional procedures guidance on lymphovenous anastomosis during axillary or inguinal node dissection for preventing secondary lymphoedema. **[2024]**

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Lymphovenous anastomosis

What is the effectiveness of lymphaticovenous anastomosis during axillary lymph node dissection for preventing secondary lymphoedema and what is the acceptability of the intervention for different groups, such as:

- women, men, trans people and non-binary people
- people from ethnic minority backgrounds
- people with disabilities.

To find out why the committee made the research recommendation on lymphaticovenous anastomosis for preventing lymphoedema, see the rationale and impact section below.

2 Vascularised lymph node transfer

What is the effectiveness of vascularised lymph node transfer during axillary lymph node dissection for preventing secondary lymphoedema, and what is the acceptability of the intervention for different groups, such as:

- women, men, trans people and non-binary people
- people from ethnic minority backgrounds
- people with disabilities.

To find out why the committee made the research recommendation on vascularised lymph node transfer for preventing lymphoedema, see the rationale and impact section below.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Non-pharmacological prevention of lymphoedema in people who have, or have had, breast cancer

Recommendations 1.1.1 to 1.1.3

Why the committee made the recommendations

While the quality of the evidence on patient education varied, the committee agreed that people at risk of breast-cancer-related lymphoedema should be actively involved in measures aimed at early identification of the condition. They also agreed educating people about their risk of lymphoedema is very important, as it allows them to be prepared and take steps to reduce their risk (for example maintaining a healthy body weight, being aware of ways to reduce their risk of infection, and following advice on skincare, movement and exercise).

The committee also suggested that skin care advice such as using an appropriate emollient or moisturiser, using sunscreen to prevent sunburn, and other similar good practice, should be included. Such practices help maintain skin integrity, reduce infection risks, and promote overall skin health which can help with managing and reducing the risk of lymphoedema. Giving people information on these topics, including information to take away so they can review it in their own time and refer back to later, was therefore recommended. The widespread use of skincare in lymphoedema management was supported by the committee's expert opinion and experience. Although there was no new evidence on skincare, it was included as a low-risk intervention with potential benefits as part of comprehensive care recommendations for breast-cancer-related lymphoedema.

The committee considered the process of lymphoedema detection, monitoring, and referral to specialist services. There was some evidence that early intervention for lymphoedema leads to better outcomes and quality of life, but the committee agreed regular hospital monitoring where baseline measurements for people can be recorded, and any early changes can be identified would be difficult to implement in practice. The committee wanted to emphasise self-monitoring as a crucial component of lymphoedema prevention, as this approach aims to empower people to be actively involved in their care. They therefore recommended that the information people are given should include advice on how to self-monitor and to

detect changes in their condition early on, information to increase awareness of early signs and symptoms of lymphoedema and advice on how to collect baseline measurements for variables such as limb volume.

The committee discussed that self-monitoring should include awareness of skin changes such as changes in colour or the appearance of rashes. Signs and symptoms to be aware of include signs or sensations of swelling, or signs of infection.

The committee also noted that, in their experience, some people may have concerns about exercise. However, they agreed that, based on the evidence and their experience and expertise, exercise (including upper limb exercise) does not worsen or cause lymphoedema. The committee agreed that clarifying that exercise is safe and potentially beneficial was important to address common patient concerns and encourage healthy lifestyle behaviours.

The committee found that the evidence on using compression therapy as a preventive strategy for breast-cancer-related lymphoedema is currently insufficient. The effectiveness appeared to vary depending on the type of compression used (for example, compression sleeves) and the comparator (for example, education, light compression sleeves). Additionally, the studies reviewed did not report on patient adherence to wearing compression garments, which is a key factor in determining their practical usefulness. The committee noted that people needed to wear compression garments daily for a long period of time in the studies, which may be uncomfortable and undesirable for many people. Given this inconsistency in the evidence and patient experience, the committee decided not to recommend compression therapy for lymphoedema prevention.

There was some evidence on surgical interventions for preventing lymphoedema, for example lymphaticovenous anastomosis (LVA) and vascularised lymph node transfer (VLNT). While some studies suggest potential benefits of immediate LVA during axillary lymph node dissection (ALND) in reducing excess limb volume, cellulitis occurrence, need for conservative therapy, and improving quality of life and physical function, the committee agreed that more research is needed before preventive surgical interventions are suitable for all at-risk patients. However, a link

to existing NICE interventional procedures guidance on LVA was added for information.

As VLNT is not covered by the existing NICE interventional procedures guidance, but the committee are aware of its use preventatively as well as for treatment of established lymphoedema, the committee made a research recommendation on this topic.

The committee recognised that, while breast cancer predominantly affects women, men can also be affected. Additionally, while clinical trials do not tend to include men in studies, the committee felt that it was appropriate to extrapolate the evidence where possible to make comprehensive recommendations that address the needs of all breast cancer patients, regardless of gender.

How the recommendation might affect practice

It is expected that more lymphoedema education will result in better outcomes. There should be no change in resource needs as the recommendations reflect current clinical practice. However, the addition of education on self-monitoring and baseline measures may mean more resources are needed in order to teach people or provide material to support these recommendations.

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2 Management of lymphoedema

Specialist lymphoedema services

2.1.1 Ensure that people with breast cancer who develop lymphoedema are referred to a specialist lymphoedema service, as soon as possible. **[2009, amended 2024]**

Lymphoedema education

2.1.2 Provide people with lymphoedema with information in a suitable format (including information to take away) on:

- lymphoedema and its management
- skin and nailcare to prevent complications of lymphoedema
- support groups
- how to recognise the serious complications of lymphoedema that need urgent medical attention, for example cellulitis or deep vein thrombosis. **[2024]**

Lymphoedema management

2.1.3 Assess people with lymphoedema for other treatable underlying factors (for example, nodal disease and cellulitis) before starting any lymphoedema management programme. **[2024]**

2.1.4 Offer all people with lymphoedema compression therapy as the first stage of management. Make a shared decision with the person about the form of compression that is best for them. **[2024]**

2.1.5 For people where compression therapy may not be appropriate or not comfortable, consider kinesiology tape. **[2024]**

2.1.6 Reassure people that there is no evidence that exercise (including upper limb exercise) will worsen their lymphoedema and explain that it may improve their overall quality of life. **[2024]**

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Lymphoedema core outcomes set

What are the most reliable, valid and clinically relevant outcomes and measures for assessing lymphoedema severity and clinical effectiveness of lymphoedema treatments?

2 Lymphoedema surgical intervention: lymphaticovenous anastomosis (LVA) and vascularised lymph node transfer (VLNT).

What is the effectiveness and cost effectiveness of lymphaticovenous anastomosis (LVA) and vascularised lymph node transfer (VLNT) in the management of breast-cancer-related lymphoedema, and what is the acceptability of the intervention for different groups, such as:

- women, men, trans people and non-binary people
- people from ethnic minority backgrounds
- people with disabilities.

3 Breast oedema management

What are the most effective interventions for the management of breast oedema for people who have or have had breast cancer, and what is the acceptability of the intervention for different groups, such as:

- women, men, trans people and non-binary people
- people from ethnic minority backgrounds
- people with disabilities.

To find out why the committee made the research recommendations on lymphoedema core outcome set, surgical interventions and breast oedema management, see the rationale and impact section below.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Non-pharmacological management of lymphoedema in people who have, or have had, breast cancer

Recommendations 2.1.1 to 2.1.7

Why the committee made the recommendations

There was mixed evidence on a variety of interventions for managing lymphoedema. Overall, the evidence was at moderate to high risk of bias, and the studies included small participant numbers with varying lymphoedema severity, interventions and outcomes. However, the committee agreed that in the first instance, people with breast-cancer-related lymphoedema of the arm, hand or chest wall should be referred by healthcare professionals who have contact with them to a lymphoedema service that will evaluate their lymphoedema and should be provided with information on lymphoedema and its complications. The committee emphasised the importance of an assessment being done before any treatment is considered.

The evidence on complete decongestive therapy and its individual components (including exercise, manual lymphatic drainage, bandaging, compression garments, skin and nailcare) varied. Most of the evidence for compression therapy (including bandages, garments and devices) and exercise showed an improvement in the outcomes of lymphoedema severity, adverse events, and quality of life. These outcomes are important from a clinical perspective as well as from the patient’s perspective for deciding on treatment options.

The committee were convinced by evidence supporting the efficacy of compression therapy, so recommended its use. However, they also acknowledged that compression therapy may not always be appropriate, for example in people who experience significant discomfort, or in cases where the affected area is difficult to compress effectively using standard garments. In these specific cases, alternative options such as kinesiology tape may be an option. There was some evidence on

kinesiology tape for the management of lymphoedema that showed improvement in patient quality of life, pain and discomfort levels, although the effectiveness of this treatment varied when compared to similar interventions such as compression garments. The committee noted that people may prefer kinesiology tape because of its convenience, ease of application and comfort. However, they noted that it may not be as effective as compression garments and so could have differing results depending on the area of oedema.

The committee discussed that, while some people may prefer kinesiology tape, this option often needed people to purchase their own tape. The committee were concerned that this additional cost could create a barrier to access, particularly for individuals from lower socioeconomic backgrounds. This disparity in access could potentially exacerbate existing inequalities. To that effect, the committee only included kinesiology tape as an alternative treatment to compression therapy.

The clinical evidence for manual lymphatic drainage (MLD) was uncertain and there was no economic evidence. The committee acknowledged that MLD is labour intensive and is often carried out by specialist lymphoedema practitioners for several sessions and, therefore, could bear a significant cost for the NHS. Given the lack of strong evidence and the potential cost for the public healthcare, the committee decided not to make any recommendation on MLD.

The committee also noted that in their experience some people may have some concerns about exercise, but they agreed that based on the evidence and their experience, exercise (including upper limb exercise), will not impact people’s lymphoedema and may improve some clinical outcomes.

Along with conservative management options for lymphoedema, there was some evidence on surgical interventions for managing lymphoedema. Lymphaticovenous anastomosis (LVA) and vascularised lymph node transfer (VLNT) were discussed. These techniques are used worldwide, and some UK centres are adopting them. Although there was low-quality evidence that LVA reduced severity of lymphoedema, overall, the evidence did not show significant effects on efficacy, safety, and quality of life outcomes. The committee highlighted that lower limb lymphoedema is well studied, but there is a significant evidence gap for truncal and upper limb

lymphoedema which are more relevant to breast cancer patients. They were also concerned that the full costs associated with the surgery are not well understood, and there is limited evidence available to carry out economic modelling. Considering these limitations, the committee made research recommendations to address these issues.

The committee discussed that the lymphoedema surgery services are not fully established and varied across the UK. As a result, there were concerns about the limited availability of lymphoedema surgery services, which could lead to health inequalities and the committee decided to not make any recommendations for surgery for managing lymphoedema. They agreed research recommendations are more appropriate given the evidence base to address knowledge gaps. As there is currently a significant evidence gap for truncal and upper limb lymphoedema, which are more relevant to breast cancer patients, the committee made a research recommendation on surgical interventions including lymphovenous anastomosis during axillary as well as vascularised lymph node transfer.

How the recommendations might affect practice

The recommendations may reduce variation in practice in terms of which interventions people are offered and the information given. As such, these recommendations highlight some interventions that may be effective, but also more comfortable and convenient for people. This might reduce any costs, improve adherence, and improve outcomes for people with breast cancer-related lymphoedema.

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