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# Evidence Summary: Managing lymphoedema: Complex lymphoedema therapy

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## QUESTION

What is the best available evidence on the effectiveness of complex lymphoedema therapy/complete decongestive therapy in managing lymphoedema?

## BACKGROUND

Complex lymphoedema therapy (CLT), also known as complete decongestive therapy (CDT) or complex physical therapy (CPT), is a holistic, multi-component management strategy for reducing the signs and symptoms of lymphoedema. There is evidence from a systematic review of clinical trials<sup>1</sup> (Level 1.b evidence), additional trials and consensus guidelines that CLT is an effective strategy for reducing limb oedema<sup>1</sup>, improving quality of life (QOL) and reducing recurrent cellulitis<sup>2</sup> (Level 3.d evidence) in patients with both upper and lower limb lymphoedema.

Lymphoedema is a form of chronic, progressive oedema in which there is significant, persistent swelling of a limb or other body region due to excess and abnormal accumulation of protein-rich fluid in body tissues. This fluid contains a range of inflammatory mediators and adipogenic factors<sup>3-7</sup>. The lymphatic system is unable to manage the volume of accumulated fluid<sup>3</sup>.

Lymphoedema occurs due to primary, secondary or mixed causes. Primary causes are described as congenital (e.g. an inherited disorder such as Milroy's disease), praecox (onset at puberty, e.g. Meigs' disease) or tarda (sudden onset no apparent cause)<sup>4-6</sup>. Secondary causes arise from direct damage or trauma to the lymphatic system such as injury, surgery or radiotherapy (usually related to treatment of breast cancer), or parasitic invasion<sup>5-7</sup>. Lymphatic filariasis (also

called elephantitis) is a cause of secondary lymphoedema in endemic areas primarily in Africa and Asia. Lymphatic filariasis a parasitic (roundworm) infection that is spread by mosquitoes and causes damage to the lymphatic system that may result in lymphoedema. Infection generally occurs in childhood. Management focuses on large-scale treatment programs to reduce disease spread<sup>8,9</sup>. Mixed lymphoedema describes lymphoedema arising from decompensation or failure of the lymphatic system associated with other disease or conditions, including but not limited to obesity, immobility, venous disease or lipoedema<sup>5,6,10</sup>.

Without management, lymphoedema may lead to:<sup>3,11</sup>

- progressive swelling;
- superficial tissue changes — increasing adiposity and fibrosis;
- physical and functional limitations;
- increased risk of chronic infection;
- lymphorrhoea (leaking of lymph fluid);
- pain and discomfort; and
- reduced ability to undertake activities of daily living (ADLs).

Complex lymphoedema therapy/complete decongestive therapy is an holistic management strategy for lymphoedema. This multi-component management strategy includes:

- patient education;
- skin care;
- manual lymph drainage (MLD);

- exercises;
- multilayer compression bandaging (in intensive phases); and
- compression garments (in maintenance phases)<sup>1,12-14</sup>.

Complete decongestive therapy may also be referred to as intensive therapy, complex physical therapy or combined physiotherapy<sup>14</sup>. The therapy is generally performed by specially trained physiotherapists with specific training that may be difficult to access in parts of Australia.

The frequency and duration of CLT is dictated by the severity of the individual's lymphoedema, but typically involves a short intensive phase (2 to 4 weeks)<sup>15</sup> to reduce lymphoedema, followed by ongoing maintenance therapy. In the trials showing effectiveness for intensive CLT reported in systematic reviews<sup>1,15</sup>, regimens generally included one hour sessions of MLD, decongestive exercises and education conducted at least three times per week for two to six weeks. However, the same regimens were also used in studies in which effectiveness was not established<sup>1</sup>. In clinical trials reported in systematic reviews<sup>1</sup>, ongoing maintenance therapy involved the use of compression garments to maintain reduction in oedema achieved during intensive therapy; continuation of exercises; good skin care and hygiene; and, in some regimens, self-performed MLD<sup>1,12-14</sup>. As lymphoedema is usually a life-long condition, ongoing maintenance generally follows a chronic disease management plan.

## CLINICAL BOTTOM LINE

The evidence on the effectiveness of CLT is somewhat mixed and effectiveness appear to be associated with degree and duration of lymphoedema and ways in which outcome measures (particularly limb volume) are measured<sup>15</sup> (Level 1.b evidence).

In a recent systematic review (Level 1.b evidence)<sup>1</sup>, 27 studies of mixed methodologies met the inclusion criteria. These studies were reported as having design flaws that placed them at moderate to high risk of bias. Fifteen of the studies (57.6%) showed a likely benefit for CLT; seven of these studies were randomised controlled trials (Level 1.c evidence). These studies were primarily conducted in participants with breast cancer-related lymphoedema. Two studies demonstrated a balance between benefits and harms, and ten studies failed to demonstrate effectiveness of CLT.

A systematic review of clinical trials investigating the effectiveness of MLD alone indicates that this intervention is not effective in achieving clinically significant improvement in lymphoedema<sup>16</sup> (Level 1.a evidence). The addition of compression bandaging or garments to maintain reductions in limb volume achieved from massage and exercise appear to be a critical component of CLT. A Cochrane review of six studies on MLD for women with breast cancer-associated lymphoedema reported that compression bandaging appeared to be more effective in reducing limb size when MLD was added to the regimen (although not for all outcome measures)<sup>15</sup>.

## Effectiveness in reducing oedema

- Evidence from 15 studies of mixed design (including RCTs, case-control studies, prospective observational

studies and retrospective analyses) indicates that a course of CLT is effective in reducing limb oedema. Effectiveness was demonstrated in participants with both upper and lower limb lymphoedema. Findings from these studies suggests that the most significant reduction in limb volume occurs following the first five days of CLT and limb volume continues to gradually decline in the following weeks until a plateau is reached<sup>1</sup> (Level 1.b evidence).

- In a small RCT (n=95) comparing CLT to compression bandaging alone for women with breast cancer-related lymphoedema the group receiving CLT achieved greater absolute limb volume loss (difference 107 ml, 95% confidence interval [CI] 13–203 ml, p=0.03), although there was no significant between-group difference (p=0.34) for mean per cent reduction in limb volume. Repeated measures analysis indicated that the significant limb volume lost occurred in the first three weeks of the 52-week trial (p<0.001)<sup>17</sup> (Level 1.c evidence).
- Another RCT found CLT was effective for reducing limb volume in women (n=45) following breast cancer surgery. The trial compared three different types of compression bandaging used in a multi-component CLT intervention. Women in all three groups had a significant reduction in limb volume after four weeks compared to before treatment (no significant difference between groups). Significant improvement was also observed in discomfort, heaviness, tension and stiffness<sup>18</sup> (Level 1.c evidence).
- In a cohort study, participants with upper or lower lymphoedema undertook a CLT as either an active plus ongoing maintenance phase, or an ongoing maintenance phase alone. Although the group receiving active therapy phase achieved larger initial reduction in limb volume, the limb volume reduction did not differ significantly between groups at the six-month stage<sup>19</sup> (Level 3.c evidence).
- In a case study describing the experience of one participant with unilateral lower limb lymphoedema secondary to surgical repair of a fracture, eight sessions of CLT over three months facilitated a decrease in affected limb size of almost 9% and return to equivalent size of the unaffected limb<sup>12</sup>. In a similar case study, a participant with unilateral lower limb lymphoedema experienced a 66% reduction in limb size after a 23-week course of CLT<sup>20</sup> (both Level 4.d evidence).

## Effectiveness in reducing recurrent cellulitis associated with lymphoedema

In one case-controlled study in which participants (n=21) who had previously had up to three hospital admissions for cellulitis in a lymphoedema affected limb acted as their own controls, a CLT protocol was effective in reducing hospital admissions from cellulitis over an 18-month period. Participants had primary (40%) and secondary (60%) lymphoedema (stages I to III) that was either unilateral or bilateral and of either upper or lower extremities (50% had bilateral lower limb lymphoedema). All participants received education and information on skin care and hygiene, MLD, multilayer comprehensive bandaging (only in the intensive phase), supervised exercise therapy, and an individualised

compression garment for long-term maintenance. Regimens were individualised and ranged from nine to 29 sessions over 3 to 14 weeks. Compression garments were also individualised and had pressure gradients from 20 mmHg to 45 mmHg. Over 18 months, one participant from the 10 who completed active therapy required hospitalisation for cellulitis, which equated to a number need to treat (NNT) of 0.13 and absolute risk reduction of 7.83 admission/year<sup>2</sup> (Level 3.d evidence).

### Long-term adherence to therapy

- In one case-controlled study, adherence to the active treatment phase of the study was 47.6% (10/21)<sup>2</sup> (Level 3.d evidence).
- In an RCT, there was no difference in adherence to therapy over 52 weeks between individuals receiving CLT and those receiving compression bandaging alone. Participants receiving CLT wore compression garments for an average of 64±25 hours/week<sup>17</sup> (Level 1.c evidence).
- A cohort study suggested that an active phase of CLT may contribute to the motivation of patients to maintain long-term therapy through identifying to patients the ideal limb shape, establishing long-term goals and role modelling the diligent performance of MLD<sup>19</sup> (Level 3.c evidence).

Further research on the role of individual components of CLT and the influence of adherence to therapy in the long term is warranted.

### CHARACTERISTICS OF THE EVIDENCE

This evidence summary is based on a structured database search combining search terms describing lymphoedema and complete decongestive therapy. The evidence comes from:

- Meta-analysis of RCTs<sup>16</sup> (Level 1.a evidence).
- Systematic reviews of studies of various design<sup>1,13,15</sup> (Level 1.b evidence).
- Randomised controlled trials<sup>17,18</sup> (Level 1.c evidence).
- Cohort study<sup>19</sup> (Level 3.c evidence).
- Case-controlled study<sup>2</sup> (Level 3.d evidence).
- Observational studies with no control group<sup>7</sup> (Level 3.e evidence).
- Case series report<sup>10</sup> (Level 4.c evidence).
- Case study report<sup>12,20</sup> (Level 4.d evidence).
- Expert consensus<sup>5,8</sup> (Level 5.b evidence).
- Expert opinion<sup>3,4,6,9,11,14</sup> (Level 5.c evidence).

### BEST PRACTICE RECOMMENDATIONS

- There is good evidence that an active phase of complete decongestive therapy is effective in decreasing limb volume associated with lymphoedema. (Grade A)
- There is some evidence that an active phase of complete decongestive therapy is effective in reducing incidence of cellulitis in patients with lymphoedema. (Grade B)

### RELATED EVIDENCE SUMMARIES

JB1 11559 Lymphedema: classification

JB1 11564 Lymphedema: objective assessment using bioimpedance spectroscopy

JB1 11562 Lymphedema: objective assessment using perometry

JB1 11870 Lymphedema: objective assessment using tonometry

JB1 11871 Lymphedema: objective assessment using volumetry

JB1 12020 Lymphedema: objective assessment using circumference measurement

JB1 11560 Lymphedema: subjective assessment

JB1 12096 Managing lymphoedema: pneumatic compression therapy

JB1 12921 Managing lymphoedema: manual lymphatic drainage

JB1 13918 Managing lymphoedema: laser therapy

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