

Evidence-based practice or practice-based evidence? Why pursuing level 1 evidence is leaving lymphoedema behind

Jan Douglass

Key words

Evidence-based practice, practice-based evidence, lymphoedema services

Jan Douglass is an Adjunct Associate Professor and member of the WHO Collaborating Centre for Vector Borne and other NTDs at James Cook University, Townsville, Queensland, and the Managing Director of Moving Lymph Pty Ltd, Adelaide, South Australia

Declaration of interest: The author declares that I am accredited by the Dr Vodder Akademie International as a Practical Instructor in Applied MLD, and that Moving Lymph Pty Ltd is the designated Dr Vodder School Australia and New Zealand.

Since the levels of evidence were first described in 1979, we have held the randomised controlled trial (RCT) as the pinnacle of evidence for health interventions (Burns et al, 2011). Systematic reviews (SR) and meta-analysis (MA) of RCT, and systematic reviews of SR, keep us climbing a never attainable peak and drive our research agenda towards a reductionist dissection of our techniques. Despite nothing about lymphoedema management being well suited to an RCT, we are beset with multiple SR on the same set of trials, mostly on unilateral arm lymphoedema, reporting the same inconclusive findings. Such reviews are at odds with decades of clinical observation, leaving therapists confused and lacking confidence in their training.

Multi-modal therapy for lymphoedema was first developed in the mid-20th century (Wittlinger et al, 2018) and the same core therapies; skin-care, exercise, lymphatic massage and compression are still considered best-practice (International

Abstract

Randomised controlled trials (RCT) have been held as the pinnacle of evidence for health interventions for over half a century and are frequently used in research on lymphedema, yet little in lymphoedema management is suited to an RCT. Nevertheless, multiple systematic reviews (SR) have been conducted, delivering results which are sometimes at odds with clinical observation and leaving therapists and patients confused. Chronic conditions require complex management integrating patient and environmental considerations, so the way that data on interventions is aggregated and synthesised needs to reflect this. In general, evidence-based public-health is moving rapidly towards accepting other levels of evidence for chronic conditions, however SR on interventions for lymphoedema are yet to include these methods.

Society of Lymphology, 2020). All elements of this approach should be investigated to ensure our recommendations and guidelines for their use are based on evidence and cost effective. Like many chronic conditions, lymphoedema requires complex management by a multidisciplinary team, and patient-centred factors and environment play a key role in treatment outcomes. There is no one size fits all therapy and attempting to single out one modality and squeeze it through the narrow parameter of a SR ignores the synergistic effects of combined modalities, and fails to tell us anything clinically useful. There are many other ways to assess health interventions, such as observational studies, and case series and case reports, and we need new ways to aggregate data on the synergistic interactions of our therapies, including those involving person-centred factors. In general, public health and the evidence-based-public field is moving rapidly towards accepting these other levels of evidence in the management of chronic diseases, however SR on

interventions for lymphoedema are yet to include these methods.

Systematic reviews and meta-analysis on MLD and lymphoedema

Therapists looking to the published literature to guide clinical decision making in the use of manual lymph drainage (MLD) and lymphoedema can be forgiven for coming away confused and overwhelmed. There are an increasing number of SR which aim to differentiate the benefits of comprehensive lymphoedema treatment with or without MLD, or in comparison to compression devices. But almost all of them fail to deliver any truly conclusive results, other than that we need more and better quality research (Wanchai and Armer, 2021). Level 1 evidence requires multiple large RCT on a relatively homogenous cohort assessing a single intervention against a placebo which can be effectively blinded to all involved. They frequently exclude the largest portion of the

population living with lymphoedema who are living with lower-limb oedema, and we end up with a disproportionate amount of research on unilateral arm lymphoedema in relation to the affected population (Huang et al, 2013; Ezzo, 2015; Liang et al, 2020, Wanchai and Armer, 2021).

In many reviews, the technique used is in-adequately described making it difficult to identify exactly what was done. For example, the MA by Shao and Zhong (2017) found that including MLD improved volume reduction compared to no MLD for arm lymphoedema, but they did not provide a detailed description on what technique was performed during the intervention. Described as "... a massage technique which helps to stimulate excess fluid reflux by mimicking pumping action of lymphatic vessels" (Shao and Zhong, 2017), this seems to infer the Dr Vodder method, but selection criteria for the studies did not stipulate this. As a description of the techniques developed by Emil and Estrid Vodder (Wittlinger et al, 2018) it falls far short of accurately describing the precise manipulation of the skin and tissue which is applied during MLD.

A further issue is the use of standardised treatment protocols to fit an intervention to the RCT criteria. This is demonstrated in the recent RCT by De Vrieze et al (2022) who applied a standardised therapy to a group receiving what they called 'Traditional MLD', which was a fixed set of hand movements and pressure "based on normal anatomy and without knowledge of the participant-specific lymphatic architecture". This was compared to a group receiving fluoroscopy-guided therapy in which the hand movements and pressures were variable and tailored to the individual. A placebo group received deep massage on the unaffected side. Since MLD is not usually applied along normal pathways in lymphoedema, nor at a fixed pressure, I wonder what this was actually measuring? Not surprisingly there was an accumulation of fluid at the shoulder in the 'Traditional MLD' group.

Some reviews have attempted a more nuanced answer. Ezzo (2015) and Thompson et al. (2020) highlighted evidence for MLD in volume reduction in mild lymphoedema. A benefit for MLD in a younger age group was reported by Liang et al. (2020) and when applied early (Thompson et al., 2020). Müller et

al. (2018) reported on a small number of studies on MLD and quality of life (QOL), finding improvement in breast cancer-related arm lymphoedema. Other reviews have noted the benefits of MLD on secondary outcomes such as pain, range of movement, QOL, and other self-reported symptoms, but with generally inconclusive results (Ezzo, 2015; Thompson et al, 2020).

Manual lymph drainage

A range of physiological responses to MLD have been investigated and shown to increase lymph flow (Lopera et al, 2017), increase lymph vessel contractility (Tan et al, 2011), increase lymphatic clearance rates (De Groot et al, 1992), and balance autonomic function (Shim and Kim, 2014). However, most RCT and SR take minimal account of the way that MLD is adapted by the stage and presentation of the oedema. This renders them of little value to the general lymphoedema therapist, who has been trained to apply a wide variety of therapeutic tools in a patient-oriented framework. The application of MLD as described by Vodder is adapted to the health of the whole person, lymphoedema stage, presentation of the skin and tissue, and other person-centred factors which influence treatment.

The general pathogenesis of lymphoedema is from a fluid rich stage towards fibrosis of all connective tissue elements and the application of MLD is adapted accordingly. The light touch pressures of 30–40 mmHg as commonly described, are correct for fluid rich oedema or where there are skin issues such as fragility that contraindicate heavier pressure techniques, so when this is applied as a standardised protocol to everybody, it is foreseeable that the benefit will be greater in mild stages (Liang et al, 2020; Thompson et al, 2020). The more tissue fibrosis and sclerosis present, the firmer the MLD techniques are applied using significant pressures up to 70–80 mmHg when necessary (Wittlinger et al, 2018). Since disease trajectory is not linear, highly variable among individuals, and all stages of lymphoedema may be present in the same body region at the same time, the therapist must consider all factors in determining the best treatment plan for each client, including the appropriate application of MLD pressure and direction.

No RCT or SR has yet reported on

MLD as it is actually used in thousands of clinics around the world. Relying only on level 1 evidence to guide our clinical practice has led to a reductionist view in lymphoedema research, and we are missing vital information to serve the bespoke needs of each person in our care. The one consistent conclusion is that we need more and better-quality research. What we do not need are more SR on RCT on unilateral arm lymphoedema.

A new research model

We need to value the information underpinning the levels of evidence pyramid. The huge volume of accumulated wisdom held by affected persons and their therapists is data that can be mined to provide a rich foundation of case reports, but it is currently being ignored in the race to attain the peak of level 1 evidence. Using an RCT to find the best way to manage the complexities of lymphoedema has not led us to conclusions that are clinically applicable. More needs to be made of other types of evidence, including observational studies, which are better suited to research on lymphoedema. Descriptive reports can be synthesised into narrative reviews to elucidate useful patterns in the data, and we will need to measure more than volume. A greater focus on patient-centred aspects such as the ability to function in daily life, quality of life, and psycho-social aspects of lymphoedema-care will ensure our approach to therapy is relevant to the lifelong nature of the lived experience of our clients.

Conclusions

Our search for evidence-based therapy at the top of the levels of evidence pyramid is not working for our therapists, nor improving outcomes for our clients. We need a new way to mine the rich pool of data underpinning the actions of therapists in the clinic, and create practice-based evidence models to build a body of clinically relevant evidence. These issues will be applicable across multiple chronic diseases and every healthcare professional should consider publishing their case reports on what works and does not work for individual clients. Every person affected by chronic disease deserves to receive the best available treatment for them, and every therapist deserves to have the best possible information on the efficacy

of the techniques they have at hand. As researchers we need to value levels of evidence that can provide more clinically useful insights into the complexities of lymphoedema management.

References

- Burns PB, Rohrich RJ, Chung KC (2011) The levels of evidence and their role in evidence-based medicine. *Plast Reconstr Surg* 128(1): 305–10
- De Groote M, Jonnart C, Puissant F et al (1992) Lymphoscintigraphic evaluation of the efficiency of manual lymphatic drainage. *European Journal of Lymphology and Related Problems* 3(11): 85–7
- De Vrieze T, Gebruers N, Nevelsteen I et al (2022) Manual lymphatic drainage with or without fluoroscopy guidance did not substantially improve the effect of decongestive lymphatic therapy in people with breast cancer-related lymphoedema (EforT-BCRL trial): a multicentre randomised trial. *J Physiother* 68(2): 110–22
- Ezzo J, Manheimer E, McNeely ML et al (2015) Manual lymphatic drainage for lymphedema following breast cancer treatment. *Cochrane Database Syst Rev* (5): CD003475
- Huang TW, Tseng SH, Lin CC et al (2013) Effects of manual lymphatic drainage on breast cancer-related lymphedema: A systematic review and meta-analysis of randomized controlled trials. *World J Surg Oncol* 11: 15
- Executive Committee of the International Society of Lymphology (2020) The diagnosis and treatment of peripheral lymphedema: 2020 consensus document of the International Society of Lymphology. *Lymphology* 53(1): 3–19.
- Liang M, Chen Q, Peng K et al (2020) Manual lymphatic drainage for lymphedema in patients after breast cancer surgery: A systematic review and meta-analysis of randomized controlled trials. *Medicine (Baltimore)* 99(49): e23192
- Lopera C, Worsley PR, Bader DL, Fenlon D (2017) Investigating the short-term effects of manual lymphatic drainage and compression garment therapies on Lymphatic function using near-infrared imaging. *Lymphat Res Biol* 15(3): 235–40
- Müller M, Klingberg K, Wertli MM, Carreira H (2018) Manual lymphatic drainage and quality of life in patients with lymphoedema and mixed oedema: a systematic review of randomised controlled trials. *Qual Life Res* 27(6): 1403–14
- Shao Y, Zhong DS (2017) Manual lymphatic drainage for breast cancer-related lymphoedema. *Eur J Cancer Care (Engl)* 26(5): e12517
- Shim JM, Kim SJ (2014) Manual lymph drainage attenuates frontal EEG asymmetry in subjects with psychological stress: a preliminary study. *J Phys Ther Sci* 26(4): 529–31
- Tan I-C, Maus EA, Rasmussen JC et al (2011) Assessment of lymphatic contractile function after manual lymphatic drainage using near-infrared fluorescence imaging. *Arch Phys Med Rehabil* 92(5): 756–64. e1
- Thompson B, Gaitatzis K, Janse de Jonge X et al (2020) Manual lymphatic drainage treatment for lymphedema: a systematic review of the literature. *J Cancer Surviv* 15(2): 244–58
- Wanchai A, Armer JM (2021) Manual lymphedema drainage for reducing risk for and managing breast cancer-related lymphedema after breast surgery: a systematic review. *Nurs Womens Health* 25(5): 377–83
- Wittlinger H, Wittlinger D, Wittlinger A (2018) *Dr. Vodder's Manual Lymph Drainage: A Practical Guide* (2nd edn.). New York: Thieme