

Decisions: they are never easy! But this is what we would like to do and here are the reasons why

Neil Piller

Over the past decade, and particularly in the past few years, we have seen a shift of focus from the specific issues presented by the patient in front of us, to actions based on reports about conditions similar (but often not exactly the same) as those presented by the patient.

Many perceive we have lost the patient as an individual in the quest to act only on the basis of “good supporting science” and further that we often don’t have or seek the answer to the question: “What is best for my patient?”

Everything seems much more complicated and intricate nowadays and a consequence of this is the need for detailed and specific use and application of our personal and acquired knowledge to improve patient outcomes. That can often make it hard for lymphoedema treatments at least, since often they are multifaceted/multimodal — sometimes called “shotgun” types of treatments.

There is a large variation (and many tensions) in the acquired knowledge we gain regarding assessment, treatment and management strategies meaning it can lead to uncertainty (or even at times), limited action or even inaction!

There is also a great variation in patient knowledge of their condition and what might (or might not) work for them. Some have in-depth knowledge on par with a trained professional and literally tell the therapist what they are seeking, while others have none or only a very superficial idea and come to the therapist for assistance and direction.

In this respect, the former type of patient will search the internet and read in the presented literature and on various websites a range of contrasting and apparently conflicting information about their condition, what the

major risk factors are, what might have caused their lymphoedema and what should be done about it. In this respect, Cernal et al (2011) stirred the pot in the *Journal of the American College of Surgeons* when they undertook a literature search and reported some of the risk factors for lymphoedema were factual while others were fictional or had inadequate information about them making it difficult to make a firm decision. I emphasise here that the outcome statements in the Cernal et al paper were based on a literature search, and, as we shall see later, these and in fact any other research is subject to a range of biases and limitations.

However, what this paper did was to contribute to significant fear and anxiety in patients when they read that what they were doing (or not) was no longer a risk factor. This created tension and sometimes distrust between patients and therapists. At the time, Dr Sarah McLaughlan from the Mayo Clinic said that “the study is right in saying the guidelines that we have are based on anecdotal evidence, but they’re also based on good intentions on top of the physiology we understand.”

Then came comments on this paper. Nudeman (2016) indicated that we need to be careful about statements relating to risk and risk-reduction behaviours and that when there is inaccurate description or interpretation of findings (Ferguson et al, 2016), it can lead to a possible increase in risk-taking behaviours by patients or healthcare professionals not recognising risks. And (importantly) if there is a risk (even if it’s not always strongly causally linked), why take a risk if you can avoid it? This certainly created active discussion and argument. You can follow some of this debate on the NLN website (www.lymphnet.org) if you wish. Dr McLaughlan further commented “... the real problem is that we don’t understand who’s going to get lymphoedema and who’s not. It’s very difficult to pick out a patient and

tell the woman that she’s not at risk because, frankly any patient who has axillary surgery is at risk for developing lymphoedema”.

Further, we and patients read articles such as by Nickolaidis and Karlsson (2013) entitled “Evidence and Tradition in conflict, The Swedish Experience of lymphoedema treatment and care.” They stated: “Less emphasis should be placed on manual lymphatic drainage and more on compression, exercise and weight reduction.” The reason for this statement was the literature the authors read. And it seems justified when they read Huang et al (2013) who summarised that “the current evidence from RCTs [randomised controlled trials] does not support the use of MLD in preventing or treating [lymphoedema]”. They then said: “Clinical and statistical inconsistencies between the various studies confounded our evaluation.” It, like other papers, was based on a systematic review and meta analysis.

We also read de Godoy et al (2015) who showed manual lymphatic therapy improved the transport of radio tracers in lymph collectors; yes, it’s only one of a number of articles showing this, but it’s in contrast to what is read in the literature when certain search criteria (which may have a range of biases and/or are based on older literature when treatments were different) are applied.

So what do we do? Generally, we look at RCTs and this is where Frieden’s (2017) *New England Journal of Medicine* paper “Evidence for health decision making — Beyond RCTs” comes in. He asserts that there are a number of issues/limitations facing RCTs that we often ignore since we are led to believe they are the best; the ultimate source of information on which we base our actions for that patient in front of us. Well what are those limitations we often ignore?

Firstly, and RCT may lack external validity — meaning we should not generalise outside

Neil Piller is Director Lymphoedema Research Unit, Department of Surgery, School of Medicine, Flinders University, Adelaide, South Australia, Australia.

of the study population. Also it's often hard to assess duration of treatment effects, the groups are often not relevant to the broader target populations (often a selection of higher risk groups) and they often don't keep pace with clinical innovations, new products or standards of care. So RCTs may not always provide the best answer to our current question for the current patient. This all means we need to be aware (and let patients know) that other data sources can provide evidence for clinical (and public health) action and that perhaps we should consider them.

In the area of lymphoedema, RCT-based data are very scarce and because of the associated costs, few are planned that will be likely to provide us with stronger evidence for our actions. Knowledge and information gaps continue to exist.

Patients will also perceive the same gaps, although they will not be aware of the validity and reliability of many of the trials, experiments and reports widely available and sometimes put more weight on them than justifiable. But, nothing is perfect, none of them provide 100% certainty of a guaranteed outcome and rarely will they be totally relevant to that patient in front of you.

As Frieden's *New England Journal of Medicine* article suggests, we all must broaden our parameters. We should seek out and acknowledge that there are other study designs, such as: meta analysis/systematic reviews, prospective cohort studies, retrospective cohort studies, case control studies, cross-sectional studies, observational studies, programme-based evidence, case reports and registries.

But what's the best?

Unfortunately, we have to acknowledge that no single best approach exists and that every trial, experiment or data set is imperfect. By the time a result is published, often, a year has gone by. Things change in that time. Overall though, we must encourage transparency, openness and honesty, and be strongly aware that conclusions and outcomes will differ with time.

What is concerning to me is that sometimes a lack of information at the RCT level may lead to inaction. By that I mean, if there is no RCT on a particular treatment or management option, then it may not be recommended, or if the patient comes in with an idea of seeking it, that strategy is refused or the patient put off for a time "when the evidence is stronger".

So in the words of Frieden and others — what we need is "actionable data"; that are sufficient for clinical action; we need to be able to say to a patient (and other healthcare professionals): "Here is what we recommend and this is why."

This is the point of the article by Frieden — we should look "to base all policy decisions on the highest-quality scientific data, openly and objectively derived" and that to "elevate RCTs at the expense of other potentially highly valuable sources of data is counterproductive". But we also need to read wider than our specific area and acknowledge that prevention is better than a cure (behaviour is the weakest link in patient wellbeing and safety), and that we should take heed of and learn from adverse events (Leistikow, 2017).

But with your patient as an individual in front of you, there will remain the need to undertake some action. In this respect, its perhaps best to treat that patient as a member of an RCT and that is to discuss with them what they holistically want (e.g., a reduction in pain, an improvement in mobility, a reduction in size) and discuss with them the knowledge base and then undertake or initialise this action. Only one intervention should be done differently at a time, give it time to work and seek feedback from the patient. If it's for them, it could form the basis of a good case study, potentially leading to a pilot trial and then an RCT. So you may get what you need and you may be the one to initiate it!

References

- Cernal Y, Pusic A, Mehrara BJ (2011) Preventative measures for lymphedema: separating fact from fiction. *J Am Coll Surg* 213(4): 543–51
- de Godoy JM, Santana KR, Godoy Mde F (2015) Lymphoscintigraphic evaluation of manual lymphatic therapy *Phlebology* 30(1): 39–44
- Ferguson CM, Swaroop MN, Horick N et al (2016) Impact of ipsilateral blood draws, injections, blood pressure measurements and air travel on the risk of lymphoedema for patients treated for breast cancer. *J Clin Oncol* 34(7): 691–8
- Frieden T (2017) Evidence for health decision making – beyond Randomized, controlled trials. *New Eng J Med* 377(5): 465–75
- 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
- Liestikow I (2017) Prevention is Better than Cure: Learning from Adverse Events in Healthcare. CRC Press: Boca Raton, FL
- Nickolaïdis P, Karlsson K (2013) Evidence and tradition in conflict: The Swedish Experience of lymphoedema treatment and care. *Journal of Lymphoedema* 8(2): 21–3
- Nudelman J (2016) Debunking lymphoedema risk-reduction behaviours: risky conclusions. *Lymphat Res Biol* 14(3): 124–6

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