RESEARCH STUDY

Treatment of lower limb leg oedema and lymphoedemia using bio-energiser quaver phase applied to the feet.

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INTRODUCTION

Oedema (oedema) is a build-up of excess fluid in the body tissues. If the fluid is in the tissue under the skin it leads to a puffy, shiny appearance and a doughy feel. Most commonly, oedema is seen in the ankles or legs, as the fluid is gravity-dependent.

Usually, applying finger pressure leaves an indentation in the skin, hence the term "pitting oedema", but oedema can also be "non-pitting", when it is caused by lymphatic obstruction.

Oedema is not a disease in itself. Rather, it is a clinical sign which may be associated with an underlying medical problem.

What are the mechanisms that cause oedema?

General principals:

Oedema occurs when the body's normal balance of fluid intake and output is disturbed. Normally, one takes in fluid by drinking and eating and gets rid of it in the form of sweat, urine, faeces and by breathing. Within the body, fluid is transported by blood vessels (arteries and veins) and also by the lymphatic system. The fluid in the bloodstream contains not only blood cells, but also oxygen and other nutrients for the body's cells. This fluid can move through the walls of the blood vessels into body tissues to provide nutrition and water for cells and then move back into the blood vessels once depleted of nutrients.

The 2 possible mechanisms that can cause an abnormal fluid build-up in the tissues are:

1) An increase in the pressure within the blood vessels (e.g.. caused by an increased amount of fluid) causing fluid to shift out of the vessels into the surrounding tissues, or

2) A decrease in the amount of proteins(e.g. albumen) in the bloodstream causing water to shift out of the vessels to make the surrounding tissues as dilute as the blood stream.

Causes of oedema

1) Heart Failure

The term 'heart failure' is used when the heart is unable to pump blood effectively around the body. If the right side of the heart is weak, blood tends to pool in the veins and this causes fluid shifts from the venous system to the tissues. Various hormones are also released when someone is in heart failure and this can increase oedema by causing salt and water retention.

Typically, someone with congestive heart failure will have ankle swelling, but the oedema may be more apparent in their sacrum (lower back) if they have been lying down .

2) Kidney disease

Nephrotic syndrome is a disease of the kidneys in which large amounts of protein are lost in the urine. This results in a generalised oedema, caused both by fluid shifts into the tissues and by the activation of hormones which increase salt and water retention. Puffy eyes might be one of the first noticeable symptoms in someone with nephrotic syndrome.

Key words: disability, bio energiser, quaver, quality of life questionnaire,

Abbreviations: QV = quaver (mJ), BE = bio energiser, DI = disability index, QOL = quality of life questionnaire

Renal (kidney) failure can also cause oedema by causing salt and water retention.

3) Other causes of decreased protein

Several other disease states can lead to a very low level of protein in the blood, resulting in oedema. Examples are:

Chronic liver disease - caused by alcohol, or hepatitis.

Malnutrition or starvation

Certain types of gastroenteritis

4) Thyroid disease

An under active and an overactive thyroid gland can cause oedema, as thyroid hormone plays an important role in many steps of metabolism. The oedema in thyroid disease can be non-pitting.

5) Venous insufficiency, or weakened veins

Long-standing problems with leg veins (e.g. varicose veins or veins with damaged valves) can cause a pooling of blood in the legs and result in swelling/ oedema.

6) Lymphoedema

The lymphatic vessels drain lymph from the peripheries to lymph nodes, forming a component of the immune system. Lymphoedema is caused by an obstruction of the lymphatic vessels. Obstruction can be caused by infection, scar tissue (e.g. from surgery or radiotherapy), parasites, tumours or hereditary conditions.

7) Medications

Certain medications can have a side effect of ankle swelling. These include commonly used drugs such as blood pressure medications (in particular the class of drugs known as 'calcium channel blockers'), steroids and antidepressants.

8) Ordinary or 'physiological' causes of oedema

Oedema can occur in a fit and healthy person under certain conditions; it will usually resolve without treatment.

Heat - hot weather causes the peripheral blood vessels to expand, resulting in fluid shifts from the blood vessels to surrounding tissues.

Immobility - lack of use of one's leg muscles, such as on a long plane flight, leads to blood pooling in the veins and can result in oedema.

Pregnancy and the menstrual cycle - changes in hormone levels can affect the rates at which fluid leaves and enters tissues.

What if only one leg is swollen?

If only 1 leg is affected by oedema, the cause is likely to be a localised problem. Commoner causes of swelling of 1 leg include:

Blood clots/ deep vein thromboses: A clot in one of the deep leg veins can cause swelling of that leg. This may be painful and possibly accompanied by a change in skin colour.

Joint inflammation: Arthritis or gout can cause swelling of joints and the surrounding tissues.

Lymphoedema: see above

Treatment of oedema

The treatment depends on the underlying cause of the oedema. If it is one of the ordinary, or physiological causes, there are a few general measures to take to improve the swelling. Some of these measures may even help people with oedema caused by an underlying medical problem. They include:

- keeping legs elevated as much as possible
- cutting down on salt intake
- exercise
- weight loss
- wearing supportive stockings

METHOD

Subjects

A total of 25 patients were referred for bio-energiser treatment to the feet and the Malvern Integrated Health Centre and The Wessex Nuffield Hospital, Hampshire, between September 2004 and July 2005.
The use of the bio-energiser as a therapy was considered when the patient’s leg oedema and lymphoedema was inadequately controlled by topical therapies alone and there are contraindications to the use of the BE.
Two groups were formed, one group of 10 patients of severe leg oedema and the other group consisted of 15 patients lympheodema.

After the expected benefits and risks of the treatment were explained, the patient signed an informed consent.

Questionnaire

Patients completed questionnaires at the beginning and again at the completion of the course of the therapy. The questionnaire (Table 1) used 15 questions based upon those devised by Finlay and co-workers in developing their PDI.[6,7,8]

We omitted some of the questions and rephrased others to make them more appropriate for our population.

We used a four-point Likert scale to rate the questions. We did not use the scoring system of the DI. However, as with the DI, we asked the patients to rate the impact of the condition on their functioning and interactions over the preceding 16 weeks. Our final question requested the patient to rate his/her condition at that point in time. In addition, in the post-therapy questionnaire, the patients were asked to rate the improvement of their condition on a scale of 1 to 10 on a visual analogue scale. One represented minor improvement while twenty four represented considerable improvement (Fig. 1).

In order to analyse the change in QOL, questions were divided into three groups including activities of daily living, physical parameters and impact on interpersonal relationships (Table 1).

Table 1 Quality of life questionnaire

Over the past four weeks:

Activities of daily living
1. How much has your condition interfered with you carrying out work around the house or garden?
2. How often have you worn different types of clothes because of your condition?
3. How much do you have to wear loose clothing?
4. Has your condition been much of a problem at any social event
5. Has your condition resulted in your having to take more baths or showers than usual?
6. Has your career been affected by your condition?

Physical
7. Is your condition making it difficult for you to do exercise?
8. Have you been criticised or stopped from using communal pools or changing facilities?
9. Have you avoided swimming or going to the general place of interest because of your condition?
10. Has your condition resulted in you smoking or drinking alcohol more than you would do normally?
11. To what extent has your condition or treatment made you or your home messy or untidy?

Interpersonal relationships
12. As a result of having your condition, have you felt aggressive, frustrated or embarrassed?
13. Has your condition interfered with your daily social life, social events or relationships?
14. How have you felt about your skin over the last month?
15. How bad do you think your condition is now?

Bio-Energiser Therapy

The therapy was administered in a standardised fashion as per protocol (Appendix I). Parameters recorded included measured water and low sodium salt, the starting time, polarity intervals, colour changes and quaver cumulative pulses (all measured as millijoules per square centimeter in the water).

Statistical analysis

In order to explore the validity of the three groups, we employed clinical decision, factor analysis and use of Cronbach's alpha coefficient. Exploratory factor analysis was carried out using the varimax rotation method with Kaiser normalization. Computation of Cronbach's alpha coefficient was utilized to measure internal consistency reliability.[1] The Cronbach's alpha coefficient of group 1, 2 and 3 were 0.7, 0.5 and 0.7, respectively. The mathematical analysis confirmed the validity of these groupings. We therefore analysed the data using these three groups.

The pre- and post-therapy responses were compared using the paired sample *t*-test. Results were expressed as a mean and standard deviation. A *P*-value of <0.05 was considered significant. Statistical analysis was performed using SPSS 11.0 for Windows.

RESULTS

Results from 25/25 subjects were analysed; 17 were men. No patients left the clinic without completing the questionnaire and were no exclusions from the study. The mean and standard deviation of the three paired groups are shown in Table 2. The improvement in QOL was statistically significant. Specifically, the improvement in activities of daily living was significant (t=2.9, d.f.=88,P=0.005), as was the improvement in physical parameters (t=6.0, d.f.=88,P<0.001) and interpersonal parameters (t=16.4, d.f. =88,P<0.001).

The visual analogue scale rating revealed that patients thought this method of therapy significantly improved their condition (P<0.001; Fig. 2). Ten (100%) thought their leg oedema was completely improved and fourteen (95%) lymphoedema thought their condition was completely improved by the bio-energiser system, while only one lymphoedema patient (5%) thought the condition showed minor improvement with the therapy.

There were no reported adverse events recorded from the treatments.

DISCUSSION

When measuring the effect of a treatment (in our case the improvement in the patient's QOL) it is important to administer the treatment in a standardised fashion. While aware that there are many unidentified environmental stimuli that may modulate the severity

Table 2 Efficacy measures before and after bio-energiser

Groups	Mean, before bio energiser	Mean, after bio energiser	Change in (Mean ± SD)	*P*-value
ADL	1.67	1.51	0.16 ± 0.51	<0.005
Physical	1.82	1.52	0.30 ± 0.46	<0.001
Interpersonal	2.95	1.80	1.13 ± 0.66	<0.001

ADL, activities of daily living; SD, standard deviation

of each exacerbation of condition and that there is a therapeutic effect from being in a supportive environment of clinic interested in treating psoriasis.

There are a number of different protocols used for the administration of this type of therapy on these conditions. We chose to use the patient as his/her own control to determine the dosing regimen rather than using a categorical scale such as a fixed frequency in which according to other systems, a set dose of milliamps is used to commence treatment with standardised alternating increments given at subsequent treatment.

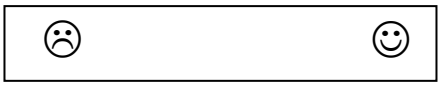

Figure 1
Visual analogue scale. The patient is shown a ruler and asked to state where he/she felt his/her leg oedema or lymphoedema was currently. The sad face represents no improvement (corresponding to a score of 1) and the happy face considerable improvement (corresponding to a score of 10).

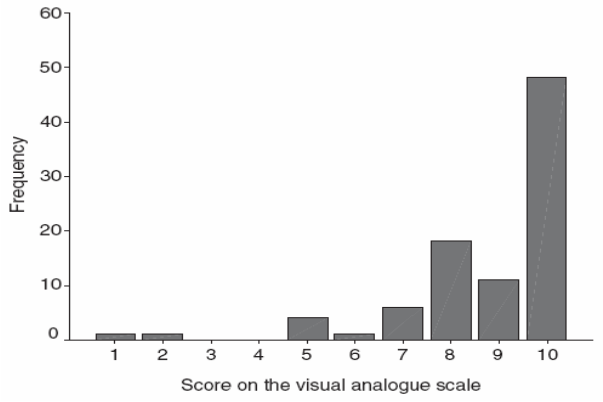

Figure 2 Results of the visual analogue scale at completion of therapy.

Discussions cont.

The concern with the protocol using the categorical scale is that two subjects with the same condition may demonstrate different responses to the same dose of quaver thus affecting their therapeutic response to the therapy. In the interest of achieving the optimal response to a course of the treatment, we adopted a protocol requiring that the patient's to stand up for 15 seconds and drink small to medium size glass of water.

The DI was used to measure the patient's QOL at the beginning of treatment and at their 3-month review. Our treatment protocol differed from theirs in that our focus was on how the QOL changed from the beginning to the completion of the BE quaver therapy treatment.

The impact of both leg oedema and lymphoedema on QOL is frequently profound and often underestimated by the physicians. The physicians tend to focus on the physical aspects of the disorder, but from the patient's perspective it is often the interactional and functional difficulties that loom largest. In the absence of a permanent cure, the goal of treatment is to minimize the extent and severity of these conditions to the point at which it no longer substantially disrupts the patient's QOL. It is important to evaluate not just the change in appearance or extent of the patient's condition but also whether at the completion of the treatment course the patient is better able to fully participate in his/her life. Evaluation of the impact of these conditions on a patient's QOL measures directly how a condition affects a patient's day-today functioning and sense of satisfaction with his/her life. It is conceptualised functionally by the patient's perceptions of performance in four areas, namely physical, occupational, psychological and social interaction.[2]

Good QOL is present when 'the hopes of an individual are matched by experience'.[3] In addition, QOL is not a static measurement, but continually changes over time.[4] For instance, those patients with chronic illnesses at the time of their initial diagnosis may demonstrate a greater impact on QOL compared with later when some degree of mental adaptation has occurred[4] Will the degree of improvement in QOL be maintained with subsequent courses of treatment? Any dermatologist or practitioner who looks after patients with leg oedema or lymphoedema knows that the severity of the condition may vary from one clinical episode to another, so response to and duration of effect from treatment may vary from one episode to another. Even if the patient starts from a worse situation than on previous occasions or does not clear as well as on other occasions, an improvement in life quality is a desirable outcome.

Our data demonstrate that there is a significant change in patient-perceived QOL from the commencement of our standardised course of quaver therapy to the completion of the course. There are many questions that still need to be answered. Leg oedema and lymphoedema demonstrates a relapsing clinical course. Our study did not measure the length of remission either in terms of continuing reports of good QOL or lack of objective evidence of condition activity. This is information we need to obtain. The long-term squeal of repeated courses of this kind of therapy are also unknown. To obtain this information will require further long-term clinical study and potential capabilities in the lymphatic system.

APPENDIX I

The Bio-Energiser system was manufactured by Xecare Limited. It contained quaver technology from Q Science. Prior to each course of treatment the patient's condition was established by exposing non-sun-exposed skin of the feet for pre-preparation doses of quaver energy. Starting doses for treatment were estimated on basis of skin colour and the severity of the leg oedema and lymphodema . Dosage increments for determining the correct quaver mJ and mAps were 0.5 times the preceding dose. For example, in this system to establish the quaver and amperage for fair skin we would start with 0.5amps. The second square would be exposed to 1×0.5=0.5amps with 1mJ, then 2×0.5=1amp with 2.0mJ, then 3×0.5=1.5amps with 3mJ. It should be noted that the numerical number of amps or millijoules delivered does not represent a figure transferable to other or similar systems. We have previously presented data demonstrating that under current calibration methodology the dose measured in amps or millijoules in one machine is not equivalent to that measured in millijoules in another machine.[5]

Treatment was given three times a week. The starting therapeutic dose was applied. At each subsequent treatment, the dose was increased by 10% unless there was improvement when the dose was adjusted as per the protocol. The feet were given a full 30 minute treatment. A maximum of 36 treatments were given in any one course. All patients were asked to drink one litre of water a day and prior to receiving the BE therapy. Patients were permitted to continue concomitant topical or conventional therapies. Treatment was terminated when the condition had resolved sufficiently to no longer be of concern to the patient, or a maximum of 36 treatments had been given. Missed treatments were handled as per protocol.

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