EXTREMITY PUMPS FOR THE TREATMENT OF PRIMARY PERIPHERAL EDEMA

Request: This Technote has been produced in response to a request from a home care nurse, to determine the efficacy of extremity pumps in the treatment of peripheral edema.

BACKGROUND

Lymphedema refers to chronic swelling of the extremities. An increase to the interstitial fluid volume of a limb occurs with the extravasation of protein into the extracellular space. This creates an osmotic gradient which then causes fluid and salt to be drawn into the interstitium. Primary lymphedema occurs as a result of a malformation of the lymphatic system. Secondary lymphedema is caused by obstruction of the lymphatic system possibly by trauma or inflammation of the surrounding tissue. Therapies which have been used to manage this condition include dietary restriction of salt, diuretics, elevation of the limb, compression hosiery, manual massage, compression devices, and, in recalcitrant cases, surgery.

The objective of using an extremity pump is to increase external pressure to an area, thereby encouraging fluid redistribution or excretion. There are several types of compression devices which may be applied to the entire limb like a stocking or glove, or to a portion of it like a sleeve. It may be composed of a single inflatable bladder or several bladders which can be adjusted for pressure, duration, and sequence of inflation.

Compression has also been used for prevention of deep vein thrombosis, treatment of stasis ulcers, and in post phlebitic syndrome. None of these indications are addressed in this paper, only its use in lymphedema.

Technotes are brief reports, prepared on an urgent basis, which draw on limited reviews and analysis of relevant literature and on expert opinion and regulatory status where appropriate. They are not subject to an external review process.
RESULTS

Abstracts of 54 articles were reviewed. Three studies that specifically investigated treatment of primary and secondary lymphedema were analyzed \(^{(1,2,3)}\). They were prospective clinical series and were neither randomized nor controlled.

Bergen, et al. \(^{(1)}\) studied thirty-five patients to determine the optimal method of mechanical compression for both primary and secondary lymphedema. Each limb was treated by three types of compression devices: a single cell pump composed of one bladder inflated to 50 mmHg around the edematous area, a three compartment pump inflated to 50 mmHg, and a ten-cell gradient pressure pump inflated to 30 mmHg proximally and 80 mmHg distally. Displacement measurements were used to compare limb volume pretreatment and immediately after the 2 hour compression therapy. The measurement post-treatment revealed negligible change with a one-cell compression pump, and in some cases the volume of the limb increased. The three-compartment device was marginally better, but the multicompartiment device was reported to have effected a significant decrease in edema over the 2 hour treatment for patients with primary or secondary lymphedema. Categorizing the participants into three groups: primary lymphedema, secondary lymphedema without radiation, and secondary lymphedema with radiation therapy, the researchers proposed that there is no difference in results amongst these groups. Difficulties with interpreting these data lie in the study design. It is unclear what time period elapsed between each of the treatments, nor is it clear what area of the limb was covered by each compression device. There is a heterogeneity in the duration, severity, and type of lymphedema, age range of the participants, and the influence from previous therapy. The study compares each limb to itself pre- and post-treatment using three different compression pumps. However, there is no evaluation of the effect of the order of treatment nor of the time between treatments.

Pappas et al. \(^{(2)}\) performed a case series non-randomized follow-up study on the long-term effects of sequential high-pressure intermittent pneumatic compression (SPIC) therapy followed by application of elastic stockings in 49 patients with primary and secondary lymphedema. Most of the participants had undergone some form of treatment prior to the study: forty were wearing elastic stockings, five used unicompartmental compression device, two had had surgery. A multicompartimental sleeve of 9 to 12 cells was used with a maximum compression per cycle of 110 mmHg for 20 seconds distally and 80 mmHg for 2 seconds proximally. This was applied for 6 - 8 hours over a 2 - 3 day hospital stay. Custom fitted compression stockings of 40 mmHg were then applied to the limb at the post treatment girth.
Treatment outcomes were divided into three groups:

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Respondents&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 – 80% had</td>
<td></td>
<td>no response excluded from the study</td>
</tr>
<tr>
<td>Lymphedema more</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Than ten years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2 – 80% had</td>
<td>10</td>
<td>Partial response&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Lymphedema more</td>
<td></td>
<td></td>
</tr>
<tr>
<td>than ten years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 3 – 50% had</td>
<td>26</td>
<td>Full response&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Lymphedema more</td>
<td></td>
<td></td>
</tr>
<tr>
<td>than ten years</td>
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</tbody>
</table>

<sup>1</sup> Six participants with arm edema were evenly distributed amongst the three categories and were excluded from the analysis on this basis

<sup>2</sup> Partial response represents at least a 2 cm reduction initially, but after 4-6 months < 3 of the 9 measured levels maintaining within 1 cm of the initial post-treatment girth

<sup>3</sup> Full response represents maintaining the girth measurement within 1 cm of post-treatment girth at more than 3 levels

About half of the participants in Groups 2 and 3 chose to use the compression device at home up to 4 hours a day. Those in Group 3 who initially responded to treatment but were edematous upon removal of the device had daily or alternate day SIPC treatment at home. All patients used compression stockings between treatments. Patients were followed up at 4 – 6 month intervals over a mean time of 25 ± 4 months. A total of sixty percent of patients had a reduction to limb girth at the nine levels of leg which were measured, and twenty percent had reduction from the distal calf to the toe on long-term follow-up. Nineteen percent had minimal limb girth reduction.

There appeared to be no effect of gender, duration of lymphedema, type of lymphedema, nor which limb was involved on predicting the outcome of the treatment. Pappas et al. (2) concluded that the degree of tissue compliance or subcutaneous fibrosis as well as the mechanics of the external pneumatic device itself (such as peak pressure, compression cycle, sequence, and distribution of compression) are the predictive measures in lowering edema by compression techniques. For the best effect they proposed compression of the limb not exceed the systolic pressure and used values around 80-90 mmHg. Four of the participants, all from the poor response group, experienced infection during the follow-up period in spite of instituting extra skin care measures. Weakness in this study design is evident in the exclusion of non-responders and those with arm edema. No comparison was made amongst the categories of those using the device daily and those choosing not to use it. There is diversity of participants in the type, duration and amount of lymphedema, gender, amount of pressure used and duration of each treatment in the home setting.

Klein et al. (3) examined the Wright Linear Pump, specifically in the lower extremity. Exclusion criteria consisted of presence of infection, metastasis, chronic heart failure and renal disease. Seventy-three subjects were treated over a 48-hour period with a gradient, three compartment device applied to the lower limb for 2-hours. After a one hour rest period the device would be applied with increasing duration to a maximum of 8 hours. The protocol was dependent on patient tolerance of pain. The distal pressure was determined by
the mean of the systolic and diastolic with the other two cells diminishing in pressure by 20 mmHg each. The total treatment cycle was 120 seconds with 90 seconds of pressure distally, 70 seconds for the middle cell and 50 seconds proximally. The limb was elevated and wrapped between treatments. In the 48-hour treatment protocol, measurements were taken at 5 levels of the leg. Ninety percent of patients showed a decrease in circumference at the ankle and mid-calf area, ranging from 1.6 – 2.1 cm. All patients had some improvement after the 48 hours post-treatment. Their results suggested that men responded better than women. It should be noted that there was variability in the participants’ degree of lymphedema, etiology, duration, and amount of compression pressure.

EXPERT OPINION

In 1982 the Lymphoedema Association of Australia was the first association established to address concerns of lymphedema. Information from their website (4) outlines complications and contraindications in the use of extremity pumps. Complications include:

- Localized discomfort and bruising.
- Displacement of the edema to another area such as adjacent to the edge of the compression cuff, the trunk, the opposite limb, or the genital area for both men and women.
- Infection.

They emphasize continuous monitoring of the procedure by a trained therapist and also advocate for the following as being contraindications:

- Evidence of arterial disease.
- More than one area of lymphedema in the body.
- Any indication of genital lymphedema.
- Primary lymphedema of the leg as it may cause complications as defined above.
- Secondary lymphedema if the inguinal or deep pelvic nodes have been removed or irradiated.

CONCLUSION

It is difficult to draw conclusions from these poorly designed studies whose results are based on low number of participants and heterogeneous population (age, duration of disease, etiology, location of edema). Measurement techniques were not identical as one study used volume displacement and the other two used circumference readings. One study used the pump in conjunction with compression stockings between treatments. Inconsistencies were noted in the use of different devices, pressure gradients, duration of pressure application and length of follow up. This calls into question the generalizability of the results.

Complications and contraindications to the application of the extremity pumps are poorly addressed in these studies but are an integral part of clinical decision-making. However, of the three devices studied, the multicompartment device, which delivers pressure in a gradient, sequential fashion in conjunction with compression stockings, appears to have the maximal effect on acute and long-term control of lymphedema. This combination of
treatment seems to be equally effective on upper and lower limbs, across gender and etiology of the lymphedema.

**METHODODOLOGY**

Databases including Medline, PreMedline, Embase, Best Evidence, HTA, Cochrane Database, HealthStar, CINAHL, ECRI, AMED, CMA Practice Guidelines, National Guideline Clearinghouse, AMA Practice Guidelines were searched using date limits 1990 to 2000. The subject headings used were “lymphedema leg” and “lymphedema pump”, as well as textwords “Jobst pump” (“lymphedema” or “lymphoedema”) and (“compression pump” or “compression device” or “extremity pump” or “foot pump”, or “ankle pump”, or “leg pump” or “intermittent pump” or “mechanical pump” or “pneumatic pump” or “pump”).

The website of www.lymphoedema.org was also accessed.

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REFERENCES


