

Vibro-Pulse® for cellulitis and venous leg ulcers

Device name and manufacturer

Vibro-Pulse® supplied by Vibrant Medical, Sheffield.

What is the Technology

Vibro-Pulse® utilises cycloidal vibration (CV) therapy. In the 1940s, a Canadian coal miner noticed how his colleagues would lean against a vibrating coal grading machine to relieve their aching backs. In 1949 he patented a therapeutic cycloid vibration device that recreated the vibration movement on a smaller scale. CV therapy is a form of 3-dimensional oscillating vibration with a small-amplitude and low frequency waveform. When applied to the skin, it is claimed to increase microcirculation and fluid flow in the soft tissues. It is used in a variety of devices on the market and is claimed as a therapy for a range of conditions including arthritis, tennis elbow, sciatica, varicose veins, night cramps, swollen ankles, spinal disorders, leg ulcers, frozen shoulder and insomnia.

Vibro-Pulse® is promoted as a therapy for cellulitis, venous leg ulcers and lower limb oedema. The company claim that stimulating the microcirculation in the infected area can enhance potential delivery of antibiotics to the tissues and reduce the associated oedema¹.

The device is a rectangular soft pillow-style pad, approximately the size of the lower leg which is connected to a transformer and run off mains electricity. The pad should be covered by a disposable cover which can then be strapped to the leg using inbuilt straps. The recommended regimen is one 30-minute treatment three times a day. The device itself is not prescribable on FP10 but the disposable covers can be prescribed on the NHS.

What is the evidence for effectiveness of the device?

Few published papers are available for CV therapy. One clinical trial has been published of Vibro-Pulse® in the management of cellulitis. No clinical trials have been identified of CV therapy for other indications.

Cellulitis

One prospective, company-sponsored, non-blinded, randomised controlled trial has been published using Vibro-Pulse® for lower limb cellulitis². Thirty-six patients with leg cellulitis were randomised to receive either standard therapy (intravenous or oral antibiotics plus bed rest - control group) or standard therapy plus CV therapy three times daily (CV therapy group). The trial was conducted in a hospital setting. Patients were followed up for 7 days. The primary outcome measure was the recovery time, defined as 100% reduction in erythema/ cellulitis. Other outcomes included pain scores, reduction in area of erythema/ cellulitis and amount of leg oedema.

In the CV therapy group, twelve (67%) of patients fully recovered in a mean of 5.6 days compared with two patients (11%) by day six in the control group. The paper states that the difference in recovery times was statistically significant ($P < 0.01$). The control group showed a mean reduction in erythema/ cellulitis of 54% (range 0-100%) at day 7 compared with 89% (range 25-100%) in the CV therapy group. Pain was reduced in all patients by day 7; pain scores were reduced to zero in the majority of patients by day four in the control group and by day two in the CV therapy group.

Antibiotic regimens used in the study were not standardised, although 50% of each group received intravenous benzylpenicillin and flucloxacillin. The remainder received a variety of regimens, both oral and intravenous. It is not clear for how long the antibiotics were given and there was no clear association between route of antibiotic and recovery although the majority of patients who recovered fully had received intravenous antibiotics. This may have had a confounding effect on the results of the trial.

A further paper describes the use of Vibro-Pulse® in 14 patients with cellulitis treated in a community setting in one English medical centre³. The authors note that patients with cellulitis were usually referred to secondary care, resulting in admission for intravenous antibiotics and bed rest. The district nurse team was trained in using CV therapy combined with oral antibiotics. In the subsequent 10 month period, 14 patients presented with lower limb cellulitis and 13 were successfully treated with CV therapy and oral antibiotics. Only one patient required hospital referral. The paper calculated cost savings with the use of Vibro-Pulse® and oral antibiotics in the community compared with hospital admission and intravenous antibiotics for 11 days, based on 2006 prices.

Venous leg ulcer

There are no comparative trials for CV therapy for venous leg ulcers or other wounds. One published paper provides a cost-analysis of CV therapy for venous leg ulcers, based on retrospective data from 29 patients treated with Vibro-Pulse® in combination with compression bandaging for an average of 15 weeks⁴. The device was loaned to a variety of community care sites in the UK over a period of 10 months. Patients were selected by the district or tissue viability nurse based on their expected ability to self-manage the treatment regimen. A questionnaire was completed by the district or tissue viability nurse before and after treatment. On inclusion, patients had a mean ulcer duration of 107 weeks. During therapy with Vibro-Pulse® patients generally received the same frequency of dressing changes as prior to Vibro-Pulse® therapy (commonly twice weekly). The paper reported savings in dressings costs and/ or in nursing time due to improved healing rates or reduced ulcer size. The paper also reported improvements in pain scores compared with baseline although the study design and data collection methods are clearly open to bias.

Costs

The device itself is non-prescribable on FP10 and is provided on loan from the company at no cost⁵. The disposable covers can be prescribed on the NHS at a cost of £15 for a pack of three⁶. A new disposable cover is recommended for each treatment, thus the cost to the NHS of using Vibro-Pulse® is £15 per patient per day.

Cellulitis

Assuming 10 days treatment, the total cost of Vibro-Pulse® therapy would be £150. Costs of antibiotics would be additional to this.

Cost differentials would need to be calculated based on local cellulitis pathways and the choice and duration of parenteral antibiotics if used and any associated additional nursing time.

Venous leg ulcers

The company suggest an initial treatment phase of 14 days for leg ulcers, oedema or other wounds⁷. After this time, if no improvement is seen, treatment with Vibro-Pulse® should be stopped. If improvement has occurred, Vibro-Pulse® can be continued until the ulcer is healed or until no further improvement is seen.

The cost of Vibro-Pulse® is currently £420 per 28 days.

Available data are inadequate to assess any impact of Vibro-Pulse® on healing rates or calculate cost-benefits.

Considerations

Data are only available for a small number of patients and from non-blinded or retrospective studies. A Cochrane review of treatments for cellulitis concluded that there was insufficient evidence on CV therapy to form a conclusion about the efficacy of such treatment⁸.

Today, patients with cellulitis are increasingly being treated in the community with oral or parenteral antibiotics and rarely require prolonged hospital admission or intravenous antibiotics.

The greatest impact to the NHS would be in its chronic use for venous leg ulcers or other wounds. There are currently insufficient data in this area to recommend its use.

References

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3. Tyrer A.; Thornalley C Cycloidal vibration for the treatment of cellulitis in a community setting Brit J Nursing 2008; 17/20: S34-37
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5. Personal Communication, Vibrant Medical March 2014
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