Treatment of chronic varicose ulcers with pulsed electromagnetic fields: a controlled pilot study

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Abstract

To evaluate the efficacy of pulsed electromagnetic fields (PEMF) in healing of chronic varicose ulcers, 19 patients with this condition were included in a double-blind controlled clinical trial. All patients received standard ulcer therapy throughout the duration of the study and were randomly divided into two groups to receive either active or inactive PEMF therapy. Active therapy was provided by the use of a pait of helmholtz coils on a twice weekly basis over a five week period and inactive therapy was provided on an identical regimen with identical coils wound so that no magnetic field was produced when an electric current was passed through them. The clinician and patients were unable to distinguish the active or inactive coils. No statistically relevant difference was noted between the two groups in the healing rates of the ulcer, change in the lower leg girth, pain or infection rates. However there was a trend in favour of a decrease in ulcer size and lower leg girth in the group treated with active PEMF. As PEMF is a novel treatment for chronic varicose ulcers, more work needs to be done to establish treatment parameters and its usefulness in the treatment of this condition.

Introduction

Venous ulcers are common and cause considerable morbidity in the adult population of the UK.[1] There is a wide variety of treatments available but it is generally agreed that elevation of the legs and compression bandaging are of central importance.[2,3] Pulsed electromagnetic fields (PEMF) have been used for over 20 years mainly in connection with healing of bone fractures.[4,5,6,7] There have also been reports of a beneficial role in the rate of regeneration of peripheral nerves[8] and of the wound healing in experimental animals.[9] PEMF has also been used in the treatment of various acute soft tissue injuries[10] and chronic disorder.[11,12] Laboratory investigations suggest that by modifying cell behaviour PEMP has a significant effect on tissue growth and repair.[13,14] Experience locally has shown that PEMF has an effect on ischaemic leg ulcers and it was with this in mind that we wondered if they had an effect on the healing of varicose ulcers.

Methods and trial design

A total of 19 patients with resistant varicose leg ulcers were recruited for this study. Patients were excluded by the presence of a palpable dorsalis pedis and posterior tibial pulsation along with the absence of ischaemic skin signs. Patients known to be suffering from neoplasia, or had cardiac pacemakers in situ or had a deep venous thrombosis within the past year were also excluded. Informed written consent was obtained from all patients. Patients were commenced on a standard treatment and after two weeks were allocated on an alternate basis, due to treatment logistics, clinical spaces and the time available, to either group A (standard treatment plus active coil). The standard treatment used was cleaning with normal saline and olive oil, application of bacitracin and polymyxin B (Polyfax) ointment under a non-adhesive dressing covered with gauze and bandaging from below the knee to the toe with crepe compression bandages. Patients who were allergic to polyfax were maintained on their current therapy, ensuring adequate cleaning and compression bandages.

PEMF therapy was provided using commercially available apparatus, magnetoplus 1500 generator and two pair of coils provided by the manufacturer. The coils were circular with a radius of 10 cm, each having 250 turns of enamelled copper wire covered overall with PVC insulating tape. The active coils were a typical pair of coils in the helmholtz arrangement, and the inactive coils were identical in every respect except that the copper wire was wound in such a way that any generated magnetic field was immediately cancelled and was covered in a different coloured PVC tape. The coils were mounted on two identical applicator stands with each coil fixed 20cm apart and the ulcer to be treated was placed in the stand between the coils being connected to the magnetic field generator. In the active coils the field generated passed at right angles to the plane of the malleoli. On the PEMF generator, the field strength was set at 60 with an intensity if 5Hz and with a treatment duration of 15 minutes. Each patient was treated thus on a twice weekly regimen over a five week period after an initial two weeks on the standardised ulcer therapy. Treatment was carried out through he ulcer dressing and for safety while the magnetic field was on, the patient was left in isolation. It is not known was effect PEMF had on pregnancy, cardiac pacemakers or malignant tumours and until this is known we felt it was wise to perform the treatment with the patient isolated.

The study was double blind in the treatment and assessment were performed by the clinician who did not know which set of coils was the active or inactive set. Patients could also not tell the coils apart except by colour as there was no difference in the sensation produced by the two coils.

The following parameters were measured and assessed pre and post treatment, ulcer size, lower leg girth, degree of pain and presence of infections.

Results

There were no significant differences in sex, age and ulcer area between the two groups on entry into the study Table 1. The duration of the ulcer (Table 1) would appear to demonstrate a significant difference. Six weeks after the last visit to the hospital on the final assessment there were similar changes in both a reduction of pain/discomfort and in the increase in the bacteria count between the two groups.

When the ulcer size was studied it was apparent that patients who had received the active therapy had had a response with a greater likelihood that the ulcer had reduced in size. To calculate the percentage change in size, the difference between the initial and final ulcer areas was divided by the initial area and converted to a percentage. When a mean percentage was taken of the individual percentage changes found in each group, patients treated with active PEMF showed a mean percentage reduction of the ulcer size of 22.04% compared to only 9.06% for the control group, fig 2. However the mean percentage change as calculated from the mean initial area and the mean final area for the two groups was basically the same and does not reflect the trend seen in the results Table 2.

The discrepancy is due to a patient in group A (active therapy) who had an initial ulcer size of 37 831 sq. mms. which increased to 39914 sq. mms which represents an increase of 5.5%, but the actual area involved is so large that it skews the mean ulcer pre and post-treatment areas. If this patient's ulcer size is removed from the group A changes 7% - 17%, a truer reflection of the results. However this trend shown by group A

Table 1 - **Personal data of the patients**

	Group A Active PEMF (10)	Group B Inactive PEMR
Sex M/F ratio	1/9	4/5
Age - mean	72.2	76.4
Range (years)	63 -*8S*	53-88
Initial Mean ulcer size (sq. mms.)	83553.9	5387.8
Ulcer duration per trial (years)	3.55	18.3

was not large enough to be significant under standard statistical analysis.

Though there was no significant difference patients who had had the active PEMF therapy were more likely to show a reduction in the girth of the affected leg (mean percentage decrease of 2.77%) when compared with the controls who had a mean percentage increase in girth of 1.16%. In the control group a large reduction in girth was associated with a reduction in ulcer size. However, in the active group of patients no pattern was discemable, the greater reduction in girth. Bacterial cultures, while not appropriate to assess the degree of ulcer healing, were very reassuring to demonstrate the PEMF therapy on its own did not encourage a proliferation in the bacterial population.

Only two patients, both of whom were in the active groups, did not complete the course of treatment and neither demonstrated a deterioration in ulcer size. One patient in the active group developed a cellulitis around her ulcer at the end of the course of treatment, which responded to oral flucloxacillin. Another patient in the active group developed cellulitis and a deep venous thrombosis in the untreated leg at the end of treatment, which also responded to therapy. There were no complications among the patients in the control group.

Table 2 - **Mean ulcer sizes by experimental group in sq. mm.**

	Group A	Group B
Baseline area	8353.9 (5078.7)	5387.84
Post treatment area	7762.0 (4189.6)	5003.7
Percentage reduction in ulcer size	7 (17.5)	7.1

Excluding patient with a very large ulcer.

Discussion

Both groups showed an overall reduction in ulcer size over the study period. This was possibly attributable to a combination of the dressing and the increased interest and attention shown by the investigator. We failed to show a statistically significant improvement in the ulcers treated with the active coils. However, there was a trend in favour of improved healing in the ulcers treated with the active coils. There was no effect on the percentage change of the lower leg girth, pain or in the infection rates between the active and inactive groups. It is a pity that the discrepancy in ulcer duration between the two groups was not noted earlier in the trial, when the patients were being assigned treatment groups. However,m if it had, and action was taken with this small group of patients, altering this one factor alone may well have altered the other variables.

Though the results are inconclusive due to the small sample size, we feel that a full trial is required to show conclusively if PEMF has a role in the treatment of varicose ulceration. In such a trial there would be a need for a greater selectivity of patients with regard to the various arterial, venous and lymphatic components to the aetiology of the ulceration using techniques such as Doopler ultrasound. It is possible that the therapy would be more effective if used on ulcers with more of an arterial insufficiency than venous stasis with gross oedema, or on an in-patient basis where with proper elevation and bandaging of the limb it might enhance the healing phase. The latter would however tend to detract from the ease of use and low cost of PEMF therapy. It is possible that treatment "failure" in this trial was due to circumstances beyond our control, such as the degree of patients mobility and the adequacy of the ulcer therapy on the days not seen in the outpatient department.

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