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The Effect of Subcutaneous Nerve Stimulation (SCNS) on Pain Associated with Osteoarthritis of the Hip

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Summary

A novel form of subcutaneous nerve stimulation (SCNS) was recently introduced for the relief of chronic pain [14,15]. We present a study using this form of SCNS applied over the radial, median and saphenous nerves in patients with clinically diagnosed osteoarthritis of the hip. Acceptable pain relief was obtained in 60% of patients receiving stimulation, however, comparable analgesia was achieved in a control group, who received no electrical stimulation through similarly placed needles. We suggest that these results may be explained by the ability of SCNS to evoke a placebo response. The efficacy of the placebo effect and the ethical implications of its use in clinical practice are discussed.

Introduction

Electrical stimulation has been increasingly employed for the relief of chronic pain in recent years. However, there are marked variations in the practical use of the technique, according to the site and duration of stimulation and the characteristics of the stimulating current.

Recently Walker and Katz reported the successful use of subcutaneous nerve stimulation (SCNS) applied over the radial, median and saphenous nerves [14,15]. SCNS produced better analgesia than stimulation at alternative random sites in a number of varied painful conditions, including osteoarthritis, lung abscess, postoperative pain and dysmenorrhoea.

The aim of this investigation was to evaluate the efficacy of SCNS in relieving pain of a single aetiology. We studied patients with osteoarthritis, a condition associated with the chronic ingestion of analgesic and anti-inflammatory drugs, many of which have marked side effects. The provision of analgesia to these patients by SCNS, whilst awaiting surgery, would thus offer significant advantages.

Subjects

Thirty-five patients agreed to take part in the trial. All had osteoarthritis of the hip, diagnosed by an orthopaedic surgeon, and were awaiting joint replacement. Of these patients one failed to complete the course of treatment and three underwent operations during the 6 month period of the study; their results were not included.

Stratified random allocation was used to divide the patients into treatment and control groups, on the basis of sex and worst recorded pain score on initial assessment (linear visual analogue score 0–7.9/8.0–10.0). The treatment group consisted of 16 patients; 9 female and 7 male, mean age 59.3 years (range 29–72 years). The control group consisted of 15 patients; 6 female and 9 male, mean age 62.3 years (range 49–72 years).

Method

Eight 26-gauge needles were placed subcutaneously in each patient; one each over the median and radial nerves 2 in. proximal to the wrist flexure, and two over the saphenous nerve, one just inferior to the medial malleolus, the other over the metatarso-cuneiform junction. Needles were placed bilaterally and their position verified by a nerve stimulator.

In the treatment group an RDG Tiger Pulse nerve stimulator provided a rectangular wave current of 220 μA to each pair of needles. The current was pulsed at 20 Hz (pulse width 100 μsec) and an indicator light on the stimulator flashed whilst the machine was functioning. The control group were similarly attached to the stimulator, but no current was delivered despite a realistically flashing light. All patients were connected to the apparatus for 1 h on 10 consecutive week days.

An assessment of each patient's pain was carried out during the treatment period, and at 1, 3 and 6 months thereafter. All assessments were performed by an independent observer, who was unaware of the group to which each patient had been allocated. Four criteria were used to assess pain. The linear visual analogue of worst pain score was recorded on a 10 cm line [10]. A subjective score was obtained from a verbal description of the pain, and mobility scores from the distance each patient could walk before being stopped by pain. Analgesic intake was recorded daily by the patients.

An initial assessment was carried out before treatment began, the results of which were used as baseline measurements for each patient. The subsequent results were compared with these initial values, and a numerical conversion score utilised as follows:

Subjective score: no change (0), some pain relief (+1), marked pain relief (+2), complete pain relief (+3), pain worse (−1).

Mobility score: no change (0), walking a greater distance (+1), walking unlimited (+2), walking less distance (−1), walking completely restricted (−2).

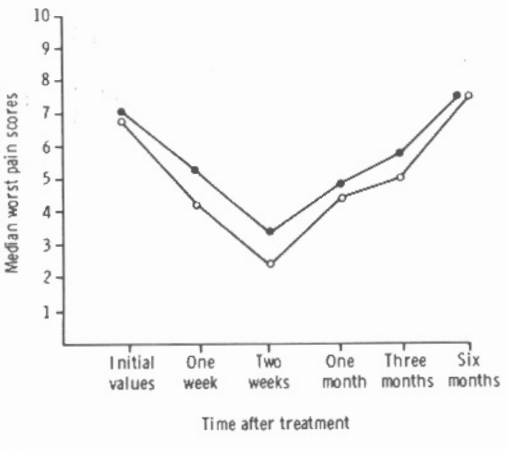
Analgesic score: no change (0), dose/strength of analgesic decreased (+1), no analgesic (+2), dose strength of analgesic increased (−1).

The results were analysed statistically by the Mann–Whitney U test and χ^2 tests as appropriate.

Results

Fig. 1 shows the median worst pain scores for each group as assessed by linear visual analogue. In both groups pain relief was maximal at 2 weeks (end of treatment period) and decreased thereafter. In comparison with initial values, statistically significant analgesia was obtained in both groups at 1 week, 2 weeks and 1 month following the start of the study, and in the treatment group only, after 3 months ($P = 0.05$).

In Fig. 2 the percentage of patients scoring more than 1 on the numerical conversion score for subjective pain relief is shown. At 2 weeks 60% of the control and 47% of the treatment group reported useful analgesia, but this number declined by 6 months, at which time only 20% of the control group and 10% of the treatment group had sustained pain relief. The only significant difference between the groups occurred at 1 month ($P = 0.05$).



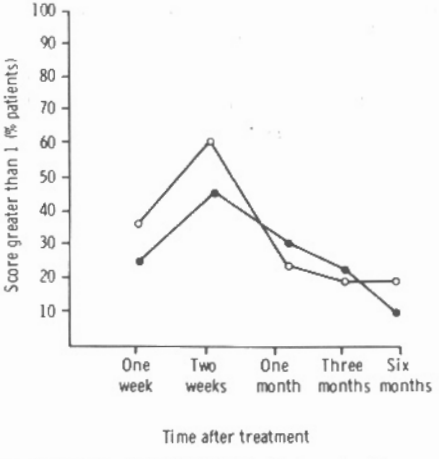


Fig. 1. Median worst pain scores measured by linear visual analogue. Readings taken before treatment and at intervals after initiation of treatment as shown. ○, control group; ●, treatment group.

Fig. 2. Percentage of patients with subjective score greater than 1 (i.e., less pain). Time after initiation of treatment is shown. ○, control group; ●, treatment group.

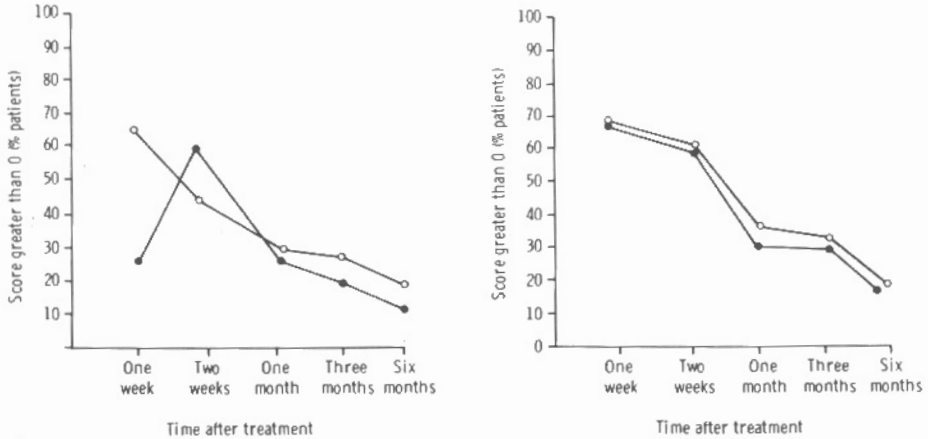


Fig. 3. Percentage of patients with mobility score greater than 0 (increased mobility). Time after initiation of treatment is shown. ○, control group; ●, treatment group.

Fig. 4. Percentage of patients with analgesic score greater than 0 (taking less medication). Time after initiation of treatment is shown. ○, control group; ●, treatment group.

The percentage of patients with improved mobility is shown in Fig. 3. At 1 week there was a significant difference between the 2 groups ($P = 0.05$) with 65% of the controls and 25% of treated patients reporting benefit. The treated group rapidly improved during the second week of treatment, but mobility declined in both groups over the rest of the study period.

There was a marked reduction in analgesic intake in both groups during the first 2 weeks of the study (Fig. 4), but thereafter the number of patients taking less medication declined steadily. Side effects of the treatment included tingling and slight pain at the site of needle insertion, and a feeling of drowsiness immediately after treatment. Up to one-third of the patients reported these side effects, and they were evenly distributed between the two groups. All side effects ceased following the first 2 weeks of the study.

Discussion

In this study we were unable to distinguish between control and treatment groups in contrast to Walker and Katz, who reported significant analgesia only in treated patients [14,15]. It may be argued that the pain relief experienced by our patients was due to an acupuncture-like effect. However, the needles were not sited in accordance with classical acupuncture sites for the hip [12], nor was any attempt made to produce low frequency stimulation by manipulation of the needles. Indeed several recent studies have failed to distinguish between acupuncture and placebo [4,6,9]. It is possible that this form of peripheral nerve stimulation is more effective

in relieving certain types of pain than others. Whereas Walker and Katz reported long-lasting analgesia in a variety of chronic painful conditions, including dysmenorrhoea, in our study of a single chronic pain population, relief was generally of short duration.

The importance of the placebo effect is well known and should be considered in relation to this study. Beecher reported that it may account for improvement in 35% of patients given placebo medication in double-blind studies [1], whilst similar values have been recorded using conventional transcutaneous nerve stimulation [13]. A positive placebo response is more likely to be evoked in the presence of severe pain or marked anxiety [2]. Although several of our patients with severe pain obtained considerable benefit, these patients were divided equally amongst our treatment and control groups. We did not evaluate levels of anxiety in our patients. The placebo response seems to be directly proportional to the apparent effectiveness of the treatment, as perceived by the patient, and to the expectations of the therapist [2,3]. This form of SCNS exposes the patient to prolonged intensive daily treatment, and it is possible that the attitude of the medical staff may have been inadvertently communicated to the patients.

We conclude that our results can be most readily explained by a placebo effect operating in both groups of patients. Nevertheless, after 2 weeks of the trial, 60% of our patients reported clinically significant analgesia, several benefited for up to 6 months, and 1 patient from each group reported complete pain relief at this time.

In our view, this method of SCNS compares favourably with conventional transcutaneous nerve stimulation techniques. Whilst SCNS produced a lower incidence of effective pain relief than conventional medication, its use was associated with fewer side effects. SCNS used in this way offers the advantage over other forms of peripheral nerve stimulation, in that treatment is applied remote from the site of pain or proposed operation site.

This investigation demonstrates the problems inherent in evaluating new methods of treatment for the relief of chronic pain. It is important that controlled trials identify possible placebo effects, but the selection of suitable controls may prove difficult. The subsequent use of such a treatment raises the question of whether it is ethical to employ a known placebo in clinical practice [11]. Although the exact mechanism of placebo effect is unknown, there is evidence to support a physiological mechanism involving opioid [7,8] and non-opioid [5] pathways. If this is the case it would be possible to regard the placebo as an effective therapeutic tool, which acts by enabling the patient to increase his own natural pain suppressing mechanisms.

We feel that further work is necessary to define the nature and effectiveness of placebo, and that SCNS and other stimulation techniques should be further investigated as posssible alternatives for the treatment of chronic pain.

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