VIBRATORY STIMULATION COMPARED TO PLACEBO IN ALLEVIATION OF PAIN

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ABSTRACT. The placebo effect of vibratory stimulation was studied in 72 patients with chronic pain syndromes in a double-blind crossover trial using a vibrator and a "placebo unit". Pain alleviation was reported by 48 % of the patients during vibratory stimulation compared with 34 % for placebo treatment; statistical significance (p<0.005).

Key words: vibratory stimulation, placebo, double-blind.

Vibratory stimulation for the alleviation of chronic pain was assessed in a double-blind trial as previous studies with vibration have not included this (7, 9, 10, 11). We know that about 35% of patients who suffer pain are relieved by different types of placebo in short term studies (4, 12). By eliminating the emotional aspects of expectation and hope in both the patient and the administrator, the effect of actual therapy can be more faithfully assessed (1, 2, 5, 6).

PATIENTS AND METHODS

Patients

The study was performed on 72 (29 males, 43 females) outpatients who had suffered pain for periods of six months to 4 years. All patients were referred for symptomatic pain treatment from the departments of neurology, orthopaedic surgery, medicine and rehabilitation, and had had a complete medical check-up before entering the study. The ages of the males ranged from 34–67 (mean 51 years) and that of the females from 33–65 (mean 48 years).

Assessment of pain

The patients rated their subjective pain intensity before, during and after treatment, using a visual analogue scale that consisted of a lever attached to a linear potentiometer whose extreme indications were 'no pain' and 'worst pain ever' (11). The potentiometer was connected to an inkwriter that was outside the patient's vision. The patient was instructed to move the lever from the position indicative of subjective pain intensity before stimulation, to one side if pain was reduced by treatment, and to the opposite side if pain increased.

Modes of treatment

Ten machines were used, 5 being actual vibrators and 5 identical looking machines that produced the characteristic humming sound without any vibration. The probe on all machines was covered by a plastic cap to conceal the occurrence, or lack, of vibration.

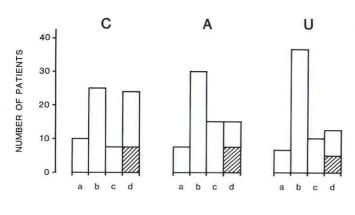
Before a session with vibratory stimulation the machine's amplitude (300 μ m peak to peak) was checked by the supervisor using an accelerometer and amplifier system (Bruel & Kjaer, 4367, 2626). The stimulation frequency used was 100 Hz. Only the supervisor knew which machines were active stimulators and which placebo, and he neither applied the devices nor recorded the results.

The patients were informed about the study according to a prepared guideline and told they were to differentiate between the sensation they experienced during stimulation and the relief of pain. The therapists were given similar directions and were instructed in the application of the stimulatory devices. They were asked to direct any questions arising from the trial to the physicians who were to see the patients after their tenth treatment.

Before the patient commenced the stimulation he was told that he might experience a vibration sensation or nothing at all, but he should disregard this, and concentrate only on his degree of pain. He should report its relief or aggravation as applicable.

Each patient had 12 treatment sessions, 6 with the stimulator and 6 with the placebo. The sessions lasted 45 min, and there were at least 2 days between treatments. Each patient received either all the stimulator treatments first or all the placebo treatments first in a randomized selection scheme, and the treatment schedule had a crossover design. The sites treated by the physiotherapists were the area of pain, the antagonistic muscle (or the area contralateral to the point of pain in the patients suffering from neurogenic pain), and an acupuncture point unrelated segmentally.

The physician conducting the study collected the records of the treatment which were analyzed and registered as total pain relief (100%), substantial relief (50–99%), minor relief (1–49%), no relief (0%) or aggravation (+). The duration of the different effects was recorded also. At the end of the 12 treatments the supervisor summarized the results and passed them to a physician other than he who collected the records, who then discussed the outcome with the patients.



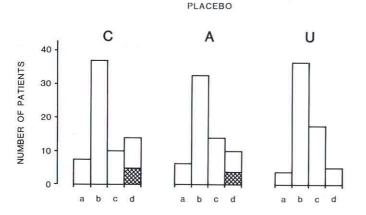


Fig. 1. Effects of vibratory stimulation and placebo vibratory stimulation on subjective pain intensity. a, pain increase; b, no changes in pain intensity; c, pain reduction less than 50%; d, pain reduction 50% or more. Number of patients who experienced total pain relief represented by hatched areas. C, over center of pain; A, over the antagonistic muscle or over the area contralateral to the point of pain—see text. U, over an acupuncture point unrelated segmentally to the point of pain.

RESULTS

A total of 72 patients entered the study, and 68 (27 men and 41 women) completed it. The major primary diagnostic groups were musculoskeletal pain (36 patients) and neurogenic pain (32 patients).

Fifty-one patients claimed to have a single centre of pain and 17 multiple centres. All patients reported that the pain was constant (not varying more than 20%). Ten of the 11 patients suffering from epicondylalgia reported that light palpation of the epicondyle increased their pain (>100%). This did not occur with palpation in the other patients apart from 3 of those suffering from myalgia.

As seen in Fig. 1 the pain relieving effect of vibratory stimulation and placebo was dependent on the site of treatment.

The results obtained with vibratory stimulation in the painful area show that 33 out of the 68 patients completing the trial reported alleviation of pain, 24 reported pain reduction exceeding 50% with 8 having total pain relief. In less than 10 min after discontinuation of vibratory stimulation 3 of the 24 patients reported a gradual return of pain which left them with a post-conditioning pain relief of less than 50%. In the remaining patients the post-conditioning relief exceeded 50% for a longer period than 30 min. Twenty-five patients were unaffected by treatment and 10 reported increased pain during stimulation. In 2 of these 10 patients the increased pain persisted for at least 30 min after the stimulation period.

The effect of placebo vibratory stimulation in the painful area show that 23 out of 68 patients reported pain alleviation, 13 reported pain reduction exceeding 50% with 5 having total pain relief. Ten patients reported a pain reduction of less than 50%. Thirty-seven patients had no relief and 8 reported an increase in pain. In less than 10 min after discontinuation of placebo vibratory stimulation 3 of the 5 patients, who had experienced a relief exceeding

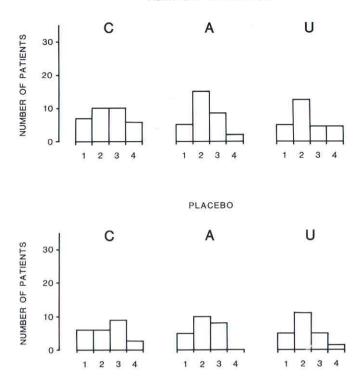


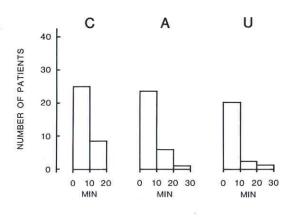
Fig. 2. Duration of pain alleviation after vibratory stimulation or placebo vibratory stimulation. 1, 0–1 hour; 2, 1–3 hours; 3, 3–12 hours; 4, >12 hours. C, over center of pain; A, over the antagonistic muscle or over the area contralateral to the point of pain—see text; U, over an acupuncture point unrelated segmentally to the point of pain.

50% during placebo, reported a gradual return of pain which left them with a post-conditioning pain relief of less than 50%. In the remaining 2 patients the period of pain reduction after placebo was longer than 30 min. Three of the patients who experienced pain increase during placebo reported increased pain for more than 20 min following cessation of stimulation.

To see if there was any difference in induction time for partial and total relief of pain between the methods used, we noted the time till the first report of subjective pain reduction and of maximal pain reduction (Fig. 3). In the two test groups vibratory stimulation and placebo, about 70% of the patients reported a reduction of pain less than 10 min after onset of treatment. The time needed to obtain maxi-

Table I. Preference by site treated both during and after treatment (N=68)

| Treatment site | Preference | | | | |
|--------------------------|------------|---------|---------|---------|--|
| | Stimulator | Placebo | Neither | p value | |
| During treatment | | | | | |
| Over center of pain | 27 | 8 | 33 | 0.005 | |
| Over antagonistic muscle | 21 | 7 | 40 | 0.01 | |
| Over an unrelated acu- | | | | | |
| puncture point | 16 | 8 | 44 | NS | |
| After treatment | | | | | |
| Over center of pain | 23 | 6 | 39 | 0.005 | |
| Over antagonistic muscle | 18 | 10 | 40 | NS | |
| Over an unrelated acu- | | | | | |
| puncture point | 14 | 8 | 46 | NS | |



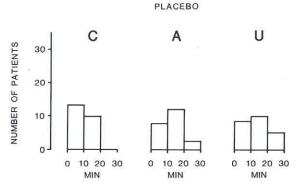


Fig. 3. Induction time for first report of subjective reduction (left side diagrams) and maximal obtained subjective pain reduction (right side diagrams) in patients who experienced pain relief during vibratory stimulation or placebo vibratory stimulation. C, over center of pain; A, over the antagonistic muscle or over the area contralateral to the point of pain—see text; U, over an acupuncture point unrelated segmentally to the point of pain.

mal pain reduction was less than 20 min in about 30% of the patients while the rest experienced maximal effect after 20-45 min of stimulation. There was no significant difference in induction time for first detectable or maximal pain reduction between the patients receiving vibratory stimulation or placebo. However, there was a clear tendency that pain alleviation induced by placebo vibratory stimulation requires a longer period of treatment.

To study if there was any difference in duration of post-treatment-analgesia for vibratory stimulation and placebo, the time taken for the pain to return to its pre-stimulation level was noted (Fig. 2). The results obtained show that the duration of analgesia parallel those of the pain alleviation. The duration of pain relief was longer when the stimulation or placebo had been applied over the painful area. The average duration of pain relief was 7 hours for vibratory stimulation and 4 hours for placebo.

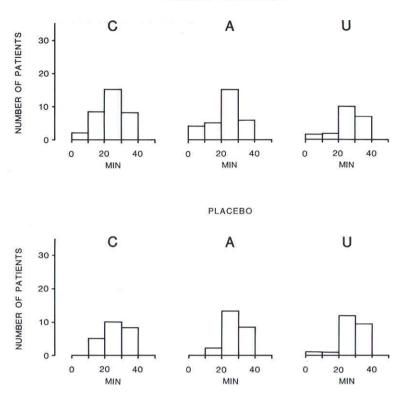
The efficacy of the stimulator was evaluated by

comparing its effect with that of the placebo for each patient (Table I). The efficacy of the vibrators was determined during treatment and continuously afterwards until the pain had returned to its initial intensity.

As shown the mode and location of treatment generally preferred was vibratory stimulation over the center of pain. Preference being significant (p <005) compared to placebo vibratory stimulation over the center of pain. However, in the patients suffering from epicondylalgia there was as great relief with treatment over the antagonistic muscle but the pain alleviation obtained was not long lasting (generally less than 2 hours).

DISCUSSION

The results of the present study show that out of the 68 patients 33 patients (48%) reported some alleviation of pain when vibratory stimulation was applied over the center of pain compared to 23



patients (34%) with placebo. The magnitude (% pain reduction) of the placebo effect in the present study is similar to that reported in other double-blind trials 4, 12).

The study revealed that the site of stimulation preferred using vibratory stimulation or placebo was over the center of pain. From a neurophysiological point of view peripheral stimulation would be expected to be most effective when applied over the center of pain and to be least effective when applied over an area or body remote from the site of pain. Interestingly, some of the patients suffering from epicondylalgia or myalgia reported that the actual effect of the stimulator was the highest over the antagonist muscle. This was not the case with placebo.

It has been proposed that the analgesic effect of vibratory stimulation involves peripheral nociceptive fibres (3). However, inhibition of pain thresholds measured in man during and after vibratory stimulation, increased bilaterally (8). Thus the pain alleviation obtained with vibratory stimulation is more likely evoked by central mechanisms.

In conclusion the present results show that vibratory stimulation is more effective than placebo in alleviating pain. However, one should take into account that a true placebo stimulation is impossible when studying peripheral stimulation techniques.

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