TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION AFTER MAJOR AMPUTATION

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We studied the effect of transcutaneous electrical nerve stimulation (TENS) on stump healing and postoperative and late phantom pain after major amputations of the lower limb. A total of 51 patients were randomised to one of three postoperative treatment regimens: sham TENS and chlorpromazine medication, sham TENS only, and active low frequency TENS.

There were fewer re-amputations and more rapid stump healing among below-knee amputees who had received active TENS. Sham TENS had a considerable placebo effect on pain. There were, however, no significant differences in the analgesic requirements or reported prevalence of phantom pain between the groups during the first four weeks. The prevalence of phantom pain after active TENS was significantly lower after four months but not after more than one year.

Nearly all patients suffer some degree of phantom pain after an amputation. We have used chlorpromazine on an empirical basis to treat this problem. In most patients pain decreases during the postoperative weeks and is no longer a problem, but in others it persists. One of the many treatments used to alleviate chronic phantom pain (Sherman, Sherman and Gall 1980) is transcutaneous electrical nerve stimulation (TENS) (Manno et al. 1982; Naidu 1982; Winnem and Amundsen 1982).

A number of authors have reported that high frequency TENS stimulation (60 Hz to 100 Hz) reduced pain after such operations as cholecystectomy (Bussey and Jackson 1981; Ali, Yaffe and Serrette 1981), herniorrhaphy, and total joint replacement (Stabile and Mallory 1978), but others have found it of no value (Strayhorn 1983). The vasodilatation effect of low frequency (2 Hz to 5 Hz) stimulation (Abram, Asiddao and Reynolds 1980) has been used successfully to treat Raynaud's syndrome (Kaada 1982) and chronic ulcers (Kaada 1983). Our study was designed to assess the effect of low frequency TENS during the first weeks after major leg amputation in comparison with chlorpromazine and

with a placebo treatment. We reviewed postoperative pain, chronic phantom pain and healing.

PATIENTS AND METHODS

We included patients who were to undergo a Syme's, below-knee (BK) or through-knee (TK) amputation for ischaemic changes due to diabetes or atherosclerosis. Cases of traumatic amputation and re-amputation at a higher level were excluded, as were uncooperative patients and those who were to be returned to a nursing home soon after operation.

The indication for the amputation and its level were determined by clinical evaluation of the circulation and skin temperature. Syme's amputation was performed as a conventional one-stage procedure. At BK amputation a long posterior flap was used, and TK amputations had a long anterior flap. A plaster cast was worn for the first three postoperative weeks.

After operation patients were allocated to one of three groups:

A: Sham TENS and chlorpromazine.

B: Sham TENS only.

C: Active TENS stimulation.

Group A patients were initially given chlorpromazine 10 mg three times daily as prophylaxis against phantom pain. This was increased up to 25 mg three times daily if required and continued for a median of 12 weeks (range, 5 to 28 weeks). All patients received analgesics on demand.

TENS stimulation was given for 30 minutes twice daily during the two first postoperative weeks with the Tenzcare stimulator (3M, Minneapolis, USA). This

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pocket size stimulator operates on rechargeable batteries and has two independently adjustable channels. Active stimulation was given through two pairs of electrodes placed over the femoral (Fig. 1) and sciatic (Fig. 2) nerves on the amputated side. The stimulator was set to "low frequency". This delivers bursts of 7 pulses (at 100 Hz, duration 90 μ sec) twice per second. The amplitude was increased until the patient complained of discomfort.

Fig. 1

Fig. 2

To show the placement of electrodes. Figure 1 – Over the femoral nerve. The inguinal ligament and femoral artery are marked on the skin. Figure 2 – Over the sciatic nerve.

Sham TENS electrodes were placed only over the femoral nerve and the electrode leads were inserted into an inactive channel on the stimulator. A separate channel was activated, causing lights to shine, and giving the impression that the stimulator was working.

A total of 52 patients were entered into the study during a two-year period. Randomisation was not perfect, since review after 18 months showed that there was an unequal distribution of levels of amputation among the treatment groups. Subsequently, randomisation was improved by taking account of the amputation level.

One patient from Group B with a TK amputation was excluded because of transfer to another department. Details of the remaining 51 patients are given in Table I.

Table I. Details of 51 patients treated prophylactically after amputation

	Group A Drug + Sham TENS	Group B Sham TENS	Group C TENS
Total number	15	19	17
Men	10	9	8
Age (range)	71 (53–82)	69 (39–86)	68 (57–88)
Women	5	10	9
Age (range)	78 (66–88)	80 (65–86)	79 (66–92)
Amputation level			
Syme's	2	4	1
Below-knee	10	13	11
Through-knee	3	2	5
Diabetic	6	7	6

All 51 patients were followed for at least one year or until re-amputation or death. The analgesic drugs taken by each patient during the first four postoperative weeks were recorded. Seven patients who were on analgesic medication for other painful conditions were excluded from this part of the review.

Patients were reviewed personally after 16 weeks and again after at least one year, and asked about phantom pain. Patients entered into the study during the second year were also asked at the end of each of the first four weeks about phantom pain, wound pain, and (during the two weeks of stimulation) about any subjective effect of TENS.

The stump was recorded as having healed when the skin was closed and free from crusts and scabs. To avoid bias caused by the varying proportions of different levels of amputation in the treatment groups, we included only patients with BK amputations in the evaluation of stump healing.

Statistical evaluation used the chi square and non-parametric (Wilcoxon) tests; probability values under 0.05 were taken to indicate significant differences.

RESULTS

One patient from Group A with a TK amputation and one from Group C with a BK amputation died during the first three weeks. Thirteen of the remaining 49 amputations did not heal. The re-amputation rate was lower among diabetic (4/20) than atherosclerotic (9/29) patients. Two of the seven Syme's amputations and five of the 10 TK amputations failed. The median time before re-amputation was 4 weeks (range, 1 to 8 weeks).

Of the 33 patients with BK amputations six failed to heal. After 6 weeks and at 9 weeks there were significantly more healed stumps ($p < 0.05$) among the 10 patients who had received active stimulation than among the 23 in Groups A and B who had received sham TENS (Fig. 3). There were nine diabetics among the BK amputees in Groups A and B and five in the active stimulation Group C.

The median number of analgesic doses was somewhat lower in Group C patients than in the other two groups (Table II), but there were very great variations in analgesic consumption within each group and differences were not statistically significant.

During the first four weeks, there was no significant difference in the proportion of patients in each group who complained of phantom pain. Sixteen weeks after operation, 4 of 11 patients in Group A and 7 out of 12 patients in Group B complained of phantom pain. None of the 10 patients in Group C had phantom pain at this time.

When questioned again over one year postoperatively, however, 3 of 8 patients in Group A, 5 of 9 in Group B and 3 of 8 in Group C had some degree of phantom pain. Most of these patients (all those in Group

Table II. Median number of analgesic doses taken (95% confidence range in brackets)

	Group A Drug + Sham TENS	Group B Sham TENS	Group C TENS
Week 1 <i>n</i>	10 (2-15) 14	10 (4-17) 14	5.5 (2-17) 14
Week 2 <i>n</i>	2 (0-8) 13	8 (0-12) 13	2 (0-8) 13
Week 3 <i>n</i>	2 (0-3) 11	2.5 (0-9) 12	0.5 (0-5) 12
Week 4 <i>n</i>	1 (0-6) 10	1.5 (0-13) 10	0 (0-7) 12

n, the number analysed

C) had only slight and occasional pain which did not merit analgesia.

All the patients in Group C who were asked at the end of the second week said that TENS had had an analgesic effect, but half of the 20 patients who had received sham TENS also thought that the stimulation had been of value.

cluded, in Group C after both six and nine weeks. This is probably due to the vasodilatation which results from low frequency TENS.

TENS had a considerable placebo effect with respect to pain. This has been found in other studies (Stabile and Mallory 1978; Langley et al. 1984; Lewis, Lewis and Sturrock 1984). However, in our series, the subjective analgesic effect of active stimulation and the placebo effect of sham stimulation were not reflected in a reduced requirement for analgesia. This lack of an objective effect may be due to the use of low frequency stimulation; this is less well documented than high frequency as an analgesic for postoperative pain. Patients receiving chlorpromazine medication also showed no significant reduction of analgesic requirement. Neither TENS nor chlorpromazine were found to be superior to a placebo in reducing pain during the first four weeks after amputation.

The prevalence of chronic phantom pain after amputation has been reported as between 0.4% and 50% (Sherman et al. 1980), but the reported prevalence must depend on the method of determination. Our patients

Fig. 3

Diagram to show the state of stump healing after 3, 6 and 9 weeks among below-knee amputees who received sham TENS (Group A + B) and active TENS (Group C).

DISCUSSION

The randomisation of patients to treatment groups was not perfect, but this is unlikely to have influenced our findings significantly since our policy on amputation level had not changed during the study period. The similar distribution of diabetic patients among the three groups was important since healing, as also reported by Termansen (1977), is more likely in these patients than in those with atherosclerosis.

The re-amputation rate in our series was similar to that reported elsewhere (Termansen 1977; Holstein, Sager and Lassen 1979; Burgess et al. 1982; Dickhaut, DeLee and Page 1984). TENS stimulation had a definite effect on stump healing. The re-amputation rate was lower among patients who received active stimulation than among those who did not, although the difference failed to reach statistical significance. There was, however, a statistically significantly higher number of healed stumps, even when re-amputations were ex-

with phantom pain over one year after amputation nearly all had very infrequent, mild pain. Most would probably not have mentioned the pain unless directly asked, and it is likely that their answer depended on the time which had elapsed since the last painful episode.

The prophylaxis of phantom pain by TENS post-operatively has not been reported previously. It seems to produce a definite reduction in the prevalence of phantom pain in the middle term, but we found no long-term difference between stimulated and control groups. The transitory reduction in phantom pain in the stimulated group is difficult to explain, there being no difference in the prevalence of phantom pain during stimulation, nor any significant change in analgesic consumption. Since none of our patients suffered significantly from chronic phantom pain, it is possible that prophylaxis is not really necessary.

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