

Smallwood, J.; Taylor, I.; Dimitriou, J.: The prognostic value of monoclonal antibodies in breast cancer. *Br. J. Cancer* 50: 100-104 (1984).

Dimitriou, J.; Bodmer, W.; Gatter, K.A.: Differentiation antigens expressed by breast cancer cells in the lactating breast. *Int. J. Cancer* 34: 100-104 (1984).

Stein, H.; Erber, W.N.; Mason, D.V.: Human epithelial membrane antigen-1: A marker for the diagnosis of human neoplasia. *Int. J. Cancer* 33: 100-104 (1984).

Presence of breast cancer in axillary lymph nodes. *Br. J. Cancer* 51: 100-104 (1985).

Strauss, D.W.; Weathers, D.W.: Axillary microdissection in breast cancer. *Ann. Surg.* 101: 100-104 (1985).

## Transcutaneous Electrical Nerve Stimulation for Pain Relief following Inguinal Hernia Repair: A Controlled Trial

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**Key Words.** Transcutaneous electrical nerve stimulation · Hernia

**Abstract.** The efficacy of transcutaneous electrical nerve stimulation (TENS) in relieving postoperative pain has been assessed by means of a prospective randomized controlled trial in 62 male patients undergoing unilateral inguinal herniorrhaphy. Thirty-four patients received TENS and 28 patients received sham TENS for 48 h after the operation. Pain was assessed by means of linear analogue pain scales, analgesic requirements and peak expiratory flow readings. We were unable to detect any significant differences in these variables when the two groups were compared. These results do not support the use of TENS.

### Introduction

Pain following inguinal herniorrhaphy may be controlled by opiate analgesics. Adequate doses of this group of drugs, given sufficiently often to control pain, may result in pulmonary complications or respiratory depression [8]. Whilst intermittent administration may result in unnecessary pain between doses, continuous infusion is associated with an increased risk of respiratory depression.

It is well known that pressure or massage over a painful area can reduce the intensity of pain – a phenomenon that can be explained by the 'gate control theory' [7],

which suggests that pain impulses can be controlled in the spinal cord by means of a special presynaptic neuron system. This has led to the introduction of transcutaneous electrical nerve stimulation (TENS) as a possible means of postoperative pain relief. Although the use of TENS is thought to be free of complications, there have been conflicting reports as to its efficacy in controlling pain [1-3, 6, 9, 10]. It has been suggested that it may be necessary to use two pairs of electrodes (one pair adjacent to the wound and the other pair situated on either side of the spinal column) in order to achieve satisfactory pain relief [3].

A single blind, randomized, prospective trial was performed to evaluate the effect of TENS on postoperative pain and respiratory function following inguinal hernia repair.

### Patients and Methods

Sixty-two male patients undergoing unilateral inguinal hernia repair were randomized to receive TENS or sham TENS. Randomization was achieved by the use of random number tables. Twenty-eight received sham TENS and 34 received TENS. Patients with a history of psychiatric illness, narcotic abuse or previous hernia repair were excluded.

Prior to surgery informed consent was obtained from the patients who were told that a tingling sensation around the wound was sometimes associated with TENS. They were also encouraged to ask for additional analgesia if required. Peak expiratory flow rates were measured, taking the best of three readings.

Patients were given standard intramuscular premedications of Omnopon (0.25 mg/kg). A Shouldice repair, through a straight incision, parallel to the inguinal ligament was performed under general anaesthetic. No local anaesthesia was used. At the conclusion of the operation a pair of sterile self-adhesive electrodes (3M, 6220) were placed on either side of the incision. The patient was then transferred to the recovery room and when sufficiently awake to be able to cooperate, a second pair of electrodes was placed on either side of the spinal column - centred over the first lumbar vertebra. Both pairs of electrodes were connected to a 3M Tenzcare Dual Channel TENS stimulator (6240) delivering a standard 70-Hz, rectangular-shaped pulse. The amplitude control on each channel was then increased until the patient was able to feel a comfortable tingling sensation. (TENS is not thought to be effective unless it can be felt.) The machine was then disconnected and immediately replaced by another TENS stimulator or completely identical sham TENS stimulator (according to randomization) with the amplitude controls set at the same level as the initial test machine.

Pain was measured by asking the patients to complete linear analogue pain scales [4] at 6, 12, 24, 36 and 48 h after operation. Completion of the analogue pain scale was delayed if Omnopon had been admin-

istered within the previous 3 h. Peak expiratory flow rates were measured at 24 and 48 h postoperatively. Omnopon requirements were recorded. The nursing staff were not aware as to whether the patients were receiving TENS or sham TENS.

### Results

The mean age of the patients in both groups was similar (57 years in the TENS group, range 21-83, and 55 years in the sham TENS group, range 24-78). We were unable to detect a significant difference in the opiate requirement between the two groups. The TENS group of 34 patients received 32 doses of opiate analgesia (0.9 doses per patient) and the sham TENS group of 28 patients 24 doses (0.85 doses per patient). Patients in both groups required between 0 and 4 postoperative doses of Omnopon (fig. 1). We were unable to detect any significant difference in the postoperative peak expiratory flow readings between the TENS and sham TENS patients at either 24 or 48 h (fig. 2). No significant difference in the linear analogue pain scale readings was detected at any time after the operation (fig. 3).

### Statistics

Opiate requirement, peak expiratory flow readings and linear analogue pain scale readings were compared in both the TENS and sham TENS groups by the Mann-Whitney U test, (fig. 1-3). Type II error was calculated at the 80, 90 and 95% power (20, 10 and 5% type II error probability). For opiate doses this was 0.31 (80% power), 0.36 (90% power) and 0.40 (95% power). For pain scale readings this was 0.78 (80% power), 0.91 (90% power) and 1.01 (95% power). For peak flows at 24 h it was 63.9 (80% power)

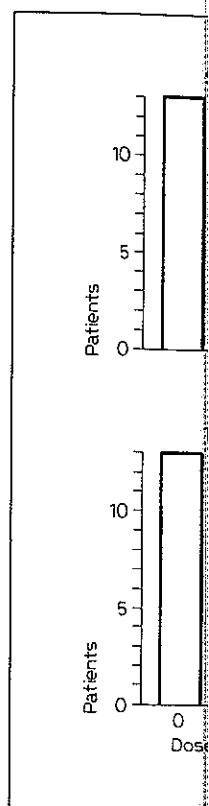
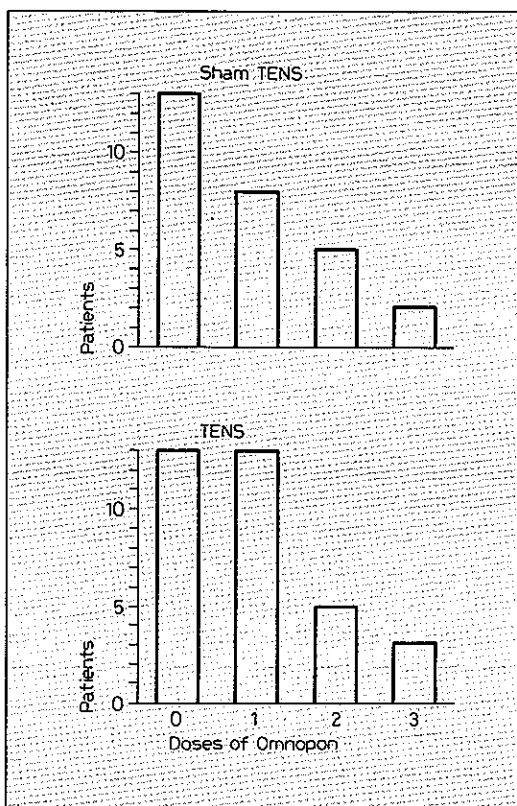


Fig. 3. Mean linear analogue pain scale readings with TENS (T) and sham TENS (ST) ( $p > 0.05$ , Mann-Whitney U test). Values are given as mean  $\pm$  SD.

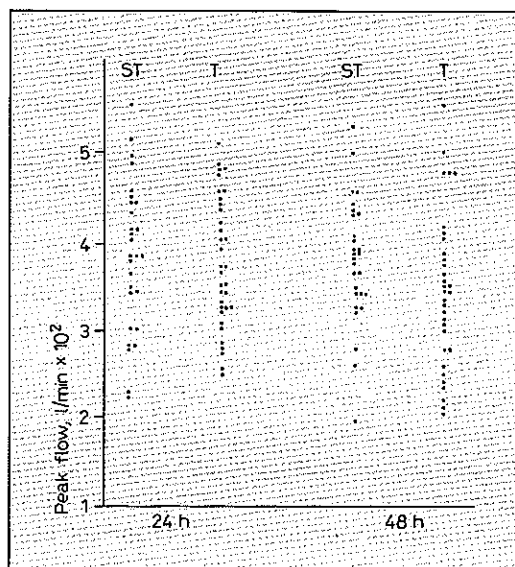
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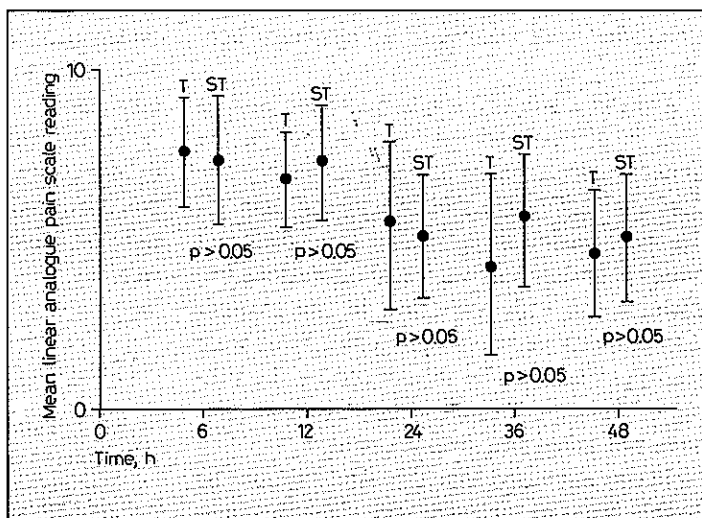


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Fig. 1. Doses of Omnopon required by patients with TENS (34 patients, 0.9 dose/patient) and sham TENS (28 patients, 0.85 dose/patient) (Mann-Whitney U;  $p > 0.05$ ).

Fig. 2. Peak flow in patients with TENS (T) and sham TENS (ST). (Mann-Whitney U;  $p = 0.6$ , 24 h;  $p = 0.08$ , 48 h.

Fig. 3. Mean linear analogue pain scale readings in patients with TENS (T) and sham TENS (ST) ( $p > 0.05$ , Mann-Whitney U test). Values are given as means  $\pm$  SD.



73.8 (90% power) and 82.8 (95% power). For peak flows at 48 h it was 54 (80%), 62.3 (90%) and 70 (95%).

### Discussion

We have shown no benefit from the use of TENS, a result which is at variance with the conclusions of several other studies [1-3, 6, 9, 10] in which similar stimulators have been utilized. The methodology of several of the previous studies can be criticized and trials purporting to measure analgesic effects are associated with many pitfalls. One of these studies was non-randomized [1] and the others based on small samples [2], heterogeneous or retrospective [6]. Two more recent studies [3, 4] have reached similar conclusions to ours.

A similar but smaller study [4] demonstrated no advantage from the use of TENS following inguinal hernia repair. It was suggested that the failure to demonstrate advantages associated with the use of TENS may have been related to the use of only a single pair of electrodes. In our study two pairs of electrodes were used with no apparent benefit.

Pain is a subjective phenomenon and as such is difficult to measure. Although the linear analogue pain scale is probably the best available means of measuring pain [5] the wide variation in results from different patients undergoing identical operations underlines the wide variation in the manner that patients perceive their pain. Pain scale readings may also be influenced by the timing of opiate administration. Other studies have not taken this into account.

It was intended that this study should be double blind as the readiness of medical and

nursing staff to administer opiates could be altered by an awareness of whether individual patients were receiving TENS or sham TENS. It is difficult to perform such a double blind study because TENS normally causes a tingling sensation and for this reason we consider our study single blind. Our patients were informed that they were taking part in a trial and some of the more perceptive patients correctly deduced that the absence of tingling indicated that they were receiving sham TENS - despite the fact that the sham TENS machines had the same identical flashing red lights as the TENS machines.

Peak expiratory flow measurement not only provides an index of respiratory function, but also indirectly measures pain. Changes in peak flow reflect alterations in the ability of a patient to cough - which is dependent in turn on adequate analgesia. However, the sudden sharp wound pain associated with coughing or movement is different from the dull 'background' pain that is experienced at other times.

We found that TENS, although well accepted by patients, was relatively demanding on the time of the hospital staff as electrodes and wires sometimes became detached and entangled.

*In conclusion*, we have been unable to demonstrate any advantage of TENS over conventional analgesics in terms of pain relief. We have abandoned TENS in our practice.

### References

- 1 Ali, J.; Yaffe, C.S.; Serrette, C.: The effect of transcutaneous electric nerve stimulation on postoperative pain and pulmonary function. *Surgery* 89: 507-512 (1981).

- 2 Cooperman, A.M.; dy, R.: Use of traction in the control of a prospective, *Am. J. Surg.* 133: 3
- 3 Cuschieri, R.J.: Transcutaneous electric nerve stimulation for operative pain. *Anesth Analg.* (1985).
- 4 Gilbert, J.M.; Gleason, R.H.: Controlled trial of transcutaneous electric nerve stimulation (TENS) following inguinal hernia repair. *Br. J. Surg.* 74: 749-751 (1986).
- 5 Huskisson, E.C.: Pain measurement. *Br. Med. J.* 1: 1127-1131 (1974).
- 6 Hymes, A.C.; Raab, D.G.; Printy, A.L.: Transcutaneous electric nerve stimulation on postoperative pain. *Surg. Forum* 24: 4
- 7 Melzack, R.; Wall, P.D.: The gate control theory of pain. *Science* 131: 938-942 (1965).

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- 2 Cooperman, A.M.; Hall, B.; Mickalacki, K.; Hardy, R.: Use of transcutaneous electrical stimulation in the control of postoperative pain. Results of a prospective, randomized controlled study. *Am. J. Surg.* 133: 185-187 (1977).
- 3 Cuschieri, R.J.; Morran, G.S.; McArdle, C.S.: Transcutaneous electrical stimulation for postoperative pain. *Ann. R. Coll. Surg.* 67: 127-129 (1985).
- 4 Gilbert, J.M.; Gledhill, T.; Law, N.; George, G.: Controlled trial of transcutaneous electrical nerve stimulation (TENS) for operative pain relief following inguinal herniorrhaphy. *Br. J. Surg.* 73: 749-751 (1986).
- 5 Huskisson, E.C.: Measurement of pain. *Lancet* *ii*: 1127-1131 (1974).
- 6 Hymes, A.C.; Raab, D.E.; Yonehiro, E.C.; Nelson, D.G.; Printy, A.L.: Electrical surface stimulation on postoperative pain and pulmonary function. *Surg. Forum* 24: 447-449 (1973).
- 7 Melzack, R.; Wall, P.D.: Pain mechanisms, a new theory. *Science* 150: 971-979 (1965).
- 8 Rutter, E.C.; Murphey, F.; Dudley, H.A.F.: Morphine; controlled trial of different methods of administration for postoperative pain relief. *Br. med. J.* 280: 12-13 (1980).
- 9 Solomon, R.A.; Viernstein, M.C.; Long, D.M.: Reduction of postoperative pain and narcotic use by transcutaneous electrical nerve stimulation. *Surgery* 87: 142-146 (1980).
- 10 Van der Ark, G.D.; McGrath, K.A.: Transcutaneous electrical stimulation in treatment of postoperative pain. *Am. J. Surg.* 130: 338-340 (1975).

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