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Is transcutaneous electrical nerve stimulation of any value during cervical laser treatment?

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ABSTRACT

Objective To assess the value of transcutaneous electrical nerve stimulation (TENS) during cervical laser therapy.

Design Randomized three arm controlled clinical trial comparing (i) TENS, (ii) local anaesthetic and (iii) TENS plus local anaesthetic (direct infiltration of 2% lignocaine and 0·03 iu/ml octopressin).

Setting Colposcopy Unit adapted to run randomized trials.

Subjects 100 women with CIN and no previous experience of cervical surgery.

Main outcome measure Visual linear analogue pain scores.

Results The median pain score associated with TENS was greater than the score associated with local anaesthesia (23% compared with 17%; $P = 0{\cdot}1$). Combining TENS with local anaesthesia did not further reduce pain scores.

Conclusion Although there was considerable consumer satisfaction with TENS it provided no additional pain relieving effect in addition to direct infiltration of lignocaine and it is inferior to lignocaine alone. We are unable to advocate the use of TENS for laser treatment of the cervix.

Cervical laser treatment is an uncomfortable procedure for many women and conventional pain relieving techniques have limitations. Paracervical blocks are ineffective (Johnson *et al.* 1989), non-steroid anti-inflammatory drugs have only a small effect on perceived pain (Al-Kurdi *et al.* 1985) and direct infiltration of local anaesthetic reduces pain scores by 40% (Lee *et al.* 1986). The support of sympathetic nursing staff who are able to distract the patient's attention during the procedure should decrease the amount of discomfort and as a last resort the surgeon may offer selected patients nitrous oxide/oxygen mixture (Entonox) or intravenous fentanyl. Patients who are likely to find laser treatment painful such as young nulliparous women and those who suffer from dysmenorrhoea (Johnson *et al.* 1990) can be offered a general anaesthetic but at present there are no other established techniques that can further reduce the pain associated with cervical laser treatment.

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive method of relieving pain. During the past few years an increasing number of reports have suggested that TENS may give temporary alleviation of pain in about half of those treated. TENS may reduce pain after operations and during parturition but it has not been widely adopted for these purposes because there are many superior analgesics and anaesthetics for these painful conditions. However, the alternatives usually involve the administration of opiates or an epidural block, and are inappropriate for outpatient treatment. Consequently, if TENS could be shown to be effective it could have a place in laser treatment clinics. The analgesic effects of TENS, direct infiltration of lignocaine with octopressin and TENS together with direct infiltration were compared in a three arm randomized clinical trial.

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Subjects and methods

The trial protocol was approved by our local ethics committee. One hundred women with a colposcopic diagnosis of cervical intra-epithelial neoplasia (CIN) were recruited. The sample size of 90 was prospectively calculated to detect a 10% improvement in one arm of the study, assuming alpha 0·05, beta 0·2, and the standard errors demonstrated previously (Johnson *et al.* 1989). However, ten more patients were studied than initially intended because we lost count of the number of recruits and failed to stop the trial. The women had had a gynaecological interview, colposcopy and a colposcopically directed biopsy. Linear analogue anxiety and HAD anxiety/depression personality trait scores (Zigmond & Snaith 1983), age and number of vaginal deliveries were recorded to assess group comparability. Women who had a past history of treatment for CIN, other cervical surgery or pelvic inflammatory disease, postmenopausal women and women with cardiac pacemakers were excluded. Two other women refused to enter the trial. All the women were given an explanation of the treatment with reassurance that the treatment would be tolerable.

Suitable subjects were then allocated to one of the following three groups according to a block randomized code. (1) TENS, (2) TENS plus direct infiltration of 2 ml 2% lignocaine plus octopressin 1 in 10 000 (0·03iu/ml); and (3) direct infiltration of 2 ml 2% lignocaine plus octopressin.

As it is impossible to conceal the use of TENS from the

attendants a sham instrument was not used in group 3. The block randomization code was held by one investigator who then allocated treatment. The nurses, clerical officers responsible for the computerized appointments, and the laser surgeon did not have access to this code. No pre-operative analgesia was offered. Local anaesthesia was administered in a separate room by the investigator responsible for the randomization. A total of 2 ml of 2% lignocaine + octopressin was injected from a dental syringe via a 30 gauge needle into four points on the transformation zone to a depth of 3–5 mm. Microtens TENS pads (Neen Pain Management Systems, Norfolk, UK) were applied 20 min before treatment. Four conductive silicone polymer electrodes were applied using conducting gel and tape fixative; two anteriorly to the abdominal wall just above the symphysis pubis and one on each side of the sacrum. The electrodes were connected to a 80 Hz nerve stimulator (pulse width 210 μs) by a cable. The single channel amplitude control was activated by the patients under instruction. Initially they were encouraged to experience a tingling sensation and then they increased the amplitude until it became uncomfortable. They were given approximately 20 min to experiment with the device until they were called into the second room for laser treatment. All the treatments were carried out in this second room by a second operator who was supported by attentive and sympathetic nursing staff who encouraged the use of TENS. The entire ectocervical transformation zone was either ablated to a depth of approximately 7 mm or excised with the aid of skin hooks using a 35 W CO_2 laser (spot size 1·5 mm). The size of the transformation zone and the amount of blood loss were estimated.

At the end of the procedure the surgeon gave a further explanation of the treatment and scored the pain experienced by the patient using 120 mm visual linear analogue scores (Huskisson 1983). The scores were converted into a percentage. At the end of the procedure the women offered TENS were given a simple questionnaire. They were asked to answer 'Yes' or 'No' to indicate whether or not they found the TENS each of the following: (1) comfortable; (2) unpleasant; (3) helpful (4) frightening; (5) soothing; or (6) pain relieving.

A 'Yes' answer to comforting, helpful, soothing and pain relieving and a 'No' answer to frightening and unpleasant was considered to be a coherent response. If a ratio of favourable to unfavourable responses was at least 3:1 they were considered to be incoherent and the responses were excluded.

The data were analysed according to the 'intention to treat', using the Mann–Whitney U test.

Results

One woman was excluded because she failed to record the pain score. Another found the treatment too uncomfortable and therefore direct local infiltration was added. She had initially scored 37% for the first half of the treatment but found the treatment much more comfortable once local anaesthesia was added.

The median pain score for the group assigned TENS only was higher than the median score for the group given direct infiltration of local anaesthetic ($U = -1{\cdot}57, P = 0{\cdot}116$). Combining TENS with direct local anaesthesia did not further reduce the median pain score. The pain score was unrelated to blood loss, lesion size or whether the lesion was excised rather than ablated (Table 1). The groups had similar anxiety and depression scores.

Fifty-one women who used TENS completed the questionnaire. Six responses were incoherent and nine women claimed the treatment was not painful and they did not need to turn the TENS on. Of the coherent responses 97% found TENS comfortable, 88% thought it was helpful, 75% thought it was pain relieving and 78% found it soothing. However, 10% described it as frightening and 45% said it was unpleasant.

Discussion

Women having laser treatment for CIN find TENS less effective than direct infiltration of local anaesthetic and TENS does not supplement the analgesia of women having local anaesthesia. We had expected TENS to contribute significantly to reducing discomfort during the procedure. The pain of labour is reported to respond to TENS (Augustinsson *et al.* 1977; Tawfik *et al.* 1982; Grim & Morey 1985) but strictly controlled randomized trials have not portrayed TENS so favourably (Simkin 1989) and they have failed to show any difference in measured pain scores (Harrison *et al.* 1986; Nesheim 1981).

Table 1. Characteristics of the three groups in the study

Variable	TENS only (n = 34)	Local anaesthetic (n = 35)	TENS and local anaesthetic (n = 29)
Mean age (years) (SD)	31·8 (9)	32·6 (9)	30·1 (8)
% Nulliparae	48%	44%	35%
Lesion			
Small	0	2	1
Average	19	11	7
Large	3	10	3
Excised	12	12	18
Blood loss			
None	25	26	19
Some	6	5	9
Troublesome	3	4	1
Median anxiety HAD score (interquartile range)	6 (5–11)	7 (4–9)	6·5 (4–8)
Median depression HAD score (interquartile range)	3 (1–4)	2 (1–4)	3 (1–3)
Median pain score (interquartile range)	24 (10–42)	17 (7–30)	18 (8–31)

TENS may be effective in relieving chronic and postoperative pain (Sylvester *et al.* 1986; Leo *et al.* 1986; Ho *et al.* 1987; Denning 1988; Anon. 1989) but the pain from laser therapy differs from chronic pain and labour, therefore these reports are not comparable with ours.

Benefit from TENS could be due to a placebo effect and it is only by strictly controlled randomized clinical trials that such an effect can be differentiated from a true effect on pain. The apparent beneficial effect of local anaesthesia must also be considered in the light of the trial's potential weaknesses. It was impossible to conceal the use of TENS from the surgeon and patients but we had intended to 'blind' the attendants to the use of local anaesthesia. Injections of lignocaine were given in a separate room before the laser surgery was carried out by a different attendant but the surgeon was able to identify points where local anaesthetic had been given. The possible influence of recruitment of 10 extra women must also be considered. This occurred because a block of randomly allocated codes was initiated but not completed. Although this would not have affected negative results, it could have influenced the apparent benefit from lignocaine. Block randomization has two advantages: it counteracts temporal bias (due, for example, to improvement in the technique of laser surgery as the study progressed) and it produces equal numbers of subjects in each group. The mismatch caused less women than expected to be recruited into the TENS and local anaesthetic group. If we had become more skilful at laser surgery with the passage of time then this might have improved the median score associated with combination therapy and portrayed it more favourably. Another unexpected outcome, which could have influenced pain scores, was the uneven distribution of large lesions, despite random allocation.

Despite the weaknesses of the trial, which limit conclusions about the effect of lignocaine, there is no evidence that TENS improves pain scores in women having laser treatment of the cervix. The response to the questionnaire could be interpreted very favourably with more than 75% of the women indicating that TENS was pain relieving and 80% of them indicating that it was helpful. We could conclude that it still had a place in our laser clinic because of such favourable responses, even if it has only a placebo effect. However, a substantial proportion of women who used the device found it frightening or unpleasant, which we consider unacceptable in the absence of an improvement in pain scores. Therefore, although we will not object to a motivated woman using her own TENS machine, we are unable to endorse it for routine use for laser treatment of the cervix.

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References

Al-Kurdi M., Hare M. J., Lowles I., Douglas C. P. & English J. R. (1985) The effect of a prostaglandin-synthetase inhibitor, naproxen sodium, and a placebo on the pain response to carbon dioxide laser treatment of the uterine cervix. *J Obstet Gynaecol* **5,** 260–262.

Anon (1989) Trans-cutaneous electrical nerve stimulation to relieve pain. *Drugs and Therapeutic Bulletin* (WHICH) **27** (7), 25–26.

Augustinsson L. E., Bohlin P., Bundsen P., Carlsson C.-A., Forssman L., Sjoberg P. & Tyreman N. O. (1977) Pain relief during delivery by transcutaneous electrical nerve stimulation. *Pain* **4,** 59–65.

Denning M. L. (1988) Retrospective review of long-term transcutaneous nerve stimulation in the management of chronic back pain. *Physiotherapy* **74** (3), 149–151.

Grim L. C. & Morey S. H. (1985) Transcutaneous electrical nerve stimulation for relief of parturition pain. *Physical Therapy* **65** (3), 337–339.

Harrison R. F., Woods T., Shore M., Mathews G. & Unwin A. (1986) Pain relief in labour using transcutaneous electrical nerve stimulation (TENS). A TENS/TENS placebo controlled study in two parity groups. *Br J Obstet Gynaecol* **93,** 739–746.

Ho A., Hui P. W., Cheung J. & Cheung C. (1987) Effectiveness of transcutaneous electrical nerve stimulation in relieving pain following thoracotomy. *Physiotherapy* **73** (1), 33–35.

Huskisson E. C. (1983) Visual analogue scores. In *Pain Measurement and Assessment.* (Melzack R., ed.), Raven Press, New York, pp. 33–37.

Johnson N., Crompton A. C. & Ramsden S. V. B. (1989) The efficacy of paracervical injections of lignocaine before laser ablation of the cervical transformation zone. A randomized placebo-controlled double-blind clinical trial. *Br J Obstet Gynaecol* **96,** 1410–1412.

Johnson N., Crompton A. C. & Parker J. (1990) The correlation between dysmenorrhoea and the pain experienced during laser ablation of a cervical lesion. *Gynecol Oncol* **36,** 215–216.

Lee E. T. C., Ozumba E. N. & Bevan J. R. (1986) A randomized trial of Citanest with Octopressin for relief of pain associated with laser vaporization of the cervix. *Br J Obstet Gynaecol* **93,** 967–969.

Leo K. C., Dostal W. F., Bossen D. G., Eldridge V. L., Fairchild M. C. & Evans R. E. (1986) Effect of transcutaneous electrical nerve stimulation characteristics on clinical pain. *Physical Therapy* **66** (2), 200–205.

Nesheim B. I. (1981) The use of transcutaneous nerve stimulation for pain relief during labour. *Acta Obstet Gynecol Scand* **60,** 13–16.

Simkin P. (1989) Non-pharmacological methods of pain relief during labour. In *Effective Care in Pregnancy and Childbirth,* vol. 2 (Chalmers I., Enkin M. & Keirse M. J. N. C., eds), Oxford University Press, ch. 56, pp. 902–905.

Sylvester K., Kendall G. P. N., Leonard-Jones J. E. (1986) Treatment of functional abdominal pain by transcutaneous electric nerve stimulation. *Br Med J* **293,** 481–482.

Tawfik O., Badraoui F. S., El-Ridi F. S. (1982) The value of transcutaneous nerve stimulation (TNS) during labour on Egyptian mothers. *Schmerz* **2,** 98–105.

Zigmond A. S. & Snaith R. P. (1983) The hospital anxiety and depression scale. *Acta Psychiat Scand* **67,** 361–370.

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