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Pain relief in labour using transcutaneous electrical nerve stimulation (TENS). A TENS/TENS placebo controlled study in two parity groups

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Summary. The analgesic effects of transcutaneous electrical nerve stimulation (TENS) in labour and effects on outcome were investigated in a double-blind TENS/TENS placebo controlled trial in 100 primigravidae and 50 women in their third labour. There were no differences between the TENS and the TENS placebo users in terms of pain concept or relief, and only 12 and 13% of primigravidae and 48 and 39% of the para 2 women completed labour without requiring other analgesia in their respective groups. The primigravidae who used either TENS or TENS placebo alone had shorter labours than those who required further analgesia. Although the outcome of labour for mother and infant were similar in the two groups, there was a higher operative delivery rate in women who also had epidural analgesia. There were highly significant differences between the TENS and the TENS placebo users in terms of favourable and unfavourable comments by the mothers and the midwives at 1 and 24 h after delivery. The evident consumer satisfaction for TENS suggests TENS has a part to play in analgesia in labour but the equivocal findings in terms of factors associated with pain relief points to the need for apparatus more specifically designed to cope with the special characteristics of the pain of labour.

Pain relief poses a major problem in labour. The present methods of analgesia appear to meet the needs of most parturients but are not without contra-indication and complication (Crawford 1984). There is clearly room for improvement

and more particularly the development of a self-administered method that is effective, non-invasive, allows ambulation and which would interfere minimally with the chances of a safe spontaneous natural vaginal delivery.

The quest for such an advance led us to investigate the use of transcutaneous electrical nerve stimulation (TENS). This method of analgesia is used for chronic pain relief in other branches of medicine (Lewith 1983). Post square wave electrical current is applied through surface electrodes placed on the skin. Analgesia is achieved, it is theorized, either by blocking pain impulses to the brain by increasing A-fibre transmission (the so-called gate theory of Melzak and Wall (1965)), or by stimulating the local release of endorphins (Sjolund *et al.* 1977).

TENS has been shown to be safe during

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labour (Bundsen & Ericson 1982), with no effect on the newborn infant (Bundsen *et al.* 1982a). Various degrees of pain relief have been reported in the few studies published to date (Shealy & Maurer 1974; Robson 1979; Stewart 1979). The largest series was a Scandinavian study (Bundsen *et al.* 1981) which also demonstrated possible advantages in outcome for mother and fetus. Placebo controlled obstetric studies are few (Neumark *et al.* 1978; Nesheim 1981) although Lewith (1983) noted a 30% positive response to TENS placebo in patients with chronic pain and the response to active TENS in other clinical situations has been shown to be greater than to sham stimulation (Jeans 1979).

As TENS has the potential to satisfy the necessary criteria for an ideal method of analgesia in labour, a double-blind study was embarked on at the Rotunda Hospital Dublin, comparing the efficacy of TENS in labour with that of TENS placebo (TPL). This initial report describes the findings in women having a first or third labour. The former were selected because it was their first experience of labour and the latter as they would have already experienced two previous different labours.

Subjects and methods

Patient selection

Primigravid women and those in their third labour admitted to the main labour ward, Rotunda Hospital Dublin, between June and December 1983 were asked if they had already decided upon a specific form of analgesia. Those who had not were given a simple explanation of the mechanics of TENS by the midwife in charge. The patient was assured that she would be instructed in its use until confident, that the use of TENS did not exclude using additional analgesia and that all current forms of analgesia would also be available. Patients were informed of the nature of the TENS/TPL control study and 100 primigravidae and 50 parous women (para 2) who all gave informed consent were admitted to it.

Apparatus

Two pairs of carbon rubber electrodes were placed on either side of the spine approximately 5 cm from it. Application sites were moistened so as to improve conductivity and adhesion.

Mindful of the dermatome distribution and the sites of pain usually experienced in labour the upper pair of electrodes (disposable) were placed to cover the dermatomes of the posterior rami from T10 to L1 inclusively. The smaller lower pair (re-usable) covered dermatomes of the posterior rami from S2 to S4. These electrodes were attached to either an active or placebo Tenzcare Dual Channel Stimulator Model 6240 (3M Minnesota St Paul, USA) one of six. Three of these machines functioned optimally but the remaining three were inactive TENS-placebo machines (the red light functioned but there was no power).

Each machine was set initially with a pulse width (duration) of 3 to 4 (60–80 μ s) and a pulse repetition rate preset to 5 to 6 (80–100 pulses per second (pps)). Patients were instructed and allowed to adjust the amplitude settings to gain analgesic relief commencing with 5 on both channels increasing gradually as the contractions gained momentum to higher amplitudes and density. Patients well advanced in labour were found to benefit from the pulse burst mode (2 burst per second, 7 pulses per burst, 100 pps intraburst rate) facility on the R dial of the machine.

Treatment allocation

Patients were allocated randomly to one of the six numbered machines. Neither patient nor midwife knew which were active and placebo machines. Numbering was changed at regular intervals by a third party to try and avoid the possibility of exposing the double-blind cover. For the same reason patients were not made aware that they should experience any sensation at the site of the electrodes.

Of the 100 primigravidae 49 used active TENS and 51 the placebo TENS; of the 50 parous women 27 used TENS and 23 the placebo.

Pain assessment

Labour was managed by the regular staff in the usual manner. Specific data collected included an initial assessment of pain threshold as measured by a Monsanto Gun (Table 1), an hourly assessment throughout labour by the patient of her pain and its sites on a scale rated from 0 (no pain) to 4 (very severe pain), with the research midwife also giving her assessment of the site and amount of pain relief on a 0 (nil) to 4

Table 1. Initial pain threshold

Pain threshold* (kg/cm ²)	Para 0		Para 2	
	TENS	TPL	TENS	TPL
≤2	0	2	0	0
2-4	26	24	1	4
4-6	20	21	20	15
>6	3	3	6	4
Total	49	50	27	23

* Measured by a Monsanto gun.
TENS, Transcutaneous electrical nerve stimulation;
TPL, TENS placebo.

(excellent) scale. These events and others such as the introduction of different analgesia were related in time to the onset of labour and to dilatation of the cervix.

All details of the birth were recorded including condition of the baby as measured by cord blood pH and Apgar scores at 1 and 5 min. One hour and 24 h after delivery, the patients were asked for their comments regarding the method of analgesia. Particular note was made of pain relief, site of relief, and any other favourable or unfavourable comments. They were also asked whether they would request TENS again. The attendant midwife recorded her assessment of the pain relief apparently achieved by the patient, its sites, the merits and demerits of TENS and the presence of any side effects that could be ascribed to the treatment.

Data processing and statistical methods

Data were collected, tabulated and computerized for further analysis. An initial check was made on factors that might introduce inter-group bias thus preventing valid direct comparison between the women using TENS and those using the TENS placebo.

Both the relevant groups of primigravidae and para 2 women using TENS or placebo TENS were comparable in terms of age, marital and socio-economic status and attendance at antenatal classes. During labour there were no differences in the number of patients who were induced, methods of induction that were used or numbers accelerated by artificial membrane rupture or oxytocin. Table 1 shows that the distributions of the initial pain threshold measurements were almost identical in the respective

TENS and TPL groups as were the pain scores at time zero (Table 2), the onset of the study before analgesia.

The validity for comparison thus established, the efficacy of TENS and TPL in both parity groups was then examined. Pain assessments, other analgesia, the outcome of labour and the comments of patients and midwives after delivery were analysed in the four groups.

Chi-squared (χ^2) tests were used for assessing the significance of contingency tables. Differences in time to requiring further analgesia and in cervical dilatation at that time were analysed using Cox's models (Cox 1972) for survival analysis with covariates. Cases requiring no further analgesia were assumed to have times greater than their delivery time and dilatation ≥ 10 cm respectively.

Results

Pain assessment during labour

In both parity groups there were no significant differences between the TENS and TPL users in terms of either the patients' concept of pain or the midwives' assessment of pain relief at any of the hourly intervals measured. Table 2 shows pain scores at times zero and 1 h (respectively $P \geq 0.1$, χ^2).

The vast majority of patients in all groups experienced pain in the suprapubic and lower back regions initially. Again no inter-group

Table 2. Pain score at times zero and 1 hour

Pain score*	Para 0				Para 2			
	TENS		TPL		TENS		TPL	
	0	1 h	0	1 h	0	1 h	0	1 h
0	0	0	0	0	0	0	0	0
1	0	0	0	0	0	0	1	0
2	5	0	9	1	8	1	4	3
3	33	17	28	11	15	8	14	2
4	11	29	14	34	4	9	4	8
Total	49	46	51	46	27	18	23	13

* 0 = Nil to 4 = Severe

TENS, Transcutaneous electrical nerve stimulation;
TPL, TENS placebo.

Scores were collapsed as appropriate because of small expected frequencies. TENS and TPL para 0 and para 2 at 0 and 1 hour respectively $\chi^2 = \text{NS}$ ($P \geq 0.1$).

Table 3. Analgesia used in addition to either TENS or TPL

Additional analgesia	Para 0		Para 2	
	TENS (n = 49)	TPL (n = 51)	TENS (n = 27)	TPL (n = 23)
None	6	7	13	9
Entonox	14	5	9	6
Pethidine and sparine	9	8	3	4
Epidural	9	13	2	1
Pethidine and sparine + Entonox	7	6	—	3
Pethidine and sparine + Epidural	4	12	—	—

TENS, Transcutaneous electrical nerve stimulation; TPL, TENS placebo.

differences were noted as labour progressed. No site of pain was better relieved than another or with TENS compared with TPL.

Other analgesia

Table 3 shows that the percentages of primigravidae who completed labour without requiring further analgesia were only 12 and 14% in the TENS and TPL groups respectively. In the para 2 women the respective percentages rose to 48 and 39%. There were no significant differences between any subgroups regarding numbers requiring further analgesia or when it was first given in relation to duration of labour or cervical dilation (Cox's models).

At the Rotunda Hospital, self-administered Entonox (nitrous oxide and oxygen) is a method of analgesia routinely accepted by many women entering the second stage of labour. If the use of Entonox is disregarded, the proportion of primigravidae not requiring any other analgesia rose to 41% and 24% in the TENS and TPL groups respectively and in the para 2 women to 81% and 65% respectively. However, the present study was intended to compare TENS and TPL not TENS + Entonox with TPL + Entonox. Nevertheless, it is interesting to note that fitting log linear models to these data show that the women treated with TENS + Entonox were significantly less likely to require further analgesia than those

treated with TPL + Entonox ($P = <0.0001$, $P = <0.025$ respectively).

Table 4 shows that the duration of labour was shorter in the primigravidae who used either TENS or TPL alone than in those needing further analgesia. Two-way analysis of variance of these patients using factors TENS/TPL and whether or not patients had further analgesia showed that patients who did not require further analgesia had significantly shorter labours ($P = <0.005$). There were, however, no significant differences between the TENS and TPL users in the para 2 groups or when the relevant Entonox users were added to the TENS and TPL users in either parity group.

Outcome of labour

Table 5 shows that there were no real differences in the occurrence of normal and operative deliveries between TENS and TPL users either in the primigravidae or the para 2 patients. Table 6 shows that all the women who used either TENS or TPL alone had normal deliveries. However, of the 38 primigravidae who also chose an epidural only three of the 13 TENS users and eight of the 25 TPL users had a non-operative delivery. There were no significant differences in Apgar scores between the groups at 1 or 5 min. The mean cord blood pH values were also almost identical in the four groups (Primigravidae: TENS 7.3, SD 0.07; TPL 7.23, SD 0.06. Para 2: TENS 7.25, SD 0.06; TPL 7.25, SD 0.06).

Table 4. Hours of labour and analgesia used in addition to either TENS or TPL

Additional analgesia	Para 0		Para 2	
	TENS	TPL	TENS	TPL
None	6.2 (2.7) (n = 6)	5.0 (1.5) (n = 7)	4.9 (2.2) (n = 13)	4.3 (2.5) (n = 9)
Various	8.5 (3.1) (n = 43)	7.9 (2.4) (n = 44)	4.7 (2.0) (n = 14)	4.8 (2.1) (n = 14)
Entonox	7.4 (2.7) (n = 20)	5.7 (1.5) (n = 12)	4.7 (2.2) (n = 22)	4.0 (2.0) (n = 15)
Various + Entonox	8.8 (3.3) (n = 29)	8.1 (2.5) (n = 39)	5.2 (1.1) (n = 5)	5.8 (2.2) (n = 8)

Results are means (SD); n = number of patients. TENS, Transcutaneous electrical nerve stimulation; TPL, TENS placebo.

Table 5. Mode of delivery

Mode of delivery	Para 0		Para 2	
	TENS	TPL	TENS	TPL
Normal	31	28	24	22
Forceps	13	19	2	0
Vacuum	2	1	1	0
Caesarean section	3	3	0	1
Total	49	51	27	23

TENS, Transcutaneous electrical nerve stimulation; TPL, TENS placebo.

$\chi^2 = 0.72$, $P = <0.25$.

The variable mode of delivery was collapsed over the categories Forceps, Vacuum and Caesarean section for χ^2 tests. No χ^2 performed on para 2 because of expected frequencies of two cells were too low even after collapsing.

Comments after delivery

Favourable and unfavourable comments on the method used are summarized in terms of adequacy, efficacy and the desire to use TENS again as intimated in the answers to a standard set of questions designed to ask specifically about TENS. Related experiences about any other form of analgesia the patient may have had during labour were not included but, as this may have played some part in the satisfaction ratings, the data are analysed not only in terms of TENS and TPL alone, but the responses are also divided according to whether or not further analgesia was given (Table 7).

Table 7 shows that there were highly significant differences in terms of favourable and unfavourable comments both from the midwives and the patients at 1 and 24 h after delivery between the TENS and TPL groups. The primigravid TENS users commented favourably whether or not they had further analgesia. Most of the TPL users who had further analgesia had unfavourable comments, unlike the TPL users who required no further analgesia but their numbers were too small for statistical significance. This overall tendency was more pronounced in the para 2 patients; again the TPL users who required further analgesia appeared the least satisfied.

Discussion

The actual mechanisms that produce pain in labour have not yet been fully determined (Bonica 1975), but during the first stage of labour, pain may be due predominantly to cervical dilatation with contractions of the uterus contributing significantly as labour progresses (Bonica 1979). Repeated stimulation may reduce the high threshold of receptors and contractions may cause cellular breakdown releasing 'pain producing substances'. Pain impulses are transmitted via the A-delta and C-afferent fibres reaching segments T11 and L2. Increasing intensity gives rise to pain referred also to adjacent segments in the region corresponding to dermatome distribution T10 to L1. From full dilatation, extension and stretching of the birth

Table 6. Type of delivery and analgesia used in addition to either TENS or TPL

Additional analgesia	Para 0				Para 2			
	TENS		TPL		TENS		TPL	
	Normal	Op.	Normal	Op.	Normal	Op.	Normal	Op.
None	6	0	7	0	13	0	9	0
Entonox	9	5	4	1	8	1	6	0
Pethidine and sparine	8	1	6	2	2	1	3	1
Epidural	2	7	2	11	1	1	1	0
Entonox + pethidine and sparine	5	2	3	3	0	0	3	0
Epidural + pethidine and sparine	1	3	6	6	0	0	0	0

Op, Forceps, vacuum or caesarean section.

TENS, Transcutaneous electrical nerve stimulation; TPL, TENS placebo.

Table 7. Patients and midwives overall comments after delivery with either TENS or TPL and in the subgroups requiring additional analgesia (+A)

Overall comment	Para 0				Para 2			
	TENS		TPL		TENS		TPL	
	Total	+A†	Total	+A†	Total	+A†	Total	+A†
Patients at 1 h								
Favourable	44	38	24	19	26	14	8	2
Unfavourable	5	5	27	25	1	0	15	12
TENS vs TPL	$\chi^2 = 21.0$ $P < 0.001$				$\chi^2 = 21.6$ $P < 0.001$			
Patients at 24 h								
Adequacy								
Favourable	38	32	15	10	22	11	7	1
Unfavourable	11	11	36	34	5	3	16	13
TENS vs TPL	$\chi^2 = 23.2$ $P < 0.001$				$\chi^2 = 13.3$ $P < 0.001$			
Efficiency								
Favourable	45	39	23	18	26	14	7	1
Unfavourable	4	4	28	26	1	0	16	13
TENS vs TPL	$\chi^2 = 25.1$ $P < 0.001$				$\chi^2 = 26.0$ $P < 0.001$			
Would request again								
Yes	30	25	20	13	22	10	10	2
No*	19	18	31	31	5	4	13	12
TENS vs TPL	$\chi^2 = 4.8$ $P < 0.05$				$\chi^2 = 7.8$ $P < 0.01$			
Midwives								
Favourable	44	38	22	17	26	13	7	2
Unfavourable	5	5	29	27	1	1	16	12
TENS vs TPL	$\chi^2 = 24.2$ $P < 0.001$				$\chi^2 = 24.0$ $P < 0.001$			

TENS, Transcutaneous electrical nerve stimulation; TPL, TENS placebo.

* includes 'no', 'don't know' and qualified 'yes'.

† The subgroup +A refers to the patients who required further analgesia in addition to either TENS or TPL.

canal activates the pudendal nerves and roots S2-4.

However, the amount of pain actually experienced depends not only on these afferent and efferent pathways but also on the so-called third dimension. This is composed of psychological factors made up of previous experiences, present expectations, stress and cultural factors. In labour not only do these have a profound effect (Nilsson 1970) but they also make measurements of pain experience in studies such as this extremely difficult even when using a double-blind placebo controlled method. It is therefore reassuring to note that in the present study the

groups were initially comparable in terms of pain threshold and pain concepts.

Pain relief in labour has been claimed following the passage of low intensity currents through electrodes supplied to the frontal and mastoid regions (Persianinov 1975), acupuncture (Wallis *et al.* 1974), acupuncture plus diazepam (Hyodo & Geger 1977), and electro acupuncture (Kubista *et al.* 1978). Although Neumark *et al.* (1978) found TENS a more effective analgesia than placebo, in a carefully designed study Nesheim (1981) found no differences between TENS and TENS placebo users in the degree of pain relief and in the need for analgesics. Non-

controlled studies have, however, been more positive. Shealy & Maurer (1974) reported good effects on back pain and 44% of the patients reported by Augustinsson *et al.* (1977) found it very good. However 12% found TENS to have no effect, which agrees with the findings of Andersson *et al.* (1976). In the largest study to-date, Bundsen *et al.* (1981) concluded that although TENS had a good effect on back pain with no other effects on mother or child, their post-delivery questionnaire tended to favour TENS but only as a complement to conventional methods.

In the present study, like all others reported to-date, no side-effects were noted from the therapy. In contrast to the studies reported by Augustinsson *et al.* (1977) and Bundsen *et al.* (1981) we found no interference with electronic monitoring of the fetal heart. We found no difference in pain assessment by patients or midwives during labour between TENS and TPL users. Only few primigravidae completed labour without requiring further analgesia but more para 2 patients did not require further analgesia and if the use of Entonox is disregarded, the proportion requiring no further analgesia was significantly higher in the TENS users. In agreement with Nesheim (1981) we found a relation between the length of labour and the need for further analgesia. Labours were significantly shorter in those primigravidae who required no further analgesia. Bundsen *et al.* (1981) and Kubista *et al.* (1978) considered that such findings show that TENS shortens labour. However, as the duration of labour shows a strong positive correlation with pain intensity (Bundsen *et al.* 1982b), we feel that a more plausible interpretation is that the use of TENS as the only analgesic is better suited to those having short labours.

The present study confirms that TENS is safe for the infant in terms of Apgar score and umbilical blood pH. The fact that all the patients who used only TENS or only TPL had normal deliveries may be again a reflection of short labours. This contrasts particularly with the higher operative delivery rates in the other groups who needed further analgesia and in particular in those primigravidae who requested epidurals. This might play some part but does not explain completely the surprisingly highly significant differences in favourable and unfavourable comments from patients and midwives between the TENS and TPL users in both

parity groups even when the use of other analgesia is taken into account.

Such evident consumer satisfaction therefore suggests that TENS has a part to play in analgesia in labour particularly where labour is likely to be short. However, the equivocal findings in this study, particularly in terms of pain assessment during labour and the necessity for further analgesia in the majority of patients, points to the need for the development and assessment of apparatus more specifically designed to cope with that most intense of all pains (Melzak *et al.* 1981), the progressive pain of labour.

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