Transcutaneous electrical nerve stimulation does not augment combined spinal epidural labour analgesia

Lawrence C. Tsen MD,
John Thomas MD,
Scott Segal MD,
Sanjay Datta MD,
Angela M. Bader MD

Purpose: The spinal portion of the combined spinal epidural technique (CSE) provides dramatic but limited labour analgesia. Transcutaneous Electrical Nerve Stimulation (TENS) has been noted to modulate pain,[1] in part by the frequency of stimulation chosen.[2] Because nerve action potentials are blocked by local anesthestics in a frequency dependent manner,[3] we speculated that a TENS unit could increase the quality and duration of the spinal portion of a CSE.

Methods: Forty parturients in active spontaneous labour, with a singleton, vertex, term fetus, requesting analgesia were enrolled in a randomized, double blind fashion to receive a standardized CSE with either an active or inactive TENS unit. Prior to CSE placement, TENS intensity thresholds were determined with electrodes placed on the paraspinus muscles at T_{10}-L_1, and $S_{2\text{-}4}$; TENS settings for mode, cycle, and pulse width were standardized. Data were collected at timed intervals on pain (VAS), sensory level (pinprick), motor blockade (Bromage), cervical dilatation, and duration of analgesia, and at delivery on fetal and neonatal outcome.

Results: The duration of the spinal portion of the CSE did not differ between groups (TENS off 91.1 ± 33 [mean ± SD] *vs* TENS on 83.1 ± 28 min, P=.42). Kaplan-Meier survival analysis and Mantel-Cox log rank analysis showed no difference between the two treatments (P=.28). Analgesia was comparable throughout the first hour of spinal analgesia.

Conclusion: In healthy labouring parturients, the application of a TENS unit did not alter the quality or duration of labour analgesia provided by the spinal portion of CSE analgesia.

Objectif : La composante rachidienne de la technique rachidienne péridurale combinée (RPC) fournit une analgésie importante, mais limitée, pendant le travail obstétrical. La neurostimulation transcutanée (NST) est connue pour moduler la douleur[1], entre autres selon la fréquence de stimulation choisie.[2] Comme les potentiels d'action nerveuse sont bloqués par les anesthésiques locaux d'une manière qui dépend de la fréquence,[3] nous avons pensé qu'une unité de NST pourrait augmenter la qualité et la durée de la composante rachidienne de l'analgésie RPC.

Méthode : Quarante parturientes en travail actif spontané, porteuses d'un fœtus unique, à terme et en présentation du sommet, ont été réparties au hasard et à double insu. Elles ont reçu une analgésie RPC standard avec une unité active ou inactive de NST. Avant la mise en place de l'analgésie RPC, l'intensité des seuils de NST a été déterminée avec des électrodes placées sur les muscles paravertébraux à T_{10}-L_1, et $S_{2\text{-}4}$; l'installation de la NST a été standardisée quant au mode, au cycle et la durée du stimulus. On a recueilli, à intervalles déterminés, des données sur la douleur (EVA), le niveau sensitif (piqûre), le blocage moteur (Bromage), la dilatation cervicale et la durée de l'analgésie et, à la naissance, sur l'évolution fœtale et néonatale.

Résultats : Il n'y a pas eu de différence intergroupe pour la durée de la composante rachidienne de l'analgésie RPC (NST inactive 91,1 ± 33 [moyenne ± écart type] *vs* NST active 83,1 ± 28 min, P = 0,42). L'analyse de survie de Kaplan-Meier et l'analyse du logrank de Mantel-Cox n'ont montré aucune différence entre les deux façons de procéder (P = 0,28). L'analgésie a été comparable pendant la première heure d'analgésie rachidienne.

Conclusion : Chez des parturientes en santé, l'application de NST n'a pas changé la qualité et la durée de l'analgésie pendant le travail fournie par la portion rachidienne d'une analgésie RPC.

From the Department of Anesthesia, Perioperative and Pain Medicine, Harvard Medical School, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115 USA.

Address correspondence to: Lawrence Tsen MD. Phone: 617-732-8216; Fax: 617-277-2192; E-mail: lctsen@bics.bwh.harvard.edu)

TENS units were provided by Staodyn, Inc, Longmont CO, USA. Departmental support was utilized for the completion of this study.

Accepted for publication October 3, 1999

THE combined spinal epidural (CSE) technique is being performed commonly for labour analgesia due to its more rapid analgesic onset, less potential for patchy or one-sided coverage, and less motor blockade.[4] Moreover, recent evidence suggests that a more rapid cervical dilatation may follow CSE analgesia than after epidural analgesia.[5] These potential benefits occur during the spinal portion of the CSE, which is limited by the duration of action of the intrathecal medications used.[6] Pharmacologically, attempts have been made to increase both the quality and duration of the CSE by adding to or altering the type or dose of opiates, local anesthetics, or other adjuvants. However, ceiling and side effects limit this manipulation.[7,8] Intrathecal bupivacaine with sufentanil has been noted to be a very effective in terms of duration and limitation of side effects.[6]

Transcutaneous electrical nerve stimulation (TENS) has been used with some success for labour analgesia[9] and has been noted to modulate nociceptive and deafferentation pain,[1] with its effectiveness dictated, in part, by the frequency of stimulation chosen.[2] Because local anesthetics, specifically bupivacaine, demonstrate a frequency-dependent blockade of nerve action potentials,[3] we speculated that a TENS unit could directly or indirectly increase the quality and duration of the spinal portion of a CSE.

Methods

The study was approved by the Brigham & Women's Hospital Committee on Human Subjects and written informed consent was obtained from all participants. Forty parturients, ASA 1-2, in active spontaneous labour with singleton, vertex, term fetuses, requesting analgesia were enrolled at cervical dilatation < 5 cm. The patients were randomized in a double-blinded fashion by sequentially numbered, opaque, shuffled envelopes to receive labour analgesia by a standardized combined spinal epidural (CSE) with either an active or inactive TENS unit (Staodyn Inc., Maxima III TENS unit, Longmont, CO, USA). Prior to CSE placement, TENS intensity thresholds were determined with electrodes (Staodyn Inc., 14.22 cm X 4.06 cm) placed on the paraspinus muscles at T_{10}-L_1, and S_{2-4}, after which the TENS unit was turned off. Intensity thresholds were determined according to the manufacturer's recommendation of a setting just below muscle contraction; all TENS intensity thresholds occurred at a knob setting between 4 and 4.25, which corresponded to approximately 18-20 mA. All other TENS settings were standardized, with all patients receiving a pulse rate which automatically modulated every three seconds from 66 to 100 Hz (modulation mode) with a pulse width of 310 μ sec.

With the request for analgesia, and after a fluid bolus of 1000 mL lactated Ringers solution, parturients were placed in the left lateral recumbent position. After sterile preparation with providone-iodine solution, and local infiltration with lidocaine 1%, the epidural space at the L_{3-4} or L_{4-5} interspace was located with a 17-gauge Weiss-Touhy epidural needle by the loss-of-resistance-to-air technique. A 25-gauge Whitacre needle was placed via the shaft of the epidural needle as described previously,[10] the dura was punctured, and when flow of cerebral spinal fluid was confirmed, bupivacaine 0.25% (1 mL) with sufentanil (10 μg in 0.2 mL) was given; the sufentanil was measured in a tuberculin syringe for accuracy. This was followed by placement of a 20G multihole epidural catheter, 3 cm into the epidural space.

Following placement of the CSE technique, the TENS unit either remained turned off, or was turned on, based on the randomization scheme described above. The unit was placed in a pouch to hide the controls from all participants. No epidural drugs were given until discomfort returned. The patient, the labour nurse, the obstetrician and the anesthesiologist recording the data were not informed of the status of the TENS unit.

Visual analogue scale pain scores, sensory level to pin prick at the midclavicular line, and motor blockade were assessed by a blinded observer at placement of CSE and at 3, 5, 10, 15, 30, 45, 60 min and at regular 30 min intervals thereafter; the assessments were also made prior to dosing of the epidural catheter. Visual analogue scores were done with an unmarked 100 mm plastic sliding scale indicator (Astra Laboratories, Worcester, MA, USA). Motor strength determinations utilized a modified Bromage score (0 = full flexion of knees and ankles, 1 = partial flexion of knees, full flexion of ankles, 2 = inability to flex knees, partial flexion of ankles; 3 = inability to flex knees and ankles). Cervical dilatation, use and amount of oxytocin and nalbuphine, fetal heart rate, neonatal sex, birthweight, and Apgar scores, and maternal side effects were recorded. Standardized protocols for pruritus, nausea, and hypotension were established.

Differences between treatment groups were tested by analysis of variance (ANOVA) for continuous data, or contingency table analysis for discrete data (chi-square with continuity correction or Fisher's exact test, as appropriate). The VAS scores were analyzed by repeated measures ANOVA. Nonparametric tests of VAS scores at individual time points yielded qualitiatively identical results. Duration of CSE analgesia during the spinal phase was tested initially by ANOVA. Inspection of the data suggested a non-normal distribution and one censored value (i.e., one patient delivered before request for additional analgesia, so the duration

of her spinal analgesia could not be assessed). Kaplan-Meier survival curves were constructed and tested for a difference between group assignment with the Mantel-Cox logrank statistic. Statistical significance was assumed when P was less than 0.05.

Sample size for this trial was selected to detect a 30 min difference in CSE duration between groups with 90% power (ß=0.1) at the 0.05 significance level, based on published duration and standard deviation data from our institution.[9] This analysis suggested 17 patients per group were necessary.

Results

All 40 women completed the study. Baseline maternal characteristics and labour management did not differ between the groups, except that there were more nulliparous patients in the group with an inactive TENS unit (Table). Nulliparity itself was not associated with a difference in CSE duration or VAS scores (P=.25, P=.87, respectively, by ANOVA or repeated measures ANOVA).

The duration of CSE analgesia during the subarachnoid phase did not differ between the groups for the 39 patients who requested additional analgesia prior to delivery (TENS off 91.1 ± 33 [mean ± SD] *vs* TENS on 83.1 ± 28 min, P=.42). Kaplan-Meier survival analysis for the two groups are shown in Figure 1. Mantel-Cox log rank analysis showed no difference between the two treatments (P=.28). Analgesia was comparable throughout the first hour of spinal analgesia (Figure 2; repeated measures ANOVA for difference between TENS groups, P=0.25). Too few patients had adequate analgesia at time points beyond 60 min to be included in the analysis of analgesic quality.

Fetal heart rate (FHR) at baseline, highest and lowest FHR, and greatest FHR change did not differ between the groups, nor did neonatal sex, birth weight, or Apgar scores. Mode of delivery was spontaneous vaginal in 37/40 patients; there was one Cesarean section and one forceps delivery in the TENS off group and one vacuum extraction in the TENS on group. The incidence of pruritus did not differ between the groups, and neither nausea nor hypotension requiring treatment occurred in any patient.

TABLE Patient characteristics

	TENS Off	*TENS On*
Age (yr)	32.3 ± 5.2	30.4 ± 4.4
Height (cm)	164 ± 6.6	164 ± 11
Weight (kg)	74.4 ± 10	76.1 ± 12
Gestational age (wk)	39.5 ± 0.79	40.0 ± 1.2
Nulliparous (%)	80	30*
Cervical dilatation at study entry (cm)	3.4 ± 1.4	3.7 ± 1.1
Oxytocin use (%)	90	85
Maximum oxytocin dose (mU/min)	15.1 ± 8.5	10.6 ± 7.0
Induced labour (%)	50	50
VAS pain score at study entry (mm)	87 ± 22	81 ± 20
Nalbuphine prior to study (%)	25	25

Values given as mean ± SD or percent of patients per treatment group

*P < .05, Fisher's exact test

Discussion

We initiated our study with an interest in finding a non-pharmacological way of prolonging the duration of the spinal portion of CSE analgesia, as we had noticed that many of the benefits of the technique occur during that phase. We speculated that transcutaneous electrical nerve stimulation (TENS), which alone had been noted to provide labour analgesia[11] and modulate nociceptive and deafferentation pain,[1] could directly or indirectly affect the quality and duration of the spinal portion of a CSE. The study represents the first randomized trial utilizing the TENS unit, not as the primary or sole analgesic for labour, but rather as an adjuvant to the combined spinal epidural technique.

We based our hypothesis on two findings. First, local anesthetics produce a greater degree of conduction blockade when the frequency of action potential impulses increases. This phenomenon, termed frequency dependent blockade, has been specifically demonstrated with bupivacaine to exist at higher than lower frequencies, i.e. 40 Hz[12] and 15 Hz,[3] but not at 9 Hz.[3] As TENS utilizes a frequency-dependent mode of stimulation,[2] in our study a frequency of 6-100 Hz, we speculated that a direct enhancement in the blocking potential of bupivacaine could occur. Second, in accordance to Melzack and Wall's electrophysiologically confirmed[13,14,15] "gate control theory",[16] the stimulation of large myelinated primary afferent A fibres act, via inhibitory circuits in the superficial laminae of the dorsal horn, to inhibit the transmission of small unmyelinated primary afferent A-delta and C fibres which are responsible for the transmission of pain. A frequency of 80 Hz has been reported to be the most effective in inhibiting nociception in the animal model,[2] confirmed clinically (50-100 Hz),[17] and thus utilized in our study (66-100 Hz). TENS has been demonstrated to provide labour analgesia in up to 44% of parturients[11] and we speculated that this could independently lead to analgesia, thereby enhancing the analgesia provided by intrathecal medication.

Our results demonstrated that TENS did not make a difference in terms of quality (Figure 2) or duration of analgesia (Figure 1). There may be several explana-

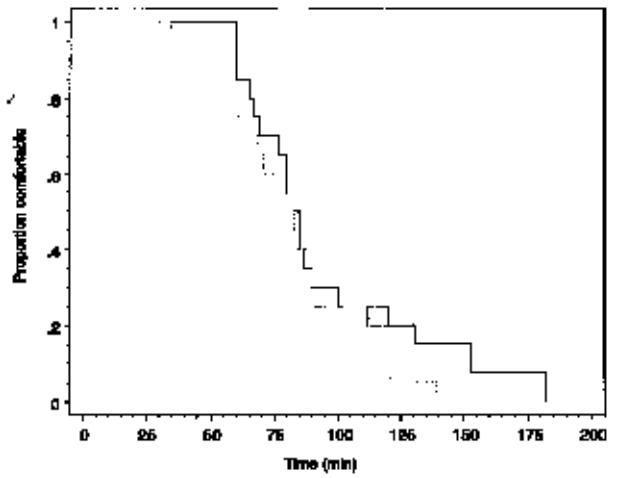

FIGURE 1 Kaplan-Meier survival curves for the duration of effective analgesia. There was no significant difference between patients with active and inactive TENS units in the duration of pain relief (Mantel-Cox logrank test, P=0.28).
—— TENS Off ---- TENS On

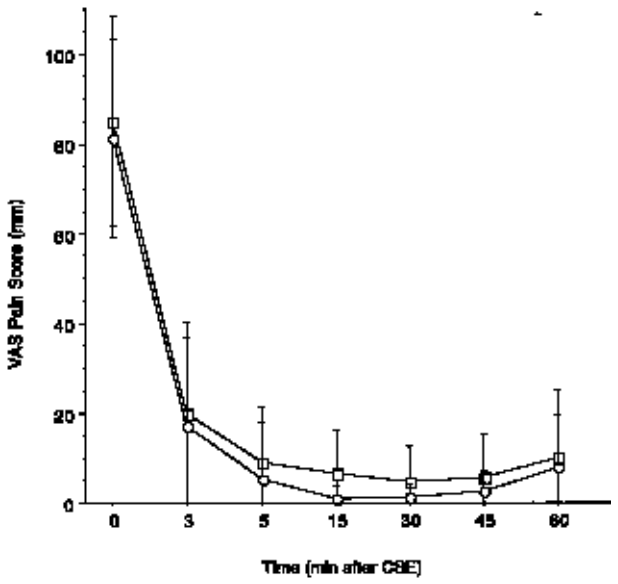

FIGURE 2 Visual analog scale (VAS) pain scores for the first hour after initiation of subarachnoid analgesia. Points indicate mean and standard deviation. There were no differences between the patients with active and inactive TENS units (repeated measures ANOVA, P=0.25)
—□— TENS Off —O— TENS On

tions for the lack of difference in quality of analgesia. First, the profound degree of analgesia provided by the CSE combination utilized in this study may have masked any benefit of the TENS unit. Bupivacaine 2.5 mg with sufentanil 10 μg has been demonstrated to provide excellent labour analgesia for first and second stages with extremely low VAS pain scores.[6] Even with the addition of epinephrine, no improvement in the quality of the analgesia was noted for the first 90 min.[18] Second, the small amount of bupivacaine used for our CSE technique may not have been sufficient to observe the frequency dependent effect described previously. Further studies are necessary to elucidate the importance of the amount of local anesthestic needed to observe the effect. Finally, a TENS unit may not add a considerable amount of analgesia; a review of randomized controlled trials of TENS during labour involving a total of 712 women concluded that, although additional analgesic interventions may be less likely with TENS during labour, 81% still requested adjuvant therapy.[19]

The absence of differences in duration may be due to the TENS unit being less effective as labour progresses.[11] When used before an epidural technique, TENS was noted to delay request for alternative analgesia for only 10-20 min.[20] In a more recent study, when TENS was used alone in nulliparous and multiparous parturients, adjuvant forms of analgesia were requested between 5 and 7 cm cervical dilatation.[9] As the spinal portion of the CSE technique has been demonstrated to last into the second stage of labour in rapidly progressing labours, it may have already eclipsed the duration of a reliable TENS effect.

We recognize that our results could be due to inadequate TENS settings, as mode, intensity, pulse rate and width must be programmed. However, as guidance for our settings, we used the two TENS studies which demonstrated the greatest labour analgesia effects.[21,11] In addition, to avoid a recent criticism of the TENS technique, we individually titrated the intensity (amplitude) settings to overcome the heterogeneous impedance of the skin and underlying tissues between the electrodes and the peripheral nerves.[22] Moreover, although other TENS pad locations, behind the mastoid processes and between the eyebrows, have been used successfully,[20,23] the location we used has been validated in positive outcome studies using TENS alone during labour.[11,21]

Some have raised the concern that TENS could interfere with fetal heart rate tracings,[11] however, this was not witnessed in our review of fetal tracings, nor did we observe any incidents of non-reassurring fetal tracings[24] subsequent to the CSE placement in either

group. Moreover, neonatal Apgar scores were not different between the two groups.

In conclusion, the quality and duration of the spinal portion of the CSE technique, utilizing 2.5 mg intrathecal bupivacaine and 10 μg sufentanil, is not enhanced by the addition of a lumbar TENS unit.

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