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Evaluation of Percutaneous Electrical Nerve Stimulation of the Auricle for Relief of Postoperative Pain Following Cesarean Section

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ABSTRACT

Objective: Percutaneous electrical nerve stimulation is a nonpharmacologic modality of analgesia. This study was conducted to evaluate such a technology (ANSiStim™, DyAnsys Inc., San Mateo, CA) prospectively, in conjunction with standard analgesia per patient demand, for managing postoperative pain following lower-segment cesarean section.

Materials and Methods: One hundred parturients were randomized into 2 equal groups (controls and study cases). The latter cohort consisted of parturients for whom nerve stimulation was exerted on the pinna. Pain scores were compared across subjects at corresponding time points with 17 intervals in 48 hours, and, in totality, using estimated area under the curves of numerical scores. Conditional inference analysis was also performed.

Results: Ninety-six parturients were finally included. The device was well-tolerated by a majority of parturients. Pain scores were significantly lower in the study group, both at corresponding time intervals and in totality. $(H - 15)*(0.74 - H)*(H^2 - 17H + 110)/440$, where H was the corresponding hour, fit the pain scores in the control group. Controls could be detected at the 11 hour with greater pain scores (≥ 4), whereas smaller scores (≤ 2) at the 42nd hour mostly revealed that electrical stimulation was performed ($p < 0.001$). Requirements for supplementary analgesics were lower for subjects who were given the electroanalgesia.

Conclusions: Neurostimulation via the ANSiStim™ is a safe and reasonably effective ambulatory analgesic adjuvant following abdominal delivery. There are no serious adverse effects.

Keywords: post–cesarean section, postoperative pain, percutaneous neuromodulation therapy, auricular acupuncture

INTRODUCTION

Postoperative pain following lower-segment cesarean section (LSCS) is often inadequately treated due to possible effects of the analgesics causing reluctance to breastfeed the baby because of opioid-induced drowsiness in the mother and potential drowsiness of the neonate.[1] Adjuvant analgesic strategies, such as transcutaneous electrical nerve stimulation (TENS), acupuncture, acupressure, and encouraging and instructing the patient to control pain (psychotherapy), might reduce the analgesic requirement and its related adverse effects.[2–5] Acupuncture is an established adjuvant analgesic modality for treating pain. Although acupuncture is said to release endogenous opioids and serotonin in the brain and the spinal cord, acupuncture lacks scientific evidence. Clinicians continue to await a nonopioid-based analgesic method with reasonable efficacy. The idea of electrically induced analgesia dates back to the Greek scholars, Plutarch and Socrates, who noticed numbing effects of standing in pools of water on a beach that contained ''electric'' fish.

The current authors use percutaneous electrical nerve stimulation (PENS) as a nonpharmacologic pain-management technique because it is relatively novel and has features

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similar to acupuncture; thus, PENS may be considered to be more effective than manual stimulation.[6] PENS is an alternative to conventional transcutaneous electrical techniques, such as the aforementioned TENS (interferential or H-wave), and to procedures such as spinal-cord surgery or deep-brain stimulation.

The current authors chose to apply PENS—minimally invasive electrical neurostimulation—to the external ear, with direct implantation into the neurovascular bundles. The human outer ear is supplied by four sensory nerves, namely, the (1) auriculotemporal nerve (ATN), (2) the great auricular nerve (GAN), (3) the auricular branch of the vagus nerve (ABVN), and (4) the lesser occipital nerve (LON). The lateral surface of the external ear has innervation from the former three (ATN, GAN, ABVN), while the medial surface is supplied by the latter two (ABVN, LON).[7] By exciting thick myelinated fibers of the ABVN, the aim was to achieve selective modulation of afferent *A*β-fibers, projecting to the nucleus of the solitary tract in the brainstem, with reduced side-effects and a low-risk profile. This study was conducted to assess the effects of auricular PENS in the postoperative period following LSCS.

MATERIALS AND METHODS

This randomized prospective study was performed at Fortis Hospital, in Bengaluru, Karnataka, India, after approval from the hospital's ethics committee. Parturients were recruited and instructed to score their pain on a numerical scale, giving a score of 0 when there was no pain up through and including 10 when the pain was intolerable.

On the basis of a pilot study conducted by the current authors, it was noted that the peak numeric rating scale (NRS) score was 6 ± 3 for pain management after LSCS. To detect a decrease of 2 (with an alpha error of 0.05 and a power of 80%), a minimum sample of 36 patients per group would be required. Assuming an attrition rate of 10%, a sample size of 40 per group was necessary. Parturients were trained to use the NRS and were randomized by means of a random number generator into 2 groups of 50 parturients each: (1) group S (study group) and (2) group C (control group). Written informed consent was obtained from all individual participants included in the study. Parturients with gestational diabetes, thrombocytopenia, contraindication to spinal anesthesia (such as infection at the site of lumbar puncture and prior lumbar spine surgery), and/or receiving opioids intraoperatively or postoperatively were excluded.

Each parturient received spinal anesthesia with a 27G spinal needle administered with the patient in a sitting position, and 2–2.5 mL of hyperbaric bupivacaine (based on the patient's height and body mass index) was deposited in the subarachnoid space. Parturients who had ''failed spinal anesthesia'' (defined as failure to elicit sensory [up to T-4] and motor block 10 minutes after deposition of the local anesthetic in the subarachnoid cavity) were excluded.

In group S, a PENS device (ANSiStim™, DyAnsys Inc., San Mateo, CA) was placed by the investigator in the postoperative period (usually $\sim$1 hour after transfer to the postanesthesia-care unit; PACU). In both groups, parturients were informed that they could demand analgesics if they felt pain. Naturally, patients in group C received the sole rescue analgesia without benefiting from PENS. NRS scores were recorded at hourly intervals for the first 12 hours, and every 6 hours for the next 36 hours. The study was terminated after 48 hours.

The Pain-Relief Protocol

The protocol for pain relief was as follows: primary choice of analgesic was 1 g of intravenous (IV) paracetamol and, if the pain relief was inadequate, a 100-mg diclofenac suppository was inserted rectally. If pain persisted in spite of these measures, 50 mg of tramadol was administered IV. The type and dose of analgesic requirement during the study period was recorded. The device was removed after 48 hours of placement. Any bleeding or rash at the placement site or any other adverse side-effects caused by the instrument were noted. Pediatricians taking care of the neonates were requested to report to the investigator if any deviations in the newborns' behavior were noted.

The PENS Device

The ANSiStim, is a miniaturized PENS device (measuring $\sim 6 \times 2$ cm) designed to administer intermittent electrical auricular-point stimulation through selectively placed needles in ambulant patients (Fig. 1). This device was used as the primary method of analgesia; yet, it was supplemented per the pain-management protocol. The battery-powered base unit was placed behind the pinna in each S

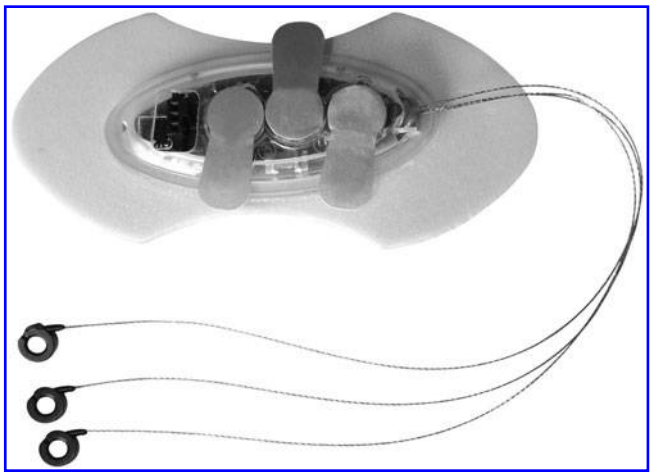

FIG. 1. ANSiStim™ PENS (DyAnsys, Inc., San Mateo, CA) battery-operated device with three electrodes. Permission received from DyAnsys, Inc. for publication of this image.

patient, and the site of placement of the microneedles was identified by using a locator provided by the manufacturer. The needles, made of titanium, were partially cylindrical (with a diameter of 0.4 mm) and conic (yielding the sharpness), at a ratio of 5:8, for a total insertion depth of 2 mm.

Needle insertion points were chosen with the aid of an ohmmeter (provided with the PENS device) by highlighting places of least resistance in the proximity of the identified points, using skin impedance. The conducting wires and needles were attached to the base unit as recommended. To relieve post-LSCS pain, 3 auricular locations were recommended by the manufacturer, the Thalamus, *Shenmen,* and Uterus points (Fig. 2). The stimulus intensity is typically below the individual's pain threshold, yet above the lowest intensity that would evoke a tingling sensation. Emitting a biphasic signal at a 1-Hz frequency with a pulse width of 1 ms, the device stimulates for 3 hours and is off for 3 hours. This stimulation may be continued up to 96 hours; however, as noted before, the study ended at 48 hours.

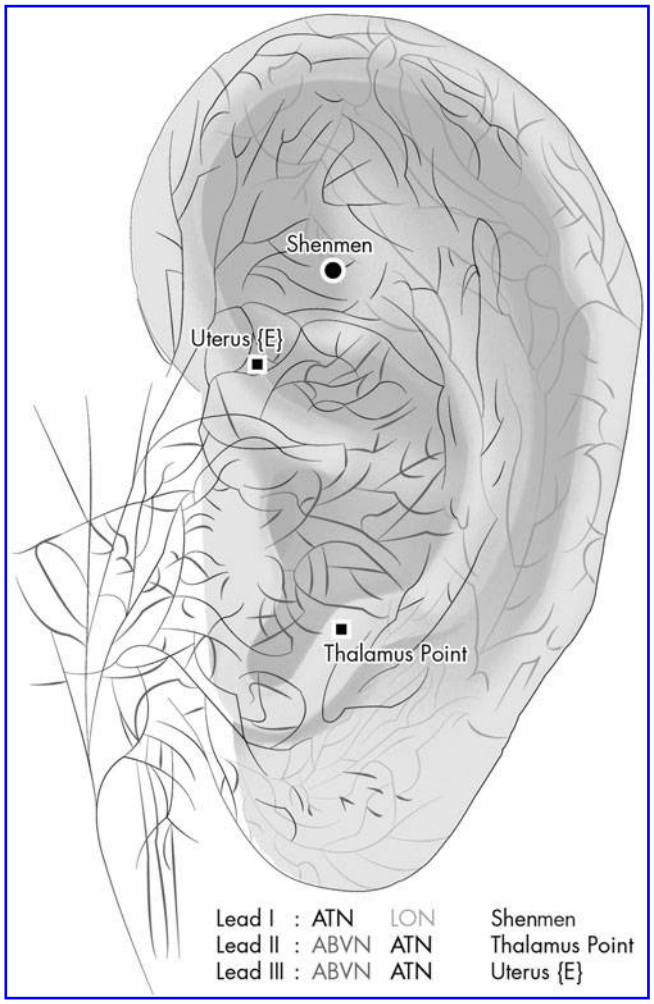

FIG. 2. Placement of electrical stimulation (3 leads) on the human auricle. {E}, European; ATN, auriculotemporal nerve; LON, lesser occipital nerve; ABVN, auricular branch of the vagus nerve.

Statistical Analyses

The parturients' acceptance of the device placement was recorded empirically as *good*, *tolerable*, or *intolerable* (requiring removal of the device). The patients in whom the device got dislodged, who wished device removal at any stage of the study, or for whom nonprotocol opioids or other analgesics were administered were excluded. Mean absolute deviation was used as the default summary statistic of dispersion (a simpler and more-interpretable measure of variability than standard deviation). To evaluate the total variation of pain scores between the 2 groups, the ''area under the (respective) curves'' (AUCs) were compared via the integration of piecewise interpolations of the discrete NRS data subsets for each patient against time. The interpolations respected real time as abscissa (with temporal rescaling for the last 36 hours); these interpolations were constrained to third-degree polynomials with overall continuity for the whole pieced function and for its first and second derivatives. Welch's generalization of Student's *t*-test was generally applied for unequal variances.

Nonetheless, for comparison of pain scores across subjects and times, the Mann–Whitney *U*-test (MWU) was used. A significant MWU-test result can be interpreted as showing a difference in medians, hence, indicating a significant difference between actually obtained discrete values. Unlike the *t*-test, the MWU-test does not require the assumption of normally distributed variables. Moreover, all datasets involved, and their respectively used subsets, were tested for normality. However, MWU-testing functions under the assumption that the shapes of the underlying distributions are the same. When solely interested in the stochastic ordering of 2 populations, endeavoring to estimate the concordance probability $p(Y>X)$, MWU may still be used even as this assumption fails. Typically, the standard $\alpha = 0.05$ cutoff was taken for rejecting the null hypothesis when $p < 0.05$, thus serving as a limit for statistical significance.

Furthermore, conditional inference analysis was applied, using bootstrap aggregated classification trees for recursive partitioning of data without bias.[8] These nonparametric tree classifiers can be used to tackle nonnormal data and a large number of possible predictors without preselecting parameters but taking into account the entire available set. The *p*-values were adjusted according to the Bonferroni correction, as many dependent statistical tests were performed simultaneously. In addition, classical decision trees were also learned and pruned[9] (thus reducing overfitting), to provide additional evidence of relations across the time variables. R version 3.3.0 was used for the data analysis.

RESULTS

Of the 100 parturients recruited, it was possible to analyze the data for 96 of them (47 in group S and 49 in group C). The device got dislodged due to sweating in 2 parturients

Table 1. Descriptive Statistical Parameters for Both Populations

Groups & p-value	Age Mean ± deviation	BMI Mean ± deviation	Pain score first 12 hr 95% CI for the population mean estimated from NRS pain scores	Pain score last 36 hr 95% CI for the population mean estimated from NRS pain scores	Area under NRS curve Mean ± deviation
Controls ($n=49$)	29.6 ± 2.4	30.4 ± 3.5	[3.8–4.2]	[3.0–3.3]	160 ± 38
Study cases ($n=47$)	30.1 ± 3.3	28.7 ± 2.6	[2.7–3.0]	[2.0–2.2]	110 ± 33
p-Value	0.5	0.08	< 0.0001	< 0.0001	< 0.0001

Deviation refers to the average absolute deviation around the mean; dimension of area under NRS curve corresponds to the product of NRS with time [hr].

BMI, body mass index; hr, hours; NRS, numerical rating scale; CI, confidence interval.

and 1 parturient in group S opted out, as she wanted the device to be removed soon after it was placed. In group C a mother received IV pethidine to control shivering in the postoperative period and, hence, had to be excluded from the study per the protocol. There was no failure of spinal anesthesia in either group. Duration of LSCS ranged from 45 minutes to 90 minutes, with an average of ~68 minutes. No abnormal behaviors of the newborns were reported.

Both groups were comparable with respect to the demographic data (Table 1). The device placement was well-tolerated by most parturients. Thirty-seven of 50 participants rated the acceptability of the device good, while 12 found it tolerable, and 1 found it intolerable.

Baseline NRS scores on arrival to the PACU started at 0 in both groups. The influence of the spinal anesthesia was expected to wear off by 3 hours. A similar trajectory of NRS curve was seen for the first 2 hours. A clear differentiation between the 2 groups was, however, observed from the 4th hour onward ($p \leq 0.015$, except for the 30th hour). In all of the parturients per considered hour (starting from the 3rd hour), the average pain score was significantly lower in group S in contrast to group C.

This relation of greater pain in the controls over the study cases was observed throughout the study period, at varying degrees of statistical significance (Fig. 3; last column of Table 1). From the ninth hour till the end of the first 24 hours, the maximal level of pain observed at each hour in the study group was consistently lower than the corresponding average score in the controls. Nevertheless, both groups showed a mean evolution of pain scores over time, which followed a definite profile, with evidence of a common local minimum at the 30th hour, and a temporary divergence around the 36th and 42nd hours, when the pain scores for the controls clearly indicated a kindling of pain,

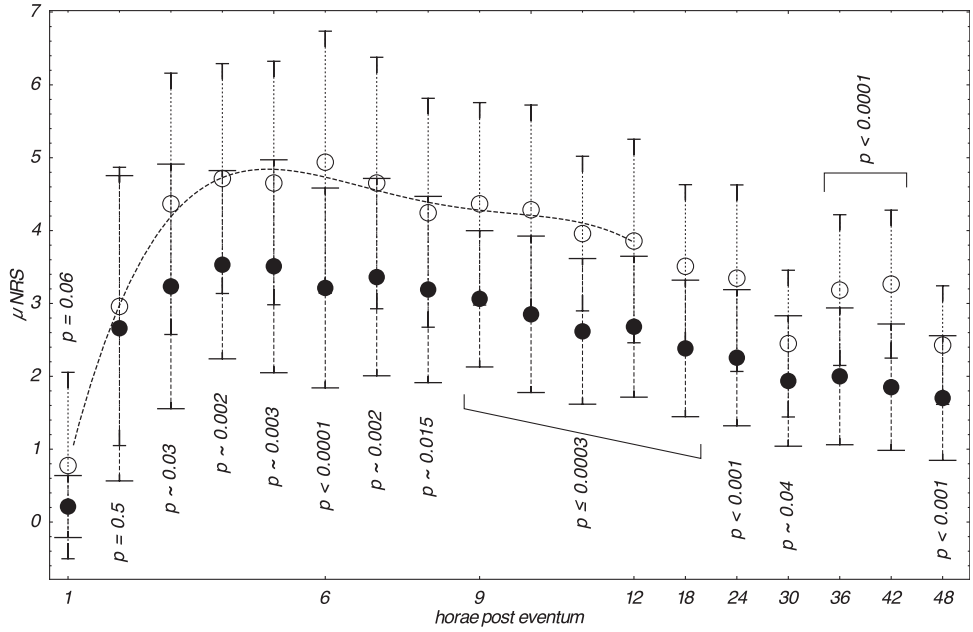

FIG. 3. Evolution graph of the average numerical rating scale (μ NRS) for both controls (group C, *empty circles*) and study cases (groups S, *solid circles*), over hours postpartum, with respective spread brackets (*dotted line* for group C; *dashed line* for group S), and indication of statistical significance of median difference between the 2 groups per hour.

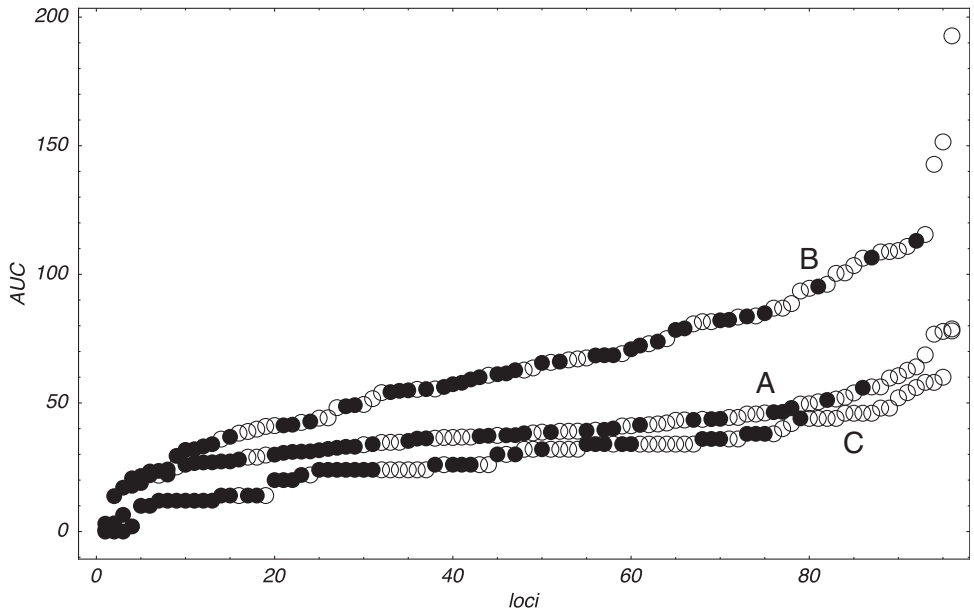

FIG. 4. Growth graphs of the area under the curve (AUC) of pain scores, for hours: **(A)** 1–12; **(B)**12–36; and **(C)** 36–48. The entire population of both study (*solid circles*) and control groups (*empty circles*) is represented, with 96 ranks on the abscissa.

which was absent ($p < 0.0001$) in group S (The overall decrease over time continued its course).

The following law modeled this mean evolution of the pain scores for group C empirically (valid for the first half-day, during which scores were sampled at hourly intervals):

$$(15 - \mathrm{H}) * (\mathrm{H} - 0.74) * \left(\mathrm{H}^2 - 17\mathrm{H} + 110\right)/440,$$

where H is the corresponding hour. This empirical law was found by virtue of robust fitting of the mean average score across controls for every hour, minimizing the polynomial degree and retaining C^2 parametric continuity. The graph of this model is shown in Figure 3 as a curved dashed line.

Furthermore, by ranking the subjects according to their AUCs, the relative location of each parturient inside the entire cohort was examined. This relative comparison is concretized in Figure 4, as it was exercised in 3 stages: (1) for the first 12 hours; (2) the later 24 hours; (3) and the last 12 hours. The distinction between groups C and S was again observed here. Peculiar aggregates were found in these growth graphs, of larger sizes for group C as the AUC increased, and of larger sizes for group S when the AUC approached 0. The differentiation between the groups was more manifest for the first and last 12 hours (Fig. 4 A and C) than for the middle portion (graph B of Fig. 4). It seems that, through this halfway timeperiod, the integration compensated slightly for the differences previously found at each hour. Additionally, the sudden agreement that was hitherto found at the 30th hour is surely implicated (*cf.* Fig. 3). Total pain as estimated by the AUC decreased between the first and last 12 hours, for the entire population (graphs A&C of Fig. 4).)

The AUC magnitude for the middle 24 hours cannot be compared on Figure 4 with the preceding and following 12 hours, because a correcting factor of ½ should then be applied. However, it was noted that the graphs A, B, and C in Figure 4 would then form a slim strip, which, in magnitude, would respect their respective order, from a large AUC in graph A of Figure 4 to a smaller AUC in graph C of Figure 4. Having distinguished the 2 groups across parturients and time, the role played by each hour in isolation was observed.

Supplemental analysis was sought through conditional inference trees, attempting to answer the following question: ''Knowing that the pain scores were always lesser in the study group in contrast to the control group, when was the difference decisive in identifying what treatment was actually applied?'' Table 2 provides two answers to this question, highlighting the importance of the 42nd and the 11th hours in distinguishing the 2 pain-management procedures intrinsic

Table 2. Results of Conditional Inference Analysis (A) & Decision-Tree Learning with Pruning (B)

	A	*B*
Parameters	*NRS pain score 42 hr* post ev.	*NRS pain score 11 hr* post ev.
Node 1	(p-value <0.001) / \ ≤ 2 >2 / \	/ \ / \ < 4 ≥4 / \
Nodes 2 & 3	Group S Group C	Group S Group C
Sensitivity	70%	83%
Specificity	76%	67%
Accuracy	73%	75%

NRS, numeric rating scale; hr, hours; post ev., *post-eventum.*

Table 3. Comparison of Analgesic Usage

Medication	*Group C (n = 49)* *Mean ± deviation*	*Group S (n = 47)* *Mean ± deviation*	*Mean reduction %*	p-*value*
Paracetamol (g)	2.45 ± 0.57	1.70 ± 0.77	31%	**<0.0001**
Diclofenac (mg)	119 ± 41	70 ± 39	41%	<0.0001

Bolding indicates significance.
C, control; S, study.

to the 2 groups. Remarkably, only the most elementary trees were found, whether by bootstrapping (Table 2, column A) or pruning (Table 2, column B). The first answer, which focused around the 42nd hour, was statistically significant ($p < 0.001$) and had highest specificity (76%). There was corroboration in the smallest spread intersection observed at the 42nd hour on Figure 3. The second answer—revolving around the 11th hour—was appreciated by its greater sensitivity (83%). Essentially, it was noted that, up to the 11th hour, the pain scores ≥4 were most frequently associated with group C (without PENS), while lesser scores at the 42nd hour were mostly associated with the presence of PENS (group S).

All of the participating mothers received paracetamol, although the requirement was considerably less in group S (Table 3). Diclofenac was required by 18% of group S and 27% of group C. One patient in the study group did not require any analgesics and requested continuation of the device for an additional day, which was conceded. Two subjects in group S required analgesics during the phase when there was no stimulation. Only 1 parturient in the control group required tramadol. The neonatal outcomes did not differ in the 2 groups.

DISCUSSION

It is desirable to be pain free at all times in the postoperative period; pain relief after surgical operations is mandatory. R.M. Waters (1883–1979) affirmed that ''the relief of pain is always purchased at a price. The price both in morbidity or mortality does not greatly differ, whatever the agent or agents used.''[10] Despite the century that has passed since this observation was made, the statement seems to hold true even today. Methods such as PENS seem to offer pain relief at none or a minimal price. Pain is complicated by many immediate and long-term negative outcomes.[11–14]

Acupuncture is an ancient method for managing more than 40 conditions, including pain. Although there still is a debate about the plausible mechanism underlying acupuncture, it provides clinical benefits in the perioperative period, especially for managing postoperative nausea and vomiting and reducing opioid consumption in the postoperative period.[15,16] Acupuncture has been used as an option to manage postoperative pain after LSCS. In a pilot study by Hesse et al., manual auricular and body acupuncture for 20 patients, with indwelling fixed needles, were used for imparting postoperative analgesia.[17] The researchers observed that, except for 1 patient who complained of paraesthesia, the remaining 19 patients tolerated their postoperative pain well. The researchers concluded that acupuncture is an acceptable method for providing adjuvant analgesia after LSCS. The current study with electrical auricular stimulation proved to be similar, showing beneficial effects while conceivably reinforcing the effects of acupuncture.

The mechanism of analgesia by auricular acupuncture is mediated by neurologic reflexes and release of neurotransmitters.[18] As previously described, the 3 auricular points chosen for pain relief following LSCS were *Shenmen*, Thalamus, and Uterus. Stimulation of *Shenmen* and Thalamus points is associated with calming and analgesic effects.[19] In the 1970s it had already been shown that electroacupuncture (EA) entails an increase in endogenous opioids in plasma or cerebrospinal fluid.[20] Low frequency (2 Hz) stimulation activates μ- and δ-opioid receptors via release of enkephalin, β-endorphin, and endomorphin in the supraspinal regions of the central nervous system, whereas high-frequency (100 Hz) involves the actions of dynorphin on κ-opioid receptors in the spinal cord.[21] The effect of EA is antagonized by a naloxone opioid-receptor antagonist.[22] Electroauricular stimulation has been effective as an adjuvant analgesic strategy for oocyte retrieval, laparoscopic nephrectomy, and chronic musculoskeletal pain relief.[23–25] Auricular EA reduced pain and remifentanil consumption during oocyte aspiration, compared with conventional auricular acupuncture or a sham treatment.[23]

Following laparoscopic nephrectomies, patients who received electroauricular acupuncture had lower visual analogue scale–measured pain scores at rest and on exertion. The postoperative consumption of morphine-hydrochloride in the first 6 hours was lower and the time of first analgesia medication was significantly later in this group.[24] However, this form of acupuncture was not effective for relieving pain following molar tooth extraction.[26] PENS is, all the more, a valid alternative to traditional acupuncture. The comparison between the two approaches already showed greater pain decrease with nonambulatory PENS applied at intervals of 12 hours, although the concluding analgesic effect after 48 hours was similar to that obtained with traditional acupuncture.[27,28] Using this ambulatory device, the aim of this current research was to make better utilization of PENS technology, by multiple applications in the course of a postoperative day. PENS treatment regimens usually consist of stimulation sessions that last from 15 to 60 minutes.[29]

Although PENS is generally utilized with several probes and repeated treatments, a beneficial effect may also be produced with a single probe and use.[30] This approach of

discontinuous stimulation led to the present form of PENS that alternates between on-and-off phases. It has been conjectured[31] that continuous electrical nerve stimulation fails to cause vasoconstriction, possibly due to the unresponsiveness of vascular smooth-muscle to continuous stimulation.[32]

The analgesia produced with PENS might be explained by the gate-control theory proposed by Melzack and Wall in 1965.[33] They mentioned a closed ''gate'' that inhibits constant nociceptive transmission via *C* fibers from the periphery to the T-cells. When pain occurs, the information carried by *C* fibers reaches the T-cells and opens the gate, thus permitting pain transmission to the thalamus and cortex, which is then experienced as pain. Furthermore, this gate-control theory posits the reclosure of the gate through inhibition of the *C*-fiber nociperception via impulses in activated myelinated fibers. Per the findings of Cramp et al.,[34] the current study's results hereby give credence to this theory, as electrical stimulation of the ABVN-myelinated fibers appeared to blur the nociceptive information response.

Indeed, it was found that both the NRS pain scores and analgesic requirements were significantly lower in group S. The average AUCs of the pain scores was reduced by 31% from group C to group S (Table 1). The analgesic requirement decreased by 36% (Table 3). This double decrease conceivably serves to allay the supposition of a placebo effect. The current study showed an empirical relationship between pain scores and hourly times following LSCS. This mean algebraic law on the controls reveals, the current authors believe, the profound evolution of pain after a cesarean section and could set a further benchmark for other pain-management techniques or simply find usage in predicting pain-relief status. On average across parturients, pain scores for the subjects receiving PENS were lower than the control parturients at every sampled hour.

All but 1 patient tolerated placement of the device. The group S parturients appeared to benefit from it. They were more comfortable, compared to the parturients in group C at all times, and compliance to the device was good. No complications were observed in either group. The device did not cause any side-effects and no patients had any itching or bleeding from the puncture points after removal of the device.

The unblinded nature of the study was a limitation. The group C cohort was different from that of group S by the absence of a preauricular device. One practical problem arose during the study: the inability of the parturients to turn on the side where the device was placed. The current authors wish to address this point with the manufacturers to modify the device to allow the patients to lie on either side while having the device connected. In light of the peculiar findings surrounding the last 12 hours, the current authors recommend reproducing this study with finer time intervals for this ending period.

CONCLUSIONS

PENS, using the ANSiStim device, is a safe and reasonably effective analgesic adjuvant following LSCS without any significant side-effects either on the mother or on her newborn.

Further study is required to optimize various aspects of this treatment, such as needle placement, electrical-modulation adjustments, finer analogue scoring, and changes in the stimulation timeperiod.

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AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

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