

Comparative evaluation of efficacy of transcutaneous electrical nerve stimulation administered by dermatomal stimulation versus acupuncture points stimulation

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ABSTRACT

Background and Aims: Transcutaneous Electrical Nerve Stimulation (TENS) is a non-pharmacological method based on gate theory of pain control and provides analgesia noninvasively. Application of TENS requires simple training and can be self administered by patients without any potential for toxicity. Patients can titrate the dosage on and whenever needed. TENS can be administered by either dermatomal stimulation or by stimulation of acupuncture points for labour analgesia. This study was undertaken to compare the efficacy of TENS administered by dermatomal stimulation with TENS administered by stimulation of acupuncture points. **Materials and Method:** The study was conducted on 40 ASA grade 1 parturients with 37 to 42 weeks gestation in active stage without any fetal or maternal complication. Parturients were randomly allocated by computer generated random number table to one of two groups (Group D- TENS by dermatomal stimulation, Group A- TENS by acupuncture points stimulation) comprising of 20 parturients each. Each group was monitored for pain scores, progress of labour and maternal and fetal outcome. The quantitative parameters were analysed using the Student-t test and Mann Whitney test. Qualitative parameters were analysed using Chi-square test/Fisher Exact test. A p value of <0.05 was taken as statistically significant. **Results:** TENS administered by dermatomal stimulation causes significant decrease in VAS score and rescue analgesic requirement as compared to acupuncture point stimulation. Parturients in Group D also reported significant decrease of back pain and better ambulation as compared to Group A. Maternal and fetal outcome were similar in both groups without any side effects. **Conclusion:** Pain relief in labour is better when TENS is administered by dermatomal stimulation as compared to acupuncture point stimulation.

Key words: Acupuncture analgesia, obstetric analgesia, transcutaneous electrical nerve stimulation

INTRODUCTION

The goal of labour analgesia is to provide adequate pain relief without causing any harm to fetus or mother. Labour analgesia can be given by several techniques. Central neuraxial analgesia is now considered the gold standard technique for labour analgesia. However, this requires continuous monitoring by a trained anesthetist. Labour pain is perceived more severe by the parturient than by the medical personnel. In many setups labour analgesia is not provided because of lack of trained personnel and monitoring. Alternative methods of labour analgesia have

been found to be safe, easy to apply and do not require continuous monitoring by a trained anesthetist.

TENS has been used for labour analgesia and there are several studies which show its effectiveness. The

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effectiveness of TENS is dependent upon the duration, frequency and amplitude of the stimulating current and the site of application of the electrodes^[1]. There are many studies where these three variables are different. TENS can be administered by either dermatomal stimulation or by stimulation of acupuncture points for labour analgesia^[2]. While most studies conclude that TENS does reduce the pain of labour, a recent Cochrane database review suggested that the evidence was weak. However, they stated that it was safe and there was no adverse effect on the mother and baby^[3].

This study was conducted to study the effectiveness of TENS on labour analgesia, maternal and fetal outcome using TENS by dermatomal stimulation technique and to compare it with TENS delivered on acupuncture points with the same frequency of current. The primary aim was to evaluate and compare the effectiveness of TENS administered by dermatomal stimulation versus acupuncture points stimulation with regard to the quality of labour analgesia. The secondary aim was to evaluate and compare the effect of two techniques on obstetrical and neonatal outcome.

MATERIAL AND METHODS

This prospective randomized study was conducted after approval of Institutional Review Board from the period January to December 2012.

A detailed pre-anaesthetic check up and all routine investigations as guided by age was carried out in all the parturients. The inclusion criteria were: ASA grade I, age ≥ 18 years, vertex presentation of fetus, established labour (effective painful uterine contractions, good cervical effacement and cervical dilatation ≥ 3 cm), primigravida with single live fetus and uncomplicated pregnancy.

The exclusion criteria were patient refusal and contraindication to TENS (infection or inflammation at the site of electrode placement). 40 parturients were randomly allocated by computer generated random number table to one of two groups comprising of 20 parturients each. In Group D- the parturients received TENS by dermatomal stimulation while as in the Group A the parturients received TENS by acupuncture point stimulation. After selecting the parturient and explaining about the whole procedure, an informed consent was taken from each patient. Monitors were applied and the maternal blood pressure, heart rate, oxygen saturation and fetal heart rate

was recorded in all patients in both groups. Obstetrician help was taken to assess the progress of labour by noting-severity of contraction, cervical effacement and cervical dilatation. The analgesia was given as per group allotment.

In Group D patients, TENS was given by Mama® TENS machine [Figure 1]^[4]. Two pairs of self adhesive skin electrodes measuring 50x100 mm were applied [Figure 2]. The top pair of electrodes was applied on either side of spinal column 5 cm apart from each other and about 7.5 cm below the shoulder blades (close to vertebra T_{10} - L_1). The lower pair of electrodes was applied on either side of spinal column about 10 cm apart and about 2.5 cm above the dimple at the base of spine (close to vertebra S_2 - S_4). The upper pair of electrodes was stimulated during first stage of labour and the lower pair during second stage of labour. Frequency of electrical pulse used was 80 Hz. Current intensity was gradually increased till pleasant tingling sensation was felt but caused no discomfort to the patient. There were three programmes A, B, and C in the machine for increasing severity of labour pains. Each programme had two modes; 1 and 2. Mode 1 was used in between the uterine contraction and mode 2 was used during the uterine contractions. During the uterine contraction, boost button on the side of machine was pressed for changing programme mode 1 to mode 2. When the uterine contraction had passed, the boost button was pressed once again and the running programme changed back to mode 1 at the same level of intensity. This was repeated with each uterine contraction. As the labour progressed and uterine contractions became more frequent, the programme was changed from A to B and then to C. During the advanced stage of labour when the pain became more intense the programme mode was changed from B to C.

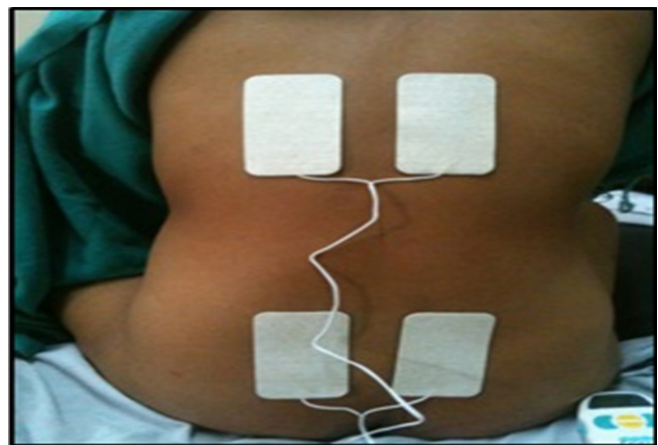


Figure 1: Application of TENS electrodes on dermatomal points

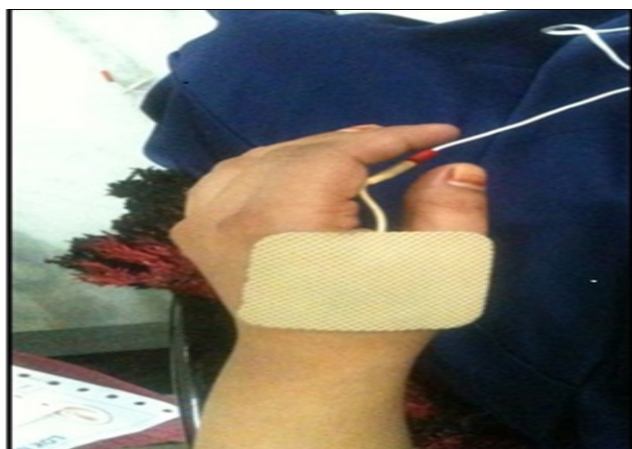


Figure 2: Application of TENS electrode on LI 4 (Hegu) point

In Group A, after selecting the parturient and recording baseline parameters as in Group D, two pairs of self adhesive skin electrodes measuring 50x50 mm were applied on bilateral LI 4 (Hegu) points [Figure 3: Midpoint between first and second carpal bones, first web space dorsal side] and Sp 6 (Sanyinjiao) points [Figure 4: 5 cm above medial malleolus in lower leg]. TENS was given by Ultima IF4 interferential machine [Figure 5]. Frequency of electrical impulse was set at 80 Hz. Current intensity was gradually increased according to comfort of the parturient. A session of TENS was applied for 30 minutes during first stage of labour and was removed after 30 minutes. TENS was again applied after 30 minutes of TENS free period. The procedure was repeated till delivery of neonate.



Figure 3. Application of TENS electrode on Sp 6 (sanyinjiao) point

- In both groups, rescue analgesic was given as per standard hospital protocol (50-100 mg tramadol by intramuscular route) if VAS score was ≥ 5 or on demand by the parturient. Following parameters were assessed during the study period, which extends from application of TENS electrodes in both groups till delivery of baby-Maternal heart rate and blood pressure were

recorded at 30 minutes interval starting from the baseline. Fetal heart rate and progress of labour with special reference to rate of cervical dilatation, obstetrical outcome and operative interventions was done by obstetrician as per standard hospital protocol. VAS (Visual Analogue Score) in scale of 0 to 10 was used for assessing pain wherein 0 was given when there was no pain and 10 was the worst pain the parturient has ever experienced. VAS score was assessed at interval of 5 minutes for first 30 minutes after application of TENS and every 15 minutes thereafter. Maternal confidence for ambulation was assessed and graded accordingly.

- Could walk herself independently.
- Could walk, but with attendant holding arm.
- Could walk with difficulty, leaning on attendant.
- The onset and duration of analgesia provided by both techniques was measured.

Degree of analgesia and patient satisfaction score was assessed by the obstetrician at the end of procedure on a subjective scale of 0 to 3. The degree of analgesia^[5] was rated on a scale as: 0-No pain relief, 1-Mild relief, 2-Moderate relief, 3- Complete relief. The patient satisfaction score was rated as: 0-Not satisfied, 1-Somewhat satisfied, 2-Acceptably satisfied, 3-Very satisfied.

Neonatal assessment was done by determining Apgar score at 1 minutes and 5 minutes. Any side effect i.e., discomfort of movement restriction, skin allergy, electrical accident etc. were also recorded. The investigator examined the parturient at least once during her stay in the hospital after delivery. The parturient was asked whether they will use the technique again in future for labour analgesia.

Taking an α error of 0.05 and power of the study as 80%, the study was conducted on a sample size of 40 patients (20 patients in each group). Data was analysed by Student-t test and Mann Whitney test for quantitative parameters and Chi-square test/Fisher Exact test for qualitative parameters. Data was analysed using SPSS statistical software. A 'p' value of ≤ 0.05 was considered as statistically significant.

RESULTS

Demographic Profile: The demographic profile of the two groups was similar. The mean (\pm S.D.) age in Group D was 24.45 ± 2.704 yrs and in Group A was 24.50 ± 2.625 yrs ($p = 0.476$). The mean Period Of Gestation (POG) in Group D was 38.145 ± 1.439 wks and in Group A was 37.925 ± 0.774 wks ($p = 0.275$).

VAS score: The comparison of VAS scores at different time intervals showed that TENS by dermatomal point

stimulation had lower score than TENS by acupuncture point stimulation [Figure 4]. The difference in mean VAS score was significant at all time interval after 5 minutes (p value = 0.00).

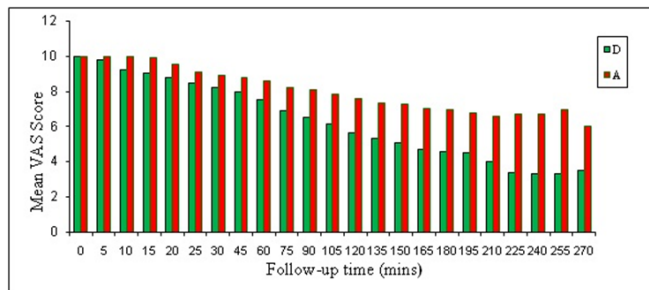


Figure 4: Mean VAS score in two groups at different time intervals

Onset and duration of analgesia: The mean (\pm S.D.) onset of analgesia in Group D was 11.25 ± 4.25 minutes and in Group A was 22 ± 3.40 minutes which was statistically significant (p value = 0.00). The mean duration of analgesia in Group D was 191.95 ± 35.18 minutes and in Group A was 190.05 ± 25.01 minutes which was statistically not significant (p value = 0.42).

Quality of analgesia: 100% of women in Group D responded to TENS as assessed by the obstetrician on a subjective scale. The analgesic response was mild in 40%, moderate in 35% and complete in 25 % of parturients. In Group A, 75% achieved pain relief, mild relief in 65% and moderate relief in 10% of parturients. None of the parturient in Group A achieved complete relief.

Rescue analgesia: 50% of parturients in Group D and 100% of parturients in Group A required rescue analgesia (i/m tramadol) which was statistically significant (p value = 0.00).

Analgesia for episiotomy: All the parturients in Group D and Group A required additional analgesia for episiotomy in the form of local infiltration of 6-8 ml of 2% lignocaine.

Obstetrical outcome: Out of 20 parturients in Group D, 17 were delivered by normal vaginal route, 1 by cesarean section, 1 by forceps and 1 by vacuum application. In Group A, 18 parturients were delivered by normal vaginal route, one by cesarean section and 1 by forceps application. The obstetrical outcome was similar in two groups (p value = 1.000).

Duration of stages of labour: The mean (\pm S.D.) duration of stage 1 in Group D was 167.37 ± 33.64 minutes and in Group A was 175.26 ± 26.95 minutes (p value = 0.215). The mean (\pm S.D.) duration of stage 2 in Group D was

$64, 39.6 \pm 12.54$ minutes and in Group A was 38.68 ± 11.14 minutes (p value = 0.451). The mean (\pm S.D.) duration of stage 3 in Group D was 11.53 ± 3.08 minutes and in Group A was 10.26 ± 0.097 minutes (p value = 0.097). There was no difference in duration of stages of labour between the two groups [Figure 5].

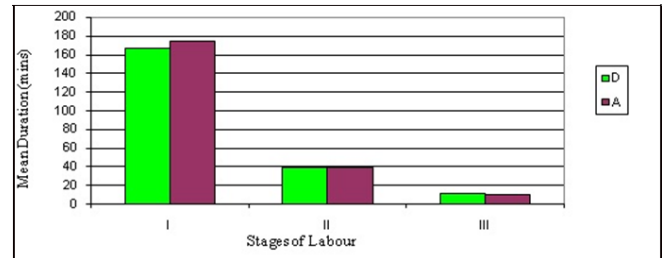


Figure 5: Duration of stages of labour (mins) in two groups

Cervical dilatation: The mean (\pm S.D.) rate of cervical dilatation in Group D was 1.942 ± 0.371 cm/hr and in Group A was 1.938 ± 0.191 cm/hr [Figure 6]. The difference in the rate of cervical dilatation was not statistically significant (p value = 0.964).

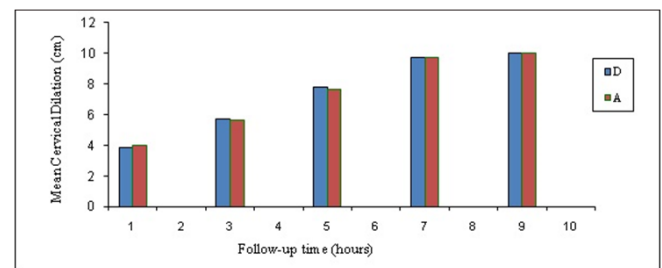


Figure 6: Cervical dilatation (cm) in the two groups

Neonatal outcome: The mean (\pm S.D.) Apgar score at 1 minute in Group D was 9 ± 0.0 and in Group A was 8.95 ± 0.224 with p value of 0.162. The mean (\pm S.D.) Apgar score at 5 minutes in Group D was 9.55 ± 0.51 and in Group A was 9.7 ± 0.47 with p value of 0.169. Neonatal outcome was comparable in both the groups.

Effect on maternal blood pressure, heart rate, spO_2 and fetal heart rate in two groups: There was no significant effect with the use of either technique on maternal B.P, heart rate, SpO_2 and fetal heart rate.

Satisfaction and ambulation: The parturients in Group D were more satisfied as compared to Group A. The mean (\pm S.D.) satisfaction score in Group D was 1.80 ± 0.813 and in group A was 0.80 ± 0.587 with p value of 0.00004. There were no difference in ambulation grade between the two

group. All parturients in both the groups had ambulation grade of 1.

Side effects of TENS: There were no side effects with the use of TENS in either of the groups. However, all patients in Group A complained of slight restriction of movement due to placement of electrodes on bilateral Hegu and Sanyinjiao points.

Use of same technique in future for labour analgesia: The parturients were examined 24 hrs after delivery and were asked whether they wanted to use same technique for labour analgesia in future. 65 % of parturients in Group D and 15 % in Group A wanted to use the same technique in future for labour analgesia which was statistically significant with *p* value of 0.008.

DISCUSSION

Labour pain has both visceral and somatic component. The body of uterus, lower uterine segment and the cervix are supplied by A-delta and C afferent nerve fibres accompanying sympathetic nerves to uterine and cervical plexuses, inferior, middle and superior hypogastric plexuses and aortic plexuses. The afferents nerve fibres then pass to lumbar and lower thoracic sympathetic chain and terminate in the dorsal horn of the spinal cord at the T₁₀ to L₁ segments^[6]. During the second stage, the direct pressure by the presenting part on the lumbosacral plexuses causes neuropathic pain. Stretching of the vagina and perineum transmits painful stimuli through pudendal nerve and sacral nerves S₂ through S₄ and finally to brain via spinothalamic tract.

TENS stimulates nerve endings by electrical stimulation and works on gate control theory of pain. The analgesic effect of TENS has been found to be dependent on duration, intensity, frequency and location of electrodes^[1]. A previous systemic review by Carrol *et al.*, concluded that the evidence for reduced pain using TENS in labour was weak, however additional analgesic interventions may be less likely with TENS use during labour^[7].

In our study, in Group D; 2 pair of skin electrodes were placed on either side of spinal column. The upper pair corresponds to T10-L₁ and the lower pair corresponds to S₂-S₄. This was similar to previous studies by Ratna *et al.*^[5], Harrison *et al.*^[8] and Pandole *et al.*^[9].

We have used the Mama® TENS machine^[4] which is a TENS unit which is specially designed for labour analgesia and has a fixed output of 80 Hz. On pressing the boost button during contractions it increases to 150Hz. Low intensity

stimulation was given continuously while high intensity stimulation was given during uterine contractions. These parameters for TENS were chosen based on studies by Ratna *et al.*^[5] and Harrison *et al.*^[8]. Pandole *et al.*^[9] did not specify the frequency which ranged from 10-100Hz.

Acupuncture has been used for pain relief in labour for centuries in China, and in recent decades has become popular and accepted in many western countries. Clinical studies in Chinese literature report 65-97% efficacy for a range of traditional Chinese acupuncture treatments, but such studies do not generally conform to western standards, and detailed data are often inaccessible. This makes it difficult to properly evaluate traditional Chinese acupuncture. Systemic reviews of most studies of acupuncture during labour found that data were not in a form that could be included in a meta-analysis and recommend conducting well designed randomised controlled trials in this area^[10].

Acupuncture points can be stimulated by different methods. They can be stimulated by using sterile stainless steel needles,^[2,11-14] manual acupressure^[15] or by use of skin electrodes^[12].

In our study, we applied 2 pair of electrodes on bilateral LI 4 (Hegu) and Sp 6 (Sanyinjiao) acupuncture points and used 80 Hz stimulating frequency. This frequency was chosen so that it would be the same as for dermatomal stimulation. Acupuncture points were stimulated for 30 minutes with an intensity of current which was easily tolerated by the patient. The procedure was repeated every 30 minutes till delivery of baby. These parameters were based on studies by Borup *et al.*^[11], Mackenzie *et al.*^[10] and Ma *et al.*^[14].

In this study, we compared TENS by dermatomal stimulation with. TENS by acupuncture point stimulation in Indian population. Our study was different from above studies in the sense that we stimulated acupuncture points using skin electrodes instead of needles.

In Group D, the results were similar to earlier studies by Ratna *et al.*,^[5] Pandole *et al.*,^[9] Thomas *et al.*^[16] and Borup *et al.*^[11] where use of TENS by dermatomal stimulation was found to decrease labour pains.

In a randomized controlled trial by Borup *et al.*^[11] on 607 parturient, traditional Chinese acupuncture was compared with TENS and traditional analgesic for pain relief and relaxation during delivery. Acupuncture was given by sterile stainless steel needles. They concluded

that the use of pharmacological and invasive methods was significantly lower in the acupuncture group but the pain scores were comparable in the two groups. The mean VAS pain score was 6.8 (median = 7). In the TENS group, 34 % of the women reported that TENS gave some or substantial pain relief and 23% that it had a somewhat or very calming effect. In the acupuncture group, 59% of the women reported some or substantial pain relief and 55% somewhat or very calming effect. Median duration of labour was not significantly different between the groups (p value = 0.480).

In our study, TENS administration by dermatomal point stimulation provided early onset and better pain relief in labour and therefore less requirement of rescue analgesia as compared to acupuncture point stimulation which was found to be statistically significant. However there was no difference in the duration of analgesia provided by both the techniques. In our study we found increased rate of cervical dilatation (normal rate is 1-1.2 cm/hr in Indianprimigravidas^[17]) with the use of TENS in both the groups. This could be attributed to the better pain relief and ambulation with the use of TENS. Firstly, effective analgesia during labour has been shown to decrease endogenous catecholamine release during labour^[18] by converting uncoordinated uterine contractions into more regular and effective contractions. Secondly, various reports have suggested an association between upright position and walking with shorter labour^[19].

In Group D all the parturients reported minimal or moderate back pain throughout labour, while parturients in Group A reported an increased intensity of low back pain as labour progressed. This pain reducing effect of TENS by dermatomal stimulation was maintained throughout the labour. The finding is consistent with the earlier studies^[16, 20] which documented good effect of TENS by dermatomal stimulation on low back pain during labour.

CONCLUSION

The use of TENS for labour pain is cost effective, non invasive, does not interfere with maternal ambulation, does not need continuous monitoring as it has no effect on the hemodynamic parameter of patient and being a non pharmacological method is free from side effects of drug which can affect mother or newborn. Many patients were willing to use it again.

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