DOI: 10.7860/JCDR/2023/63368.18063

Original Article

Anaesthesia Section

Non Narcotic Pain Relief in Postcaesarean Women by Percutaneous Stimulation of Auricular Pressure Points: A Randomised Controlled Study

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ABSTRACT

Introduction: Caesarean sections are the most common surgeries performed globally now-a-days. The postoperative period is associated with immense pain which if not mitigated can be detrimental to both mother and baby. An inadequate analgesia can lead to postpartum depression, and can also affect mother-baby bonding, breastfeeding including delay in ambulation.

Aim: To assess the efficacy of non narcotic pain relief and to study the additional need of rescue analgesics.

Materials and Methods: A randomised controlled study was carried out at the Institute of Social Obstetrics and Government Kasturba Gandhi Hospital after registering with Clinical Trials Registry-India CTRI/2022/04/041633. A total of 60 antenatal women undergoing caesarean section under spinal anaesthesia were randomly allocated into two groups of 30 each. Group P received stimulation of auricular pressure points with a stimulation device at the end of caesarean procedure and Group C was a control group. The cases were monitored for 48 hours, and the following parameters were recorded: spinal regression time, pain score Visual Analogue Scale (VAS), rescue analgesic need including time and total dosage, sedation scores using the modified Ramsay sedation scale and postoperative nausea and vomiting. Data analysis was done using International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS) software version 23.0. Data was expressed as mean±Standard Deviation (SD). Quantitative analysis was done using Pearson's Chi-square test and Independent t-test. A p-value of <0.05 was considered significant.

Results: Group P had VAS scores 2.53±0.64 and Group C had VAS scores 4.97±0.47 with highly significant p-value of <0.001. Only 2 (7%) of patients in Group P needed rescue analgesic whereas all patients of Group C required rescue analgesic with highly significant p-value of 0.001. Postoperative nausea vomiting was noted in only 1 (3%) patient of Group P as opposed to 12 patients (40%) in Group C with highly significant p-value <0.001. Group P showed maximum sedation score of two as compared to three in Group C as assessed by Modified Ramsay Sedation scale with statistically significant p-value of 0.01.

Conclusion: The percutaneous stimulation of auricular pressure points is efficacious in providing good analgesia with early ambulation, breastfeeding, and no adverse effects.

Keywords: Analgesia, Auriculotherapy, Caesarean section, Non opioid analgesics

INTRODUCTION

There are three components of postcaesarean pain- burning or somatic pain, colicky pain due to visceral uterine contractions, and iatrogenic due to oxytocin-induced visceral pain which can complicate the postoperative recovery [1]. Opioid analgesics are associated with sedation, respiratory depression, postoperative nausea and are excreted in the breast milk causing opioid toxicity in the baby. Postcaesarean pain relief can be a challenge to many professionals [2]. Some of the challenges faced are prolonged convalescence period with risk of thromboembolism, inappropriate neonatal care, delay in hospital discharge, chronic pain (post-traumatic stress disorder) [3]. An ideal analgesic should meet the following criteria: quick acting and safe should require minimal monitoring. The drug must not be secreted into breast milk. Patient must be able to move freely, with minimal side-effects and it should be non sedating [4]. Neurophysiology of pain involves interaction between autonomous nervous system, motor and nociceptors [5]. An endogenous pain modulating network has links in mid brain, medulla, and spinal cord which produces analgesia by interfering with afferent transmission of neural messages produced by noxious stimuli [6].

Pharmaceutical options have been the first and best choice for acute pain. Opioids like morphine and meperidine, produce analgesia by mimicking the action of endorphins [4,7,8], but are associated with a variety of adverse effects e.g., drowsiness, constipation, dry mouth, gastrointestinal bleeding, and potential for addiction [9-11]. Also, because of its transfer through the breast milk, alternate and better pain management strategies are indicated [12]. Auriculotherapy is a well-recognised element of Traditional Chinese Medicine (TCM) [13] Auriculotherapy was modified and updated by Dr. Paul Nogier, the "Father of Auriculotherapy," in the 1950s. Auriculotherapy involves relationship between the ear, energy lines (channels and meridians), and muscle regions comprising the whole body, according to a theory known as somatic reflexology. Theory behind analgesic effect in auriculotherapy is suppression of hypersensitive reflex neuronal pain pathways interconnecting the ear microsystem and the somatotopic regions of the brain [13-15]. It is believed that the stimulation of acupoints in the ear leads to vasodilative effects due to the release of either beta-endorphins or neuropeptide induced anti-inflammatory cytokines which elicit short-term and long-term analgesic effects, respectively [16-18]. Systematic reviews and many randomised controlled trials have found auriculotherapy as a useful adjuvant for both acute and chronic postoperative pain following various surgeries including caesarean section, hysterectomy, and orthopaedic surgeries and conditions thereby reducing the use of patient controlled analgesia and postoperative nausea and vomiting [16-18].

Therefore, the aim of the study was to assess the efficacy of non narcotic pain relief, to overcome the adverse effects associated with narcotic analgesics and to study the additional need of rescue analgesics.

MATERIALS AND METHODS

A randomised controlled double blinded study was planned at Institute of Social Obstetrics and Government Kasturba Gandhi Hospital, Chennai, Tamil Nadu, India for a duration of three months between May 2022 to July 2022 after registering with Clinical Trials Registry-India CTRI/2022/04/041633. After obtaining Institutional Ethical Committee approval (IEC NO 04012022).

Inclusion criteria: A total of 60 antenatal women undergoing caesarean section, belonging American Society of Anaesthesiologists (ASA)-II in the age group of 18 to 35 years, with term gestation were randomly allocated into two groups of 30 each by block randomisation.

Exclusion criteria: Patients with ASA grade ≥ III, history of cardiac, pulmonary and renal diseases such as rheumatic heart disease, ischaemic heart disease, bronchial asthma, chronic obstructive pulmonary disease, acute/chronic renal failure, epilepsy, skin lesions such as psoriasis, eczema, Body Mass Index (BMI) >35 kg/m^2, bleeding diathesis, pregnancy-induced hypertension, drug allergies, presence of pacemakers, biomedical implants and patients with altered mental status were excluded from this study.

Sample size calculation: Sample size was estimated by using nMaster software version 2.0. Based on the study by Toca-Villegas J et al., which shows that at six hour postoperatively, 87% of the auriculotherapy group had a VAS of < 4 vs 48% in placebo group (p=0.004) [19].

Formula:

$H_0: P_1 = P_2$; $H_1 : P_1 \neq P_2$

$$n = \frac{\left\{ Z_{1-\frac{\alpha}{2}} \sqrt{2\bar{P}(1-\bar{P})} + Z_{1-\beta} \sqrt{P_1(1-P_1)+P_2(1-P_2)} \right\}^2}{(P_1-P_2)^2}$$

Where: $\bar{P} = \frac{P1+P2}{2}$

P_1: Proportion in the first group

P_2: Proportion in the second group

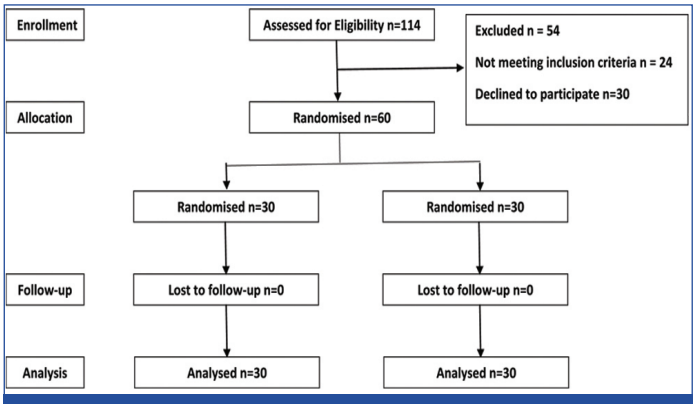
α: Significance level

1-β: Power

Two proportions

Proportion in Group-I	0.87
Proportion in Group-II	0.48
Estimated risk difference	0.39
Power (1-beta) %	90
Alpha error (%)	5
1 or 2 sided	2
Required sample size for each arm	**28**

Based on the above parameters with an alpha of 0.05 (two-sided) and power of 90%, sample size was estimated using the sample size formula for two proportion comparison which gives us a sample size of 28 samples per group and after considering data loss, 30 samples per group were included in the study [Table/Fig-1].



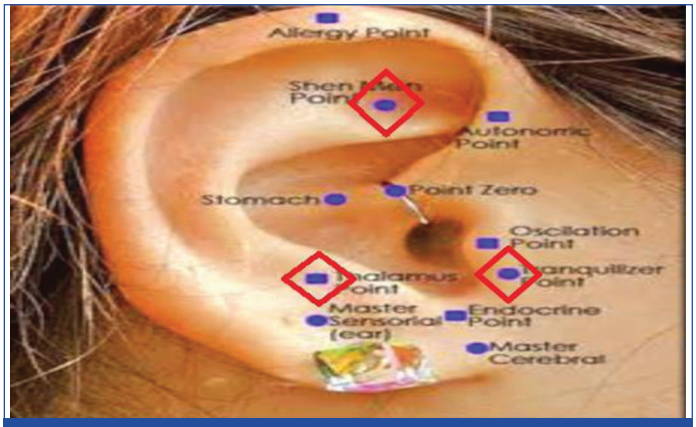
[Table/Fig-1]: Consort flow diagram of enrollment and allocation of groups.

Preoperatively demographic parameters such as age, height, weight and baseline haemodynamic parameters pulse rate, mean arterial pressure and oxygen saturation were recorded for all patients. All patients in both groups received premedication with inj. metoclopromide 10 mg and inj. ranitidine 50 mg i.v., 30 minutes before caesarean section. Caesarean section was performed under subarachnoid block, using 25G Quincke needle and 2.0 mL of 0.5% heavy bupivacaine was administered in the L3-L4 space.

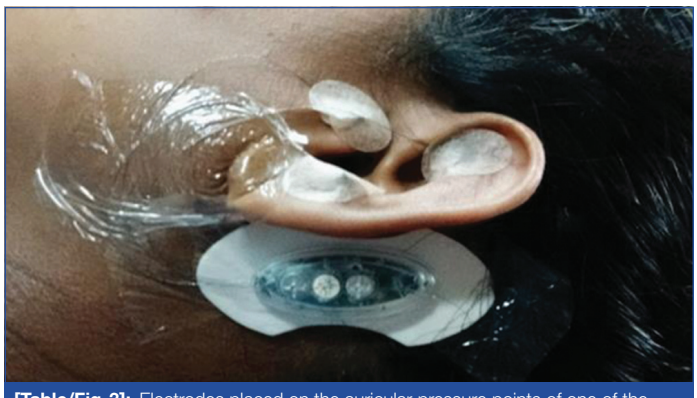
Towards the end of surgery when the level of sensory blockade had receded to T10 in all patients:

- Group P was given percutaneous stimulation of auricular pressure points.
- Group C was a control group.

Percutaneous stimulation of auricular pressure points involves application of cyclical stimulation by means of continuous low frequency electrical (dc) impulse at the ear on specific pressure points namely, the Shenmen Point, Thalamus Point, and the Tranquilizer Point [20]. Focused auricular point stimulation was provided by wearable, light weighted battery-operated mobile and portable aids known as auricular point stimulation devices [Table/Fig-2] which alleviate pain by application of cyclical low frequency electrical stimulation lasting for 20 minutes [21]. The stimulation needles were inserted at the three specific points on the ear-Shenman point, Thalamus point, and the Tranquilizer point [Table/Fig-3]. These needles have the ability to stimulate the brain and release natural opiates, control the hormones, thereby relieving pain [22,23].



[Table/Fig-2]: Anatomy of auricular pressure points [21].



[Table/Fig-3]: Electrodes placed on the auricular pressure points of one of the patients under study.

Rescue analgesics: Interventional analgesic- inj. tramadol 100 mg i.v., backup analgesic- inj. fentanyl 2 µg/kg.

This was a double blinded study and postoperatively, all patients were monitored in the ward during the first 48 hours by an anaesthesiology resident who was blinded to the study and the following parameters were recorded: duration of surgery, spinal regression time to L1, time to first rescue analgesic, pain score measured using VAS [22]. Number of patients requiring rescue analgesic with VAS >4, average opioid consumption, sedation score using modified Ramsay's

scoring [22] and postoperative nausea and vomiting. The above parameters were monitored every hour for the first six hours, every two hours upto 12 hours, every six hours upto 24 hours and every 12 hours upto 48 hours.

VAS scores ≥4 were treated with interventional analgesic of inj. tramadol 100 mg i.v. if analgesia was still inadequate after 60 minutes, a back-up analgesic of inj. fentanyl 2 µg/ kg i.v. was administered.

STATISTICAL ANALYSIS

Data analysis was done using IBM SPSS software version 23.0. Data was expressed as mean±SD. To describe the data, mean and SD were used for continuous variables and descriptive statistics, frequency analysis, percentage analysis were used for categorical variables. Quantitative analysis was compared with Pearson's Chi-square test and independent t-test. A p-value of <0.05 was considered significant.

RESULTS

There were no significant differences in the age, weight, height and preoperative haemodynamic parameters for patients in both the groups [Table/Fig-4].

Parameter	Group P (n=30)	Group C (n=30)	p-value
Age (years)	25.33±4.56	24.17±3.48	0.34
Weight (Kg)	65.4±5.75	64±4.45	0.58
Height (cm)	154.97±4.33	153.43±4.20	0.35
Preoperative Pulse Rate (bpm)	75.4±8.08	77.4±7.4	0.30
Mean Arterial Pressure (mm/Hg)	90.2±5.74	92±8.35	0.12
Preoperative SpO_2 (%)	98.03±0.82	98.10±0.75	0.75

[Table/Fig-4]: Comparison of demographic and preoperative haemodynamic parameters between Group P and Group C.
Data: Mean±SD: Independent Student t-test

The duration of surgery, spinal regression time and the time to first interventional analgesic dose were noted. The duration of surgery and the spinal regression time were not significant in both the groups. The time for the first interventional analgesic- Tramadol 100 mg i.v. was 65.50±10.05 minutes in Group C [Table/Fig-5].

Parameter	Group P	Group C	p-value
Duration of surgery (in min.)	68.72±22.98	70.56±19.54	0.74
Spinal regression time (till L1)	75.55±20.50	80.33±15.45	0.55
Time to first rescue analgesic (in minutes)	-	65.50±10.05	-

[Table/Fig-5]: Comparison of intraoperative parameters and time to first rescue analgesic.
Data: Mean±SD: Independent Student t-test

Almost 90% of the patients in Group C needed inj. tramadol i.v. in the 2nd hour postoperatively. However, only 7% of patients in Group P needed interventional analgesic at the 3rd hour. They did not require any analgesic for the next 48 hours [Table/Fig-6]. All patients in Group C required interventional analgesic inj. tramadol 100 mg i.v., thrice in the first 24 hours, and twice in the second postoperative window of 24 hours [Table/Fig-7].

Further, four patients (13% of the population) in Group C needed rescue analgesic- inj. fentanyl 2 µg/kg in the first 24 hours postoperatively [Table/Fig-8]. Group P, on the other hand, did not require any interventional analgesic throughout the postoperative period of 48 hours. This excludes the two patients who had to be administered one dose of inj. tramadol 100 mg i.v., at the 3rd hour as they were under physiological and psychological stress with them being separated from their babies who had to be admitted in the neonatal intensive care unit [Tables/Fig-7,8].

Group P had VAS scores <3 (p<0.05) with only one patient reporting emesis and two patients having the need for rescue analgesic

Interventional Analgesic... VAS ≥4			
Time	Group P n=30	Group C n=30	Remarks
1st Hour	-	-	
2nd Hour	-	27 (90%)	
3rd Hour	2 (7%)	3 (10%)	
4th Hour	-	-	
5th Hour	-	4 (13%)	Fentanyl
6th Hour	-	-	
8th Hour	-	15 (50%)	
10th Hour	-	6 (20%)	
12th Hour	-	9 (30%)	
18th Hour	-	30 (100%)	
24th Hour	-	-	
36th Hour	-	30 (100%)	
48th Hour	-	30 (100%)	

[Table/Fig-6]: Requirement of rescue analgesics.

Avg. Opioid Consumption/Day	Group P n=30	Group C n=30
Tramadol		
Day 1	6.66 mg	300 mg
Day 2	-	200 mg
Fentanyl		
Day 1	-	13.33 micrograms
Day 2	-	-

[Table/Fig-7]: Average opioid consumption in both groups.

Parameter	Group P	Group C	p-value
Max. VAS score in 24 h†	2.53±0.64	4.97±0.47	<0.001**
Patients receiving tramadol (n%) in 24 h‡	2 (7%)	30 (100%)	<0.001**
Patients receiving fentanyl (n%) in 24 h‡	0	4 (13%)	0.01*
Postoperative nausea and vomiting†	1 (3%)	12 (40%)	<0.001**
Max. sedation score in 24 h†	2	3	0.01*

[Table/Fig-8]: Comparison of pain scores, adverse effect and sedation scores.
Data: Mean±SD: †t-test ‡Pearson's Chi-square; *p<0.05 statistically significant **p<0.001 statistically highly significant

throughout the study. Group C had VAS scores >6 and had to receive rescue analgesic (inj. tramadol) thrice a day. Further they had instances of vomiting (40%) and cognitive impairment, thereby affecting ambulation and breastfeeding.

DISCUSSION

With dramatic rise in the rate of caesarean sections, many patients still suffer from moderate to severe pain although new drug delivery systems are available. The analgesia produced by auriculotherapy depends on the release of endogenous opioid substances, generically referred to as endorphins. This analgesia network controls pain at the level of spinal cord. Complex psychologic factors also play an important role in the variability of perceived pain, partly because of their ability to trigger this pain-suppressing system [24].

Chang L et al., conducted a randomised controlled study to investigate the potential benefits of auriculotherapy for postoperative pain relief in patients who underwent total knee replacement. Sixty-two patients were randomly allocated to either the interventional group or the control group. The acupressure was performed three times a day for three days. Analgesic drug consumption showed a remarkable decrease in the acupressure group in comparison to the control group (p<0.05) and improved passive knee motion was also seen by the third postoperative day in patients treated with acupressure (p<0.05) [25]. Usichenko T et al., found that auriculotherapy is effective in the treatment of postoperative pain conditions including total hip arthroplasty and total knee replacement [26]. Sim CK et al., compared preoperative

versus postoperative body acutherapy for lower abdominal gynaecologic surgery. Preoperative acutherapy was found to be more effective in reducing postoperative morphine consumption in these patients [27]. The present study demonstrated high opioid consumption in the control group in the first 48 hours compared to the auriculotherapy group. Similarly Hendawy AH and Albuenga ME demonstrated in their study that the total postoperative Patient Controlled Analgesia (PCA) morphine consumption in the first 24 hours was reduced in the auriculotherapy intervention group versus the control group; also the time of the first request for supplemental analgesia was delayed in the intervention group-compared with the control group [28].

In the present study, the rescue analgesic requirement in intervention group vs control group was much reduced which was highly statistically significant p<0.001. In the present study, the VAS pain scores were lower in the auriculotherapy group (2.53±0.64) compared to the control group (4.97±0.47). Similar to the present study findings, a prospective, randomised study was conducted by Wu HC et al., on 60 primigravida women scheduled for caesarean section under spinal anaesthesia. Patients were allocated to one of three groups: control group, acutherapy group, and electro acutherapy group. Electroacutherapy was started postoperatively after recovery from anaesthesia and was applied for San yin Jiao (Sp6) body acupoint for 30 minutes. The results showed delayed first analgesic request in both the electroacutherapy group (39.5±16.9 minutes) and the acutherapy group (40.3±13.8 minutes) versus the control group (29.0±15.0 minutes). The total PCA morphine consumption during the first 24 postoperative hours was much reduced in the acutherapy group (10.66±4.68 mg), and the electroacutherapy was (9.89±5.18 mg) than in the control group was (15.28±4.99 mg). They Hung-Chien WU et al., also found that VAS pain scores were significantly lower in the auriculotherapy group versus the control group at 0.5, 1, 1.5, and 2 hours in the postoperative period [29].

Iacobone M et al., found reduced postoperative pain scores as well as decreased postoperative acetaminophen consumption in auriculotherapy treated groups when compared to the control group in patients who underwent thyroidectomy under general anaesthesia [30]. Chen CC et al., have investigated the effect of auriculotherapy on pain relief following total knee arthroplasty in a randomised controlled trial. The total amount of postoperative fentanyl consumption was found much reduced in the auriculotherapy treated group in comparison with the control group {mean (SD), 620.7 (258. 2) vs. 868.6 (319.3) µg, respectively}, as well as delayed first request for fentanyl {median time, 89 vs. 37 min}, in the acupuncture group and the control group respectively. Postoperative pain scores were much reduced in the acupuncture group versus the control groups at 2, 4, 8, 12, and 24 hours [31]. Dingemann J et al., have found in their study the efficacy of acutherapy in reducing postoperative swallowing pain scores following tonsillectomy in patients aged 16 years or more [32].

Complementary and Alternative Medicine (CAM) therapies, especially auriculotherapy tend to be cheaper, less invasive, and of lower risk than treatment with strong narcotics and invasive interventions.Auriculotherapy can reduce the severity of pain, allowing for reduced doses of analgesics [33,34]. Considering the complex interaction between cytokines, neuropeptides, and neurotrophins possible pathways of auriculotherapy therapy in increasing threshold of somatic pain include downregulation of proinflammatory cytokines and the upregulation of anti-inflammatory cytokines, downregulation of proinflammatory neuropeptides (e.g., calcitonin gene-related peptide), downregulation of neurotrophins {e.g., Nerve Growth Factor (NGF)}, release of spinal natural opioids dynorphin, endorphin, enkephalin, increase in local blood flow that aids in healing process, gate control theory of pain [35,36]. Hence, auriculotherapy is effective for treating various types of pain, especially postoperative pain following various types of surgeries predominantly abdominal and orthopaedic surgeries. Auriculotherapy analgesia works on a central mechanism independent of the type of pain with early ambulation, breastfeeding, and no adverse effects of opioids.

Limitation(s)

As this study was conducted in special population of antenatal women undergoing caesarean section, authors were able to carry out only in the minimum limit with restricted sample of willing mothers. Study needs to be correlated in a larger population size which would reinforce the results and justify the study objectives. Two patients in Group P required rescue analgesics which was attributed to psychological and physiological stress from separation of their babies, the reason for which were not able to justify which could be a confounding factor in this attribute. Another limitation of the study is that auriculotherapy cannot act as a full replacement to analgesic drugs for postoperative analgesia. It can always function only as an adjuvant and reduce the requirement of postoperative analgesics.

CONCLUSION(S)

Percutaneous stimulation of auricular pressure points has the ability to stimulate brain and release natural opiates, control hormones thereby, relieving pain. The above is proved in the study (Group P), over a period of 48 hours, by low VAS scores, low sedation scores, less incidence of postoperative nausea and vomiting and no drug related side-effects. This non narcotic method of pain management is excellent in improving essential aspects of mother-baby emotional bonding with early and successful breastfeeding, early ambulation, pain free postoperative period, thereby avoiding opioid side-effects such as nausea, vomiting, sedation, pruritus, urinary retention and constipation.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Feb 24, 2023
- Manual Googling: Apr 12, 2023
- iThenticate Software: May 03, 2023 (23%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Feb 15, 2023**
Date of Peer Review: **Mar 14, 2023**
Date of Acceptance: **May 08, 2023**
Date of Publishing: **Jun 01, 2023**