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Comparison of Intravenous Ondansetrone versus Stimulation of P6 Acupuncture Point in Prevention of Intraoperative Nausea and Vomiting during Caesarean Section

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ABSTRACT

Objective: To draw a comparison between acupuncture point stimulation with prototype drug ondansetron to establish its efficacy.

Study Design: Quasi-Experimental study.

Place and Duration of Study: Anesthesia department, Combined Military Hospital, Quetta Pakistan, from Aug 2022 to Jan 2023.

Methodology: Hospitals ethical committee given its permission with IERB number# ERC/88/2023. 50 patients were included in the study, with 25 in each study group as OS (Ondansetrone), who received intravenous ondansetron and OP (Acupuncture) group who received stimulation of P6 acupunture point. The gravid ladies with reproductive age group (18 to 40 years) were included. The patients were monitored for any nausea/retching and vomiting as primary outcome.

Results: The frequency of nausea and vomiting was analogous in both study groups. 10(20%) patients who received ondansetron developed nausea and vomiting while 23(46%) patients did not have any episode of nausea, vomiting or retching. Similarly, 38(76%) group OP patients who were underwent transcutaneous stimulation of Nei-Kuan point didn't show any signs of nausea and vomiting. 12(24%) patients in group OP developed nausea and vomiting which was comparable to group OS statistics with p value of 0.405. This shows that there was no significant difference between two study group.

Conclusion: Stimulation of P6 acupunture point was analogous to ondansetron for prevention of intra-operative nausea and vomiting.

Keywords: Acupunture Point, Ondansetron and Vomiting.

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INTRODUCTION

Perioperative Nausea and Vomiting (PONV) is a common complication of surgery and anaesthesia that adds to misery and distress of patient's. It contributes to extended hospital stay and increased healthcare costs with incidence escalating to eighty percent in vulnerable population and thirty percent in non-vulnerable population.[1] According to the American Society of Anaesthesiologists (ASA), post-operative nausea and vomiting is thirty percent in patients undergoing laparoscopic or gynaecologic procedures.[2] A systematic review published in 2018 by the European Society of Anaesthesiology and Intensive Care Medicine showed that female patients, non-smokers, patients with history of motion sickness or nausea are more prone to it and use of opioid and general anaesthesia can further aggravate it.[3] The authors emphasized that early detection and timely intervention could reduce the incidence of PONV as when it is fully established, it becomes hard to treat. Their study highlighted the importance of prophylaxis.

There are a number of treatment options for prophylaxis and treatment of nausea and vomiting which include pharmacological and non-pharmacological approaches. However, for intra-operative nausea and vomiting, there is predominance of pharmacological agents which are 5-HT3 receptor antagonists, such as ondansetron and neurokinin 1 receptor antagonists, such as aprepitant. Non-pharmacological treatments for PONV are less common for perioperative or intra-operative use , some of which are acupuncture, ginger, and acupressure.[4,5]

Acupuncture has been recently used for postoperative nausea and vomiting (PONV).[6] The stimulation of the P6 (Neiguan) acupuncture point been postulated to modulate the vomiting centre in the brain and reduce the incidence of PONV.[7] According to meta-analysis conducted by A Bao *et al.*, which comprised data analysis involving over a thousand patients, acupuncture was found more

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effective than ondansetron in some cases of peri-operative nausea and vomiting.[8] The study of X. Zhang *et al.,* done on 120 patients found that both ondansetrone and acupuncture were effective in treatment of nausea and vomiting and there was no significant difference in their efficacy.[9] The incidence of nausea& vomiting in vulnerable patients like gravid ladies undergoing spinal anaesthesia is very high and once fully established, it takes time to settle. Therefore, prevention and timely prophylaxis is way to go. Therefore, the rational of our study is to compare ondansetrone with non-pharmacological technique that is stimulation of P6 accupunture point for intraoperative nausea and vomiting in gravid ladies undergoing caesarean section under spinal anesthesia. The origins of acupuncture can be traced back over 2,000 years to ancient China, where it was developed as part of the broader system of traditional Chinese medicine (TCM). In TCM, the body is believed to have a natural flow of energy, or "qi," that can be influenced by the insertion of acupuncture needles. By stimulating specific points on the body, practitioners aim to balance the flow of qi and restore health. Acupuncture has been now the subject of scientific research, and there is ongoing research to support its efficacy for treating a range of conditions, including chronic pain, headaches, and digestive disorders. Our study will also help understand it and explore its efficacy.

METHODOLOGY

This Quasi-Experimental research was carried out at Combined Military Hospital, Quetta Pakistan. The data was collected over a period of six months 1st August 2022 to January 2023. Hospitals ethical committee given its permission with IERB number# ERC/88/2023.The sample size of 104 patients (52 patients in each group) was estimated using 5% level of significance, 80% power of test, expected percentage of nausea& vomiting in both groups i.e. 76[10] and 36.[10] Sampling technique was non-probability consecutive sampling. Both groups were labelled as OS (Ondansetrone) group and OP (Acupuncture) group.

Inclusion Criteria: The gravid ladies with reproductive age group (18 to 40 years) undergoing caesarean section with American society of anaesthesiology physical status classification II were included in the study.

Exclusion Criteria: Pregnant ladies with pre-eclampsia, eclampsia, neuropsychiatric disorders, gestational diabetes, gestational hypertension, epilepsy and gastroesophageal reflux disease were excluded from the study. The informed consent of the patients was taken and purpose of study was explained.

All the Group OS patients were laid supine on operation theatre table on day of surgery. 16-gauge cannula (B Braun) was passed under aseptic condition and standard monitoring was applied. Crystalloid solution (lactated ringer) was co-loaded along with subarachoid block at L4-L5 interspace with 2ml of 0.5% hyperbaric bupivacaine (sensocainespinal 0.5%, Hogwarths). They were given 8mg of ondansetrone after spinal anesthesia. All the patients were monitored for any nausea/reching or vomiting along with standard monitoring. All the Group OP patients were laid supine on operation theatre table on day of surgery. 16-gauge cannula (B Braun) was passed under aseptic condition and standard monitoring was applied. The p6 ocuupuncture point was identified. It was area on flexor surface of forearm, in the middle of tendons of flexor carpi radialis and Palmaris longus muscles two centimetres cranial to the most distal skin crease of wrist joint.[11] Two Self adhesive electrodes with conductive gel were applied to the area marked as p6 accupunture point. The proximal electrode was applied 6 cm cranial to the p6 point and distal was applied 6 cm distal to the point. The current amplitude was kept constant at 60mA (high intensity and low frequency current) for uniformity. After application of TENS, Crystalloid solution (lactated ringer) was co-loaded along with subarachoid block at L4-L5 interspace with 2ml of 0.5% hyperbaric bupivacaine (sensocainespinal 0.5%, Hogwarths). Patients were laid supine with wedge under right buttock. Immediately after assumption of supine position TENS was applied to the P6 acupuncture point for thirty minutes. The patients were monitored for any nausea/retching and vomiting along with standard monitoring.

The most notable outcome was frequency and percentage of nausea/retching/ vomiting in both groups. The data was recorded on statistical package of social science (SPSS) version 26 and analysed to figure out Mean$\pm$SD and frequencies (& percentages) of different variables (quantitative and qualitative). Chi-square analysis was employed to understand the difference of effectiveness between both study groups indicated by *p*-value. The *p*-value less than 0.05 was seen as statistically significant.

RESULTS

The outcome was frequency of nausea/retching in both study groups. The demographics of both study

sets were analogous. The mean age of patients in group OS was 27.70±4.11 while it was 27.80±3.94 in group OP patients. The mean weight of gravid ladies was 70.46±4.76 in OS group and 67.34±2.47 in OP group. Other demographics like height, gestational age and duration of surgery was also comparable. Total 5(10) patients in group OS were having 1st pregnancy, 23(46) had 2nd pregnancy, 19(38) has 3rd pregnancy and 3(6) had 4th pregnancy. While in group OP frequency of parity was: 5(10) para one, 22(44) para 2, 21(42) para 3 and 2(4) para four as presented in Table-I.

Table-I: The Dempgraphic Variables of Study Groups (n=50)

		Group OS n=50 Mean±SD	Group OP n=50 Mean±SD
Age (years)		27.70 ±4.11	27.80±3.94
Weight (Kg)		70.46 ±4.76	67.34±2.47
Height (cm)		152.28± 3.55	153.52±3.05
Gestational age (weeks)		38.18 ±0.89	38.14±0.88
Duration of surgery (minutes)		38.28± 0.88	38.20±0.70
		Frequency (%)	**Frequency (%)**
parity	1	5(10)	5(10)
	2	23(46)	22(44)
	3	19(38)	21(42)
	4	3(6)	2(4)

The frequency of nausea and vomiting was analogous in both study groups. In ondansetron group (OS), 10(20%) patients developed nausea and vomiting while 23(46%) patients did not have any episode of nausea, vomiting or retching. 38(76%) patients of group OP patients who were underwent trans-cutaneous stimulation of Nei-Kuan pointdidn't show any signs of nausea and vomiting. 12(24%) patients in group OP developed nausea and vomiting which was comparable to group OS statistics with *p*-value of 0.405. This shows that there was no significant difference between two study groups (Table-II).

Table-II: The Frequency of Nausea and Vomiting in both Study Groups (n=50)

		Frequency n(%)	*p*-value
OS Group	Yes	10(20)	0.405
	No	40(80)	
OP Group	Yes	12(24)	
	No	38(76)	

DISCUSSION

Although the risk of nausea and vomiting encompasses whole of the peri-operative period but the maximum risk is intra-operative. Once established fully the patients get anxious and disturbed. The anxiety remains throughout the procedure and nausea tends to stay. Therefore, the focus of our study was intra-operative period. Our study showed that the efficacy of electrical stimulation of P6 acupuncture point was comparable to ondansetron, which is a prototype antiemetic.

The use of non-pharmacological methods seems appealing as it avoids polypharmacy and adverse effects related to drugs. Generally 5-HT3 receptor antagonists are considered safe drugs but there are case reports of urticaria[11] to fatal anaphylaxis with ondansetron.[12]

The use of non-pharmacological methods seems a little unusual in intra-operative setting as it seems time consuming and cumbersome but careful observation led us to the conclusion that its application took not more than application of other standard monitoring leads like electrocardiography. Patients tolerated it well and it didn't cause any interference with electrocardiography or cautery.

The use of acupressure for prevention of nausea and vomiting induced by pregnancy had been studied by Mobarakabadi *et al.,* in their RCT.[13] They applied sea-band button to seventy eight gravid ladies for 3 days and found out that there was substantial improvement in symptoms. All ladies were in second trimester of pregnancy. The result of their study pointed at the use of acupressure as a modality for nausea and vomiting. The use of acupressure does not seem realistic for whole of gestational period but its use for short time period seems promising and practical. We therefore used more pragmatic approach for using it for intra-operative period and we easily managed to carry the intervention.

The study population in our study were pregnant females who already have a predisposition for nausea which is made worse by spinal anaesthesia induced hypotension. The stimulation of P6 acupuncture point has been suggested to be effective in chemotherapy induced nausea and vomiting. Suh *et al.,* studied the effect of P6 acupuncture point stimulation in their randomized controlled trial. They studied this intervention on almost hundred females undergoing chemotherapy due to breast malignancy.[14] They used this intervention along with counselling by nurse attending the case. They found that the stimulation of P6 acupuncture point along with counselling by nursing staff was effective in treatment of nausea and vomiting. However, we applied TENS to our patients and omitted the counselling part.

We used TENS as it produces a pleasant and soothing sensation instead of producing discomfort. It has no potential for injury or harm.[15] The P6 point is also called Pericardium Channel of Hand-Jueyin and Nei-Kuan point.[16] The traditional Chinese medical practice involves the insertion of fine needles into specific points on the body to relieve pain and improve physical function. We didn't use needle insertion as it is traumatic.[17]

The exact mechanism by which P6 stimulation (also known as Neiguanacupoint stimulation) reduces postoperative nausea and vomiting (PONV) is not well understood. Some theories propose that P6 stimulation may affect the activity of the autonomic nervous system and the release of certain neurotransmitters, such as serotonin and dopamine, that are involved in controlling nausea and vomiting.[18] One proposed mechanism is that P6 stimulation stimulates the release of endogenous opioids, such as beta-endorphins, which have anti-nociceptive and antiemetic effects.Another theory suggests that P6 stimulation may activate the vagus nerve, which modulates the activity of the vomiting center in the brain and helps to prevent PONV.[19]

Formenti *et al.,* investigated various methods of stimulating the P6 acupoint in their review article including manual pressure, electrical stimulation, and acupressure wristbands in critically ill patients. They established that acupuncture had high patient acceptance. They studied whole body effects of acupuncture including its effects on respiratory system, nutrition, pain, dizziness, depression, homeostasis and delirium. They suggested research to learn the efficacy of acupuncture. However we confined ourselves to nausea and vomiting involving stimulation of Nei-Kuan point for flow of Qi along meridians.[20]

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LIMITATION OF STUDY

Our study only focused on intra-operative period due to limited availability of TENS machine and increased turnover of patients. Profound hypotension leads to nausea and vomiting in non-vulnerable individuals as well but we focused the high risk population.

CONCLUSION

We concluded that stimulation of P6 acupunture point was analogous to ondansetron for prevention of intra-operative nausea and vomiting.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

TF & KM: Data acquisition, data analysis, critical review, approval of the final version to be published.

NA & SQ: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

CAA & AH: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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