

A COMPARATIVE STUDY TO EVALUATE THE EFFECTIVENESS OF P6 ACUPOINT STIMULATION VERSUS ONDANSETRON FOR PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING

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ABSTRACT

BACKGROUND AND AIMS

Postoperative Nausea and Vomiting (PONV) is one of the most common and distressing problems after anaesthesia and surgery. 5-HT₃ receptor antagonist ondansetron is widely used for PONV prophylaxis. P6 acupoint stimulation, a non-pharmacological technique is a simple, inexpensive, and effective method for prevention of PONV. We compared the efficacy of P6 acupoint stimulation against monotherapy with intravenous ondansetron for prophylaxis of PONV.

METHODS

One hundred American Society of Anaesthesiologists - I or II patients, aged between 18 and 65 years, scheduled for thyroidectomy under general anaesthesia were included in this prospective, randomised, double-blind study. The patients were randomised into two groups: Group A (acupuncture) and Group O (ondansetron). PONV was assessed in two epochs of 0-6 and 6-24 hrs. Primary outcome measure was incidence of PONV and secondary outcome measures were severity of PONV, need for rescue antiemetic, overall patient satisfaction, and side effects to either intervention. Outcome was compared using Mann-Whitney U-test or chi-square test as applicable.

RESULTS

Data of 100 patients were analysed. The incidence of PONV was similar during the 24 hrs. period in both groups. Complete response was seen in 82% of patients in both groups in the first 6 hrs. and in 98% in the late postoperative period. There was no difference in the requirement of rescue antiemetic or severity of PONV between the groups. Over all patient satisfaction was comparable in both groups.

CONCLUSION

P6 acupoint stimulation is safe, inexpensive, and equally effective as monotherapy with intravenous ondansetron in preventing PONV.

KEYWORDS

Ondansetron, Postoperative Nausea and Vomiting, Thyroidectomy, P6 Acupoint.

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INTRODUCTION: Postoperative Nausea and Vomiting (PONV) is a relatively common complication that result in patient discomfort and prolonged stay in the postanesthesia care unit. Patient satisfaction after anaesthesia is significantly reduced when PONV occurs. Reported incidence varies from 20-30%, but maybe as high as 70-80% depending on surgical and patient factors.^[1,2] There are a number of drugs that are used to manage PONV including antihistamines, phenothiazine derivatives, anticholinergics, and dopamine receptor antagonists, which have unwanted side effects like sedation, dysphoria, extrapyramidal symptoms, dry mouth, restlessness, and tachycardia.^[1,3]

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5-HT₃ receptor antagonists are devoid of such side effects and highly effective in prevention and treatment of PONV. Commonly used drug is ondansetron, which has proved its benefit both in cancer therapy and management of postoperative nausea and vomiting.^[1-3] There is considerable evidence that acupuncture applied at the traditional acupuncture point P6 is effective at preventing PONV with very few side effects.^[4] Stimulation of acupuncture point P6 by acupuncture needles, acupressure, electropuncture, wrist band, etc. has been used to prevent and treat nausea and vomiting.^[4-6] National Institutes of Health Consensus Panel concluded that acupuncture is effective for PONV and P6 acupoint stimulation could be used as an adjunct to antiemetics or was an acceptable alternative in patients with high risk of PONV.^[4] Acupuncture point P6 (Neiguan) lies 2 inches proximal to wrist joint (3 patient's fingerbreadth proximal to proximal wrist joint crease), 0.5-1 inches deep between palmaris longus and flexor carpi radialis tendon [Figure 1, 2].



Fig. 1: P6 Acupoint

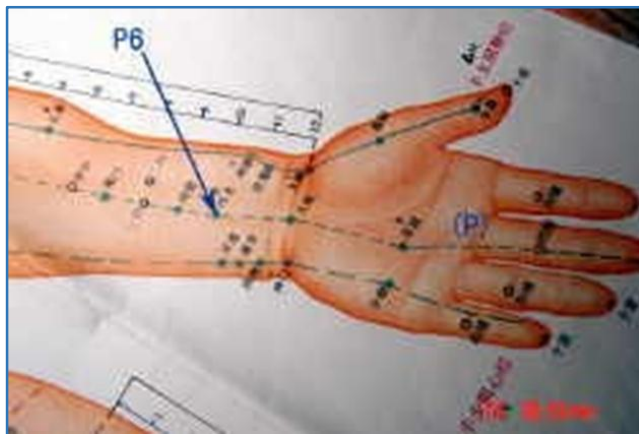


Fig. 2: P6 Acupuncture Point

AIM AND OBJECTIVES: The present study was done to compare the efficacy of P6 acupoint stimulation against monotherapy with intravenous ondansetron for prevention of postoperative nausea and vomiting in patients undergoing thyroidectomy.

MATERIALS AND METHODS: After obtaining approval of the hospital ethical committee and written informed consent from patients, 100 American Society of Anaesthesiologists Physical Status Classification Class I and II patients, in the age group 18-65 years, scheduled for thyroidectomy under general anaesthesia were included in this prospective, randomised, double-blind study. Patients with history of motion sickness or previous history of PONV, peptic ulcer disease, intrathoracic goiter, and those who had received antiemetics within 24 hrs. preoperatively menstruating females and patients with a body mass index greater than 30 were excluded from the study.

After overnight fasting and premedication with oral omeprazole 20 mg the night before and on the morning of surgery, patients were randomised into two groups: Group A - acupuncture group (n=50) and Group O - ondansetron group (n=50) using random number table. In the operating room, after obtaining venous access and attaching routine monitoring, all patients were premedicated with midazolam 0.5 mg IV (intravenously) and glycopyrrolate 0.2 mg IV. Anaesthesia was standardised. Following induction with thiopentone sodium (3-5 mg/kg), tracheal intubation was facilitated with succinylcholine 1.5 mg/kg.

Anaesthesia was maintained with oxygen (33%), nitrous oxide (66%), halothane (0.5%), vecuronium 0.1 mg/kg, and morphine 0.1 mg/kg. Patients were randomised according to a computer generated random number table to receive ondansetron or P6 stimulation. P6 acupoint stimulation was given after induction of anaesthesia by injection of 1 mL sterile water subcutaneously on both forearms at 3 finger breadth proximal to wrist joint between palmaris longus tendon and flexor carpi radialis tendon. Ondansetron 4 mg IV was given at the beginning of surgical closure. In both groups, a plaster was taped to P6 points. These drugs were prepared and administered by an anaesthetist, not otherwise involved in patient care, to maintain the double-blind nature of study.

Intraoperative fluid management consists of administration of normal saline solution sufficient to correct half of the fluid deficit in the first hour followed by maintenance fluids according to body weight. Intravenous diclofenac sodium (75 mg) was administered for postoperative analgesia. At the end of surgery, oral suction was given and residual neuromuscular blockade was antagonised with 0.05 mg/kg neostigmine and 0.01 mg/kg glycopyrrolate and trachea was extubated when patient was awake. The duration of surgery and anaesthesia were noted. After the operation, the patient was transported to the postanaesthesia care unit (PACU).

The incidence and severity of PONV and need for rescue antiemetic were recorded over the next 24 hrs. in two epochs of 0-6 and 6-24 hrs., early and late respectively. Nausea was defined as the desire to vomit. An episode of vomiting was defined as either vomiting (expulsion of stomach contents) or retching (an involuntary attempt to vomit, but not productive of stomach contents). All episodes of nausea and vomiting in the first 24 hrs. period were evaluated using a numeric scoring system for PONV by Mathew et al (0 = no nausea, no vomiting, 1 = nausea present, no vomiting, 2 = nausea ± vomiting present, and 3 = vomiting >2 episodes in 30 min) by PACU or ward nursing staff who were aware of the nature of the study, but blinded to the study drug.^[7] Any patient having score of 3 was considered to have severe PONV and was treated with metoclopramide 10 mg IV as a rescue antiemetic.

The criteria for discharge from PACU to ward include stable vital signs and no nausea and vomiting in first 2 hrs. after surgery. Those who had PONV and pain in the first 2 hrs. of stay were observed in PACU till they remained free of PONV and pain for an hour. Finally, at the end of 24 hrs. after surgery, the primary care taker was asked to give a global assessment and their satisfaction over the entire postoperative experience of the patient using an 11-point verbal numeric scoring system (0-not at all satisfied, 1-4 less satisfied, 5-9 more satisfied, but not fully satisfied and 10-fully satisfied). The primary outcome measure was the incidence of PONV during the first 24 hrs. Secondary outcome measures were severity of PONV, need for rescue antiemetic, overall patient satisfaction, and side effects to either intervention like headache, dizziness, swelling, erythema at wrist, etc.

Continuous data was presented as mean, standard deviation or median as appropriate. Qualitative or categorical variables were described as frequencies and percentages. Quantitative variables were compared using Mann-Whitney U test. Chi-square test was used to compare qualitative variables between the two groups. A p value <0.05 was considered as significant.

RESULTS: The study enrolled 100 patients randomised into two groups. The two groups were comparable with respect to their age, gender, and weight. There was no statistically significant difference among two groups with respect to duration of surgery and anaesthesia [Table 1].

Parameter	Group A (n=50)	Group O (n=50)	P value
Mean Age±SD (years)*	39.8±11	39.1±11.2	0.994
Gender: Male/Female+	6/44	6/44	1
Mean weight±SD*	51.88±4.9	51.04±4.8	0.43
Duration of Surgery (h)*	2.02	1.91	0.159
Duration of Anaesthesia (h)*	2.245	2.191	0.961

Table 1: Demographic Profile

SD = standard deviation, *Mann-Whitney U test, + chi-square test, P>0.05 not significant.

Time Period		Group A n (%)	Group O n (%)	P value
0-6 hrs.	PONV score 0	41 (82)	41(82)	1
	PONV score 1	6	5	
	PONV score 2	2	3	
	PONV score 3	1	1	
	Rescue Antiemetic	1	1	
6-24 hrs.	PONV score 0	49 (98)	49 (98)	1
	PONV score 1	0	0	
	PONV score 2	0	0	
	PONV score 3	1	1	
	Rescue Antiemetic	1	1	1
0-24 hrs.	PONV score 0	41	41	1
	Rescue Antiemetic	1	1	1

Table 2: Postoperative Nausea and Vomiting

Group	Score 0 (Not at all Satisfied)	Score 1-4 (Less Satisfied)	Score 5-9 (More Satisfied)	Score 10 (Fully Satisfied)
Acupuncture	3	3	0	44
Ondansetron	2	3	4	41

Table 3: Patient Satisfaction Score

P value = 0.23

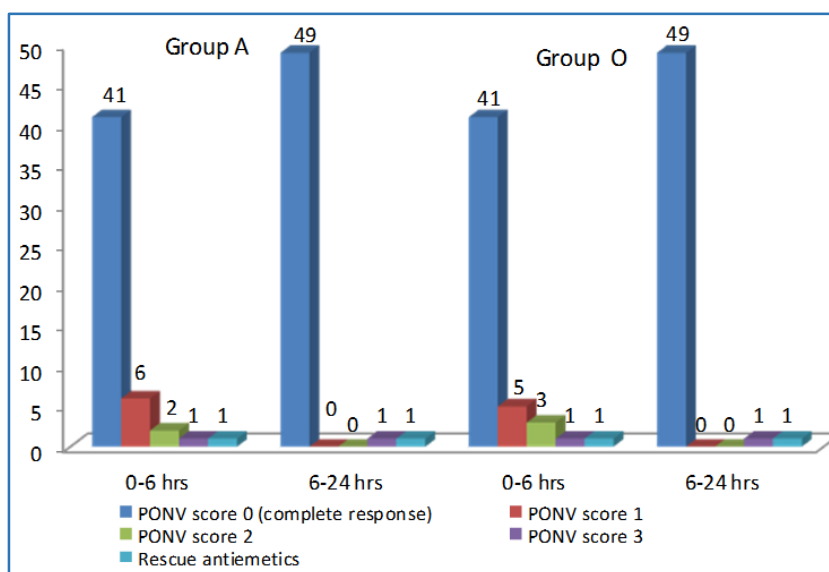


Fig. 3: PONV Score Over 24 Hrs.

There was no significant difference in the incidence of PONV or in the PONV scores during the early and late postoperative period between the two groups [Figure 3]. Complete response was seen in 82% of patients in both

groups in the first 6 hrs. and in 98% in the late postoperative period. The requirement of antiemetic was similar between the two groups in the 24 hrs. period [Table 2]. There was no significant difference in the patient satisfaction score

between the two groups [Table 3]. In our study, the side effects like tingling sensation, swelling, and erythema at the wrist were not seen in acustimulation group. Also, in ondansetron group, side effects like headache, Q-T interval abnormalities, and dizziness were not seen.

DISCUSSION: The commonest cause of morbidity after anaesthesia and surgery are pain and postoperative nausea and vomiting. Fear of PONV is worse than fear of potential surgical pain. The incidences of PONV range from 65% to 75% when antiemetic treatment is not considered prophylactically in patients undergoing thyroidectomy.^[8] This high incidence may justify the use of prophylactic antiemetic after thyroidectomy. The aetiology of PONV following thyroidectomy is not fully understood. Probably, it is related to several factors like age and gender of patients (more in women), intense perioperative parasympathetic stimulation (surgical handling of neck structures), use of inhalational agents, opioids, and postoperative pain.^[8] The two study groups were not significantly different with respect to patient characteristics. They had comparable duration of anaesthesia and surgery. Patients in both groups underwent a standardised anaesthetic technique. Therefore, the difference in control of PONV may reasonably be attributed to the intervention done. For ethical reasons, we did not include a control group using placebo as these patients had high risk for PONV. So, the basic incidence rate for PONV in this particular procedure was not determined.

Ondansetron is one of first line drugs for prophylaxis of PONV with minor adverse effects.^[1,2,6,9] However, 5-HT₃ antagonists especially the newer ones are costly. An ampoule of ondansetron 4 mg costs about 35 Indian rupees in addition to the expense of disposables. The half-life of ondansetron is approximately 3.5-4 hrs. in adults. Administering it towards the end of procedure ensures maximum duration of action postoperatively. Considering the lower body mass of our patient population ondansetron 4 mg was used as the prophylactic dose. This was in accordance with the recommendation of recent consensus guidelines for management of PONV.^[3]

In a recent meta-analysis of 40 randomised clinical trials on PONV by Lee and Fan, they concluded that P6 acupoint stimulation prevented PONV and the need for antiemetic rescue. In this, they compared 10 methods of P6 acupoint stimulation (Acupuncture, Acupressure, Infiltration, Laser Stimulation, etc.) with five commonly used antiemetic drugs and found that P6 acupoint stimulation is equally effective for prophylaxis of PONV. They found no difference in the effectiveness of P6 stimulation for adults and children or for invasive and non-invasive acupoint stimulation techniques. Effect of P6 stimulation on PONV was similar irrespective of the time of initiation before or after induction.^[4] White PF in his review course lecture on PONV suggested that consideration should be given to routine use of less costly devices like acupressure bands as first line prophylaxis against PONV.^[2]

This study was conducted to compare the efficacy of P6 acupoint stimulation against ondansetron in prophylaxis of

PONV. We included 50 patients who underwent thyroidectomy in each group. The study results showed that in the initial 6 hrs. after anaesthesia a complete response (No PONV, no rescue antiemetic) occurred in 82% of patients of both groups. PONV score was comparable between the two groups in the early postoperative period. One patient in both groups had a PONV score of three requiring rescue antiemetic.

A randomised controlled trial comparing acupoint P6 stimulation or ondansetron versus placebo for prevention of PONV in patients undergoing major breast surgery under general anaesthesia found that electroacupoint stimulation of P6 was as effective as single dose of ondansetron. Nausea was better controlled in P6 stimulation group. They found that acustimulation of P6 also had analgesic effects.^[6] The effect of acupuncture at P6 on nausea and vomiting and consumption of propofol in caesarean section performed under spinal anaesthesia was evaluated by Kilic and colleagues. P6 point stimulation by acupuncture was demonstrated to decrease nausea and vomiting during caesarean section and requirement of propofol for the same.^[5]

In our study, we compared PONV in 6-24 hours and found that complete response is obtained in 98% of patients in both groups. The two patients who had a PONV score of three in first 6 hrs. continued to have vomiting requiring rescue antiemetic in late postoperative period also. In the 24 hrs. period, complete response was observed in 82% patients of both groups. Patient satisfaction score was 10 in 44 patients of acupuncture group and 41 patients of ondansetron group. The difference was not significant. Similar results were obtained in study conducted by Gan and colleagues.^[6]

Another systematic review and meta-analysis recommended popularising P6 acupoint stimulation for prevention of PONV for its efficacy, safety, and cost effectiveness.^[10] Combination of P6 and L14 acupoints stimulation was found to be more effective than P6 alone in the study by Alizadeh and co-workers.^[11] Margarita et al studied the efficacy of P6 acustimulation, ondansetron, and both in 90 patients with established PONV after laparoscopic surgery. P6 stimulation and ondansetron was found to be equally effective and combining the two improved the complete response rate.^[12] The acupuncture relief bands is of great value in setting of daycare procedures and as a part of multimodal therapy for prophylaxis and treatment of PONV in patients with high risk of emesis.^[3] Acupuncture stimulation of P6 was found to be more effective than ondansetron in preventing carboprost-induced vomiting in patients undergoing caesarean under subarachnoid block.^[13] P6 stimulation is an upcoming treatment for nausea and vomiting of pregnancy.^[14] It was also found to be effective in treating vomiting following radiation and chemotherapy.^[15]

Using the prophylactic or a similar class antiemetic as rescue medication is considered ineffective and current recommendation is to use an agent belonging to a different class when prophylaxis fails.^[3] We used metoclopramide 10

mg as rescue antiemetic. In our study, the side effects like tingling sensation at wrist, swelling at wrist, and erythema at wrist were not seen in acustimulation group. Also, in ondansetron group, side effects like headache, dizziness were not seen.

There are a few limitations of our study. Unrelieved pain is an important cause of PONV. We did not measure and compare the pain and anxiety in the perioperative period, which may influence the incidence of PONV. However, we used a predefined dose of opioid and diclofenac for perioperative analgesia and followed a standardised anaesthesia protocol. This may have eliminated the influence of pain on the incidence of PONV. We also did not assess individual patients risk for PONV using scoring systems like Apfels.^[16] Future studies with larger sample size are necessary to demonstrate efficacy of one over another or effect of combining the two on PONV.

When patients undergoing a pre-anaesthetic evaluation were asked which postoperative side effects were of greatest concern, PONV accounted for 49% of the responses. Over 70% of patients considered avoidance of PONV to be very important.^[17] Prevention of PONV improves quality of patient care and reduces length of hospital stay and healthcare expenses. As anaesthetists continue to search for more cost effective approaches for patient care, P6 stimulation should be encouraged as a simple, effective, minimally invasive, and inexpensive technique for prophylaxis of PONV.

CONCLUSION: The study shows that P6 acupoint stimulation is equally efficacious and maybe more cost effective than ondansetron for preventing PONV.

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