

Comparison of P6 Acupoint Stimulation, Ondansetron and Dexamethasone for Prevention of Postoperative Nausea and Vomiting after Laparoscopic Surgeries: A Randomised Clinical Study

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ABSTRACT

Introduction: Non pharmacological techniques have an established role in treatment of chronic pain and related conditions. A few non pharmacological techniques have been employed to avoid the adverse effects of drugs. They have also proven to be cost-effective. Liberal fluid administration is the most common non pharmacological methodology used for the prevention of Postoperative Nausea and Vomiting (PONV). However, the associated volume overload can be detrimental.

Aim: To compare the efficacy of P6 acupoint stimulation, ondansetron and dexamethasone in the prevention of PONV in laparoscopic surgeries.

Materials and Methods: This was a randomised clinical study, conducted in the Department of Anaesthesiology, SRM Institute of Science and Technology, Tertiary Care Medical College and Hospital, Chennai, Tamil Nadu, India. The duration of the study was five months, from June 2022 to October 2022. A total of 120 patients posted for laparoscopic surgeries were divided randomly into three groups, group A, group O and group D. Patients were allocated by computer-generated randomisation. Patients in group A received capsicum plaster at P6 point. Patients in group O received 4 mg of ondansetron and patients of group D received 8 mg of dexamethasone. They were given 30 minutes before induction. Postoperatively, patients were extubated and shifted to postanesthesia care unit for further monitoring. The demographic data, baseline vitals, surgical procedure, duration of surgery and duration of Carbon Dioxide (CO₂) insufflation were noted intraoperatively.

Additional fentanyl requirement, total analgesic requirement, postoperative heart rate, Mean Arterial Pressure (MAP), the incidence of PONV, nausea and vomiting score, number of episodes the requirement of rescue antiemetic, postoperative complication, adverse reactions and patient satisfaction score were all recorded postoperatively and was compared between the three groups using one-way Analysis of Variance (ANOVA). The data was analysed using Statistical Package for Social Sciences (SPSS) version 21.0.

Results: The mean age of the study participants for group A was 40.42±11.05 years, group O was 40.92±10.49 years and group D was 40.30±10.01 years, respectively. The three groups were comparable with respect to the demographics, baseline vitals, surgical procedure, duration of surgery, duration of CO₂ insufflation, additional fentanyl requirement, total analgesic requirement, postoperative heart rate, and MAP. The incidence of PONV was insignificant between the groups with p-value=0.866. The p-value of nausea and vomiting scores were insignificant. The number of episodes of nausea and vomiting was also comparable between the groups p-value=0.880 and 0.375, respectively. The requirement of rescue antiemetic vomiting was insignificant with p-value=0.810.

Conclusion: Ondansetron, dexamethasone and P6 acupoint stimulation are equally effective as prophylaxis for the management of PONV. It can be concluded that, P6 acustimulation can be used as an alternative to pharmacological agents for the management of PONV.

Keywords: Antiemetics, Fentanyl, Laparoscopy

INTRODUCTION

The PONV is a neglected entity with physical, metabolic, psychological and socio-economical consequences [1]. Ondansetron and dexamethasone are the most frequently used pharmacological agents for the prevention of PONV [2]. However, ondansetron has associated side-effects like constipation or diarrhoea, headache and light headedness, QT prolongation in Electrocardiogram (ECG) [3]. Dexamethasone has adverse effects like hyperglycaemia, muscular weakness, susceptibility to infection, delayed healing, osteoporosis etc. Factor creates a need for safer alternatives [4]. Pharmacological agents are used routinely for the management of PONV. A variety of drugs like 5-hydroxytryptamine 3 receptor (5-HT₃) antagonists, Neurokinin 1 (NK1) receptor antagonists, corticosteroids, antidopaminergics, antihistaminics and anticholinergics are available for this purpose. A few non pharmacological techniques have

been employed to avoid the adverse effects of drugs. They have also proven to be cost-effective. Liberal fluid administration is the most common non pharmacological methodology used for the prevention of PONV. However, the associated volume overload can be detrimental [5]. Administration of carbohydrate drinks two to 12 hours before surgery has been shown to decrease insulin resistance in the perioperative period, without an increased risk for aspiration or other postoperative complications [6]. In aromatherapy, vapours of essential oil or other substances are inhaled for the treatment of physical or emotional symptoms. It uses substances like isopropyl alcohol (rubbing alcohol), peppermint oil, ginger, spearmint, cardamom, lavender or mixtures for PONV [7]. The inspired high oxygen concentration in hyperbaric oxygen therapy also has been found to decrease the chance of PONV [8].

Acupoint stimulation is a non pharmacological intervention, which has been in use for the treatment of nausea and vomiting for thousands of years in China [9]. Various studies have suggested that, P6 acupoint stimulation as an effective modality for management of PONV [10,11]. P6 point is situated between the tendons of the flexor carpi radialis and palmaris longus on the anterior surface of the forearm, about 1 cm deep to the skin and two body inches from the distal crease of the wrist joint. Acupoint stimulation can be done by various techniques like acupressure wristbands, Transcutaneous Electrical Nerve Stimulation (TENS), capsicum plaster, acupuncture injections and electroacupuncture [12]. The mechanism of action of the capsicum plaster is a continuous low-intensity stimulation of the P6 acupoint by the resin impregnated in the plaster. It also directly affects vagal modulation and causes gastric relaxation, thereby, inhibiting PONV [13]. The surgical factors associated with PONV include the type of surgery, anatomical region operated, duration of surgery and anaesthetic agents used. Surgeries like laparoscopy, bariatric procedures, gynaecological procedures, strabismus correction, tonsillectomy, middle ear surgeries and cholecystectomy have increased risk for PONV [14]. The peritoneal stretching on creation of pneumoperitoneum during laparoscopy stimulates the vagus nerve, which in turn may cause PONV. This is influenced by the intra-abdominal pressure set and the duration of pneumoperitoneum [15].

Misra MN et al., found that, capsicum plaster application at P6 was effective in the prevention of PONV in middle ear surgeries [13]. Koo MS et al., opined that, capsicum plaster application at P6 and Korean hand acupuncture point (K-D2) were equally effective in PONV prophylaxis [11]. The effectiveness of P6 acupoint stimulation in prevention of PONV has been studied less in the Indian population. Hence, the present study was devised to compare the efficacy of P6 acupoint stimulation, ondansetron and dexamethasone for the prevention of nausea and vomiting in laparoscopic surgeries. The primary objective of the present study was to find the incidence of PONV during the first 24 hours of postoperative period. Secondary objective was to assess the incidence of early and late PONV, severity of nausea and vomiting and total rescue antiemetic requirement.

MATERIALS AND METHODS

A randomised clinical study was conducted in the Department of Anaesthesiology, SRM Institute of Science and Technology, Tertiary Care Medical College and Hospital, Chennai, Tamil Nadu, India. The duration of the study was five months, from June 2022 to October 2022. Institutional Ethics Committee approval (IEC NO: 2425; CTRI/2022/05/042857) was obtained and patients were enrolled after proper informed consent.

Inclusion criteria: A total of 120 patients of either sex, aged 18-60 years and American Society of Anaesthesiologists (ASA) Physical Status I and II (PS I and II) with Body Mass Index (BMI) between 18.5 and 24.9 kg/m² were included in the study.

Exclusion criteria: Patients with history of PONV, travel sickness, allergy to study drugs, impairment in renal function, diabetes mellitus, Gastroesophageal Reflux Disease (GERD), pregnancy, cardiac diseases, documented intake of antiemetic within last 72 hours and surgeries lasting more than 120 minutes and Mallampati Classification 3,4 were excluded from the study.

Sample size calculation: Based on study by Rajeeva V et al., and substituting their values (postoperative nausea score 4-24 hours), the sample size was calculated using the formula $(20.99) \frac{(S1^2+S2^2)}{(M1-M2)^2}$, (95% confidence interval and 80% power) [16].

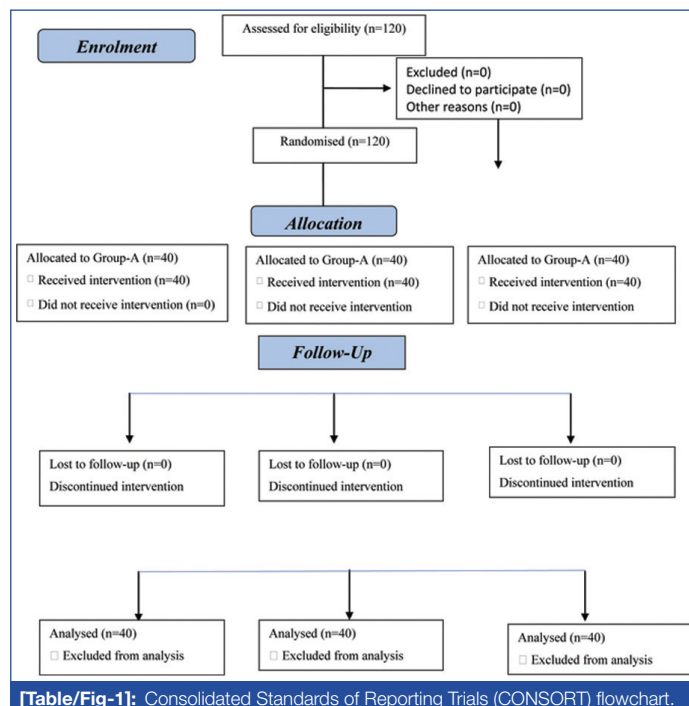
S1 and S2: standard deviation

M1 and M2: Mean

$$=(20.99)(0.69)^2+(1.29)^2/(3.81-2.64)^2$$

$$=32.816$$

Finally, 32.816 taken as sample size in each group, but for better statistical purposes and to compensate for the dropouts, the authors have included 40 subjects in each group, according to CONSORT standards [Table/Fig-1].



Study Procedure

Patients were given tab. alprazolam 0.25 mg as premedication on the previous night of surgery. Routine use of any antiemetic agents as premedication was avoided. Ringer's lactate was administered intravenously at 75 mL/hour six hours before surgery. Patients were shifted to the premedication room and baseline blood pressure, heart rate, respiratory rate and saturation were noted. They were randomised by computer generated random numbers and sealed opaque envelop method into three groups:

- **Group A** (40 patients): Capsicum plaster of dimension 1×1 cm was applied to P6 point on both forearms. The plaster was maintained till six hours postoperatively [13].
- **Group O** (40 patients): Inj. ondansetron 4 mg i.v. was administered [2].
- **Group D** (40 patients): Inj. dexamethasone 8 mg i.v. was administered [2].

The interventions were made in all the groups, 30 minutes before induction. In patients of group O and D, a similar sized placebo plaster was applied at a point near P6. Likewise, patients in group A were given 2 mL of distilled water for blinding purposes. Patients were induced with propofol 2 mg/kg and vecuronium 0.1 mg/kg was used to aid tracheal intubation. The intraoperative analgesic used was fentanyl 2 mcg/kg i.v. and sevoflurane with air-oxygen mixture at 1:1 was used for the maintenance of anaesthesia. The intra-abdominal pressure was maintained at 12 mmHg, intraoperatively. Neostigmine 50 mcg/kg and glycopyrrolate 10 mcg/kg were used as the reversal agent for the residual neuromuscular blockade. After extubation and full recovery, patients were transferred to postanesthetic care unit for observation. A blinded observer monitored the patient postoperatively. The patients were monitored for the incidence of nausea and vomiting and were noted down as early and late PONV. Early PONV was events within six hours and late PONV, at six to 24 hours. The number of episodes of nausea and vomiting were also noted. The severity was assessed by a scoring system for PONV separately [17]. Nausea: 0- no nausea, 1- mild nausea (not requesting pharmacological rescue), 2- moderate nausea (requesting pharmacological rescue) and 3- severe nausea

(resistant to pharmacological treatment). Vomiting: 0- no vomiting, 1- mild vomiting (not requesting pharmacological rescue), 2- vomiting (requesting pharmacological rescue) and 3- severe vomiting (resistant to pharmacological rescue) [17].

The rescue antiemetic administered was inj. metoclopramide 10 mg i.v., upto a maximum dose of 30 mg/day [18]. Rescue antiemetic was not administered for mild nausea and mild vomiting (scores:1). Patients with PONV resistant to rescue antiemetic was considered a failure and inj. palonosetron 75 mcg i.v. was scheduled as the second rescue antiemetic. inj. paracetamol 1 gm i.v. was administered 8th hourly and inj. ketorolac 30 mg i.v. was given as the second analgesic if, Visual Analogue Scale (VAS) >3. The haemodynamic parameters were also monitored for 24 hours. At the end of 24 hours, patient satisfaction was assessed by using 5-point Likert scale, having values between 1 to 5, with 1 being not satisfied and 5 being extremely satisfied, and was documented.

STATISTICAL ANALYSIS

The study data were entered in Microsoft office excel 2013 and analysed using SPSS version 21.0. Continuous variables were expressed as, mean and Standard Deviation (SD). One-way ANOVA was used to compare the three groups. The distribution of qualitative variables between the groups was compared using the Chi-square test. Alpha error was considered as 0.05, confidence interval as 95%. The results were considered statistically significant if, the p-value <0.05. All the data were presented as Mean±SD or as number of patients and percentages.

RESULTS

There were no dropouts during the study period. The mean age, sex, ASA PS and weight distribution was comparable between the three groups. Further, the mean duration of surgery, duration of CO₂ insufflation and total fentanyl requirement were equally distributed in all three groups [Table/Fig-2]. The surgical procedures included, laparoscopic cholecystectomy, laparoscopic appendicectomy and laparoscopic meshplasty which was also equally distributed among the groups with p-value=0.896 [Table/Fig-3]. The overall incidence of PONV was among 9 (22.5%) patients in group A, 8 (20%) patients in group O and 10 (25%) patients in group D with p-value=0.866. Early PONV was seen in 5 (12.5%), 6 (15.0%) and 7 (17.5%) patients in group A, O and D, respectively (p-value=0.822) [Table/Fig-4]. Similarly, late PONV was seen in 4 (10.0%), 2 (5.0%) and 3 (7.5%) patients in group A, O and D, respectively (p=0.697). The severity of nausea and vomiting as recorded by a score was comparable at all points of observation and the differences were statistically insignificant [Table/Fig-5].

Variables	Group A Mean±SD	Group O Mean±SD	Group D Mean±SD	p-value
Age (years)	40.42±11.05	40.92±10.49	40.30±10.01	0.962
Gender (male/female)	18/22	24/16	21/19	0.406
Weight (kg)	64.17±9.66	65.12±8.78	65.60±8.69	0.774
Duration of surgery (minute)	85.20±20.0	88.0±19.47	90.75±19.27	0.457
CO ₂ insufflation (minute)	64.90±17.46	66.62±23.08	68.62±18.78	0.705
Total fentanyl requirement (mcg)	142.57±24.43	139.75±28.42	147.25±24.09	0.423

[Table/Fig-2]: Comparison of parameters. p-value based on one-way ANOVA

Requirement of rescue antiemetic was comparable between the groups (p-value=0.810) [Table/Fig-6]. One patient each in group A and O required two doses of inj. metoclopramide 10 mg in the postoperative period. Similarly, one patient in group D had four episodes of nausea. However, three of those episodes scored 1 as per the scoring system and did not require any intervention

Surgical procedure	Group A	Group O	Group D	p-value
	n (%)	n (%)	n (%)	
Appendicectomy	14 (35.0)	10 (25)	12 (30)	0.896*
Cholecystectomy	21 (52.5)	23 (57.5)	22 (55)	
Meshplasty	5 (12.5)	7 (17.5)	6 (15)	
Total	40 (100)	40 (100)	40 (100)	

[Table/Fig-3]: Surgical procedure. p-value based on Chi-square test
*not significant N=120

PONV	Group A n (%)	Group O n (%)	Group D n (%)	p-value (A, O and D)
Incidence of PONV				
Yes	9 (22.5)	8 (20)	10 (25)	0.866*
No	31 (77.5)	32 (80)	30 (75)	
Early PONV				
Yes	5 (12.5)	6 (15)	7 (17.5)	0.833*
No	35 (87.5)	34 (85)	33 (82.5)	
Late PONV				
Yes	4 (10)	2 (5)	3 (7.5)	0.697*
No	36 (90)	38 (95)	37 (92.5)	

[Table/Fig-4]: Incidence of PONV. Note: p-value based on Chi-square test
*not significant

Time (in hours)	Score	No. of patients with nausea and vomiting scores												p-value
		Group A				Group O				Group D				
		0	1	2	3	0	1	2	3	0	1	2	3	
1	Nausea	39	1	0	0	38	2	0	0	37	3	0	0	0.591*
	Vomiting	39	1	0	0	40	0	0	0	40	0	0	0	0.365*
2	Nausea	36	4	0	0	37	3	0	0	35	5	0	0	0.757*
	Vomiting	39	1	0	0	28	2	0	0	39	0	1	0	0.404*
3	Nausea	34	4	2	0	34	5	1	0	35	3	2	0	0.922*
	Vomiting	35	3	2	0	38	1	1	0	39	0	1	0	0.375*
6	Nausea	39	1	0	0	40	0	0	0	39	1	0	0	0.369*
	Vomiting	39	1	0	0	39	0	1	0	39	0	1	0	0.411*
12	Nausea	36	3	1	0	35	5	0	0	36	3	1	0	0.782*
	Vomiting	38	1	1	0	38	1	1	0	39	1	1	0	0.907*
24	Nausea	39	1	0	0	40	0	0	0	39	1	0	0	0.601*
	Vomiting	40	0	0	0	39	1	0	0	39	1	0	0	0.601*

[Table/Fig-5]: Severity of nausea and vomiting. p-value based on Chi-square test
*not significant (N=120)

[Table/Fig-6]. The number of episodes of nausea and vomiting was insignificant between the groups with p-values=0.880 and 0.375 [Table/Fig-7]. The groups were haemodynamically stable throughout the study period and the difference was statistically insignificant [Table/Fig-8,9]. The respiratory rate and saturation was also comparable between the groups. The patient satisfaction score was also insignificant (p=0.492) [Table/Fig-10]. Since, none of the patients experienced PONV at 24 hours, the cases were discharged on first postoperative day. Hence, recovery/discharge criteria were not assessed further in the study.

No. of rescue antiemetic	Group A n (%)	Group O n (%)	Group D n (%)	p-value
0	35 (87.5)	35 (87.5)	34 (85)	0.810*
1	4 (10)	4 (10)	6 (15)	
2	1 (2.5)	1 (2.5)	0	
Total	40 (100)	40 (100)	40 (100)	

[Table/Fig-6]: Requirement of rescue antiemetic. *not significant

Episodes of nausea and vomiting	Group A n (%)	Group O n (%)	Group D n (%)	p-value
Nausea				
No episode	31 (77.5)	32 (80)	30 (75)	0.880*
One	2 (5.0)	1 (2.5)	1 (2.5)	
Two	3 (7.5)	4 (10)	3 (7.5)	
Three	2 (5)	3 (7.5)	5 (12.5)	
Four	1 (2.5)	0	1 (2.5)	
Five	1 (2.5)	0	0	
Vomiting				
No episode	33 (82.5)	34 (85)	34 (85)	0.375*
One	4 (10)	1 (2.5)	5 (12.5)	
Two	2 (5)	4 (10)	1 (2.5)	
Three	0	1 (2.5)	0	
Four	1 (2.5)	0	0	
Total	40 (100)	40 (100)	40 (100)	

[Table/Fig-7]: Episodes of nausea and vomiting.

p-value based on Chi-square test

* =not significant

Heart rate (in hours)	Group A (n=40)	Group O (n=40)	Group D (n=40)	p-value
	Mean±SD	Mean±SD	Mean±SD	
1	82.80±10.13	82.25±9.44	82.23±11.84	0.963*
2	83±10.69	81.85±10.28	82.80±11.62	0.880*
3	83.08±9.02	81.48±9.09	82.93±9.46	0.692*
4	81.80±8.55	79.63±7.89	81.53±8.66	0.452*
5	80.33±8.00	78.88±7.93	80.03±8.70	0.707*
6	80.48±7.89	78.88±7.43	79.80±9.30	0.685*
12	78.93±7.97	77.63±7.75	78.33±8.85	0.778*
18	79.13±7.40	77.28±7.86	78.53±7.97	0.554*
24	78.95±7.36	76.73±8.11	78.15±8.01	0.439*

[Table/Fig-8]: Postoperative heart rate among study participants.

Note: p-value based on repeated measures ANOVA

* =not significant (N=120)

MAP (in hours)	Group A Mean±SD	Group O Mean±SD	Group D Mean±SD	p-value
1	66.80±4.50	64.73±4.30	67.68±5.92	0.027
2	67±4.67	65.85±4.23	68.15±5.32	0.102*
3	66.35±10.75	66.85±4.25	68.78±13.78	0.546*
4	68.65±4.88	68.20±6.03	69.43±5.85	0.615*
5	68.28±4.84	68.73±5.64	70.20±7.03	0.316*
6	68.43±5.64	70.08±6.48	69.65±5.80	0.443*
12	71.93±9.14	70.30±6.81	70.03±5.94	0.467*
18	71.85±9.16	70.13±6.56	70.23±5.51	0.491*
24	71.28±8.34	69.05±5.44	69.78±5.29	0.300*

[Table/Fig-9]: Postoperative Mean Arterial Pressure (MAP) distribution among study participants.

p-value based on repeated measures ANOVA

* =not significant (N=120)

Groups	Frequency (n)	Patient satisfaction score Mean±SD	F-value	p-value
Group A	40	4.22±0.77	0.71	0.492*
Group O	40	4.30±0.69		
Group D	40	4.10±0.81		

[Table/Fig-10]: p-value based on one-way ANOVA.

* =not significant (N=120)

DISCUSSION

The PONV is a common limiting factor for early recovery in laparoscopic surgeries and plays an important role in patient dissatisfaction. Pharmacological drugs have been in use for

management of PONV routinely. Hence, in the present study, an alternate non pharmacological method, P6 acupoint stimulation has been discussed. The Nei-guan point (P6 point) is primarily used for the prevention of nausea and vomiting due to motion sickness, pregnancy and postsurgery [9, 19]. The low frequency stimulation by acupuncture activates the skin A β and A δ fibres and this activation influences neurotransmission in the dorsal horn. This causes stimulation at low frequency. There is an increase in β -endorphins secretion in cerebrospinal fluid after acupuncture [20]. The P6 acupoint stimulation might also activate the norepinephrine and serotonergic fibres and can cause a change in the serotonin levels, which can prevent nausea and vomiting [20].

The incidence of PONV over the immediate 24 hours of the postoperative period was distributed equally between the three groups ($p=0.866$) in the present study. There are no previous studies comparing P6 acupoint stimulation, ondansetron and dexamethasone. Misra MN et al., found that, capsicum plaster application at P6 was effective in the prevention of PONV in middle ear surgeries [13]. Koo MS et al., opined that, capsicum plaster application at P6 and Korean hand acupuncture point K-D2 points were equally effective in PONV prophylaxis [11]. Harmon D et al., conducted a prospective randomised double-blinded study on acupressure and found that, there was a significantly lower incidence of nausea and vomiting on acupressure application with wrist bands [21]. In the present study, the incidence of early and late PONV was not statistically significant among the groups. A similar outcome has been demonstrated in a previous study by Agarwal A et al., on comparing ondansetron and acupressure [10].

Coloma M et al., on comparison of acustimulation and ondansetron for management of established PONV opined that, the combination group was significantly better than the acustimulation group (73% vs 40%) [22]. Patient satisfaction and quality of recovery were similar, between the groups. He suggested acustimulation alone with the relief band can be an alternative to ondansetron for the management of established PONV. However, using ondansetron in combination with the relief band, improved the response rate better than acustimulation therapy [19]. Agarwal A et al., in their study, graded nausea using the VAS from 1-10 and the severity of vomiting using the number of episodes. The severity scores were compared between the groups and was found to be insignificant [10]. In contrast, Gan TJ et al., opined that, the severity of nausea was much lesser in the acupoint stimulation group than the ondansetron group [23]. The total dose of antiemetic requirement did not significantly differ between the three groups. The authors did not encounter any drug related side-effects in the present study.

Limitation(s)

Placebo group was not included in the present study. Addition of combination groups could have helped in the formulation of multimodal approach.

CONCLUSION(S)

The P6 acupoint stimulation, ondansetron and dexamethasone were equally effective as prophylaxis for the management of PONV. The authors conclude that, P6 acupoint stimulation can be used as an alternative to pharmacological agents for the management of PONV. Further studies are required to analyse the efficacy of non pharmacological techniques in the prevention and management of acute postoperative undesirable events.

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