COMPARISON BETWEEN ACUPRESSURE AND PALONOSETRON IN PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING IN PATIENTS UNDERGOING LAPAROSCOPIC TUBAL STERILISATION. A RANDOMISED CONTROL TRIAL

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ABSTRACT

BACKGROUND AND OBJECTIVES

To compare the effectiveness of acupressure at P6 point and palonosetron in prevention of postoperative nausea and vomiting in patients undergoing laparoscopic tubal sterilisation.

METHODS AND MATERIALS

After obtaining institutional ethical clearance and patient consent, this study was conducted during the period of July 2015 to November 2015. Patients undergoing laparoscopic tubal sterilisation belonging to ASA 1 and 2 were included, and patients with hypertension, diabetes neurological diseases, peripheral vascular diseases, local skin diseases, patients on antiemetics and unwilling patients were excluded from the study. Randomisation done by sealed envelope method into two groups of sample size 25 each; group A (acupressure, at P6 point) and group B (palonosetron 0.075 mg IV). Acupressure band and Inj palonosetron were given just before the induction of anaesthesia. Episodes of PONV were recorded at 0-2 hours, 2-6 hours, 6-12 hours and evaluated separately as none, mild, moderate and severe. Rescue antiemetic was given to those who had episode of vomiting. Data analysed using Student 't' test and P value <0.05 considered to be significant.

RESULTS

Between two group comparisons no significant differences in terms of severity of PONV was observed and Group B showed no incidence of PONV.

CONCLUSION

Acupressure being non-invasive, non-pharmacological, inexpensive and better patient acceptability can be effectively used as an alternative for the prophylaxis of PONV. However, palonosetron was more effective than acupressure in preventing PONV.

KEYWORDS

PONV, Acupressure, Palonosetron, Laparoscopic tubal sterilisation.

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INTRODUCTION: Nausea and vomiting in the postoperative period occurs in 20% to 30% of the patients and together are the second most common complaints reported.[1] Patients fear PONV more than postoperative pain, with 14% worrying about pain compared with 23% worrying about PONV. If PONV does occur, this is a strong reason for the patient to rate the entire course of surgery negatively. Patients rate its avoidance and control of more importance than that of alleviating pain.[2]

PONV is thought to be multifactoral, involving anaesthetic, surgical, and individual risk factors. PONV is common with rates of more than 50% associated with strabismus surgery, tonsillectomy, adenoidectomy, orchidopexy, hernia repair, laparoscopic cholecystectomy for cholelithiasis and major gynaecologic surgery performed under general anaesthesia. The risk factors for PONV are female gender, non-smoking status, history of motion sickness or PONV, use of opioid analgesics and volatile anaesthetics is well established.[3]

Acupuncture and acupressure are among the non-pharmacological techniques which have also been evaluated for the prevention of postoperative nausea and vomiting with varying degrees of success.[4]

Palonosetron 0.075 mg was more effective at reducing PONV than ondansetron 8 mg. This could reflect the high receptor affinity of palonosetron for 5-HT3, with a low affinity demonstrated for other receptors including 5-HT1A, 5-HT1D, 5-HT2A and 5-HT2C, and the longer duration of action.[9]

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Our aim was to compare the efficacy of acupressure and palonosetron in prevention of postoperative nausea and vomiting in patients undergoing laparoscopic tubal sterilisation.

METHODS: A randomised clinical study was planned on patients scheduled for laparoscopic tubal sterilisation at Vani Vilas and Bowring and Lady Curzon Hospitals attached to Bangalore Medical College and Research Institute. After obtaining approval from the Ethics Committee of Bangalore Medical College and Research Institute, 50 patients scheduled for surgery, with American Society of Anaesthesiologists physical status 1 or 2 were recruited in this study. Written informed consent was obtained from all participants after describing all aspects of the study. Patients were randomly allocated to either Group A to whom acupressure band was applied or control Group B who received Inj. palonosetron 0.075 mg IV based on simple randomisation process.

Patients were excluded if they had any comorbid diseases like hypertension, diabetes, peripheral neural disease, peripheral vascular diseases. Unwilling patients and patients on any antiemetics were also excluded from the study.

After obtaining detailed history and physical examination, acupressure band (at P6 point) was applied to the patients belonging to group A, and Inj. palonosetron 0.075 mg IV was given to the patients belonging to group B just before the induction of general anaesthesia. All patients were premedicated with intravenous Inj. glycopyrrolate 20 ug/kg, Inj. fentanyl 2 ug/kg and Inj. midazolam 0.02 mg/kg. Anaesthesia was induced with Inj. propofol 2 mg/kg and intubated with LMA of appropriate size, and maintained with nitrous oxide: oxygen (50:50).

Intraoperatively, patients were assessed for number of episodes of nausea and vomiting and also vital parameters like HR, SPO2, BP every 10 minutes.

During the followup period (up to 12 hours after surgery), average of MAP, HR, severity of nausea and vomiting were monitored and recorded between 0-2 hours, 2-6 hours and 6-12 hours after surgery. Acupressure band was removed 6 hours after surgery for patients belonging to Group A.

Severity of nausea based on visual linear analogue scale (VLAS) was measured using a 10 cm ruler according to self-reporting by patients. In this method, patients were asked to indicate zero in case of having no symptoms and 10 if she has the most severe symptoms. Score ≤ 5 was considered as mild, 5-9 as moderate and 10 as severe. Similarly, patients were asked to count the number of episodes of vomiting, vomiting score was recorded as mild (if less than 2 episodes), moderate (if 2 episodes) and severe (if more than 2 episodes).

A dose of rescue antiemetic (metoclopramide 10 mg) would be given intravenously if vomiting occurred. The incidence of side-effects such as agitation and during 12 hours, patients' satisfaction were evaluated.

STATISTICAL METHODS: Keeping power of study at 80%, confidence interval of 95%, with marginal error of 20% VAS score the sample size of 23 was required in each group; however, 25 patients were included in each group.

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Intergroup analysis) on metric parameters.

Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

Significant figures

+ Suggestive significance (P value: $0.05<P<0.10$).
* Moderately significant (P value: $0.01<P \leq 0.05$).
** Strongly significant (P value: $P \leq 0.01$).

Statistical Software: The statistical software namely SPSS 20.0 was used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs, tables etc.

RESULTS: There were no significant differences ($P<0.05$) among two groups in terms of age (mean age was 25.92±3.616 in group A and 25.72±3.911 in group B). However, there was moderately significant difference (P= 0.033) in the duration of surgery (mean duration was in group A and in group B). The results suggest that the levels of severity of postoperative nausea and vomiting, MAP, HR made across the study and control groups, studied at specific time points are dependent on the type of treatment groups- who have received acupressure or Inj. palonosetron. Between group comparisons indicate no significant differences in terms of severity of postoperative nausea ($P >0.05$) and vomiting ($P>0.05$), MAP ($P>0.05$) and Basal HR ($P>0.05$), while significant difference for intraoperative HR ($P <0.05$)

Parameters	Group	BASAL	t-score	P-value	10 min	t-score	P-value	20 min	t-score	P-value
Heart rate	Acupressure	90.48±12.47	1.935	0.059	94.56±13.75	2.954	0.005*	92.69±12.28	2.744	0.010*
	Palonosetron	83.88±11.62			83.68±12.24			80.56±12.06		
SBP	Acupressure	122.72±12.80	-0.195	0.846	118.64±12.17	-1.200	0.236	125.15±13.03	0.162	0.872
	Palonosetron	123.40±11.77			122.96±13.25			124.31±13.51		
DBP	Acupressure	78.32±10.71	-0.567	0.574	73.08±9.98	-1.269	0.211	85.31±10.91	0.860	0.398
	Palonosetron	80.00±10.24			76.92±11.36			81.08±13.99		
MAP	Acupressure	92.66±10.16	0.466	0.643	88.57±9.28	-1.375	0.175	97.59±11.39	0.529	0.602
	Palonosetron	90.67±18.74			92.39±10.35			95.13±12.30		

SPO2	Acupressure	99.76±0.436	0.777	0.441	99.60±0.577	0.000	1.000	99.85±0.555	0.807	0.428
	Palonosetron	99.64±0.638			99.60±0.500			99.62±0.870		
	Palonosetron	17.08±1.152			17.76±1.300			17.00±1.000		

Table 1: Intraoperative study parameters in different group

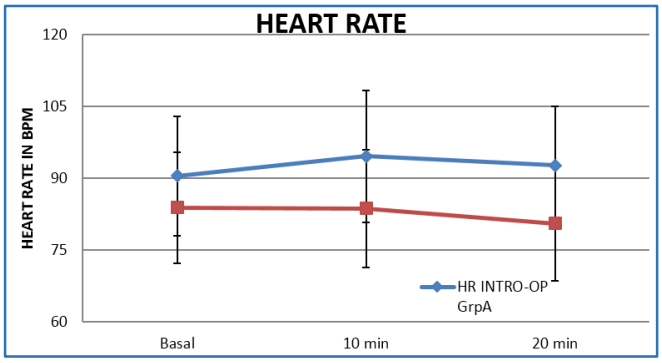

Fig. 1: Graph depicting comparison of heart rate between the two groups in the intraoperative period

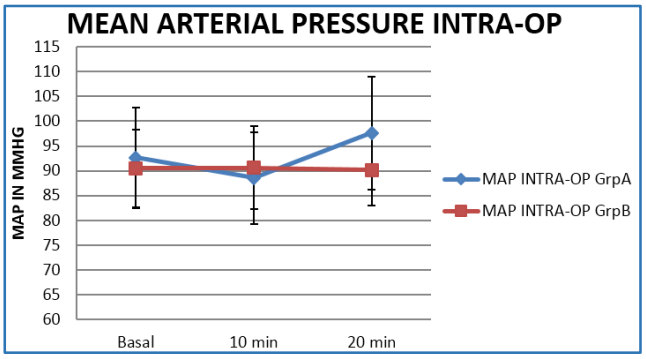

Fig. 2: Graph depicting comparison of MAP between the two groups in the intraoperative period

Parameters	Group	0-2 Hours	t-score	P-value	2-6 Hours	t-score	P-value	6-12 Hours	t-score	P-value
HEART RATE	Acupressure	87.40±11.64	0.099	0.921	87.24±12.34	0.464	0.645	81.80±10.00	-0.011	0.992
	Palonosetron	87.08±11.15			85.60±12.66			81.83±11.97		
SBP	Acupressure	119.52±10.29	0.138	0.890	119.04±6.96	0.132	0.895	122.08±9.30	1.251	0.217
	Palonosetron	119.12±10.14			118.76±7.96			118.16±12.59		
DBP	Acupressure	78.56±6.53	0.656	0.515	77.24±6.93	0.522	0.604	77.92±5.60	0.764	0.448
	Palonosetron	77.20±8.04			76.00±9.64			76.48±7.57		
MAP	Acupressure	91.92±5.91	0.724	0.472	90.87±7.62	0.111	0.912	91.20±6.27	0.545	0.589
	Palonosetron	90.50±7.78			90.62±8.34			90.16±7.19		
SPO2	Acupressure	99.88±0.33	2.698	0.010*	99.48±0.96	.477	0.636	99.68±0.55	0.224	0.824
	Palonosetron	99.28±1.06			99.36±0.81			99.64±0.70		

Table 2: Post-operative study parameters in different group

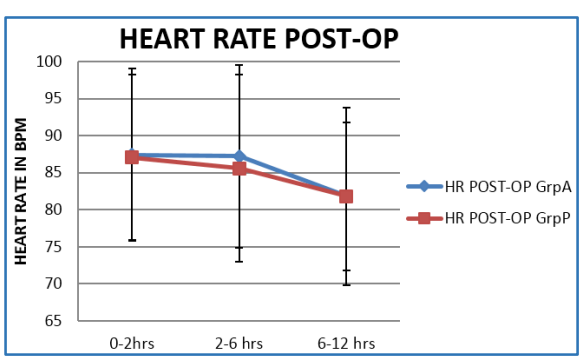

Fig. 3: Graph depicting comparison of HR during post-operative period

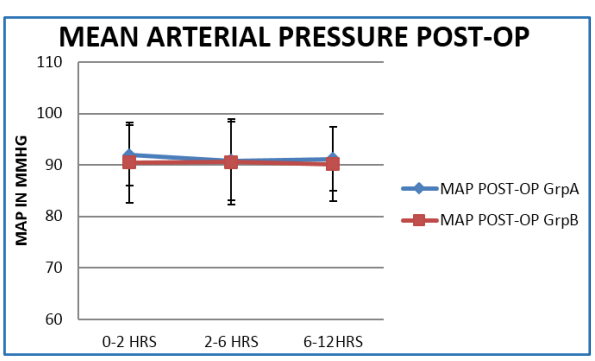

Fig. 4: Graph depicting comparison of MAP during post-operative period

Group	0-2 Hours	2-6 Hours	6-12 Hours
Acupressure	0.16±0.624	0.20±0.577	0.28±1.061
Palonosetron	0.00±0.000	0.08±0.400	0.00±0.000
t-test value	1.281	0.854	1.319
P-value	0.206	0.397	0.193

Table 3: Post-operative mean nausea score (VLAS)

Group	0-2 Hours	2-6 Hours	6-12 Hours
Acupressure	0.00±0.000	0.00±0.000	0.08±0.400
Palonosetron	0.00±0.000	0.00±0.000	0.00±0.000
t-test value	-	-	1.000
P-value	-	-	0.322

Table 4: Post-operative mean vomiting score

DISCUSSION: The main objective of our study was to compare acupressure and palonosetron in preventing postoperative nausea and vomiting in patients undergoing laparoscopic tubal sterilisation and results obtained in this study with respect to effectiveness of acupressure in preventing PONV were in line with various studies.(2–8)

The results of this study were in line with Duggal Geetika et al study who concluded that ondansetron and acupressure were significantly more effective in controlling nausea and vomiting postoperatively. However, ondansetron showed superior results in comparison to acupressure technique but acupressure being a non-pharmacological, non-invasive technique, can be used as an adjuvant for antiemesis.[4]

The results of our study are similar to Fan C F et al who concluded that acupressure at the P6 (Nei-Guan) point is an effective prophylaxis for postsurgical nausea and vomiting and therefore a good alternative to conventional antiemetic treatment.[5]

Gieron C et al in their study have concluded that in longer gynaecological surgery as well as in chemotherapy-induced nausea and vomiting, acupressure is an effective method of preventing nausea and vomiting without any side-effects. It is a valuable addition to the prevention of postoperative nausea and vomiting.[6]

D. Harmon et al in their study have concluded that the use of acupressure reduced the incidence of nausea or vomiting from 42% to 19% compared with placebo and also have summarised that non-pharmacological technique of acupressure at P6 was effective in preventing nausea and vomiting after laparoscopy as acupressure is devoid of side effects, easy to apply and economical.[7]

Aidah Alkaissi et al have concluded that in females with a history of motion sickness P6 acupressure increased tolerance to experimental nauseogenic stimuli, and reduced the total number of symptoms reported.[8]

With respect to palonosetron, our study was also in line with the study of SK Park, EJ Echo, who have concluded that the incidence of PONV was significantly lower in the palonosetron group than in the ondansetron group during the overall 0–24 hour time interval ($P < 0.05$,). More patients in the palonosetron group had a complete response (no PONV and no rescue antiemetic) compared with the ondansetron group; this difference was statistically significant for the 0–24 hour time interval ($P < 0.05$). The severity of nausea (VAS), need for rescue antiemetics, incidence of adverse effects and patient satisfaction ratings were not significantly different between the two groups.[9]

Kovac Anthony L et al, in their study have shown that in the inpatient surgical setting, a single 0.075 mg IV dose of palonosetron significantly reduced emesis, intensity of nausea and the use of rescue antiemetics in addition to delaying the time to emesis and treatment failure, particularly during the first 24 hours after surgery.[10]

CONCLUSION: Acupressure being non-invasive, non-pharmacological, inexpensive and better patient acceptability can be effectively used as an alternative for the prophylaxis of PONV. However, palonosetron was more effective than acupressure in preventing PONV.

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