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Original Research Article

EFFECTIVENESS OF AURICULAR ACUPRESSURE FOR PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING IN ADULT PATIENTS UNDERGOING ELECTIVE ABDOMINAL LAPAROSCOPIC SURGERIES UNDER GENERAL ANAESTHESIA, A PROSPECTIVE RANDOMISED CONTROLLED STUDY

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Abstract

Background: Postoperative nausea & vomiting (PONV) is any nausea, Retching or vomiting occurring during the first 24 hours after surgery in in-patients. Despite the minimally invasive nature of laparoscopy, high incidence of postoperative nausea, retching and vomiting remains a major cause for morbidity. In spite of plenty of antiemetic drugs available, no single agent is 100% effective against PONV. It is proven that Acupressure reduces the incidences of PONV when combined with pharmacological treatment, but there are no studies conducted till now to prove the effectiveness of triple therapy of Auricular acupressure combined with Ramosetron and Dexamethasone. **Aims and Objectives:** This study aims to know the efficacy of triple therapy: Auricular acupressure, Ramosetron IV 0.3mg &and IV dexamethasone 4mg in preventing PONV in adult patients undergoing elective abdominal laparoscopic surgeries under general anaesthesia **Materials and Methods:** Patients were randomized into two groups. Group ARD: the case group, auricular pressure beads taped to the traditional antiemetic auricular points. Group RD: the Control group received a placebo of auricular Acupressure. Both groups received IV Ramosetron 0.3mg & IV dexamethasone 4mg as a part of premedication during the surgery. General Anaesthesia (GA) was administered, and intra-op vials were recorded. Postoperative nausea (PON) was assessed using Verbal Rating Score (VRS). All patients were interviewed regarding nausea and vomiting every 2nd hour up to 6 hours and at 24 hours postoperatively, and the number of rescue antiemetics required was noted. **Results:** With not much difference in demographic characters, comorbidities, intra-op and post-op vitals, scores, duration and type of laparoscopic surgeries, the incidence of nausea showed a significant difference of 8.3% in group RD and 1.7% in the ARD group, whereas the incidence of vomiting was equal in both the groups, 1.7% (p= 1.0). In the first 24 hours after surgery, the incidence of retching in group RD was 5.0%, whereas that in group ARD was 1.7% (p=0.309), and the requirement of rescue antiemetics in group RD was 11.6%, compared to 3.3% in ARD group (p=0.083). Patient satisfaction in the ARD group was 100% compared to 96.7% (p=0.154) in the control group. **Conclusions:** Triple therapy of Auricular Acupressure with Ramosetron and Dexamethasone is equally effective as Ramosetron plus Dexamethasone in preventing PONV in adult patients.

INTRODUCTION

Postoperative nausea & vomiting (PONV) is any nausea, Retching or vomiting occurring during the first 24-48 hours after surgery in in-patients.[1] It is not an uncommon complication during the postoperative period, and the incidence is as high as 80% in major abdominal or pelvic surgeries when no antiemetic prophylaxis is used.[2]

In addition to patient discomfort with nausea and vomiting, other clinically important risks include anorexia, dehydration, electrolyte imbalance, acid-base imbalance, surgical site scar dehiscence, oesophageal rupture, increased abdominal pressure, increased central venous pressure, aspiration of gastric contents, sympathetic nervous system response with increased blood pressure and heart rate, parasympathetic responses producing bradycardia and hypotension. The incidence of PONV following laparoscopy can reach up to 42%. The most common reason for a extended stay following ambulatory surgery is postoperative emetic symptoms (nausea, vomiting, and retching) in patients undergoing general anaesthesia for laparoscopic cholecystectomy.[3]

The occurrence of PONV typically coincides with both the declining effects of antiemetics and the increasing oral intake following surgery. The use of opioids, volatile agents, nitrous oxide (which raises the risk of PONV), a high dose of neostigmine to reverse neuromuscular blockade, and the selection of induction agents are all factors that can enhance the risk of PONV (ketamine and etomidate possess a higher risk of PONV).

The sites and pathways in the brain that are connected to PONV provide the basis for treatment. Neurokinin-1 receptor antagonists and serotonin antagonists (Ondansetron, Ramosetron, Granisetron, etc.) are beneficial in treating PONV. Dexamethasone may be less effective early on after surgery because of its slower onset of action.[4]

Although many antiemetic medications are available, none are 100% effective against PONV. It could be a result of the multifocal origin of PONV. As a result, combination therapy has received considerable attention. A serotonin receptor antagonist (Ondansetron, Ramosetron, Granisetron, etc.) combined with Dexamethasone is one of the most effective antiemetic treatments for avoiding PONV following laparoscopic cholecystectomy.[5]

Subjective effects are felt by the patient alone and cannot be scientifically explained. However, the physiological changes incidental to Acupressure and the change in the patient's clinical condition constitute the very basis of acupuncture.

Hence, this study is conducted to statistically evaluate this triple regimen's efficacy in reducing the incidence of postoperative nausea, Retching and vomiting.

MATERIALS AND METHODS

This randomized, double-blinded study was conducted between December 2020 and July 2022. After getting ethical approval, 120 adults in each age group 18-60 years, belonging to ASA I/ II, planned for abdominal laparoscopic procedures under general anaesthesia, participated in this study. The sample size was calculated using the shuffled seal opaque envelope technique, and 60 participants were included in the study.

Study setting & data collection method: Adult patients of both genders posted to undergo abdominal laparoscopic surgeries under general anaesthesia were evaluated thoroughly as a part of the pre-anaesthetic evaluation. All patients were included in the study after obtaining informed consent. The Apfel scoring for PONV was evaluated, and the scores were noted. On the day of surgery, patients were randomized into two groups by using computer-generated numbers:

GROUP ARD: Auricular acupressure beads were taped onto the right external ear, on the traditional anti-emetic points by the person who randomized the study in pre-operative holding before shifting the patient to the operation theatre. All group ARD patients also received IV Ramosetron 0.3m and IV Dexamethasone 4mg during premedication during the surgery.

GROUP RD: Control group received a placebo of auricular Acupressure, which includes taping auricular pressure beads in the right external ear at sites other than the traditional antiemetic points and received the same amount of pressure on those beads for the same duration as that of the group ARD and received IV Ramosetron & IV Dexamethasone as a part of premedication during the surgery. Auricular pressure was administered, soon after patients were shifted to PACU and every second hourly up to 6 hours by the same person. PONV was assessed using VRS (Verbal rating score).All patients were interviewed regarding the occurrence of nausea, retching and vomiting every 2nd hourly up to 6 hours and at 24 hours post operatively, the Incidence of PONV was noted and was treated with Inj Metoclopramide 10mg(as a rescue antiemetic) and the number of rescue antiemetics required was noted.

Statistical Analysis

Data were analyzed using SPSS version 22 (IBM SPSS Statistics, Somers, NY, USA) was used to analyze data. Data were entered into a Microsoft Excel data sheet and analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. The chi-square test was used as a significance test for qualitative data <0.05 and was considered statistically significant Continuous data were represented as mean and standard deviation. The normality of the continuous data was tested by Kolmogorov–Smirnov test and the Shapiro–Wilk

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test. An Independent t-test was used as a significance test to identify the mean difference between two quantitative variables.

RESULTS

[Figure 1] indicates that the mean Age in Group RD was 45.27 ± 11.689 years, and in Group ARD was 41.65 ± 11.019 years. There was no significant difference in the mean age distribution comparison between the two groups.

[Table 1] shows that 40% were female in Group RD, and 60% were Male. In Group ARD, 41.7% were Female, and 58.3% were Male. In Group RD, 16.7% had Diabetes Mellitus, 5% had Diabetes mellitus & Hypertension, 18.3% had Hypertension, and 3.3% had Hypothyroidism. In Group ARD, 8.3% had Diabetes Mellitus, 11.7% had Diabetes mellitus & Hypertension, 13.3% had Hypertension, and 8.3% had Hypothyroidism. There was no significant difference in age, sex and comorbidities distribution comparison between the two groups. The mean height was 164.53 ± 6.27 cm, weight was 66.55 ± 6.26 kgs, and BMI was 24.62 ± 2.47 in group RD, 165 ± 5.46cms height, 68.87 ± 6.93 kg weight and 23.57 ± 2.13 of BMI in group ARD.

Table 2 shows Group RD; 53.3% had ASA 1, and 46.7% had 2. In Group ARD, 50% had ASA 1, and 50% had 2. In Group RD, 43.3% had an APFEL Score of 0, 55% had 1, and 1.7% had 2. In Group ARD, 30% had an APFEL Score of 0, and 70% had 1, which is not significant?

[Table 3] shows Group RD, 15% had acute calculus cholecystitis, 83.3% had Cholelithiasis, and 1.7% had Gall Bladder Polyp. In Group ARD, 1.7% had Abnormal Uterine Bleeding with Adenomyosis, 5% had Abnormal Uterine Bleeding with Leiomyoma, 5% had acute appendicitis, 13.3% had acute calculus cholecystitis, 71.7% had Cholelithiasis, 0% had Gall Bladder Polyp, 1.7% had Ovarian Cyst, and 1.7% had Right Adnexal mass. In Group RD, 1.7% had Laparoscopic Appendicectomy, and 98.3% had Laparoscopic cholecystectomy.

In Group ARD, 5% had Laparoscopic Appendicectomy, 85% had Laparoscopic cholecystectomy, 1.7% had Laparoscopic Myomectomy, 3.3% had Laparoscopic Ovarian Cystectomy, and 5% had Total Laparoscopic Hysterectomy. It has not been found not significant in our study settings.

The two groups had no significant difference in mean SBP comparison at any interval. At other intervals, there was no significant difference. There was a significant difference in mean DBP comparison between groups from 0 to 2 hours, as indicated in Table 4.

[Table 5] There was no significant difference in mean heart rate and SpO2 comparison between groups at any interval.

[Table 6] shows group RD; 5.0% had Retching and 1.7% in Group ARD. There was no significant difference in the Retching comparison between the two groups.

In our study, Retching (3 patients in group RD) and one patient in group ARD was observed during the immediate postoperative period, i.e., during the observation time of 0-2 hours (immediately after shifting to PACU), managed with i.v Metoclopramide 10mg. There was no significant difference in the incidence of vomiting between the two groups. Incidence of vomiting was assessed every second hour up to 6 hours and at 24 hours. In our study, one patient from both groups experienced one episode of vomiting immediately after shifting to PACU, managed with i.v Metoclopramide 10mg. There was no significant difference in the need for rescue antiemetics comparison between the two groups.

[Table 7] There was no significant difference in Incidence and Grade of PONV comparison between the two groups at any interval.

The two groups had no significant difference in the Patient Satisfaction Score comparison. In Group RD, 3.3% had a Patient Satisfaction Score of 1, and 96.7% had a 2. In Group ARD, 100.0% had Patient Satisfaction Score shown in [Figure 2].

Table 1: The table depicts the distribution of sex, anthropometry findings and comorbidities in both RD and ARD groups

		Group RD		Group ARD		P value
		Count	%	Count	%	
Sex	Female	24	40.00%	25	41.70%	0.853
	Male	36	60.00%	35	58.30%	
Anthropometry Findings	Height (Cms)	164.53	6.27	166	165.83	0.228
	Weight (Kgs)	66.55	6.26	68	64.87	0.165
	BMI	24.62	2.47	25	23.57	0.014*
Comorbidities	Diabetes Mellitus	10	16.70%	5	8.30%	0.283
	Diabetes mellitus & Hypertension	3	5.00%	7	11.70%	
	Hypertension	11	18.30%	8	13.30%	
	Hypothyroidism	2	3.30%	5	8.30%	
	Nil	34	56.70%	35	58.30%	

Values are expressed as frequencies and percentages; a p-value is by Chi-square test. A p-value less than 0.05 is considered to be statistically significant

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Table 2: The table depicts the distribution of ASA grade and APFEL scores in RD and ARD groups

		Group RD		Group ARD		P value
		Count	%	Count	%	
ASA Grade	1	32	53.30%	30	50.00%	0.715
	2	28	46.70%	30	50.00%	
	Total	60	100.00%	60	100.00%	
APFEL Score	0	26	43.30%	18	30.00%	0.171
	1	33	55.00%	42	70.00%	
	2	1	1.70%	0	0.00%	

Values are expressed as frequencies and percentages; a p-value is by Chi-square test. A p-value less than 0.05 is considered to be statistically significant

Table 3: The table depicts the distribution of diagnosis and proposed surgery in RD and ARD groups

		Group RD		Group ARD		P value
		Count	%	Count	%	
Diagnosis	Abnormal Uterine Bleeding with Adenomyosis	0	0.00%	1	1.70%	0.158
	Abnormal Uterine Bleeding with Leiomyoma	0	0.00%	3	5.00%	
	Acute appendicitis	0	0.00%	3	5.00%	
	Acute calculus cholecystitis	9	15.00%	8	13.30%	
	Cholelithiasis	50	83.30%	43	71.70%	
	Gall Bladder Polyp	1	1.70%	0	0.00%	
	Ovarian Cyst	0	0.00%	1	1.70%	
	Right Adnexal mass	0	0.00%	1	1.70%	
Proposed Surgery	Lap Appendicectomy	1	1.70%	3	5.00%	0.108
	Lap cholecystectomy	59	98.30%	51	85.00%	
	Lap Myomectomy	0	0.00%	1	1.70%	
	Lap Ovarian Cystectomy	0	0.00%	2	3.30%	
	Total Lap Hysterectomy	0	0.00%	3	5.00%	

Values are expressed as frequencies and percentages; a p-value is by Chi-square test. A p-value less than 0.05 is considered to be statistically significant

Table 4: The table depicts the distribution of hourly SBP and DBP postoperatively in RD and ARD groups

	Group RD			Group ARD			P value
SBP	Mean	SD	Median	Mean	SD	Median	
0 hr	124.5	11.38	120	125.67	11.84	125	0.583
2 hrs	123.5	8.99	120	124.33	10.15	120	0.635
4 hrs	122.58	9.85	120	122	10.38	120	0.753
6 hrs	122.43	10.1	120	121.68	10.13	120	0.685
24 hrs	122	9.88	120	121.17	9.93	120	0.646
DBP							
0 hr	70.25	6.54	70	73.5	8.4	70	0.02
2 hrs	70	7.48	70	73	6.19	70	0.018
4 hrs	71.32	6.67	70	73	6.71	70	0.171
6 hrs	71.92	7.08	70	71.83	6.76	70	0.948
24 hrs	71.42	6.38	70	74.67	7.69	80	0.013

Values are expressed as frequencies and percentages; a p-value is by Chi-square test. A p-value less than 0.05 is considered to be statistically significant

Table 5: The table depicts the distribution of heart rate and SPo2 in RD and ARD groups

Heart Rate	Group						P value
	Group RD			Group ARD			
	Mean	SD	Median	Mean	SD	Median	
0 hr	76.73	9.7	76	75.2	8.04	75	0.348
2 hrs	73.82	7.62	74	74.48	8.28	75	0.647
4 hrs	75.53	8.58	77	73.57	7.77	72	0.191
6 hrs	75.77	9.11	75	73.58	7.78	74	0.161
24 hrs	75.27	8.89	75	73.38	7.65	74	0.216
SPO2							
0 hr	98.78	1.09	99	98.85	0.88	99	0.713
2 hrs	98.68	1.11	99	98.87	0.83	99	0.309
4 hrs	98.62	1.15	99	98.95	0.83	99	0.072
6 hrs	98.65	1.13	99	98.87	0.93	99	0.254
24 hrs	98.65	1.13	99	98.53	2.86	99	0.769

Values are expressed as frequencies and percentages; a p-value is by Chi-square test. A p-value less than 0.05 is considered to be statistically significant

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Table 6: The table depicts the distribution of retching, vomiting and rescue antiemetics in RD and ARD groups.

		Group RD		Group ARD	
		Count	%	Count	%
Retching	Absent	57	95.00%	59	98.30%
	Present	3	5.00%	1	1.70%
Vomiting	Absent	59	95.00%	59	98.30%
	Present	1	5.00%	1	1.70%
Rescue Antiemetics	Nil	53	88.40%	58	96.70%
	Inj. Metoclopramide	7	11.60%	2	3.30%
Values are expressed as frequency and percentage.					

Table 7: The table depicts the Grades of PON hourly distribution in RD and ARD groups

		Group RD		Group ARD		
		Count	%	Count	%	
Grade of PON (at 0 hr)	0	56	93.3%	59	98.3%	0.299
	1	2	3.3%	1	1.7%	
	2	2	3.3%	0	0.0%	
Grade of PON (2nd hr)	0	60	100.0%	60	100.0%	-
Grade of PON (4th hr)	0	60	100.0%	60	100.0%	-
Grade of PON (6th hr)	0	59	98.3%	60	100.0%	0.315
	2	1	1.7%	0	0.0%	
Grade of PON (24th hr)	0	60	100.0%	60	100.0%	-
Values are expressed as frequencies and percentages; a p-value is by Chi-square test. A p-value less than 0.05 is considered to be statistically significant						

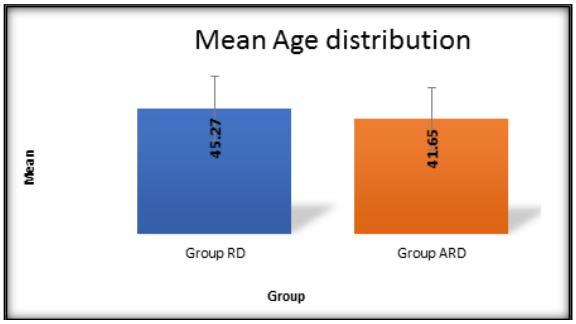

Figure 1: The graph illustrates the mean age distribution in RD and ARD groups

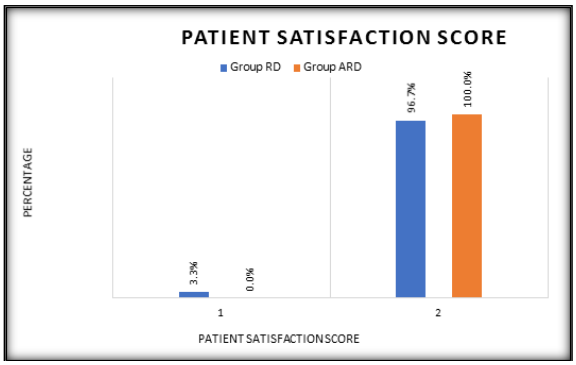

Figure 2: The graph illustrates the patient satisfaction score in RD and ARD groups

DISCUSSION

An average of 20% and 30% of patients who undergo general anaesthesia with volatile anaesthetics experience postoperative nausea and vomiting (PONV). PONV causes significant negative clinical outcomes and is distressing for the patient.

The incidence of PONV is 5% in infants, 25% in children under the age of 5, 42-51% in children aged 6 to 16, and 14-40% in adults. We have selected adult patients in the age group of 18-60 years in our study.

5HT3 receptor Antagonists are the most commonly used drugs for PONV. Ondansetron was the first in this category approved by Food and Drug Administration in 1991. According to Sameer N Desai et al., compared to better-established 5-HT3 receptor antagonists, Ramosetron has a stronger and longer-lasting antagonistic impact on the receptor. Additionally, the elimination half-life of Ramosetron (9 hours) is longer than Ondansetron's (3.5 hours). Due to its pharmacological characteristics, Ramosetron is anticipated to be more effective and have a longer duration of action than conventional 5-HT3 receptor antagonists in the therapeutic setting. According to numerous trials, Ramosetron 0.3 mg is superior to Ondansetron 4 mg for PONV prevention.[6]

The Glucocorticoid dexamethasone produces an antiemetic effect, possibly via the release of endorphins and inhibition of prostaglandins and serotonin production. In a study conducted by Jung-Hee Ryu et al., comparing the efficacy of Ramosetron 0.3mg and a combination of 0.3mg Ramosetron plus Dexamethasone 8mg, it was observed that the group which received combination therapy had a lower incidence of PONV, hence the lesser requirement of rescue antiemetics and also decreased postoperative pain.[5] In our study, we administered Inj. Dexamethasone 4mg after induction and Inj. Ramosetron 0.3mg 20 minutes before the end of the surgery, as the peak action time of Ramosetron is 20 minutes.

Recently, there has been an increase in the use of complementary and alternative medicines (CAM) to treat PONV or compare these treatments to conventional pharmacological approaches. Auricular Acupressure is one of the non-pharmacological methods for preventing postoperative nausea, Retching and vomiting. There

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are various theories postulating the mechanism of action of Acupressure, the most popular being the Neurophysiological concepts which include the Gate control theory of pain, Motor gate theory and thalamic neuron theory.[7]

Ronald Melzack and Patrick Wall established pain's gate control theory (GCT) in 1965. It was the first theory to suggest that pain perception is not just the result of a straightforward linear process that starts with stimulating pain pathways in the peripheral nervous system and concludes with the central nervous system experiencing pain. Instead, before the perception of pain is conveyed to the central nervous system, neural impulses that could signal pain from the peripheral nervous system are subject to several modulations in the spinal cord via a "gatelike" process in the dorsal horn.[8] Similarly, when deep pressure is applied to the specific sites via Acupressure, there is modulation in the pathway, which can decrease the initial severe pain. Acupressure is thought to trigger the release of endorphins from the hypothalamus via deep-lying sensory receptors in the muscle, which is a neuropeptide that occurs naturally with the ability to relieve pain.

According to Melo RN et al., the auricular pavilion, regarded as one of the primary microsystems of the human, is stimulated at precise spots according to conventional principles of auricular Acupressure to prevent PONV.[9]

The incidence of PON during the first two hours after the patient was shifted to PACU was 6.6% in group RD whereas none from group ARD complained of any incidence of post-op nausea (p=0.299). This is comparable to the study by L.Lopez -Olaondo et al. to compare the efficacy of Ondansetron and dexamethasone combination with individual drugs, where the incidence of nausea in the first 2 hours in the Ondansetron plus dexamethasone group was 4%.[10]

In the study done by Ryu JH et al. to compare Ramosetron versus Ramosetron plus Dexamethasone to prevent postoperative nausea and vomiting (PONV) after laparoscopic cholecystectomy, the incidence of PON in the first two hours was 25% in the combination group with 36 participants (p=0.44).

At the end of 24 hours, the total incidence of nausea in group RD was 8.3%, which is not comparable to the study done by Ryu JH et al., which showed an incidence of 33% in the Ramosetron plus Dexamethasone group, by the end of 24 hours. In our literature research, no study has been done to assess the efficacy of triple therapy- Auricular Acupressure, Ramosetron and Dexamethasone.

In the first 24 hours after surgery, the incidence of retching in group RD was 5.0%, whereas that in group ARD was 1.7%. In the study by Ryu JH et al., the incidence of retching in the group receiving Dexamethasone was 3% by the end of 24 hours. There is no statistically significant difference between the two groups in both studies. (5)

The incidence of Retching could not be compared with the study done by L.Lopez -Olaondo et al. as they have not separately assessed the incidence of Retching.[10]

In our study, the incidence of vomiting in both groups during the first 24 hours post-surgery was 1.7% (p=1.00) with no statistical significance. In the study done by Ryu JH et al., there was no incidence of vomiting in the Ramosetron plus Dexamethasone group in the initial 24 hours, whereas in the study done by L.Lopez -Olaondo et al., the incidence of vomiting was 8% in the Ondansetron plus dexamethasone group. There was no significance in emetic episodes between patients of both groups.[10]

In our study, the requirement of rescue antiemetics in group RD was 11.6%, comparable to 8% in the study done by L.Lopez -Olaondo et al. and 11% as per the study of Ryu JH et al.[5-10] Requirement of rescue antiemetics in group ARD, in our study was 3.3%.

In the study by L.Lopez -Olaondo et al., a note on the variables such as postoperative comfort, postoperative analgesia, and night sleep (rated as bad, fair, good and very good) was made. The time before the first postoperative oral intake, the time before standing up, and the point at which the nasogastric tube and urine catheter were removed are all measures of postoperative comfort in comparison to prior experiences (reported as worse, similar, better, and not comparable) and was observed that postoperative comfort was not rated as poorly by any patient. At 24 hours, it was discovered that group Ondansetron plus Dexamethasone had more comfort (P 0.05). In that study, 11% of patients described their postoperative comfort as fair, primarily due to PONV, and there were no changes between groups at 48 hours.[10]

CONCLUSION

Our study concluded that both drug regimes (Ramosetron plus Dexamethasone) and the triple drug (Auricular Acupressure plus Ramosetron plus Dexamethasone) were equally effective in preventing postoperative nausea and vomiting. However, the triple-drug regime is more effective in producing a 94.9% complete response which was clinically significant compared to the two drug regimes. Auricular Acupressure can be used as a safe adjuvant to routine antiemetic drugs to reduce the incidence of nausea, retching and vomiting during the postoperative period. To recommend Auricular Acupressure alone as an alternative to routine pharmacological therapy is not attractive due to ethical considerations. However, Auricular Acupressure can be used as part of a multimodal antiemetic regimen to take advantage of its unique mechanism of action.

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