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ORIGINAL RESEARCH PERIOPERATIVE MEDICINE

Comparison of the efficacy of acupressure on P6 point, dexamethasone and ondansetron versus palonosetron monotherapy for preventing postoperative nausea and vomiting in laparoscopic surgery

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) is a common occurrence, affecting approximately 70-80% of patients who have undergone surgery, particularly those with multiple risk factors. The aim of our study was to compare the effectiveness of palonosetron as monotherapy versus a combination of ondansetron with dexamethasone and acupressure P6 wristband in preventing PONV and reducing the need for rescue anti-emetics after laparoscopic surgery.

Methodology: A randomized controlled trial involving a total of 90 ASA I and II patients with APFEL scores ≥ 2 was conducted. These patients were recruited and randomly assigned to either the monotherapy or the combination therapy group. In the monotherapy group, patients received intravenous (IV) palonosetron 0.075 mg immediately after induction of anesthesia. In the combination therapy group, patients received dexamethasone 8 mg IV and an acupressure P6 wristband immediately after induction. Subsequently, ondansetron 4 mg IV was administered, and the wristband was removed prior to emergence from anesthesia. For both groups, metoclopramide 10 mg IV was available as a rescue anti-emetic if needed. The frequency of PONV and the requirement of rescue anti-emetics were recorded at multiple time points: at 0, 6, 12, 24, and 48 h postoperatively.

Results: In the combination therapy group, 13.3% of patients experienced PONV, compared to 33.3% in the palonosetron group. The difference was statistically significant (95% CI 0.107-0.888, P = 0.025). The combination therapy group had a lower incidence of nausea compared to the palonosetron group, particularly at 6 h (2.2% vs 24.4%, 95% CI 0.009-0.571, P = 0.002) and at 12 h (0% vs 11.1%, 95% CI 1.696-2.662, P = 0.021). The incidence of vomiting was significantly lower in the combination therapy group at 6 h (2.2% vs 15.6%, 95% CI 0.015-1.048, P = 0.026). None of the patients in the combination therapy group required rescue anti-emetics, while 17.8% of patients in the palonosetron group requested these post-operatively. The difference was statistically significant (95% CI 1.746-2.814, P = 0.003).

Conclusion: The combination therapy with ondansetron, dexamethasone and acupressure P6 wristband significantly reduced the incidence of PONV and the need for rescue anti-emetics when compared with the palonosetron alone. The benefits of the combination therapy were particularly notable at 6 and 12 h postoperatively, as evidenced by the significantly lower incidence of nausea and vomiting during these time periods.

Key words: Combination Therapy; Monotherapy; Palonosetron; PONV; Rescue Anti-Emetics

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1. INTRODUCTION

Postoperative nausea and vomiting (PONV) refer to the occurrence of nausea and vomiting within 24 h after surgery. While it affects around 20-30% of patients undergoing surgery, the prevalence can be significantly higher, reaching 70-80% in individuals with multiple risk factors. The aetiology of PONV is complex and involves various factors related to the patient, anesthesia, and the surgical procedure.

Patient factors that contribute to the risk of PONV include being female, non-smoking status, having a history of previous episodes of nausea and vomiting, and a susceptibility to motion sickness. On the other hand, anesthesia-related factors, such as the use of volatile agents (particularly nitrous oxide), intra-operative or post-operative administration of opioids, and high doses of neostigmine for reversal, can also increase the likelihood of PONV. Furthermore, certain surgical procedures are considered to carry a higher risk of PONV, including strabismus surgery, laparoscopic surgery, cholecystectomy, gynaecological surgery, and otolaryngology surgery. These surgeries may involve specific physiological or anatomical factors that contribute to the development of PONV. [1]

The APFEL score has been established as a useful tool for stratifying the risk of PONV. Each cumulative factor in the APFEL score corresponds to a specific risk percentage, ranging from 10% to 80%.[2] This scoring system helps guide the management of PONV, with combination therapy being recommended for patients categorized as medium or high risk according to consensus guidelines on the management of PONV in 2014. [3]

The effectiveness of combination therapy has been supported by various studies. G. Dewinter et al. formulated a simplified PONV management algorithm and found that the incidence of PONV was significantly lower when combination therapy was utilized compared to other approaches (33% versus 22%; P = 0.02). [4]

Another study conducted by Bhattarai et al. in 2011 compared the combination of ondansetron and dexamethasone with ondansetron alone. The results demonstrated that the incidence of PONV was significantly lower in the combination group (8% versus 24%; P < 0.029), and there was also a lower requirement for rescue anti-emetics (2% versus 22%; P < 0.05). [5]

Furthermore, palonosetron, a newer 5HT3 antagonist introduced in 2013 and approved by the U.S. Food and Drug Administration (FDA) for PONV prophylaxis, has shown promising efficacy as a monotherapy. [6] Several studies have been conducted to assess the effectiveness of palonosetron in preventing PONV. Kim et al. concluded that palonosetron exhibited the greatest efficacy in preventing PONV compared to ramosetron and ondansetron. [6]

Similarly, in a study comparing palonosetron and granisetron in 2016, the incidence of PONV was significantly lower in the palonosetron group (20%) compared to the granisetron group (56.66%). The requirement for rescue anti-emetics was also lower in the palonosetron group during the 24–72 h postoperative period (20% versus 56.66%; P < 0.05). [7]

The use of acupressure at the P6 point has gained interest in the prevention of PONV due to its ease of application and absence of significant drug-related side effects. Several studies have demonstrated the efficacy of acupressure at the P6 point in preventing PONV.

A study by Alirexa et al. compared the effect of acupressure at the P6 point with ondansetron and found that both interventions showed comparable efficacy in preventing PONV (20% versus 18%).[8]

Similarly, a study by Mansoor et al. compared acupressure with metoclopramide and found that the incidence of nausea within 24 h was significantly lower in the acupressure group compared to the control group (45% versus 27.5%, P = 0.005). The incidence of vomiting within 24 h did not show a significant difference between the acupressure and metoclopramide groups (37.5% versus 20%, P = 0.219).[9] Another study by Afshin et al. concluded that acupressure was more

effective than metoclopramide, particularly within the initial two h postoperatively.[10]

From a Western scientific perspective, it is postulated that acupressure at the P6 point may stimulate the release of endogenous opioids such as beta-endorphins, modulate inhibitory neurotransmitters like norepinephrine or serotonin, and influence the hypothalamic limbic system, thereby exerting analgesic and antiemetic effects.[10-11]

Although palonosetron has been proven to be superior to acupressure, dexamethasone, and ondansetron when used individually [6-7,12], its cost-effectiveness may be a consideration since it is more expensive than other agents. Additionally, combination therapy has shown to be more effective than monotherapy in preventing PONV. [13,16]

Therefore, the objective of this study is to compare the efficacy of palonosetron monotherapy with a combination of acupressure at the P6 point, dexamethasone, and ondansetron in preventing PONV. The aim is to investigate whether combination therapy can achieve equal or better results compared to palonosetron monotherapy, considering both efficacy and cost-effectiveness considerations.

2. METHODOLOGY

The methodology of the study involved obtaining approval from the Ethics Committee of University Science Malaysia (USM) (USM/JEPeM/19120955) and ClinicalTrials.gov number NCT04461093 and conducting the study at Hospital Universiti Sains Malaysia (USM) from April 30, 2020, to April 29, 2021.

The primary outcome measured was the proportion of PONV in each study group at 48 h, and the secondary outcome was the proportion of patients requiring rescue anti-emetics in each group at 48 h. (Figure 1)

The sample size was determined using a power and sample size calculation program. Based on a pilot study, the aim was to detect a 19% difference in the proportion of PONV and anti-emetic requirements between the two study groups (P0 20% versus P1 1%) with 80% power and a significance level of 0.05. To account for potential dropouts and ensure statistical power, a minimum of 45 patients were aimed to be included in each group.

Patients classified as ASA I and ASA II who were scheduled for laparoscopic surgery with an APFEL score of ≥ 2 were eligible for recruitment. Patients with allergies to the medications used, recent intake of anti-emetics or emetogenic drugs, glucocorticoids within 24 h pre-operatively, upper limb deformities, obesity (BMI ≥ 35), and vertigo was excluded from the study.

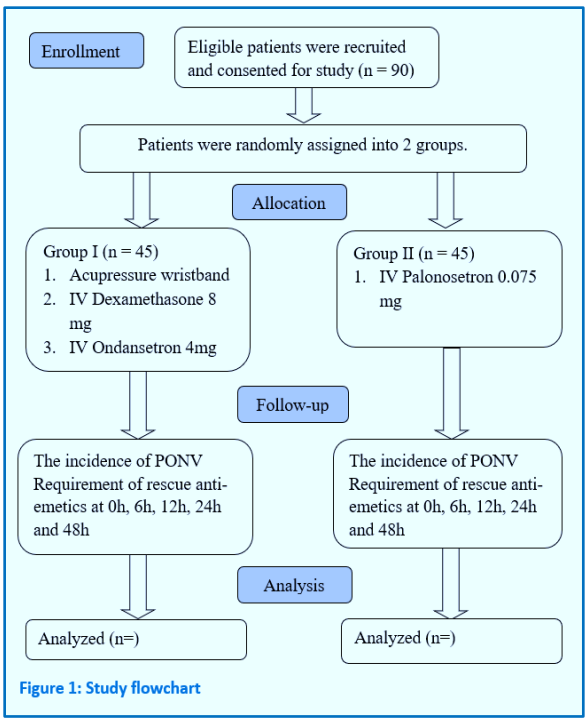

Figure 1: Study flowchart

Both the patients and assessors were blinded, and a random sequence of numbers was generated using online research randomizer tools. Sequentially numbered assessment forms for PONV were attached to the patient's information sheet according to the random sequence. Patients with odd-numbered forms received intravenous dexamethasone 8 mg and intravenous ondansetron 4 mg, while patients with even-numbered forms received intravenous palonosetron 0.075 mg and wore a Sea-band anti-nausea acupressure wristband.

A standardized anesthetic protocol was followed, including induction with IV Fentanyl, IV Propofol, and IV Rocuronium. Anesthesia was maintained with sevoflurane, and additional opioids and muscle relaxants were administered as needed. Standard monitoring procedures were implemented, and fluid replacement was performed intraoperatively. Postoperatively, patients received rescue anti-emetics and oral analgesia.

After surgery, patients were prescribed intravenous metoclopramide 4 mg as an emergency antiemetic and oral tramadol 100 mg for eight hours as an analgesic. Postoperative monitoring for nausea and vomiting was conducted by a blinded observer at 0, 6, 12, 24, and 48 h after surgery (Figure 1).

Statistical analysis

Data were collected and entered SPSS version 22 for analysis. Descriptive statistics were used to summarize the socio-demographic characteristics of the subjects and numerical data were presented as mean (SD) or median

(IQR) depending on the distribution. Categorical data were presented as frequency (percentage). The comparison between two groups was carried out with the chi-square test.

3. RESULTS

The study included a total of 90 patients, with 45 patients assigned to each group (combination group and palonosetron group). The demographic characteristics, APFEL scores, smoking status, and gender distribution were similar between the two groups. The combination group had 75.6% females, while the palonosetron group had 88.9% females (P = 0.098). There was only one smoker in the combination group and none in the palonosetron group (P = 0.315). In terms of APFEL scores, 71.1% of patients in the combination group had scores of 3-4 compared to 82.2% in the palonosetron group (P = 0.217) (Table 1)

Table 1: Patient demographics and clinical characteristics (n = 90)

Parameter		Combination group	Palonosetron group	P value[b]
Age[a] (y)		34.20 ± 12.13	35.98 ± 13.35	0.520
Weight (kg)[a]		64.98 ± 14.61	65.69 ± 11.66	0.799
Height (cm)[a]		159.84 ± 7.99	161.51 ± 17.22	0.557
BMI[a] (kg/m^2)		25.04 ± 4.84	25.29 ± 4.41	0.803
Gender	Male	11 (24.4)	5 (11.1)	
	Female	34 (75.6)	40 (88.9)	0.098
ASA	I	32 (71.1)	32 (71.1)	
	II	13 (28.9)	13 (28.9)	1.000
APFEL	2	13 (28.9)	8 (17.8)	
	3	31 (68.9)	33 (73.3)	0.217
	4	1 (2.2)	4 (8.9)	
Smoker		1 (2.2)	0 (0.0)	0.315
Discipline	Gynecology	12 (26.7)	12 (26.7)	
	General	32 (71.1)	33 (73.3)	0.602
	Urology	1 (2.2)	0 (0.0)	
Morphine (mg)[a]		3.67 (1.86)	3.78 (1.74)	0.771

ASA = American Society of Anesthesiologists; BMI = Body Mass index; [a]Mean ± SD, [b]Chi-square test; P < 0.05 considered as significant

Table 2: Total incidence of PONV (n = 90)

PONV	Combination group (n = 45)	Palonosetron group (n = 45)	P value	95% Confidence Interval
PONV	6	15	0.025	0.107-0.888
Rescue anti-emetic	0	8	0.003	1.746-2.814

PONV = Postoperative nausea and vomiting; P < 0.05 considered as significant

The laparoscopic surgeries included gynecology, general surgery, and urology cases, with similar distribution between the two groups (P = 0.602). The mean dose of morphine used intraoperatively was 3.67 mg in the combination group and 3.78 mg in the palonosetron group, which was not statistically significant (P = 0.602) (Table1).

The total incidence of PONV was lower in the combination group compared to the palonosetron group. In the combination group, 13.3% of patients experienced PONV, while in the palonosetron group, 33.3% of patients experienced PONV. This difference was statistically significant (95% CI 0.107-0.888, P = 0.025). None of the patients in the combination group required rescue anti-emetics, while 17.8% of patients in the palonosetron group requested rescue anti-emetics postoperatively (95% CI 1.746-2.814, P = 0.003) (Table 2).

Table 3: Incidence of post-operative nausea (n = 90)

Time	Combination group (n = 45)	Palonosetron group (n = 45)	P value	95% Confidence Interval
Immediately	41	10	0.157	0.136-1.403
6 h	1	11	0.002	0.009-0.571
12 h	0	5	0.021	1.696-2.662
24 h	0	1	0.315	1.639-2.496
48 h	0	1	0.315	1.639-2.496

P < 0.05 considered as significant

Table 4: Incidence of post-operative vomiting (n = 90)

Time	Combination group (n = 45)	Palonosetron group (n = 45)	P value	95% Confidence Interval
Immediately	0	2	0.153	1.653-2.534
6 h	1	7	0.026	0.015-1.048
12 h	0	0	NA	NA
24 h	0	0	NA	NA
48 h	0	0	NA	NA

NA = Not applicable; P < 0.05 considered as significant

Table 5: Incidence of anti-emetic requirement (n = 90)

Time	Combination group (n = 45)	Palonosetron group (n = 45)	P value	95% Confidence Interval
Immediately	0	2	0.153	1.653-2.534
6 h	0	0	0.021	1.696-2.662
12 h	0	1	0.0315	1.639-2.496
24 h	0	1	0.315	1.639-2.496
48 h	0	0	NA	NA

NA = Not Applicable; P < 0.05 considered as significant

When looking at the incidence of nausea at different time intervals, it was found that most patients experienced nausea immediately, at 6 h, and at 12 h postoperatively. At 6 h postoperative, 2.2% of patients in the combination group and 24.4% of patients in the palonosetron group experienced nausea, which was statistically significant (95% CI 0.009-0.571, P = 0.002). At 12 h postoperative, none of the patients in the combination group experienced nausea, while 11.1% of patients in the palonosetron group did, which was statistically significant (95% CI 1.696-2.662, P = 0.021). (Table 3).

Only one patient in the combination group vomited at 6 h postoperatively. In the palonosetron group, two patients vomited immediately in the recovery room, and 7 patients vomited at 6 h postoperatively, which was statistically significant (95% CI 0.015-1.048, P = 0.026) (Table 4). None of the patients in the combination group required anti-emetics postoperatively. In the palonosetron group, 2 patients requested rescue anti-emetics immediately, 5 patients requested them at 6 h, and 1 patient requested them at 12 h and 24 h postoperatively, but these differences were not statistically significant (P > 0.05) (Table 5).

4. DISCUSSION

Postoperative nausea and vomiting (PONV) is a common and distressing complication following surgery, which can lead to various undesirable effects and complications. To prevent PONV, multiple algorithms and strategies have been developed.

It has been demonstrated in previous studies that combination therapy is often superior to monotherapy in preventing PONV, particularly in high-risk patients[5,13]. The synergistic effects of different agents acting at different receptors contribute to the enhanced efficacy of combination therapy.

However, newer agents like palonosetron have shown promising results and may offer better efficacy in preventing PONV. A study conducted by Park et al. compared palonosetron monotherapy with a combination of palonosetron and dexamethasone, and it demonstrated that palonosetron alone was effective in preventing PONV. [14] This suggests that palonosetron as a single agent may be as effective as combination therapy involving palonosetron and dexamethasone. [15]

The study aimed to recruit patients who were truly at high risk for PONV. The study stratified the risks based on patient factors using the APFEL score, as well as considering surgical and anesthetic factors such as laparoscopic surgery and opioid usage. This approach strengthens our study compared to other studies in the literature. One study by Park et al. in 2012 compared palonosetron monotherapy with combination therapy and demonstrated comparable risk stratification in patient recruitment. [14]

By using the APFEL score, it was estimated that patients had 40%, 60%, and 80% risk of developing PONV with APFEL scores of 2, 3, and 4, respectively. Importantly, there were no significant differences in demographic characteristics and estimated risk between the combination group and the palonosetron group (Table 1).

The findings reveal that the combination of acupressure P6 wristband with ondansetron and dexamethasone was more effective in preventing PONV compared to palonosetron monotherapy. The incidence of PONV in the palonosetron group was higher (33.3%) than in the

combination group (13.3%). These results align with the study conducted by Bala et al., where they observed a higher incidence of nausea and vomiting in the palonosetron group compared to the combination group.[16]

Based on these findings, it can be concluded that the addition of acupressure P6 wristband to ondansetron and dexamethasone therapy provides enhanced efficacy in preventing PONV. Moreover, the combination of acupressure P6 wristband with ondansetron and dexamethasone may potentially offer comparable or even superior efficacy to a combination of palonosetron and dexamethasone, especially when incorporated into routine anti-emetic prophylaxis protocols.

The inclusion of non-pharmacological measures, such as the acupressure P6 wristband, in PONV prevention strategies may present a valuable approach to managing this common complication in surgical patients. However, further research and larger-scale studies are necessary to validate these findings and establish the optimal combination therapy approach for PONV prevention.

The study demonstrated statistically significant differences in the occurrence of nausea and vomiting at 6 h and 12 h postoperative, with lower rates observed in the combination group. These findings align with the study conducted by Afshin et al., which concluded that acupressure at the P6 point significantly reduced PONV, particularly at 2 and 6 h after surgery.[10] The addition of an acupressure P6 wristband to the combination therapy in our study greatly improved the effectiveness in preventing early PONV.

It is worth noting that the lack of statistical significance in the efficacy of PONV prevention at 12 h postoperative in our study could be attributed to the small sample size. Larger sample sizes are generally more robust in detecting significant differences. However, the overall comparable outcomes between the groups at 24 and 48 h after surgery suggest that the combination therapy and palonosetron monotherapy had similar efficacy in preventing late PONV. These results are consistent with a study by Amrita et al., which highlighted the high efficacy of palonosetron specifically in the 24-72 h postoperative period.[7]

In the study, none of the patients in the combination group required additional anti-emetics, whereas 17.8% of patients in the palonosetron group required rescue anti-emetics, particularly at 6 h after surgery. Comparing these results with the literature review, it appears that the collection of data regarding the requirement for rescue anti-emetics was limited in most studies[8-10], including those comparing palonosetron with a combination of palonosetron and dexamethasone. Park et al. did not collect such data on rescue anti-emetics[14], and Bala et al. reported a lower requirement for rescue anti-emetics in the combination group (14.3%) compared to the palonosetron group (42.9%).[16]

The study contributes to the understanding of the efficacy of combination therapy with the addition of an acupressure P6 wristband in reducing the requirement for rescue anti-emetics. Although the statistical significance of this outcome may not have been achieved in your study due to the small sample size, the trend towards lower rescue anti-emetic use in the combination group suggests a potential benefit of the combined approach.

5. LIMITATIONS

The duration of wristband application varied based on the duration of surgery and the need for removing the wristband prior to emergence to maintain blinding. This lack of standardization may introduce variability in the treatment approach and could potentially impact the outcomes. However, consensus guidelines for the management of PONV have indicated that the timing of P6 application is not a significant factor, as its efficacy has been shown to be similar regardless of the timing. The study only recorded the proportion of patients who developed PONV, without evaluating the severity of the symptoms. Patients who developed PONV might have experienced varying degrees of nausea and vomiting, which were not assessed. Assessing the severity of these symptoms could provide a more detailed understanding of the effectiveness of the interventions. Due to ethical considerations, the study did not include a control group where no anti-emetics were prescribed to patients at high risk of PONV. While this decision is understandable, the absence of a control group limits the ability to directly compare the efficacy of the combination therapy with the natural course of PONV in high-risk patients.

6. CONCLUSION

The combination of acupressure P6 wristband with ondansetron and dexamethasone demonstrated superior efficacy in preventing PONV compared to palonosetron monotherapy. The combination therapy was particularly effective at reducing PONV incidence at 6 hours after surgery.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Acknowledgement

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9. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

10. Authors' contribution

CWZ: conduction of the study work

AMM, NA: Concept

MO, NM, MZM: manuscript editing

All authors have read and approve the final draft of the manuscript.

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