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Comparison of Efficacy of Intravenous Palonosetron Versus Ondansetron and Dexamethasone for Prevention of Post-Operative Nausea and Vomiting (PONV) in Patients Undergoing Laparoscopic Surgeries

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ABSTRACT

Background: A high prevalence of PONV severely hinders a smooth recovery from anaesthesia and significantly increases postoperative patient discomfort. The introduction of numerous preventive antiemetic regimens in the late nineteenth century is known to be successful in lowering the incidence of the same, however there is scant evidence comparing ondansetron and Palonosetron, particularly when used for laparoscopic procedures.

Materials and methods: This is an analytical cross-sectional study, to be done in a total number of 50 patients who are posted for undergoing Laparoscopic surgeries under department of anaesthesia at Sree Balaji Medical College and Hospital, Chennai. Patients who were subjected to comparison of the respective two drugs were divided into two groups, group A- Palonosetron (0.075mg) IV and group B - Ondansetron (4mg) IV & Dexamethasone (4mg) IV and are then evaluated for effect on PONV. Patients are monitored and managed as per guidelines. Duration of post-operative Nausea and vomiting assessment and effects are noted in a comparative manner after observing the outcomes and the data will be analysed statistically.

Results: Mean age in group A is 48.47 and in group B it is 47.87.The two groups are comparable with respect to age ($P>0.05$). The two groups are comparable with respect to ASA grading ($P>0.05$). Extra antiemetic requirement is higher in group B than group A. There is difference is statistically significant between two groups with respect to Extra analgesia requirement ($P=0.001$).VAS score is better in group A compared to group B during all the assessment. There is statistically significant difference between both the groups with respect to VAS score from 6 to 24 hours ($P<0.05$). VCS score is better in group A compared to group B during all the assessment. There is statistically significant difference between both the groups with respect to VCS score from 6 to 24 hours ($P<0.05$).

Conclusion: Ondansetron has been often used for PONV prophylaxis, either alone or in combination with other medications, mostly due to its affordability. Contrarily, Palonosetron has a much higher affinity to the receptors and a greater half-life, resulting in an increased duration of activity that helps manage PONV better

Keywords: *Post-op nausea and vomiting, Palonosetron, Ondansetron, laparoscopic procedures.*

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1. INTRODUCTION

Post-Operative Nausea and Vomiting is a serious side effect of general anaesthesia. Although being typically transient, persistent nausea, vomiting, or retching has been linked to more serious and unfavourable outcomes, including dehydration, electrolyte imbalance, and increased pain threshold, aspiration of gastric contents, suture dehiscence, and oesophageal rupture. Even though such severe side effects are uncommon, PONV causes dysphoria, discontent, and a negative experience with anaesthesia and surgery. Almost 20% to 30% of surgical patients were found to experience post-operative nausea and vomiting. Laparoscopic surgeries, particularly laparoscopic cholecystectomy considerably increases the

incidence of PONV to as high as 50%. Criteria such as Female gender, non-smoker, previous experience of motion nausea, and using post-operative intravenous (IV) opioids contributes about 20% of the occurrence of PONV, in Apfel's simplified risk score. Because of this, when all four risk factors are present, PONV incidence might reach 80%.

A high prevalence of PONV severely hinders a smooth recovery from anaesthesia and significantly increases postoperative patient discomfort. The introduction of numerous preventive antiemetic regimens in the late nineteenth century is known to be successful in lowering the incidence of the same, however there is scant evidence comparing ondansetron and palonosetron, particularly when used for laparoscopic procedures.

5-HT3 receptor antagonist is currently the chosen therapy for surgeries like laparoscopic, gynaecologic, and middle ear surgery, among others, due to its effectiveness, safety, and favourable side effects profile, which eliminates the sedative, dysphoric, and extrapyramidal adverse effects of other medicines. The first 5-HT3 receptor antagonist utilised in therapeutic settings was ondansetron, whose antiemetic effectiveness is well known. Its 3-to-5-hour halflife is moderately brief. Palonosetron's specific chemical makeup allows it to interact with the 5-HT3 receptor in a way that the earlier 5-HT3 receptor antagonists with additional allosteric site binding capabilities cannot fully accomplish.

An affordable, long-lasting antiemetic medication is dexamethasone, it acts by enhancing the effects of other antiemeticsby a number of mechanisms, including bradykinin reduction, endorphin release, and prostaglandin antagonism. Due to advances in medications, anaesthesia practise has considerably improved inrecent years. However, pain is still the most upsetting symptom, followed by postoperative nausea and vomiting (PONV). PONV has the potential to prolong hospital stays and postpone recovery. Additionally, complications from morbidities such as aspiration pneumonia, haemorrhage, wound dehiscence, and dehydration might occur in cases of persistent vomiting.

Laparoscopic surgery is presently the preferred approach for diagnostic and/or therapeutic procedures. However, such operations have a substantial (40–75%) prevalence of PONV. Due to their superior pharmacodynamic properties 5-Hydroxytryptamine type-3 receptor antagonists (5-HT3RA) have replaced previous antiemeticssuch phenothiazines, antihistamines, metoclopramide, and droperidol. Ondansetron is the most common 5-HT3RA that is being used. Thanks to the second-generation 5-HT3RA Palonosetron, which was recently found to have increased receptor binding affinity and a very long plasma half-life of 40 hours, the anti PONV activity can now last into the second and third postoperative days. Ondansetron or Palonosetron can be used, according to recent literature, but some studies favour using one over the other.

New long-acting 5-HT3 antagonist Palonosetron has the potential to reduce the occurrence of PONV in clinical settings. Palonosetron is safer and equally effective as other antiemetics, with a lower incidence of side effects such extrapyramidal symptoms and dysphoria. Ondansetron and Palonosetron, both 5HT3 antagonists, are effective antiemetic drugs. Ondansetron has been often used for PONV prophylaxis, either alone or in combination with other medications, mostly due to its affordability. Palonosetron, on the other hand, has a substantially higher affinity for the receptor and a longer half-life, resulting in a prolonged duration of activity that can be beneficial for controlling PONV.The aim of the study is to determine the efficacy of Palonosetron versus Ondansetron and Dexamethasone for prevention of PONV in Laparoscopic surgeries and to monitor any potential pharmacological side effects.

MATERIALS AND METHODS

This is an analytical cross-sectional study, to be done in a total number of 50 patients who are posted for undergoing Laparoscopic surgeries under department of anaesthesia at Sree Balaji Medical College and Hospital, Chennai. Patients who were subjected to comparison of the respective two drugs were divided into two groups, group A- Palonosetron (0.075mg) IV and group B - Ondansetron (4mg) IV &Dexamethasone (4mg) IV and are then evaluated for effect on PONV. Patients are monitored and managedas per guidelines. Duration of post-operativeNausea and vomiting assessment and effects are noted in a comparative manner after observing the outcomes and the data will be analysed statistically. The study group participation is completely voluntary in this study.

All patients aged between 15 and 60 years undergoing Laparoscopic surgeries at Sree Balaji Medical College and Hospital with ASA grade — 1, 2, 3were included in this study. Patient who refused for giving consent, patients with ASA grade 4, Pregnant and lactating women, Known case of hypersensitivity reaction to Palonosetron and Dexamethasone and Ondansetron, Patients on steroid therapy, Antiemetics, or on treatment with other medications known to produce nausea and vomiting and Patients with history of motion sickness, nausea and vomiting pre-operatively.Patients were taught about visual analogue scale (VAS) for nausea vomiting & verbal categorical scale (VCS) for nausea and vomiting

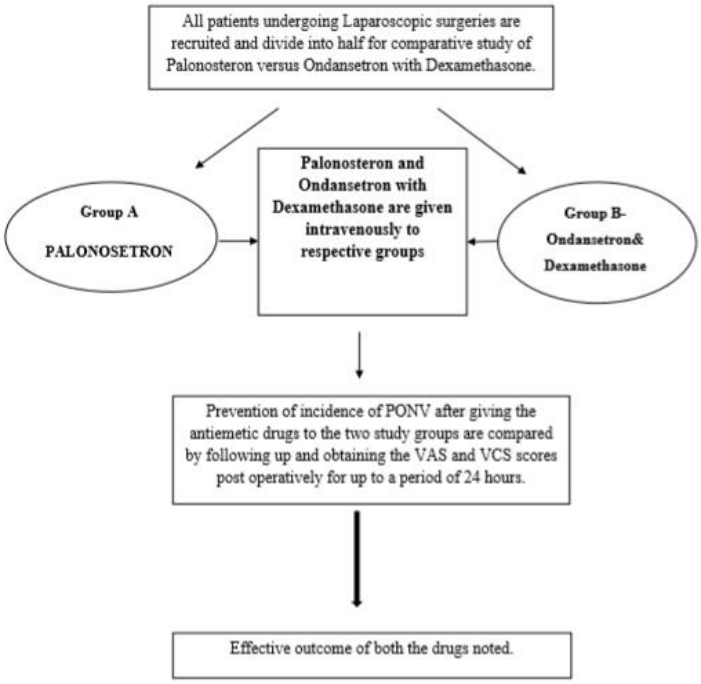

Figure 1: Methodology

2. RESULTS

This is a randomised controlled trial comparing the efficacy of Palonosetron (Group A) and ondansetron with dexamethasone (Group B) for prevention of postoperative nausea and vomiting.Mean age in group A is 48.47 and in group B it is 47.87.The two groups are comparable with respect to age(P>0.05). The two groups are comparable with respect to ASA grading (P>0.05).

Parameters	Group A	Group B	P value
Age	48.47±6.3	47.87±8.4	0.93
ASA I ASA II	14 11	15 10	0.78
Antiemetic requirement	2.12±0.78	2.98±1.01	0.001

Extra antiemetic requirement is higher in group B than group A. There is difference is statistically significant between two groups with respect to Extra analgesia requirement (P=0.001).

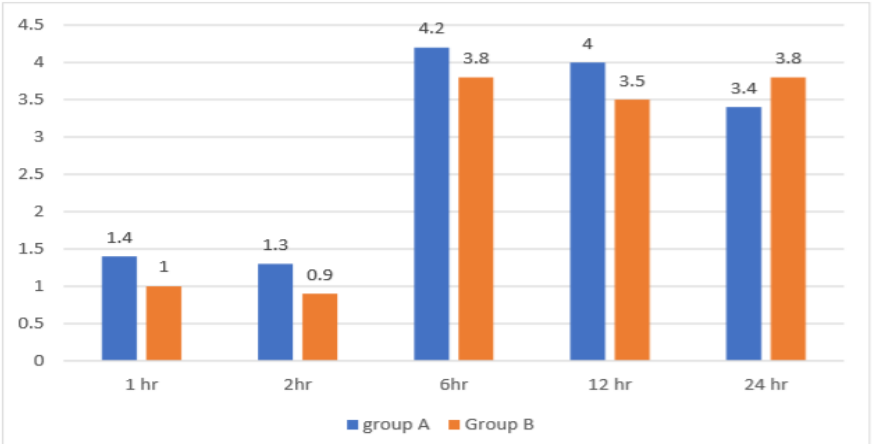

Figure 2: VAS score among study participants

VAS score is better in group A compared to group B during all the assessment. There is statistically significant difference between both the groups with respect to VAS score from 6 to 24 hours(P<0.05).

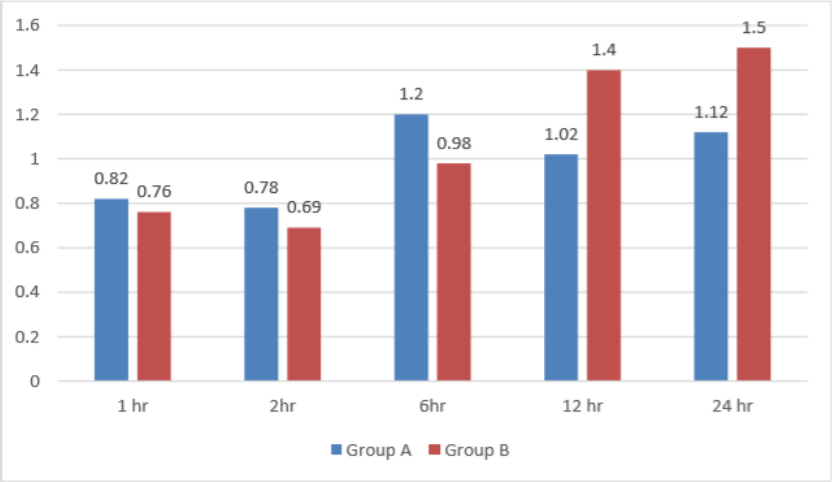

Figure 3: VCS score among study participants

VCS score is better in group A compared to group B during all the assessment. There is statistically significant difference between both the groups with respect to VCS score from 6 to 24 hours (P<0.05).

3. DISCUSSION

Patients who have surgery experience discomfort andunhappiness because of PONV. There are several approaches to both preventing and treating it. Nevertheless, 20–30% of people have PONV. Surgery, anaesthesia, and patient-related variables all have an impact on it [11]. The processes behind PONV's many mediators and various routes are complicated and uncertain [12]. Females, young population, opiate users, non-smokers, h/o of motion sickness or PONV, prolonged anaesthesia, and usage volatile anaesthetics are all known risk factors for PONV [13]. Since both groups in this study have risk factors more than two for PONV, the difference between the two groups wasn't significant. In terms of age and ASA rating, the two groups are comparable.

Palonosetron, a second-generation 5-HT3 receptor antagonist, has unique features compared to first generation 5-HT3 receptor antagonists.

1. Palonosetron has a bonded tricyclic ring system, as opposed to the first-generation medications' 3-substituted indolestructure that mimics serotonin.
2. Unlike first-generation drugs, its plasma half-life is larger than 40 hours, and its sensitivity for the 5-HT3 receptor is much higher (pKi = 10.45).
3. Third, Palonosetron displays allosteric fusing with favorablecooperativity and causes receptor integration, which results in long-term suppression of receptor function, whereas conventional 5-HT3 receptor antagonists preferentially antagonize serotonin via bimolecular competitive binding and occupancy at the 5-HT3 receptor.

Palonosetron functions successfully because of this distinct binding activity. Its lengthy half-life and long-lasting suppression of receptor activity by causing receptor internalization are additional factors contributing to its long duration of effect [14]. In previous studies, Ondansetron and dolasetron have been compared for their ability to prevent acute and delayed CINV, but compared to them palonosetron has been shown to be more effective. Palonosetron is the only 5-HT3 selective inhibitor approved for use in preventing both immediate and delayed CINV. To determine the response to effective dose and safety of 3 different dosages of palonosetron for reducing incidence of PONV within 72 hours post operatively, two pivotal placebo-controlled studies were done. These studies concluded stating 0.075 mg of palonosetron given intravenously is the most effective and tolerated dosage, and it had the better prophylactic effect especially in the 1st 24 hours post operatively. Following this, the US Food and DrugAdministration approved 0.075mg as the dosage to reduce PONV incidence till 24 hours post operatively [15]. Kim et al. [16] studied the effects of palonosetron (0.075 mg, i.v.) given pre operatively with a regimen of ondansetron (8 mg, i.v.) pre operatively and 16 mg added in women undergoing laparoscopic gynaecological surgery using fentanyl IV-PCA for 72 h postoperatively, but substantial differences were not found between the two groups in the PONV occurrence at any point of time of evaluation (2, 24, 48, and 72 h), despite bolus dosages being administered before anaesthesia induction.

Palonosetron offers various benefits over ondansetron that make it more promising and beneficial than ondansetron, despite the fact that we observed that its prophylactic effectiveness for the first 24 hours was equivalent to that of ondansetron. Regarding safety, palonosetron has no QT prolongation problem. Additionally, because to its prolonged duration of action, it prevents delayed PONV, especially post-discharge nausea and vomiting, which is a developing issue in outpatient anesthesia [17]. According to reports, palonosetron 0.075 mg is more efficient than 0.025 mg and 0.050 mg at preventing PONV [18].Extra antiemetic requirement is higher in group B than group A. There is significant statistical difference between 2 groups with respect to Extra antiemetic requirement (P=0.001) VAS score is better in group A than group B during all the assessment. There is significant statistical difference between the groups in VAS score from 6 to 24 hrs.(P<0.05) VCS score is better in group A than group B during all the assessment. There is significant statistical difference between both the 2 groups with respect to VCS score from 6 to 24 hrs.(P<0.05)

When comparing infusion of ondansetron with single dose of palonosetron, palonosetron does not significantly reduce emetic activity but is effective for the treatment of nausea up to 24 hours [19-20].

4. CONCLUSION

Ondansetron has been often used for PONV prophylaxis, either alone or in combination with other medications, mostly due to its affordability. Contrarily, palonosetron has a much higher affinity to the receptors and a greater half-life, resulting in an increased duration of activity that helps manage PONV better. More studies to be conducted in future to find out temporal association.

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