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COMPARATIVE STUDY OF PALONOSETRON AND ONDANSETRON FOR PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING

Anaesthesiology

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ABSTRACT

Introduction: Post operative nausea and vomiting remains a significant problem in modern anesthetic practice, with an incidence of upto 80% in high risk group patients.
Methods: 60 patients were conducted and divided into 2 groups. They received either inj Ondansetron 4mg iv or inj Palonosetron 0.075mg iv which was given 30 min before the end of surgical procedure.
Results: At time 0-6 hours, 6-24 hours,24-48 and 48-72 hours overall PONV was less in Palonosetron as compared to ondansetron
Conclusion: Palonosetron more significantly reduces the incidence of postoperative nausea and vomiting than Ondansetron.

KEYWORDS

INTRODUCTION

Post-operative nausea & vomiting (PONV) remains a significant problem in modern anaesthetic practice, with an incidence of upto 80% in high risk group patients.[1] Postoperative nausea and vomiting are one of the most common distressing symptoms occurring after surgery. The consequences of PONV are physical, surgical and anaesthetic complications for patients.[2] Persistent nausea & vomiting may result in dehydration, electrolyte imbalance can cause tachycardia, increased chances of oesophageal tear, wound dehiscence, tension on suture line, venous hypertension & increased bleeding under skin flaps. PONV is less commonly associated with more serious postsurgical complications such as disruption of vascular anastomosis, surgical site bleed and increased intracranial pressure.[3] The anaesthetic consequences are aspiration pneumonitis if airway reflexes are depressed from the residual effects of anaesthesia & analgesic drugs and discomfort in recovery.

MATERIALS AND METHOD

After approval from College and Hospital ethical commitee and written informed consent from the patient and/or attendant, the present study has been carried out in 60 adult patients of ASA grade 1& 2 between the age of 18-40 yrs, undergoing general surgeries under general anesthesia in the Department of Anesthesiology, Jhalawar Medical College, Jhalawar. All the patients under the study were subjected to detailed preanaesthetic check up and they were also explained about visual analog scale (VAS) for both nausea and pain. For nausea, it consists of a 10 cm unmarked linear scale where 0 = no nausea and 10 = worst possible nausea and for pain, it is 0 = no pain and 10 = worst possible pain. The risk of PONV wasdetermined according to Apfel simplified risk scoring system. All patients were instructed for nil per oral according to ASA guidelines. Evidence-based routine investigations were done. Patients were randomized into one of the two groups using a computer-generated list of random number chart and were allocated in Group I (n = 30), patients received intravenous (i. v.) palonosetron (0.075 mg), and in Group II (n = 30), ondansetron (4 mg) was given. All study drugs were diluted with 0.9% saline to get the final volume 5 ml in identical syringes by a person. All the patients were given preanaesthetic medication with inj Glycopyrolate 0.2 mg, inj Midazolam 0.04mg/kg IV and inj Pentazocine 30 mg IV. Preoxygenation of all the patients was done for 3 minutes in operation theatre before induction of anaesthesia. Induction of anaesthesia was done with inj. Propofol 2mg/kg IV slowly followed by inj. Succinylcholine 1.5mg/kg and IPPV with 100% oxygen was given. Intubation with proper size of disposable PVC cuffed endotracheal tube was done after muscle fasiculations passed off from hand muscles and complete muscle relaxation is achieved. **Maintenance** of anaesthesia was done with 100% oxygen + 1.5 to 2% halothane and nondepolarizing muscle relaxant (Atracurium Besylate) and patients were mechanically ventilated to maintain EtCO2 (35 to 45mm of Hg). All the patients were given the study drug blindly (by some other person) either Ondansetron 4mg (2ml) or Palonosetron 0.075mg (2ml) 30 min before the end of surgery who was not involved in the study. All patients were observed for emetic episodes (include retching) nausea and adverse effects for first 72hrs after recovery from anaesthesia and recorded during 0-6hrs, 6-24hrs, 24-48hrs, 48-72hrs. The hemodynamic parameters were also noted for the same time intervals. Rescue antiemetic metoclopramide 10 mg IV was given for VAS ≥4 score in nausea, vomiting episode and repeated if necessary. The time to receive the first rescue antiemetic and the total dose was also recorded. Complete response (CR) was also noted which is defined as no incidence of PONV during the 48 h observation period. The investigator also recorded any adverse effects related to drugs such as dizziness, headache, and arrhythmia.

All the observational data were noted and results were found out and statically analysed.

OBSERVATIONS AND RESULTS

COMPARISON OF THE INCIDENCE OF NAUSEA IN BOTH THE GROUPS

Time	Group-I	Group-II	(PVALUE)
0-6hrs	8(26.66)	7(23.3)	0.77 (P>0.05)
6-24hrs	6(20)	12(40)	0.024 (P<0.05)
24-48hrs	6(20)	13(43.33)	0.052 (P>0.05)
48-72hrs	4(13.33)	5(16.6)	0.71 (P>0.05)

The difference in incidence of nausea was 40% in ondansetron as compared to 20% in Palonosetron group in first 6-24 hrs & was statistically significant (P<0.05). The incidence of nausea at 0-6hrs, 24-48hrs and 48-72hrs postoperatively were also less with Palonosetron as to Ondansetron but statistically were not significant.

COMPARISON OF THE INCIDENCE OF EMESIS IN DIFFERENT GROUPS IN THE FIRST 72 HRS AFTER OPERATION

	Group-I	Group-II	(PVALUE)
0-6hrs	4(13.33)	4(13.33)	1
6-24hrs	3(10)	4(13.33)	.59
24-48hrs	2(6.66)	8(26.66)	.019
48-72hrs	3(10)	7(23.33)	.070

As compared to ondansetron group, incidence of emesis was less in the palonosetron group at all times, though this difference was not statistically significant (p>0.05) in 0-6 hrs,(13.33 for ondansetron, 13.33% for palonosetron), 6-24 hrs (13.33% for ondansetron, 10% for palonosetron) and 48-72 hrs (23.33% for ondansetron, 10% for palonosetron) but statistically significant (P<0.05) in 24-48 hrs (26.66% for ondansetron, 6.66 % for palonosetron).

COMPARISON OF THE SEVERITY INCIDENCE OF PONV by VAS IN BOTH THE GROUPS

TIME	Group-I	Group-II	PVALUE
0-6Hrs	0.44±1.23	0.93±1.61	0.190 (P>0.5)
6-24Hrs	0.74±1.5	0.87±.1.65	0.75 (P>0.5)
24-48Hrs	0.70±2.00	0.81±1.65	0.82 (P>0.5)
48-72Hrs	0.75±2.70	0.76±1.51	0.98 (P>0.5)

In our study we compared PONV at time 0-6hrs 6-24 hrs, 24-48 hrs and 48-72 hrs by determining the severity using VAS score. We found

palonosetron to be better at all time though it was statistically not significant (P>0.05).

DISCUSSION

Post-operative nausea and vomiting (PONV) is the common complication following anaesthesia and incidence is 20-25%. In addition to patient s dissatisfaction, PONV may have other adverse consequences such as delayed recovery, unexpected hospital stay and delayed return to work. Serotonine release initiates the stimulation of chemoreceptor trigger zone in the central nervous system, resulting nausea and vomiting. Etiological factors for PONV include female gender, age, non smoker, h/o motion sickness, procedural factors (duration of surgery, type of surgery) intraoperative use of opioids, use of N_2O.

HEAMODYNAMIC CHANGES-There was no significant difference in the haemodynamic parameters i.e. pulse, systolic blood pressure & SPO2 during & after the surgery in the both groups. Pulse, BP & SPO2 remained stable without any fluctuation.

INCIDENCE OF NAUSEA AND VOMITING

Episodes of nausea & vomiting were recorded for 0-6hrs, 6-24hrs, 24-48hrs and 48-72hrs of post-operative period in the both groups.

In our study we noticed the incidence of nausea as 26.66% in ondansetron and 23.3% in palonosetron after 0-6 hrs of surgery, 40% in ondansetron and 20% in palonosetron group after 6-24 hrs of surgery, 43.33% in ondansetron and 20% in palonosetron group after 24-48 hrs of surgery, 16.6% in ondansetron and 13.33% in palonosetron after 48-72 hrs of surgery. Although it is statistically not significant (P>0.05), but percentage of incidence of nausea supports that Palonosetron more significantly reduces the nausea than Ondansetron as also noticed in previous studies conducted by **Shadangi et al (2013)[4]&Arya et al (2015) [5].**

The difference in incidence of nausea was 40% in ondansetron as compared to 20% in Palonosetron group in first 6-24 hrs & was statistically significant (P<0.05) and at 0-6hrs, 24-48hrs and 48-72hrs postoperatively results were statistically non significant which also coincides with study conducted by **Shadangi et al (2013)[4]**

As compared to ondansetron group, incidence of emesis was less in the palonosetron group at all times, though this difference was not statistically significant (p>0.05) in 0-6 hrs,(13.33 for ondansetron, 13.33% for palonosetron), 6-24 hrs (13.33% for ondansetron, 10% for palonosetron) and 48-72 hrs (23.33% for ondansetron, 10% for palonosetron) but statistically significant (P<0.05) in 24-48 hrs (26.66% for ondansetron, 6.66 % for palonosetron).

In our study we found that Palonosetron more significantly reduces the incidence of nausea and emesis than Ondansetron which also coincides with the studies recently done by **Park SK & Cho EJ (2011)[6]& Moon et al (2012)[7]** who compared Ondansetron and Palonosetron and found Palonosetron better.

Shandangi K et al (2013)[4]found Incidence for emesis free patients for placebo and palonosetron were 56.6% and 86.6% (p-value=0.009 significant), and for placebo and ondansetron were 56.6% and 80% (p-value= 0.05 significant) respectively. The incidence of nausea in the first 24 hours was much less in the palonosetron group than the ondansetron group (16.7% vs. 43.4%, p-value=0.006),that a single dose of 0.075 mg palonosetron produced a considerable decrease in the incidence and severity of nausea than ondansetron (16.7% vs 43.3%, p=0.006) over 24 hours postoperatively)but there was no significant difference in the incidence of vomiting over 24 hours postoperatively.

Arya A et al (2015)[5]compared palonosetron with Ondansetron in their study and found that the incidence of nausea with Ondansetron was 10% and in patients with Palonosetron was 3.33% during 0-6 hrs (statistically comparable incidence in all study groups, p value>0.05). After that no episode of nausea (0%) was recorded in patients with Palonosetron, whereas during 6-24 hrs 6.67% patients had nausea with Ondansetron (p value>0.05) and during 24-48 hrs 6.67% in patients with Ondansetron had nausea (p value>0.05). After 48 hrs no patients had nausea.

Candiotti KA et al (2014)[8], Kovac AL et al (2008)[9] found that 0.075 mg palonosetron significantly reduced PONV in the first 24 h after anaesthesia as compared with placebo.

Park SK &Cho EJ (2011)[6]compared ondansetron 8mg and palonosetron 75mcg for the duration of 24h and observed that the incidence of PONV was significantly lower in the palonosetron group compared with the ondansetron group during the overall 0 – 24 h time interval (42.2% vs 66.7%, respectively) which coincides with our study.

Moon et al (2012)[7] compared the effects of IV ondansetron and palonosetron administered at the end of surgery in preventing postoperative nausea and vomiting (PONV) in high-risk patients receiving IV PCA after thyroidectomy. The incidence of PONV during the 24 h postoperative period was lower in the palonosetron group than in the ondansetron group (42% vs 62%, P=0.045). No differences were observed between the groups during the first 2 h. However, the incidence of nausea and vomiting and nausea severity were significantly lower in the palonosetron group than in the ondansetron group during 2-24 h.

Severity of Nausea & Vomiting (By VAS)

In our study we compared PONV at time 0-6hrs 6-24 hrs, 24-48 hrs and 48-72 hrs by determining the severity using VAS score. We found palonosetron to be better at all time though it was statistically not significant (P>0.05).

Similar results were obtained by **Laha B et al (2013)**[10] in their study. They compared Mean Visual Analog Scale (VAS) score for nausea at successive time points in the two study groups (Ondansetron & Palonosetron) . There was no statistically significant difference between groups.VAS scoring of nausea severity was comparable between groups at 2, 6 and also 24hrs following surgery.

SIDE EFFECTS & PATIENTS SATISFACTION

The difference in the incidence of all adverse events in the ondansetron, palonosetron were statistically insignificant. The majority of the adverse events reported were those that would be expected in patients having minor surgery performed under general anaesthesia.

In our study we observed headache in 15%, constipation in 10% and dizziness in 6.6% cases with Ondansetron and incidence of headache in 10%, constipation in 10%, dizziness in 6.6% and drug reaction in 3.3% cases with palonosetron. Our results coincides with the study of **Yoon DG et al (2009)**[11] who observed headache in 14%, constipation in 6% and dizziness in 17% cases with ondansetron. Incidence of adverse effects with palonosetron were headache in 11%, constipation in 9%, dizziness in 17%. **Chun H.R.et al (2014)**[12] observed headache in 19%, constipation in 9% cases with palonosetron which also coincides with our results.

Unlike the other antiemetics currently used ondansetron and palonosetron does not appear to cause drowsiness, sedation or affect the mental status. The overall side effect profile was similar in the both groups of present study and same was found by other workers in their studies.

The result of this study indicate that palonosetron is more effective and safe as conventional prophylactic therapy with ondansetron for preventing PONV in patients undergoing general anaesthesia for general surgery.

CONCLUSION

From this study it can be concluded that comparatively the Palonosetron is more effective and safe as conventional therapy with Ondansetron for preventing PONV in patients undergoing general anaesthesia for general surgery.

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