Section: Anaesthesia & Critical Care

Research

THE INCIDENCE OF POSTOPERATIVE NAUSEA AND VOMITING IN PATIENTS RECEIVING PALONOSETRON FOR GENERAL ANAESTHESIA IN LAPAROSCOPIC CHOLECYSTECTOMY- AN OBSERVATIONAL STUDY

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Abstract

Background: Postoperative nausea and vomiting is often referred to as the "big, little problem" within the anaesthesia world and has been a common complication for both in-patients and outpatients undergoing virtually all types of surgical procedures. **Materials and Methods:** This is an observational, longitudinal, single centre, prospective study, conducted at our tertiary care hospital, among 90 patients who underwent laparoscopic cholecystectomy. Palonosetron 75mcg was administered intravenously to patients just before induction and patients were observed for nausea vomiting postoperatively for 24 hours. Observational variables were described using counts and percentages. Qualitative data analysis was done using Fischer Exact Test. Progress of symptoms over 24 hours after surgery are described using line diagrams. **Result:** The incidence of early (0-4 hrs) nausea was seen in 25 (34.44%) patients, early retching in 4 (5.55%), early vomiting 8 (8.88 %) patients while late nausea (4-24 hrs) was seen in 2 (2.22%) patients. **Conclusion:** Our study concludes that the incidence of postoperative nausea, retching and vomiting was higher during early postoperative period (0-4 hrs) than during late postoperative period (4-24 hrs).

INTRODUCTION

Postoperative nausea and vomiting (PONV) is often referred to as the "big, little problem" within the anaesthesia world and has been a common complication for both in-patients and outpatients undergoing virtually all types of surgical procedures.[1,2] PONV frequently results in prolonged postoperative stay, unanticipated admission and increased health care costs.[3] Patients often perceive PONV as one of the most bothersome complications of anaesthesia – related adverse effects and may consider it as distressing as the pain associated with the surgical procedure. The consequences of PONV are surgical, physical and anaesthetic complications for patients and financial implications for the hospitals or institutions. Surgical consequences include disruption of vascular anastomoses and increased intracranial pressure.[4] Physical consequences include sweating, pallor, tachycardia, pain in abdomen, increased chances of esophageal tear, wound dehiscence and electrolyte imbalance.[4] The anaesthetic consequences are increased chances of aspiration pneumonitis and discomfort in recovery. For institutions there is increased financial burden because of increased nursing care, delayed discharge and unexpected admissions. In ambulatory surgery too, PONV delays the hospital discharge. This necessitates the use of prophylactic antiemetics. [5] The management of PONV has improved greatly in recent years, with the introduction of 5-Hydroxytryptamine (5-HT3) receptor antagonists.[6] Palonosetron is one of the latest 5-HT3 receptor antagonists, exhibiting significantly different characteristics from older 5-HT3 receptor antagonists because of its unique chemical structure.[7,8] Palonosetron has a greater receptor binding affinity and a much longer half-life, conferring a prolonged duration of action, exceeding 40 hrs, compared with other 5-HT3 receptor antagonists.[9] In addition, Palonosetron exhibits allosteric interactions and triggers receptor

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internalisation resulting in a long-lived inhibition of receptor function.[10] Hence this study was designed to observe incidence of PONV in patients undergoing laparoscopic cholecystectomy who were given Palonosetron 75mcg intravenously just prior to induction of anaesthesia.

MATERIALS AND METHODS

An observational, longitudinal, single center and prospective study, conducted at our tertiary care hospital, among patients who underwent laparoscopic cholecystectomy. Institutional ethical clearance (Registration no: 201-31253-142-202654) was obtained. Information about the study procedure was given to the patients or legally responsible attenders and consent was obtained. The privacy and confidentiality of the research participants was protected. Patients of 18- 65 years of age, classified under ASA grade I and II who underwent laparoscopic cholecystectomy surgery under general anaesthesia were included in the study. Patients belonging to ASA grade III and IV, pregnant women, patients with a history of motion sickness who have received antiemetic within 24 hrs of surgery, body mass index (BMI) of >30, complicated/prolonged surgery, patients converted to open laparoscopic cholecystectomy were excluded.

Based on the literature, it was found that on an average there was 40 % incidence of PONV for Palonosetron in patients undergoing laparoscopic cholecystectomy.[11] We considered the incidence of PONV would be 30%, taking desired precision +/- 10%, with 80% power and 5% level of significance. Using formula [n=(Z2 x P (1-P))/e] the sample size was estimated at 81 patients. 90 patients were enrolled to allow for possible incomplete data collection or patient dropout. All patients underwent pre-anaesthetic check-ups, routine investigations (Haemoglobin, complete blood count, renal function test, chest-X ray, Electrocardiogram and if necessary special investigations like 2D-ECHO, PFT were advised to rule out risk factors). All patients were pre-medicated with oral pantoprazole 40 mg and their medications as per their systemic diseases like hypertension, hypothyroidism etc. on the day of surgery in the morning. All patients were kept nil per oral from midnight before surgery. On the day of surgery, basal parameters were recorded with ECG monitor, heart rate, non-invasive blood pressure (NIBP) monitor, pulse oximeter (SPO2), End tidal carbon dioxide (EtCO2) and an intravenous line with 18/20 G iv cannula was secured. All patients received Inj. Glycopyrrolate (0.004 mg/kg), Inj. Midazolam (0.02 mg/kg) and Inj. Fentanyl (2 mcg/kg). All patients were oxygenated for 3 mins and induced with Inj. Propofol (2 mg/kg) till the loss of eyelash reflex. Inj. Atracurium (0.6 mg/kg) as a neuromuscular blocking agent was given. After 3 min patients were intubated with the appropriate size of the cuffed endotracheal tube and a nasogastric tube was also inserted. Anaesthesia was maintained with air: oxygen (50:50) with a fresh gas flow of 2 liters with Sevoflurane (1-3 %) to maintain the depth of anaesthesia targeting MAC value between 0.8-1. All patients were given Inj. Atracurium 25 mg/hour infusion for muscle relaxation and Inj. Fentanyl 20-30 mcg/hour for pain relief and sedation. Patients were monitored 24 hours postoperatively and incidence of PONV, the requirement of rescue antiemetic and side effects were observed. Repeated vomiting within 1–2-minute period was recorded as single emesis and the data was taken as follows:

Nausea was measured using an 11-point visual numerical scale as shown above with 0 = No Nausea, 10 = Nausea as bad as can be. A score of > 5 = Severe, 5 = moderate, < 5 = minimal. The severe and moderate scores were considered major nausea. If there is a vomiting episode of > 2 then it was considered as severe, 2 as moderate and < 2 as mild. Rescue antiemetic consisted of 75 mcg Palonosetron. All data were collected according to the proforma designed for the study. Premedication included oral pantoprazole 40 mg on the morning of surgery with sips of water. The type of anaesthesia was GA with IPPV. Inj. Palonosetron 75 mcg was given just before induction.

Observational variables were described using counts and percentages. Qualitative data analysis was done using Fischer Exact Test.

RESULTS

The mean age group of the study participants was 47.04 ± 12.003 (mean ± SD) yrs. 47 (52.22 %) were females and 43 (47.78 %) were males in the study population. The mean BMI was 24.4 ± 2.374 (mean ± SD). 55 (61.11 %) patients belonged to ASA grade I and 35 (38.89 %). to ASA grade II. Out of 90 patients, 21(23.33%) episodes of nausea, 4(4.44%) number of retching episodes, 7 (7.77%) number of vomiting episodes 0-1 hrs of surgery. [Table 1] The incidence of early (0-4 hrs) nausea was seen in 25 (34.44 %) patients, early retching in 4 (5.55 %), early vomiting 8 (8.88 %) patients while late nausea (4-24 hrs.) was seen in 2 (2.22 %) patients. [Table 2] Complete response was seen in 69 (76.66%) patients, while incomplete response in 21 (23.33%) patients to treatment with Palonosetron in 0-1hrs after surgery. 90 (100%) patients showed complete response to Palonosetron in 8-12 hrs after surgery. [Table 3] A total of 5 (9.1 %) cases in ASA grade I required rescue antiemetic and 3 (8.6 %) cases of ASA grade II required rescue antiemetic with a P-value of 1. There was no significant difference between ASA I and II cases. [Table 4] A total of 4 (8.5 %) females had side effects (headache) and none of the males had any side effects. So P-value could not be calculated as there was no incidence of headache. [Table 5]

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Table 1: Comparison of episodes of nausea, retching and vomiting

Time after surgery	Number of nausea episodes	Number of retching episodes	Number of vomiting episodes
0-1 HRS	21(23.33%)	4(4.44%)	7(7.77%)
1-2 HRS	5(5.55%)	1(1.11%)	1(1.11%)
2-3 HRS	5(5.55%)	0	0
3-4 HRS	0	0	0
4-8 HRS	0	0	0
8-12 HRS	0	0	0
12-16 HRS	0	0	0
16-20 HRS	1(1.11%)	0	0
20-24 HRS	1(1.11%)	0	0

Table 2: Number of patients who had early and late PONV

Time after surgery	Number of patients who had nausea	Number of patients who had retching	Number of patients who had vomiting
0-4 HRS	25 (27.77%)	4 (4.44%)	8 (8.88%)
4-24 HRS	2 (2.22%)	0	0

Table 3: Response to the treatment with Palonosetron

Time after surgery	Complete response	Incomplete response
0-1 HRS	69 (76.66%)	21 (23.33%)
1-2 HRS	84 (93.33%)	6 (6.66%)
2-3 HRS	85 (94.44%)	5 (5.55%)
3-4 HRS	90 (100%)	0(0%)
4-8 HRS	90 (100%)	0(0%)
8-12 HRS	90 (100%)	0(0%)
12-16 HRS	90 (100%)	0(0%)
16-20 HRS	89 (98.88%)	1 (1.11%)
20-24 HRS	89 (98.88%)	1 (1.11%)

Table 4: Frequency of rescue antiemetic versus ASA grade cross-tabulation.

			ASA grade		Total	p value
			I	II		
Frequency of rescue antiemetic	0	Count	50	32	82	p = 1.0 by Fischer Exact Test
		%	90.9%	91.4%	91.1%	
	1	Count	5	3	8	
		%	9.1%	8.6%	8.9%	
Total		Count	55	35	90	
		%	100.0%	100.0%	100.0%	

Table 5: Side effects versus Gender cross-tabulation.

		GENDER		Total	p-value
		F	M		
Side effects (Headache)	Count	43	43	86	p-value not calculated due to no headache observed in males.
	%	91.5%	100.0%	95.6%	
	Count	4	0	4	
	%	8.5%	0.0%	4.4%	
Total	Count	47	43	90	
	%	100.0%	100.0%	100.0%	

DISCUSSION

Present study was conducted for evaluating incidence of PONV on 90 patients who underwent elective laparoscopic cholecystectomy under general anaesthesia. Patients were given Palonosetron 75mcg intravenously just before induction of anaesthesia. Occurrence of nausea, vomiting and retching in the postoperative period was documented for 24 hours. We evaluated incidence of postoperative nausea and vomiting as early PONV (0-4 hrs) and late PONV (4-24 hrs).

Total episodes of nausea including multiple episodes in few patients is 33 episodes (36.66%), with 21 (23.33%) during first hour, 5 (5.55%) during second hour, 5 (5.55%) during third hour and 2 (2.22%) episodes in delayed time interval between 16-24 hours of post-operative period. Our findings were similar to a study done by Park SK et al.[12] In their study incidence of nausea was 33.3% over 24 hours and incidence of early PONV was 20%. But in their study late PONV was seen in 20% of patients, which was contradictory to observations made by us, in our study late PONV was seen in only 2.2% of the patients. This could be because all patients enrolled were females and postoperatively patients were given intravenous infusion of fentanyl for pain relief.

In our study the overall number of patients who had retching was 4 (4.44%), of which one patient had two episodes of retching all during the first four hours of postoperative period (early retching). These findings were similar to a study done by Bhattacharjee DP et al. in which total incidence of

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retching over 24 hours was around 6.66% of which 3.33% incidence was during early period and 3.33% during late period in the Palonosetron group.[13]

The overall number of patients in present study who had vomiting is 8 (8.88%), of which 7 (7.77%) patients had vomiting during first hour of post-operative period and only 1(1.11%) patient had vomiting during second hour of study, all patients had single episode of vomiting. In a study done by Bhattacharjee DP et al. incidence of vomiting during early period was 3.3% and during late period was 6.6% which are contradictory to our study. [13]

Complete response was 70% during early period (0-4 hrs) and during late period only 2 (2.22%) patients had PONV with 97.7% of complete response. In a study done by Bhattacharjee DP et al complete response during early and late period was 90%.[13]

4 (4.44%) patients, all females, (8.5% of female population in study) had headache for which no treatment was given and it subsided on its own. No other side effects were seen in the study population. In a study done by Kim SH et al. incidence of headache as side effect was 5.6% in the Palonosetron group, and in a study done by Park SH et al incidence of headache was 6.7% which were similar to our study.[12,14]

CONCLUSION

From present study we conclude incidence of postoperative nausea, retching and vomiting was higher during early postoperative period (0-4 hrs) than during late postoperative period (4-24 hrs) in patients receiving Palonosetron for general anaesthesia in laparoscopic cholecystectomy.

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