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A comparative study between ramosetron and palonosetron in preventing postoperative nausea and vomiting in laparoscopic surgeries

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Abstract
Objective: To study the efficacy and side effects of single dose of ramosetron and palonosetron i.v. for the prevention of postoperative nausea and vomiting in patients undergoing laparoscopic surgeries.
Methods: 60 patients of JSS hospital, Mysore posted for elective laparoscopic surgeries in the age group 18- 55 yrs of either sex & physical status ASA I and ASA II were included in the study.
Group I (n= 30) received (0.075mg) palonosteron i.v. Group II (n= 30) received (0.3 mg) ramosetron i.v.
Results: The age and sex distribution of both the groups were similar. There was a significant reduction in the incidence of nausea and vomiting in palonosetron group compared to ramosetron, need for rescue antiemetic, side effects were less in palonosetron group, when compared to ramosetron.
Conclusion: In our study, we observed that the incidence of nausea and vomiting was low with palonosetron when compared with ramosetron, but statistically not significant.

Keywords: laparoscopic surgeries, postoperative nausea and vomiting, palonosetron, ramosetron

Introduction

Nausea and vomiting have been associated for many years with the use of general anaesthetics for surgical procedures. With the change in the emphasis from an inpatient to outpatient, hospital and office-based medical/surgical enhancement, there has been increased interest in the 'big little problem' [1] of PONV.

One of the first extensive descriptions of the phenomenon was by John Snow, published in 1848, within 18 months of the introduction of anaesthesia into Britain. He observed that vomiting was more likely to occur if the patient had eaten recently [2].

There has been a general trend towards a decrease in the incidence and intensity of the problem because of the following –

1) Use of less emetic anaesthetic agents.
2) Improved pre-and postanaesthetic medication (e.g. analgesics)
3) Refinement of operative technique and
4) Identification of patient predictive factors.

However, in spite of these advances, nausea and vomiting still occur with unacceptable frequency in association with surgery and anaesthesia and the description of it as "the big little problem" encapsulates much of the general perception [2]. Incidence of nausea and vomiting is high in laparoscopic surgeries. Creation of pneumoperitoneum is an essential part of laparoscopy, leading to stretching of mechanoreceptors, increased serotonin synthesis and PONV.

The various detrimental effects of PONV are

1) **Physical:** Retching and vomiting are fairly violent acts. It causes considerable distress which may lead to serious complications like oesophageal tears, resulting in haemorrhage (Mallory – Weiss syndrome) and rupture of the oesophagus (Boerhaave syndrome), rib fracture, gastric herniation, muscular strain and fatigue. Inpostoperative cases,vomiting may cause wound dehiscence, intraocular bleeding, raises CVP,intra cranial pressureand bleeding of skin flaps in the upper body after plastic surgery.

The major problem associated with vomiting in the postoperative period is aspiration of vomitus, respiratory obstruction and aspiration pneumonia in deeply sedated patients.

2) **Metabolic:** The metabolic effects include anorexia, dehydration and electrolyte imbalance.
3) **Psychological:** Nausea is a very aversive stimulus and if experienced for first time may create fear complex and life-long aversion to surgery.[2]

Over the years, numerous approaches have been used in the management of PONV. Various techniques including olive oil and insulin-glucose infusions were reported to be effective. Robert Ferguson described the use of olive oil in 1912, he postulated that oil in the stomach "absorbed any ether that may be present there". The effect of atropine was appreciated by Brown – Sequard as early as 1883 when he wrote "in the very great majority of cases, the addition of a certain amount of atropine to morphine prevents the nausea and vomiting occurring with morphine alone [3].

Phenothiazines were synthesized originally in the late 19th century. In the late 1930s, promethazine was found to have antiemetic property. Charpentier synthesized chlorpromazine in 1949, but sedation and hypotension were limiting side-effects [4].

The traditional antiemetics include anticholinergics (scopolamine); Dopamine receptor antagonists which include the phenothiazines (promethazine), benzamides (metoclopramide) and butyrophenones (droperidol). The non–traditional antiemetics include ephedrine, propofol and corticosteroids.

The latest class of antiemetics used for prevention and treatment of PONV are serotonin (5-HT_3) receptor antagonists–ondansetron, granisetron, tropisetron, dolasetron and ramosetron (1st generation 5HT3 receptor antagonists). Palonosetron was recently introduced(2nd generation).These antiemetics do not have adverse effects of older traditional antiemetics [4].

Available antiemetics like 5-HT_3 antagonists are effective in very low doses [5]. Thus, costs can be lowered and drug side-effects prevented when given as prophylaxis, lowering the economic burden imposed due to complications and increased medical care resulting from PONV. In the present study, intravenous ramosetron and palonosetron are being compared in the prevention of postoperative nausea and vomiting.

Methodology

This clinical study consisting of 60 adult patients slated to undergo elective laparoscopic surgeries was undertaken. In this randomized, clinical comparative study, we studied 60 ASA Grades I and II patients between the ages of 18 and 55 years undergoing elective laparoscopic surgeries under general anaesthesia. Approval was taken from the ethical committee and written informed consent was taken from all the patients. They were randomly divided into two groups, Group I and Group II, each consisting of 30 patients. Group I received 0.075 mg of palonosetron i.v and group II received 0.3 mg of Ramosetron i.v, 2 minutes before the induction of anaesthesia.

Inclusion criteria

1. Patients of ASA grade I and II.
2. Age group –18-55 yrs of age of both sex.
3. Mallampatti classification 1 or 2 patients.
4. Elective surgeries under general anaesthesia.

Exclusion criteria

1. Patients having upper gastrointestinal disorder, advance liver disease uremic patients, cardiovascular disease, neurological disease and hypotension.
2. Morbidly obese patients having a BMI >35kg/m2.
3. Patients with allergy to study drugs.
4. Patients with ASA grade 3 and 4.
5. Patients with history of alcohol or drug abuse within last 3months.
6. Patients receiving anti emetics within 24 hrs preceding surgery

Methods

Preoperative visit was conducted on the previous day of surgery and a detailed history and present complaints were noted. General and systemic examinations of cardiovascular, respiratory and central nervous system were done. Routine laboratory investigations like complete haemogram, routine urine, blood urea, serum creatinine, and blood sugar, ECG, bleeding time and clotting time were done.

All patients received Tab. Alprazolam 0.5 mg and Tab. Ranitidine 150 mg on the previous night of surgery. Patients were instructed to remain nil orally after 10 PM on the previous night of surgery.

Results

The duration of surgery in group I was 115±50.9 minutes and 127.3±41.3 minutes in group II. This is shown in table 10 and was found to be statistically non- significant.

Table 1: Duration of surgery

Groups	No. of cases	Mean Duration (minutes)	Standard Deviation
Group I	30	115.0	50.9
Group II	30	127.3	41.3

P =0.3

Table 2: Distribution of the sample by the occurrence of nausea in the postoperative period in Groups I and II

Duration	Groups				Total		CC	P
	Group I		Group II		No. of cases	Percent		
	No. of cases	Percent	No. of cases	Percent				
0-2 hours	1	3.3	2	6.7	3	5	0.1	0.5
2-24 hrs	1	3.3	3	10	4	6.7	0.13	0.3
Total	2	6.7	5	16.7	7	11.7	0.14	0.2

Table 2 shows the occurrence of nausea and vomiting during 1st 24 hours postoperative period. During the 0-2hrs interval, 1 patient (3.3%) in group I and 2 patients (6.7%) in group II had nausea. These results were found statistically non significant (p=0.5) In 2-24 hrs interval 1 patient (3.3%)in group I and 3 patients in group II had nausea.

These results were found statistically non significant (P=0.3) Overall 2 patients in group I (6.7%) and 5 patients (16.7%) in group II had nausea and vomiting, were found statistically non significant (p=0.2)

Table 3: Distribution of the sample by the occurrence of retching in the postoperative period in Groups I and II

Duration	Groups				Total		CC	P
	Group I		Group II		No. of cases	Percent		
	No. of cases	Percent	No. of cases	Percent				
0-2 hours	0	0	0	0	00	0	-	-
2-24 hours	0	0	1	3.3	1	1.76	0.13	0.3
Total	0	0	1	3.3	1	1.76	0.13	0.3

Table 3 shows incidence of retching in first 24 hours period during 0-2 hrs. None of patients in group I and group II had retching.

In 2-24hrs none of cases in Group I and 1 patient (3.3%) in group II had retching which is found statistically non significant (p=0.3).

Table 4: Distribution of the sample by the occurrence of vomiting in the postoperative period in Groups I and II

Duration	Groups				Total		CC	P
	Group I		Group II		No. of cases	Percent		
	No. of cases	Percent	No. of cases	Percent				
0-2 hours	0	0	1	3.3	1	1.7	0.13	0.31
2-24 hours	1	3.3	2	6.7	3	5.0	0.08	0.6
Total	1	3.3	3	10	4	6.7	.19	0.2

Table 13 shows incidence of vomiting in group I and group II during 0-24hrs interval.

In 0-2 hrs none of patients in group I and 1 patient (3.3%) in group II had nausea which is found to be statistically non significant (p=0.31)

During 2-24hrs interval 1 patient(3.3%) in group I and 2 patients in group II(6.7%) had vomiting, which is found to be statistically non significant (p= 0.6)

Overall 1 patient (3.3%) in group I and 3 patients in group II(10%) had vomiting, Which is found statistically non significant (p=0.2)

Table 5: Incidence of PONV in Groups I and II.

Groups	PONV				Total	
	Present		Absent		No. of cases	Percent
	No. of cases	Percent	No. of cases	Percent		
Group I	1	3.3	29	100	30	100
Group II	3	10	27	96.7	30	100
Total	4	13.3	56	93.3	60	100

CC= 0.1; P =0.4

More number of patients in group II had high incidence of nausea and vomiting compared to group I was found statistically non significant.

Discussion

In our study we have taken oral questionnaire as the method to assess the nausea and vomiting as most of our patients are from rural area.

We conducted a study on 60 patients of ASA grade I and grade II divided into two groups, Group I receiving palonosetron and group II receiving ramosetron with similar demographic data in terms of age, sex and weight.

A high incidence of PONV is found in female patients and it increases with age. In our study incidence of PONV in 5 out of 30(16.7%) with ramosetron and 2 out of 30(6.7%) with palonosetron group which was found to be not statistically significant (p=0.2)

Gautampiplai, *et al.* [6] in patients undergoing laparoscopic cholecystectomy showed incidence of nausea between 0-24hrs was 4 out of 30 (13.3%) with ramosetron and 3 out of 30 (10%) with palonosetron found statistically not significant 9(p=0.69).

A study conducted by Sarbari Swanika, *et al.* [7] showed that ramosetron was more effective than palonosetron and ondansetron in early postoperative period (0-2 hrs), but there was no significant difference in overall incidence of nausea suffered (p=0.065). In our study it showed that palonosetron was more effective than ramosetron but it was statistically not significant (p=0.5)

Soumyendu *et al.* [8] conducted a study comparing two groups palonosetron and palonosetron with dexamethasone showed no statistical difference in incidence of nausea suffered (p<0.718).

Sukhminderjit *et al.* [9] conducted a study in patients undergoing day care gynecological surgeries showed that palonosetron was more effective than ondansetron in preventing PONV (p<0.05). The need for rescue antiemetic was significantly high in patients receiving ondansetron (p=0.036) which was again comparable with our study i.e. the need for rescue antiemetic was less in palonosetron when compared to that of ramosetron.

Soo Kyoung Park, *et al.* [10] conducted randomized control study comparing incidence of PONV between ramosetron and palonosetron in patients undergoing gynecological laparoscopic procedures showed no statistical difference between both the groups.

The incidence of side effects were significant among the two groups. Incidence of headache in Ramosetron was 6.7% and nil in Palonosetron group. This data shows statistically no significant difference (p value = 0.15) this is in contrast

to the results in the similar study done by Gautam Piplai *et al* and other study [6, 11] showed that no significant difference between ramosetron and palonosetron in terms of headache (p = 0.62).It has been established that an equal dose of 0.3 mg ramosetron is effective for prevention or treatment for CINV and PONV. For palonosetron, the recommended initial treatment dose for CINV is 0.25 mg and the minimum effective dose for PONV is 0.075 mg However, Tang *et al.* [12] reported that 30 μg/kg of palonosetron is the effective dose in reducing postoperative vomiting. In addition, a post-marketing surveillance reported tolerable adverse events at a higher dose of palonosetron in prophylaxis for CINV. Therefore, we think that studies are necessary to determine the efficacy and safety of higher doses of palonosetron in the prevention of PONV.

In terms of side effects, in the Ramosetron group (2 patients) and in Palonosetron group(none) had headache which is not significant. This is consistent with the observation of Kim, *et al.* where there was no difference in the incidence of side effects in the two groups.

Serious side effects like diarrhoea, arrythymias and extrapyramidal side effects were not observed in our study which is similar to the previous studies reported.

The requirement of antiemetic was higher in the ramosetron group (16.7%) as compared Palonosetron (0%). This difference is significant. Similar study conducted by Soo young, *et al* showed need for rescue antiemetic was more in ramosetron group compared to palonosetron.

Conclusion

- In our study, Incidence of nausea and vomiting was less in palonosetron group as compared to ramosetron, though the results were statistically insignificant.
- The need for rescue antiemetic was less in palonosetron as compared to ramosetron.

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