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Research Article

A Comparative Study of Intravenous Ondansetron and Granisetron for Prevention of Nausea and Vomiting Following Laparoscopic Cholecystectomy

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Abstract: Laparoscopic cholecystectomy is associated with significantly high rate of post operative nausea and vomiting (PONV). This study was designed to compare the effectiveness of Ondansetron with that of Granisetron for prevention of PONV after laparoscopic cholecystectomy. In a randomized, prospective study, 100 patients were selected and randomly divided into two groups of 50 each. Group one received Ondansetron 4mg intravenously and group two received 2mg Granisetron intravenously before induction. Perioperative anaesthetic care was standardized in all patients. They were then observed for 24 hours after administration of the study drug. A complete response (defined as no PONV and no need for another rescue antiemetic) was achieved in 66% of the patients given Ondansetron and 82% of the patients given Granisetron. Increased incidence of side effects seen in Ondansetron group than Granisetron group. This study concludes that Granisetron is slightly more effective than Ondansetron as prophylactic antiemetic in laparoscopic cholecystectomy.
Keywords: PONV, Ondansetron, Granisetron, Laparoscopic cholecystectomy

INTRODUCTION

Post-operative nausea and vomiting (PONV) is an unpleasant, distressing and exhausting experience for patients [1]. The consequences of PONV are various complications for the patient as well as financial implications for the Hospitals or Institutions. Physical consequences include sweating, pallor, tachycardia, and stomach ache, increased chances of wound dehiscence and electrolyte imbalance [2-3]. The anaesthetic consequences are aspiration pneumonitis and discomfort in recovery. Therefore, prophylactic antiemetic therapy is needed for all these patients. PONV is seen in laparoscopic cholecystectomy due to residual pneumo-peritoneum. Use of nitrous oxide, opoids, obese, past history of nausea and vomiting motion sickness are additional risk factors. $5HT_3$ receptor antagonists are highly effective in prevention and treatment of PONV [4].

The present study will be undertaken to compare the antiemetic effects of intravenous Granisetron and Ondansetron for prophylaxis of PONV in patients undergoing laparoscopic cholecystectomy.

METERIALS AND METHODS

100 patients between 25-60 years of age, either sex, 45-80 kg weight, between class ASA1 or ASAII were selected for laparoscopic cholecystectomy. Patients were randomly divided into two groups of 50 each. Exclusion criteria were patients of ASA III and ASA IV, history of drug allergy, history of motion sickness, previous history of PONV, history of Gastro-esophageal reflux disorder & history of taking anti-emetic drugs in previous 24 hours.

The study was prospective and randomized one. Ethical clearance was taken; written informed consent was taken from patients of both groups. All the patients were treated as pre-operative basis as Tablet Ranitidine (150mg) & Tablet Alprazolam (0.5mg) per orally at the night before surgery. Nil per orally for 6-8 hours, prior to surgery.Diclofenac sodium suppository 100mg was given one hour before surgery.In the preoperative room, intravenous line was secured.

In the operation theatre pulse oximetry, NIBP, ECG monitors were attached, and baseline blood pressure, heart rate and O2 saturation values were recorded. Later capnography was attached after the intubation. 100 patients were randomly divided into 2 groups of 50 each.

Group A (n=50): received intravenous ondansetron 2ml (4mg)

Group B (n=50): received intravenous granisetron 2ml (2mg).

All the drugs were given slowly two minutes before induction. All the patients were assigned into one of the two groups using blinded envelopes prepared with the help of a random number chart. A fellow anesthesiologist, not involved in the patient assignment gave the study drug. The anaesthetic regimen and surgical procedure were standardized for all patients. Intravenous Ringer's lactate was used during intra-operative and immediate post-operative period. Induction of anaesthesia was done with injection thiopentone 5mg/kg and intubation was facilitated with injection succinylcholine 2mg/kg.

A naso-gastric tube was introduced and suction was applied to empty the stomach of air and other contents that was removed before extubation. Maintenance of anaesthesia was maintained with nitrous oxide (66%) and oxygen (33%) and halothane (0.5%). Muscle relaxation was maintained with inj. Vecuronium (0.1mg/kg). Ventilation was controlled mechanically and adjusted so as to keep the end tidal carbon dioxide 35-40 mm of Hg. Laparoscopic surgeries were performed under video guidance. During surgery the patients were placed in trendlenberg position wherever required and the abdomen was insufflated with carbon dioxide with an intra-abdominal pressure of 12-15 mm of Hg. At the cessation of surgery patients were made supine and residual neuromuscular block was reversed with inj. glycopyrrolate 10mcg/kg and neostigmine 0.05mg/kg, patient was extubated in fully awake condition. In post anaesthesia care unit blood pressure,spo2,heart rate was recorded every 10 min. for 30 min. Episodes of nausea and vomiting experienced by each patient was recorded by direct questioning. The number of patients who suffered nausea/vomiting was noted during the period's 0-1hrs, 2-4hrs, 5-8hrs, 9-12hrs, 13-24hrs. Rescue antiemetic (Inj. Metoclopramide 10mg slow intravenous) was used if patient had vomiting. Side effects like headache, dizziness, dry mouth, restlessness, constipation was observed and registered by direct questioning.

RESULTS

Total 100 patients were included in the study. Patient population were comparable across the two groups with respect to Age, weight,systolic BP,diastolic BP,heart rate. Statistical analysis was done by using student 't'test and rest of the study data have been categorically analyzed.

Table 1: Age distribution (N=50)

Age Distribution	Ondansetron	Percentage	Granisetron	Percent
18 to 30 yrs	16	32%	15	30%
31 to 40 yrs	20	40%	24	48%
41 to 50 yrs	8	16%	6	12%
Above 50 yrs	6	12%	5	10%
Mean Age ± SD	36 ± 9.3		35.2 ± 8.6	

Fisher's exact test 2-tailed p value 1.000.Age Group: Most of the patients in both groups belonged to age group 31-40. There was no statistically significant difference in the two groups.

Table 2: Sex distribution (N=50)

Sex	Ondansetron	Ondansetron	Granisetron	Granisetron
Male	12	24%	13	26%
Female	38	76%	37	74%

Fisher's exact test 2-tailed p value 1.000 In our study females predominated males in Ondasetron group (24%) and Granisetron group (26%).

Table 3: Weight distribution (N=50)

Weight Range	Ondansetron	Percentage	Granisetron	Percentage
45 to 60kg	17	34%	24	48%
61 to 70kg	19	38%	12	24%
Above 70kg	14	28%	14	28%
Mean weight ± SD	65.8 ± 11		64.1 ± 12.2	

Fisher's exact test 2-tailed p value .658(>.05).There was no significant weight difference in mean weight between the two groups.

Table 4: ASA grade wise (N=50)

ASA	Ondansetron	Percentage	Granisetron	Percentage
Grade I	43	86%	40	80%
Grade II	7	14%	10	20%

Fisher's exact test 2-tailed p value 0.595(p>0.05). Both groups had no significant difference in ASA I and ASA II category

Table 5: Comparison of systolic BP, Diastolic BP, HR and SPO_2% (N=50)

Grade	Ondansetron	Granisetron
Mean Pulse	83.4 ± 7.7	86.3 ± 7.5
Mean SBP	135.3 ± 8.9	133.2 ± 8.9
Mean DBP	82.7 ± 6.4	80.6 ± 7.3
Mean SPO_2%	99.8 ± 0.4	99.8 ± 0.5

Table 6: Incidence of Nausea (N=50)

Duration of Nausea	Ondansetron	Percentage	Granisetron	Percentage
0 to1 hrs	6	12%	4	8%
2 to 4 hrs	4	8%	2	4%
5 to 8 hrs	4	8%	2	4%
9 to 12 hrs	2	4%	1	2%
13 to 24 hrs	1	2%	0	0

Occurrence of nausea in Ondanstron group and Granisetron group showed that incidence of nausea in 0-1 hours were 6 cases (12%)in Ondansetron group as compared to 4 cases (8%) in Granisetron group. P value 0.741(p>0 .05) . Incidence of nausea in 2-4 hours were 4 cases (8%)in Ondansetron group ascompared to 2cases (4%) in Granisetron group. p vaue 0.678 (p> 0.05). Incidence of nausea in 5-8 hours was 4 case (8%)in Ondansetron group as compared to 2 cases (4%) in Granisetron group. p value 0.678(p> 0.05). Incidence of nausea in 9-12 hours was 2 case (4%)in Ondansetron group ascompared to 1 cases (2%) in Granisetron group. p value 1.00(p> 0.05) . Incidence of nausea in 13-24 hours was 1 case (2%)in Ondansetron group as. compared to 0 cases (0%) in Granisetron group. p value 1.00(p > .05). The incidence of nausea was maximum during the first four hours and it was more in the Ondansetron group. But no statistically significant difference in post operative nausea seen in between these two group.

Table 7: Incidence of Vomiting (N=50)

Duration of Vomiting	Ondansetron	Percentage	Granisetron	Percentage
0 to1 hrs	5	10%	3	6%
2 to 4 hrs	3	6%	2	4%
5 to 8 hrs	3	6%	1	2%
9 to 12 hrs	2	4%	1	2%

Incidence of vomiting episodes in Ondansetron group were 5 cases (10%) as compared to 3 cases (6%) in granisetron group in 0-1 hours. p value 0.432(p>0.05). Incidence of vomiting episodes in Ondansetron group were 3 cases (6%) as compared to 2 cases (4%) in granisetron group in 2-4 hours. p value 1.00(p>0.05). Incidence of vomiting episodes in Ondansetron group were 3 cases (6%) as compared to 1 cases (2%) in granisetron group in 5-8 hours. p value 0.017(p<0.05) (significant). Incidence of vomiting episodes in Ondansetron group were 2 cases (4%) as compared to 1 cases (2%) in granisetron group in 9-12 hours. p value 1.00(p>0.05). No incidence of vomiting occurred in 13-24 hours in both group.Vomiting was maximum in 0-1 hours.Only vomiting episodes between 5-8 hours are statistically significant between two groups.

Table 8: Comparison of Rescue Antimetic (N=50)

Anesthetic Sequale	Ondansetron	Percentage	Granisetron	Percentage
Rescue antimetic	13	26%	7	14%

Fisher's exact test 2-tailed p value (0.211). Need for rescue antiemetic is more in Ondansetron group 13(26%) compared to Granisetron group 7(14%). But there is no statistical difference between two groups

Table 9: Comparison of Side Effects (N=50)

Side Effects	Ondansetron	Percentage	Granisetron	Percentage
Headache	8	16%	6	12%
Constipation	4	8%	3	6%
Dizziness	5	10%	3	6%

Headache: Fisher's exact test 2-tailed p value (0.774), Constipation: Fisher's exact test 2-tailed p value (1.000), Dizziness: Fisher's exact test 2-tailed p value (0.432).

Occurrence of side effects like headache, constipation and dizziness in Ondansetron group are 8(16%), 4(8%), 5(10%) respectively compared to 6 (12%), 3(6%), 3(6%) in Granisetron group. The number of patients who suffered side effects was more in Ondansetron group. Difference between two groups are statically non significant.

DISCUSSION

Post operative nausea and vomiting is very common complication in laparoscopic suregery. It is a limiting factor in the early discharge of laparoscopic surgery patients and is a leading cause of unanticipated hospital re-admission. The incidence of PONV after anaesthesia, despite the advances in antiemetic therapy in the last decades is still found to be relatively high. Factors affecting PONV include patient related factors (age, sex, history of motion sickness), anaesthesia related factors (use of volatile anesthetic agents, N_2O, Opioid) and surgery related factors (laparoscopy) [2-3]. Female gender has been associated with higher incidence of PONV compared to male patients.

In our study the factors that would have contributed to nausea and vomiting may be due to halothane & laparoscopic surgery. Use of facemask, use of Nitrous Oxide may or may not have contributed to nausea and vomiting. Avoidance of opoids and use of naso-gastric tube towards the end of surgery must have helped in preventing PONV. We have conducted studies on 100 patients of ASA I and II with demographic data in terms of age, weight, which were similar in the two groups. There was no significant difference in Ondansetron and Granisetron ($P > 0.05$) in terms of Age and Weight. Incidence of nausea in our study group was 34% in Ondansetron group, 18% in Granisetron group.

Vomiting in the present study group was 26% in Ondansetron, 14% in the Granisetron group. In our study group incidence of vomiting was highly significant in first 4hrs. Present study showed that Granisetron is better than Ondansetron for preventing PONV (5-8 hrs $p<0.05$).

Our study shows no statistically significant difference in the baseline values of haemodynamic variables between the two groups before, during or after giving study drug.In PACU we have recorded the SBP, DBP and HR over a period of 30min at regular interval. According to our study there was no haemodynamic alteration between these results. Incidence of side effects is statistically not significant in our study groups. Headache was 16% in Ondansetron group while it was 12% in Granisetron group shows no statistically significant difference .Incidence of constipation is 8% in Ondansetron and 6% in Granisetron group. Incidence of dizziness in Ondansetron group is 10% and in Granisetron group is 6% shows no significant difference beteen two groups statistically. The use of rescue antiemetic in ondansetron group which was about 13(26%) whereas in Granisetron group about 7(14%) of the patients received rescue antiemetic.

CONCLUSION

This study concludes that the prophylactic intravenous administration of Granisetron is a little more effective drug than Ondansetron for controlling postoperative nausea and vomiting. Safety profile is slightly more with Granisetron and it is slightly more potent than Ondansetron. So we observed minimal difference in emetic and nauseating episodes in postoperative period in patients who had received i.v. Granisetron in comparison to. Ondansetron, undergoing laparoscopic cholecystectomy under general anaesthesia.

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