



Anesthesiology

EFFICACY OF RAMOSETRON AND ONDANSETRON IN PREVENTION OF POST-OPERATIVE PONV IN CASES UNDER ABDOMINAL SURGERIES – A COMPARATIVE STUDY.

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ABSTRACT Post-operative nausea and vomiting (PONV) is an important cause of patients discomfort after surgery. Selective 5-hydroxytryptamine type 3 (5-HT₃) receptor antagonists are considered first-line for prophylaxis, ondansetron being the most commonly used agent. Ramosetron, another selective 5-HT₃ receptor antagonist, is more potent and longer acting than ondansetron. This study designed to assess the efficacy & safety of Ramosetron and Ondansetron in preventing the PONV after elective abdominal surgeries undergone spinal anaesthesia. A total 180 patients aged between 21-60 years with ASA class I and II, allotted for abdominal surgeries under spinal anaesthesia were recruited. Based on drug administered cases were equally divided in to 3 groups, group 1 with Ondansetron (4mg), group 2 with Ramosetron (0.3mg) and group 3 with Normal saline (only rescue anti-emetic). The incidence of nausea, vomiting and retching was studied for a period of 24 hours post operatively followed by PONV scoring system. In group 1, complete response (Score-0) was 88.3%, 95%, 96.6% and 96.6% in first 6 hours, 6-12hrs, 12-18hrs and 18-24hrs respectively. Complete response was 90% in first 6 hrs, 98.3% in 6-12hrs, 98.3% in 12-18hrs and 100% in 18-24hrs. In group 3, complete response was 76.6% in first 6 hrs, 80% in 6-12hrs, 90% in 12-18hrs and 91.6% in 18-24hrs. Ramosetron 0.3mg with has a significantly higher complete response than the Ondansetron 4mg (96.6% vs 94.1%) in the 24 hour postoperative period.

KEYWORDS : Post-operative nausea and vomiting (PONV), Ondansetron, Ramosetron, Nausea.

INTRODUCTION

Post-operative nausea and vomiting (PONV) is a common complication in patients undergoing all types of laparoscopic surgeries which has incidence up to 70-80% (1, 2). PONV is potentially harmful to a patient's recovery as it can result in wound dehiscence, bleeding, aspiration of gastric contents, electrolyte imbalances, and delayed hospital discharge (3).

Management of PONV after surgeries is a challenging task for perioperative physicians as it is distressing for the patients and more and more such surgeries are performed on day care basis. So, an effective prophylactic regimen is need for early home discharge (4).

The most common prophylactic antiemetic combination used to prevent PONV in India is Intravenous Ondansetron, a 5HT₃ receptor antagonist. Ramosetron is a newly introduced 5HT₃ receptor antagonist with potential advantage of greater efficacy with prolonged duration of action. Studies showed ondansetron to have less anti-nausea and more anti-vomiting efficacy (5) with concerns in cardiac safety(6) whereas Ramosetron has higher potency and prolonged activity with better safety.(7-9).

The present study aimed to assess the efficacy & safety of Ramosetron and Ondansetron in preventing the PONV after elective abdominal surgeries undergone spinal anaesthesia.

MATERIALS AND METHODS

The present randomized, double blinded comparative study was conducted in Department of Anaesthesia, Gandhi medical College and Hospital, Secunderabad during April 2017 to June 2018. A total 180 patients aged between 21-60 years with ASA class I and II, allotted for abdominal surgeries under spinal anaesthesia were recruited. Based on drug administered cases were equally divided in to 3 groups, group 1 with Ondansetron (4mg), group 2 with Ramosetron (0.3mg) and group 3 with Normal saline (only rescue anti-emetic).

Cases belongs to ASA class I and II, between 21-60 years, with body weight 41-60 kg, allotted for abdominal surgeries under spinal anaesthesia were included. History of nausea, vomiting or retching in 24 hours before anaesthesia, history of motion sickness, prolonged Q-T interval on ECG were excluded from the study. Informed consent was obtained from all the cases and study protocol was approved by institutional ethics committee. All cases undergone with routine laboratory investigations and received alprazolam 0.25mg & Ranitidine hydrochloride 150mg orally on the night before surgery. Patients were randomly allocated to receive one of the three study antiemetic drug combination therapy according to a closed sealed opaque envelope technique:

- Group 1 (n=60): Ondansetron (4mg) intravenously was given immediately before Spinal anaesthesia and Intravenous Ondansetron 4 mg (2ml) was given 20 minutes before completion of surgery.
- Group 2 (n=60): Ramosetron (0.3mg) Intravenously was given immediately before Spinal anaesthesia and Intravenous Ramosetron 0.3 mg (2ml) was given 20 minutes before completion of surgery.
- Group 3 (n=60): Normal saline (only rescue anti-emetic). For blinding process Normal saline 2 ml was given immediately before spinal anaesthesia and once again given 20 minutes before completion of surgery

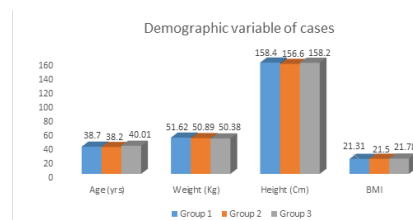
The incidence of nausea, vomiting and retching was studied for a period of 24 hours post operatively followed by PONV scoring system.

Score	Condition
0	No Nausea
1	Presence of Nausea
2	Nausea with Retching
3	Vomiting

The Descriptive procedure displays univariate summary statistics for several variables in a single table and calculates standardized values (z scores). All the statistical calculations were done through SPSS for windows (v 16.0).

RESULTS

Figure 1: Demographic variables of participants



Average age of cases was 38.7 years, 38.2 years and 40.01 years in group 1, 2 & 3 respectively. BMI was 21.31 in group 1, 21.5 in group 2 and 21.78 group 3 (Figure 1). The mean duration of surgery was 98.8 minutes in group 1, 93.72 minutes in group 2 and 98.24 minutes in

group 3 (Table 1).

Table 1: Details of mean duration of surgery and Anaesthesia.

	Group 1	Group 2	Group 3
Mean duration of surgery (Mean±S.D) in minutes	98.81±18.96	93.72±17.42	98.24±17.80
Mean duration of Anaesthesia (Mean±S.D) In minutes	102.14±18.62	97.22± 18.06	102.98±18.92

Figure 2: Details of mean systolic blood pressure (mm of Hg) in study groups.

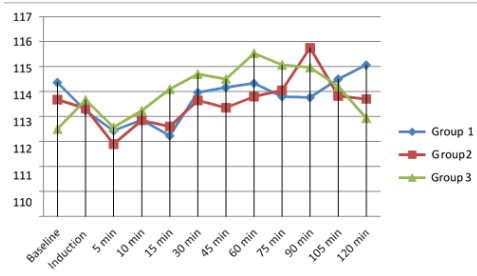


Figure 3: Details of mean diastolic blood pressure (mm of Hg) in study groups.

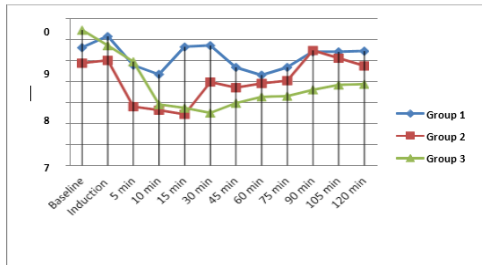


Table 4: Comparison of PONV scores between three groups.

Time	Group 1				Group 2				Group 3			
	6	6-12	12-18	18-24	6	6-12	12-18	18-24	6	6-12	12-18	18-24
Score 0	53	57	58	58	54	59	59	60	46	48	54	55
Score 1	05	03	02	02	06	01	01	0	08	05	04	04
Score 2	0	0	0	0	0	0	0	0	02	04	02	01
Score 3	02	0	0	0	0	0	0	0	04	03	0	0

Table 5: Complete response in all the groups in 24hrs.

Groups	Percentage
Group 1	94.1%
Group 2	96.6%
Group 3	84.5%

There was no requirement of rescue antiemetics in Group 1 & Group 2. 8% of patients in control group required antiemetics. The adverse effects were not observed in all the three groups during the study period.

DISCUSSION

Post-operative nausea and vomiting (PONV), is the most common and distressing complications after anaesthesia and surgery it has an 80% incidence in emergency cases. This is despite the availability of several antiemetic drugs. Selective 5-hydroxytryptamine type 3 (5-HT3) receptor antagonists are considered first-line for prophylaxis, ondansetron first drug choice. Ramosetron, a 5-HT3 receptor antagonist, which has long time action compared to ondansetron (10, 11). This study was designed to assess the efficacy & safety of Ramosetron and Ondansetron in preventing the PONV after elective

abdominal surgeries undergone spinal anaesthesia.

The mean duration of surgery was 98.8 minutes in group 1, 93.72 minutes in group 2 and 98.24 minutes in group 3 (Table 1). Blood pressures were recorded throughout the surgery and mean recordings were taken from every group. Hemodynamic parameters were comparable in all the groups and were statistically insignificant.

The incidence of PONV in group 1 shows, Majority of the patients had complete response during the study period. The complete response (Score-0) was 88.3%, 95%, 96.6% and 96.6% in first 6 hours, 6-12hrs, 12-18hrs and 18-24hrs respectively. Whereas in group 2, majority of the patients had complete response during the study period. Complete response was 90% in first 6 hrs, 98.3% in 6-12hrs, 98.3% in 12-18hrs and 100% in 18-24hrs. Whereas in group 3, complete response was 76.6% in first 6 hrs, 80% in 6-12hrs, 90% in 12-18hrs and 91.6% in 18-24hrs (Table 4).

Nausea was observed in first 6 hrs of all the groups and in later hours it was reduced. Nausea with retching and vomiting was not observed in group 1 and 2, whereas in group 3 it was observed at all time intervals (Table 4).

S. I. Kim, et al., most frequently reported adverse events were dizziness and headache (11). L.Lopez-Olaondo, et al., most commonly reported adverse events were headache, perineal itching (12). R. Thomas and N. Jones most frequently reported adverse events were fatigue, headache & dizziness (13). Maulana M. Ansari, et al., transient dizziness, headache, dyspepsia and weakness were noted (14). In our study, we did not observe any adverse effects like headache, dizziness, drowsiness, flushing and sedation in any of the three study groups.

CONCLUSION

The antiemetic Ramosetron 0.3 mg is effective in prevention of post-operative nausea and vomiting, in patients undergoing elective abdominal surgeries under spinal anaesthesia. The incidence of post-operative nausea and vomiting is less after regional anaesthesia than after general anaesthesia. However, Ramosetron 0.3mg with has a significantly higher complete response than the Ondansetron 4mg (94% vs 84%) in the 24 hour postoperative period. No significant adverse effects due to antiemetic therapy were noted in the both the groups.

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