

A comparative study between ondansetron and drosalesetron for prevention of post operative nausea and vomiting

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Abstract

Introduction: Post operative nausea and vomiting (PONVS) is the most common complication of surgery and anaesthesia, leading to adverse consequences including patient dissatisfaction, unexpected hospital admission, and delayed recovery. The present study is done to compare the efficacy of a single dose of Ondansetron Versus Drosalesetron for preventing post operative nausea and vomiting (PONY) in patients undergoing abdominal surgery under general anaesthesia within 24 hrs post operatively. **Aims and Objectives:** To compare the incidence of post-operative nausea and vomiting in Ondansetron and group of patients and to compare the severity of nausea in Ondansetron and Drosalesetron group of patients and to compare the need for rescue medications in Ondansetron and Drosalesetron groups of patients undergoing abdominal surgery under general anaesthesia within 24 hours. **Methodology:** The present one year prospective randomized clinical trial was conducted in the department of anaesthesiology during the period of 2013 - 2014 on 90 patients undergoing abdominal surgeries under GA. The patients were randomly allocated into two groups, Group A (Ondansetron group) and Group B (Drosalesetron) of 45 each by computer generated randomization. **Results:** It was observed that incidence of nausea and vomiting in Ondansetron and Drosalesetron was not significantly different from each other (33.33% and 26.67% with $P > 0.05$) and (35.56% and 31.11% with $P > 0.05$) respectively. Also the severity of nausea was significantly lesser in Drosalesetron group as compared to Ondansetron group (1.47 ± 3.10 Vs ± 3.85 respectively) during 0-24 hrs. ($P < 0.05$) It was observed that the need of rescue medication was lower in Drosalesetron group as compared to Ondansetron group (15.56% vs 40% respectively) during 0-24 hrs. The difference was statistically significant. ($P < 0.05$). **Conclusion:** From the above study we conclude that Drosalesetron is more cost-effective than Ondansetron as less amount of rescue medicine are required, in preventing in preventing post operative nausea and vomiting in patients undergoing abdominal surgery under anaesthesia within 24 hrs post operatively.

Keywords: Ondansetron, Drosalesetron, Post operative nausea and vomiting (PONVS).

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INTRODUCTION

The etiology of PONV is complicated and multifactorial¹. Its overall incidence is approximately 30%, although some surgical procedures have an 80% incidence^{1,2,3}. Post

operative nausea and vomiting (PONV) remains a significant problem in modern day anesthesia practice and continues to be a significant challenge following many types of anesthetics⁴. It is one of the most common complaint following anesthesia and serious complication of clinical concern in the postoperative period⁵. PONV associated with ambulatory surgery increases health care cost due to hospital admissions and accounts for 0.1%-0.2% of these unanticipated admissions⁶. although PONV is almost always self-limiting non fatal, it can cause significant morbidity and dehydration and electrolyte abnormality, esophageal rupture, life threatening airway compromise^{7,8}. The 5-HT receptor antagonist do not have side effects of commonly used anti emetics, do not cause drug interactions so increasingly being used for treatment

of PONV⁵ Ondansetron is the prototype of this class of drugs. Dolasetron, another serotonin antagonist, was introduced into clinical practice after Ondansetron had been widely used for some years. Dolasetron is at least as effective as Ondansetron in preventing postoperative nausea and vomiting (PONV) in adults compared with placebo, but costs less^{9, 10}.

AIMS AND OBJECTIVES

To compare the incidence of post-operative nausea and vomiting in Ondansetron and group of patients and to compare the severity of nausea in Ondansetron and Dosalesetron group of patients and to compare the need for rescue medications in Ondansetron and Dosalesetron groups of patients undergoing abdominal surgery under general anesthesia within 24 hours.

METHODOLOGY

The present study is conducted in department of anaesthesiology..... All indoor patients undergoing abdominal surgery under general anesthesiawere enrolled into the study. A total of 90 cases of either sex are taken as sample size, with 45 in each group. (n=45) Sample size calculated (n) by using formula¹³.

$$N = \frac{pqz^2}{(me)^2}$$

→ P=0.03 ,Q=1-P=0.97, z=1.96 (z score at 95% confidence interval) me=0.05 (margin of error). The study were conducted for a period of 1 years betweenafter approval of institutional ethics committee.

Inclusion Criteria

All patients between 18-60 yrs undergoing abdominal surgery under general anaesthesia. American Society of Anesthesiologist (ASA) grade I and Grade II, all elective surgery between 1-4 hr duration., Use of opioids (inj Fentanyl 1mcg/kg intra-operatively for analgesia)Patients ready to give informed consent and abide by the study procedure

Exclusion Criteria

Patient who have received antiemetics, steroids of psychoactive substances within 24 hrs of surgery All Elective surgeries of less than 1 hrs and more than 4hr duration. Patients with h/o vomiting, retching or vertigo prior to surgery Patients with elevated intracranial pressure. Neurosurgical patients. Pregnant patients. Patients not agreeing for the study.

Consent

All the patient were explained about the nature of the study in the language they understand the best and all the queries related to the study were cleared. After that informed written consent was obtained from all patients.

Method of randomization: simple random sampling method, using process of computer generated randomization code

Statistical Analysis

Mean and standard deviation was calculated for all the parameters under study. Statistical analysis was carried out using students-t test for comparing quantitative data between the study groups. Comparison of qualitative data between the study group was done by using chi-square test and z-test of proportion.

RESULTS

Table 1: Incidence of post-operative nausea

Grou ps	Post operative period(hrs)			
	0-2	2-6	6-24	0-24
Grou p A	7(15.5 6%)	5(11.1 2%)	3(6.67 %)	15(33.3 3%)
Grou p B	4(8.89 %)	6(13.3 3%)	2(4.44 %)	12(26.6 7%)
P	0.11	0.25	0.17	0.15
value				

From **Table No. 1** It was observed that the incidence of post-operative nausea during 0-24 hrs group A is 33.33% as compared to 26.67% in group B ,with P >0.05 which is statistically not-significant.

Table 2: Incidence of post-operative vomiting

Groups	Post operative period(hrs)			
	0-2	2-6	6-24	0-24
Group A	7(15.56%)	5(11.11%)	4(8.89%)	16(35.56%)
Group B	5(11.11%)	7(15.56%)	2(4.45%)	14(31.11%)
P value	0.46	0.15	0.12	0.14

From **Table No. 2** It was observed that the incidence of post-operative nausea during 0-24 hrs group A is 35.56% as compared to 31.11% in group B ,with P >0.05 which is statistically not-significant.

Table 3: Severity of Nausea

Grou p	Post operative period			
	0-2	2-6	6.24	0-24
Grou p A	1.18±2.7	1.62±3.3	0.6±2.0	3.40±3.8 5
Grou p B	0.58±2.1	0.71±2.1	0.18±1.1	1.47±3.1
P	9	7	9	0
value	0.25	0.126	0.229	0.01**

** Significant p<0.05

From **Table No. 3** It was observed that severity of post-operative nausea was significantly higher in Group A as compared Group B with P<0.05.

Table 4: Rescue of medications

Group	Rescue medications	P value
Group A	18(40.00%)	0.009**
Group B	7(15.56%)	

** Significant p<0.05

From **Table No. 4** It was observed that use of rescue medications was more in Group A (40%) as compared to Group B (15.56%) with $P < 0.01$ which is statistically significant.

DISCUSSION

In our study, It was observed that the incidence of nausea overall 0-24 hrs post operative, was 33.33% in Ondansetron group while it was 26.67% in Dosalesetron group, P value by test of proportion is >0.05 which is statistically not significant. (table No.1) thus the incidence of nausea was not significantly different in Ondansetron and Dosalesetron group. This finding is similar to Tricia A. Meyer *et al* (2005)¹¹ they observed no any statistical difference in incidence of Nausea in Ondansetron and Dolasetron group. In our study, it was observed that the incidence of vomiting was 35.56% in Ondansetron group while it was 31.11% in Dosalesetron group during 0-24 hr. P value by the test of proportion is >0.05 which is statistically not significant from (table No.2) thus the incidence of vomiting was not significantly lower in Ondansetron group as compared to Dosalesetron group during the overall 0-24 hrs post operative period. This finding is similar to Tricia A. Meyer *et al* (2005) they observed no any statistical difference in incidence of Nausea in Ondansetron and Dolasetron group. In our study, the severity of nausea was lower in Dosalesetron (1.47 ± 3.10) as compared to Ondansetron group (3.40 ± 3.85) during 0-24 hrs. P value by student t test is <0.01 which is significant statistically. (Table No. 3) the severity of nausea was lower in Dosalesetron group during 0-2 hrs and 6-24 hrs. was not statistically significant. In our study, the use of rescue medication was higher in Ondansetron group (40%) as compared to Dosalesetron group (15.56%) during 0-24 hrs. p value by test of proportion is <0.005 which is statistically significant. (table No.4) this is similar to Tricia A. Meyer *et al* (2005)¹¹ they observed 33 (70%) 18 (40%) use of rescue medicine in Ondansetron and Dosalesetron groups which was statistically significant $P < 0.005$ also similar to Olutoyin Olutoye *et al* (2003)¹²

CONCLUSION

From the above study we conclude that Dosalesetron is more cost-effective than Ondansetron as less amount of rescue medicine are required, in preventing in preventing post operative nausea and vomiting in patients undergoing abdominal surgery under anaesthesia within 24 hrs post operatively.

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