

## Comparison of single dose of intravenous ramosetron and ramosetron plus dexamethasone as prophylactic anti PONV in patients coming for elective ENT surgeries.

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### Abstract:-

**Introduction** - PONV is a major complication after anaesthesia, present in 20-30% range<sup>1</sup>. We compared efficacy and tolerance of ramosetron alone and ramosetron plus dexamethasone for PONV prophylaxis in elective ENT surgeries.

**Method** - 60 patients of age 20-60 years, ASA I and II, scheduled for elective ENT surgeries were randomized double blindly to receive either 0.3 mg ramosetron (R group), or 0.3 mg ramosetron plus 8mg dexamethasone (R+D group). Pregnancy, known hypersensitivity to both drugs, migraine, motion sickness were excluded. Chi square test and Fisher exact test were used for statistical evaluation. Microsoft excel and epi info version 3.4.3 were used. P value <.05 considered significant. PONV (0 no nausea, 1 nausea, 2 retching, 3 vomiting), rescue antiemetics and side effects were assessed in 24 hr postoperative period.

**Result** - Both groups were comparable in demographic parameters (age, sex, weight). Overall incidence of PONV did not differ significantly (p=.57) but patients, who needed rescue antiemetics were significantly less in group R+D than group R (P=<.05). Additionally side effects were also less in group R+D.

**Conclusion** - In patients undergoing elective ENT surgeries, combined use of ramosetron and dexamethasone significantly reduced need of rescue antiemetics. Incidence of PONV and side effects were also less with R+D group.

**Keywords** - PONV, Ramosetron, Dexamethasone, ENT

## I. INTRODUCTION

Postoperative nausea and vomiting, remains a significant problem in modern anaesthetic practice, occurs after both general and regional anaesthesia. The incidence of postoperative emesis in large studies has been reported to be in the 20-30% range.[1] These factors prevent patients to return home at the end of the day, after surgery. Sometimes these factors necessitate readmission to the hospital.

Nausea is defined as a subjectively unpleasant sensation associated with an urge to vomit. This is felt mainly in the back of the throat and epigastrium, accompanied by loss of gastric tone, duodenal contractions and reflux of the gastric contents into the esophagus. It is associated with prodromal symptoms such as salivation, swallowing, pallor and tachycardia. Retching is defined as labored spasmodic rhythmic contractions of the respiratory muscles including the diaphragm and chest wall and abdominal wall muscles without expulsion of gastric contents. Although a number of therapies are available for the management of PONV, none is entirely effective. Most of the published trials indicate an improved antiemetic prophylaxis when using a combination of agents acting at different receptor sites, compared with monotherapy. So we decided to study the efficacy of a combination of two antiemetic drugs in preventing PONV, after a surgery with a high incidence of PONV.

## II. METHODOLOGY

Data was randomly collected from 60 ASA I and II patients scheduled for ENT surgeries aged between 20-60 years at MBS Hospital Kota, Rajasthan. Both study groups were selected from these patients. The study was conducted over a period of two years, September (2013-15).

### 2.1 Inclusion criteria

- ASA 1 and ASA 2 patients.
- 20-60 age group.

### 2.2 Exclusion criteria

- Documented hypersensitivity to any of the study drugs.
- Patients with history of migraine, motion sickness or previous PONV.

- Patients who are pregnant or menstruating.
- Patients who have taken antiemetic drugs within 24 hours before surgery.
- Patients with history of neurological or renal diseases.

### 2.3 Technique

The study was a prospective, randomized, double blinded one. Written informed consent was taken from all patients. Pre-anaesthetic medication was given with ranitidine 150 mg and tab alprazolam 0.5 mg, the night before and morning of surgery. SpO<sub>2</sub>, NIBP, ECG monitors were attached. The baseline values were recorded. IV access was established. Patients were randomly allocated into two groups.

- 1) Those who receive Ramosetron alone (0.3 mg) IV.(Group R)
- 2) Those who receive Ramosetron (0.3 mg) and Dexamethasone 8mg IV. (Group-R+D)

The drugs were given 5 minutes before induction of anaesthesia by anesthetists who were not involved in the study.General anaesthesia was given in usual manner.

Postoperatively all episodes of PONV experienced by the patient during the first 24 hours after anaesthesia, was recorded by direct questioning. These were assessed by a nausea and vomiting score. Rescue anti-emetic i.e. inj.metoclopramide was used if patient had nausea or vomiting.

### 2.4 Statistical analysis

At the end of the study, the data was compiled systematically and was subjected to statistical analysis using 'Chi-square' test and Microsoft excel and Epi info version 3.4.3.

## III. RESULTS

### 3.1 Demographic data & Type of surgery

The age,sex,weight of patients & type of surgery in the two groups (R and R+D) were comparable and there was no significant difference. (p value >0.05).

### 3.2 Hemodynamic parameters

Study period was from baseline to 24 hrs.(5 min.,15min.,30min., 1hr, 2hr, 12 hr,24 hr) in both groups R and R+D groups. Patients were hemodynamically stable in both groups.

There was no statistically significant difference in mean pulse rate ,Systolic BP & SPO<sub>2</sub> throughout the study period(baseline to 24 hr) in both group.

### 3.3 PONV and Adverse effects

In Early(<1 hr) Period .In group R 19 out of 30 didnot have any nausea.While in R+D 23 out of 30 did not have any nausea.P value(>.05).In Late (1-24 hr)period,In group R 20 out of 30 did not have any nausea,while in R+D 27 out of 30 did not have any nausea.p value(>.05) .In early study period(0-1 hr) 5 patients out of 30 showed adverse effects like headache and dizziness in group R. 1 patients out of 30 showed adverse effects like headache and dizziness in group R+D. In late study period(1-24 hr) 1 patients out of 30 showed adverse effects in group R. 0 patients out of 30 showed adverse effects like headache and dizziness in group R+D. There was no statistically significant difference in both group(p value>.05).

### 3.4 Need Of Rescue Antiemetic

In group R;9 out of 30 patient needed rescue antiemetic and in group R+D, 2 out of 30 needed it in early study period(<1 hr). In group R+D,8 out of 30 patient needed rescue antiemetic and in group R+D 1 out of 30 needed it in late study period(1-24 hr). This result showed ststistically significance.p value in early period was .04.in late period p value was .015.both these values were statistically significant.

**Table 1: INCIDENCE OF PONV <1 HR**

	Group R	Group R+D	P Value
< 1 hr			
No Nausea=0	19	23	>.05
Nausea=1	10	7	.57
Retching=2	1	0	>.99
Vomiting=3	0	0	0

**Table 2: PONV SCORE IN 1-24 HOUR**

	Group R	Group R+D	P Value
1-24 hr			
No Nausea=0	20	27	>.05
Nausea=1	8	3	.18
Retching=2	1	0	>.99
Vomiting=3	1	0	>.99

**Table 3: INCIDENCE OF ADVERSE EFFECTS IN BOTH GROUPS**

Side effect	Group R	Group R+D	P value
<1 hr	5	1	.19
1-24 hr	1	0	>.99

**Table 4: NEED OF RESCUE ANTIEMETIC I.V.METOCLOPRAMIDE**

Rescue antiemetics	Group R	Group R+D	P value
<1 hr	9	2	.04
1-24 hr	8	1	.015

#### IV. DISCUSSION

Post operative nausea and vomiting (PONV) is a common problem and distressing symptom in surgical patient population. Pathophysiology, of PONV in middle ear surgeries being vestibular stimulation, increase in middle ear pressure, and presence of swallowed blood in adenotonsillectomy procedures.[1]General anaesthesia with inhalational agents is associated with an average PONV incidence of 20-30 % in surgical patients.[2]

The incidence largely depends on pre operative patient characteristics, operation, anaesthesia, gender, intensity of pain and its post operative management. Post operative vomiting will harm skin flaps, abdominal wall sutures, vascular anastomosis, and other areas recently operated on. It increases intra-ocular, intra-cranial pressure and may also cause tachycardia, electrolyte imbalance, wound dehiscence, oesophageal tears and aspiration pneumonitis.[3] PONV after minor and ambulatory surgery delays the hospital discharge. Many treatments are available for PONV, but none has been described as a panacea.[4] Present study was done in 60 patients undergoing Elective ENT surgeries after ethical committee permission and informed consent from all patients. Study period was upto 24 hr postoperative period by assessing PONV score. Patients were divided in 2 groups: Gr-I =30 patients received inj ramosetron 0.3 mg

Gr-II =30 patients received inj ramosetron 0.3mg + inj dexamethasone 8mg. Study drugs were given 5 min. before induction by anaesthetist who were not involved in study to make it double blind.

Our result coincides with Jung-Hee Ryu et al[5]. In this study ,Seventy six patients scheduled for laparoscopic cholecystectomy were randomized to receive either i.v. 0.3 mg ramosetron (group R), or 8 mg dexamethasone plus 0.3 mg ramosetron (group D). Postoperative nausea, retching, vomiting, rescue antiemetics, pain scores, rescue analgesics and side effects were assessed at 0-2, 2-24 and 24-48 h postoperatively. Seventy two patients were randomized. The overall incidence of PONV did not differ (p value: 0.31) but fewer patients needed rescue antiemetics in group D than in groups R (3 vs. 13 patients, respectively;(p < 0.01) during 0-48 h postoperatively.

One more study done by Younghoon Jeon MD et al [6] performed for comparison of ramosetron, dexamethasone, and combination of ramosetron and dexamethasone for prevention of PONV in thyroidectomy. 198 patients were approached for study design. Result of this study was that combination of ramosetron was more effective in reducing PONV than dexamethasone monotherapy. However the combination did not show any additional benefit in preventing PONV.

This result is not in line with the results of previous studies like Elhakim et al [7] in which dexamethasone combined with a 5HT<sub>3</sub> antagonists like Ondansetron decreased the incidence of PONV significantly. Reason for this is that Ramosetron is more potent, highly selective and long acting 5HT-3 antagonist than previous drugs.<sup>59</sup> Addition of dexamethasone to ramosetron did not affect the incidence of adverse effects. Although prolonged glucocorticoid use may cause infection, delayed wound healing, glucose intolerance, and adrenal suppression, a single dose of dexamethasone is rarely associated with these serious side effects as studied by Holte et al[8]

#### V. CONCLUSION

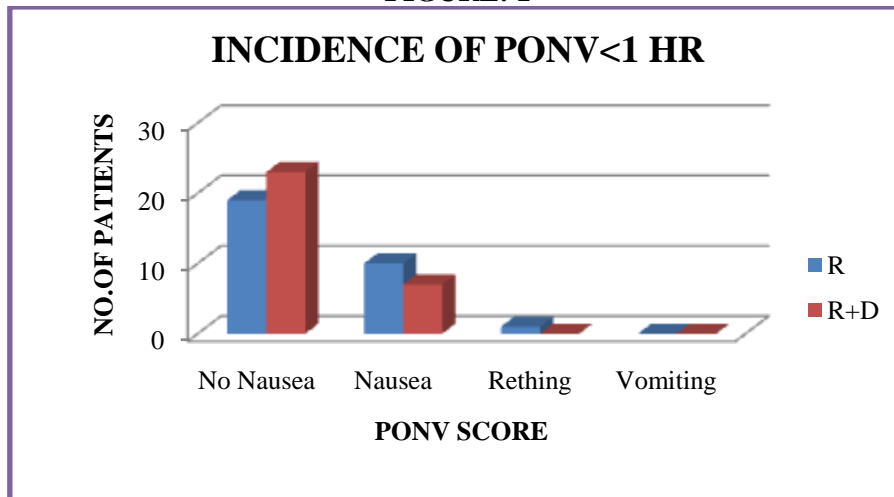
PONV is multifactorial and combination of drugs with different mechanisms of action is more effective. Patients at moderate risk for PONV should receive combination therapy with one or more prophylactic drugs from different classes. It is also found that combinations act synergistically Overall incidence of PONV and adverse effects were less with combination of drugs. Need of antiemetic was significantly less with combination of ramosetron and dexamethasone (pvalue<.05) in elective ENT surgeries.

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**VII. FIGURES**

**FIGURE: 1**



**FIGURE: 2**

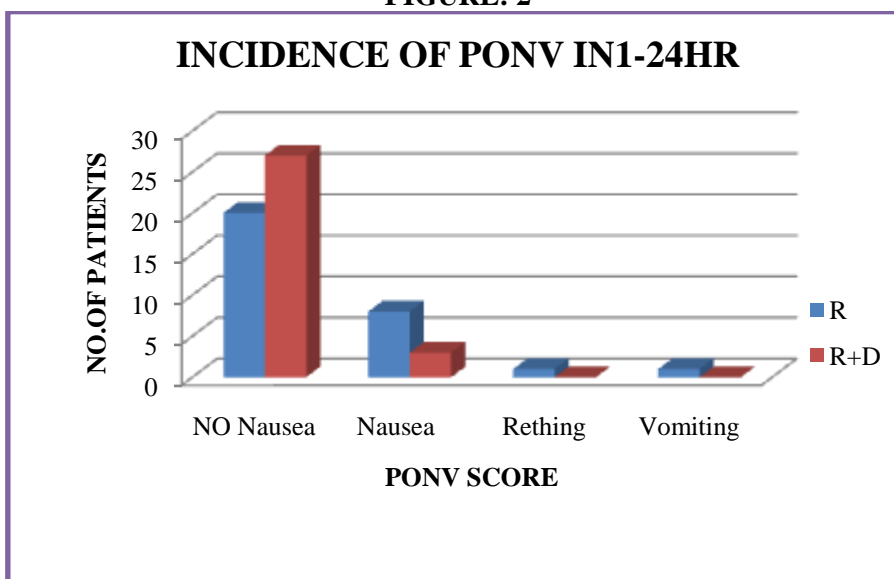


FIGURE: 3

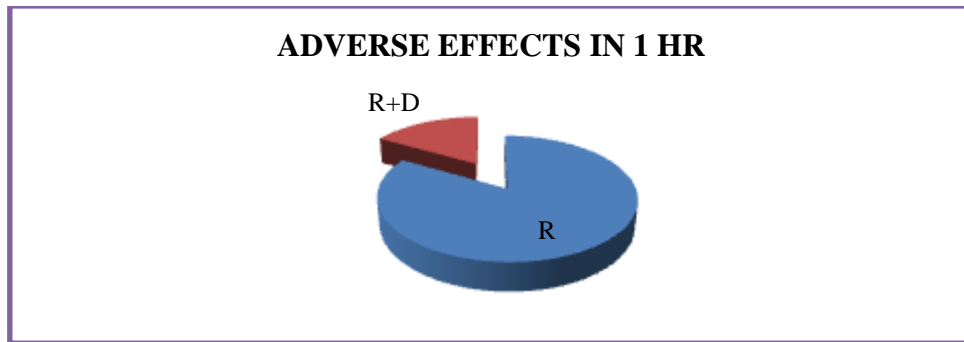


FIGURE: 4

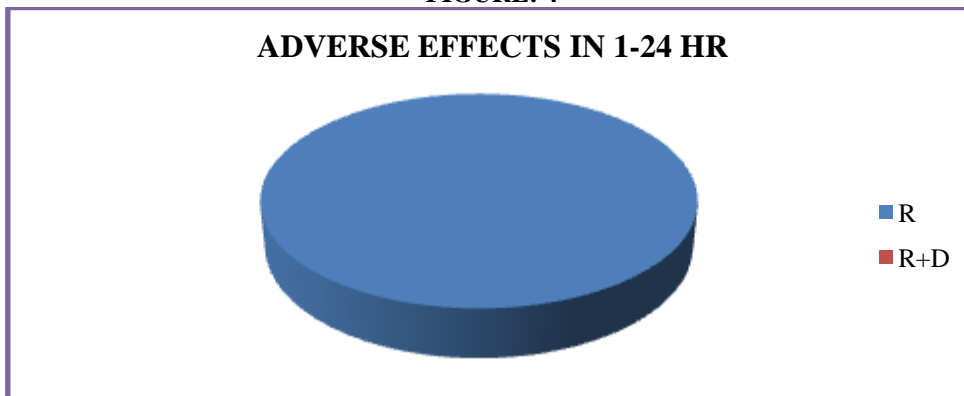


FIGURE: 5

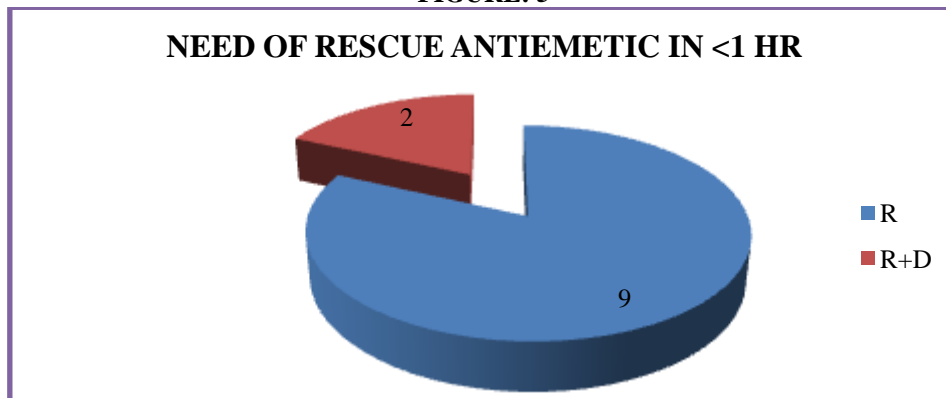


FIGURE: 6

