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A comparative clinical study of ramosetron and ramosetron with dexamethasone for the prevention of postoperative nausea and vomiting in laparoscopic surgeries

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ABSTRACT

Introduction: Postoperative nausea and vomiting (PONV) along with pain and shivering are frequently observed in patients recovering from surgery and general anesthesia.

Objectives: To compare the efficacy of Ramosetron alone and in Combination with Dexamethasone in patients undergoing laparoscopic surgeries, with respect to nausea, vomiting, requirement of rescue analgesia and antiemetics, discharge time, and also side effects.

Materials and Methods: Current study was a prospective observational double-blind study conducted at a tertiary care hospital. A total of 60 ASA grade I and II patients of age group 20-50 years undergoing elective laparoscopic surgeries under general anesthesia with Body mass index between 18-25 were included in the study. Participants were divided by using a computer-generated random number table into two groups of 30 each with Group R and Group RD each consisting of 30 patients. Group R received 0.3 mg. of Ramosetron intravenous (IV) and group RD received both 0.3mg. P value < 0.05 was considered statistically significant. coGuide version V.1.0.3 was used for statistical analysis.

Results: The mean duration of surgery in group R was 35.83 ± 6.44 minutes and 35.66 ± 6.26 minutes in group RD. The difference in the proportion of PONV scores between the study group was statistically not significant (P value 0.982). The rescue antiemetic was used in 5 (16.67%) patients in group R and in 2 (6.67%) patients in group RD.

Conclusion: Combination therapy of Ramosetron with dexamethasone had better efficacy than Ramosetron alone in reducing PONV on patients undergoing laparoscopic surgeries.

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1. Introduction

Patients recuperating from laparoscopic surgery under general anesthesia commonly have postoperative nausea and vomiting (PONV). PONV causes patients distress and suffering obstructs the continuation of treatment and delays hospital release.¹⁻³ Nausea is a subjectively unpleasant sensation when a person is conscious of the desire to vomit. Retching is characterized as a laboured, spasmodic, rhythmic contraction of the respiratory muscles, including

the diaphragm, chest wall, and abdominal wall muscles, without any stomach contents being expelled. Vomiting is the violent ejection of stomach contents from the mouth caused by a vigorous prolonged contraction of the abdominal muscles, diaphragm descent, and opening of the gastric cardia.⁴ PONV is a challenge for the perioperative physician and a substantial cause of anxiety among patients nowadays, as laparoscopic procedures are commonly conducted as daycare surgeries. Postoperative nausea and vomiting (PONV) are described as nausea, retching, or vomiting that develops within 24 hours following surgery and persists despite antiemetic treatment.

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After general anesthesia, around 30% of patients present with PONV.⁵ After gynecological laparoscopic surgery, it might be as high as 80%.⁶ Inadequate care of PONV can result in several systemic problems, including dehydration and electrolyte imbalance, as well as a delay in recovery and a more extended stay in the hospital.^{7–9}

Because of their demonstrated effectiveness and low side effect profile, selective serotonin receptor (5-hydroxytryptamine type 3 [5-HT₃]) antagonists are now regarded as the first line in the treatment of PONV. 5-HT₃ antagonists work by inhibiting serotonin from binding to 5-HT₃ receptors on the vagus afferent nerve terminals, which transmit signals directly to the medulla oblongata's vomiting center and the brain's chemoreceptor trigger zone (CTZ). 5-HT₃ antagonists work by blocking the activation of these receptors, interrupting one of the mechanisms that lead to vomiting.⁴ Ramosetron, a selective serotonin 5-hydroxytryptamine type 3 (5-HT₃) receptor antagonist, in terms of antiemetic activity, outperforms previously available antagonists like granisetron, ondansetron, and tropisetron. Ramosetron is more effective and has longer-lasting antiemetic effects than earlier treatments because of its slower rate of dissociation from the target receptor and enhanced binding affinity. Serotonin binding to 5-HT₃ receptors at the terminals of the vagal afferent branches is prevented by this family of selective 5-HT₃ receptor antagonists, which directly signals the vomiting center in the medulla oblongata and the chemoreceptor trigger zone of the brain.^{10,11} It has a stronger affinity for serotonin receptors and a slower dissociation time, resulting in a prolonged action time.¹² A significant decrease in the incidence and severity of PONV during the 6- to 24-hour period was observed in patients treated with a multimodal pain and PONV prophylaxis protocol that included Ramosetron, a 5-hydroxytryptamine type 3 (5-HT₃) receptor antagonist, according to a study conducted by Koh JJ et al.¹³

Dexamethasone is a 9 α -fluoro-11 β , 17 α ,21-trihydroxy-16 α -methylpregna-1, 4-diene-3, 20-dione.¹⁴ It's a corticosteroid anti-inflammatory drug that's been shown to help with postoperative nausea and vomiting (PONV).¹⁵ Dexamethasone has a comparable antiemetic impact on both nausea and vomiting, which is accentuated in the late postoperative period by its longer biological half-life of 36 to 72 hours. Dexamethasone has been chiefly used to treat late PONV.^{16–18} It is more effective in Combination with a 5-HT₃ receptor antagonist.¹⁹ Previous literature results show that Ramosetron alone is effective in preventing PONV in children and adults.²⁰ Study by Lee MJ et al. concluded that the Combination of Ramosetron and dexamethasone significantly reduced not only the incidence of nausea but the need for rescue antiemetics.² Another prospective randomized double-blind research indicated that the Combination of Ramosetron and dexamethasone

was more beneficial than Ramosetron alone in patients undergoing laparoscopic Cholecystectomy.²¹ Previous literature does not show studies comparing the effect of Ramosetron and Ramosetron with dexamethasone in patients undergoing laparoscopic surgeries. Hence, the current research was conducted to compare the efficacy of Ramosetron alone and in Combination with Dexamethasone for preventing Post Operative Nausea and Vomiting(PONV) in laparoscopic surgeries under general anesthesia, with respect to vomiting, Requirement of rescue antiemetic, Pain, and Side effects.

2. Materials and Methods

This was a prospective observational study. A total of 60 ASA grade I and II patients aged 20-50 years undergoing elective laparoscopic surgeries under general anesthesia and Patients with Body mass index between 18-25 were included in the study. Patients belonging to ASA grade III or IV, those with known hypersensitivity or contra-indications to study drugs, with a history of nausea, vomiting, or retching 24 hours before anesthesia, those who received antiemetic drugs or drugs with the antiemetic property during 24 hours before anesthesia were excluded from the study. Approval was granted by the institutional ethical committee, and written informed consent was obtained from all participants before involving them in the study.

Participants were divided using a computer-generated random number table into two groups of 30 each with Group R and Group RD, each consisting of 30 patients. Group R received 0.3 mg. of Ramosetron intravenous (IV), and group RD received both 0.3mg. Ramosetron and 8 mg Dexamethasone intravenous (IV) as a prophylactic antiemetic, 05 min after induction.

During the pre-operative period, the medication was prepared by a PG Trainee who was not related to the study, in two identical syringes named R and RD, which had Ramosetron 0.3mg, Ramosetron 0.3mg, and Dexamethasone 8 mg each being diluted to 5 mL with Normal Saline and given to patients 5 min after induction of anesthesia.

The patient was premedicated with Fentanyl 2 μ g per kg body weight & induced by Thiopentone at the dose of 4 to 5 mg per kg body weight. Tracheal intubation was facilitated by Vecuronium 100 μ g per kg body weight and appropriate sized endotracheal tube. A Nasogastric tube was placed for emptying the gastric contents. Anesthesia was maintained by N₂O + O₂ (60:40)+ Sevoflurane (0.8 to 1%). Intermittent doses of Vecuronium were given during anesthesia to maintain adequate muscle relaxation using neuromuscular monitoring.

The number of episodes of emesis and nausea was recorded. Repeated vomiting within a 1-2 minutes period was recorded as single emesis. All post-operative cases were followed up at 0-6 hours, 6-12 hours, and 12-24 hours

for PONV. PONV was evaluated on a five-point ordinal scale 0=none, 1=nausea, 2=retching, 3=vomiting, 4= severe vomiting (> 4 episodes). The number of episodes of emesis and nausea was recorded. Nausea was measured using an 11 point visual numerical scale with 0 = No Nausea, 10 = Nausea as bad as can be, A score of > 5 = Severe, 5= moderate, < 5 = minimal. Severe and moderate scores were considered major nausea. Vomiting was measured as > 2 = Severe, 2 = Moderate, < 2 = Mild. Rescue antiemetic consisted of 0.15 mg./kg. metoclopramide IV and was given even for a single episode of vomiting. Rescue analgesia consisted of 75 mg. diclofenac sodium IM, given when the pain was more than 5 on the scale.

2.1. Statistical methods

The intraoperative parameter was considered as the primary outcome variable. The study group (R Vs. RD) was considered as Primary explanatory variable. The quantitative variables were expressed as mean $\pm$ SD (standard deviation), while the qualitative variables were expressed as a percentages. Age, height, weight, BMI, duration of surgery, and CO₂ insufflation pressure were analyzed by using student t-test. In contrast, gender, frequency of nausea and vomiting, and use of rescue antiemetic were analyzed by using chi-square test. P-value <0.05 was considered statistically significant. coGuide version V.1.0.3 was used for statistical analysis.²²

3. Result

A total of 60 patients were randomized into 2 groups. R & RD of 30 patients each and received intravenous Ramosetron and Ramosetron and dexamethasone combination respectively as PONV prophylaxis.

The mean age in group R was 35.83 ± 6.44 years and 35.66 ± 6.24 years in group RD. This was found to be statistically insignificant. (p value 0.918). The Group R 14 (46.67%) males and 16 (53.33%) females and Group RD having 14 (46.67%) males and 16 (53.33%) females. The difference in the proportion of gender between study group was statistically not significant (P value 1.000). The mean weight in group R was 65.66 ± 5.42 kg and 65.93 ± 5.92 kg in group RD. This was found to be statistically insignificant. (p value 0.855). The mean BMI in group R was 21.90 ± 1.44 kg/m² and 21.86 ± 1.54 kg/m² in group RD. This was found to be statistically insignificant. (p value 0.918). The mean duration of surgery in group R was 35.83 ± 6.44 minutes and 35.66 ± 6.26 minutes in group RD. This was found to be statistically insignificant. (p value 0.917). The Mean CO₂ insufflation pressure during the procedure was 9.37 ± 1.41 mm of Hg in group R and 9.46 ± 1.38 mm of Hg in group RD. The p value was insignificant. (P value 0.804). (Table 1).

There was no statistically significant difference in heart rate(bpm), systolic blood pressure(mm/hg) and diastolic blood pressure (mm/hg) between the two study groups (p value >0.05). In group R 12 patients out of 30 had PONV. 12 (40%) had PONV score of 1, 1 (3.33%) had a score of 2 and 5 (16.65%) had score of 3. In group RD 25 (83.33%) patients out of 30 had PONV. Out of them 3(10%) had PONV score of 1, 1 (3.33%) had a score of 2 and 1 (3.33%) had score of 3, there was statistically significant difference observed in PONV score between 2 groups with p value of 0.005. In group R 11 out of 30 (36.67%) patients had nausea in (0 –6 hrs) and in RD group, 3 (10%) had nausea in (0 to 6 hours). The difference in the proportion of nausea at 0-6 hours between study group was statistically significant (P value =0.014). In group R 05 out of 30 (16.65%) patients had vomiting in (0 –6 hrs). In group RD 01 out of 30 (3.33%) patients had nausea (0 – 6 hrs). The difference in the proportion of vomiting at 0-6 hours between study group was statistically not significant (P value 0.085). The rescue antiemetic was used in 5 (16.65%) patients in group R and in 1(3.33%) patients in group RD. There was a statistically not significant difference in use of rescue antiemetic in the groups. (p value =0.085). The need for rescue analgesic was not statistically significant in either group (p value = 0.68). Among the patients 4 (13.33%) patients in group R and 3 (10%) patients in group RD needed rescue analgesic but were not statistically significant (p value 0.987). The above-mentioned procedures in Table 2 were included in our study, in which Laparoscopic Cholecystectomy predominated in both groups than any other surgeries. Patients in neither group had any side effects for which treatment was needed.

4. Discussion

The results of the present study demonstrated that the Combination of Ramosetron with dexamethasone therapy was more effective in reducing the incidence of PONV than ramosetron therapy alone. Time duration during the surgery in minutes was comparatively more in the ramosetron therapy group than Ramosetron with a dexamethasone therapy group. These findings were in line with research conducted by Lee M J et al.² Evidence from previous research suggests that prophylaxis with dexamethasone and 5-HT₃ antagonist provides a better antiemetic effect when compared with a 5-HT₃ antagonist alone.^{19,23} In the present study, we found that the PONV score was less in the combination therapy group than the ramosetron group alone. It was observed that the frequency of nausea and vomiting showed a rapid decrease in the Combination of Ramosetron with a dexamethasone therapy group. The results of our study also show that the use of rescue antiemetic and the need for rescue analgesia was less in the combination group. Our results were similar to another study conducted by Jo YY et al. as they found that the ratio of complete response (no PONV and no rescue antiemetic)

Table 1: Comparison of baseline parameter between study group (N=60)

Parameter	Study groups		P value
	R group(N=30)	RD group(N=30)	
Age (in years)	35.83 ± 6.44	35.66 ± 6.24	0.918*
Gender			
Male	14 (46.67%)	14 (46.67%)	1.000†
Female	16 (53.33%)	16 (53.33%)	
Weight (in kg)	65.66 ± 5.42	65.93 ± 5.92	0.855*
BMI (in kg/m ²)	21.90 ± 1.44	21.86 ± 1.54	0.918*
Duration of surgery (in minutes)	35.83 ± 6.44	35.66 ± 6.26	0.917*
CO ₂ insufflation pressure (in mm/hg)	9.37 ± 1.41	9.46 ± 1.38	0.804*

*Independent sample t test †Chi square test

Table 2: Comparison of intraoperative parameters between study group (N=60)

Parameter	Study groups		P value
	R group	RD group	
Heart rate (bpm)	71.13 ± 4.86	71.40 ± 4.64	0.827‡
systolic blood pressure(mm/hg)	125.60 ± 5.07	124.06 ± 5.94	0.285‡
Diastolic blood pressure(mm/hg)	79.53 ± 3.17	78.93 ± 3.54	0.492‡
PONV score			
0	12 (40%)	25 (83.33%)	0.005 †
1	12 (40%)	3 (10%)	
2	1 (3.33%)	1 (3.33%)	
3	5 (16.67%)	1 (3.33%)	
Nausea			
0 to 6 hours	11 (36.67%)	3 (10%)	0.014 †
6 to 12 hours	1 (3.33%)	0 (0%)	*
12 to 24 hours	0 (0%)	0 (0%)	*
Vomiting			
0 to 6 hours	5 (16.65%)	1 (3.33%)	0.085 §
6 to 12 hours	0 (0%)	0 (0%)	*
12 to 24 hours	0 (0%)	0 (0%)	*
Rescue antiemetic	5 (16.67%)	1 (3.33%)	0.085 §
Rescue analgesic	4 (13.33%)	3 (10%)	0.687 §
Surgical type of procedure			
Laparoscopic Cholecystectomy	18 (60%)	15 (50%)	*
Laparoscopic Ovarian Cystectomy	2 (6.67%)	6 (20%)	
Total Laparoscopic Hysterectomy	7 (23.33%)	5 (16.67%)	
Laparoscopic Appendectomy	3 (10%)	3 (10%)	
Laparoscopic Hernioplasty	0 (0%)	1 (3.33%)	

‡-Independent sample t test, †-Chi square test, *No statistical test was applied- due to '0' subjects in the cells, §-Fishers exact test

was higher at 6-12h in Ramosetron 0.3 mg (group R) and Ramosetron 0.3 mg combined with dexamethasone 8 mg (group RD) than in dexamethasone 8 mg (group D) ($p < 0.05$) and at 12-24 h in group RD than in group D ($p < 0.05$). The incidence of nausea was lower at 6-12 h in groups R ($p = 0.043$) and RD ($p = 0.003$) compared to group D and at 12-24 h in group RD ($p = 0.01$) compared to group D. The severity of nausea was also significantly reduced at 6-12 h in groups R and RD compared to group D ($p < 0.05$).²⁴ The study by Jeon Y et al. found that in PONV, there was no significant difference in the combination group of Ramosetron and dexamethasone compared to the ramosetron alone group (95% CI, 0.04–0.22).²⁵ Research

by Ryu J-H et al. supported our study findings. In their study, the incidence of PONV for 48 h postoperatively was 39% with Ramosetron alone and 28% with Ramosetron plus dexamethasone.²¹ An updated systematic review and meta-analysis pooled data from 14 RCTs (1542 patients) favored dexamethasone combined with other antiemetics over single antiemetics as a prophylaxis against postoperative nausea and vomiting after laparoscopic cholecystectomy in the early postoperative period (OR = 0.39, 95% CI [0.27 to 0.54], $p < 0.00001$), late postoperative period (OR = 0.36, 95% CI [0.23 to 0.56], $p < 0.00001$), and overall postoperative period (OR = 0.34, 95% CI [0.23 to 0.51], $p < 0.00001$). Subsequently, rescue antiemetic usage was

significantly lower in the combination group (OR = 0.25, 95% CI [0.16 to 0.41], $p < 0.00001$).²⁶ Considering our results and findings from the previous literature, we can safely say that it is plausible to include a combination of dexamethasone with Ramosetron in laparoscopic surgeries.

5. Conclusion

In patients undergoing laparoscopic surgeries under general anaesthesia the combination therapy of Ramosetron with dexamethasone given intravenously after induction of general anaesthesia had better efficacy in prevention of PONV than with Ramosetron alone.

6. Limitations

The limitations of the current study were firstly, this study was a single-center study and the sample size was low as with a lower sample size we cannot generalize our results. Secondly, we did not measure postoperative pain using a standard pain scale this restricts our study result to demonstrate postoperative pain among the study participants. Also, we only included a combination of dexamethasone with Ramosetron and did not explore multiple combinations. The current study's findings likewise failed to discover any negative impacts in either group. We recommend that researchers conduct well-designed RCT trials with larger sample sizes in the future, and that they compare various antiemetic combinations with Ramosetron and ondansetron, dexamethasone, or metoclopramide to identify the ideal that has few to no side effects and provides the best antiemetic efficacy.

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8. Conflict of Interests

The authors declare no conflicts of interest.

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