

## Original Research Article

# A comparative study of granisetron, dexamethasone and combination of granisetron-dexamethasone as prophylaxis for postoperative nausea vomiting during laparoscopic surgeries

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**Received:** 17 January 2019

**Accepted:** 01 March 2019

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### ABSTRACT

**Background:** In laparoscopic surgeries, insufflation with carbon dioxide triggers vagal afferents on the bowel and peritoneum which induces emesis by activating the vomiting center. It is hypothesized that combined antiemetics with different sites of activity would be more effective than one drug alone for the prophylaxis against PONV. So, the present study was planned to compare the efficacy of granisetron, dexamethasone and combination of granisetron with dexamethasone to prevent PONV.

**Methods:** This randomized prospective double-blind study was performed on 120 patients, aged between 18 and 58 years of ASA physical status I and II of either sex undergoing laparoscopic surgeries under general anesthesia. Patients were randomized in three groups, group I (granisetron 2 mg I.V.), group II (dexamethasone) 8 mg I.V., group III (granisetron+dexamethasone) 2 mg+8 mg I.V. with 40 patients in each group. Complete response, incidence of nausea, vomiting, and rescue antiemetic were recorded at specified intervals.

**Results:** A complete response (defined as no PONV and no need for another rescue antiemetic) was achieved in 75% of the patients given granisetron, 70% in dexamethasone and in 92.5% of the patients given granisetron plus dexamethasone ( $P < 0.05$ ). The overall cumulative incidences (0-24 hours) of PONV were 10 (25%) in the granisetron, 12 (30%) in the dexamethasone and 3 (7.5%) in the combination group. No difference in adverse events were observed in any of the groups.

**Conclusions:** The prophylactic therapy of granisetron 2 mg plus dexamethasone 8 mg just before induction of anaesthesia is significantly effective in prevention of PONV in patients undergoing laparoscopic surgeries.

**Keywords:** Dexamethasone and granisetron +dexamethasone, Granisetron, Laparoscopic surgeries, PONV

### INTRODUCTION

Nausea, retching and vomiting are among the most common postoperative complaints and can occur after surgery, general, regional and local anaesthesia. In addition to patient dissatisfaction, PONV may have

adverse consequences such as wound dehiscence, pulmonary aspiration, surgical site bleeding and dehydration leading to delayed recovery, unexpected hospital admission and delayed return to work of ambulatory patients. The etiology of postoperative nausea and vomiting is multifactorial and complex. Patient-

related factors (anxiety, obesity) as well as other causes (anesthetic agents, technique, hypotension, hypoxemia, pain) can contribute to or result in nausea and vomiting.<sup>1</sup>

In laparoscopic procedure, the peritoneal cavity is inflated with carbon dioxide due to which vagal afferents on the bowel and peritoneum are triggered which induces emesis by activating the vomiting center. The insufflations also lead to abdominal discomfort if abdominal cavity is not adequately decompressed after the procedure, further adding to the general level of unpleasant sensations.<sup>2</sup>

The 5HT<sub>3</sub> receptor antagonists (ondansetron, granisetron, dolosetron) and steroids (dexamethasone) are considered effective in controlling PONV but have their own adverse effects varying from lethargy, restlessness, tachycardia, extrapyramidal symptoms, dystonic reactions increasing the incidence of delayed discharge and unintended hospital re-admission. None of the available antiemetics is entirely effective, perhaps because most of them act through the blockade on one type of receptor. There is a possibility that combined antiemetics with different sites of activity would be more effective than one drug alone for the prophylaxis against PONV. Thus, combination of antiemetic drugs could be an effective method to control severe postoperative nausea and vomiting (PONV), perhaps because there is no single stimulus or cause for PONV.<sup>3</sup>

A recent meta-analysis on prevention of PONV suggested that a combination of dexamethasone with the 5-HT<sub>3</sub> receptor antagonists is likely to be the best antiemetic prophylactic regimen among the drugs currently available.<sup>4</sup> So, the present study was planned to compare the efficacy of granisetron, dexamethasone and combination of granisetron with dexamethasone to prevent PONV in patients undergoing laparoscopic surgeries under general anaesthesia.

## METHODS

This single center prospective randomized double-blind study was conducted on 120 patients aged 18-58 years of ASA physical status I-II of either sex scheduled for elective laparoscopic surgical procedures under general anaesthesia after approval from institutional ethical committee.

### Exclusion criteria

Patients with physical status of ASA status III or greater, severe cardiorespiratory, hepatic, renal, neurological or endocrinal disease, pregnant and lactating women, obesity diabetes mellitus, patients with known hypersensitivity or drug allergies, patients who had taken H<sub>2</sub> antagonists, antiemetic or psychoactive medication, nausea, retching or vomiting within 48 hours before surgery and patients who refuse to participate in the study.

### Randomization and blinding

Patients were randomly divided in three groups by simple randomization technique of card method. A total of 120 cards were prepared by anesthesiologist who was not involved in the study. After recruitment every patient was asked to draw one card and grouped accordingly

- Group I (40) received I.V. granisetron 2 ml (2 mg) plus 2 ml saline,
- Group II (40) received I.V. dexamethasone 2 ml (8 mg) plus 2 ml saline,
- Group III (40) received I.V. granisetron 2 ml (2 mg) plus 2 ml dexamethasone (8 mg).

The study medication was given intravenously along with premedication, 5 mins before induction of general anaesthesia by anesthesiologist who was not aware of the study and data was collected by resident who was blinded about the group allocation. Even patient was also not aware about the group allocation. Group allocation of participant through the study shown in Figure 1.

All patients were premedicated with Tab alprazolam 0.25 mg and Tab ranitidine 150 mg, night before surgical procedure. Patients were kept fasting for 6 hours prior to surgery. On arrival to operation theatre, routine monitoring of heart rate, NIBP, SpO<sub>2</sub>, ECG was done. An intravenous line was established, and ringer lactate infusion was started.

Anaesthesia was standardized and given by an anesthesiologist blinded to group assignment. All patients received study drug according to group allocation, 5 mins prior to induction followed by I.V. premedication Inj. midazolam (0.05 mg/kg), Inj. fentanyl (2 mg/kg), Inj. glycopyrolate (0.2 mg). After preoxygenation for 3 minutes, patient was induced with propofol 2 mg/kg till loss of verbal contact followed by intubation dose of vecuronium bromide 0.1 mg/kg to facilitate the direct laryngoscopy and tracheal intubation. Anaesthesia was maintained with isoflurane, N<sub>2</sub>O (60%) and oxygen. At the end of surgery, I.V. glycopyrolate and neostigmine was administered to reverse residual neuromuscular block.

Postoperative analgesia was provided by 75 mg diclofenac I.M. every eight hours or 1 gm paracetamol I.V. every six hours in patients who did not tolerate diclofenac. Post-operative follow up was done at 0-6 hours, 6-12 hours, 12-24 hours after transfer to the postoperative unit by a blinded observer. Nausea is defined as an unpleasant sensation associated with the awareness of vomiting. Vomiting is defined as forceful expulsion of gastric contents from the mouth. Retching is defined as an active attempt to vomit without expulsion of gastric contents. Retching was included in vomiting. Rescue anti-emetic (metoclopramide 10 mg I.V.) was given to patients who experience persisting nausea for more than 5 min had two or more episodes of

vomiting/retching in 15 min or who demanded treatment for their emetic symptoms. PONV was assessed based on the following verbal descriptive scale (VDS, 0-3 point) grade 0 indicates no nausea/vomiting, grade 1 was only nausea, grade 2 was one episode of vomiting and grade 3 was more than one episode of vomiting.<sup>5</sup> Apfel scores for

4 risk factors (history of motion sickness or PONV, nonsmoking status, post-operative opioid use, female gender) with 1 point assigned for each was recorded. Patient's satisfaction score was also evaluated as worse, moderate and good post operatively.<sup>5</sup>

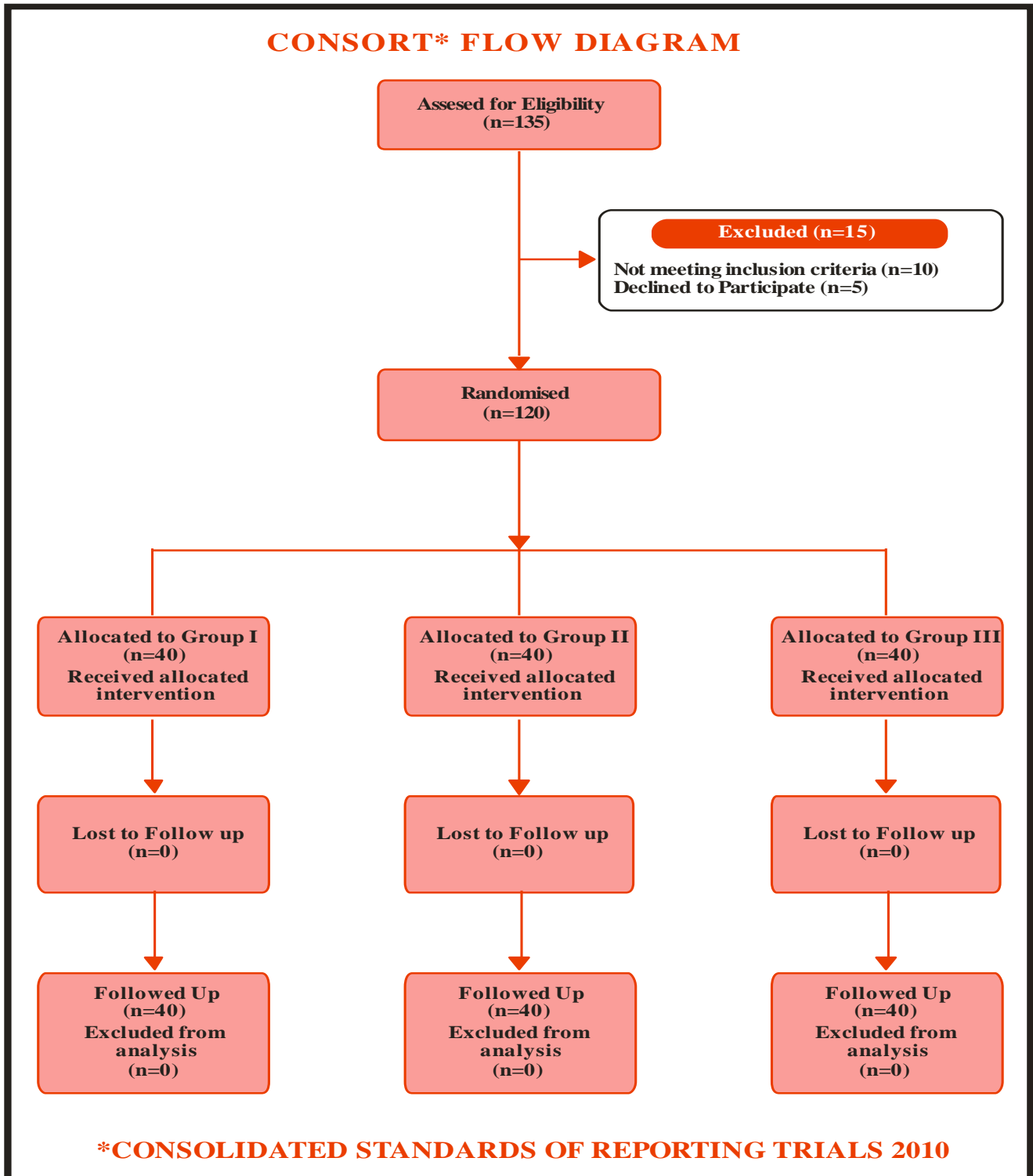


Figure 1: CONSORT flow diagram of participants through the study.

## RESULTS

All the three groups were comparable in terms of age, height, weight, BMI, duration of surgery and duration of anaesthesia (Table 1). The APFEL score among the three

groups was similar and statistically comparable. There were 55% patients with Apfel score 2 in group I, 62.5% patients in group II and 60% in group III respectively. The maximum number of patients were of score 2 among the three groups (Table 2).

**Table 1: Demographic profile.**

Patients characteristics	Group I Granisetron	Group II Dexamethasone	Group III Grani+ Dexa	P value
Age (years)	44.88±10.62	41.75±11.64	40.78±8.81	0.189
Height (Centimeter)	161±0.060	162±0.067	162±0.050	0.895
Weight (kg)	64.85±6.22	63.93±6.05	64.90±6.84	0.744
BMI (kg/m <sup>2</sup> )	24.78±2.61	24.21±2.09	24.64±2.75	0.570
Duration of surgery (mins)	52.95±7.47	53.75±7.39	51.35±5.48	0.283
Duration of anaesthesia (mins)	65.28±7.15	67.58±8.45	64.20±10.17	0.211

Data are presented in Mean±SD, P value <0.05 is statistically significant.

**Table 2: Apfel score.**

Patients characteristics	Group I (n=40) Granisetron Frequency (%)	Group II (n=40) Dexamethasone Frequency (%)	Group III (n=40) Grani+Dexa Frequency (%)	P value
0	3 (7.5%)	1 (2.5%)	2 (5.0%)	0.671
1	11 (27.5%)	8 (20%)	12 (30%)	
2	22 (55%)	25 (62.5%)	24 (60%)	
3	4 (10%)	6 (15%)	2 (5%)	
Total	40 (100%)	40 (100%)	40 (100%)	

Data are presented in absolute numbers, P value <0.05 is statistically significant.

**Table 3: Comparison of complete response, incidence of nausea and vomiting, use of rescue antiemetic among the groups.**

Parameters	Group I (n=40) Granisetron Frequency (%)	Group II (n=40) Dexamethasone Frequency (%)	Group III (n=40) Grani+Dexa Frequency (%)	P value
<b>0-6 hours after anaesthesia</b>				
Complete response**	31 (77.5%)	30(75%)	37 (92.5%)	0.040*
Nausea	6(15%)	6 (15%)	2 (5%)	0.329
Vomiting	3(7.5%)	4(10%)	1 (2.5%)	0.544
Rescue antiemetic	3 (7.5%)	6(15%)	1 (2.5%)	0.078
<b>6-12 hours after anaesthesia</b>				
Complete response**	36(90%)	36(90%)	37 (92.5%)	0.757
Nausea	3(7.5%)	2(5%)	2 (5%)	0.859
Vomiting	1(2.5%)	2(5%)	1 (2.5%)	0.433
Rescue antiemetic	1 (2.5%)	2(5%)	1 (2.5%)	0.433
<b>12-24 hours after anaesthesia</b>				
Complete response**	37(92.5%)	37(92.5%)	40(100%)	0.206
Nausea	3 (7.5%)	1(2.5%)	0(0%)	0.163
Vomiting	0(0.0%)	2(5%)	0 (0%)	0.224
Rescue antiemetic	0 (0.0%)	2 (5%)	0 (0%)	0.130

\*\*Complete response = no PONV, no rescue medication, Data are presented in absolute numbers, P value <0.05 is statistically significant, \* Statistically significant.

Incidence of complete response, nausea and vomiting, rescue anti-emetic was compared among the three groups. (Table 3).

Total cumulative data of nausea, vomiting and rescue antiemetic over 24 hours shows that group III had maximum percentage of complete response (92.5%) and group II had minimum percentage of complete response

(70%). The difference in complete response among the three groups was statistically significant (p value-0.030).

Whereas incidence of nausea and vomiting among the three group was comparable (p value-0.089, 0.078). Percentage of rescue anti emetic usage was highest in group II though statistically comparable (p value-0.055) (Table 4).

**Table 4: Cumulative frequency of complete response, incidence of nausea and vomiting, rescue anti emetic in 24 hours among the groups.**

Parameters	Group I Granisetron Frequency (%)	Group II Dexamethasone Frequency (%)	Group III Grani+ Dexa Frequency (%)	P value
<b>Cumulative PONV 0-24 hours after anaesthesia</b>				
Complete response**	30 (75%)	28 (70%)	37 (92.5%)	0.030*
Nausea	7 (17.5%)	6 (15%)	2 (5%)	0.089
Vomiting	3 (7.5%)	6 (15.0%)	1 (2.5%)	0.078
Rescue antiemetic	3 (7.5%)	8 (20.0%)	1 (2.5%)	0.055

\*\*Complete response = no PONV, no rescue medication, Data are presented in absolute numbers, P value <0.05 is statistically significant, \*Statistically significant.

**Table 5: Comparison of verbal descriptive scale (0-24 hrs) among the groups.**

Grade	Group I Granisetron Frequency (%)	Group II Dexamethasone Frequency (%)	Group III Grani+ Dexa Frequency (%)	P value
0	30 (75%)	28 (70%)	37 (92.5%)	0.030*
1	7 (17.5%)	6 (15%)	2 (5%)	0.089
2	2 (5%)	4 (10%)	0 (0.0%)	0.121
3	1 (2.5%)	2 (5%)	1 (2.5%)	0.772

\*VDS score description: Score 0 = no nausea/vomiting, Score 1= nausea, Score 2 = one episode of vomiting, Score 3 = more than one episode of vomiting; \*\*Pearson Chi-Square Test, P value <0.05 indicates statistically significant correlation.

**Table 6: Comparison of patient’s satisfaction score among the groups.**

Satisfaction score	Group I Granisetron Frequency (%)	Group II Dexamethasone Frequency (%)	Group III Grani+ Dexa Frequency (%)	P value
Good	24 (60%)	20 (50%)	32 (80%)	0.017*
Moderate	12 (30%)	14 (35%)	7 (17.5%)	0.195
Worse	4 (10%)	6 (15%)	1 (2.5%)	0.149

P value <0.05 = statistically significant correlation, \*statistically significant.

Cumulative complete response in 0-24 hours was higher in group I (75%) than group II (70%) but was statistically non-significant.

Incidence of nausea was higher in group I (17.5%) but incidence of vomiting was higher in group II (15%). The difference was statistically non-significant. Similarly, use of rescue antiemetic was higher in group II (20%) than group I (7.5) but statistically non-significant.

Cumulative complete response in 0-24 hours was higher in group III (92.5%) than group II (70%) and was statistically significant (p value-0.028). Incidence of nausea (15%) in group II was higher than in group III (5%) but was statistically non-significant.

Incidence of vomiting was also higher in group II (15%) than in group III (2.5%) and was statistically significant (p value-0.047). Similarly, use of rescue antiemetic was

higher in group II (20%) than group III (2.5%) and was also statistically significant (p value-0.039).

Cumulative complete response in 0-24 hours was higher in group III (92.5%) than group I (75%) and was statistically significant (p value-0.033). Incidence of nausea (17.5%) was higher in group I than group III (5%) and was statistically significant (p value-0.046). Incidence of vomiting was also higher in group I (7.5%) than group III (2.5%). The difference was statistically non-significant. Similarly, use of rescue antiemetic was higher in group I (7.5%) than group III (2.5%) but statistically non-significant. Verbal descriptive scale was compared among the three groups using Pearson Chi square test score 0 i.e., no nausea and vomiting was highest (92.5%) in group III and least (70%) in group II

and was statistically significant. (p value 0.03). 1 patient in group I and III had repeated episodes of vomiting (score 3) as compared to group II in which 2 patients had repeated episodes of vomiting (score 3) (Table 5). Patient satisfaction score was compared among the three groups using Pearson Chi square test. Maximum (80%) patients in group III responded good followed by group I (60%) and group II (50%). The results were statistically significant (p value-0.017). Worse response was given maximum (15%) by patients of group II though statistically non-significant (Table 6).

Incidence of adverse effects were also comparable among the groups except the incidence of perineal itching which was found in 2 patients of only dexamethasone group (Table 7).

**Table 7: Comparison of incidence of adverse events among the groups.**

Adverse events	Group I Granisetron Frequency (%)	Group II Dexamethasone Frequency (%)	Group III Grani+ Dexa Frequency (%)	P value
Headache	1 (2.5%)	1 (2.5%)	1 (2.5%)	1.0
Dry mouth/lips	2 (5.0%)	1 (2.5%)	1 (2.5%)	0.772
Dizziness	1 (2.5%)	1 (2.5%)	1 (2.5%)	1.0
Perineal itching	0 (0%)	2 (5%)	0 (0%)	0.131
Total	4 (10%)	5 (12.5%)	3(7.5%)	0.757

Data are presented in absolute numbers, P value <0.05 is statistically significant, \*Statistically significant.

## DISCUSSION

Post-operative nausea and vomiting is a very common occurrence after any surgical procedure under general anaesthesia. Laparoscopy benefits the patient by fast recovery, short hospital stays and prompt return to normal activities. Stretching and irritation of the peritoneum from insufflation of gas during laparoscopy may be a specific emetogenic stimulus and laparoscopy has been associated with a relatively high absolute risk of PONV in several reports.<sup>6,7</sup> Many studies are done on PONV so far, but most of them compared the anti-emetic drugs with placebo only and either reported emetic episodes or nausea only. Very less number of studies compared two or three approaches for control of PONV in post-operative period in laparoscopy surgery which is increasing now a days.

Apfel et al, gave four risk factors, which are female gender, prior history of PONV, nonsmoking, and the use of postoperative opioids which are directly related to PONV. If no or only one risk factor is present the incidence of PONV may vary between about 10% and 21%, whereas if at least two risk factors are present it may rise to between 39% and 78%. Finally, this score might be useful for patient selection in antiemetic trials. In the present study, all the three groups were comparable with respect to patients APFEL score, demographic

profile, type and duration of surgery and anaesthesia, anaesthetic technique and post-operative analgesia, so the difference in complete response (no PONV and no rescue medication) between the groups could be attributed only due to the clinical efficacy of the study medication drugs. So, the comparison of primary outcome parameter of complete response and incidence of PONV can be easily compared among the groups without any confounding.<sup>5</sup>

Granisetron is a selective 5 HT3 receptor antagonist that exhibits an anti-emetic action by antagonizing vomiting signals in the afferent pathway from the stomach or small intestine and solitary tract nucleus and is effective at preventing PONV. Dexamethasone is a corticosteroid anti-inflammatory drug with an established role for the prevention of PONV. At present, mechanism of action of dexamethasone in PONV prevention is still not fully understood but probably dexamethasone is a synthetic form of adrenocorticoid and acts mainly as a glucocorticoid receptor with almost no mineralocorticoid receptor function and some glucocorticoid receptors are related to the physiological conduction path for vomiting. It may also be acting by inhibition of prostaglandin synthesis, decrease in 5HT3 levels in CNS.<sup>8</sup>

Combination of anti-emetic drugs could be an effective method to control severe post-operative nausea and vomiting (PONV), perhaps because there is no single

stimulus or cause of PONV. A combination of anti-emetics of different class can increase the clinical efficacy compared with single drug alone.

Biswas BN et al, conducted a study on 120 patients for comparison of granisetron with granisetron plus dexamethasone for prevention of PONV after laparoscopic cholecystectomy. They gave granisetron 40µg/kg in group I and granisetron and dexamethasone 8 mg in II group. The total incidence of PONV in granisetron plus dexamethasone group was 5% and 18.3% in granisetron alone group. The complete response was seen in 95% patients receiving granisetron plus dexamethasone as compared to 83% patients in granisetron alone group which was statistically significant. Rescue anti emetic used was 2% in patients of granisetron plus dexamethasone group and 3% in granisetron alone group in 0-4 hours post-surgery. They concluded that the combination further increases the chance of complete response than granisetron alone in high risk settings. Their results are similar to the results of present study.<sup>9</sup>

Wadaskar DR et al, conducted a study for prevention of PONV in 120 patients undergoing laparoscopic cholecystectomy. Group I received granisetron 40µg/kg, group II received granisetron 20 microgram/kg plus dexamethasone 160µg/kg, group III received granisetron 40µg/kg plus dexamethasone 160µg/kg. The total incidence of PONV in 0-24 hours was 36.66% in group I, 26.67% in-group II and 13.33% in group III. Complete response was seen in 63.44% in group I, 73.33% in group II and 86.67% in group III which was statistically significant (p value-0.03). Rescue anti emetic used was 26.67% in-group I, 16.67% in-group II, 3.3% in group III. They concluded that granisetron 40µg/kg plus dexamethasone 160µg/kg is best for prevention of PONV in highly emetogenic surgeries like laparoscopic cholecystectomy. Their results are similar to the results of the present study.<sup>10</sup>

Nanjundaswamy NH et al, conducted a study for prevention of PONV in 75 patients undergoing laparoscopic cholecystectomy. Group I received ondansetron 4 mg plus dexamethasone 8 mg. Group II received granisetron 1 mg plus dexamethasone 8 mg and group III received saline with dexamethasone 8 mg. The incidence of PONV was 16% in group I and II in comparison to 68% in group III which was statistically significant. The complete response after 24-hour period was 32% in control group III, 84% in group I and group II. . Rescue anti emetic were required only in group III. They concluded that granisetron 1 mg and ondansetron 8 mg in combination with dexamethasone 8 mg are equally effective and safe in decreasing the incidence of PONV in laparoscopic cholecystectomy under general anaesthesia. Their results are statistically similar to the results of present study although incidence of PONV in their study are higher as compared to present study. This difference could be because they have not taken APFEL

score into consideration which is an important confounding factor in case of PONV and all their patients are females.<sup>11</sup>

Moussa AA et al, conducted a study on 120 patients undergoing laparoscopic bariatric surgery. Patients were randomized in 4 groups receiving either granisetron 1 mg, granisetron 1 mg plus droperidol 1.25 mg, granisetron 1 mg plus dexamethasone 8 mg or placebo immediately before induction of anaesthesia. The incidence of PONV was 30% in granisetron alone and granisetron plus droperidol group, 20% with granisetron plus dexamethasone and 67% in placebo group. Rescue anti emetic was required in 46.6% patients in placebo group, 6.66% patients in granisetron and droperidol group and none in granisetron plus dexamethasone group. They concluded that granisetron is effective and safe drug for reducing PONV and becomes highly effective when combined with dexamethasone. The incidence of PONV in dexamethasone and granisetron group was 20% as compared to the 7.5% in present study. This variation in results is probably a result of under powering of this study for the size of the actual difference observed i.e., because of smaller sample size 30.<sup>12</sup>

Dalvi NP et al, conducted a study for prevention of PONV in 60 patients undergoing laparoscopic abdominal surgery. Group I received 40µg/kg (approx 2 mg) of granisetron and group II received 160µg/kg (approx 8 mg) of dexamethasone just before induction of anaesthesia. The incidence of nausea was 16% and vomiting was 3.3% in granisetron group as compared to 16% had nausea and 6.7% vomiting in dexamethasone group in 0-4-hour period. In 0-4 hours, rescue anti emetic was required in 20% patients in granisetron group and 23% patients in dexamethasone group. In 4-24 hours, the incidence of nausea in dexamethasone group was 10% and vomiting was 20% as compared to 0% in granisetron group which was statistically significant (p value-0.005). They concluded that granisetron 40µg/kg is more effective in preventing PONV with minimal adverse effects and cost effective in patients undergoing laparoscopic surgeries. The difference in their results at 24 hours may be due to the variable dosing of drugs used in their study according to weight of the patient in comparison to static dosing of the present study.<sup>13</sup>

The patient satisfaction score is closely tied to PONV and if patient satisfaction score is considered a major outcome, eliminating vomiting to a degree that was found in this study is noteworthy.

Sheikh FS et al, in their study granisetron versus combination of granisetron with dexamethasone in prevention of PONV in patients undergoing head and neck surgical procedures also discussed patient satisfaction score. Their scores were comparable to this study.<sup>14</sup>

## CONCLUSION

The present study concluded that in patients of laparoscopic surgeries which are high risk for PONV, all the three anti emetics namely 5HT<sub>3</sub> antagonist (granisetron), steroid (dexamethasone) and the combination of both the drugs are found to be effective in prevention of PONV. Although, combination of both the drugs is superior to any drug when used alone in reducing the incidence of PONV without any increase in adverse events. The prophylactic therapy of granisetron 2 mg plus dexamethasone 8 mg just before induction of anaesthesia is significantly effective in prevention of PONV in patients undergoing laparoscopic surgeries.

The limitation of the study were that the placebo group was not kept in the present study because of the nature of the study (laparoscopic surgeries are high risk surgeries for PONV) to avoid ethical issues.

## ACKNOWLEDGEMENTS

Authors would like to thank technical staff and patients of the surgical operating theatres for assisting during the work.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Chilana D, Rastogi B, Kumar A, Singh BVP, Arora R, Gupta A. A comparative study of granisetron, dexamethasone and combination of granisetron-dexamethasone as prophylaxis for postoperative nausea vomiting during laparoscopic surgeries. *Int J Res Med Sci* 2019;7:1200-7.