# A Study to Compare and Evaluate the Efficacy of Granisetron and Granisetron Dexamethasone Combination as Anti-Emetic

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## **Abstract**

**Background:** Dexamethasone, a glucocorticoid is shown to produce stronger antiemetic effect, probable mechanism is prostaglandin antagonism, serotonin inhibition, releasing endorphins and 5HT3 antagonism with biological half life 36 to 72 hrs, confers longer duration of prophylaxis. Since etiology of PONV is multifactorial, combination of different classes of antiemetic can increases clinical efficacy compared to single drug alone. **Subjects and Methods:** A detail preoperative assessment was performed on preoperative visit on the day before surgery. Where detail history, thorough general examination, airway assessment and systemic examination was performed. All routine investigations were done like haemogram, routine urine examination, random blood sugar, blood urea, serum creatinine and serum liver function test.X-ray chest and ECG were done when indicated. **Results:** In Group-GD, only 13.33% had PONV which was statistically significantly low as compared to Group-G which was 36.66% (P<0.05). Complete response in Group-GD was 86.67% which was statistically significantly high as compared to Group-G which was only 63.34% (P<0.05). **Conclusion:** Requirement of Rescue anti-emetic was less in Granisetron-Dexamethasone combination group than Granisetron group.

Keywords: Granisetron, Granisetron Dexamethasone combination, Anti-emetic.

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#### Introduction

Post operative nausea and vomiting is still one of the most common and distressing symptom Following surgery and anaesthesia despite significant advances in conduction of general anaesthesia and surgery, kapur has described this as "THE BIG LITTLE PROBLEM"

The overall incidence of PONV is 25-30% and second most common compliant reported, and incidence of severe and intractable PONV is 0.19%. Several large prospective cohort studies now suggest that the varying incidences of PONV observed after different types of surgeries are largely a reflection of important patient specific and anaesthesia related risk factors rather than surgery itself. [1]

Regarding anaesthesia related risk factor the inhalation agents are invariably associated with PONV, nitrous oxide, cyclopropane, ether are associated with high incidence while currently used agents like isoflurane, enflurane and sevoflurane cause less but still significant PONV. IV anaesthetics are also associated with different degrees of emesis, though newer agents like propofol is less emetoginic and opoids used is also emetoginic.

Patient related factor also being important, PONV is more prevalent in females than males, obesity,

pregnancy, children more susceptible, previous h/oPONV, motion sickness are known risk factors

Although PONV is almost always self limiting and non fatal it can cause significant morbidity and longer stays in recovery room. It can have psychological impact which will cause aversion to further surgery and apprehension of repeated vomiting. [2]

Thus PONV leads to physical, metabolic, psychological and economical impact. Etiology of PONV is multifactorial, at least 7 neurotransmitter types are documented namely serotonin, dopamine, muscarine, ach, neurokinin1, histamine and opoids. Stimulation of vestibulocochlear, glossopharyngeal, vagus nerve is also being involved.

Granisetron a newer highly specific 5HT3 receptor antagonist, having both central and peripheral action, having longer half life twice that of ondensetron and fewer side effect as compared to metoclopramide, is effective in PONV.<sup>[3]</sup>

Recently, Dexamethasone, a glucocorticoid is shown to produce stronge antiemetic effect, probable mechanism is prostaglandin antagonism, serotonin inhibition, releasing endorphins and 5HT3 antagonism with biological half life 36 to 72 hrs, confers longer duration of prophylaxis. Since etiology of PONV is multifactorial, combination of different classes of antiemetic can increases clinical efficacy compared to single drug alone. Therefore, Combination of

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Granisetron and Dexamethasone is effective in preventing PONV by their synergistic effect 5HT3 antagonism, and multiple receptor site action.

Laparoscopic surgery also called minimal invasive surgery, banded surgery, key hole surgery, in which operation in abdomen is performed through small incision. laparoscopic surgeries have been rapidly increased because of tremendous benefits to patients with smaller incision than convention technique, scarless surgery (minimal tissue trauma), decrease post operative pain, decrease post operative ileus, decrease post operative pulmonary impairment, shorter hospital stay and earlier ambulation, despite all these high incidence of PONV remains a major cause of morbidity. [4]

Laparoscopic cholecystectomy is now a days the preferred procedure for cholelithiasis although it can decrease surgical morbidity in comparison to open cholecystectomy the incidence of PONV is appreciably high, relatively high incidence 53-72% compared to other laparoscopic surgeries. It is more common in female and obese patients. This high incidence justifies the use of prophylactic antiemetic for prevention of PONV following laparoscopic cholecystectomy. [5]

Therefore, we decided to carry out comparative study of combination of Granisetron with Dexamethasone and Granisetron alone for prevention of PONV in laparoscopic cholecystectomy.

# Subjects and Methods

The randomized prospective clinical study of 60 patients undergoing Laparoscopic cholecystectomy were carried out at Medical College. Patients were randomly divided into two group;

#### **GROUP - G**

Inj. Granisetrone (40μg/kg) in 5ml NS Intravenously.

#### **GROUP-GD**

Inj. Granisetrone  $(40\mu g/kg)$  + Inj. Dexamethasone  $(150\mu g/kg)$  in 5ml NS intravenously.

## **Patient Selection and Preoperative Assessment**

A detail preoperative assessment was performed on preoperative visit on the day before surgery. Where detail history, thorough general examination, airway assessment and systemic examination was performed. All routine investigations were done like haemogram, routine urine examination, random blood sugar, blood urea, serum creatinine and serum liver function test.

X-ray chest and ECG were done when indicated.

#### **Anaesthesia Technique**

On the day of surgery, nil by mouth status of patient was confirmed and written and informed consent obtained. Intravenous line was secured with crystalloid infusion was started.

## **Premedication**

In all the patients of either group premedication was given in the form of

Injection Glycopyrrolate [5µg/kg] intramuscularly 1 hour

before induction

Moniters were attached and all baseline parameters pulse rate, blood pressure, respiratory rate & Spo2 & ECG were recorded and patients were randomaly divided on two groups;

#### GROUP - G

Inj. Granisetrone (40μg/kg ) in 5ml NS Intravenously.

#### **GROUP - GD**

-Inj. Granisetrone ( $40\mu g/kg$ ) + Inj. Dexamethasone ( $150\mu g/kg$ ) in 5ml NS intravenously.

Haemodynamic parameters were observed by same observer after giving drugs.

• Then, Inj. Fentanyl  $[1\mu g/kg]$  was given intravenously 5minute before induction in both the groups.

#### **Induction**

All patients received general anaesthesia. After pre oxygenation 100% O2 for 3minutes. Patients were induced with Inj. Sodium Thiopentone 4-7mg/kg i.v.till loss of eye lash reflex, Inj. Succinyl choline i.v. 2mg/kg followed by tracheal intubation with cuffed portex ET tube of appropriate SIze. Appropriate size ryle's tube was inserted and aspiration was done.

#### **Maintenance**

Anaesthesia was maintained with controlled ventilation oxygen (50%) + N2O(50%) + Isoflurane(0.8-2%) and intermittent Inj. Vecuronium bromide (0.02/KG) intravenously.

Intraabdominal pressure was kept between 11-15mmhg.throughout the course of anaesthesia patients were monitored forhaemodynamic parameters pulse, blood pressure, ETCO2, Spo2 and ECG.

#### Reversal

After completion of surgery, ryle's tube aspiration was done, than patients were reversed with Inj. Glycopyyrolate  $10\mu g/kg$  and Inj. Neostigmine  $50\mu g/kg$  i.v.and after fulfilling all the criteria of extubation, patients were extubated.

Vital data were recorded postoperatively and all the patients were shifted to recovery room and oxygen was given through ventimask.

In the post operative period, patients were monitored immediately, than 15mins, 30mins, 45mins, 1 hour, 2 hour, 3 hour, 4hour, 6hour, 8hour, 12hour and 24 hour for haemodynamic parameters,sp02, respiratory rate, any episode of nausea, retching or vomiting, Emesis score, requirements of rescue anti-emetic and side effects.

#### **Emesis Score**

- SCORE 0 ;- No Nausea
- SCORE 1 ;- Nausea only
- SCORE 2 ;- Nausea with Retching
- SCORE 3 ;- Vomiting

Rescue Anti-Emetic was given in the form of Inj. Ondensetron 4mg Intravenously when Emesis score was  $\geq 2$  & this was considered as end point of study.

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- Nausea: It is defined as a subjective unpleasant sensation associated with awareness and a desire to vomit but not associated with expulsive muscular movement.
- Retching: It is defined as a labored, spasmodic, rhythmic contraction of respiratory muscle including diaphragm, chest wall and abdominal muscle without

expulsion of gastric content.

• **Vomiting:** It is defined as a forceful expulsion of gastric content from the mouth and brought about by powerful sustain contraction of abdominal muscle, descent of diaphragm and opening of cardiac sphincter.

## Results

**Table 1: Demographic characteristics** 

Variables	Group- G Mean±SD	Group- GD Mean±SD	Intergroup'P' Value
Age(year)	42.63±8.48	43.56±8.05	> 0.05
Weight(kg)	55.13 <b>±</b> 6.47	57.13±7.41	> 0.05

The patients in Group- G had average age 42.63 years and average weight of 51.13 kg. Group- GD patients had average

age 43.56 and average weight of 57.13 kg. Both groups were comparable with respect to age and weight (P>0.05).

**Table 2: Gender Distribution** 

Variables	Group- G	Group- GD	Intergroup'P' Value
Male	11[36.66%]	12[40%]	> 0.05
Female	19[63.33%]	18[60%]	> 0.05

[Table-2] shows gender distribution, 36.66% of patient in Group- G were male and 63.33% were females. Group- GD

had 40% male and 60% were female.both groups were comparable (P>0.05)

**Table 3: ASA Status** 

ASA Grade	Group – G		Group - GD	
	No.	%	No	%
I	14	46.66	18	60
II	16	53.33	12	40

As shown in [Table-3] In Group-G 46.66% were ASA-I and 53.33 were ASA-II while in Group-GD 60% were ASA-I

and 40% were ASA-II grade.

#### Table 4: Duration of Anaesthesia

	Group – G Mean±SD	Group - GD Mean±SD	Intergroup 'P' Value
<b>Duration(minutes)</b>	111±14.52	115.66±8.97	> 0.05

As shown in [Table-4], Mean duration in Group-G and GD were 111 & 115.66 minutes respectively. Group- G and

Group- GD patients were comparable with respect to duration of Anaesthesia.

**Table 5: Post Operative Nausea & Vomiting (%)** 

Postoperative Period	Group- G (out of 30)	% of patients	Group- GD (out of 30)	% of patients
Immediate	0	0	0	Ô
15 min	0	0	0	0
30 min	0	0	0	0
45 min	0	0	0	0
1hr.	0	0	0	0
2 hrs.	1	3.33%	0	0
3 hrs.	1	3.33%	0	0
4 hrs.	2	6.66%	1	3.33%
6 hrs.	3	10%	2	6.66%
8 hrs.	4	13.33%	1	3.33%
12 hrs.	0	0	0	0
24 hrs.	0	0	0	0

As shown in [Table-5], we observed that complete response (no nausea & vomiting) was noted up to 4 hrs in Group-GD and only up to 2hrs in Group-G. The incidence of nausea and vomiting was statistically significantly low in Group-GD at

different interval (at 4hrs-3.33%, 6hrs-3.33% & 8hrs-6.66%) as compared to Group-G (at 2hrs-3.33%, 3hrs-3.33%, 4hrs-6.66%, 6hrs-10% & 8hrs-13.33%).

Table 6: Overall Incidence Of Ponv In 24 Hrs

	Group-G		Group-GD		
	No. of patients	%	No. of patients	%	P Value
PONV	11	36.66%	4	13.33%	0.05
No PONV	19	63.34%	26	86.67%	<0.05
(Complete response)					

As shown in above table, In Group-GD, only 13.33% had PONV which was statistically significantly low as compared to Group-G which was 36.66% (P<0.05). Complete response

in Group-GD was 86.67% which was statistically significantly high as compared to Group-G which was only 63.34% (P<0.05).

Table 7: Emesis Score

Post -	Emesis score Rescue Antiemetic						tiemetic				
operative	1		2		3	3		No. of patient		%	
Period	Group G	Group GD	Group G	Group GD	Group	Group GD	Group G	Group GD	Group G	Group GD	
					G						
Immediate	0	0	0	0	0	0	0	0	0	0	
15 min	0	0	0	0	0	0	0	0	0	0	
30 min	0	0	0	0	0	0	0	0	0	0	
45 min	0	0	0	0	0	0	0	0	0	0	
1 hr.	0	0	0	0	0	0	0	0	0	0	
2 hrs.	1	0	0	0	0	0	0	0	0	0	
3 hrs.	0	0	1	0	0	0	1	0	3.33%	0	
4 hrs.	1	1	1	0	0	0	1	0	3.33%	0	
6 hrs.	1	1	0	1	2	0	2	1	6.66%	3.33%	
8 hrs	0	0	2	0	2	1	4	1	13.33%	3.33%	
12 hrs	0	0	0	0	0	0	0	0	0	0	
24 hrs	0	0	0	0	0	0	0	0	0	0	
Total	03	02	04	01	04	01	08	02	26.66%	6.66%	

[Table-7] shows severity of nausea and vomiting by Emesis score in both groups as described above in material and method i.e. Score 0; - No Nausea, Score 1; - Nausea only, Score 2; - Nausea with Retching, Score 3; - Vomiting. Rescue antiemetic was given when emesis socre≥2 in the form of Inj. Ondensetron 4mg intravenously.

At 2hrs, 1 patient had score-1 in Group-G & none in Group-GD

At 3hrs, 1 patient had score-2 in Group-G, which required rescue antiemetic.

At 4hrs, 1 patient had score-1in both groups, 1 patient had score-2 in group-G, which required rescue antiemetic was.

At 6hrs, 1 patient had score-1 in both groups, 1 patient had

score-2 in group-GD, which required rescue antiemetic & 2 patients had score-3 in Group-G, which also required rescue antiemetic.

At 8hrs, 2 patients had score-2 in group-G, 2 patients had score-3 in group-G & 1patient in Group-GD, so total 4 patients in group-G & 1 patient in Group-GD required rescue antiemetic.

After12 hrs no incidence of nausea and vomiting was observed.

Requirement of Rescue Anti-Emetic was earlier in Group-G at 3<sup>rd</sup>hr as compared to Group-GD which was at 6<sup>th</sup> hrs. At different interval, Requirement of rescue antiemetic was also lower in Group-GD as compared to Group-G

Table 8: Emesis Score In 24 Hrs

EMESIS SCORE	Group-G	Group-GD
Score - 0	19	26
Score – 1	03	02
Score – 2	04	01
Score - 3	04	01
	P<0.05	

As shown in above table,

Emesis Score was 0 that is complete response in 26 patients in Group-GD and 19 patients in Group-G.

Emesis Score was 1 in 2 patients in Group-GD and 3 patients in Group-G.

Emesis Score was 2 in 1 patient in Group-GD and 4 patients in Group-G.

Emesis Score was 3 in 1 patient in Group-GD and 4 patients in Group-G.

Emesis score was lower in Group-GD as compared to Group-G which statistically highly significant (P<0.05). At different interval, Emesis score was also lower in Group-GD as compared to Group-G.

Table 9: Overall Incidence Of Rescue Anti-Emetic In 24 Hrs

			Group-GD		
			No. of pt.	%	
Rescue antiemetic	8	26.66%	2	6.66%	

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As shown in above table, overall 8 (26.66%) patients out of 30 required rescue anti-emetic in group-G, while in Group-GD it was only 2(6.66%) patients out of 30 required anti-emetics, requirements of rescue antiemetic was low in Group-GD as compared to group-G.

## Discussion

As shown in demographic data, mean age in group-G 42.63±8.48 years and in group-GD 43.56±8.05 years. Difference between these two group is statistically insignificant (P>0.05).

B.N. Biswas& A. Rudra et al (2002); they had taken the patients having mean age in group G-41.3 yrs and group GD-42.4yrs. Mohd.Parvez Khan & Monica Kohali et al (2006)<sup>[6]</sup>: they had taken the patients having mean age in group G 38±9.96 and group GD 38.84±9.84yrs.Thus our study is in consonance with their study

On comparing weight, mean weight in Group-G was 55.13±6.47kg and in Group-GD 57.13±7.41kg. Thus, the weight was comparable between both groups. Difference between the two was statistically not significant (P>0.005).

B.N. Biswas, & A. Rudra et al  $(2002)^7$ ; they had taken in his study with mean weight in group G 54kgs and group GD 56kgs. Mohd.Parvez Khan & Monica Kohali et al  $(2006)^6$ : they had taken in his study with mean weight in group G 55.68±7.12 and group GD 56.28±6.63.

Thus our study is in consonance with their study.

Demographic variable in relation to duration of anaesthesia

was 111 14.52mins in Group-G and 115.66±8.97 mins in Group-GD. Difference was statistically insignificant (P>0.005).

B.N. Biswas, A. Rudra et al  $(2002)^7$ ; duration of anaesthesia in group G was  $90\pm6$ mins and group GD  $87\pm8$ mins. Mohd.Parvez Khan & Monica Kohali et al  $(2006)^6$ : duration of anaesthesia in group G was  $105\pm8.59$ mins and group GD  $107\pm12.37$ mins.

Thus our study is in consonance with their study.

The incidence of nausea and vomiting in patients in Group-GD was lower than Group-G at different interval. We observed that no nausea and vomiting (complete response) up to 4hrs in Group-GD and only up to 2hrs in Group-G post-operatively. After 12 hrs, we had not found any incidence of nausea and vomiting in both the groups

The cause of nausea and vomiting in early post operatively period can be explained by the effect of residual CO2 irritating peritoneum, post-operative pain & effect of inhalation agent used intraoperatively. After 12hrs, there was no incidence of emesis in both groups, which is due to effect of drug and complete removal of residual  $CO_2$ . [8,9]

The emesis free period was up to 2 hours in Granisetron group and up to 4 hours in Granisetron Dexamethasone combination group which indicates the longer duration of action of combination group.

On comparing the incidence of nausea and vomiting in 24hrs between two groups, the overall incidence of post-operative nausea & vomiting were 13.33% in group-GD, which was low, as compared to group-G that was 36.66% in 24 hrs.

We achieved complete response (no nausea & vomiting, no rescue anti emetic during 24 hr) in 86.67% (26) of the patients in group-GD and 63.34% (19) of the patients in group-G. Thus, complete response was more in group-GD as compared to group-G.

Difference in incidence of PONV between the groups was statistically significant (P<0.05).

The mechanism of Dexamethasone induced anti emetic activity is not fully understood, but may involve central inhibition of prostaglandin synthesis, decrease in 5HT turnover in central nervous system (i.e. decrease serotonin release) or change in permeability of blood CSF barrier to serum proteins. Granisetron being 5-HT3 receptors antagonist, combining Dexamethasone with it will havesynergistic action on 5-Ht3 receptor. So, the potency of combination group would be higher than single drug in this study.

Our result was similar to B.N. Biswas& A. Rudra et al (2002), Mohmad. Parvez Kahn & Monica Kohali et al (2006) and Fujii Y & Saitosh Y et al (2000).

B.N. Biswas& A. Rudra et al (2002)<sup>[7]</sup> observed that the overall incidences (0-24hr) of PONV were 18.3% (11) in group-G and5% (3) in the group-GD (P<0.05). Completed response (No PONV) were achieved in 83% of patients in group-G and 95% of the patients of group-GD. Which showed incidence of PONV in group-GD was significantly low as compared to group-G. Thus, Our result in consonance with this study.

Mohmad Prvez Khan & Monica Kohali et al (2006)<sup>[6]</sup> also observed that the incidence of nausea and vomiting was reduced from 75% in control group to 23.33% in Grnisetron group and to 5% in Granisetron Dexamethasone combination group. A complete response (No PONV)occured in 95% of patients in Granisetron with Dexamethasone group, & 76.67% of patients of Granisetron alone (P<0.05). Thus, Our result in consonance with this study.

Fujji Y et al (2000)<sup>[10]</sup> observed that completed response (No PONV) was achieved in 83% of patients in group-G and 98% of the patients of group-GD. Thus, Our result in consonance with this study.

MohmadPrvez Khan & Monica Kohali et al (2009)<sup>6</sup> complete response was observed in 92.5% in Granisetron Dexamethasone group.

Yamacerhan et al (2007)<sup>[11]</sup>:observed PONV in 30% with Granisetron group.

Vishal gupta et al  $(2007)^{[12]}$ :observed PONV in 45% with Granisetron group.

Our study was comparable to Mohd.Parvez Khan & Monika Kohali et al (2006), Mohd. Parvez Khan & Monika Kohali et al (2009).

Requirement of Rescue Anti-Emetic was earlier in Group-G at  $3^{rd}$ hr as compared to Group-GD which was at  $6^{th}$  hrs. At different interval, Requirement of rescue antiemetic was also lower in Group-GD as compared to Group-G (P<0.05). Rescue anti-emetics given in our study was inj. Ondensetron 4mg intravenously when emesis scores $\geq 2$ , this was taken as end point of study.

Mohd.Parvez Khan & Monica Kohali et al(2009) they used inj. Ondensetron as rescue antiemetic when emesis score≥2. Requirement of rescue antiemetic was lower in group-GD as

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compared to group-G.

Thus, our study was comparable with their study.

In Group-GD only 6.66% patients required rescue antiemetic while in Group-G it was 26.66% .So overall requirements of rescue antiemetic was lower in Group-GD as compared to Group-G.

B.N. Biswas& A. Rudra et al (2002). They observed that 8.33% (5) of patients in group-G and only 2% (1) of patients in group-GD required rescue anti emetics during their study. Mohd. Parvez Khan & Monica Kohali et al (2009): none of the patients required rescue antiemetic in granisetron dexamethasone group. Yamacerhan et al(2007):10% of patients required rescue antiemetic in granisetron group. Thus, our study was comparable with their study.

#### Conclusion

- The overall incidence of post operative nausea and vomiting was significantly less in Granisetron-Dexamethasone combination group than Granisetron group during 24 hour post operative period.
- The Granisetron-Dexamethasone combination provided longer duration of prophylaxis against post-operative nausea & vomiting than granisetron alone.

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