



# Role of Prophylactic Dimenhydrinate Versus Ondansetron as an Adjunct to Dexamethasone on Post-Operative Nausea and Vomiting in Laparoscopic Abdominal Procedures

<sup>1</sup>Sadaf Bukhari, <sup>2</sup>Aaifa Khalid Niazi, <sup>1</sup>Syed Mahmood Ali, <sup>2</sup>Maria Arshad, <sup>3</sup>Muhammad Taqi

<sup>1</sup>Department of Anesthesia, Shaikh Zayed Medical Complex, Lahore

<sup>2</sup>Department of Anesthesia, Jinnah Hospital, Lahore

<sup>3</sup>Department of Anesthesia, Gulab Devi Hospital, Lahore

## ABSTRACT

**Introduction:** Post-operative nausea and vomiting (PONV) is a common complication in patients undergoing surgery. Anti-emetic prophylaxis is recommended for all high risk patients. Combination therapy is considered superior to single dose prophylaxis however its efficacy in varied laparoscopic abdominal surgical situations has not been investigated. **Aims & Objectives:** To compare the post-operative nausea and vomiting with Dimenhydrinate plus Dexamethasone versus Ondansetron plus Dexamethasone in patients following laparoscopic abdominal procedures. **Place and duration of study:** Operation Theatre, Shaikh Zayed Hospital Lahore, for one year (1<sup>st</sup> April 2015 – 31<sup>st</sup> March 2016). **Material & Methods:** 464 patients were placed in two groups of 232 each. Group A received prophylaxis with Dexamethasone 8 mg I/V + Dimenhydrinate 50mg I/V and Group B received prophylaxis with Dexamethasone 8 mg I/V + Ondansetron 4 mg I/V. Efficacy was judged with absence of nausea and vomiting in first 24 hours after surgery. Data was analyzed in SPSS version 27. **Results:** The frequency of nausea was 6% with Dimenhydrinate while was 9% with ondansetron. Similarly, vomiting was 18% vs. 24% respectively. The efficacy of Dimenhydrinate was 88% while and Ondansetron achieved efficacy in 65% cases, which was statistically significant ( $p < 0.05$ ). **Conclusion:** The combination Dexamethasone & Dimenhydrinate was more efficacious in preventing PONV than the combination Dexamethasone & Ondansetron.

**Key words:** Post-operative nausea and vomiting, Antiemetic prophylaxis, Dexamethasone, Dimenhydrinate, Ondansetron

## INTRODUCTION

Post-operative nausea and vomiting (PONV) is the most disturbing and a very commonest problem often after surgery due to anesthesia. PONV may lead to severe patient's anxiety, requirement of nursing care increases, delay in ambulation, also increases pain and in few severe cases, it also badly affects the outcome of the surgery as well as disturb the hemodynamics of patients.<sup>1,2</sup> It is a troublesome complication and has been the subject of interest of researchers for the past many years.<sup>3</sup> PONV is an unpleasant emotional experience that provokes both fear and anxiety in the patient. It might instill in the memory of patient for life time. In addition to the fear that it instills in patients, PONV can lead to serious medical complications.<sup>4</sup> PONV occurs in 20-30% of patients undergoing surgery.<sup>5</sup> In high risk patients who receive no prophylaxis the incidence of PONV goes up to 70-

80%.<sup>6,7,8</sup> Effective prevention of PONV improves patient satisfaction ratings. All these factors make the prevention and management of PONV a challenge for most anesthesiologists.<sup>9</sup>

The optimal control of PONV is based on three steps. Firstly high risk patients at risk for PONV need to be identified. Secondly such an anesthetic technique should be employed which uses low emetogenic agents and favors use of antiemetogenic agents. Thirdly all patients at risk for PONV should receive antiemetic prophylaxis.<sup>6</sup> Antiemetic prophylaxis can be provided by pharmacological and non-pharmacological methods. Pharmacological methods include a variety of drugs from different classes.<sup>10,11,12</sup>

Combination therapy of more than one drug is considered far more efficacious as compared to single drug therapy. Drugs with different mechanisms of action should be used in combination.<sup>13,14</sup> This multi modal approach has

shown better results when compared with single mode of action prophylaxis.<sup>14,15,16,17,18</sup>

The novelty of our study is this, that it's been done in the face of many risk factors of PONV. Where laparoscopy itself is a risk factor for PONV and in the presence of other PONV risk factors (females, use of nitro oxide, use of opioids, use of volatiles). We have tried to demonstrate Dexamethasone plus Dimenhydrinate combinations' substantial effectiveness which is also very cost effective as per requirement in our country. Other studies are done on tonsillectomy, breast surgeries, and laparoscopic cholecystectomies but not on all types of laparoscopic abdominal procedures. This being another attribute of our study as we have conducted this study in various abdominal laparoscopic surgeries, not just one. So keeping in mind PONV and its challenging outcomes, an effective drug combination is the need of the hour particularly in high risk cases.

#### MATERIAL AND METHODS

After taking IRB permission no: 1371, informed consent of 464 patients, 18 years age and above, ASA I & II, undergoing abdominal laparoscopic surgery was obtained in pre-op area of Shaikh Zayed Hospital Lahore, over a period of one year. The patients were divided into two groups A & B by lottery method. I/V lines were secured: group A patients were given injection Dexamethasone 8mg I/V and Inj Dimenhydrinate 50mg I/V. The patients in group B were given Inj. Dexamethasone 8mg and Inj Ondansetron 4mg I/V.

In the operation theatre standard monitoring was done. Injection Ringer's Lactate(R/L) was given by 4,2,1 formula respective of their weights. All the patients were given standard general anesthesia. After pre-oxygenation using 100% Oxygen, anesthesia was given along with injection Fentanyl 1-2mcg/kg body weight followed by injection propofol 1-2mg/kg body weight. Inj Atracurium was given 0.5mg/kg body weight, patient was ventilated for 3 minutes and endotracheal tube was inserted in all patients. Mechanical ventilation was done. Anesthesia was sustained with 50% oxygen and 50% nitrous with 1% isoflurane. Intra-operatively, the muscle relaxation was attained by adding incremental doses of atracurium i.e. 1mg/KG on SOS basis. After surgery, anesthesia was stopped and remaining neuromuscular blockade was provoked by applying neostigmine injection along with glycopyrrolate.

To minimize the effects of confounders standardized dose of opioid was used. Also adequate, standardized hydration was done using ringer lactate

with the 4,2,1 formula. Inj Fentanyl upto 50mcg I/V was permitted as need for management of post-op pain. After procedure Patients were shifted to Post Anesthesia Care Unit (PACU) where they were monitored for 2 hours and then to ward where they were monitored for 24 hrs by PACU Doctor and nurse on duty.

#### Statistical analysis:

Data was fed into SPSS version 17 and analyzed using this program. Chi Square test was used to compare the efficacy in both groups keeping P-value  $\leq 0.05$  as significant.

#### RESULTS

The mean age was  $45.65 \pm 9.37$  years. In group A, mean age was  $45 \pm 9$  and in group B was  $46 \pm 9$  years. In group A, nausea was observed in 14 (6%) cases while in group B, nausea was present in 42 (18%) cases ( $p < 0.05$ ). Within first 2 hours, nausea was observed in 14 (6%) cases in group A while in 27 (11%) cases in group B ( $p < 0.05$ ) while doing first 24 hours, nausea was observed in 0 (0%) cases in group A while in 15 (6%) cases in group B ( $p < 0.05$ ). Similarly, in group A, vomiting was observed in 21 (9%) cases while in group B, vomiting was present in 55 (24%) cases ( $p < 0.05$ ). Within first 2 hours, vomiting was observed in 14 (6%) cases in group A while in 25 (11%) cases in group B ( $p > 0.05$ ) while doing first 24 hours, vomiting was observed in 7 (3%) cases in group A while in 30 (12.9%) cases in group B ( $p < 0.05$ ). Efficacy was achieved in 204 (88%) cases in group A while in 152 (65%) cases in group B. The difference between both group was significant ( $p < 0.05$ ). (Table-1)

	Dimenhydrinate	Ondansetron	p-value
Age (years)	45±9	46±9	
<b>Nausea</b>			
Yes	14(6%)	42(18%)	<0.001
No	218 (94%)	190(82%)	
Nausea at 2 hrs	14(6%)	27 (11%)	0.033
Nausea at 2-24 hrs.	0(0%)	15(6%)	0.0001
<b>Vomiting</b>			
Yes	21(9%)	55(24%)	<0.001
No	211 (91%)	177(76%)	
Vomiting in first 2 hrs.	14(6%)	25(11%)	0.066
Vomiting in 2-24 hrs.	7 (3%)	30 (12.9%)	0.0001
<b>Efficacy achieved</b>			
Yes	204(88%)	152(65%)	<0.001
No	28(12%)	80(35%)	

**Table-1:** Characteristics of patients

## DISCUSSION

PONV is one of the most common, heavy on the pocket and debilitating complication of general anesthesia. PONV occurs in 20-30% of patients undergoing surgery.<sup>19</sup> In high risk patients for PONV who receive no prophylaxis the incidence of PONV goes up to 70-80%.<sup>4,8</sup> Although PONV is typically self-limiting, lasting less than 24 hours, the sequences are grave. It can lead to dehydration, electrolyte imbalance, metabolic alkalosis, gastric erosions and aspiration of GI contents with subsequent respiratory problems.<sup>20</sup> It can also delay oral nutrition and oral drug intake. PONV, thereby delays convalescence and increases hospital stay and cost.<sup>21</sup>

The incidence of PONV depends upon the presence or absence of certain risk factors. Factors that may play a role in development of PONV include sex, age, previous history of PONV, motion sickness and migraines, smoking status, type of surgery, duration of surgery, type of anesthesia, use of opioid analgesics and hydration during surgery.<sup>22,23</sup> These factors can be broadly categorized to “patient factors” which includes females, people who do not smoke, past history of PONV/motion sickness, “Anesthetic Factors” like volatile anesthetic gases, nitrous oxide and use of perioperative opioid analgesics and lastly “Surgical Factors” that include type of surgery and duration of surgery.<sup>10</sup>

The optimal control of PONV is based on three steps. Firstly high risk patients at risk for PONV need to be identified. Secondly such an anesthetic technique should be employed which uses low emetogenic agents and favors use of antiemetic agents. Thirdly all patients at risk for PONV should receive antiemetic prophylaxis.<sup>6</sup> PONV must be controlled effectively especially in high risk patients. Combination therapy of more than one drug is considered far more efficacious as compared to single drug therapy due to its multifactorial origin. Therefore, drug combinations should be used which comprise of drugs that have different mechanisms of action.<sup>24,25</sup> This multimodal approach has shown better results when compared with single mode of action prophylaxis. The combinations widely used include 5HT-3 receptor antagonist + Dexamethasone, 5HT-3 receptor antagonist + Droperidol, Droperidol + Dexamethasone, Dimenhydrinate + Dexamethasone.<sup>26,27,28</sup>

Despite the presence of a plethora of publications on PONV only little is known on how to treat it.

Our study is another effort to know how to control this distressing PONV, best.

In our study a clinically relevant question about the efficacy of two combination drug regimens was asked. With the knowledge that all these drugs (among them dexamethasone and ondansetron which are considered as gold standard for PONV and a relatively newer drug, dimenhydrinate, which is more widely available and very cost effective) reduce PONV with similar efficacy in patients at high risk, the better of two combinations was sought out. Multimodal interventions are required to control PONV in high risk patients. Dexamethasone is a good drug for combination therapy. It effectively reduces PONV of delayed onset that occurs after 12 hours. When combined with a short acting agent which reduces PONV in the short term (0-12 hrs.) the risk of PONV is reduced both in the short term (0-12 hrs.) and in the long term (12-24 hrs.).

The combination Dexamethasone plus Ondansetron is a popular one which has been studied extensively and has shown very good results. Ondansetron is effective in early PONV while Dexamethasone controls late PONV. However there are not many studies that have compared it with other combination. Dimenhydrinate is a cheap and widely available drug. It has been shown to be effective in the management of PONV. It hasn't gained as much popularity due to its side effects, sedation, and dry mouth. In theory it should make a good combination with Dexamethasone for the same reasons as Ondansetron. Both of them are effective in prevention of early PONV.

Voight et al.,<sup>18</sup> tried the combination and found results which are equivalent to the combination of dexamethasone plus Ondansetron similar to our study. However no studies have proved superiority of one combination to another which our study hoped to do, in a PONV prone environment. All patients received a standardized anesthetic protocol. Nitrous oxide was used as an analgesic. Although nitrous oxide is a risk factor itself for PONV, it reduced the intraoperative usage of opioids which are a stronger risk factor for PONV. Hydration and opioid doses were standardized to minimize confounding.

Aftab et al.,<sup>29</sup> conducted a study of risk factor assessment for PONV in Dow Medical University Karachi, Pakistan. They concluded that PONV was significantly higher in females, patients with h/o PONV or motion sickness and patients undergoing laparoscopic and eye surgery. Our study has addressed two of these risk factors among others



and observed the effects of anti-emetics in the high risk population.

In India, in year 2014, Bendre and associates, in accordance to our study determined incidence nausea/vomiting, early and delayed with Ondansetron and Dexamethasone. Their results demonstrated for early nausea 26.7% vs our study 11%. For delayed nausea their result was 23.3% vs our 6%. For early vomiting they calculated incident of 10% vs our 24% and for delayed vomiting their 6.7% vs our 18%.<sup>30</sup>

Voigt and associates (2011) carried out a randomized, double blinded, placebo controlled trial. Their results are almost same as of our study. One of their study group received Dimenhydrinate and Dexamethasone, half of this groups' patients received Total intravenous anaesthesia (TIVA) and half of them received volatile anesthesia. They recorded incidence of nausea, emesis or both, in early 0-2 hours and late 2-24 hours post operatively, similar to us. Their result showed significant reduction of PONV 11.4% with volatiles. Our results showed that the combination of dexamethasone and Dimenhydrinate was significantly better in preventing nausea and vomiting than the Ondansetron and Dexamethasone combination. We observed that Dexamethasone and Dimenhydrinate showed an efficacy of 88% which is consistent to Voigt et al.<sup>18</sup>

Like us Dabbous and fellows (2010) did a randomized study on elective laparoscopic surgeries where they compared efficacy of the combination of Dexamethasone and Ondansetron in prevention of PONV. During 24 hours post operatively Dabbous et al observed that no patient had vomiting (100%) compared to our 97.6%.<sup>31</sup>

Imam et al studied the effects of Ondansetron 4 mg plus Dexamethasone with Ondansetron 4 mg alone and placebo in patients undergoing general anesthesia for cesarean section. Episodes of nausea and vomiting were observed in the first 24 hours of extubation. In the combination group 5% of the patients had PONV. In Ondansetron alone group 22.5% of the patients had PONV and in the placebo group 52.5% of patients required anti-emetics. The study showed that Ondansetron and Dexamethasone is more effective in preventing PONV with minimal adverse effects,<sup>32</sup> which is comparable to our study.

Bano and associates studied the effects of Dexamethasone plus Ondansetron with Dexamethasone alone in patients undergoing laparoscopic cholecystectomy. They found that the combination of Dexamethasone plus Ondansetron

is more effective in preventing postoperative nausea and vomiting (P 0.035), close to our <0.05.<sup>17</sup>

Kothari at al., results are contrasting to ours. They conducted a randomized trial, in patients undergoing laparoscopic cholecystectomy. They observed anti-emetic efficacy of Dimenhydrinate vs Ondansetron. Of the patients receiving Ondansetron post-op vomiting occurred in 6% versus our 24% and nausea in 42% vs our 24% of the patients. While of the patients who received Dimenhydrinate 29% vs our 9% of them vomited and 34% vs our 42% of them had nausea. Concluding that ondansetron was superior in controlling vomiting than Dimenhydrinate, in contrast to our results. The discrepancy probably due to our use of these drugs in combination with dexamethasone while Kothari gave them alone.<sup>33</sup>

Contrary to our results Piwko C & associates showed that for vomiting the Ondansetron group had an efficacy of 45.3% vs the Dimenhydrinate group's 38.2% while ours was 75% for Ondansetron vs a 91% in Dimenhydrinate group. Piwko evaluated prevention of vomiting only in children whereas our study population were adults. Another factor leading to this dis-similarity in result could be due to the difference of surgical procedure, Piwko chose strabismus surgery while our interest was in abdominal laparoscopic surgeries.<sup>34</sup>

## CONCLUSION

Our research suggests the combination of Dexamethasone and Dimenhydrinate is more efficacious and also more cost effective than the combination of Dexamethasone and Ondansetron. This study can be done on a much larger scale including all kinds of surgeries and ASA categories. In light of its promising results Dexamethasone and Dimenhydrinate combination seems to be an excellent arsenal for an anesthetic for better patient care against PONV.

**Limitations:** PONV was considered as equivalent condition regardless of the surgical procedure duration, or length of anesthesia. Therefore, future studies can be done by standardizing the dose and checking its efficacy on different anesthesia lengths. A further limitation was that although we recorded side effects of the drugs used but we did not include them in our studies. In future we can do the same study but instead of PONV we can observe side effects of these drugs.

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**The Authors:**

Dr. Sadaf Bukhari  
Senior Registrar,  
Department of Anaesthesia,  
Shaikh Zayed Hospital, Lahore.

Dr. Aaifa Khalid,  
Senior Registrar,  
Department of Anaesthesia,  
Jinnah Hospital, Lahore.

Dr. Syed Mahmood Ali  
Associate Professor,  
Department of Anaesthesia,  
Shaikh Zayed Hospital Lahore

Maria Arshad  
Senior Registrar,  
Department of Anaesthesia,  
Jinnah Hospital, Lahore.

Dr. Muhammad Taqi  
Senior Registrar,  
Department of Anaesthesia,  
Gulab Devi Hospital, Lahore.

**Corresponding Author:**

Dr. Sadaf Bukhari  
Senior Registrar,  
Department of Anaesthesia,  
Shaikh Zayed Hospital, Lahore.  
E-mail: dr.sadaf.bukhari@gmail.com