

# Compare the Effectiveness of Ondansetron Only Versus Dexamethasone and Ondansetron Combination for Preventing Nausea/Vomiting in Patients Undergoing Laparoscopic Cholecystectomy

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## ABSTRACT

**Objective:** To examine the effectiveness of dexamethasone and ondansetron combination and compare with ondansetron only for reducing the incidence of postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy.

**Study Design:** Randomized controlled trial

**Place and Duration of Study:** This study was conducted at the Department of Surgery DHQ Teaching Hospital Mirpur AJK from December 2018 to December 2019.

**Materials and Methods:** One hundred and forty patients of both genders with ages 20 to 65 years undergoing laparoscopic cholecystectomy were enrolled in this study. Patients were divided into two groups I and II. Each group comprised 70 patients. Group I received combine dose of ondansetron and dexamethasone while group II received ondansetron only. Efficacy between both groups was examined at 24 hours after surgery.

**Results:** There were 50 (71.42%) patients were females and 20 (28.57%) were males in group I while in group II 48 (68.57%) were females and 22 (31.43%) were males. No significant difference was observed regarding mean age in both groups ( $p > 0.05$ ). In group I 5 (7.14%) patients had nausea/vomiting while in group II 25 (35.71%) patients had nausea/vomiting. A significant difference was observed between both groups I and II regarding effectiveness of doses with p-value 0.001.

**Conclusion:** Dexamethasone and ondansetron combination is very effective for preventing postoperative nausea and vomiting in patients with laparoscopic cholecystectomy.

**Key Words:** Cholecystectomy, Laparoscopic, Ondansetron, Dexamethasone, Nausea, Vomiting

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## INTRODUCTION

Post-operative nausea and vomiting (PONV) is most common complication encountered after laparoscopic cholecystectomy under general anaesthesia.<sup>1</sup>

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It often causes pulmonary aspiration electrolyte imbalance, dehydration and esophageal rupture.<sup>2</sup> The incidence of PONV is as high as 60-70% and is influenced by various patient related factors, anaesthesia technique, type of surgery, drugs used and post-operative factors such as pain, dizziness, ambulation etc.<sup>3,4</sup>

We have modified our anaesthetic techniques to secure more rapid and smooth recovery as a result of improved pre-operative and post-operative medication, refinement of operative techniques and identification of patient's predictive factors.<sup>5,6</sup> The management of nausea and vomiting has been improved in last couple of years with the introduction of 5 Hydroxytryptamine (5-HT<sub>3</sub>) receptor antagonists. Ondansetron is a prototype of 5-HT<sub>3</sub> receptor antagonist and commonly used drug. ondansetron is considered as a gold standard drug for treatment of PONV.<sup>7</sup> Dexamethasone is very potent and highly selective long lasting glucocorticoid. It causes prostaglandin antagonism serotonin inhibition in Gut and release of endorphins that elevates mood and

stimulates appetite.<sup>8</sup> It augments efficacy of other primary antiemetic drugs like ondansetron.<sup>9</sup> A number of pharmacological agents have been tried for prevention and management of PONV but no agent is found to be 100% successful. It has been proved that combination pharmacological modality is better than monotherapy in this regard.<sup>10-12</sup> The present study was conducted to examine the efficacy of ondansetron only and compare with combined dexamethasone and ondansetron for preventing postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy.

**MATERIALS AND METHODS**

This randomized controlled trial was conducted at Department of Surgery DHQ Teaching Hospital Mirpur AJK from 15<sup>th</sup> December 2018 to 20<sup>th</sup> December 2019. A total of 140 patients of both genders with ages 20 to 65 years undergoing laparoscopic cholecystectomy were enrolled. Patients detailed demographic including age, sex, body mass index (BMI) and physical examination (ASA class I and II) were recorded. Patients who received antiemetics within 48 h before surgery, patients with cardiovascular diseases, pregnant women, and Patients with a history of recurrent vomiting in the postoperative period were excluded. All the patients were equally divided into two groups I and II. Group II consist of 70 patients and received ondansetron 4mg and group I contains 70 patients received combined dose of ondansetron 4mg and dexamethasone 8mg. The study medications were prepared and presented to anesthetist as identical 2ml filled syringes, who administered drugs at the time of induction of anesthesia. Effectiveness of medication was examined at 24 hours after surgery and compares the frequency of nausea and vomiting between both groups. All the data was analyzed by SPSS 24. Chi-square test was applied to compare the effectiveness of medication with p-value <0.05 was taken as significant.

**RESULTS**

In group I, 50 (71.42%) patients were females and 20 (28.57%) were males with mean age 40.52±9.48 years while in group II, 48 (68.57%) patients were females and 22 (31.43%) were males with mean age 41.06±10.14 years. No significant difference was observed regarding BMI between both groups I and II 25.4±2.57 kg/m<sup>2</sup> and 25.8±3.06 kg/m<sup>2</sup> (p-value >0.05). 60 (85.71%) and 10 (14.29%) patients in group I had ASA class I and II. In group II 58 (82.86%) and 12 (17.14%) patients had ASA class I and II with no significant difference between both groups (p=>0.05) (Table 1).

In group I, 5 (7.14%) patients had nausea/vomiting while in group II, 25 (35.71%) patients had nausea/vomiting. A significant difference was observed between both groups I and II regarding effectiveness of

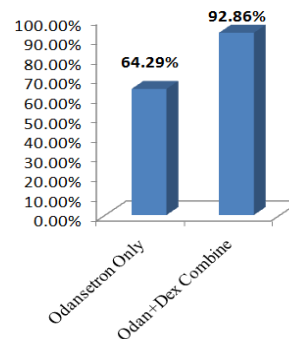
doses with p-value 0.001 (Table 2). According to the comparison of effectiveness between both groups we found that Dexamethasone+Ondansetron had efficacy 92.86% while Ondansetron only had efficacy 64.29% for the prevention of postoperative nausea and vomiting (Fig. 1).

**Table No.1: Demographics of all the patients**

Variable	Group I	group II	P-value
Age (years)	40.52±9.48	41.06±10.14	>0.05
Gender			
Male	20 (28.57)	22 (31.43)	>0.05
Female	50 (71.42)	48 (68.57)	
BMI	25.4±2.57	25.8±3.06	>0.05
ASA Class			
I	60 (85.71)	58 (82.86)	>0.05
II	10 (14.29)	12 (17.14)	

**Table No.2: Comparison of efficacy of medication between both groups (nausea/vomiting)**

Nausea/vomiting	Group I	group II	P-value
Yes	5 (7.14)	25 (35.71)	<0.001
No	65 (92.86)	35 (64.29)	<0.001



**Figure No. 1: Comparison of effectiveness**

**DISCUSSION**

Laparoscopic cholecystectomy is one of the commonly perform surgical intervention in all over the world. Postoperative nausea and vomiting are most common complications associated with surgical procedures.<sup>13</sup> Many of many of medications have been used for the prevention of post-operative nausea and vomiting, in which Ondansetron is considered as a drug for choice in prevention of postoperative nausea and vomiting.<sup>14</sup> We conducted this study with aimed to compare the efficacy of Ondansetron alone versus Ondansetron and Dexamethasone combination for the prevention of postoperative nausea and vomiting in patients underwent laparoscopic cholecystectomy. In the present study, majority of patients 70% were females while male patients population was 30% and the mean age was 40.86±11.8 years. These results showed similarity to many of previous studies conducted regarding

laparoscopic cholecystectomy in which female patients population was high as compared to males and accounted 65% to 78%. Studies demonstrated that majority of patients were ages above 40 years.<sup>15,16</sup>

This study showed that no significant difference regarding body mass index and ASA class I and II between both groups with p-value >0.05. A study conducted by Hammad et al<sup>17</sup> regarding efficacy of Ondansetron only versus combine Ondansetron and Dexamethasone for preventing postoperative nausea/vomiting. In their study no significant difference was reported regarding BMI between both groups. They also reported that 82% in Ondansetron group and 80% patients in Ondansetron and Dexa group had ASA class I.

In the current study, we found that n group I, 5 (7.14%) patients had nausea/vomiting while in group II 25 (35.71%) patients had nausea/vomiting at 24 hours postoperatively. A significant difference was observed between both groups I and II regarding effectiveness of doses with p-value 0.001. A study conducted by Halimi et al<sup>18</sup> reported that Ondansetron and dexamethasone combination was effective in 90% patients where as Ondansetron alone was effective in 68% patients which was statistically significant with P-value=0.0001.

Hammad et al<sup>17</sup> reported that at postoperative 6 hours patients in Ondansetron group had high rate of nausea and vomiting 27.5% as compared to combine dose group 7.5% with p-value 0.019. However at 24 hours 100% patients in both groups had no complications of nausea and vomiting.

Meitra et al<sup>19</sup> reported that incidence of postoperative nausea at 4–6 h is significantly lower when dexamethasone was used instead of ondansetron (; OR 0.49, 95% CI 0.24–0.98, M-H fixed). Incidence of nausea is similar at 24 hours (p=0.08). Azim et al<sup>20</sup> reported that ondansetron and dexamethasone combination group had significantly lower rate of nausea and vomiting as compared to ondansetron alone group with p-value <0.001.

We found that the effectiveness of ondansetron and dexamethasone combination was 92.86% and significantly higher than the ondansetron alone group with p-value <0.001. These results were comparable to study by Halimi et al<sup>18</sup> and Azim et al.<sup>20</sup> A study by Besra et al<sup>21</sup> regarding prevention of postoperative nausea and vomiting, in which they used palonosetron 0.05 mg in group I and other group received intravenous ondansetron and dexamethasone combination. They demonstrated that no significant difference was observed between both groups in term of postoperative nausea and vomiting with p-value >0.05.

## CONCLUSION

Postoperative complications such as nausea and vomiting can create the severe complications and highly contributed in increasing length of hospital stay

and cost. We concluded that dexamethasone and ondansetron combination is very effective for preventing postoperative nausea and vomiting in patients with laparoscopic cholecystectomy.

### Author's Contribution:

Concept & Design of Study: Mohammad Arif Mahmood  
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 Data Analysis: Sajid Razzaq, Nisar Ahmed, Mohammad Nadeem Khan  
 Revisiting Critically: Mohammad Arif Mahmood, Zardad Khan  
 Final Approval of version: Mohammad Arif Mahmood

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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