

# **Comparison of Ondansetron and Combination of Ondansetron and Dexamethasone for Prevention of Post-Operative Nausea and Vomiting in Patients Undergoing Elective Laparoscopic Cholecystectomy**

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## **ABSTRACT**

**Aim:** To compare the frequency of post-operative nausea and vomiting within 24 hours of operation in patients undergoing lap. cholecystectomy administered ondansetron with and without dexamethasone.

**Methods:** This randomized control trial was carried out from 1<sup>st</sup> February 2015 to 30<sup>th</sup> September 2015. One hundred and sixty four patients of either sex and age ranging from 20 to 60 years undergoing laparoscopic cholecystectomy were included. Both ASA grade I and II patients were randomly distributed in two groups. Group A received ondansetron and dexamethasone while in group B only ondansetron was administered I/V. Frequency of postop nausea & vomiting was compared.

**Results:** Twenty two patients (13.4%) were in ASA Grade I while 142 patients (86.6%) were in Grade II. 43 patients (71.7%) were female while 17 (28.3%) were males. There were PONV 61 patients (37.2%). Twenty eight (45.9%) patients out of eighty two from Ondansetron group and 33/82 patients (54.1%) from Ondansetron plus dexamethasone group developed nausea or vomiting post operatively ( $p$  value=0.41). Ondansetron & Dexamethasone group was more effective as shown by our results in male and younger patients in terms of nausea or vomiting post operatively.

**Conclusion:** It is concluded that at current sample size, there is no difference in frequency of post-operative nausea and vomiting in patients undergoing laparoscopic cholecystectomy with combination of dexamethasone and ondansetron as compared to ondansetron alone for whole cohort.

**Keywords:** Post-operative nausea & vomiting, Dexamethasone, Ondansetron

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## **INTRODUCTION**

Post-operative nausea and vomiting (PONV) are the most common unpleasant experiences following laparoscopic surgeries.<sup>1</sup> It remains a significant clinical issue that can detract from patient's quality of life in hospital/treatment facility, as well as in the days immediately post-discharge.<sup>2-5</sup> In addition, PONV may increase perioperative costs, increase perioperative morbidity, increase post-anesthesia care unit stay, prolong hospital stays, length of stay/delay discharge, delay the time that the patient can go back to work, and lead to readmissions.<sup>6,7</sup> Despite the existence of multiple tools to stratify patients according to their risk of developing PONV and multiple PONV treatment guidelines, clinicians do not appear to systematically address the treatment and/or prophylaxis of PONV in a uniform fashion with both pharmacologic and non

pharmacologic strategies in attempts to minimize PONV occurrences.<sup>8-10</sup> Several factors have been implicated specifically in laparoscopic cholecystectomy like carbon dioxide insufflation, distension of the abdomen and irritation of the diaphragm and other abdominal viscera.<sup>11-14</sup>

Different medications have been evaluated in PONV prophylaxis and patient satisfaction after cholecystectomy<sup>5</sup>. Ondansetron, a 5-hydroxytryptamine (5-HT3) receptor antagonist, and dexamethasone have been found to reduce PONV significantly after laparoscopic cholecystectomy compared with placebo<sup>6,14,15</sup>. A study conducted by Bhattari and colleagues<sup>5</sup> showed that no nausea or emesis and no need for rescue antiemetic during first 24 h, was noted in 76% of patients who received ondansetron alone, while similar response was seen in 92% of patients in combination group.

## **SUBJECTS AND METHODS**

This randomized control trial was carried out in Departments of Anaesthesia of Akhtar Saeed Medical & Dental College and Sharif Medical and Dental College from 1<sup>st</sup> February 2015 to 30<sup>th</sup> September 2015. One hundred and sixty four

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patients of either sex and age ranging from 20 to 60 years undergoing laparoscopic cholecystectomy were included. Using lottery method, patients were randomized either in control or in study group. Written informed consent was taken for participation in the research project. The baseline characteristics of patients were recorded on the study proforma. The patients in group A received intravenous ondansetron 4 mg and dexamethasone 4 mg whereas Group B patients received 4 mg of ondansetron only 30 minutes prior to the induction of anesthesia, and any side effect during injection was recorded. The anesthetic sequence was standardized. The patients received a single dose of injection ceftriaxone 1gm at the time of induction of anesthesia. All patients received injection Diclofenac 75mg I/M thrice on the first postoperative day and then as required. After surgery, patients were observed for any episode of nausea or vomiting, or whether the patient required any anti-emetic drug in the postoperative period. Patients were evaluated for nausea and vomiting in the first 24 hours after intervention. The episodes of nausea and vomiting were noted on the proforma specifically designed for the study by the resident surgeon.

## RESULTS

There were 17 males (28.3%) and 143 female (71.7%) patients with mean age  $42.68 \pm 11.56$  years. Only 22 patients (13.4%) were ASA Grade I while rest 142 patients (86.6%) were in ASA Grade II (Table 1). When compared the postoperative nausea and vomiting in either group with ketamine and ondanestron, the resultant distribution was same i.e. non-significant ( $p$  value=0.419) (Table 2). Differences in results were statistically not significant for prevention of shivering (0.26) and age (0.827) with ASA grades (Tables 3-4). To evaluate the effect of age distribution on outcome in either group, nausea/vomiting with groups for age showed difference in results was statistically significant ( $p$ =0.01) (Table 5).

Table 1: Demographic information of the patients

Variable	No.	%
<b>Age (years)</b>		
<40	67	40.9
>40	97	59.1
<b>Gender</b>		
Male	17	28.3
Female	143	71.7
<b>ASA Grade</b>		
I	22	13.4
II	142	86.6

Table 2: Comparison of efficacy (prevention of shivering) in both groups

Prevention of shivering	Ketamine		Ondansetron	
	No.	%	No.	%
Yes	6	7.3	8	9.7
No	76	92.7	74	90.3

Using Pearson Chi-Square,  $p$  value = 0.419 (Not significant)

Table 3: Comparison of prevention of shivering according ASA grades

Prevention of shivering	ASA Grade I		ASA Grade II	
	No.	%	No.	%
Yes	72	87.8	73	89.0
No	10	12.2	9	11.0

Using Pearson Chi-Square,  $p$  value = 0.26 (Not significant)

Table 4: Comparison of age according to ASA grades

Age (years)	ASA Grade I		ASA Grade II	
	No.	%	No.	%
<25	51	62.2	45	54.8
25 – 30	11	13.4	12	14.7
>30	20	24.4	25	30.5

Using Pearson Chi-Square,  $p$  value = 0.827 (Not significant)

Table 5: Comparison of age according to efficacy

Age (years)	Prevention of shivering			
	Yes		No	
	No.	%	No.	%
<25	89	54.2	13	7.8
25 – 30	25	15.2	4	2.4
>30	27	16.3	10	6.1

Using Pearson Chi-Square  $p$  value = 0.01 (Significant)

## DISCUSSION

Post-operative nausea and vomiting is one of the leading causes of discomfort for patients recovering from general anesthesia. PONV can lead to sweating, tachycardia, abdominal pain, prolonged recovery duration and increased risk of aspiration.<sup>3</sup> It can be very distressing to the patient, sometimes more than the surgery itself, and it can result in several complications like dehydration, gastric aspiration and wound disruption. Ondansetron, a 5-hydroxytryptamine (5-HT3) receptor antagonist, and dexamethasone have been found to reduce PONV significantly after laparoscopic cholecystectomy compared with placebo.

In our study, 28/82 patients (45.9%) from Ondansetron group and 33/82 patients (54.1%) from Ondansetron plus dexamethasone group developed nausea or vomiting post operatively. When chi square test was applied, difference was non-significant ( $p$  value = 0.419). A study conducted by Bhattari and colleagues<sup>5</sup> showed that no nausea or emesis and no need for rescue antiemetic during first 24 h, was noted in 76% of patients who received ondansetron alone, while similar response was seen

in 92% of patients in combination group. Our results differed from Bhattari et al<sup>5</sup>.

## CONCLUSION

It is concluded that there is no difference in frequency of post-operative nausea and vomiting in patients undergoing laparoscopic cholecystectomy with combination of dexamethasone and ondansetron as compared to ondansetron alone for whole cohort. Ondansetron & Dexamethasone group was more effective as shown by our results in male and younger patients in terms of nausea or vomiting post operatively.

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