

Comparison of Ondansetron V/S Dexamethasone for Preventing Post-Operative Nausea and Vomiting in Patients Undergoing Laparoscopic Cholecystectomy - An Observational Study

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ABSTRACT

BACKGROUND AND OBJECTIVES: Postoperative nausea and vomiting (PONV) are one of the foremost common complications of anaesthesia. To enhance patient outcomes and satisfaction, it is crucial to identify efficient approaches to prevent or eliminate post-operative nausea and vomiting. The most widely used medications for post-operative nausea and vomiting prophylaxis in current day practice are ondansetron and dexamethasone. The current study aims to compare the efficacy of 4mg ondansetron and 8mg dexamethasone in preventing postoperative nausea and vomiting following laparoscopic cholecystectomy.

MATERIALS AND METHOD: The observational study includes 78 patients who underwent laparoscopic cholecystectomy. Patients were randomly allocated into group A or group B. Patients in group A received injection ondansetron and patients in group B received injection dexamethasone. The episodes of Post operative nausea and vomiting were observed using a 4-point ordinal scale at intervals of 0-3 hours and 3-24 hours after surgery. For statistical association, The Mann-Whitney U test is used to compare the proportion of nausea and vomiting in two drug groups; a p-value less than 0.05 is considered significant.

RESULTS: The episodes of PONV in 0-3 hours ($p=0.928$) were comparatively higher than in 3-24 hours ($p=0.360$) following surgery. The episodes of PONV were found to be less with dexamethasone than ondansetron in the late 3-24 hours although it was not statistically significant.

CONCLUSION: The intraoperative use of either Dexamethasone 8mg or ondansetron 4 mg for patients undergoing laparoscopic cholecystectomy appears to reduce the incidence of PONV but does not reach statistical significance.

Keywords: Ondansetron, Dexamethasone, post-operative nausea vomiting, laparoscopic cholecystectomy

INTRODUCTION

The term "postoperative nausea and vomiting" (PONV) refers to any nausea, retching, or vomiting that takes place in inpatients within the first 24 to 48 hours of

surgery (2). Nausea is the unpleasant feeling that creates the impression that you are about to puke or retch. It causes discomfort in the stomach area. Vomiting is the

involuntary forceful evacuation of stomach contents through the mouth or nose (3).

Incidence of post operative nausea and vomiting is high in patients undergoing laparoscopic surgery compared to other types of surgery. Several factors contribute to this high incidence including the effect of general anaesthesia, the manipulation of the abdominal organs during surgery, and the position during surgery.

Dexamethasone antiemetic efficacy has been reported in patients undergoing laparoscopic cholecystectomy and other abdominal laparoscopic procedures (4). Many studies show that a combination of ondansetron with dexamethasone is simpler in controlling PONV, but many studies aren't unanimous in reporting their results of administering a single dose of every drug separately. Hence, we planned a prospective comparative study where ondansetron has been compared with dexamethasone for PONV prophylaxis in patients undergoing laparoscopic cholecystectomy

MATERIALS & METHODS

The study was conducted at Yenepoya Medical College, Mangalore after clearance from an institutional ethics committee. 78 patients who were scheduled for elective laparoscopic surgery under general anaesthesia were enrolled in this study. Both male and female patients aged between 18-60 with ASA grade I & II who were to remain in the hospital for at least 24 hours post-operatively were selected. Patients posted for emergency surgeries and patients who received antiemetic medication or experienced nausea and vomiting before surgery were excluded. Pregnant patients or patients having a history of motion sickness were also excluded

Then written informed consent was obtained from patients. The duration of the study spanned from November 2022 to June 2023. The data for the study was gathered from the operation theatre complex and the post-operative ward of Yenepoya Medical College Hospital.

Pre anaesthetic check-ups were performed on each patient one day before surgery, including identity, NPO status, informed consent, and general examination. All subjects had the same pre anaesthesia regimen, anaesthesia process, and laparoscopic technique. When the patient arrived in the operating room, routine monitoring instruments such as non-invasive arterial pressure, capnography, and pulse oximetry were installed. An appropriate peripheral vein was cannulated to allow anaesthetic drugs and IV fluid to be administered. The induction of anaesthesia and paralysis with muscle relaxants is done according to the institutional protocols by the anaesthetist.

The study was carried out as a double-blind observational study. Either of the study drug was administered to the patient by the anaesthesiologist after the induction of anaesthesia. Patients were randomly allocated into group A or group B. Randomization was done using computer generated random number tables. Both the drug was given intravenously as a part of the antiemetic regimen for patients undergoing general anaesthesia. The patients were divided into 2 groups according to the drugs they received.

GROUP A – Inj. Ondansetron 4mg IV is administered after induction of the general anaesthesia (39 participants).

GROUP B – Inj dexamethasone 8 mg is administered after induction of general anaesthesia. (39 participants)

The patients were supine during the surgery, and the pneumoperitoneum's normal pressure ranged from 12 to 16 mmHg CO₂. The patients were monitored for PONV after the surgery during the first 24 hours after anaesthesia, 0-3 hours in post-operative ward and 3-24 hours in the ward, all the episodes of PONV were recorded using a 4-point ordinal scale.

The following parameters were recorded; Register number, age, sex, weight, height, smoking history, ASA grade, and duration of anaesthesia and surgery

4-point nausea vomiting scale.

- 0- No nausea
- 1- Mild nausea
- 2- Moderate nausea
- 3- Severe nausea (about to vomit)
- 4- severe vomiting (continuous 1 or more episodes of vomiting) (1)

Nausea: The unpleasant sensation accompanied by a sense of the urge to vomit.

Vomiting: described as the forced expulsion of stomach contents through the mouth (1)

Data was collected and computed on an Excel sheet.

All participant's recorded data were statistically analysed using SPSS 27 software. For statistical analysis the continuous variables are summarized using mean and standard deviation. Percentage and frequency are used for categorical variables. The Mann-Whitney U test is used to compare the proportion of nausea, and vomiting in two drug groups

RESULT

During the study period, 78 patients were examined in total – 39 (50%) in the ondansetron group (group A) and 39 (50%) in the dexamethasone group (group B).

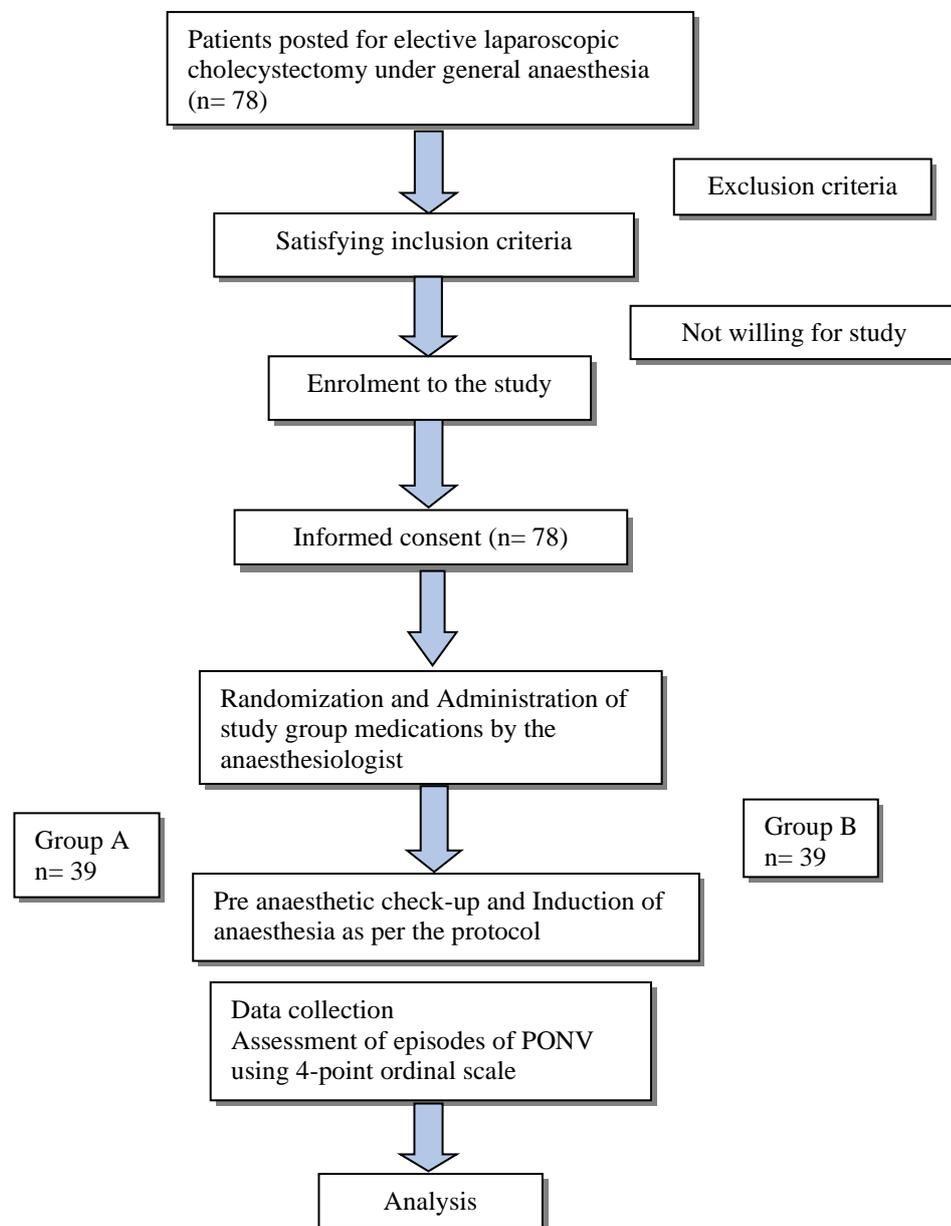


Figure 1: CONSORT Diagram

The non-parametric tests are used in the analysis since the data indicated the deviation from normality. Mann-Whitney U test is used to compare two groups.

Table 1: Mann-Whitney U test used to compare the PONV between two groups in 2-time intervals.

		25 th	50 th (median)	75 th	Mann-Whitney U test	P value
0-3 hours	Group A	0	1	2	752	0.928
	Group B	0	1	1		
3-24 hours	Group A	0	0	1	689	0.360
	Group B	0	0	0		

p <0.05 is considered as significant

Conclusion:

There is **no significant difference** between Group A and Group B in 0 to 3 hours.

There is **no significant difference** between Group A and Group B in 3 to 24 hours.

Based on these p-values, the study does not provide sufficient evidence to suggest a significant difference in the occurrence of PONV between the compared groups in either the 0-3 hours or 3-24 hours' time intervals.



Figure 2: Graph showing PONV comparison between Group A and Group B

The 4- point ordinal scale of PONV was comparable between groups at intervals of 0-3, and 3-24-hours following surgery [figure 6.6].

The episodes of PONV were higher in the 0-3 hours' time interval compared to the 3-24-hour time interval in both drug groups. Also, the study findings demonstrate that the dexamethasone group exhibited a lower incidence of postoperative nausea and vomiting during the 3-24 hour (0.25641) compared to the ondansetron group (0.333)

DISCUSSION

PONV arises as a complication following anaesthesia, and if not averted, the duration of recovery and hospital stay can be

extended, resulting in unfavourable hospital experiences and increased healthcare expenses (1). Various factors are responsible like the type of surgery, anaesthesia technique, medications used, and patient factors. In clinical use, the two most widely utilized medicines for PONV prophylaxis are dexamethasone and ondansetron. Many trials have confirmed the efficiency of ondansetron with its minimum side effects. Dexamethasone a corticosteroid is widely used as an antiemetic agent in patients undergoing cancer chemotherapy. Individual clinical investigations have revealed that dexamethasone is an effective antiemetic prophylaxis at a dose of 5-8 mg, while

ondansetron's recommended dose for prophylaxis is 4 mg (31).

This study assessed the impact of dexamethasone and ondansetron on the occurrence of PONV in individuals who underwent Laparoscopic cholecystectomy. Our study findings are associated with less incidence of postoperative nausea and vomiting and both drugs have similar effects on preventing postoperative nausea and vomiting at 24 hours. However, there was no significant difference in the occurrence of PONV between the ondansetron and dexamethasone groups.

In the clinical trial Farzad Qasemi, Tahmina Aini *et al.*, (23) examined the efficacy of dexamethasone and ondansetron in reducing PONV in patients undergoing laparoscopic cholecystectomy. Their study findings show that ondansetron was significantly more effective than dexamethasone. Cattleya Thongrong *et al.*, (21) state that both dexamethasone and ondansetron administration intraoperatively reduces the incidence of PONV but did not reach statistical significance. Our findings are consistent with the previous studies that reported no significant difference in the efficacy of both drugs.

According to Souvik Maitra *et al.*, (22) when dexamethasone was given instead of ondansetron, the incidence of postoperative nausea was considerably lower at 4-6 hours. However, both medicines are equally effective in preventing post-operative vomiting up to 24 hours following surgery. Similarly, Yamac Erhan *et al.*, (26) in their clinical trial evaluated the efficacy of ondansetron, granisetron, and dexamethasone. The overall incidence of PONV was 75% with placebo, 25% with dexamethasone, 30% with granisetron and 35% with ondansetron. V Rajeev MD *et al.*, (41) When compared to ondansetron alone, a combination of 4 mg ondansetron and 8 mg dexamethasone reduced the frequency of emetic episodes (P 0.05). Additionally, the study findings also added that combination therapy decreased the likelihood of significant postoperative

nausea and emesis, but it had no greater effect on controlling early nausea and vomiting than ondansetron alone

While our study aimed to compare the efficacy of ondansetron and dexamethasone in preventing PONV in patients after surgery, there were several limitations that need to be acknowledged. First of all, our study was limited by its sample size. While we included a significant number of patients, a larger sample size would have provided greater statistical power and more robust results. Second, we did not include patients with a history of PONV or those who were at high risk of developing PONV. As a result, our findings may not be generalizable to these patient populations. Also, we did not analyze the side effects of these drugs in our study. While ondansetron and dexamethasone are generally considered safe, they can cause adverse effects in some patients.

However further research with larger sample size and longer follow up periods are needed to confirm these findings and provide more definitive recommendations for clinical practice. These studies could evaluate the effectiveness of each drug in specific patient populations, different surgical procedures, and various risk categories for PONV. Additionally, more research may be needed to explore the combination of ondansetron and dexamethasone or other antiemetic agents for enhanced PONV prevention.

CONCLUSION

In conclusion, we found that the intraoperative use of either Dexamethasone 8mg or ondansetron 4 mg for patients undergoing laparoscopic cholecystectomy appears to reduce the incidence of PONV but does not reach statistical significance. A single dose of both drugs was effective in preventing vomiting in most of the subjects

Declaration by Authors

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