

Comparative Study of Ondansetron Versus Dexamethasone in the Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Laparoscopic Cholecystectomy Under General Anesthesia

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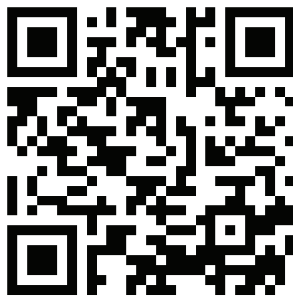
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ABSTRACT

Introduction: Postoperative nausea and vomiting (PONV) have been termed as the “big little problem” for anesthesiology during laparoscopic surgery. Pain and postoperative nausea and vomiting are the most common causes of morbidity after anesthesia and surgery. We aimed to evaluate the effects of Ondansetron and Dexamethasone in preventing postoperative nausea and vomiting following laparoscopic cholecystectomy, as well as to note any pharmacological side effects that occurred after their usage.

Methods: In this prospective, randomized, double blind controlled study, trial was done after approval from the IRB and trial registry, 60 female patients of American Society of Anesthesiologists physical status I and II, aged 18 to 65 years, weighing 50-60 kg, and standing 150 to 160 cm, were given institutional ethical committee clearance and written informed consent before undergoing laparoscopic cholecystectomy (duration 90 minutes) under general anesthesia. Patients arriving in the operating room were sorted into two groups of 30 patients each. All patients were monitored after surgery, documenting vital signs and any difficulties that arose. For the first 12 hours after surgery, all bouts of PONV (nausea, vomiting, and retching) were documented. Each patient's data was gathered and tallied.

Results: The patients in the study group were similar in age, weight, height, ASA status, and operation duration (p 0.05), and there was no significant statistical difference between the data gathered throughout the study

Conclusions: Ondansetron is just as effective as Dexamethasone at lowering nausea and vomiting after laparoscopic cholecystectomy, and it comes with less adverse effects.

INTRODUCTION

For anesthesiology, postoperative nausea and vomiting (PONV) has been referred to as the “huge little problem.”^{1,2} Pain and postoperative nausea and vomiting are the most prevalent causes of morbidity following anesthesia and surgery.^{3,4,5} PONV is frequently caused by unrelieved discomfort. PONV is also caused by the use of opioids

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for pain treatment.⁶ Despite a thorough understanding of the physiology of nausea and vomiting and the availability of antiemetic drugs, certain surgical procedures are linked to an unacceptably high rate of PONV. One of these is laparoscopic surgery, which is popular due to its minimum invasiveness but is linked to higher morbidity due to PONV. Strict decompression of the belly by the surgeon, 10 irritation of parasympathetic nerve endings in the abdomen, and the influence of carbon dioxide on the emetic center are all thought to play a role. Despite the fact that nausea and vomiting are considered minor complications of anesthesia and surgery by medical and nursing professionals, they are a common source of severe suffering for patients.

Our study's objectives were to evaluate the effects of Ondansetron and Dexamethasone in preventing postoperative nausea and vomiting following laparoscopic cholecystectomy, as well as to note any pharmacological side effects that occurred after their usage.

METHODS

Institutional ethical committee clearance and written informed consent were obtained in their own language before conducting the prospective, randomised, double blind controlled study. All 60 female patients of the study group belonged to American Society of Anaesthesiologists physical status I or II, between 18 to 65 years of age, 50- 60 Kg. in weight with height between 150 to 160 cm. They were scheduled for laparoscopic cholecystectomy (Duration < 90 minutes) under general anaesthesia Patients suffering from any systemic or lifestyle diseases, receiving medications for any chronic diseases (Hypertension, diabetes mellitus, cardiac disease, bleeding diathesis, neurological disorder) patients with motion sickness and known allergy to study drugs were excluded from our study. Patients who were sensitive to vomiting, experienced nausea, vomiting or both in 24 hrs. Before anaesthesia and had received antiemetic drug in 24 hrs. before anaesthesia and during study were also excluded. In the night (At 8 pm) before the day of operation, oral Midazolam 7.5 mg was given, and patients were advised overnight fasting. In the preoperative area, patient's vital parameters (Pulse rate, blood pressure,

respiratory rate, ECG, SpO₂) were recorded as baseline by a non-invasive monitor. Sample size was calculated using the formula $n > 2(Z_{\alpha} + Z_{1-\beta})^2 \times p \times q / d^2$, where $p = (p_1 + p_2) / 2$, $q = 1 - p$, and d is $p_1 - p_2$. Now assuming p value <0.05 to be significant and considering effect to be two sided, we get $Z_{\alpha} = 1.96$; assuming power of study to be 80% we get $Z_{1-\beta} = 0.84$. Taking p_1 and p_2 as the percentage of PONV, in the 2 groups as 30% and 5% respectively (based on a pilot study of 10 patients in each group) using the above formula we get $n = 29$ in each group. Hence 30 patients were finally taken in each group. Patients coming to operation theatre were divided by computer generated randomization in two groups of 30 each, Group-A ($n=30$) and Group-B ($n=30$). Monitors were attached and intravenous line was secured. A person, who was blind to the randomisation schedule, prepared the drugs in 2 ml syringes and gave the drug intravenously 1 minute prior to other I.V. drugs. According to the group of the patient, one of the following regimens: Group: A – Ondansetron 4 mg in 2 ml or Group – B – Dexamethasone 8 mg in 2 ml was administered. On the operation table routine monitoring (ECG, Pulse oximetry, NIBP) was started and baseline vital parameters like heart rate, BP (Systolic, diastolic, mean) and arterial O₂ saturation (SpO₂) were recorded. Inj Glycopyrrolate 0.2 mg was given.

After preoxygenation for 3 minutes, Anaesthesia was induced with Thiopentone Sodium (5 mg/Kg.) and Fentanyl (2 microgram/Kg.). Endotracheal intubation was facilitated with Succinylcholine (2 mg/Kg.). Anaesthesia was maintained with N₂O, O₂ @ 60:40, and Isoflurane. Vecuronium bromide, in intermittent doses was used to maintain muscle relaxation. Stomach was evacuated with a nasogastric tube and intra- abdominal pressure was kept <14 mmHg throughout the laparoscopic procedure. After completion of surgery anaesthetic agents were discontinued, intravenous Glycopyrrolate and Neostigmine were used to reverse residual neuromuscular blockade.

Before tracheal extubation nasogastric tube was suctioned and removed. For postoperative analgesia Paracetamol (1000 mg) I.V. was administered. All patients were observed post operatively by noting vital signs and complications,

if any. All episodes of PONV (nausea, vomiting, retching) were recorded for 12 hrs., in post operatively. Rescue drug Inj. Metoclopramide 10 mg I.V. was given, if required. All data from each patient was obtained and tabulated.

Nausea is defined as unpleasant sensation associated with awareness of urge to vomit. Retching is defined as laboured, spastic, rhythmic contraction of respiratory muscles without expulsion of gastric contents. Vomiting is defined as forceful expulsion of gastric contents from mouth. Complete response (Free from emesis) is defined as no PONV and no need for rescue medication.

All recorded data was analysed using Mann-Whitney- Wilcoxon tests or Chi-square test or Students unpaired t test as appropriate and the findings were discussed in detail to draw appropriate conclusion. Categorical variables are expressed as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate. Continuous variables are expressed as Mean and Standard Deviation and compared across the 2 groups using unpaired t test. The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

RESULTS

Patients were equivalent in terms of age, weight, height, and ASA status, and there was no statistically significant difference in age, weight, height, or ASA status between the study group and the control group ($p > 0.05$). Group A (Ondansetron) had an average age of 41.83 years, while Group B (Dexamethasone) had an average age of 41.30 years. Group-A (Ondansetron) had an average weight of 54.5 kg, while Group-B (Dexamethasone) had an average weight of 53.47 kg. In Group-A, the procedure took an average of 68.67 minutes, while in Group-B, it took an average of 67.5 minutes. There was no statistically significant difference in surgery duration across the study groups, and the groups are equivalent in terms of operation duration.

In the first hour, nausea is more common in both groups, while the difference is not statistically

significant. Patients in the dexamethasone (Gr B) group exhibited a greater incidence of nausea within 3-6 hours, but it was not statistically significant. Retching was more common in both groups in the first hour. It didn't have any statistical significance. Both groups vomited more in the first three hours. It didn't have any statistical significance. Both groups required the same amount of rescue medication (inj. metoclopramide 10 mg I.V.).

DISCUSSION

In this study, we investigated the efficacy and safety of IV Ondansetron and Dexamethasone as PONV prevention in laparoscopic cholecystectomy, which was chosen because to the high risk of PONV.

In a meta-analysis published in 2015, Wang X, Zhou Q, et al. found that dexamethasone was just as effective and safe as ondansetron in preventing PONV.⁷ In our research, 86% of patients in both groups had no emesis. In both groups, the incidence of emesis was increased in the first three hours. Separately from vomiting, retching was noticed. In both groups, 93 percent of patients had no retching. In the first hour, there was a lot of retching. Patients in the ondansetron group experienced 33% nausea, whereas those in the dexamethasone group experienced 30% nausea. At 6 and 12 hours, the incidence of PONV was very low in both groups. Ondansetron and dexamethasone were shown to be equally efficient in reducing PONV in this investigation.⁸

Isoflurane and laparoscopic cholecystectomy were two factors that may have led to nausea and vomiting in our study. The usage of a face mask and nitrous gas may have contributed to nausea and vomiting. The insertion of a nasogastric tube near the conclusion of surgery and the avoidance of painkillers must have helped to prevent PONV.

In a 2011 study, Bhattarai B, Shrestha S, et al. found that a combination of ondansetron and dexamethasone is more effective than ondansetron alone in avoiding post-operative nausea and vomiting in patients following laparoscopic surgery.⁹

Gautam B, Shrestha BR et al. demonstrated that a combination of Ondansetron and Dexameth-

asone is more effective than either medicine alone in reducing PONV following laparoscopic cholecystectomy in a study published in 2008.¹⁰ When compared to a combination of Dexamethasone and Ondansetron, Dexamethasone alone is significantly less effective in avoiding early vomiting, while Ondansetron alone is less efficient in preventing late PONV.¹¹

CONCLUSIONS

Dexamethasone reduced the incidence of post-operative nausea and vomiting in laparoscopic cholecystectomy with minor adverse effects, according to our findings. Ondansetron and Dexamethasone both require the use of a rescue antiemetic. We may conclude from this study that Ondansetron, a 5-HT₃ antagonist, and Dexamethasone, a glucocorticoid, at doses of 4 mg and 8 mg, respectively, are both efficient prophylactic agents in the prevention of PONV during laparoscopic cholecystectomy under general anesthesia.

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