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Original Research Article

Comparative Analysis of Ondansetron and Normal Saline in the Prevention of Post-Operative Nausea and Vomiting Following Day Care Gynaecological Laparoscopy

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Abstract:

Introduction: Postoperative nausea and vomiting (PONV) is a major concern in day care procedures following gynecological laparoscopy. Despite advancements in anesthesia and surgical techniques, PONV continues to cause patient distress and hospitalization. Ondansetron, a selective serotonin 5-HT3 receptor antagonist, is a key pharmacological intervention for PONV prevention. However, differences in dosing regimens, patient populations, and surgical techniques necessitate thorough evaluation of the available evidence. This study aims to provide evidence-based guidance for antiemetic prophylaxis in day care gynecological laparoscopy and inform clinical practice.

Aim: The present study was to determine the efficacy of ondansetron in the prevention of post-operative nausea and vomiting following day care gynecological laparoscopy. This research was carried out at Government Lalla Ded Hospital, a hospital associated with GMC, Srinagar, and involved 120 females aged 20-40 years with ASA-I and ASA-II classifications who underwent elective day care gynecological laparoscopic procedures under general anesthesia. The investigation excluded individuals with motion sickness or vestibular issues, those taking other antiemetic medications, patients with cardiovascular, respiratory, or liver diseases, and renal dysfunction. The study aimed to compare the effectiveness of ondansetron versus normal saline in preventing PONV in patients who underwent day-care gynecological laparoscopy. The results demonstrated that ondansetron was more effective in preventing PONV due to its ability to block serotonin receptors. These findings suggest that ondansetron could be a better choice for clinicians in similar surgical settings, but additional research is necessary to determine optimal dosage schedules and assess long-term outcomes.

Conclusion: The study found ondansetron, compared to normal saline, more effective in preventing post-operative nausea and vomiting (PONV) in patients undergoing day-care gynecological laparoscopy, suggesting further research for optimal dosage schedules.

Keywords: Ondansetron, Normal Saline, Postoperative Nausea And Vomiting, Day-Care Gynecological Surgical Laparoscopy Procedures, Blood Pressure.

Introduction

Postoperative nausea and vomiting (PONV) is a significant concern for day care procedures following gynecological laparoscopy. Despite advancements in anesthesia administration and surgical techniques, PONV continues to cause patient distress, prolonged recovery, and extended hospitalization [1]. It is essential to address PONV not only to improve patient satisfaction but also to optimize the effectiveness of day care surgeries [2]. Ondansetron, a selective serotonin 5-HT3 receptor antagonist, is a key pharmacological intervention for PONV prophylaxis.

By inhibiting serotonin receptors in the central nervous system and gastrointestinal tract, ondansetron produces antiemetic effects [3,4]. The agent's safety and effectiveness have been established in various surgical contexts, including gynecological laparoscopy, leading to its widespread use in clinical practice [3]. However, differences in dosing regimens, patient populations, and surgical techniques necessitate a thorough evaluation of the available evidence [5]. Understanding the factors that impact the efficacy of ondansetron in this specific setting is crucial to

optimize its use and improve patient outcomes [6-9]. This study aims to provide evidence-based guidance for antiemetic prophylaxis in day care gynecological laparoscopy and inform clinical practice.

The research will also address strategies for enhancing ondansetron's efficacy in preventing PONV and identify areas that require further investigation. The primary objective is to contribute to the improvement of perioperative care and patient satisfaction in day care gynecological laparoscopy. Hence, the present study was to determine the efficacy of ondansetron in the prevention of post-operative nausea and vomiting following day care gynecological laparoscopy.

Materials & Methods

The present study was conducted at Government Lalla Ded Hospital, an associated hospital of GMC, Srinagar, with 120 female patients aged 20-40 years, ASA-I, and ASA-II, undergoing elective day care gynecological laparoscopic procedures under general anesthesia. The study excluded patients with a history of motion sickness, vestibular problems, patients receiving other antiemetic drugs, patients with cardiovascular, respiratory, or liver diseases, and renal dysfunction. To minimize the impact on the interpretation of study data, the risk factors for post-operative nausea and vomiting, such as periods of CO2 insufflations and anesthetic techniques, were controlled in this study. After obtaining informed consent and approval from the Institutional Ethics Committee, 120 patients were randomly allocated into two groups of 60 each in a double-blind, placebo-controlled manner. One group received Ondansetron (0.08/Kg), named Group A, and the other group, Group B, received normal saline (2mL) intravenously slowly. Pre-anesthetic preparations included clinical assessments 24 hours before anesthesia and a 12-hour fast before surgery, without premedication. The anesthetic procedure involved routine monitoring devices, baseline vital signs, ECG, and pulse oximetry, an 18G intravenous cannula, and 5% dextrose infusion. Two minutes before anesthesia induction, patients received antiemetic drugs, either Ondansetron (0.08/kg) intravenously slowly or normal saline (2mL) intravenously. After pre-oxygenation for 3 minutes, all patients were induced with sodium thiopentone (5mg/kg body weight) followed by Scoline (2mg/kg body weight) and endotracheal intubation with an adequately sized endotracheal tube.

Anesthesia was maintained through a combination of oxygen, nitrous oxide, and isoflurane vapors at a concentration of 0.2-0.4%. The muscle relaxant atracurium besylate was administered at a dose of 0.5 mg/kg body weight, with a top-up dose of one-quarter of the initial dose used. Tramadol was given intravenously at a dose of 1 mg/kg body weight 10 minutes after induction for analgesia. The patients were placed in the Trendelenburg position during laparoscopic surgery, and the abdomen was insufflated with CO2 to achieve an intra-abdominal pressure of 10-15 mmHg.

The patient's blood pressure, heart rate, and oxygen saturation were recorded every 10 minutes during surgery and two minutes after extubation. At the end of surgery, the residual neuromuscular block was reversed with intravenous injections of Neostigmine 2.5 mg and atropine 1.2 mg. After surgery, patients were monitored for six hours, with vital signs such as arterial blood pressure, heart rate, and respiratory rate checked every hour for six hours. The incidence of nausea and vomiting was recorded at one-hour intervals for six hours, with nausea and vomiting evaluated using a five-point scale described by [4,5]. Nausea was graded as 0 for no nausea, 1 for mild nausea, 2 for moderate to severe nausea, 3 for occasional vomiting (≤2 episodes per hour), and 4 for recurrent vomiting (>2 episodes per hour).

Statistical Analysis: SPSS 20 was used in the process of carrying out statistical analysis. Utilizing the unpaired t-test, compare the mean values of the groups' respective variables. When comparing the means of two groups with t test. Percentages were calculated. The threshold for significant differences was set at less than 0.05.

Results & Discussion

The present study was conducted at the Lalla Ded Hospital, Srinagar, in the department of Anaesthesiology and intensive care medicine, Government Medical College, Srinagar. A total of 120 female patients, age 20-40 years, ASA-I and ASA-II undergoing elective day care gynecological laproscopic procedure under general anaesthesia were included in the study. The patients were randomly allocated into two equal groups of 60 each in a double-blind randomized placebo-controlled manner. These groups randomly received the different antiemetics. All the data obtained was tabulated and results subjected to statistical analysis. The following observations were made.

Demographic Characteristics: The patients' ages ranged from 25 to 36 years. The mean age in Group A was 28.43 years, while the mean age in Group B was 28.78 years. There was no significant difference in age between the two groups (p=0.547). The patients' weights ranged from 40 to 70 kilograms. The mean weight in Group A was 56.10 kilograms, while the mean weight in Group B was 56.08 kilograms. There was no significant difference in weight between the two groups (p=0.999). The distribution of ASA status among the patients was not significantly different among

the different groups ($p > 0.05$). Both diagnostic laparoscopic and laparotomy surgeries were performed in the different groups, and there was no significant difference in the type of surgery between the two groups ($p > 0.05$). The duration of anaesthesia ranged from 30 to 60 minutes, with a mean duration of 39.42 minutes in Group A and 40.33 minutes in Group B. There was no significant difference in the duration of anaesthesia between the two groups ($p = 0.473$). The duration of CO2 insufflation ranged from 10 to 30 minutes, and there was no significant difference in duration of CO2 insufflation between the two groups ($p = 0.869$).

Post-operative nausea and vomiting: It is a distressing side effect of general anaesthesia and surgery. Although the incidence has been decreasing with changes in practice and surgical techniques, there is still a high incidence in certain patient subgroups like patients undergoing gynecological laparoscopic surgery. These represent a susceptible group with both anesthetic and non-anaesthetic factors contributing to the problem. This may be accentuated when care is provided on a day care basis and may require unplanned admission to hospital. So leading to recommendation of routine prophylactic administration of antiemetics.

The analysis of post-operative nausea and vomiting in the two study groups:

In group A: During the first hour, the number of patients with grade 0 PONV are 24 (40%), with grade 1 are 15 (25%), with grade 2 are 11 (18.3%, with grade 3 are 10 (16.7%) and no patient with grade 4 are observed. During the 2nd hour, the number of patients with grade 0 PONV are 24 (40%), with grade 1 are 10 (16.7%), with grade 2 are 16 (26.7%), with grade 3 are 10 (16.7%) and no patient with grade 4 are observed.

During the 3rd hour, the number of patients with grade 0 PONV are 28 (46.7%), with grade 1 are 12 (20%), with grade 2 are 13 (21.7%), with grade 3 are 7 (11.7%) and no patient with grade 4 are observed. During the 4th hour, the number of patients with grade 0 PONV are 33 (55%), with grade 1 are 17 (28.3%), with grade 2 are 9 (15%), with grade 3 is 1 (1.7%) and no patient with grade 4 are observed.

During the 5th hour, the number of patients with grade 0 PONV are 44 (73.3%), with grade 1 are 15 (25%), with grade 2 is 1 (1.7%), and no patient with grade 3 and 4 are observed. During the 6th hour, the number of patients with grade 0 PONV are 58 (96.7%), with grade 1 is 1 (1.7%), with grade 2 are 1 (1.7%), and no patient with grades 3 and 4 are observed. When compared the intra group variance of group A, from 1st to 6th hour statistically there is a significant difference ($P < 0.05$).

The numbers of patients with grade 0 PONV are increasing and the patients with grade 3 and 4 are decreasing with the passage of time. These findings rae in accordance with those of [6-8]. The overall incidence of post-operative nausea and vomiting in group A was 61% (n=37). This observation was in accordance with the studies of [9] which shows 54% incidence of PONV; the incidence of PONV was 18% [8] and [10], the incidence showed 20% of PONV.

Group B patients here were a statistically significant difference ($P < 0.05$) in post-operative nausea and vomiting between the two groups during the first hour after surgery. Patients with grade 0 PONV accounted for 40% (n=24) of group A and 5% (n=3) of Group B. Patients with grade 1 PONV made up 18.3% (n=11) of group A and 33% (n=20) of Group B. Patients with grade 2 PONV made up 16.7% (n=10) of group A and 45% (n=27) of Group B. Patients with grade 3 PONV made up 3.3% (n=2) of Group B, and no patients with grade 4 PONV were found in group A or B during the first hour.

During the second hour after surgery, patients with grade 0 PONV made up 40% (n=24) of group A and 5% (n=3) of Group B. Patients with grade 1 PONV made up 16.7% (n=10) of group A and 6.7% (n=4) of Group B. Patients with grade 2 PONV made up 26% (n=16) of group A and 60% (n=36) of Group B. Patients with grade 3 PONV made up 16.7% (n=10) of group A and 23.3% (n=14) of Group B. Patients with grade 4 PONV made up 5% (n=3) of Group B, and no patients with grade 4 PONV were found in group A.

During the third hour after surgery, patients with grade 0 PONV made up 46.7% (n=28) of group A and 5% (n=3) of Group B. Patients with grade 1 PONV made up 20% (n=12) of group A and 15% (n=9) of Group B. Patients with grade 2 PONV made up 21.7% (n=13) of group A and 38.3% (n=23) of Group B. Patients with grade 3 PONV made up 11.7% (n=7) of group A and 33.3% (n=20) of Group B, and no patients with grade 4 PONV were found in group B. Patients with grade 4 PONV are 8.3% (n=5) in Group B and no patients found in group A.

The fourth hour after surgery, the incidence of patients with grade 0 PONV was 55% in group A (n=33) and 10% in Group B (n=6). For grade 1 PONV, the incidence was 28.3% in group A (n=17) and 33.3% in Group B (n=20). For grade 2 PONV, the incidence was 15% in group A (n=9) and 30% in Group B (n=18). For grade 3 PONV, the incidence was 1.7% in group A (n=1) and 20% in Group B (n=12). For grade 4 PONV, the incidence

was 6.7% in Group B (n=4) and no patients were found in group A.

At the fifth hour after surgery, the incidence of patients with grade 0 PONV was 73.3% in group A (n=44) and 26.7% in Group B (n=16). For grade 1 PONV, the incidence was 25% in group A (n=15) and 41.7% in Group B (n=25). For grade 2 PONV, the incidence was 1.7% in group A (n=1) and 21.7% in Group B (n=13). For grade 3 PONV, the incidence was 5% in Group B (n=3) and no patients were found in group A. For grade 4 PONV, the incidence was 5% in Group B (n=3) and no patients were found in group A.

At the sixth hour after surgery, the incidence of patients with grade 0 PONV was 96.7% in group A (n=58) and 58.3% in Group B (n=35). For grade 1 PONV, the incidence was 1.7% in group A (n=1) and 33.3% in Group B (n=20). For grade 2 PONV, the incidence was 1.7% in group A (n=1) and 5% in Group B (n=3). For grade 3 PONV, the incidence was 3.3% in Group B (n=2) and no patients were found in group A. No patients were found with grade 4 PONV in group A.

Group B comparison of PONV, the results were found to be statistically significant ($P < 0.05$) in both group A and Group B. The incidence of post-operative nausea and vomiting in group A was 61.7% (n=37), these findings are in accordance with the studies of [6] who reported the incidence of PONV 96% with placebo group. In one study [11] showed the incidence of PONV 67%, in the placebo group. Studies showed [12,13] showed the incidences of 35% [12], study [13] showed the 50% incidence of PONV. Further on comparing the group A with group B, the results found are statistically significant ($p < 0.05$) during the 1st to 6th hour. It means that group A is better than Group B and group A is better in preventing the PONV among two groups. These findings were in agreement with the studies of [14-18] where the incidence of PONV was shown to be 12% and in another study [13] showed 7% incidence of PONV.

Analysis of heart rate in the two study groups: The heart rate variations observed during the pre-operative, intra-operative and post-operative periods in the ondansetron group and control group were found to be statistically significant ($P < 0.05$). These results align with previous studies [13-15].

Analysis of blood pressure and SPO2 in the two study groups: The results of our study showed that there was statistically significant variation in either systolic or diastolic blood pressure or SPO2 levels between the ondansetron and control groups during the post-operative, intra-operative, and post-operative periods. This finding is consistent with prior research conducted by various studies [16-19].

Conclusion

The study examined the use of ondansetron versus normal saline for preventing PONV in patients undergoing day-care gynecological laparoscopy. The results showed that ondansetron was more effective in preventing PONV due to its antagonistic effect on serotonin receptors. These findings suggest that ondansetron could be a better option for clinicians in similar surgical settings, but further research is necessary to determine optimal dosage schedules and long-term outcomes.

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