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Original Research Article

Comparison of the Efficacy of Granisetron and Normal Saline in the Prevention of Postoperative Nausea and Vomiting Following Day Care Gynecological Laparoscopy

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Abstract:

Aim: The present study aimed to determine the efficacy of Granisetron in the prevention of post-operative nausea and vomiting following day care gynecological laparoscopy.

Materials & Methods: The present study was carried out at Government Lalla Ded Hospital, which is affiliated with GMC, Srinagar and involved 120 female patients aged 20-40 years with ASA-I and ASA-II who underwent elective day care gynecological laparoscopic procedures under general anesthesia. Patients with a history of motion sickness, vestibular problems, other antiemetic drugs, cardiovascular diseases, respiratory diseases, liver diseases, and renal dysfunction were excluded from the study.

Result & Conclusion: A study comparing granisetron and normal saline for the prevention of PONV after day-care gynecological laparoscopy revealed that granisetron is more effective. This finding has significant practical implications such as improving patient satisfaction, reducing healthcare costs, and enhancing postoperative recovery. Clinicians can use these findings to make informed decisions regarding antiemetic prophylactic techniques in similar surgical situations. However, further research is needed to establish the optimal dosage schedules, potential side effects, and long-term consequences of granisetron use in this patient population.

Keywords: Granisetron, normal saline, postoperative nausea and vomiting, day care gynecological surgical laparoscopy procedures, blood pressure.

Introduction

Gynecological laparoscopy is a surgical procedure that has been known to cause post-operative nausea and vomiting (PONV), particularly in day care operations. Although anesthesia management and surgical procedures have improved, PONV continues to cause pain, slow recovery, and consume more healthcare resources [1]. To improve patient outcomes and day care operations, it is essential to address PONV [1,2].

Granisetron, a selective serotonin 5-HT3 receptor antagonist, has shown promise in reducing PONV during gynecological laparoscopy [3]. By blocking serotonin receptors in the brain and digestive tract, it decreases anesthesia- and surgery-induced nausea and vomiting [1].

While granisetron has demonstrated effectiveness in preventing PONV in other surgeries, its role in day care gynecological laparoscopy requires further investigation [4]. Given the shorter anesthetic durations and faster recovery times in day care settings, granisetron's effectiveness may differ from that in inpatient settings [5,6]. To improve patient care and educate professionals, it is crucial to thoroughly assess granisetron's usefulness in preventing PONV following day care gynecological laparoscopy [1-5]. This study aims to evaluate the efficacy of granisetron in preventing PONV in this surgical group, considering dosing regimens, patient characteristics, and surgical factors. By identifying areas for further research and discussing ways to improve granisetron's use, this debate seeks to enhance patient outcomes and perioperative care in day care gynecological laparoscopy. Hence, the present study aimed to determine the efficacy of granisetron in the

prevention of post-operative nausea and vomiting following day care gynecological laparoscopy.

Materials & Methods

The present study was carried out at Government Lalla Ded Hospital, which is affiliated with GMC, Srinagar, and involved 120 female patients aged 20-40 years with ASA-I and ASA-II who underwent elective day care gynecological laparoscopic procedures under general anesthesia. Patients with a history of motion sickness, vestibular problems, other antiemetic drugs, cardiovascular diseases, respiratory diseases, liver diseases, and renal dysfunction were excluded from the study.

The investigators aimed to control the risk factors for postoperative nausea and vomiting, including periods of CO2 insufflation and anesthetic technique, to minimize their impact on the interpretation of study data. The patients were randomly assigned to two equal groups of 60 patients each in a double-blind manner after obtaining informed consent and approval from the Institutional Ethics Committee. In one group, patients received granisetron (0.02 mg/Kg), while the other group received normal saline.

The patients were clinically assessed 24 hours before anesthesia and fasted for 12 hours before surgery. Premedication was not administered. Upon arrival in the operating room, the patients' baseline vital signs were recorded, and an intravenous line was secured with an 18G cannula. An infusion of 5% dextrose was initiated, and two minutes prior to induction of anesthesia, patients received either granisetron or normal saline. After pre-oxygenation for 3 minutes, all patients were induced with sodium thiopentone and Scoline, followed by endotracheal intubation with an adequately sized endotracheal tube.

Anesthesia was maintained by employing a combination of oxygen, nitrous oxide (50:50), and isoflurane vapors at 0.2-0.4% concentration. Muscle relaxant atracurium besylate was administered at a dose of 0.5 mg/kg body weight, with additional doses given as needed. Tramadol was used for pain relief, given intravenously at a dose of 1 mg/kg body weight after induction. Ventilation was provided through intermittent positive-pressure ventilation with a closed circuit and CO2 absorber. During laparoscopic surgery, patients were placed in the Trendelenburg position, and the abdomen was insufflated with CO2 to achieve an intra-abdominal pressure of 10-15 mmHg.

Intraoperative monitoring included recording blood pressure, heart rate, and oxygen saturation every ten minutes and two minutes after extubation. At the end of surgery, neuromuscular block was reversed with neostigmine (2.5 mg) and atropine (1.2 mg) administered intravenously. After surgery, patients were observed for six hours with vital signs checked hourly, including arterial blood pressure, heart rate, and respiratory rate. Nausea and vomiting were recorded using a 5-point scale, with grades of 0 for no nausea, 1 for mild nausea, 2 for moderate to severe nausea, and 3 for occasional vomiting (≤2 episodes per hour) [6-8]. Four or more recurrent vomiting episodes (>2 episodes per hour) were recorded.

Statistical analysis: SPSS version 20 was used for statistical analysis. Using the unpaired t-test, we compared the mean values of the groups' respective variables. The t-test was used to compare the means of the two groups. Percentages were calculated. The threshold for significant differences was set at $P < 0.05$.

Results

The study was conducted at the Lalla Ded Hospital in Srinagar, Jammu and Kashmir, India. It focused on female patients aged between 20 and 40 who were classified as ASA-I or ASA-II and undergoing elective day care gynecological laparoscopic procedures under general anesthesia. The patients were randomly divided into two groups of 60 each and administered different antiemetics in a double-blind, randomized, and placebo-controlled manner. The results were analyzed using statistical methods and the following observations were made: the age of the patients ranged from 25 to 36 years, with a mean of 28.78 ± 2.84 years in group A, and there was no statistically significant difference in age between the two groups (p=0.547).

The weight of the patients ranged from 40 to 70 kg, with a mean of 56.12 ± 5.74 kg in group A and 56.08 ± 5.07 kg in group B, and there was no statistically significant difference in weight between the two groups (p=0.999). There was no significant difference in ASA status between the different groups ($p > 0.05$). Two types of surgeries were performed in different groups: diagnostic laparoscopy and laparoscopy, and there was no statistically significant difference in the type of surgery between the two groups ($p > 0.05$). The duration of anesthesia ranged from 30 to 60 minutes, with a mean of 40.33 ± 4.10 minutes in group A, and there was no statistically significant difference in the duration of anesthesia between the two groups ($p = 0.473$).

The CO2 insufflation time varied between 10 and 30 minutes, and there was no significant difference ($p = 0.869$) observed between the two groups. Regarding heart rate, Group A showed a highly significant difference ($P < 0.0001$) when compared to the heart rate recorded two minutes before induction with after induction. This difference

remained significant when compared to heart rates recorded at 10, 20, 30, and 40 minutes after induction. However, the difference became insignificant after 1 hour and 2 hours of surgery (P = 0.144 and P = 0.069) and after 6th hour of surgery (P = 0.202), only to regain significance at 3, 4, and 5 hours of surgery. Group B also showed a highly significant difference in heart rate when compared to the heart rate recorded just before induction with 2 minutes after induction (P = 0000). This difference remained significant when compared to heart rates recorded at 10, 20, and 30 minutes after induction. Significant differences were also observed at 40 minutes after induction and 2 minutes after extubation. However, the difference became insignificant after 5 hours of surgery (P = 0.080).

In Group A, there was a highly significant statistical difference in systolic blood pressure pre-induction values when compared with 10, 20, and 30 minutes after induction (all P values < 0.05). However, the difference was not statistically significant at 40 minutes after induction (P = 0.0895) and after 1 hour (P = 0.787) and 2 hours (P = 0.300) after surgery. The difference became highly significant again at 3 hours (P = 0.000), 4 hours (P = 0.000), and 5 hours (P = 0.000) after surgery and remained so up to 6 hours after surgery (P = 0.000).

In Group B, there was a highly significant statistical difference in systolic blood pressure pre-induction values when compared with 10 and 20 minutes after induction (both P values < 0.05), but not at 30 minutes after induction (P = 0.201) or 40 minutes after induction (P = 0.248). The difference was highly significant at 2 minutes after extubation (P = 0.000) and remained so up to 1 hour (P = 0.499) and 2 hours (P = 0.290) after surgery. However, the difference was not statistically significant at 3 hours (P = 0.871) or 4 hours (P = 0.519) after surgery, and at 5 hours (P = 0.848) and 6 hours (P = 0.262) after surgery.

Diastolic blood pressure values were found to have a highly significant statistical difference when compared to values taken 10 minutes after induction (P = 0000), 20 minutes after induction (P = 0.0001), 30 minutes after induction (P = 0.002), and 40 minutes after induction (P = 0.000). Additionally, the values were significant after 2 minutes of extubation (P = 0.000), but not significant at 1 hour after surgery (P = 0.293). However, the values were significant again at 2 hours after surgery (P = 0.019) and at 5th and 6th hours after surgery (P < 0.05).

Similarly, in Group B, there was a highly significant statistical difference in diastolic blood pressure pre-induction values when compared to values taken 10 minutes after induction (P = 0.000), 20 minutes after induction (P = 0.0001), 30 minutes after induction (P = 0.002), and 40 minutes after induction (P = 0.000). Additionally, the values were significant after 2 minutes of extubation (P = 0.000), but not significant at 1 hour after surgery (P = 0.293). However, the values were significant again at 2 hours after surgery (P = 0.019) and at 5th and 6th hours after surgery (P < 0.05), respectively.

There was no significant difference (P > 0.05) in the SPO2 (%) between the two groups at two minutes before induction (P = 0.862) and this insignificant difference persisted at ten minutes (P = 0.821), twenty minutes (0.229), thirty minutes (P = 0.097), forty minutes (P = 0.051), and two minutes after extubation (P = 0.958).

There was no significant difference in respiratory rate between the two groups at one, two, three, four, five-, and six-hour post-surgery. However, a significant difference was observed in postoperative nausea and vomiting between the two groups during the first hour after surgery. The incidence of grade 0 PONV is 85% in group A and 5% in group B, group is better than group B. For patients with grade 2 PONV, the incidence was 1.7% in group A and 33% in group B.

The proportion of patients with grade 3 PONV was 1.7% in group A and 45% in group B. No patients in group A had grade 4 PONV during the first hour, while 3.3% of patients in group B had grade 4 PONV. During the second hour after surgery, the incidence of PONV for patients with grade 0 was 88.3% in group A and 5% in group B. The incidence of PONV for patients with grade 1 was 8.3% in group A and 6.7% in group B. The proportion of patients with grade 2 PONV was 1.7% in group A and 60% in group B.

One patient in Group A experienced grade 3 PONV, while 14 patients in Group B experienced grade 3 PONV. Three patients in Group B experienced grade 4 PONV, while no patients in Group A experienced grade 4 PONV. At the 3rd hour after surgery, 55 patients in Group A experienced grade 0 PONV, while only 3 patients in Group B experienced grade 0 PONV. Twelve patients in Group A experienced grade 1 PONV, while 5 patients in Group A and 9 patients in Group B experienced grade 1 PONV. No patients in Group A experienced grade 2 PONV, while 23 patients in Group B experienced grade 2 PONV. Twenty patients in Group B experienced grade 3 PONV, while no patients in Group A experienced grade 3 PONV.

Five patients in Group B experienced grade 4 PONV, while no patients in Group A experienced grade 4 PONV. At the 4th hour after surgery, 60 patients in Group A experienced grade 0 PONV, while 6 patients in Group B experienced grade 0 PONV. Eighteen patients in Group B experienced

grade 1 PONV, while no patients in Group A experienced grade 1 PONV. Sixteen patients in Group B experienced grade 2 PONV, while no patients in Group A experienced grade 2 PONV. Twelve patients in Group B experienced grade 3 PONV, while no patients in Group A experienced grade 3 PONV. Four patients in Group B experienced grade 4 PONV, while no patients in Group A experienced grade 4 PONV.

After five hours, 60 patients in Group A experienced no PONV, compared to 16 patients in Group B, with 26.7% experiencing no symptoms. Grade 1 PONV occurred in 25% of Group B and 41.7% of Group A patients, while Grade 2 PONV occurred in 21.7% of Group B and none of Group A's patients. Only 3 patients in Group B had Grade 3 PONV, compared to none in Group A. At the sixth hour, 35 patients in Group B and all 60 patients in Group A experienced no PONV. Grade 1 PONV occurred in 33.3% of Group B and none of Group A. On intragroup comparison, the results were statistically significant in both groups ($P < 0.05$). The overall incidence of post-operative nausea and vomiting was 18.3% in Group A and 95% in Group B.

Discussion

The primary objective was to improve perioperative care and patient satisfaction in day-care gynecological laparoscopy. Hence, the present study aimed to determine the efficacy of granisetron in the prevention of post-operative nausea and vomiting following day care gynecological laparoscopy.

PONV is a distressing side effect of general anesthesia and surgery. Although the incidence has decreased with changes in practice and surgical techniques, there is still a high incidence in certain patient subgroups, such as patients undergoing gynecological laparoscopic surgery. These represent a susceptible group, with both anesthetic and non-anesthetic factors contributing to the problem. This may be accentuated when care is provided on a day-care basis and may require unplanned hospital admission. Therefore, the routine prophylactic administration of antiemetics is recommended.

A placebo-controlled study was undertaken to determine the efficacy of granisteron 0.02 mg/kg and administered at induction of anesthesia in patients who underwent day care gynecological laparoscopic surgery under general anesthesia. Because many of the factors can interfere with the interpretation of the result of the study, we designed the study in such a way as to control all these factors.

In Group A, during the 1st hour, 85% of patients (n=51) had no nausea or vomiting, while 11.7% (n=7) experienced mild symptoms, 1.7% (n=1) had moderate symptoms, and 1.7% (n=1) had severe symptoms. From the 2nd to 6th hour, 100% of patients (n=60) had no symptoms, and there was a statistically significant decrease in symptoms within the group over time ($P < 0.05$). The overall incidence of PONV in Group A was 18.3% (n=11), which is similar to studies by [13,14], who reported incidences of 12% and 7%, respectively.

During the 3rd hour, 5% of patients had grade 0, 15% had grade I, 38.3% had grade II, 33.3% had grade III, and 8.3% had grade IV. During the 4th hour, 10% had grade 0, 33.3% had grade I, 30% had grade II, 20% had grade III, and 6.7% had grade IV. During the 5th hour, 26.7% had grade 0, 41.7% had grade I, 21.7% had grade II, 5% had grade III, and 5% had grade IV.

During the 6th hour, 58.3% had grade 0, 33.3% had grade I, 3% had grade II, 3.3% had grade III, and no patient had grade IV. Group B had an overall incidence of 95% (n=57). Statistically significant results were found when comparing the intra-group variance in Group C from the 1st to 6th hours ($p <0.05$.These findings are in accordance with those of Praxton et al [9], who reported an incidence of PONV of 96% in a placebo group.

The study [15] showed the incidence of PONV 67%, in the placebo group. Visalyaputra et al [16] showed the incidences of 35%, Bhattacharya and Banerjee study [17] showed the 50% incidence of PONV. Comparison of Group A with Group A, Group A with Group B, Group A with Group B, and all two groups. The results were statistically significant ($p < 0.05$) during the 1st to 6th hour. This means that group A was better than group B and group A was better in preventing postoperative nausea and vomiting among all the other groups.

The heart rate variations observed during the preoperative, intraoperative, and postoperative periods in the granisetron and control groups were statistically significant ($P < 0.05$). These results are consistent with those of previous studies [18-20]. The results of our study showed a statistically significant variation in either systolic or diastolic blood pressure or SPO2 levels between the granisetron and control groups during the postoperative, intraoperative, and postoperative periods. This finding is consistent with prior research conducted by various studies [21-23].

Conclusion

A study comparing granisetron and normal saline for the prevention of PONV after day-care gynecological laparoscopy revealed that granisetron is more effective. This finding has significant practical implications such as improving patient satisfaction, reducing healthcare costs, and enhancing postoperative recovery. Clinicians can

use these findings to make informed decisions regarding antiemetic prophylactic techniques in similar surgical situations. However, further research is needed to establish the optimal dosage schedules, potential side effects, and long-term consequences of granisetron use in this patient population.

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