Original Research Article

Study between intravenous droperidol and granisetron as prophylactic antiemetic in prevention of PONV in gynaecological laparoscopic surgery

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Abstract

Background: Postoperative nausea and vomiting is one of the most common complications following general anaesthesia and surgery. It is one of the most bothersome adverse effects associated with surgery, as distressing as the pain associated with surgery. **Method:** Study was carried out in the department of Anaesthesiology, M.G.M. Medical College and L.S.K. Hospital during the period of January 2018 to September 2019 to determine the safety, efficacy and practicability of these two drugs as prophylactic antiemetic for prevention of Postoperative nausea and vomiting in adult female patients. 60 adult female patients with physical status of ASA grade I, II, scheduled for gynaecological laparoscopic surgery were randomly allocated to fall in three groups. **Results:** In this study we found that 11 cases of nausea and 09 cases of vomiting occurred in normal saline or placebo group. Where in droperidol group there were 4 cases of nausea and 5 cases of vomiting. In granisetron group there was 6 cases of nausea and 4 cases of vomiting. When calculated statistically it was found that the result was statistically significant when placebo group was compared with droperidol and granisetron group. But by using test of proportion (t- test) between droperidol and granisetron no statistically significant difference was found regarding Postoperative nausea and vomiting. **Conclusion:** Undergoing gynaecological laparoscopic surgery, both droperidol and granisetron were equally effective as prophylactic antiemetic in the prevention of Postoperative nausea and vomiting without any untoward side effects in the intraoperative and postoperative Time.
Key Word: droperidol, granisetron.

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INTRODUCTION

Postoperative nausea and vomiting is one of the most common complications following general anaesthesia and surgery. It is one of the most bothersome adverse effects associated with surgery, as distressing as the pain associated with surgery.[1] Minimizing patient morbidity and maximizing patient satisfaction are the important goal for health care providers. PONV is a complex condition that assumes greater importance as major mortality rating to surgery now decreases[2]. PONV costs have been estimated at $ 1.2 billion a year in the United States alone[3]. In the "ether era" incidence of PONV reported was as high as 80%. The replacement of older anaesthetic agent with shorter- acting and less emetogenic agent in conjunction with surgical refinements has reduced the overall incidence to 20% - 30%, which has been remarkably consistent over the past two decades[4]. Factors responsible for increased incidence of PONV are grossly divided into **fixed factors** and **variable factors**. Apfel *et al.* in 1999 found four highly predictive factors related to PONV.[5] They are female gender, history of motion sickness or PONV, nonsmoker, and the use of perioperative opioids. Apfel CC *et al.* in 2002 found that if none, 1, 2, 3 or 4 of these risk factors were present then the incidence of PONV were 10%, 21%, 39%, 61% and 79% respectively. The

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simplified risk score was found favorable when compared with other predictive models[6].

METHODOLOGY

Study was carried out in the department of Anaesthesiology, M.G.M. Medical College and L.S.K. Hospital during the period of January 2018 to September 2019 to determine the safety, efficacy and practicability of these two drugs as prophylactic antiemetic for prevention of Postoperative nausea and vomiting in adult female patients. 60 adult female patients with physical status of ASA grade I and II, scheduled for gynaecological laparoscopic surgery were randomly allocated to fall in any of the following three groups:

- GROUP- A will receive intravenous Normal Saline as placebo.
- GROUP- B will receive intravenous Droperidol (25mcg/kg).
- GROUP- C will receive intravenous Granisetron (40mcg/kg)

The ages of the patients ranged from 21 to 38 years and body weight was 51 to 72 kgs. The patients were monitored intraoperatively from the beginning to the end of the operative procedure and postoperatively in terms of continuous ECG monitoring, pulse rate, NIBP, SPO_2, at an interval of 15 minutes. Postoperative assessment for occurrence of nausea, vomiting, recovery from anaesthetic effect, adequacy of ventilation and movement were carried out in the post anaesthesia care unit. The assessments were done first at 30 min after the arrival of the patient in the post anaesthesia care unit, then at 30 mins interval for upto 3 hours. Then at 6 hourly interval for upto 24 hours. Emesis score was assessed after asking the patients for any occurrence of nausea, retching, or vomiting. Recovery score was judged by noting the patient sedation status. It was done on the basis of seeing the spontaneous eye opening, response to verbal command and orientation to time, place and date of birth. Movement score was judged by the spontaneous and purposeful movement present or not or whether the patient can perform it on demand. During intraoperative period no patient developed significant hypoxia, hypercarbia, hypotension or hypertension. Hemodyanamic stability was maintained throughout the procedure in all three groups.

RESULTS

Table 1: Mean and SD value of pulse rate (beats/ min) In three groups (Intraoperative)

TIME INTERVAL	GROUP – A	GROUP - B	GROUP- C
0 min	102.23 ± 4.37	101.09 ± 4.37	98.58 ± 3.35
15 minutes	107.0 ± 3.46	99.0 ± 3.43	101.21 ± 3.42
30 minutes	97.87 ± 2.45	98.91 ± 3.93	104.82 ± 2.42
45 minutes	97.23 ± 4.56	98.10 ± 4.66	98.09 ± 5.23
60 minutes	98.17 ± 4.55	98.27 ± 5.57	98. 27 ± 4. 55
75 minutes	96.89 ± 1.33	95.33 ± 2.33	96. 23 ± 4.66
90 minutes	96.42 ± 4.23	97.34 ± 5.45	97.24 ± 4.66
105 minutes	100.58 ± 6.23	104.67 ± 7.22	99. 25 ± 6.74

showing pulse rate in three groups. The base line values were comparable in all three groups. Pulse rate was slightly decreased after 30 minutes in all groups. There was no statistical significance in these three groups.

Table 2: Mean and SD value of arterial blood pressure in three groups

TIME INTERVAL	GROUP – I	GROUP- II	GROUP –III
0 min	98.71 ± 4.31	96.72 ± 4.35	98.71 ± 3.34
15 minutes	95.75 ± 4.92	95.47 ± 4.93	94.73 ± 4.91
30 minutes	90.12 ± 6.51	91.17 ± 6.53	90.17 ± 6.52
45 minutes	96.51 ± 1.91	95.50 ± 1.92	94.50 ± 1.91
60 minutes	97.71 ± 4.35	98.70 ± 4.36	98.71 ± 4.33
75 minutes	94.6 ± 5.36	97.30 ± 6.52	96.3 ± 6.51
90 minutes	94.3 ± 4.37	94.7 ± 5.37	95.8 ± 5.36
105minutes	95.67 ± 1.79	94.6 ± 1.82	95.7 ± 1.81

shows the changes in mean arterial blood pressure in three groups. The base line mean arterial blood pressure were comparable in three groups. At 15 minutes there was slight fall in blood pressure in all three groups. However, when compared statistically there was no significant difference in three groups at different time intervals.

Table 3: Mean and SD value of peripheral oxygen saturation (spo_2) in three groups

TIME INTERVAL	GROUP – I	GROUP- II	GROUP- III

0min	99.26 ± 1.47	97.36 ± 1.18	97.76 ± 1.39
15 minutes	98.26 ± 1.85	99.04 ± 0.64	99.24 ± 0.04
30 minutes	98.23± 0.28	99.74± 0.37	99.92 ± 0.92
45 minutes	99.12± 1.11	99.50± 0.09	99.34 ± 1.38
60 minutes	99.81± 0.56	99.82 ± 0.67	98.82 ± 0.55
75 minutes	98.92 ± 1.37	99.76± 1.28	97.61 ± 1.11
90 minutes	98.48 ± 0.46	99.34± 0.38	98.42 ± 0.34
105 minutes	99.42 ± 1.21	99.56 ± 1.38	99.41 ± 1.24

The intraoperative changes in SPO2 in three groups. There was no statistically significant changes in preoperative value in three groups.

Table 4: Comparison of emesis score in 3 groups in 24 hours

Groups	Nausea and / or retching	Vomiting
GROUP-A	11	09
GROUP-B	04	05
GROUP-C	06	04

Postoperative nausea and vomiting in all three groups, in 24 hours postoperative period. The test of proportion (z-test) shows that there is statistically significant difference ($P < 0.01$) regarding nausea and retching among Group- A (placebo) and Group-B (Droperidol); and also among the placebo and (granisetron) Group- C ($p< 0.05$). But there was no significant statistical differences found among Group-B and group-C regarding nausea and/ or retching.

DISCUSSION

The high incidence of PONV after laparoscopic surgery gives rise to the question of antiemetic prophylaxis. It is evident from several studies that antiemetic prophylaxis is justified after laparoscopic surgery and an antiemetic should be given regularly, using standard drug and dose. Recently Scuderi *et al.* in his study raised a query regarding use of this antiemetic prophylaxis[7]. Fisher *et al.* also supported this findings[8]. According to them there appears to be little evidence to support routine prophylactic administration of antiemetics. But there are lots of works that clearly show increased patient satisfaction with prophylactic antiemetics, in contrast to placebo with rescue therapy in PACU for patients with symptoms in wait- and-see- approach[9,10]. Palazzo and Strunin in 1984 in a study concluded that now a days, the incidence of emetic problems associated with anaesthesia in the absence of antiemetic is still around 30%[11]. In this placebo-controlled, prospective, randomized, clinical study the efficacy of two different groups of antiemetics was compared for preventing PONV following gynaecological laparoscopic surgery. The two study drugs were inj droperidol (butyrophenone group) and inj granisetron ($5HT_3$ receptor antagonist). As PONV was being evaluated, so routine use of antiemetic was withheld as premedication. This current study was also carried out to find out the safety, efficacy and practicability of these two drugs in terms of PONV and to compare the recovery profile of patients in these groups (Group-A, Group-B, Group-C). 60 adult non-pregnant female patients aged 21 – 38 years were enrolled in the study, belonging to ASA physical status grade I and II, scheduled for gynaecological laparoscopic surgery. The mean age was 29.45 ± 1.30 for placebo (group – A), 28.48 ± 1.77 for droperidol (group – B) and 28.47 ± 2.33 for granisetron (group – C) group. Patients of age group of 21 years to 38 years were chosen because, this age group was associated with highest incidence of PONV. The rate of PONV is controversial in younger age group and less in older patients [12]. Female patients were selected because, it was evident from the study that females are 2 – 4 times more prone to PONV than males [13]. Non-pregnant patients were chosen because; pregnancy is a contraindication to laparoscopy. Furthermore, anaesthesia and surgical stress may have some adverse outcome over the foetus. Also the pregnancy may influence the rate of PONV than in the non-pregnant female because of the delayed gastric emptying[14]. The physical status of these patients selected for this study was of the grade of ASA I and ASA II, so that the effect of the disease process in the pharmacokinetics and pharmacodyanamics of the drugs as well as the effect on the assessment of PONV could be eliminated and also the adverse pathophysiological effects of laparoscopy might not be increased. Therefore, the patients who had the evidence of major cardiovascular, pulmonary, hepatic, renal, hematological, endocrinal or metabolic disorders were excluded from the study. The surgical procedure included diagnostic gynaecological laparoscopy mainly for infertility and pelvic inflammatory diseases, ovum retrieval surgery. Laparoscopic surgery was chosen because, apart from strabismus surgery, this surgery is regarded as the standard operation for the study of PONV, with gynaecological laparoscopic surgery still having the higher rates[15]. Preoperative visit before the day of surgery was conducted routinely to establish a good rapport with the patients. Patients were given light non-residue diet on the night before surgery and kept on overnight fasting to clear the gut and stomach of food material. The patients were premedicated with tablet

diazepam 5 mg orally the night before and 90 minutes before arrival to operating room to achieve a desirable anxiolytic property, as anxiety has been suggested as a factor which can increase the incidence of PONV[16.] The patients were hydrated before anaesthesia with physiological solution like Ringer's lactate before induction of anaesthesia to replenish the loss during overnight fasting. This had also a favorable outcome on the hemodyanamic variables during the intraoperative period. Also it is evident from the study that preoperative hydration reduce the incidence of nausea and vomiting[17.] In our study in the postoperative period we found that 11 cases of nausea and 9 cases of vomiting in the placebo group who got normal saline, whereas in droperidol group there were 4 cases of nausea and 5 cases of vomiting and in granisetron group there were 6 cases of nausea and 4 cases of vomiting. When calculated statistically it was found that both droperidol and granisetron groups were superior in reducing nausea and vomiting than placebo group.

CONCLUSION

As prophylactic antiemetic in prevention of ponv in gynaecological laparoscopic surgery, both droperidol and granisetron were equally effective as prophylactic antiemetic in the prevention of Postoperative nausea and vomiting without any untoward side effects in the intraoperative and postoperative Time.

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