Randomised, Prospective, Controlled Trial comparing Tropisetron with Metoclopramide and Placebo in controlling Postoperative Nausea and Vomiting

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Abstract

Objective: To Compare the results of Tropisctron, Metoclopramide and placebo on postoperative nausea and vomiting in patients undergoing minilaparotomy cholycystectomy.
Setting: Patients operated for minilaparotomy cholecvstectorny in two Private hospitals in Karachi.
Subjects: Filly Consecutive patients of all ages and both SCX who had simple cholelithiasis and underwent minilaparotomy Cholecystectomy by a single surgeon.
Main outcome measures: Postoperative nausea and vomiting (PONV) at 2 hours and within 24 bout's and requirement of rescue antienietic.
Results: Tropisetron was better than Metoclopramide and placebo in controlling postoperative nausea and vomiting.
Conclusion: Tropisetron when given at induction at a dose 012 mg. intravenously prevents PONV better than Metoclopramide and placebo in 2 hours amid 24 hours. JPMA 50:386, 2000).

Introduction

Postoperative nausea and vomiting (PONV) is a common complication of operations. Although nausea and vomiting is typically self-limiting lasting less than 24 hours, the consequences must he considered. It can lead to dehydration electrolyte imbalance, metabolic alkalosis, gastric erosions and aspiration of GI contents with subsequent respiratory problems[1] It can also delay oral a nutrition and oral drug intake as well as release from hospital[2].
Factors which predispose to postoperative nausea and vomiting include age and sex (more common in children and women)[1] obesity- prolonged fasting, intake of food soon before induction of GA. previous history of It also reduces the need for rescue antiemetic significantly nausea. Vomiting or motion sickness, duration and depth of anesthesia[3] Carbon dioxide retention, rough handling, relative inexperience of anesthetist, type of surgical procedure and number of visitors during recovery.
Many antiemetic have been tried to reduce the incidence of postoperative nausea and vomiting. Some have been successful more than others have. Recently 5-H T3 receptor antagonists especially Tropisetron[4] and Ondansetron[5,6] have been found useful in controlling postoperative nausea and vomiting. Patients, Methods and Results Over a period of 7 months 50 patients with little or no other risk factor for Anesthesia (American Society of Anaesthetists class 1 and 2), between 22-71 years of age with cholelithiasis but no obvious bile duct pathology had minilaparotomy cholecystectomy by a single surgeon. They were controlled for age and sex and a standardised anesthetic techti ique consisting of thiopental for induction and Halothane and Nitrous Oxide for maintenance was used. All patients were randornised to receive immediately after induction one of the following three: Injection Tropisteron 2mg. i/v (group 1).
Injection Metoclopramide 10 rug. i/v (group 2) or injection Normal Saline (N/S) 10 nil. i/v (group 3).
The end points recorded were postoperative nausea and vomiting within 2 hours of operation, postoperative nausea and vomiting within 24 hours of operation and requirement for salvage antiemetic (Metoclopramide 10 mg). Statistical significance was derived using Fisher two— tailed P—value from Epi info software version 6.

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Results

Postoperative nausea and vomiting within 2 hours
Postoperative nausea and vomiting occurred within 2 hours in only one patient (6.25%) of tropisetron group (group I). Six patients (37.5%) in rnetoclopramide group (group 2) and 10 patients (55.5%) in Placebo group (group 3) had Postoperative nausea and vomiting. Difference between group I and 2 is statistically' significant (p value <0.05). Difference between group I and 3 is also statistically significant (p value <0.05). Whereas difference between group 2 and 3 is not Statistically significant (p value >0.05).

Postoperative nausea and vomiting within 24 hours
Postoperative nausea and vomiting occurred within 24 hours in 2 (1 2.5%) patients of tropisetron group. Nine (56.25%) patients in metoclopramide Group and 11(61%) in placebo group. Difference between group 1 and 2 was statistically significant (p value < 0.05).

Table.

Study	Tropisetron (%)	Metoclopramide (%)	Placebo (%)
Yilmazlar	5	50	60
Alon E	35		60
Purhonen	19		57
Capouet	30		44
Naguib M	48	70.8	72.4
Present study	12.5	56.25	61

Difference between group 1 and 3 was also statistically' significant (p value <0.05) but difference

between group 2 and 3 is not statistically significant (p value >0.05).

Need for rescue antiemetic

Two (l2.5%) patients of tropisetron group required rescue antiemetic as compared to 7 (43.75%) in metoclopramide group and 9 (50%) patients in Placebo group. Difference between group 1 and 2 was not statistically significant (p value >0.05) Nor is difference between group 2 and 3 (p value >0.05). But difference between group I and 3 was statistically significant (p value<0.05).

Discussion

Postoperative nausea and vomiting can occur in 40% to just over 70% of patients after general surgical. gynacological[4,7] and orthopaedic[6] operations under general anaesthesia. Various regimes have been tried to reduce the incidences of postoperative nausea and vomiting. Recently, there has been interest in comparing the efficacy of new selective 5-hydroxytryptamine type 3 (5-hT3 receptor antagonist such as tropisetron (4- 12). granisetron[5] and ondansetron[5,7] with placebo alone[6,9] or including a third group of traditional antiemelic such as metoclopramide[5,10]. or droperidol[4] Understandably, these studies were conducted in the west. Most of these studies showed that the incidence of postoperative nausea & vomiting in placebo group was very high ranging from 40% to 72.4%. Use of metoclopramide reduced it by in various studies. However HT3 receptor antagonists such as Tropisetron has been shown to be more effective in controlling postoperative nausea and vomiting than either placebo14 or Metoclopramide. Table shows studies on the effect of metoclopramide and! or tropisetron on postoperative nausea and vomiting.

Another point of debate has been the optimum dose o of Tropisetron As the cost is directly related to the dosage. it is perhaps more important issue in developing world. We know that the dose of Tropisetron required to prevent postoperative nausea & vomiting is smaller than that needed to control cancer chemotherapy induced nausea and vomiting[12], Fortunately it has been shown t hat Tropisetron at a smaller dose of 2 mg. is as effective as higher doses in the prophylaxis of postoperative nausea and vomiting[7,12,13]. Pre operative anxiety, especially in children can predispose to increased incidence of postoperative nausea & vomiting[15].

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