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Research Article

Comparison of Ondensetron and Combination of Ondesetron and Dexamethasone as a Prophylaxis of Post-Operative Nausea and Vomiting in Adults with Laparoscopic Surgeries: A Randomized, Parallel Group, Non Crossover Trial

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ABSTRACT

Introduction: The incidence of Postoperative Nausea and Vomiting (PONV) associated with laparoscopy is very high. With increase in day care surgeries as well as laprascopic techniques, the problem of PONV has grown bigger. There are many classes of drugs, there are very less studies where combination therapy was used. So we intend to try combination therapy with ondensetron and dexamethasone for this problem and compare it with only ondensetron.

Materials and methods: In this randomized, parallel group and Non crossover clinical trial, we studied 50 ASA grade I and II patients of age group 20-45 years undergoing elective laparoscopic surgeries under general anaesthesia.those who met with inclusion criterion, patients were randomized to receive injection ondensetron 4 miligram Intravenous and injection ondensetron 4 miligram and injection dexamethasone 8 miligram .Demographic variables were compared.The incidence of Nausea, vomiting as well as any untoward side effects were compared in both the groups.

Results: A total 50 patients were enrolled in the study. They were randomized in Group A (ondensetron) verses Group B (ondensetron and dexamethasone).Demographic variables were comparable in both the groups. The incidence of nausea was 52% in ondensetron group while it was 20 %in combination group. The incidence of vomiting also was significantly less in combination group with 12%participants experiencing vomiting in Group A while 8%in Group B.There were no side effect observed in any patients related to study medication.

Conclusion: Ondansetron and dexamethasone given intravenously just after intubation is safe and more effective than intravenous ondansetron alone in nausea and vomiting in patients undergoing elective laparoscopic surgeries under general anesthesia.

Keywords: Dexamethasone; Ondensetron; Post-Operative Nausea and Vomiting (PONV)

INTRODUCTION

The most common and distressing symptoms following surgery and anaesthesia are pain followed by nausea and vomiting (PONV). Pain causes suffering and draws first attention. At times nausea and vomiting may be more distressing especially after minor and ambulatory surgery, potentially increasing financial burden [1]. But postoperative pain management has received much more consideration in earlier period than post-operative nausea and vomiting. Incidence of post-operative nausea and vomiting is still very high even though we have lot of newer medications till date. It is in the range of 20-30% in all post-surgical patients and up to 80% in high-risk patients. It has been seen that superior antiemetic effects are possible with the combination of drugs [2,3].

There has been a universal tendency towards a decrease in the incidence and intensity of the problem because there is a rapid change in practice from non-opioid to opioid use, utilization of less emetic anesthetic agents, better medicines, sophistication of operative techniques and identification of patient at risk factors. However in spite of these advances, nausea and vomiting still

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occurs with high incidence in association with surgery and anesthesia.

Persistent nausea and vomiting can have serious medical consequences to the patient as well as financial implication in delayed discharge from the hospital. Now a number of surgical procedures have increased in the field of ambulatory anesthesia, the necessity to find more useful alternatives has become more imperative.

Dexamethasone has been proven effective in reducing PONV in combination with ondansetron [4,5]. A single dose of dexamethasone (4-8 mg IV) is effective for PONV prophylaxis predominantly when it is combined with other antiemetics, though it may not be valuable for treatment. There is no substantiation that a single antiemetic at any dose can achieve more than higher prevention of nausea and vomiting. Therefore various combinations of drugs are indispensable to get an optimal result. There are many causes of PONV and so antagonising only one type of recepter may not be sufficient .It is reasonable to give drugs which have different mechanism of action. New evidence suggests that combination of antemetics act synergistically [6]. So this study was undertaken to compare the efficacy of combination of ondansetron and dexamethasone with ondansetron alone in preventing PONV in laparoscopic surgeries under general anaesthesia.

MATERIAL AND METHODS

This study was undertaken at the prathima institute of medical sciences during the year 2020-2021.The study consisted of 50 adult female patients, posted for elective laparoscopic surgeries. In this randomized, parallel group and Non crossover clinical trial, we studied 50 ASA grade I and II patients of age group 20-45 years undergoing elective laparoscopic surgeries under general anesthesia.

Sample size calculation

With anticipated incidence of PONV in these types of surgeries between 30-80% from previous studies, and considering the anticipated difference of 20% betweeen two groups, with alpha error of 0.05 and power of 80%, the minimum sample size calculated was 28 (14 in each group).

Approval was taken from ethical committee and written informed consent was taken from all patients. They were randomly divided into two groups. Group A and Group B, each consisting of 25 patients. Group A received 4miligrams of Ondansetron intravenous (IV) and group B received 4 miligrams(mg) Ondansetron and 8 miligrams (mg) Dexamethasone intravenous (IV), soon after intubation.The inclusion criteria of the patients were of ASA grade I and II, between 20 to 45 years of age, between 30 to 70 kilogram. The exclusion criteria were

Patients belonging to ASA grade III and IV,Patients who were obese,Pregnant women,Patients with history of motion sickness,Patients who had received antiemetic within 24 hours of surgery,Patients on chronic steroid therapy,Patients suffering from diabetes mellitus, intestinal obstruction and hiatus hernia, renal and hepatic diseases. Preoperative visit was conducted on the previous day of surgery. Detailed history and present complaints were noted. General and systemic examination of cardio vascular, respiratory and central nervous system were done. Routine laboratory investigations were done on all participants.

General anaesthesia with intermittent positive pressure ventilation was planned for all cases.Preoperative blood pressure and pulse rate were recorded in operation theatre after connecting routine monitors. Intravenous cannulation with 18G catheter was established. After 3 minutes of preoxygenation, anaesthesia was induced with 5miligram/kg thiopentone sodium and relaxed with vecuronium 0.1miligrams/kilograms and ventilated with combination of oxygen,Nitrous oxide and isoflurane for 3 minutes and then intubated with 7.5 size cuffed endotracheal tube. Anaesthesia was maintained with O_2 and N_2O at 50:50% with isoflurane 0.5 macs to maintain heart rate and blood pressure near preinduction values.

Group a received 4 milligram of Ondansetron intravenous (IV) and group B received 4 miligram Ondansetron and 8 milligram Dexamethasone intravenous (IV) soon after intubation.Injection Fentanyl was supplemented as needed. Ventilation was controlled. Muscle paralysis was reversed at the end of surgery with 0.05 miligrams per kilogram (mg/kg) neostigmine and 0.015 mg/kg Glycopyrrolate. Diclofenac sodium 75 miligram Intramascular (IM) was given before reversal of neuromuscular blockade for post operation pain. Duration of surgery and anesthesia was noted. Patient was observed for 24 hours post operatively. Nausea, vomiting and pain were recorded hourly for 4 hours and then at the end of 24 hours. Any other complications were also noted. Repeated vomiting within 1-2 minutes period was recorded as single emesis, the data were taken as follows.

Statistical analysis

Incidence of nausea, vomiting, discharge scores side effects and number of patients needing rescue antiemetic and analgesic were compared using 'Chi Square' test. 'p-Value' of <0.05 was considered significant. P-Value of >0.05 was considered insignificant.

RESULTS

Fifty patients were randomized into 2 groups A&B of 25 patients each. The mean age in group A was 28.96 ± 4.25 as against 29.92+4.07 in group B (Table 1). This was found to be statistically insignificant. (P>0.05) .The Mean weight of group A was 49.2+4.1 as against 49.4+3.93 in group B. this was statistically insignificant with a p value of more than 0.05.The Mean duration of surgery was 62.4+20.2 minute in group A as against 63.6+20.94 minute in group B. The Mean duration of anesthesia was 75.2+18.9 minutes in group A as against 76.4+20.02 minutes in group B. The p value was not significant. The Mean duration of CO_2 insufflations during the various procedures was 44.4+16.81 minute in group A compared to 41.6+1638 minute in group B. The p value was more than 0.05.The demographic characters of the participants are mentioned (Tables 1 and 2).

Demographic variable	Group A	Group B	p Value	Significance
Age (mean +sd)	28.96 ± 4.25	29.92 ± 4.07	>0.05	Not significant
Weight (mean+sd)	49.24 ± 4.10	49.4 ± 3.93	>0.05	Not significant
Duration of surgery (mean+sd)	62.4 ± 20.2	63.6 ± 20.94	>0.05	Not significant
Duration of anaesthesia (mean+sd)	75.2 ± 18.9	76.4 ± 20.02	>0.05	Not significant
Duration of co_2 insufflation (mean+sd)	44.4 ± 16.81	41.6 ± 16.38	>0.05	Not significant

Table 1: Demographic characteristics of the participants.

Variable	(n) Number of participants (%) in group A	(n)Number of participants in group B (%)	P value
Mild	13(52%)	5(20%)	0.002
Moderate	2(8%)	0(0%)	-
Severe	0(0%)	0(0%)	-

Table 2: Postoperative nausea scores for the participants.

Incidence of nausea was statistically significant (p<0.05).Thirteen (52%) patients of group A had mild nausea compared to 5 patients (20%) of group B. Two patients of group A had moderate nausea compared to none in group B. None of the patients in both groups had severe nausea (Table 3).

Variable	(n) Number of participants (%) in group A	(n)Number of participants in group B (%)	P value
Mild	3(12%)	2(8%)	0. 0345
Moderate	0(0%)	0(0%)	-
Severe	1(4%)	0(0%)	-

Table 3: Postoperative vomiting score for participants.

In group A 3 patients (12%) compared to 2 patients in group B (8%) had mild vomiting. None of them had moderate vomiting. One patient (4%) in group A had severe vomiting. Difference is not statistically significant.

DISCUSSION

PONV is the most unpleasant experience for a patient undergoing anesthesia and surgery. It is a common sequel of general anesthesia and unanticipated hospital admission after day care surgery. The etiology of nausea and vomiting after laparoscopic surgeries are not fully understood. Risk factors such as a long period of CO2 insufflation, intraoperative use of halothane, fentanyl and glycopyrrolate, female sex and post-operative use of opioids may contribute to these episodes [7,8]. Other factors are intraoperative hypotension, manipulation of abdominal visceras. All these factors were avoided in our study.

Ondansetron is selective 5HT3 receptor antagonist and it has been shown to be effective in the treatment and prevention of PONV in gynecological laparoscopy, laparoscopic cholecystectomy,Since none of the available antiemetics, including ondansetron is entirely effective in all the patients, the concept of combination therapy was introduced. Although role of steroids as antiemetic was established in 1981, dexamethasone was introduced later. The mechanism of action of corticosteroids is unknown but may be related to inhibition of prostaglandin synthesis, decrease in 5HT3 level in CNS and by an anti-inflammatory action at operative site [9,10].

Different studies have been done to control PONV with various combination therapies. In all these studies incidence of nausea has been very variable, probably related to different types of and duration of surgery. In our study mild nausea was observed in 52% of group A patients while 20% of combination group. Moderate nausea was observed in 8% of group A patients while 0%of group B patients. The difference is statistically significant which concludes that combination therapy is more useful. Similarly when we compared vomiting scores in postoperative period, though the incidence of mild nausea was lower in combination group, while incidence of severe nausea was 0% in combination group while it is 4% in single drug group.

Our findings are in agreement with other authors of the similar study [11]. The usefulness of dexamethasone as a cheaper alternative [12] combination drug is also important in the resource limited country like India, where cheaper alternatives are immediately favored. It is necessary to favour the combination therapy which is cheaper, rather than costly medications in Indian scenarios [13].

Adverse effects related to a single dose of dexamethasone are extremely rare. Less than 24 hour of dexamethasone therapy is considered safe and almost without adverse effects. In our study complication due to steroid were not observed in any group.

CONCLUSION

We conclude that ondansetron and dexamethasone given intravenously just after intubation is safe and more effective than intravenous ondansetron alone in early nausea and delayed vomiting and long term prevention of post-operative nausea and vomiting in patients undergoing elective laparoscopic surgeries under general anesthesia.

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