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A RANDOMIZED PROSPECTIVE STUDY OF ONDANSETRON ALONE VERSUS ONDANSETRON-DEXAMETHASONE COMBINATION FOR THE PREVENTION OF POST-OPERATIVE NAUSEA AND VOMITING IN ADULTS UNDERGOING LAPAROSCOPIC SURGERIES UNDER GENERAL ANAESTHESIA

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ABSTRACT

Introduction: Postoperative nausea and vomiting (PONV) are common complications following general anaesthesia, particularly in laparoscopic surgeries. Multimodal antiemetic therapy has been shown to improve outcomes. This study aimed to compare the efficacy of ondansetron alone versus a combination of ondansetron and dexamethasone for prevention of PONV. **Methods:** This single-blinded randomized controlled trial was conducted in a tertiary care centre over two years. Eighty patients undergoing elective laparoscopic surgery were randomized into two groups of 40 each. Group A received intravenous ondansetron (4 mg), while Group B received ondansetron (4 mg) combined with dexamethasone (8 mg) after intubation. Patients were assessed for incidence of nausea, vomiting, postoperative pain, need for rescue antiemetics and analgesics, side effects, and discharge time over 24 hours. **Results:** The combination group demonstrated a statistically significant reduction in early nausea and both early and delayed vomiting compared to the ondansetron-only group. **Conclusion:** The combination of ondansetron and dexamethasone is more effective than ondansetron alone in preventing PONV in patients undergoing laparoscopic surgery, without increasing adverse effects. This supports the use of combination antiemetic prophylaxis in routine clinical practice.

KEYWORDS

Postoperative nausea and vomiting, ondansetron, dexamethasone, laparoscopic surgery, randomized controlled trial

INTRODUCTION

Nausea and vomiting have been associated with the use of general anesthetics for surgical procedures [1]. Despite the rapid progress and better techniques in the field of modern anaesthesia, the incidence of postoperative nausea and vomiting (PONV) remains around 20-30% with laparoscopic surgeries being the second leading cause with an incidence of 50-70% [2,3].

PONV causes significant distress amongst patients. It can lead to tension on the sutures, bleeding under skin flaps and venous hypertension [4]. In addition to dehydration and electrolyte imbalance, it increases the risk of pneumothorax, esophageal rupture, aspiration of vomitus and subcutaneous emphysema [2].

Ondansetron is a 5-Hydroxytryptamine (5-HT3) receptor antagonist that works on peripherally (vagal nerve terminals) and centrally (chemoreceptor trigger zone) located 5-HT3 receptors. They avoid the side-effects caused due to dopaminergic antagonists as well as cholinergic and histaminergic antagonists like sedation, dysphoria and extrapyramidal effects [5,6].

Prostaglandin antagonism (anti-inflammatory and membrane stabilizing) and release of endorphins has been proposed to be the mechanism of action for corticosteroids [7,8]. Dexamethasone is considered to potentiate the effect of other anti-emetics by sensitizing the pharmacological receptors [9], decreasing the levels of 5-hydroxytryptamine in neural tissue [10] and preventing the release of serotonin in the gastrointestinal tract [11].

Among patients undergoing ambulatory laparoscopy, multimodal management with general anaesthesia resulted in a 2% incidence of PONV compared with a 24% incidence after standard anaesthesia with prophylaxis of ondansetron 4 mg, and a 41% incidence after standard anaesthesia without any prophylaxis [12].

In the light of current data, this study was undertaken to assess and compare the efficacy of combination of ondansetron and dexamethasone with ondansetron alone in preventing PONV in laparoscopic surgeries under general anaesthesia.

AIMS AND OBJECTIVES

To compare the efficacy of combination of ondansetron and dexamethasone with ondansetron alone in preventing Postoperative nausea and vomiting in laparoscopic surgeries under general anaesthesia, with respect to:

1. Nausea
2. Vomiting
3. Requirement of rescue antiemetic
4. Pain
5. Requirement of rescue analgesic
6. Side effects
7. Discharge time.

MATERIAL AND METHODS

This prospective randomised single blind control study was undertaken at Department of Anaesthesia of a Tertiary care hospital over a period of 2 years.

In this randomized, single-blinded clinical trial, 80 ASA grade I and II patients of age group 20-65 years undergoing elective laparoscopic surgeries under general anaesthesia were studied. Randomization was carried out using a random number table to assign patients into two groups-A and B with 40 patients each. Group allocation was concealed using sealed opaque envelopes. Group A received 4 mg of ondansetron intravenous (IV) and Group B received 4 mg ondansetron and 8 mg dexamethasone intravenous (IV), soon after intubation.

Approval was taken from ethical committee and written informed consent was taken from all patients.

Inclusion criteria

1. Patients belonging to ASA (American Society of Anaesthesiologists) grade I and II.
2. Patients between 20 to 65 years of age.
3. Patients weighing between 40 to 70 kgs.

Exclusion criteria

1. Pregnant women.
2. Patients with history of motion sickness.
3. Patients on chronic steroid therapy.
4. Patients with diabetes mellitus, intestinal obstruction, hiatus hernia, renal and hepatic diseases.

Anaesthesia

Patients were advised to remain fasting for at least 8 hours before surgery. General anaesthesia with intermittent positive pressure ventilation was given to all patients. After pre-oxygenation, induction was done with 5 mg/kg thiopentone sodium. Muscle relaxant vecuronium 0.1 mg/kg given and patient ventilated with O_2 + N_2O + halothane 1 mac. Intubation done with cuffed endotracheal tube and $ETCO_2$ monitor was connected. Anaesthesia was maintained with O_2 and N_2O at 50:50% with halothane 0.5 mac to maintain HR and BP near pre-induction values. Muscle paralysis was reversed at the end of surgery with 0.05 mg/kg neostigmine and 0.02 mg/kg atropine. Study drugs were injected Intravenous (IV) over a period of 30 seconds just after intubation.

Monitoring

Intraoperative HR, BP, $ETCO_2$ and ECG were monitored continuously. Duration of surgery and anaesthesia was noted.

Patients were monitored for 24 hours post operatively. Nausea, vomiting, and pain observations were recorded. Discharge time from

recovery room to ward and any other complications were noted.

Assessment

- Number of episodes of nausea and vomiting in 24 hours was recorded
- > 2 = Severe. 2 = Moderate < 2 = Mild.
- Rescue antiemetic consisted of 0.15 mg/kg metoclopramide IV and was given for more than 2 episodes of vomiting.
- Pain was measured on an 11-point numerical scale from 0-10
- > 5= Severe 5 = moderate < 5 = mild
- Rescue analgesic consisted of 75 mg diclofenac sodium IM, was given when pain was more than 5 in the scale.

Statistical Analysis

Incidence of nausea, vomiting, pain, 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.

RESULTS

The two groups were well randomized and statistically comparable in terms of age, sex, weight, duration of surgery, anaesthesia and CO2 insufflation. The surgeries carried out included diagnostic laparoscopy, laparoscopic sterilization, laparoscopic appendectomy and laparoscopic cholecystectomy which were similarly distributed in both the groups.

The Mean duration of anaesthesia was 51.9 13.82 minutes in group A as against 53.8 15.41 minutes in group B. The p value was not significant.

Table 1: Comparison of incidence of nausea in both groups

Early Nausea						Delayed Nausea				
	Group A		Group B		P-Value	Group A		Group B		P-Value
	N	%	N	%		N	%	N	%	
Mild	26	65	9	20	< 0.05	11	27.5	3	7.5	> 0.05
Moderate	5	12.5	0	0		6	15	2	5	
Severe	0	0	0	0		0	0	0	0	

Incidence of early nausea was statistically significant (***P*<0.05**).
The difference between the groups for delayed vomiting was not significant (***P*>0.05**).

Table 2- Comparison of incidence of vomiting in both groups

Early Vomiting						Delayed Vomiting				
	Group A		Group B		P- Value	Group A		Group B		P Value
	n	%	n	%		n	%	n	%	
Mild	6	15	4	10	< 0.05	3	7.5	2	5	<0.05
Moderate	0	0	0	0		8	20	0	0	
Severe	2	5	0	0		0	0	0	0	

There was statistically significant difference between the two groups for both early and delayed vomiting (Table 3).

Need for rescue antiemetic was not statistically significant (***P*>0.05**). Eight patients (20%) in group A and four patients (10%) in group B needed rescue antiemetic

Table 3: Incidence of pain in both groups

Early Pain						Delayed Pain				
	Group A		Group B		P- Value	Group A		Group B		P- Value
	n	%	n	%		n	%	n	%	
Mild	24	60	22	55	> 0.05	6	15	4	10	>0.05
Moderate	8	20	6	15		2	5	0	0	
Severe	8	20	8	20		0	0	0	0	

Both early and late post-operative pain was not statistically significant in group A and group B (Table 4).

Nine patients (22.5%) in group A compared to seven patients (17.5%) in group B needed rescue analgesic. This was not statistically significant.

Headache was found to be the most common side effect in both the groups. Six patients (15%) in group A had a mild headache in comparison to four patients (10%) group B. One patient in group A had flushing of face for which no treatment was needed. None had diarrhoea, pruritus or cough. Difference was not statistically significant.

DISCUSSION

PONV is the most unpleasant experience for a patient undergoing anaesthesia and surgery. It is a common sequel of general anaesthesia and unanticipated hospital admission after day care surgery [13].

In this study 65% of patients in group A showed early nausea and 27.5% of patients showed delayed nausea. Postoperative nausea was less in combination group which is comparable to the study of Rajeeva et al [14]. Fewer patients in combination group had late nausea like the finding of Lopez et al [15], where only 7.5% of patients in combination group had delayed nausea as compared with 27.5% in the ondansetron alone group.

In present study incidence of early vomiting in ondansetron group is 20% and delayed vomiting is 27.5%. This is comparable to Rajeeva et al [14], who had 15% early emesis and 35% delayed emesis after ondansetron. In the combination group it was less, 10% (early vomiting) compared to 5% (late vomiting). This is also comparable to the same study [14], but does not agree with Lopez et al [15] where no patient vomited in early period but 4% vomited by 24 hr.

A wide range of dexamethasone (2-16mg) has been used in the management of PONV and emesis related to chemotherapy and after laparoscopic surgeries [16]. Dexamethasone 8 mg was used most widely and was the reason behind selection for the present study.

D'Souza et al [17] found that single dose dexamethasone decreased the incidence of PONV, was safe, had a lesser cost and could be an alternative to single dose ondansetron in gynaecological laparoscopic surgeries.

Bhattarai et al [18] compared use of ondansetron alone with combined use of 4 mg ondansetron plus 8 mg dexamethasone in the control of PONV in patients undergoing laparoscopic surgery and found that the combined use of two agents was more effective. The combination was also safe and well tolerated by the patients.

Peri-operative corticosteroids may be beneficial in controlling postoperative pain by modulating the systemic physiological responses and anti-inflammatory mediators [19]. In present study, a potent opioid (pethidine) was administered as premedication and during intraoperative period. Therefore, the influence of dexamethasone on postoperative pain may have been masked.

CONCLUSION

It has been observed that no single drug has been successful in effectively controlling PONV. This has led to several studies investigating the efficacy of combination of various anti-emetics acting on different receptors can further reduce the incidence of PONV.

In this study we have observed that ondansetron and dexamethasone given intravenously just after intubation is safe and more effective than intravenous ondansetron alone in early nausea, delayed vomiting and long-term prevention of postoperative nausea and vomiting in patients undergoing elective laparoscopic surgeries under general anaesthesia.

LIMITATIONS OF THE STUDY

- Not all laparoscopic surgeries were included in the study.
- The present study did not address the issues of cost of medications and for management of PONV.

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