



COMPARATIVE STUDY OF EFFECT OF DEXAMETHASONE WITH ONDANSETRON V/S DEXAMETHASONE WITH GRANISETRON IN REDUCING POST OP NAUSEA VOMITING INCIDENCE IN LAPAROSCOPIC GYNAECOLOGICAL SURGERY

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Abstract

Background: Post-operative nausea and vomiting (PONV) is generally self-limiting, associated with high level of patient dissatisfaction and may delay hospital discharge. With this issue we aim to compare the effectiveness of dexamethasone with granisetron or ondansetron in patients undergoing laparoscopic gynaecological surgery.

Methods: 144 patients were registered in this prospective, randomized double blind study. Study conducted in Santokba Durlabhji Memorial Hospital, Jaipur, Rajasthan. Group I (n=72) received ondansetron 4 mg intravenously (IV)+dexamethasone 8mg (IV) and Group II (n=72) received granisetron 1 mg IV+dexamethasone 8 mg IV prior to induction. Post-operative data of PONV was recorded at pre-defined intervals. During the study period from February 2018 to July 2020.

Results: The majority of the patients were of the age group 20-35 years. The mean score of Group I subjects was 22.10 ± 1.762 and that of Group II was 22.00 ± 1.601 ($p=0.741$). There are 4.16% of patients in group-I having vomiting episodes, and 2.77% of patients in group-II having vomiting episodes, none of the patients developed 2nd episodes of vomiting in either group. Thus, it appears that dexamethasone in combination with granisetron is more effective in decreasing incidence of PONV than dexamethasone with Ondansetron. Haemodynamic variables showed no significant difference recorded in postoperative care unit between the study groups.

Conclusions: Dexamethasone 8 mg with granisetron 1 mg has more anti emetic efficacy with minimal side effects and excellent patient satisfaction than dexamethasone 8mg with ondansetron 4 mg.

Keywords: General anaesthesia, Laproscopic surgery, post-operative nausea vomiting

INTRODUCTION

Post-operative nausea and vomiting (PONV) can be one of the most distressing corridors of the surgical trip. It affects roughly 20- 30 cases within the first 24- 48 hours post-surgery. The consequences of PONV can include increased anxiety for unborn surgical procedures, improved recovery time and sanitarium stay, and, in severe cases, aspiration pneumonia, metabolic alkalosis, and surgical complications. The etiology of PONV is complex and depends upon a variety of factors, including patient characteristics, types of surgery, anesthetic ways, and postoperative care.[1] circumstance of PONV has dropped significantly from 75 – 80 of the “ether ” period to about 25- 30 of post-surgical cases, where severe and intractable vomiting occurs roughly in 0.18 of this population. [2]

Various factors contribute to the development of PONV like- gender (female > male) ,Age (<50 years), previous history of PONV , history of motion sickness, anxiety, Use of opioid analgesia, and Non-smoker. Surgical factors include Intra-abdominal laparoscopic surgery, Intracranial surgery, middle ear surgery, eye surgery, Gynaecological surgery, especially ovarian, prolong duration of surgery, Poor pain control post-operatively. Anesthetic Factors- Anesthetic analgesia or spinal anesthesia, Inhalational agents (e.g., Isoflurane, nitrous oxide), Since laparoscopic surgery is an egregious threat factor for PONV in cases, the prudent tradition of antiemetics is maintainable and has been described in the literature.[3]

This increased threat of PONV is due to pneumo-peritoneum causing stimulation of mechanoreceptors in the gut. Various antiemetic curatives are being used routinely during intraoperative and postoperative ages, but their use has not fully excluded the prevalence of PONV which still remains a pressing problem in laparoscopic surgeries. The literature revealed PONV as the most inferior symptom after laparoscopic surgeries.[4]

The preface of 5-hydroxy tryptamine receptor antagonists like ondansetron was a major advancement in the treatment of PONV because of lower adverse effects that were observed than generally used traditional anti-emetics. Granisetron, another 5 hydroxy tryptamine receptor antagonists, with a more robust 5HT₃ list, is a more potent and a longer-acting antiemetic agent compared to ondansetron against emesis associated with chemotherapy with lower side effects. [5,6] Dexamethasone is a glucocorticoid that produces a strong antiemetic effect by an undetermined medium. It may act through prostaglandin enmity, serotonin inhibition in the gut, and by releasing endorphins. The precautionary antiemetic effect of dexamethasone is proven in laparoscopic surgery.[7]

None of the presently available antiemetics is able to fully bear the prevalence of PONV. 5 still, the current understanding of threat factors for PONV is deficient, in part because important remains to be illustrated about the pathophysiology of these symptoms, particularly their molecular biology. With this issue, we aim to compare the effectiveness of dexamethasone with granisetron and ondansetron in cases undergoing laparoscopic gynecological surgery.

METHODS

After obtaining institutional ethics review board approval and informed parental consent, this prospective randomized control trial was carried out in Santokba Durlabhji Memorial Hospital, Jaipur (Rajasthan). During the study period from February 2018 to July 2020, 145 cases of laparoscopic gynecological surgery were included for study.

An aggregate of 145 cases is included in this study, between 20- 35 years of age with ASA grade I and II, undergoing laparoscopic gynecological surgery were enrolled. Cases with known allergy or hypersensitivity to the study medicine, history of motion sickness, previous severe PONV, and long-term steroid remedy were barred from the study. Cases having a history of acid peptic complaints, gastrointestinal, liver, or renal conditions, and diabetes mellitus or on any anti-emetic drug within 24 hours before surgery were also barred.

After computer-generated randomization, cases were assigned to either group I (n = 72) who received ondansetron 4 mg intravenously (IV) dexamethasone 8 mg I/ V and group II(n = 72) received granisetron 1 mg IV dexamethasone 8 mg IV. Cases were kept Nil by mouth for 12 hours before surgery. In the preoperative room, an intravenous line was secured. In the operation theatre routine monitoring devices pulse oximetry,non-invasive blood pressure(NIBP), and electrocardiogram(ECG) observers were attached, and baseline blood pressure, heart rate(HR), and O2 saturation values(SpO2) were recorded. later capnography was attached after securing the airway. The study medications were administered before induction of anesthesia in all treatment groups.General anesthesia (GA) was given as per standard protocol to all the enrolled cases in either group. Maintenance of anesthesia was achieved by isoflurane (MAC 1%) and oxygen (60%)air mixture (13). Neuromuscular blockade was reversed at the end of surgery with neostigmine (0.05 mg/ kg) and glycopyrrolate (0.01 mg/ kg) IV. All cases received analgesia in the form of paracetamol 15mg/ kg IV, cases were covered in a post-care unit for any effect at 1 hour, 6, and 24 hours. To assess the severity of PONV the scoring system was evolved which was as follows (No nausea- 0, Nausea only- 1, Nausea with retching-2, Vomiting- 3).6 In case,had an episode of vomiting, rescue medicine was planned, injection of metoclopramide 10 mg IV bolus dose. Symptoms of nausea and retching weren't treated with rescue antiemetic. Nausea and Vomiting assessments were done up to 30 minutes following deliverance of medication administration and the response was defined as enhancement or resolution of PONV symptoms. Complete response was also defined as no emetic symptoms and no need for another deliverance antiemetic medication. The details of any other adverse goods were noted throughout the study after general questioning of the cases by the anesthesiologist.

was analyzed using computer IBM- SPSS Version 25 software for further statistical analysis. The descriptive analysis had done using frequency and proportion, mean, variance, paired t-test, and frequency tables and graphs used for presenting the information. The finding decided to use crude and adjusted or with a 95% confidence interval. Overall frequentness was compared using the Fisher exact test. Adverse goods of study medicines were compared using the ki-square test and Fisher exact test.

RESULTS

Efficacy of dexamethasone with granisetron or ondansetron for prevention of post-operative nausea vomiting in patients undergoing laparoscopic gynaecological surgery was studied in 145 admitted patients. Both the groups were comparable with respect to demographics, ASA Physical status grade, duration of surgery and type of surgery. The majority of the patients were of the age group 20-35 years. The mean score of Group I subjects was 22.10±1.762 and that of Group II was 22.00±1.601. There was no significant association found between both groups (p value=.741) (Table 1).

Table 1: Demographic profile and clinical characteristics of patients in both the group (all values expressed as Mean±Sd or as expressed otherwise).

Paired Samples Test												
			Mean	Std. Deviation	Paired Differences					t	df	Sig. (2-tailed)
					Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
								Lower	Upper			
Pair 1	Age	Group I	22.10	1.762	.097	2.490	.293	-.488	.682	.331	71	.741
		Group II	22.00	1.601								
Pair 2	Weight	Group I	52.10	3.674	1.014	5.207	.614	-.210	2.237	1.652	71	.103
		Group II	51.08	3.356								
Pair 3	ASA Status	Group I	0.17	.375	.069	.513	.060	-.051	.190	1.150	71	.254
		Group II	0.10	.298								
Pair 4	Diagnostic Hysterolaprosopic	Group I	0.68	.470	-.083	.575	.068	-.219	.052	-1.229	71	.223
		Group II	0.76	.428								
Pair 5	Laparoscopic Sterilization	Group I	0.38	.488	.111	.316	.037	.037	.185	2.979	71	.004
		Group II	0.26	.444								

There are 4.16% of patients in group-I having vomiting episodes, and 2.77% of patients in group-II having vomiting episodes, none of the patients developed 2nd episodes of vomiting in either group. Thus, it appears that dexamethasone in combination with ondansetron and granisetron is effective in decreasing the number of episodes of PONV. The occurrence of sickness episodes within 24 hrs of surgery revealed no significant different in both groups ($p>0.05$) (Table 2).

Table 2: Postoperative observation in both groups with Percentages.

		Group I (n 72)	Group II (n 72)	p- Value
Post-Operative Sickness	Nausea	12 (16.66%)	9 (12.5%)	
	Retching	6 (8.33%)	4 (5.55%)	
	Vomiting	3 (4.16%)	2 (2.77%)	
Mean PONV Score (Postoperative Nausea and Vomiting)		0.54 (SD .918)	0.35 (SD .754)	.022
Number of Vomiting Episode	0 Time	69 (95.83%)	70 (97.22%)	
	1 Time	3 (4.16%)	2 (2.77%)	
	2 Times	0	0	
Incidence of Overall Sickness	Nausea (0-1 hrs)	4 (5.55%)	3 (4.16%)	
	Retching (0-1 hrs)	3 (4.16%)	2 (2.77%)	
	Vomiting (0-1 hrs)	2 (2.77%)	1 (1.38%)	
	Nausea (1-6 hrs)	4 (5.55%)	3 (4.16%)	
	Retching (1-6 hrs)	2 (2.77%)	2 (2.77%)	
	Vomiting (1-6 hrs)	1 (1.38%)	1 (1.38%)	
	Nausea (6-24 hrs)	4 (5.55%)	3 (4.16%)	
	Retching (6-24 hrs)	1 (1.38%)	0	
	Vomiting (6-24 hrs)	0	0	

Systolic blood pressure (SBP), diastolic blood pressure (DBP), Heart rate (HR) and Oxygen saturation (SpO2) in post operative period after 10 min. and 30 min. showed no statistically significant difference recorded in postoperative care unit between the study groups (Table 3).

Table 3: Patients haemodynamic parameters at different time interval in post-operative period.

SBP-Systolic blood pressure 10 Min	Group-I (O+D)	122.5±13.3	0.3
	GROUP-II (G+D)	120.1±12.4	
DBP-Disystolic blood Pressure 10 Min	Group-I (O+D)	77.8±8.6	0.3
	GROUP-II (G+D)	76.2±8.9	
HR-Heart rate 10 Min	Group-I (O+D)	76.43±8.04	0.37
	GROUP-II (G+D)	77.7±7.9	
SpO2-Oxygen saturation 10 Min	Group-I (O+D)	99.2±0.5	0.09
	GROUP-II (G+D)	99.3±0.6	
SBP-Systolic blood pressure 30 Min	Group-I (O+D)	115.7±10.9	0.93
	GROUP-II (G+D)	115.9±10.9	
DBP-Disystolic blood Pressure 30 Min	Group-I (O+D)	72.33±6.8	1
	GROUP-II (G+D)	72.3±6.8	
HR-Heart rate 30 Min	Group-I (O+D)	76.1±7.05	0.73
	GROUP-II (G+D)	76.5±7.1	
SpO2-Oxygen saturation 30 Min	Group-I (O+D)	99.2±0.5	0.86
	GROUP-II (G+D)	99.2±0.5	

The incidences of post-operative adverse effects were noted in both study groups. In group - I, 19 (26.38%) patients had headache, 19 (26.38%) constipation and abdominal distress, 12 (16.66%)

dizziness, 14 (19.44%) sedation, and 10 (13.88%) facial flushing. In group-II, 21 (29.16%) patients had headache, 18 (25%) constipation and abdominal distress, 15 (20.83%) dizziness, 12 (16.66%) sedation, and 9 (12.5%) facial flushing. None of the antiemetic in our study leads to any significant hemodynamic changes or serious adverse effects. The most common complaint was headache 40 (27.77%) and abdomen pain 37 (25.69%) in both groups.

DISCUSSION

In the present study, the factors that would have contributed to PONV may be pneumoperitoneum, use of inhalational medications, use of fentanyl, or use of nitrous oxide. In present study, cases aged 20- 35 years with a BMI of <35 kg/ m² were included. Young age, obese cases in laparoscopic surgeries were included because a study done by Pearman et al showed that PONV is more common among the young age group and obese cases.[8] Laparoscopic surgery was chosen because of the high prevalence of PONV associated with it. However, the incidence rate of PONV after laparoscopic cholecystectomy is higher than that after other types of surgery. [9,10,11]

In the study, frequency of PONV was reported maximum in the first 12 hours and there were no differences in prevalence in the later 12 hours. Vishal et al demonstrated in their study that the frequency of PONV was minimal in the first 12 hours and there were no statistical differences in the later 12 hours in study groups.[12] Kim et al. In their study found not statistically significant difference between the two methods of anesthesia, despite the lower VAS range in cases undergoing intravenous anesthesia.[13] Indeed Visser et al. In their study found no difference between intravenous and inhalational anesthesia in terms of the prevalence of PONV and the need for antiemetic drug is not significant.[14]

Raphael et al. observed that after 6 hours of surgery, 2 mg of granisetron is more effective than 4 mg of ondansetron for precluding PONV.[15] The effect of an 8 mg oral disintegrating tablet is equivalent to a 4 mg IV dose. [16,17] It's less effective than aprepitant for reducing emesis and palonosetron for the prevalence of PONV. [18,19] 4 mg ondansetron and 1 mg granisetron dose with 8 mg dexamethasone was used to help PONV and found granisetron plus dexamethasone is more effective compared to ondansetron plus dexamethasone but not any statistically significant difference. Chidambaram et al. concluded that the prophylactic IV administration of granisetron is more effective than ondansetron for controlling PONV with fewer frequent side effects.[20] According to Shirin Salajegheh et al. in their study they found that Granisetron is more effective in preventing PONV during 6 hours after the surgery in comparison with Ondansetron which makes it a favourable alternative for preventing PONV. [21,22]

Pearman concluded in their study they found no differences between treatment groups with respect to vital signs, laboratory values, or adverse events and concluded that intravenous ondansetron is safe and effective at preventing PONV in male and female cases undergoing day-case surgery.8 Aspinall and Goodman have suggested that if active drugs are available, placebo controlled trials may be unethical because PONV episodes are highly distressing after laparoscopic surgery.[23] Yap JC et al. Study found Pharmacological prophylaxis can result in hypertension and tachycardia.[24] Gigilla reported some hemodynamic variation in SBP, DBP, and HR. Ondansetron-mediated bradycardia and hypotension were reported in his study group.[25] Trabelsi et al.[26] In comparison to the control group, they found that patients who took ondansetron (5 mg) had higher SBP, DBP, and MAP. The current study shows no statistically significant difference in the baseline values of hemodynamic variables between the two groups before, during, or after giving study medicine.

Study concluded that dexamethasone 8 mg with either granisetron 1 mg is more effective antiemetic drugs to reduce PONV as compared to dexamethasone 8mg with Ondansetron 4mg with overall minimum side effects and excellent patient satisfaction.

LIMITATION -

The present study results, " Effect of ondansetron in patients undergoing laparoscopic gynecological surgery," were statistical, and it's a short-term and area-based study to study the long-term effects of post-operative nausea and vomiting (PONV) after laparoscopic gynecological surgery to obtain results for a more extended population.

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Conflict of Interest- The authors declare that they need no conflict of interest.

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