



Anesthesiology

DEXAMETHASONE VERSUS ONDANSETRON IN THE PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING IN PATIENTS UNDERGOING ABDOMINAL SURGERY UNDER SPINAL ANAESTHESIA: A RANDOMIZED CONTROLLED TRIAL

Harshitha Tayi

Post graduate, Department of Anaesthesia, Yenepoya Medical College,

Syed Mohamed Shimar

Assistant professor, Department of Anaesthesia, Yenepoya Medical College, Mangaluru

ABSTRACT

Postoperative nausea and vomiting (PONV) is a common distressing symptom in patients undergoing elective abdominal surgeries. Reduction of incidence of PONV, by utilizing various antiemetic interventions, has been shown to improve patient satisfaction and reduce the time to recovery and discharge. **METHODS:** A Randomized control study was conducted in Yenepoya Medical College Hospital from October 2018 – November 2018. The study was conducted among 148 patients admitted for abdominal surgeries in the Yenepoya Medical College Hospital for period of one month. Before administering ondansetron or dexamethasone, blood pressure and heart rate of the patients were recorded. The patients received 70 mg of 5% lidocaine for spinal anaesthesia. Patients who received 4 mg of ondansetron were considered as group O, while group D received 8 mg of dexamethasone. The level of nausea and vomiting, blood pressure, heart rate and respiratory rate of each patient was measured at 1, 5, 10, 15 and 30 minutes after spinal anaesthesia. **RESULTS:** There was a significant difference between nausea and vomiting between the two groups of ondansetron and dexamethasone after spinal anaesthesia within the first and fifth minutes ($p < 0.05$). There was no significant difference between nausea and vomiting between the two groups within 10, 15 and 30 minutes. There was no statistically significant difference between the mean levels of heart rate, systolic and diastolic blood pressures, respiration and oxygen saturation among both groups of ondansetron and dexamethasone. **CONCLUSION:** Dexamethasone and ondansetron were equally effectively reducing the incidence of nausea and vomiting under spinal anaesthesia and can be recommended for prevention of nausea and vomiting during surgeries using spinal anaesthesia

KEYWORDS :**INTRODUCTION/BACKGROUND:**

Postoperative nausea and vomiting (PONV) is a common distressing symptom in patients undergoing elective abdominal surgeries and can contribute to anxiety, dehydration, meta-bolic abnormality, wound disruption, delayed recovery and other issues. It can also increase the risk of aspiration, wound dehiscence and prolonged wound bleeding [1]. The incidence of PONV varies from 20 to 80 %, and it is an economic and social burden. Reduction of incidence of PONV, by utilizing various antiemetic interventions, has been shown to improve patient satisfaction and reduce the time to recovery and discharge [2]. Ondansetron is a selective 5-HT₃ receptor antagonist, that exhibits an anti-emetic action by antagonizing vomiting signals in the afferent pathway from the stomach or small intestine and solitary tract nucleus, and is effective at preventing PONV. The optimum prophylactic dose of ondansetron alone appears to be 4–8 mg [3, 4], however the high cost of this drug has prevented it from being widely used. Dexamethasone, a corticosteroid, was first reported as an effective anti-emetic agent in patients undergoing cancer chemotherapy in 1981. The optimum prophylactic dose of ondansetron alone appears to be 8 to 10mg [5, 6]. Wang et al. [7] confirmed that dexamethasone is most effective when it is compared with ondansetron. However, the mechanism underlying the anti-emetic effects of dexamethasone is still unknown. It may be involved in central inhibition of prostaglandin synthesis, or it may cause a decrease in serotonin turnover in the central nervous system [6, 8, and 9].

MATERIALS AND METHODS:

Study Area: A Randomized control study was conducted in Yenepoya Medical College Hospital from October 2018 – November 2018. The study was conducted among patients admitted for abdominal surgeries in the Yenepoya Medical College Hospital for period of one month.

The sample size estimated by using the formula $n = n = Z^2 * P * Q / (P - P)^2$ was 147. Sample size was calculated by using the Proportion formula and Incidence of PONV was taken from the study “The Effect of Ondansetron and Dexamethasone on Nausea and Vomiting under Spinal Anaesthesia”

Simple random sampling method was adopted to select the study participants. Inclusion criteria was all abdominal surgeries cases from November will be included for the study. Exclusion criteria was patient who were using of drugs having antiemetic like steroids, opioid tolerance, hypertensive, diabetes and Patient who are contraindicated to nonsteroidal anti-inflammatory drugs.

After the approval of the project, patient admitted for abdominal surgeries in the Yenepoya Medical College Hospital will be requested to participate in the study from November 2018 – December 2018.

Based on a computer-generated random number sequence, stratified for history of motion sickness or PONV, patients were allocated using sealed opaque envelopes to one of two groups: dexamethasone 8 mg and ondansetron 4 mg (Group O/D). On arrival in the operating room, routine monitoring devices were placed, and baseline blood pressure, heart rate and pulse oximetry values will be recorded. We will give spinal anaesthesia with 0.5% bupivacaine. Identical syringes containing each treatment regimen will be diluted with normal saline to make a volume of 5 ml by a personnel not involved in the study. Drug preparations were administered IV just immediately after giving spinal anaesthesia.

The levels of nausea and vomiting, blood pressure, heart rate and respiratory rate of each patient were measured at 1, 5, 10, 15 and 30 minutes after spinal anaesthesia and While they were in the post anaesthesia care unit (until 6 hrs after operation) and in the ward (12 and 24 hrs post operation) the occurrence of PONV was recorded using the following numeric scale based on the patients' complaints:

- 0 = no nausea or vomiting
- 1 = nausea only
- 2 = nausea and vomiting

All observations were recorded by direct questioning (with only two possible answers of yes/no) by trained principal investigators. The primary end point was a “complete response”, defined as no episode of PONV during the first 24 hrs after recovery from anaesthesia. Nausea was defined as the subjectively unpleasant sensation associated with an awareness of the urge to vomit. Vomiting was defined as the forceful expulsion of gastric contents from the mouth. Retching was defined as the laboured, spasmic, rhythmic contraction of the respiratory muscles without the expulsion of gastric content⁷. Retching was not assessed as a separate entity and was classified under vomiting.

Study Analysis: Data was analysed using Statistical package for social sciences (SPSS) – 22. Descriptive analysis will be reported as frequencies, percentages, ranges, mean and standard deviation (SD). Comparisons of incidence of PONV and need for a rescue antiemetic between groups were performed for overall study period and at different time intervals. Statistical analyses of data among the treatment groups were performed by one-way analysis of variance

with Bonferroni correction for multiple comparisons, chi-squared test, or Fisher's exact probability test, as appropriate. A p value of less than 0.05 will be considered significant.

RESULTS:

Table 1 shows that there was a significant difference between nausea and vomiting between the two groups of ondansetron and dexamethasone after spinal anaesthesia within the first and fifth minutes (p<0.05, Table 1). During 1, 5, 10, 15 and 30 after spinal anaesthesia, 8(10.81%), 10(13.51%), 4 (5.4%), 11(14.8%)and 4 patients (5.4%) in the dexamethasone group experienced nausea and vomiting, respectively, while these figures ondansetron group experiencing nausea and vomiting were1(1.3%), 2(2.7%), 8(10.81%) ,5(6.7%)and 12 patients (16.2%), respectively.

Table 1: The frequency of nausea and vomiting in two ondansetron and dexamethasone groups at 1, 5, 10, 15 and 30 minutes after spinal anaesthesia

Minute	Group	Nausea and vomiting		p value
		Yes	No	
1 minute	Ondansetron	1(1.3%)	73(98.7%)	0.027
	Dexamethasone	8(10.81%)	66(89.19%)	
5 minute	Ondansetron	2(2.7%)	72(97.3%)	0.007
	Dexamethasone	10(13.51%)	64(86.49%)	
10 minute	Ondansetron	8(10.81%)	66(89.19%)	0.284
	Dexamethasone	4(5.4%)	70(94.6%)	
15 minute	Ondansetron	5(6.7%)	69(93.3%)	0.162
	Dexamethasone	11(14.86%)	63(94.14%)	
30 minute	Ondansetron	12(16.21%)	62(84.79%)	0.050
	Dexamethasone	4(5.4%)	70(94.6%)	

Table 2: Ondansetron and dexamethasone vital signs in both groups during recovery and after spinal anaesthesia

Haemodynamic parameters	Group		p value
	Ondansetron	Dexamethasone	
Heart Rate	70.46±4.82	71.24±4.76	0.065
Systolic blood pressure	128.82±4.92	126.40±5.08	0.072
Diastolic blood pressure	78.42±3.62	78.74±3.62	0.07
Respiration	12±2.4	12±2.1	0.21
Oxygen saturation	94%±3	95±3.2	0.31

Table 2 shows that there was no statistically significant difference between the mean levels of heart rate, systolic and diastolic blood pressures, respiration and oxygen saturation among both groups of ondansetron and dexamethasone during the recovery and after spinal anaesthesia (p>0.05, Table 2). None of the patients in both groups had dysrhythmia or bradycardia. A total of 12(16.21%) patients in both groups had systolic hypotension. 5(6.7%) patients in the two groups experienced diastolic hypotension. None of the patients in the two groups experienced increase in respiratory rate, oxygen saturation drop and oxygen desaturation drop after spinal anaesthesia.

DISCUSSION

The main endpoint of our study, i.e., PONV among patients who received dexamethasone, was compared with the ondansetron. The obtained result in the current study was in line with the majority of the other studies that have confirmed the effectiveness of dexamethasone and ondansetron after different surgeries.

Navid Kalani et al10. study showed that significant difference between nausea and vomiting between the 6mg of ondansetron and 8mg of dexamethasone groups after spinal anaesthesia within the first and fifth minutes. There was no significant difference between nausea and vomiting between the two groups within 10, 15 and 30 minutes and during recovery at 5, 10, 15 and 30 minutes.

In this study, a dose of 4 mg of ondansetron was chosen because is as effective in the prevention and treatment of nausea and vomiting after

surgery similar to the higher dose. Moreover, there will not be any side effects at this dosage. Contrary to our study Pearman et al.16 suggested that the effect of 6 mg ondansetron might be more effective than 4 mg ondansetron in pregnant women who are more prone to nausea and vomiting. Borgeat et al17. found out the direct therapeutic and anti-nausea effect of sub-hypnotic doses of propofol in gynaecological, gastroenterological and orthopaedic surgeries.

In this study, a dose of 8 mg of dexamethasone was chosen because is as effective in the prevention and treatment of nausea and vomiting after surgery similar to the higher dose. Prabha Parthasarathy et al9 also suggested that 8mg of dexamethasone is efficient in reducing postoperative pain, requirement of rescue analgesia on the first postoperative day, and incidence of PONV with no significant changes in vital signs.

CONCLUSION

Dexamethasone and ondansetron were equally effectively reducing the incidence of nausea and vomiting under spinal anaesthesia and can be recommended for prevention of nausea and vomiting during surgeries using spinal anaesthesia.

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