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A Comparative study of Efficacy, Tolerability, and Safety of Ondansetron and Metoclopramide for Postoperative Nausea and Vomiting in Elective Lower Segment Cesarean Section

Joginipally Ashwin
Associate Professor, Department of Anesthesia, Prathima Institute of Medical Sciences, Naganoor, Karimnagar.

Abstract

Background: *Postoperative nausea and vomiting are some of the important post-surgical complications. Its adequate management is necessary because it may be distressing for both patients as well as the doctor. Therefore, the use of antiemetic agents is crucial during the post-operative period to prevent PONV. We in this study tried to compare the efficacy of prophylactic metoclopramide and ondansetron in Elective LSCS patients given spinal anesthesia.* ***Methods****: Present study was conducted in the Department of General Anesthesia, Prathima Institute of Medical Sciences, Karimnagar. Inclusion criteria were patients with ASA I and II grade undergoing elective LSCS who were willing to participate in the study. A total of n=50 patients divided randomly into two groups of n=25 each was done. Group I (metoclopramide) received 10mg I.V. 3-5min before surgery. In second Group II (Ondansetron) were randomly received ondansetron 4mg I.V. 3-5min before surgery. The patients were evaluated for episodes of nausea vomiting during the 1st, 2nd, 6th and 24 hours post-surgery other parameters were also monitored. Results: The incidence of PONV was found in 80% of group I patients and 40% of patients in Group II. Episodes of retching were found in 20% of group I and 4% of group II. The p values, however, found significant only during the 2nd hour between the two groups. The incidence of adverse reactions was minimal in both the groups with the group I having one patient with an episode of feeling drowsy or tiredness and one patient with tremors or shaking in arms and legs (Extrapyramidal symptoms). In group II one patient showed the presence of headache. In both, the groups the symptoms were self-limiting and managed adequately.* ***Conclusions:*** *As far as the efficacy and tolerability of ondansetron and metoclopramide are concerned, Ondansetron 4mg IV is found to be more efficacious than metoclopramide 10mg I.V. The episodes of PONV were lesser in Ondansetron group. Hence ondansetron must be considered for the management of PONV in elective LSCS if no other contraindication exists in patients.*

Keywords*: LSCS Metoclopramide Ondansetron, Postoperative nausea and vomiting [PONV], Spinal Anesthesia.*

Address for correspondence: Dr. Joginipally Ashwin, H. No. 2-10-1952, Bhagyanagar, Karimnagar-505001 Telangana State. Email: ashwinj0281@gmail.com
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Introduction

The common and troublesome symptom which follows anesthesia and surgery includes pain, nausea, and vomiting. Some studies have indicated that the incidence of postoperative nausea and vomiting (PONV) may be as high as 75-80% [1]. Despite advances in medicine and lesser of emetic anesthetics, the prediction of PONV is difficult. The etiology appears to be multifactorial and complicated [2]. The incidence of PONV is generally greater in females undergoing LSCS under spinal anesthesia. Anesthetics tend to reduce gastric motility the delay or stasis leads to the accumulation of fluid secretions and also facilitates the reflux of bile into the stomach causing accumulation of gas (anesthetic, air swallowed before surgery).

This leads to the activation of GI visceral afferents leads to nausea and vomiting [3]. PONV can cause complications like wound dehiscence, pulmonary aspiration, wound bleeding, dehydration and electrolyte disturbances. It can result in an increased stay in hospital and treatment costs [2]. Therefore, its management is necessary for the overall outcome of treatment. The use of antiemetic drugs is one of the methods by which the incidences of PONV are reduced. Ondansetron is a highly selective antagonist of 5-HT3 receptors. 5-HT3 receptors are located at the highest densities in the area postrema, Nucleus Tractus solitarius (NTS), in other areas of the brain, and on afferent terminals of the vagus nerve. Ondansetron blocks nausea and vomiting by antagonizing the activity at postrema/NTs and peripherally by the vagus nerve terminals [4]. Metoclopramide is a D2 receptor antagonist it acts as an antiemetic by acting on CTZ by blocking the D2 receptors. It increases gastric peristalsis and relaxes the pylorus in the first part of the duodenum. It increases the speed of gastric emptying. The action is independent of vagal innervations however; it is stronger when the vagus is intact. It has also been used intravenously to control nausea and vomiting of intensive cancer chemotherapy, such as with cisplatin [5]. With this background, we in the present study tried to evaluate the efficacy, tolerability and safety of Ondansetron 4mg IV with metoclopramide 10mg IV in female patients undergoing Elective LSCS in our tertiary care hospital.

Materials and Methods

The present study was undertaken in Prathima Institute of Medical Sciences, Naganoor, Karimnagar. Institutional Ethical committee permission was obtained as per the protocol. Written consent was obtained from all the participants of the study. A total of n=50 patients above 20 years undergoing elective LSCS under spinal anesthesia belonging to ASA grade I and II categories were included. Exclusion criteria were Patients with renal impairment, Hepatic disease, Neurological and Endocrinal Abnormalities were excluded. Patients with a history of PONV in previous surgery and patients with a history of motion sickness were excluded. Patients with a history of vomiting and/or Ryle's tube in situ in the last 24 hours were excluded. They were randomly allotted into two groups Group-I the group which received, IV Metoclopramide 10 mg, Group-II the group which received IV Ondansetron 4 mg. A pre-operative evaluation was conducted a day before surgery. A detailed history of patients was noted and general and systemic examination was done. Laboratory investigations were performed which included CBP, BT and CT, LFT, RFT, Fasting Blood sugar and ECG were done. The patients were kept NBM for 8 hours before the commencement of surgery. The patient was brought to OT, her pulse and BP were recorded. IV access with 18G cannula was done and in n=25 patients of group I Inj. Metoclopramide 10mg IV and n=25 patients of group II received 4 mg Inj. Ondansetron IV 3-5 minutes before the subarachnoid block. Pulse, BP and any side effects of the drug, given was noted. A preloading infusion of dextrose saline 500ml was given. Subarachnoid block was performed in a left lateral position using 25 G spinal needle at L3-L4 or L2-L3 interspace a 0.5% Bupivacaine 2ml was given. Following injection, the patient was immediately brought on supine position and the time of onset of action to the level of T4 level was noted using the pinprick method. The desired operative position was given after 5 minutes. Duration of surgery was noted and the patients were observed for 24 hours postoperatively. Nausea, retching, and emesis were recorded at 1 hour, 2 hours, 6 hours and 24 hours respectively. The number of episodes of emesis and type was recorded. Repeated vomiting within 1-2 minute period was recorded as a single emesis. Any side effects appreciated were also recorded. The results were tabulated at 1hr, 2hr, 6hr and 24hours post-operatively.

Results

The study was conducted in n=50 patients undergoing elective LSCS under spinal anesthesia. They were allotted randomly into two groups. Group I received IV Metoclopramide 10 mg and Group II received IV Ondansetron 4mg. The most common age group was 26-30 years with n=9(36%) patients

included in group I and n=11(44%) were present in group II.

The mean age in group 1 was 29.5 years and in group II 28.0 years. The age group 21- 25 years had n=8(32%) in group I and n=6(24%) in group II. The other details are given in table 1.

Table 1: **Demographic profile of the patients**

Age group	Group I (Metoclopramide)		Group II (Ondensetron)	
	Number of patients	%	Number of patients	%
21 – 25	8	32	6	24
26 – 30	9	36	11	44
31 – 35	6	24	5	20
> 35	2	8	3	12
Total	25	100	25	100

The comparison of mean parameters between the two groups including the height, weight, gestational age in weeks, Gravidity and duration of surgery were recorded. There was no significant difference between the two groups regarding the mentioned parameters. The details are shown in table 2. The vital parameters were recorded before the beginning of surgery. There was no significant difference between the vital parameters in both the groups before surgery shown in table 3.

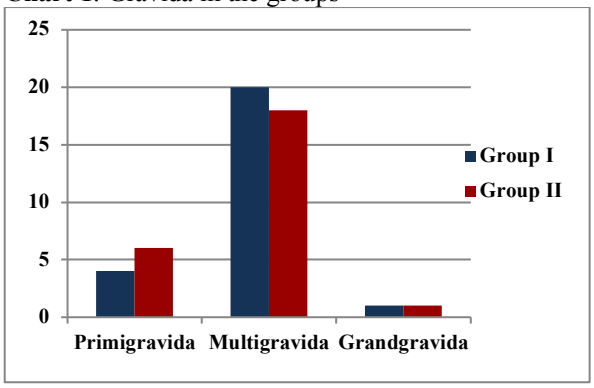
Table 2: **Mean parameters**

Parameter		Group I	Group II	*p* Values
Height (cms)	Mean	152.5	151.9	0.23
	SD	3.5	2.9	
Weight (Kgs)	Mean	56.65	55.06	0.88
	SD	5.5	6.10	
Gestational age (weeks)	Mean	37.5	38.0	0.112
	SD	1.5	1.1	
Gravidity	Mean	2.0	1.8	0.336
	SD	1.22	1.41	
Duration of Surgery	Mean	50.1	48.5	0.189
	SD	5.5	6.5	

Table 3: Vital parameters

Vital parameters	Mean ± SD	Group I	Group II	*p* Values
Respiratory Rate	Mean	19.5	18.0	1.22
	SD	1.5	2.0	
SBP (mmHg)	Mean	111.5	115.5	0.652
	SD	2.6	1.5	
DBP (mmHg)	Mean	78.5	79.0	1.1
	SD	2.5	3.0	

Chart 1: Gravida in the groups



The episodes of emesis were recorded at various intervals in group I during the first hour n=6(24%) patients had emesis and in group II n=2(8%) had emesis episodes. The p values were not significant. At the end of 2nd hour the number of patients with emesis episodes in group I was n=3(12%) and n=1(4%). The p values were found to be significant. No values were further found to be significant between the two groups at the end of 6 hours, 12 hours and 24 hours shown in table 4.

Table 4: **Episodes of emesis**

Emesis Episodes	Group I		Group II		*p* Value
	Number	%	Number	%	
1 hour	6	24	2	8	0.87
2 hours	3	12	1	4	0.043*
6 hours	2	8	1	4	1.3
12 hours	1	4	0	0	1.8
24 hours	0	0	0	0	0.0

The incidence of nausea and grading was done in both the groups the scores of 1= Mild, 3= Moderate, 3= Severe were given and it has been found that in the group I the number of episodes of nausea at the end of 1st hour was found in n=15(60%) of patients and in group II the number of episodes were much less n=6(24%). The p values were found to be <0.02 hence found to be significant. The other details have been shown in table 5.

Table 5: **Episodes of Nausea**

Nausea Episodes	Group I		Group II		*p*Value
	Number	%	Number	%	
1 hour	15	60	6	24	0.023*
2 hours	7	28	3	12	0.995
6 hours	2	8	1	4	1.1
12 hours	1	4	0	0	1.5
24 hours	0	0	0	0	0.0

Retching is defined as dry heaves; they were also recorded as the number of episodes. The total number of retching in 5 minutes was taken as one episode. The numbers of episodes in group 1 were generally found to be greater as compared to group II however none of the values were found to be significant.

Table 6: **Episodes of Retching**

Retching Episodes	Group I		Group II		*p*-Value
	Number	%	Number	%	
1 hour	3	12	2	8	1.14
2 hours	4	16	1	4	1.8
6 hours	1	4	0	0	0.99
12 hours	0	0	0	0	0.0
24 hours	0	0	0	0	0.0

The incidence of adverse reactions was minimal in both the groups with the group I having one patient with an episode of feeling drowsy or tiredness and one patient with tremors or shaking in arms and legs (Extrapyramidal symptoms) the patient was treated with IV diazepam. In group II one patient showed the presence of headache the symptoms were self-limiting and managed adequately.

Discussion

Postoperative nausea and vomiting [PONV] is a well-recognized outcome of patients undergoing surgical procedures under anesthesia. Although rare, postoperative vomiting can result in life-threatening complications like aspiration pneumonia. In the subarachnoid block for LSCS hypotension, manipulation of abdominal viscera and hormonal influences are strong emetic stimuli. Pain, anxiety, and usage of drugs such as opioids, NSAIDs have also been implicated in postoperative nausea and vomiting [6]. Many antiemetic agents have been in use for the treatment of PONV such as Metoclopramide, Domperidone, Phenothiazines, Butyrophenones, Anticholinergics, and Antihistiminics. Ondansetron is a newer drug that is the 5-HT3 antagonist. It was evident that Ondansetron was highly or equally effective in preventing PONV in some studies [6, 7]. The average age in the present study was in the group I was 29.5 years and 28.0 years in group II. A study by Burtles R et al;[8] found a correlation between an increase in age and a decrease in episodes of emesis. In this study also we found increased PONVincidence in younger patients of both the groups. Obesity is one of the factors for the increased incidence of PONV. In this study we found the mean weight in group I was 56.65 Kgs and group II was 55.06 Kgs. It was observed that the increased body was correlated with a greater incidence of PONV. A study by McKenzie R et al; [9] found a higher percentage of patients with emetic episodes in higher-weight patients. In this study, we found 76% of patients were emesis episodes free in the metoclopramide group whereas in the ondansetron group 92% were emesis free in the first hour. In the second-hour emesis free episodes in the metoclopramide group were 88% and ondansetron group it was 94%. A study by Rabey PG et al; [10] found that the prophylactic efficacy of Ondansetron with droperidol and metoclopramide in patients undergoing D&C under general anesthesia the incidence of vomiting was 13% with ondansetron, 45% with droperidol and 54% with metoclopramide. The episodes of retching were observed separately from vomiting. The incidence of retching was comparatively lesser in the ondansetron group as compared to the metoclopramide group. The episodes of retching in the first hour in the ondansetron group were 12% compared to the ondansetron group 8% the values were not found to be significant. The nausea control in the metoclopramide group in the first-hour post-surgery was present in 40% of the patients and the Ondansetron group was 76% the p values were <0.05 hence considered significant. Pan PH et al; [11] compared the effect of ondansetron 4mg IV versus metoclopramide 10mg IV for PONV for patients undergoing LSCS. Cumulative nausea and vomiting scores in patients for 24 hours found that the incidence of PONV was lesser in the ondansetron group as compared to the metoclopramide group.

The results of the study are in agreement with the results of the current study. The safety profiles of both the drugs in the study were observed because it should not compromise the patient's condition due to adverse effects. In the current study, we found low incidences of adverse effects in metoclopramide group 2 patients were showing adverse effects. One patient was feeling drowsy excessively and one patient was shaking in arms and legs (Extrapyramidal symptoms) the patient was treated with IV diazepam.

In the ondansetron group, one patent complained of headache which was managed adequately. Dupreyron JP et al; [12] in their study found a low incidence of adverse effects with ondansetron with headache and constipation being the most common side effects. Scuderi P et al; [13] found no side effects with ondansetron in their study. Similarly, the other studies in this field have also reported a low incidence of adverse reactions [6, 7, 14].

Conclusion

As far as the efficacy and tolerability ofondansetron and metoclopramide are concerned, Ondansetron 4mg IV is found to be more efficacious than metoclopramide 10mg I.V. The episodes of PONV were lesser in Ondansetron group. The incidence of adverse reactions was also lesser in both groups. Hence ondansetron must be considered for the management of PONV in elective LSCS if no other contraindication exists in patients.

Conflict of Interest: *None declared*
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