ISSN: 0975-1556

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2021; 13(5); 208-214

Original Research Article

Comparison of Ondansetron and Metoclopramide for Prevention of Nausea and Vomiting in Elective LSCS under Spinal Anaesthesia

Amol Hendre[1], Rameshwar Bhale[2*]

Assistant Professor, Department of Anaesthesiology Vedantaa Institute of Medical Sciences, Dahanu Road, Palghar

Received: 10-05-2021 / Revised: 04-06-2021 / Accepted: 14-08-2021
***Corresponding author: Dr Rameshwar Bhale**
Conflict of interest: Nil

Abstract

Background: Post operative Nausea Vomiting (PONV) is the most unpleasant and distressing consequence in the immediate post operative period. The problem of PONV has become challenging through appear small problem, tough to control postoperatively. Many drugs have been tried as prophylaxis and treatment of PONV, no drug has been proved significantly effective and hence, the present study was undertaken to compare the efficacy and safety of IV Metoclopramide and IV Ondansetron as prophylaxis for postoperative nausea and vomiting in lower-segment caesarean section (LSCS) under spinal anaesthesia. **Materials:** After institutional approval and informed consent 100 ASA I & II patients undergoing non emergent LSCS taken for study. The patients were divided randomly into 2 groups of 50 each. Group I received IV Metoclopramide 10mg and Group II received IV. Ondansetron 4mg. Anaesthetic management was standardised. The incidence of vomiting and retching as number of episodes was studied. Nausea was graded depending on the severity and data derived. **Results:** The mean age, weight and duration of surgery was not significantly different when compared group-1 parturients with group-2. The mean episodes of emesis, nausea and retching at different postoperative duration were significantly decreased in Ondansetron group when compared to metoclopramide group as postoperative time progresses. **Conclusions :** Injection ondansetron 4mg provided decrease in the incidence of PONV than Metoclopramide as the side effects with these drugs were minimal.

Keywords: PONV, Antiemetic drugs, Metoclopramide, Ondansetron.

Introduction

Nausea and vomiting are the most common side effects in the post- anaesthesia care unit. But post operative nausea and vomiting have received less attention, though there are extensive literature, data are frequently difficult to interpret and compare. Nausea and vomiting have been associated for many years with the use of general anaesthetics for surgical procedures. First extensive description was given by John Snow, published in 1848.

Early studies reported incidence of post operative nausea and vomiting (PONV) as high as 75-80%. But in the second half of this century, however these incidences have decreased by almost 50% for various reasons.[1] It is noted that incidence is more

common in females especially in LSCS under subarachnoid block.

PONV may be associated with wound dehiscence, pulmonary aspiration of gastric contents, bleeding, dehydration and electrolyte disturbance. Hence vomiting can potentially delay hospital discharge or lead to unexpected hospital admissions and increased hospital cost and can result in serious medical and surgical complications.[2]

There are many different modes of intervention to prevent PONV. Antiemetic drugs play an important role in therapy of PONV. Though many drugs have been tried as prophylaxis and treatment of PONV, no drug has been proved significantly effective and a search for better drug continues.

The study conducted about the astounding efficacy of 5HT3 receptor antagonists as a antiemetic in the management of vomiting induced by chemotherapy and radiotherapy was followed by new era in the treatment of PONV.[3] Metoclopramide is in use as antiemetic for many years but ondansetron is being used recently.

In this study aim was to compare effectiveness of these two drugs in reducing and preventing incidence of Post operative nausea and vomiting in LSCS under subarachnoid block was evaluated in this study.

Materials & Methods:

This Prospective study was conducted in the department of anaesthesiology at Vedantaa institute of medical sciences, Dahanu road Palghar after obtaining approval from the ethical committee and an informed consent from all the patients. A total of 100 women aged above 18 years belonging to ASA grade I and II schedule to undergoing elective LSCS under spinal anaesthesia were enrolled for the study. All the patients were randomly allocated into two groups as, Group I (n = 50) received Metoclopramide 10 mg i.v. and Group II (n = 50) received Ondansetron 4 mg i.v.

The selection of patients was carried out randomly. Patients were explained in their own language the anaesthetic procedure they are going to undergo. Pre-anaesthetic examination was done prior to the day of surgery.

Specially designed proforma was used to collect the data which includes patient's particulars, indication for surgery, the anaesthetic details, intraoperative monitoring, observation for side effects, etc.

Patients were divided into 2 groups of 50 each by simple randomisation and single blinded technique as, Group-I (n = 50): received IV Metoclopramide 10mg & Group-II (n = 50): received IV Ondansetron 4mg. Each patient received their study drug 3-5 minutes before subarachnoid block.

The patients were observed for 24 hours post operatively. Nausea, retching and emesis were recorded at 1 hour, 2-hour, 6 hour and 24 hours respectively. The number of episodes of emesis and type were recorded. Repeated vomiting within 1–2-minute period was recorded as single emesis. The data were recorded as follows. No emesis - complete control, 1-2 episodes - Nearly complete control, 3-5 episodes - Partial control and >5 episodes as Failure. Similarly, the number of episodes of retching (dry heaves) was also registered. The nausea was graded as 0 as none, 1 as Mild, 2 as Moderate and 3 as Severe. Any side effects appreciated were also recorded. The results were tabulated at 1 hr, 2hr, 6 hr and 24 hours post operatively. Severe nausea and vomiting were labelled as failure and rescue therapy was initiated with i.v. ondansetron with i.v. fluids.

Statistical analysis:

The data obtained in the present study was expressed as Mean ±Standard Deviation. The data were analysed by 'z test'. The level of significance was taken as $P < 0.05$.

Result:

In this prospective study of 100 patients in ASA I & II undergoing LSCS under spinal Anaesthesia was undertaken to compare the efficacy and safety of i.v. Metoclopramide and ondansetron for PONV. Majority of the cases were in the 23-26 years age group mean age was 24.9 years in group I and 25.7 years in group II. The mean weight in-Group I patient was 54.48 and group II was 54.48. PONV was more common in patient's weight below 54.48 in both group I and group II (Table 1).

In the table number 2 shows that the comparison of number of emetic episodes at the different interval of time as: 1 hour, 2-hour, 6 hour and 24 hours. About 24% of group, I patients experienced emesis, while in group II it was 14%. It was recorded a significantly decreased emetic episodes in ondansetron group as compared to Metoclopramide group, but it was not a statistically significant different.

Table 1: Patient Characteristics according to the two different study group.

Variables		Group I (n = 50)	Group II (n = 50)	P value
Age Group	19 - 22	7 (14.0%)	13 (26.0%)	0.508 (NS)
	23 - 26	22 (44.0%)	18 (36.0%)	
	27 - 30	15 (30.0%)	14 (28.0%)	
	30 - 34	06 (12.0%)	05 (10.0%)	
Age	Mean (SD)	26.5 $\pm$ 10.3	25.7 $\pm$ 13.2	0.736 (NS)
Weight	Mean (SD)	54.48 $\pm$ 4.21	54.48 $\pm$ 4.52	0.989 (NS)

Table 2: Comparison of EMESIS Episodes at different time interval of two different groups.

Time Interval	Emesis (Episodes)		P value
	Group I (n = 50)	Group II (n = 50)	
1 hr	12 (24.0%)	7 (14.0%)	0.204 (NS)
2 hr	5 (10.0%)	3 (6.0%)	0.460 (NS)
6 hr	1 (5.0%)	1 (5.0%)	0.999 (NS)
24 hr	0 (0.0%)	1 (5.0%)	0.313 (NS)

Also, In the table number 3 shows that the comparison of average episodes of emetic at the different interval of time as,1 hour, 2-hour, 6 hour and 24 hours. It was shown that EMESIS means episodes not a statistically significant difference at the different time of interval of the two study groups.

Table 3: Comparison of EMESIS Mean Episodes at different time interval of two different groups.

Time Interval	Group I	Group II	P value
	Mean (SD)	Mean (SD)	
1 hr	0.24 (0.52)	0.14 (0.40)	0.08 (NS)
2 hr	0.10 (0.30)	0.06 (0.24)	0.69 (NS)
6 hr	0.02 (0.14)	0.02 (0.14)	0.31 (NS)
24 hr	0.0 (0.0)	0.02 (0.14)	0.98 (NS)

In the table number 4 shows that the comparison of number of Nausea grades at the different interval of time as: 1 hour, 2-hour, 6 hour and 24 hours. About 62% of group, I patients experienced Nausea, while in group II it was 36%. It was recorded a significantly decreased nausea grades in ondansetron group as compared to metoclopramide group, but it was a statistically significant different.

Similar, In the table number 5 shows that the comparison of average grades off nausea at the different interval of time as,1 hour, 2-hour, 6 hour and 24 hours. It was shown that NAUSEA mean grades not a statistically significant difference at the different time of interval of the two study groups.

Table 4: Comparison of Nausea at different time interval of two different groups.

Time Interval	Nausea (Grades)		P value
	Group I (n = 50)	Group II (n = 50)	
1 hr	31 (62.0%)	18 (36.0%)	0.009 (S)
2 hr	14 (28.0%)	3 (6.0%)	0.003 (S)
6 hr	1 (5.0%)	1 (5.0%)	0.999 (NS)
24 hr	0 (0.0%)	1 (5.0%)	0.313 (NS)

Table 5: Comparison of Nausea Mean grades at different time interval of two different groups.

Time Interval	Group I	Group II	P value
	Mean (SD)	Mean (SD)	
1 hr	0.62 (0.83)	0.36 (0.56)	0.001 (S)
2 hr	0.28 (0.54)	0.06 (0.24)	0.006 (S)
6 hr	0.02 (0.14)	0.02 (0.14)	0.31 (NS)
24 hr	0.0 (0.0)	0.02 (0.14)	0.98 (NS)

In the table number 6 shows that the comparison of number of Retching Episodes at the different interval of time as: 1 hour, 2-hour, 6 hour and 24 hours. About 10% of group, I patients experienced Retching, while in group II it was 6%. It was recorded a significantly decreased

Retching episodes in ondansetron group as compared to metoclopramide group, but it was not a statistically significant different.

Table 6: Comparison of RETCHING Episodes at different time interval of two different groups.

Time Interval	RETCHING (Episodes)		P value
	Group I (n = 50)	Group II (n = 50)	
1 hr	5 (10.0%)	3 (6.0%)	0.460 (NS)
2 hr	7 (14.0%)	0 (0.0%)	0.006 (S)
6 hr	0 (0.0%)	0 (0.0%)	Not Applicable
24 hr	0 (0.0%)	0 (0.0%)	

Also, In the table number 7 shows that the comparison of average episodes of Retching at the different interval of time as,1 hour, 2-hour, 6 hour and 24 hours. It was shown that retching mean episodes not a statistically significant difference at the different time of interval of the two study groups.

Table 7: Comparison of RETCHING Mean Episodes at different time interval of two different groups.

Time Interval	Group I	Group II	P value
	Mean (SD)	Mean (SD)	
1 hr	0.1 (0.30)	0.06 (0.24)	0.503 (NS)
2 hr	0.14 (0.35)	0.0 (0.0)	0.011 (NS)
6 hr	0.0 (0.0)	0.0 (0.0)	Not Applicable
24 hr	0.0 (0.0)	0.0 (0.0)	

Side Effects:

In the Group-M, one patient had extrapyramidal syndrome, which was treated with IV diazepam. In the Group-O, one patient complained of headache.

Discussion:

Post operative nausea and vomiting is the most distressing and unpleasant experience for a patient undergone anaesthesia and surgery. Furthermore, severe post operative emesis may lead to dehydration, electrolyte imbalance, which in turn may alter the overall outcome of the entire surgical procedure. Postoperative vomiting may though rarely, lead to a life-threatening complication like aspiration pneumonitis.[4]

In subarachnoid block for LSCS hypotension, manipulation of abdominal viscera and hormonal influences are strong emetic stimuli. Pain, anxiety and drugs like opioids, NSAID also have been implicated in postoperative vomiting.[5] There are many drugs used for treatment of PONV like metoclopramide, domperidone, phenothiazines, butyrophenones, anticholinergics, antihistamines. Even though these drugs have either alone or in

combination has been proved effective to a certain extent, a search was on for a newer antiemetic drug, which leads to the invention of 5-HT3 antagonist, ondansetron.[6]

Studies comparing many of these drugs with ondansetron have been carried out in the recent years. It was evident that ondansetron was highly or equally effective in preventing PONV in some studies. But the incidence of side effects was low with ondansetron. Whereas, most of the other drugs the incidence of side effects was high like extrapyramidal symptoms in Metoclopramide, domperidone, perphenazine, droperidol, hematological abnormalities in prochlorperazine), sedation in chlorpromazine, droperidol, cyclizine etc. and adverse cardiovascular effects in metoclopramide. Chlorpromazine etc.[7]

In this study we compared the efficacy and safety of IV ondansetron and metoclopramide as prophylaxis for PONV in LSCS under subarachnoid block. In their study of prevention of PONV after LSCS under epidural anaesthesia proved that ondansetron 4mg IV is more effective in preventing nausea than metoclopramide 10mg.[8] In their studies of prevention of nausea and vomiting after day care gynecological laparoscopy, that ondansetron is superior for prophylaxis against PONV than metoclopramide.[9]

In the present study 76% of ondansetron group patients were emesis episodes free while in metoclopramide group 64% patients experienced no emesis.[10] The incidence of vomiting was more at 1 hour and 2 hour in both groups and incidence was less in ondansetron group at both time intervals. Severity of vomiting also was less in Ondansetron group than metoclopramide group. We observed retching separately from vomiting. The incidence of retching was less in ondansetron group than metoclopramide group. 94% experienced no retching in ondansetron group while it was 76% in metoclopramide group. This observation was very significant at 2 hours. Severity also was less in ondansetron group.

Nausea control was significant with incidence in metoclopramide group 92% which reduced to 46% in the ondansetron group and severity of nausea was less in ondansetron group than metoclopramide group (6% Vis 24% at 2 hour). Incidence of PONV was very less at 6 hour and 24 hours in both groups. This study proved that ondansetron significantly reduced the incidence of PONV at 1 hour and 2 hours than metoclopramide.

In a study they found a correlation between increase in age and decrease in emesis. Average age in present study was 24.9 in group I and 25.7 years in group II.[11] In this study the incidence of PONV was more in younger patients in both groups. Obesity is usually seen to be associated with increased incidence of PONV. In a study they found a higher percentage of patients with emetic episodes in heavier group average weight in the study were 47.5 kg.[12]

In the present study, the mean weight was 54.48 kg. The incidence of vomiting was more in patients with weight more than 54.48 kgs. While the purpose of using prophylactic drug is to prevent PONV, it is imperative that drugs used do not compromise the patient's condition due to the side effects. Drugs commonly used like metoclopramide, droperidol, domperidone are associated with sedation, hypotension and extrapyramidal symptoms. In a study they observed low incidence of side effects with ondansetron and reported Headache and constipation being the most common side effects.[13]

In another study they found no side effects with ondansetron. The side effect in this study was very low, with one patient had extrapyramidal syndrome in metoclopramide group which was treated with IV diazepam and one patient

complained of headache in ondansetron group which relieved without and any treatment. Thus, ondansetron was much more effective in decreasing the PONV in LSCS under subarachnoid block with low side effect profile.[14]

Conclusion:

It is fair to conclude from this study that ondansetron, a 5HT3 antagonist in the dose of 4mg has proved as a better prophylactic drug than I.V metoclopramide in prevention of PONV in LSCS under spinal anaesthesia.

Reference:

1. Rowbotham DJ. "Current management of postoperative nausea and vomiting". Br J Anaesth. 1992; 69:60S-2S.
2. Patel RI, Hanrallah RS. "Anaesthetic complications following pediatric ambulatory surgery". Anaesthesiology, 1988;69:1009-12.
3. Bunce KT, Tyers ME. "The role of 5-HT in postoperative nausea and vomiting". Br J Anaesth. 1992; 69:60S-2S.
4. Alon E, Himmelseher S. "Ondansetron in the treatment of postoperative vomiting: A randomized double-blind comparison with droperidol and metoclopramide". Anesth Analg. 1992; 75:561-5.
5. Kortilla K. "The study of postoperative nausea and vomiting". Br J Anaesth. 1992; 69:205-35.
6. Rabey PO, Smith O. "Anaesthetic factors contributing to postoperative nausea and vomiting". Br J Anaesth. 1992; 69:40S-5S.
7. Russell D, Kenny ONC. "5-HT3 antagonists in postoperative nausea and vomiting". Br J. Anaesth. 1992; 69:63S-8S.
8. Pan PH, Moore CH. Comparing the efficacy of prophylactic metoclactic metoclopramide on placebo in cesarean section patients giving epidural Anesthesia. J. Clin Aneath. 2001:13(6):4305.
9. Furst SR, Rodarte A. "Prophylactic antiemetic treatment with ondansetron in children undergoing tonsillectomy" Anaesthesiology. 1994; 81:799-803.
10. Burtles Peerr B. Postoperative vomiting: Some factors affecting its incidence. Br. J Anaesth 1957; 29:114-23.
11. Gan TJ, Collins R, Hetreed M. "Double blind comparison of ondansetron, droperidol and saline in the prevention of postoperative nausea and vomiting". Br J Anaesth. 1994; 72:544-7.
12. Paxton LD, Mackay AC, Mirakhur RK. "Prevention of nausea and vomiting after day care gyaecological laparoscopy". Anaesthesia. 1995;50:403-6.
13. Dupreyron Jp, Conseiller C, Levarlet M. "The effect of oral ondansetron in the prevention of postoperative nausea and vomiting after major gynaecological surgery performed under general anaesthesia". Anaesthesia. 1993; 48:214-8.
14. Scuderi P, Wetchler B, Fong-Sung Y. "Double- blind, randomized comparison of ondansetron and intraoperative propofol to prevent postoperative nausea and vomiting". Anaesthesiology.1993; 78:15-20.