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Research Article

Pre-operative ondansetron vs. metoclopramide for prevention of post-operative nausea and vomiting in elective lower-segment caesarean section under spinal anaesthesia

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ABSTRACT

Background: The problem of nausea and vomiting is a very old but a less thought of problem. Nausea and vomiting are the most common distressing symptom in the postoperative period. Antiemetic drugs play an important role in therapy of post-operative nausea and vomiting (PONV). Though 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.
Methods: 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 standardized. 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 parturiants with group-2. The mean episodes of emesis, nausea and retching at different postoperative duration were significantly decreased ($p<0.05$) 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

The problem of nausea and vomiting is a very old but a less thought of problem. Before any specific anti-emetic agents became available, various techniques, including olive oil and insulin glucose infusions were reported to be effective in reducing the incidence of postoperative nausea and vomiting. In 1912, Robert Ferguson described the use of olive oil.[1] The effect of atropine was appreciated by Brown Sequard as early as 1883, when he wrote in the very great majority of cases, the addition of a certain amount of atropine to the morphine prevents the vomiting and also the nausea occasioned by morphine alone.[2]

The common and distressing symptoms which follow anaesthesia and surgery are pain, nausea and vomiting. 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. It has been associated for many years with the use of general anesthetics for surgical procedures.

Inspite of the advances like using less emetic anaesthetic agents, improved pre and post operative technique and identification of patient predictive factors, nausea and vomiting still occur with unacceptable frequency in association with surgery and anaesthesia, and is described as "the big little problem". Early studies[1] 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. 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[2] and can result in serious medical and surgical complications.

Today, the anti-emetic drugs are the mainstay of therapy for PONV. There are several types of anti-emetics used in the management of PONV. Gastrointestinal prokinetic drugs with anti-dopaminergic actions (e.g., metoclopramide, domperidone) are anti-emetics. Phenothiazines (e.g., Prochlorperazine, Perphenazine) and butyrophenones (e.g. droperidol) have anti-emetic properties resulting from anti dopaminergic actions. Central anti-cholinergic action is associated with anti-emetic activity and is seen not only in classical anti-cholinergic drugs such as hyoscine and atropine, but also in some antihistamine receptor type I antagonists (e.g., cyclizine). It may be that the anti-cholinergic effects of these drugs are responsible for their anti-emetic activity.[3-5] Recently, the 5-HT_3 antagonists such as ondansetron have been proved effective in the management of PONV and also in emesis induced by cancer chemotherapy.

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[7] conducted about the astounding efficacy of $5HT_3$ 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.

Metoclopramide is in use as antiemetic for many years but ondansetron is being used recently. A comparative effectiveness of these two drugs in reducing and preventing incidence of PONV in LSCS under subarachnoid block was evaluated in this study. Therefore, this study was undertaken to compare the efficacy and safety of prophylactic use of intravenous metoclopramide and ondansetron in preventing or reducing the incidence of PONV, in women patients undergoing LSCS under subarachnoid block.

METHODS

The study was carried out after the approval from ethical committee, and an informed, written consent from all the parturiants. 100 parturiants undergoing elective LSCS were selected. All participants belonged to ASA grade I or II and were aged above 18 years. They were divided into 2 groups as, Group-I (n = 50) received Metoclopramide 10 mg i.v. and Group-II (n = 50) received Ondansetron 4 mg i.v.

Selection of patients

Parturiants undergoing LSCS under subarachnoid block were selected. Parturiants with renal impairment, hepatic disease, neurological and endocrinal abnormalities were excluded. Parturiants with history of PONV in previous surgery and patients with history of motion sickness were excluded. Patients with history of vomiting and/or Ryle's tube in situ in the last 24 hours were also excluded.

Pre-operative evaluation

Pre-operative visit was conducted on the day before surgery. Detailed history of parturiants complaints was noted. General and systemic examination of cardiovascular and respiratory system was done.

Pre-operative order

Patients were advised to remain nil orally after 10 P.M. the day before surgery.

Anaesthesia

When the patient was brought to the operation theatre, her pulse rate and BP were recorded. An i.v. access with 18G i.v. cannula was obtained. The patients were received 4 mg injection Ondansetron i.v., 3-5 minutes before subarachnoid block and 2 ml normal saline to controls. Pulse, BP and any side effects of drug given was also noted.

Sub arachnoid block was performed in a left lateral position using 23G spinal needle at L3-L4 or L2-L3 interspace. 0.5% bupivacaine 2-2.5ml depending on patients, were given. Following injection, patient was immediately brought on supine position and time of onset of action, T6 level was noted using pinprick method. Desired operative position was given after 5 minutes.

Intra operative pulse, BP monitored and maintained with fluids. Duration of surgery was noted.

The parturiants 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 was 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 analyzed by 'z test'. The level of significance was taken as P <0.05.

RESULTS

A clinical 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. Large numbers of 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 (Table 1). 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 2).

Table 1: Distribution of patients according to age in two different groups. N=50 each.

	Group - I		Group - II		P value
Age group	No of patients	%	No of patients	%	
19-22	7	14	13	26	<0.05 Sig
23-26	22	44	18	36	<0.05 Sig
27-30	15	30	14	28	>0.05 NS
30-34	06	12	05	10	>0.05 NS

Table 2: Patient characteristics according to weight in two different groups. N=50 each.

Group	Weight (kg)		P value
	Range	Mean ± S.D.	
I	40-60	54.48 ± 4.21	NS
II	40-65	54.48 ± 4.52	

Comparison of number of emetic episodes between 1hour and 24 hour is shown in Table 3 and 4. About 24% of group I patients experienced emesis, while in group II it was 16%. It was recorded a significantly decreased ($p<0.05$) emetic episodes in ondansetron group as compared to metoclopramide group.

Table 3: Episodes of emesis at different interval of time in two different groups. N=50 each.

Duration	Emesis (Episodes)		P value
	Metoclopramide group	Ondansetron group	
1 hr	12	7	<0.05 Sig
2 hr	5	3	<0.05 Sig
6 hr	1	1	>0.05 NS
24 hr	0	1	<0.05 Sig

Table 4: Comparison of emesis (mean episodes) Number of emetic episodes at different interval of time in two different groups. N=50 each.

Comparison of emesis (Mean episodes)				
Duration	Metoclopramide Mean ± S.D	Ondansetron Mean ± S.D	Z - value	P - value
1 hr	0.24 ± 0.52	0.14 ± 0.40	1.12	<0.05 Sig
2 hr	0.10 ± 0.30	0.06 ± 0.24	0.73	<0.05 Sig
6 hr	0.02 ± 0.14	0.02 ± 0.14	0.0	>0.05 N.S
24 hr	0.0 ± 0.0	0.02 ± 0.14	1.0	>0.05 N.S

When the incidence of nausea was compared between the groups, showed a significantly low nausea grades in the group-II compared to group-I at 2nd hours. Though grading of nausea was less in 1st hour also, it was not significant statistically (Table 5 and 6). The total number of retching in 5 minutes was taken as one episode. The findings are tabulated in Table 7. Incidence of retching was more in the 1st hour in group-II and 2nd hour in group-I. 18% of group-I patients experienced retching, while 6% of group-II patients were experienced retching. Incidence of retching was reduced significantly in the group-II patients.

Table 5: Nausea grades at different interval of time in two different groups. N=50 each.

Duration	Nausea Grades		P-value
	Metoclopramide group	Ondansetron group	
1 hr	31	18	<0.05 Sig
2 hr	14	3	<0.05 Sig
6 hr	1	1	>0.05 N.S
24 hr	0	1	>0.05 N.S

Table 6: Comparison of nausea grades at different interval of time in two different groups. N=50 each.

Comparison of nausea (Mean grades)				
Duration	Metoclopramide group	Ondansetron group	Z-value	P-value
	Mean ± S.D	Mean ± S.D.		
1 hr	0.62± 0.83	0.36± 0.56	1.83	>0.05 N.S
2 hr	0.28± 0.54	0.06± 0.24	2.65	<0.05 Sig
6 hr	0.02± 0.14	0.02± 0.14	0.00	>0.05 N.S
24 hr	0± 0	0.02± 0.14	1.00	>0.05 N.S

Table 7: Comparison of retching episodes at different interval of time in two different groups. N=50 each.

Duration	Retching Episodes		P value
	Metoclopramide	Ondansetron	
1hr	5	3	<0.05 Sig
2hr	7	0	<0.05 Sig
6hr	0	0	-
24hr	0	0	-

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.[8]

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.[9] 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-HT_3 antagonist, ondansetron.[10]

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.[11]

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[12] of prevention of PONV after LSCS under epidural anaesthesia proved that ondansetron 4mg IV is more effective in preventing nausea than metoclopramide 10mg. In their studies of prevention of nausea and vomiting after day care gynecological laparoscopy, that ondansetron is superior for prophylaxis against PONV than metoclopramide.[13]

In the present study 76% of ondansetron group patients were emesis episodes free while in metoclopramide group 64% patients experienced no emesis.[14] 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 hour. 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 hour in both groups. This study proved that ondansetron significantly reduced the incidence of PONV at 1 hour and 2 hour than metoclopramide.

In a study[15] 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. 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[16] they found a higher percentage of patients with emetic episodes in heavier group average weight in the study were 47.5 kg.

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[17] they observed low incidence of side effects with ondansetron and reported Headache and constipation being the most common side effects.

In another study[18] 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.

Therefore, it is fair to conclude from this study that ondansetron; a $5HT_3$ antagonist in the dose of 4mg has proved as a better prophylactic drug than IV metoclopramide in prevention of PONV in LSCS under spinal anaesthesia.

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