www.jmscr.igmpublication.org **Impact Factor-1.1147**

ISSN (e)-2347-176x

IGM Publication Journal Of Medical Science And Clinical Research An Official Publication Of IGM Publication

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-

Post Operative Nausea Vomiting (PONV) is the most unpleasant and distressing consequence in the immediate post-operative period . PONV can delay discharge and may result in unplanned over night hospital admissions. 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.

Keywords: LSCS,PONV, Ondansetron Metoclopramide.

INTRODUCTION

Nausea and vomiting are the most common side effects in the post- anaesthesia care unit. Early studies reported incidence of post operative nausea and vomiting (PONV) as high as 75-80%.[1] The etiology of PONV is complicated and multifactorial [2].

It is observed that incidence is more common in females especially in LSCS under spinal

anaesthesia. Ondansetron has been demonstrated to be an effective and well-tolerated drug for the prevention and treatment of postoperative nausea and vomiting[3]. Its use in surgical procedures accompanied by frequent postoperative nausea and vomiting seems reasonable[4] The purpose of this study was to determine the effectiveness of 10 mg of metoclopramide versus ondansetron 4 mg IV for treatment of PONV in patients undergoing elective LSCS.

METHODS

This was a prospective, randomized, double-blind,active-controlled study of 100 womans undergoing elective lscs. Approval from ethical committee, and an informed, written consent from all the patients were taken. 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 spinal anaesthesia were selected. parturiants with cardiovascular , renal , hepatic , and neurological 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 receiving antiemetic within 24 hrs were excluded from the study

Pre-operative evaluation

A thorough preoperative anaesthetic check up was done. Detailed history 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.

When the patient was brought to the operation theatre, and was connected to multiparameter moniters. An i.v. rest half received access with 18G i.v. cannula was obtained. Half of the patients were given 4 mg injection Ondansetron i.v., 3-5 minutes before subarachnoid block and Metoclopramide 10 mg i.v. . Pulse, BP and any side effects of drug given was also noted. patient were preloaded with 15 ml/kg of ringer lactate.Sub arachnoid block was performed in a left lateral position using 23G spinal needle at L3-L4 or L2-L3 inter space. 0.5% bupivacaine 2-2.5ml depending on patients, were given. The parturiants were observed for 24 hours post operatively. Nausea, retching and emesis were recorded at 0-1 hour, 3 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 iv. fluids.

Statistical analysis - The data obtained in the present study was expressed as Mean ± Standard Deviation. The data were analyzed by 'chi-square test'. The level of significance was taken as P <0.05.

DISCUSSION

(PONV) is one of the commonest complaints following anaesthesia, and can result in morbidity like wound dehiscence, bleeding, pulmonary aspiration of gastric contents, fluid and electrolyte disturbances, delayed hospital discharge, unexpected hospital admission, and decreased patient satisfaction.[5]

Factors which affect the incidence of PONV include age, sex, history of previous PONV or motion sickness, smoking, surgical procedure, duration of surgery and anaesthesia, and patient and parental anxiety. Sinclair et al reported that the incidence of PONV decreased after age 50 years. Age decreased the likelihood of PONV by 13% for each 10-year increase[6]. The reported incidence of PONV associated with spinal anaesthesia varies widely.[7] Carpenter et al[7] studied 952 patients undergoing all types of procedures. They found an intraoperative rate of nausea of 18% and vomiting of 7%, but it must be noted that 12% of their patients received additional inhalational anaesthesia. Older prospective studies reported postoperative retching and vomiting in 11.1%[8] or nausea and vomiting in 21.1%[9] of patients after spinal anaesthesia. Several different mechanisms may play a role in causing PONV in patients who receive regional anaesthesia. Low blood pressure may lead to brain stem ischemia, which is thought to activate the circulatory, respiratory, and vomiting centers grouped together in the Neuraxial anaesthesia also changes the function of the gastrointestinal tract.[10] Sympathetic blockade by local anesthetics creates unopposed vagal action, resulting in gastrointestinal hyperactivity. The efficacy of vagolytic agents to relieve nausea during spinal anaesthesia has been taken as evidence of the importance of this mechanism[.11]

There are many drugs used for treatment of PONV like metoclopramide, domperidone, phenothiazines, butyrophenones, anticholinergics, antihistaminesEven 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.[12]

In a study by Gan et al.734 mg IV ondansetron for PONV was compared with placebo,patients who received ondansetron ODT had less severe nausea and fewer vomiting episodes (3% vs. 23%) after discharge[.13]

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.[14]

. In this study we compared the efficacy and safety of IV ondansetron and metoclopramide as prophylaxis for PONV in LSCS under spinal anaesthesia. In their study[15] 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.[16]

Paxton et al have observed in their study that nausea occurred in 25 % of patients who received ondansetron as compared to 59% of patients with metoclopramide. The visual analogue scores were significantly lower (P<0.01) in ondansetron group at 1, 2 and 4 hrs as compared to metoclopramide. The number of patients with no PONV in first 6 hours after operation was 87% in ondansetron group and 60% in metoclopramide (P<0.001) group. In first 24 hrs study patients with no PONV were 82% in ondansetron group and 47% in metoclopramide group (P<0.001). In those patients with previous history of PONV the severity of nausea was less in ondansetron group then metoclopramide (P<0.05). [17] Malins et al have observed 59% nausea in the ondansetron group and 63% in metoclopramide group[18]. In our study there was 23.33% incidence of nausea in ondansetron group and 53.33% incidence of nausea in metoclopramide group. The visual analogue scores were significantly lower (P<0.05) in ondansetron group at 1, 2 and 4 hrs as compared to metoclopramide.

Paxton et al observed 6 % patients vomited in ondansetron group as compared to 12% in metoclopramide group , postoperatively in 24 hrs the percentage of emesis free patients were 65.5% in the ondansetron group than 29.2% in metoclopramide group.[17] Naguile et al has observed prophylactic anti-emetic treatment with ondansetron resulted in a lower incidence of PONV than metoclopramide (P<0.02).[19]

Polati et al concluded that early antiemetic efficacy (abolition of vomiting within 10 min and of nausea within 30 min from the administration of the study drugs with no further vomiting or nausea episodes during the first hour was reported as 93.1% in the ondansetron group, in 66.7% in the metoclopromide group, 35% in the placebo group, suggesting ondansetron 4 mg is more effective than metoclopromide 10 mg and placebo in the treatment of established PONVs[20].

CONCLUSION

The development of 5-HT_3 antagonist drugs, of which ondansetron is the most widely used, offers a novel and possible more effective approach to control post-operative nausea and vomiting as compared to metoclopramide.

RESULTS

As per demographic data mean age was 24.6 years in ondansetron and 25.8 years in metoclopramide group in our study. Mean weight was 65.3 kgs in ondansetron and 66.4 kgs in metoclopramide group. The results indicated that both ondansetron and metoclopramide are effective in controlling the incidence of nausea in 1 hours, 4 hours and 12 hours. But ondansetron is more effective than metoclopramide for control of nausea, by applying chi-square test $P < 0.05$, which is statistically significant (Table 1). Our results also further indicated that ondansetron is more effective in controlling the incidence of vomiting by applying chi-square test ($P<0.005$) which is highly significant (Table 2). Ondansetron significantly reduce the incidence of vomiting in first 24 hours of post-operative period. The chi-square test shows that $P < 0.001$ value is highly significant (Table 3). In the ondansetron group, 2 patients complained of headache, no treatment failures and, no rescue medication was required by any of them. In metoclopramide group, two patients complained of giddiness (6%) and one drowsiness (3%) respectively (Table 4).

TABLE 1: Maternal and obstetrics characteristics. Data are expressed as mean ± SD, except for Apgar score, which is expressed as median. There were no statistical differences among the two groups.

	ONDANSETRON GROUP I (n=50)	**METOCLOPRAMIDE GROUP II (n=50)**
Age (yr)	30± 5	29± 4
Weight (kg)	66± 9	65± 8
Height (cm)	159± 9	160± 7
Gestational age (wk)	39.1± 1	38.8± 1
Newborn weight (g)	3280± 54	3373± 47
Newborn pH venous cord	7.3± 0.1	7.26± 0.1
Apgar score		
1st min	9 (7-10)	9 (7-10)
5th min	10 (9-10)	10 (9-10)

Table 2: Comparison of episodes of vomiting between ondansetron and metoclopramide groups

	ondansetron	**Metoclopramide**
0-1hr	**4(13.3%)**	**7(23.33%)**
3 hr	**4(13.3%)**	**8(26.66%)**
12 hr	**2(6.6%)**	**4(13.33%)**
24 hr	**0(0%)**	**0(0%)**

X^2=5.4;p value<0.05(highly significant)

Table 3-Comparison of episodes of nausea between ondansetron and metoclopramide groups

	ondansetron	**Metoclopramide**
0-1 hr	**2(3.66%)**	**6(20%)**
3 hr	**3(10.0%)**	**6(20%)**
12 hr	**1(3.3%)**	**5(16.6%)**
24 hr	**0**	**1(3.33%)**

X^2=8.4;p value<0.005(highly significant)

Table 4: Side effects with ondansetron and metoclopramide

Side effects	ondansetron	Metoclopramide
headache	2	0
Drowsiness	0	1
Giddiness	0	2

Table-5 No. of Vomiting episode in 24 hrs X2=13.98; p value <0.001(highly significant)

	ondansetron	metoclopramide
No of vomiting episodes	4	12
Absence of vomiting	25	16

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