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A COMPARATIVE STUDY OF METOCLOPRAMIDE VERSUS ONDANSETRON FOR POSTOPERATIVE NAUSEA AND VOMITING (PONV) IN ELECTIVE LOWER SEGMENT CAESAREAN SECTION UNDER SPINAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

Background : Caesarean section is one of the most prevalent surgical procedures among women. Pain, nausea and vomiting are the most common adverse effects of surgery, which are reported in more than 66% of patients undergoing caesarean section under spinal anesthesia

Methods: A Hospital based, Prospective, Randomized, Double-Blind Interventional study was conducted in the Department of Anaesthesiology and Critical Care, at Zanana hospital and Mahila Chikitsalya, SMS Medical College, Jaipur. after obtaining the permission from the institutional ethics committee and after obtaining written informed consent in 84 patients aged above 18 years belonging to ASA grade 1 and 2 scheduled to undergo elective LSCS under spinal anaesthesia.

Results: Incidence of nausea was significantly more in group B than groups A from 1 hrs starting, incidence of vomiting decreased in group-A than group-B, incidence of retching was significantly more in group B than groups A at 2 hrs.

Conclusion: Ondansetron (4 mg=2 ml) dose was better than Inj. Metoclopramide dose is 10 mg= 2ml in patients undergoing caesarean section under spinal anesthesia.

KEYWORDS

metoclopramide, ondansetron, spinal anaesthesia

BACKGROUND

Nausea and vomiting are the most common complications of surgery done under regional or general anaesthesia and is frequently seen in the postanaesthesia care unit. Incidence of postoperative nausea and vomiting is as high as 75-80%.[1] PONV remains a continuing problem with an average incidence of 20-30%. It is noted that the incidence is more common in females, especially in LSCS under subarachnoid block. PONV can be such unpleasant experience that patients often rate it worse than postoperative pain.[2] 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.[3]

The predictors of PONV are-[4]

- Female gender.
- Non-smoking status.
- Previous history of PONV.
- Motion sickness.
- Use of postoperative opioids.
- Age.
- Hydration status.
- Body habitus.
- Medical condition.
- Type of anaesthesia.
- Duration of anaesthesia.
- Type of surgery.

Hypotension

Low blood pressure may lead to brain stem ischaemia, which is thought to activate the circulatory, respiratory and vomiting centres grouped together. Neuraxial anaesthesia also changes the function of the gastrointestinal tract.[5] Sympathetic blockade by local anaesthetics 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.[6] PONV can result from stimulation of any of these receptors, namely dopamine, serotonin, muscarinic, cholinergic, histamine and opioid receptors etc .

AIMS

- To compare the efficacy and safety of prophylactic use of intravenous ondansetron (4 mg) and metoclopramide (10 mg) in preventing or reducing the incidence of postoperative nausea and vomiting in women undergoing elective LSCS under subarachnoid block.
- To evaluate any side effects associated with the use of these drugs.

MATERIAL AND METHODS

A Hospital based, Prospective, Randomized, Double-Blind Interventional study was conducted in the Department of Anaesthesiology and Critical Care, at Zanana hospital and Mahila Chikitsalya, SMS Medical College, Jaipur. after obtaining the permission from the institutional ethics committee and after obtaining written informed consent in 84 patients aged above 18 years belonging to ASA grade 1 and 2 scheduled to undergo elective LSCS under spinal anaesthesia.

Patients were advised to remain nil orally after 10 p.m., the day before surgery. When patient is brought to the operation theatre, her pulse rate and BP were recorded. An IV access with 18G cannula was secured. 42 patients received Inj. Metoclopramide 10 mg IV and 42 patients received Inj. Ondansetron 4 mg IV 3-5 minutes before subarachnoid block. Pulse, BP and any side effects were noted. A preloading infusion of dextrose saline 500 mL was given. Subarachnoid block was performed in a left lateral position using 25G Quincke's spinal needle at L3-L4 interspace with Inj. 0.5% heavy bupivacaine of 1.5-2 mL depending on patients was given. Following injection, patient was immediately brought to supine position and time of onset of action to T6 level was noted using pinprick method. Desired operative position was given after 5 minutes. Intraoperative pulse, BP and SpO2 were monitored and maintained. Duration of surgery was noted. The patients were observed for 24 hours postoperatively. Nausea, retching and emesis were recorded at 1st hour (0-1 hr.), 2nd hour (1-2 hrs.), 6th hour (2-6 hrs.) and 24th hours (6-24 hrs.), respectively.

The number of episodes of emesis and type were recorded. Repeated vomiting within 1-2 minutes period was recorded as single emesis. The data was taken as follows- No emesis - Complete control, 1-2emesis - Nearly complete control, 3-5 emesis - Partial control, >5 episodes - Failure.

Similarly, the number of episodes of retching (dry heaves) also were recorded. Nausea was graded as 0, 1, 2 and 3.
0 - None.
1 - Mild.
2 - Moderate.
3 - Severe.

Any side effects appreciated were recorded. The results were tabulated at 1st hr., 2nd hr., 6th hr. and 24th hours, postoperatively. Severe nausea and vomiting were labelled as failure and rescue therapy was initiated with IV ondansetron or metoclopramide and with IV fluids.

Statistical Analysis

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using SPSS version 20 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. Descriptive statistics included computation of percentages, means and standard

deviations. The unpaired t test (for quantitative data to compare two independent two groups) was used for quantitative data comparison of all clinical indicators. Chi-square test was used for qualitative data whenever two or more than two groups were used to compare. Level of significance was set at P≤0.05.

RESULTS

Table 1: Demographic Wise Comparison Of The Study

		Mean	Std. Dev.	Mini.	Max.	P value
Age	Group A	26.10	4.017	20	35	0.93
	Group B	26.02	4.164	20	37	
Weight	Group A	59.95	5.099	50	70	0.002 (S)
	Group B	63.50	4.999	54	75	

Mean age was 26.1 among group A and mean age was 26.02 among group B. Comparison of age and groups showed statistically non-significant results.

Mean weight was 59.95 among group A and mean weight was 63.5 among group B. Comparison of weight and groups showed statistically non-significant results**.**

Table 2: Vital Statistics Wise Comparison Of The Study

		Mean	Std. Deviation	Minimum	Maximum	P value
PR	Group A	82.38	6.854	68	92	0.13
	Group B	84.45	5.684	69	92	
SBP	Group A	120.19	6.652	110	128	0.71
	Group B	120.67	5.126	110	128	
DBP	Group A	77.71	6.287	68	88	--
	Group B	77.71	6.287	68	88	
RR	Group A	16.45	1.01	15.00	18.00	0.53
	Group B	16.59	1.105	15.00	19.00	

Mean PR was 82.38 among group A and mean PR was 84.45 among group B. Mean SBP was 120.19 among group A and mean SBP was 120.67 among group B. Mean DBP was 77.71 among group A and mean DBP was 77.71 among group B. Mean RR was 16.45 among group A and mean RR was 16.59 among group B. Comparison of vital statistics and groups showed statistically non-significant results**.**

Table 3: Emesis Wise Comparison Of The Study

			1 hr	2 hrs	6 hrs	24 hrs
			Grade II	Grade I	Grade I	
Groups	Group A	N	6	2	0	0
		%	14.3%	4.8%	0.0%	0
	Group B	N	12	3	1	0
		%	28.6%	7.1%	2.4%	0
Total		N	18	5	1	0
		%	21.4%	6.0%	1.2%	0
P value			0.11	0.64	0.31	–

The incidence rate of emesis during the first hour (P=0.11), 2 hours (P=0.64), 6 hours (P=0.31) and the entire 24 hrs period was not a significant difference among the two groups.

Table 4: Retching Wise Comparison Of The Study

			1 hr	2 hrs	6 hrs	24 hrs
			Grade II	Grade I		
Groups	Group A	N	3	0	0	0
		%	7.1%	0.0%	0	0
	Group B	N	4	4	0	0
		%	9.5%	9.5%	0	0
Total		N	7	4	0	0
		%	8.3%	4.8%	0	0
P value			0.69	0.04 (S)	–	–

The incidence rate of retching during the first hour (P=0.69), 2 hours (P=0.04), 6 hours and the entire 24 hrs period was not a significant difference among the two groups.

Table 5: Nausea Wise Comparison Of The Study

			1 hr	2 hrs	6 hrs	24 hrs
			Grade II	Grade I	Grade I	
Groups	Group A	N	12	2	0	0
		%	28.6%	4.8%	0.0%	0
	Group B	N	26	12	1	0
		%	61.9%	28.6%	2.4%	0
Total		N	38	14	1	0
		%	45.2%	16.7%	1.2%	0
P value			0.002 (S)	0.003 (S)	0.31	–

The incidence rate of emesis during the first hour (P=0.002), 2 hours (P=0.003), 6 hours (P=0.31) and the entire 24 hrs period was not a significant difference among the two groups.

Table 6: Side Effect Wise Comparison Of The Study

			Side effect		Total
			nil	present	
Groups	Group A	N	40	2	42
		%	95.2%	4.8%	100.0%
	Group B	N	37	5	42
		%	88.1%	11.9%	100.0%
Total		N	77	7	84
		%	91.7%	8.3%	100.0%

P value=0.23

Only two patients have side effects in group A and five patients have side effects in group B. Comparison of side effects among groups showed statistically non-significant results.

DISCUSSION

Postoperative Nausea and Vomiting (PONV) is described as "The Big Little Problem" and from the patients perspective PONV is among the most distressing complication of anaesthesia and surgery.[7] The aetiology of Postoperative Nausea and Vomiting (PONV) is complicated and multifactorial. (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.[8] Early studies reported incidence of Postoperative Nausea and Vomiting (PONV) as high as 75-80%.[9]

As per demographic data mean age was 26.1 years in ondansetron and 26.02 years in metoclopramide group in our study. Mean weight was 59.95 kgs in ondansetron and 63.5 kgs in metoclopramide group.

In this study we compared the efficacy and safety of ondansetron and metoclopramide as prophylaxis for PONV in elective lower segment caesarean section under spinal anaesthesia. 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. In their studies of prevention of nausea and vomiting after day care gynecological laparoscopy, that ondansetron is superior for prophylaxis against PONV than metoclopramide.[10]

We have calculated retching, nausea and emesis according to grade of severity. grade III was severe, grade II was moderate and grade I was mild.

In our study, there was 12 (28.6%) incidence of nausea in ondansetron group and 26 (61.9%) incidence of nausea in metoclopramide group at 1 hour according to grade II. There was 2 (4.8%) incidence of nausea in ondansetron group and 12 (28.6%) incidence of nausea in metoclopramide group at 2 hours according to grade I. At 6 and 24 hours, there was no patient recorded in ondansetron group while only one patient (2.4%) have found in metoclopramide group.

In our study, there was 3 (7.1%) incidence of retching in ondansetron group and 4 (9.5%) incidence of nausea in metoclopramide group at 1 hour according to grade II. At 2, 6 and 24 hours, there was no patient recorded in ondansetron group while four patient (9.5%) have found in metoclopramide group at 2 hours only.

In our study, there was 6 (14.3%) incidence of emesis in ondansetron group and 12 (28.6%) incidence of nausea in metoclopramide group at 1 hour according to grade II. There was 2 (4.8%) incidence of nausea in ondansetron group and 3 (7.1%) incidence of emesis in metoclopramide group at 2 hours according to grade I. At 6 and 24 hours, there was no patient recorded in ondansetron group while only one patient (2.4%) have found in metoclopramide group.

Additionally, Mishriky and Habib in a meta-analysis reviewed the effect of Metoclopramide administration for prophylaxis of nausea and vomiting and resulted that administering 10 mg IV metoclopramide

before the spinal block can significantly prevent nausea and vomiting in pregnant patients who underwent spinal anesthesia for C-section surgery.[11] In the present study, the incidence of nausea and vomiting was 29.9% in metoclopramide group which is relatively low although it was higher than that of the group who received the combination therapy. In addition, Garcia-Miguel et al investigated the prophylactic effect of metoclopramide and ondansetron on IONV and compared the impact of these 2 drugs with that of the placebo. They indicated that the occurrence of nausea and vomiting during caesarean with spinal block were lower in both metoclopramide and ondansetron groups compared to the placebo. However, such an occurrence was not different between the patients who received metoclopramide or ondansetron.[12]

Agah J (2019)[13] et al was performed on a large number of cases admitted to a crowded hospital. The obtained results of the study showed that an intramuscular injection of 10 mg prophylactic metoclopramide could significantly diminish the incidence of nausea following cesarean and subside its severity in case of occurrence. However, metoclopramide could spontaneously eliminate nausea in 85% of women in the intervention group, who expressed nausea at a mild level. Moreover, only 15% of cases who expressed nausea at a moderate level required treatment. In contrast, about 44% of women in the control group expressed nausea at a moderate level, which needed treatment. Furthermore, 13 and 16 cases in the intervention and control groups revealed the occurrence of vomiting at a low rate, respectively. The low incidence of vomiting could be due to the administration of ondansetron for participants who suffered from significant nausea mainly those in control group. Of note, the women who had received prophylactic metoclopramide clearly had more tolerance to feeding during the day after cesarean. A large number of many women undergo cesarean section daily worldwide, and based on the report, PONV is considered as the most disturbing complication.[14,15]

In the study, low incidence (4.8%) of side effects with ondansetron was found and higher incidence (11.9%) seen in metoclopramide group. In a study they observed low incidence of side effects with ondansetron and reported headache and constipation being the most common side effects.[16] Drugs commonly used like metoclopramide, droperidol, domperidone are associated with sedation, hypotension and extrapyramidal symptoms.

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.[17]

Metoclopramide hydrochloride is a dopamine receptor antagonist that is structurally similar to procainamide and a potent prokinetic drug, which stimulates motility of the upper gastrointestinal tract leading to rapid gastric emptying and is used in the management of nausea and vomiting. The common side effects of metoclopramide are extrapyramidal syndrome, Parkinsonism, dizziness, headache and tardive dyskinesia.

Other side effects are depression, neuroleptic malignant syndrome, supraventricular tachycardia and hypertension. Metoclopramide hydrochloride is a dopamine receptor antagonist and a potent prokinetic drug, which stimulates motility of the upper gastrointestinal tract leading to rapid gastric emptying and is used in the management of some form of nausea and vomiting and in gastroesophageal reflux and gastric stasis.

Ondansetron is the prototype drug of the group, serotonin 5HT3 antagonist, which is primarily used for the treatment of chemotherapy and radiotherapy induced nausea and vomiting. The common side effects of ondansetron are headache, tachycardia, prolongation of QT interval, mild sedation, constipation, diarrhoea, dry mouth and hypersensitivity reactions.

CONCLUSION

The development of 5-HT3 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. Ondansetron (4 mg=2 ml) dose was better than metoclopramide (10mg=2 ml) in patients undergoing caesarean section under spinal anesthesia

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