Original Research Paper

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"A COMPARATIVE STUDY OF RAMOSETRON AND ONDANSETRON FOR PREVENTION OF NAUSEA AND VOMITING AFTER CARBOPROST IN LSCS PATIENTS UNDER SPINAL ANAESTHESIA"

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ABSTRACT **Background And Objectives:** Post-Operative Nausea and Vomiting, is unpleasant, distressing and exhausting experience for patients. The aim of the study is to compare the effectiveness of ramosetron and ondansetron to prevent post-opertive Nausea and Vomiting with carboprost in LSCS patients operated under spinal anaesthesia.

Methods: 110 patients of age group 18-35and ASA grade 2 scheduled for LSCS with use of carboprost IM under spinal anesthesia. They were randomly allocated into two groups namely group R and group O, inj ramosetron 0.3mg iv and inj ondansetron 4mg iv respectively. Patients were observed intraoperatively and post operatively for any episodes of nausea and vomiting. Rescue antiemetic was given if the patient had PONV score of 2 and was recorded. Incidence of complete response and adverse effects were assessed for the first 24hours following surgery.

Results:

1. There was no statistically significant difference between Ondansetron &Ramosetron on incidence of nausea, retching, vomiting, need for rescueantiemetic at intervals of 3-6 hours and 6-12 hours. However, in 12-24 hours postoperatively, incidence of vomiting and need for rescue antiemetic wassignificantly higher in Ondansetron group, as compared to Ramosetron group.
2. Both Ondansetron & Ramosetron were well tolerated, with minimum adverse effects; most common adverse effect observed was headache and dizziness. There was no significant difference between the two groups with respect to adverse effects.
3. overall incidence of complete response in ramsetron group (76%)is higher than ondansetron group (56%) and is statistically suggestive of significance($p<0.023$)

Conclusion: Ramosetron at an iv dose of 0.3mg is more effective than iv inj ondansetron 4mg to prevent postoperative nausea and vomiting with carboprost in LSCS patients.

KEYWORDS : Ramosetron, Ondansetron, Spinal anesthesia, LSCS

INTRODUCTION

Post-Operative Nausea and Vomiting (PONV) in Lower Segment Caesarean Section (LSCS) followed by carboprost under spinal anesthesia is very common, although it is self-limiting. However, it can cause significant morbidity including dehydration, electrolyte imbalance, suture tension, wound dehiscence, venous hypertension and bleeding, esophageal rupture and life threatening airway compromise.[1]

Incidence of nausea is about 1/3 patient while vomiting is about 2/3 patients in LSCS patients in which carboprost was given IM (intramuscular). Carboprost tromethamine administered intramuscularly stimulates the gravid uterine myometrial contractions similar to labour contractions at the end of a full term pregnancy. Postpartum, the resultant myometrial contractions provide hemostasis at the site of placentation.[2]

Carboprost tromethamine also stimulates the smooth muscle of the human gastrointestinal tract. This activity may produce vomiting or diarrhea or both that is common when carboprost tromethamine is used to terminate pregnancy and for use postpartum following normal labour or LSCS.[2]

Many drugs are used for management of PONV but few of them have side effects like sedation, dysphoria, extrapyramidal symptoms, dryness of mouth, restlessness and tachycardia. 5HT3 receptors antagonists are devoid of such side effects. Ondansetron, granisetron and newer drug such as ramosetron and palonosetron are commonly used drugs to prevent PONV.[3-5]

In our study, we have compared intravenous ondansetron 4 mg verses ramosetron 0.3 mg as a premedication in LSCS patients with usage of carboprost IM under spinal anesthesia in terms of prevention of nausea and vomiting intraoperative and postoperatively.

MATERIALS AND METHODS

Source Of Data

Patients scheduled for LSCS with use of carboprost IM under spinal anaesthesia in Bapuji hospital, Chigateri General Hospital, Women and Child Health Hospital attached to JJM Medical College, Davangere.

Method Of Data Collection:

Study Type: Prospective Comparative study.

Duration Of Study: Two years.

Sample Size: 110 patients.

Inclusion Criteria:

1. Age between 18 to 35 years
2. A patient who fits into American Society of Anaesthesiologists (ASA) physical status criteria I & II scheduled for LSCS.
3. Patients who are willing and able to give informed written consent.

Exclusion Criteria:

1. Patient refusal.
2. Age more than 35 years or less than 18 years.
3. ASA physical status III or IV.
4. Patients allergic to local anaesthetics.
5. Patients on anti coagulants or known coagulation disorder.
6. Patients with asthma, hepatic disorder
7. Local infection at the site of proposed puncture for spinal anaesthesia.

Plan Of Study:

A detailed history will be taken and complete clinical examination will be done. Routine investigations will be done.

Written and informed consent will be taken from patients/ guardian prior to scheduled operation and the procedure of spinal anaesthesia will be explained in detail to the patient.

Patients will be divided randomly into two groups:

Group R - Receiving Ramosetron 0.3mg IV.

Group O- Receiving Ondansetron 4mg IV.

METHODOLOGY:

Pre anaesthetic check up will be done on previous day of surgery with a detailed history, general physical examination, systemic examination, airway assessment and spine examination. Patient's weight and height will be recorded. All patients will be kept nil orally for 8-10 hours. Premedication will be administered with tablet Ranitidine on previous night.

On the day of surgery, patient will be shifted onto operation table and intravenous access established on the forearm with 18G intravenous cannula and randomly allocate into two groups ; group R and group O.inj ramosetron 0.3mg and inj ondansetron 4mg IV is given respectively and Lactated Ringer's solution 10ml/kg will be infused before the block to prevent intraoperative hypotension followed by nausea and vomiting. Baseline hemodynamic parameters like heart rate (HR), non invasive blood pressure (NIBP), electrocardiogram (ECG) and oxygen saturation (SpO2) will be recorded.

Patients in sitting or left lateral position, under aseptic precautions subarachnoid block will be performed by midline approach using 23G Quincke Babcock spinal needle L3-L4 intervertebral space and 2ml of 0.5% (H) Bupivacaine will be given into subarachnoid space Patients were observed intraoperatively and in recovery room and ward for any episodes of nausea , vomiting and were evaluated on a 3 point PONV score,

0- No nausea or vomiting.
1- Episode of nausea.
2- Episode of vomiting.

All the patients were observed for any other side effects if present and were treated accordingly.

Statistical Tests:

The appropriate statistical tests will be applied during the time of analysis of data.

RESULTS

Based on the inclusion and exclusion criteria, 110 Patients of ASA Grade 2 posted for LSCS were selected and randomly divided into 2 equal group of 55 each, using computer generation randomization.

Group R patients received ramosetron 0.3mg IV
Group O patients received ondensetron 4mg IV.

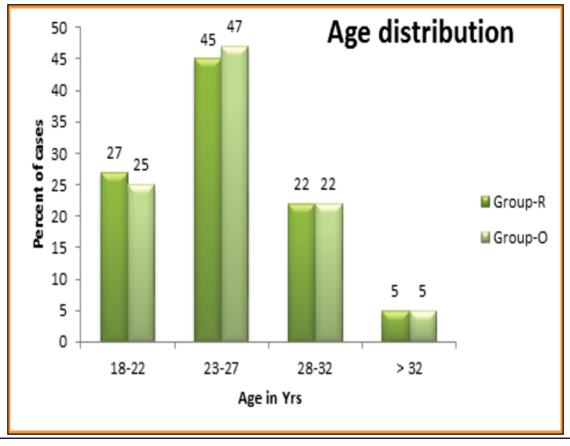
A. Demographic Data

1) Age

In Ramosetran group, 15 patients were belong to age group of 18 to 22 years (27%), 25 patients were 23-27 years(45%) , 12 patients were 28-32 years (22%) and 3(5%) patients in >32 years age group.

In Ondensetran group, 14 patients were belong to age group of 18 to 22 years (25%), 26 patients were 23-27 years(47%) , 12 patients were 28-32 years (22%) and 3(5%) patients in >32 years age group.

The average age of patients in ramosetron group was 25.07years with the standard deviation of 4.04, whereas it was 25.27years with the standard deviation of 4.08 in Ondensetron group. This distribution of sample was both group was found to be statistically non significant and matched eith p=0.80.



Graph 1 : AGE Distribution Of Study Participant In Ramosetron And Ondensetron Groups

Table 1 : Age Distribution Of Study Participant In Ramosetron And Ondensetron

Age	Group-R		Group-O	
	No	%	No	%
18-22	15	27	14	25
23-27	25	45	26	47
28-32	12	22	12	22
> 32	3	5	3	5
Total	55	100	55	100

Table Comparsion Of Mean (SD) Age Of Study Participant In Ramosetron And Ondensetron

Parameters	Group-R		Group-O		Unpaired t Test	
	Mean	Std. Deviation	Mean	Std. Deviation	P Value	Significance
Age	25.07	4.04	25.27	4.08	0.80	Not Sig

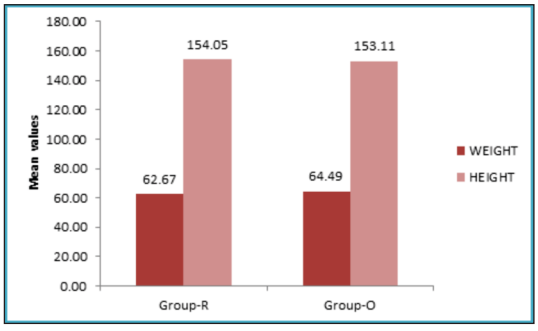
2) Weight And Height:

The mean body weight of patients in Ramosetron group was 62.67kilogram(kg)with the standard deviation of 8.00 and in Ondensteron group was 64.49kg with standard deviation of 8.03. the weight distribution was statistically similar in 2 groups with p=0.24.

The mean body height of patients in Ramosetron group was 154.05centimeter(cm)with the standard deviation of 7.08 and in Ondensteron group was 153.11cm with standard deviation of 6.81. the height distribution was statistically similar in 2 groups with p=0.48.

Table 3 : Comparison Of Mean (SD) Weight In Kilogram And Height In Centimeter Among Study Paricipant In Ramosetron And Ondensetron

Parameters	Group-R		Group-O		Unpaired t Test	
	Mean	Std. Deviation	Mean	Std. Deviation	P Value	Significance
WEIGHT	62.67	8.00	64.49	8.03	0.24	Not Sig
HEIGHT	154.05	7.08	153.11	6.81	0.48	Not Sig

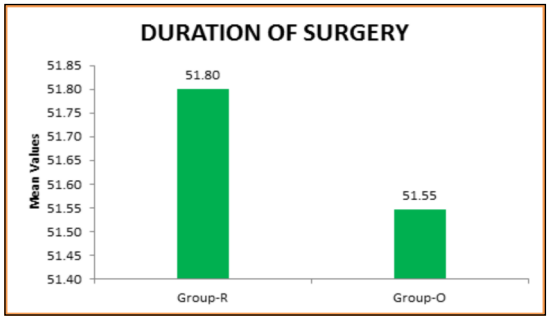


Graph2: Comparison Of Mean (SD) Weight In Kilogram And Height In Centimeter Among Study Paricipant In Ramosetron And Ondensetron

3) Duration Of Surgery:

The mean duration of surgery in Ramosetron group was 51.80 minutes with the standard deviation of 10.16 and in Ondensetron group was 51.55minutes with the standard deviation of 11.00.

Mean duration of surgery is statistically similar in 2 groups with p=0.90.



Graph 3: Distribution Of Duration Of Surgery In Two Group Of Patients Studied.

Table 4: Distribution Of Duration Of Surgery In Two Group Of Patients Studied.

Parameters	Group-R		Group-O		Unpaired t Test	
	Mean	Std. Deviation	Mean	Std. Deviation	P Value	Significance
DURATION OF SURGERY	51.80	10.16	51.55	11.00	0.90	Not Sig

B. Post-operative Data

1) Incidence Of Nausea:

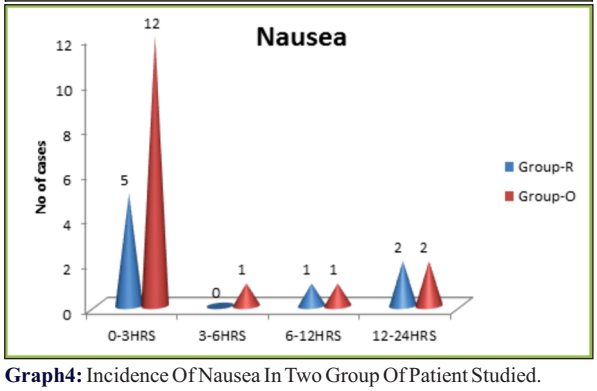
Occurance of nausea in post-operative follow up among study participant in Ramosetron with duration of 0-3hrs were 5 patients, no patient had nausea in the duration of 3-6hrs, only one patient had nausea on 6-12hrs, 2 patient had nausea in duration of 12-24hrs.

In the Ondensetron group 12 patient had nausea in 0-3hrs, one patient had nausea in 3-6hrs. one patient had nausea in 6-12hrs and 2patient had nausea in 12-24hrs.

These results were found to be statistically non significant.

Table 5: Incidence Of Nausea In Two Group Of Patient Studied.

Nausea	Group-R	Group-O	Chi Square/Fisher's Exact Test
0-3HRS	5	12	0.06, NS
3-6HRS	0	1	0.315, NS
6-12HRS	1	1	1.00, NS
12-24HRS	2	2	1.00, NS
NS=Not Sig			



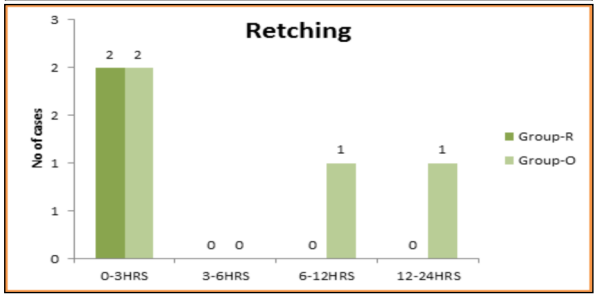
Graph4: Incidence Of Nausea In Two Group Of Patient Studied.

Incidence Of Retching

Occurance of retching during first 24hrs post-operative period. During the 0-3hrs both in Ramosetron and Ondensetron 2 patients had retching. After that none of the patient had retching in ramosetron group but one patient had at 6-12hrs duration and one more in 12-24hrs duration had retching in ondensetron group. These results were found to be statistically non significant.

Table6 : Incidence Of Retching In Two Group Of Patients Studied.

Retching	Group-R	Group-O	Chi Square/Fisher's Exact Test
0-3HRS	2	2	1.00, NS
3-6HRS	0	0	
6-12HRS	0	1	0.315, NS
12-24HRS	0	1	0.315, NS
NS=Not Sig			



Graph 5 : Incidence Of Retching In Two Group Of Patients Studied.

3) Incidence Of Vomiting:

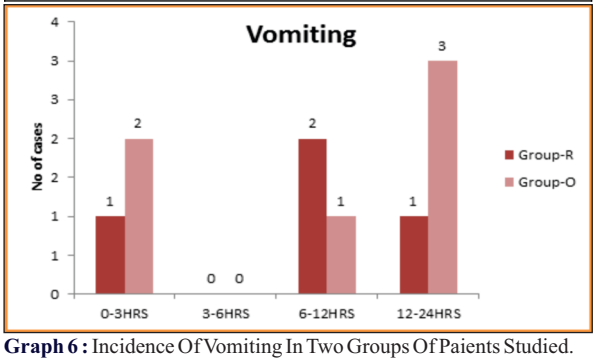
Occurance of vomiting during the first 24hrs postoperative period. During the 0-3hrs1 patients of ramosetron and 2 pt of ondensetron had vomiting. None of patient had vomiting in duration of 3-6hrs in both the groups.

In the duration of 6-12hrs, 2 patients of ramosetron and 1 patient of ondensetron had vomiting. 1 patient of ramosetron and 3 patient of ondensetron groups had vomiting in the duration of 12-24hrs.

These results were found to be statistically non significant.

Table 7: Incidence Of Vomiting In Two Groups Of Paients Studied.

Vomiting	Group-R	Group-O	Chi Square/Fisher's Exact Test
0-3HRS	1	2	0.558, NS
3-6HRS	0	0	
6-12HRS	2	1	0.547, NS
12-24HRS	1	3	0.308, NS
NS=Not Sig			



Graph 6 : Incidence Of Vomiting In Two Groups Of Paients Studied.

4)incidenceof Rescue Antiemetics Required.

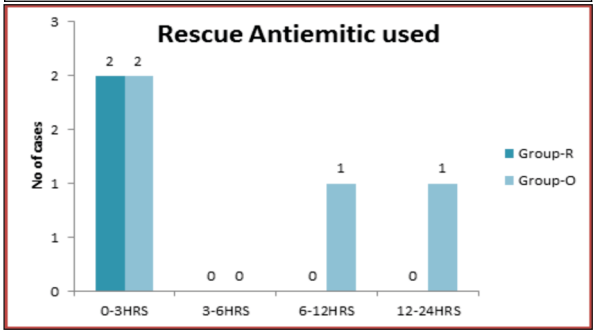
The rescue antiemetics used was Metoclopramide 10mg I.V

Suring 0-3hrs 2patients of ramosetron and 2pt of ondensetron needed rescue antiemetic.in duration of 6-12hrs 0 patients of ramosetron and 1 patient of ondensetron needed rescue antiemetics. None of patient in ramosetron group and 3 patients in ondensetron group needed rescue antiemetic in the duration of 12-24hrs.

These results were statistically non significant.

Table 8 : Incidence Of Rescue Antiemetics In Two Group Of Patients Studied.

Rescue Antiemitic used	Group-R	Group-O	Chi Square/Fisher's Exact Test
0-3HRS	2	2	1.0, NS
3-6HRS	0	0	
6-12HRS	0	1	0.315, NS
12-24HRS	0	1	0.315, NS
NS=Not Sig			



Graph 7 : Incidence Of Rescue Antiemetics In Two Group Of Patients Studied.

5) Incidence Of Complete Response

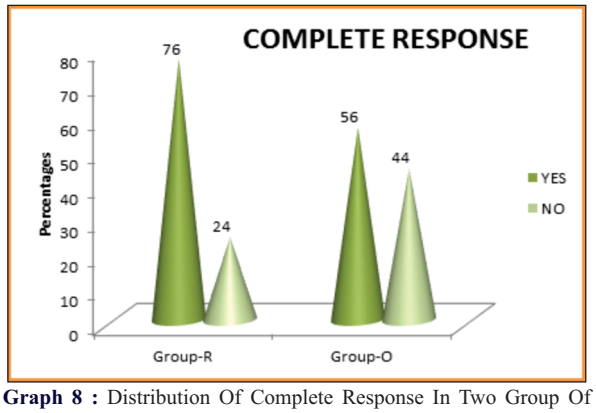
Complete response defined as the absence of nausea, retching or vomiting and no need of rescue antiemetic during the 24hrs observation period.

The incidence of complete responders in Ramosetron group was 42 patients (76%) and in Ondensetron group it was 31patients(56%).

Complete response is significantly more in ramosetron with p<0.023.

Table 9: Distribution Of Complete Response In Two Group Of Patients Studied.

COMPLETE RESPONSE	Group-R	Group-O
YES	42 (76)	31 (56)
NO	13 (24)	24 (44)
Total	55	55
Chi Square Test P<0.023, Sig		



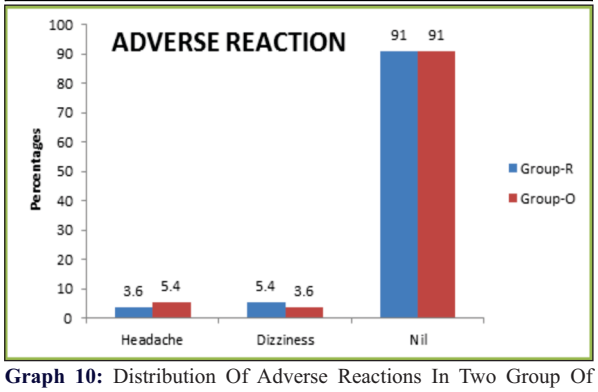
Graph 8 : Distribution Of Complete Response In Two Group Of Patients Studied.

6) Incidence Of Adverse Reaction

In Ramosetron group, 2 patients complained of headache and 3 patient complained of dizziness. In Ondensetron group 3 patients complained of headache and 2 complained of dizziness. These results were statistically non significant.

Table 10 : Distribution Of Adverse Reactions In Two Group Of Patients Studied.

ADVERSE REACTION	Group-R	Group-O
Headache	2 (3.6)	3 (5.4)
Dizziness	3 (5.4)	2 (3.6)
Nil	50 (91)	50 (91)
Total	55	55
Chi Square Test P<0.819, Not Sig		



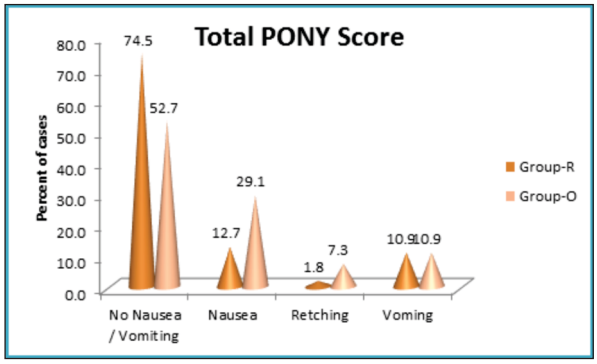
Graph 10: Distribution Of Adverse Reactions In Two Group Of Patients Studied.

7) Overall Incidence Of Nausea, Retching, Vomiting And Rescue Antiemetic:

In Ramosetron group, 7 patients (12.7%) had nausea, 1 retching and 6 patients had vomited. Whereas in ondensetron group 16 patients had nausea, 4 patient retching and 4patient had vomiting.

Table 11 : Overall Incidence Of Nausea, Retching, Vomiting And Rescue Antiemetic In Two Group Of Patients Studied.

Total PONY Score	Group-R		Group-O	
	N	%	N	%
No Nausea / Vomiting	41	74.5	29	52.7
Nausea	7	12.7	16	29.1
Retching	1	1.8	4	7.3
Vomiting	6	10.9	6	10.9
Total	55	100	55	100



Graphs 11 : Overall Incidence Of Nausea, Retching, Vomiting And Rescue Antiemetic In Two Group Of Patients Studied.

DISCUSSION

Postoperative nausea and vomiting (PONV) are common sequelae of general anaesthesia. PONV is an unpleasant, distressing, and exhausting experience for patients. PONV are the most common distressing symptoms occuring after carboprost in LSCS . PONV increases the duratíon of hospítal stay, the readmission rates after discharge. Hence control of PONV after carboprost during LSCS is of utmost importance. The incidence of PONV varies from 36-82 % during immediate postoperative recovery and can be as high as 40-70% . Because of this high incidence of PONV; we decided to conduct our study after carboprost in LSCS.

This high incidence of PONV after CARBOPROST in LSCS under spinal anaesthesia may justify the use of prophylactic antiemetic therapy and therefore, we did not believe it to be ethical to include a placebo group.

Numerous factors can affect PONV, such as age, obesity, history of motion sickness and/ or PONV, use of opioids, anaesthetic technique and its duration, duration and postoperative pain. In the present study, majority of these factors (age, weight, height, duration of surgery) were statistically insignificant between both the groups (Pp> 0.05). The anaesthetic technique was standardized (spinal anaesthesia) in all patients. Even analgesic used postoperatively for pain in both the groups was same i.e, NSAIDs like Diclofenac infusion (2mg/kg) thereby avoiding Opioids post-operatively.

The study population of 110 patients was randomly selected regardless of a past history of motion sickness and / or PONV, opioids or other analgesics taken in the previous 24 hours[6]. Therefore, the difference in a complete response (the absence of nausea, retching or vomiting and no need for rescue antiemetic during the 24-hour observation period) between the groups can be attributed to the study drugs.

5HT3 receptor antagonists suppress nausea and vomiting at the Nucleus Tractus Solitarus and Chemoreceptor Trigger Zone sites. The 5-HT3 receptor antagonists prevent serotonin from activating and sensitizing the vagal afferent nerves which causes nausea and vomiting. The 5-HT3 receptor antagonists ameliorate nausea/ vomiting in a number of circumstances and have been utilized as important antiemetics for multiple conditions like chemotherapy induced nausea/vomiting (CINV), radiation-induced emesis (RIS), and PONV.

In the early 1990s, Fozard and Maurice Gittos synthesized the tirst truly potent, S-Hl3 receptor antagonist, Ondansetron. The most commonly used, 5-HT3 receptor antagonist is Ondansetron. Ondansetron, a selective blocking agent of serotonin 5-HT3 (5-hydroxytryptamine type 3) receptor type, is a highly effective antiemetic that has been used successfully for both the prophylaxis and treatment of PONV in the surgical outpatient population. This drug, which was considered to represent the first universally effective antiemetic for post-operative nausea and vomiting, was later found to have less antinausea and more antiemetic efficacy[7].

Ramosetron is a potent and selective serotonin 5-HT3 receptor antagonist. Ramosetron is effective for the treatment of nausea and vomiting induced by anti-cancer drugs. Ramosetron has more potent

and longer acting properties against Cisplatin-induced emesis than granisetron. It exhibits a higher affinity for the receptors with a slower dissociation, resulting in a longer duration of action."

Hence this study was done to determine the efficacy of prophylactic Ondansetron and Ramosetron im preventing the incidence of postoperative nausea and vomiting after carboprost in LSCS and assess the requirement of other rescue antiemetic in the postoperative period and assess any adverse etfects associated with their use[8].

Recommended dose of Ondansetron for PONV prophylaxis is 4 mg. In Our Study, the dosage selection of Ondansetron (4 mg, iv) was based on the previous studies done by McKenzie R et al, in 1993, Raphacl JH and Norton AC" in 1993 propnylactic Ondansetron-meta analysis by Figueredo and Canosa in 1998, Dershwitz M. et al in 1998, and Chidambaram A et al in 2010.

Ching-Liang lo, et al demonstrated Ramosetron effectiveness in the dose of 0.3 mg in the control of CINV caused by Cisplatin and non cisplatin patients with a good safety profile. S. L Kim, ct al have shown Ramosetron 0.3 mg to be effective in decreasing the incidence of PONV and reducing severity of nausea during the first 24 hours after gynaccological surgeries. The dosage of 0.3 mg Ramosetron was adequate in controlling PONV following laparoscopic choleeystectomy (Maulana M Ansari, et al) and in total thyroidectomy in females (Dong Chul Lee, ct al).

Metoclopramide (10 mg i.v) was chosen as the rescue antiemetic based on previous studies done by Naguib M et al in 1996, Chidambaram A et al" in 2010.

Therefore we chose Ramosetron in the dose of 0.3 mg IV, Ondansetron 4 mg IV, and Metoclopramide 10 mg V for our study.

In our study we decided to administer the study drugs two minutes before the induction of anaesthesia on the basis of previous studies done by Kuldip C. Gupta, Nandita Mehta, Kulbhushan Malhotra et al." The onset of action of an intravenous dose of Ondansetron occurs in less than 30 minutes but for time taken for the peak effect to manifest is variable. The duration of action is 12 to 24 hours, The onset of the antiemetic action of Ramosetron occurs within approximately 30 minules after a single intravenous administration, with a duration of action of more than 24 hours.

Hence intravenous administration of both the drugs just before induction, is supposed to provide sufficient postoperative antiemetic effect.

In our study postoperative assessment of nausea, retching and vomiting at 0-3hours, 3-6hours, 6-12hours and 12 -24 hour intervals in both the Ondansctron, Ramosetron groups were 1ound to be statistically insignificant (p> 0.05), which is comparable to studies done by Maulana M Ansari et al in 2015 who compared Ramosetron and Ondansetron for control of postoperative nausea and vomiting following laparoscopic cholecystectomy. However, in the 0-3 hour post-operative period,, while incidence of nausea and retching were similar in both the groups, 2 patients had vomiting in Ondansetron group while 3 patient had vomiting in Ramosetron group. This is statistically no significant and is in accordance with the results found by Sarbari Swaika et al in 2011.

During the 0-2 hr postoperative period, 2 patients in the Ondansetron group needed rescue antiemetic, whereas 2 patient needed it in the Ramosetron group. This is statistically non significant and the result is in accordance with studies done by S I Kim et all and Maulana M Ansari," . In 12-24 hour 1 patient in the Ramosetron group needed rescue antiemetic whereas 3 patient in ondensetron group.

These are statistically non-significant, With regard to adverse effects, both the drugs were relatively well tolerated. In Ondansetron group 3 patients complained of headache and 2 patient complained of dizziness, whereas in Ramosetron group 2 patients complained of headache and 3 patients complained of dizziness. The side eftects of both the groups were comparable in accordance with the study done by Sameer Denai in 2015.

"Complete response" to the prevention of PONV was defined as the absence of nausea, retching or vomiting and no need tor rescue antiemetic during the 24-hour observation period postoperatively. In our study, the complete response occurred in 31 patients (56%) in Ondansetron group whereas it was 42(76%) patients in Ramosetron group. This is in accordance with studies done by Kuldip C Gupta et al in 2014.

Finally it can be concluded that Ramosetron at an intravenous dose of 0.3 mg is safe and well-tolerated and more effective in controlling the incidence of vomiting and need for rescue antiemetic, and increasing the incidence of complete response in the first 24 hour post-operative period, than 4 mg intravenous Ondansetron when used for antiemetic prophylaxis after carboprost in LSCS in patients under spinal anaesthesia. Benefits of Ramosetron like high receptor specificity, high potency, and longer duration of action, make it a valuable alternative to Ondansetron.

We did not address the issues of economy and surrogate variables like hospitaldischarge times, expenses incurred towards treating established PONV and sequelae of PONV and can be considered as the shortcomings in this study.

CONCLUSION

Patients undergoing LSCS under spinal anaesthesia are at moderate to high risk for PONV. PONV are the most common distressing symptoms occurring after LSCS after carboprost injection. PONV increase the duration of hospital stay, the readmission rates after discharge. PONV might lead to wound dehiscence, increased intraocular and intracranial pressure, dehydration, clectrolyte imbalance, and aspiration. Hence control of PONV after LSCS after carboprost s is of utmost importance.

The need for more effective antiemetic drugs without the potential for sedation or extrapyramidal side-cffects have led to the development of a relatively newer class of drugs, the 5-HT3 antagonists of which Ondansetron is a prototype. The need for drugs with improved performance within this group arose on account of relatively less potency and shorter duration of action, besides detectable binding to other 5-HT receptors by Ondansetron. Ramosetron is a potent and highly selective 5-HT; receptor antagonist that has little or no affinity for other 5-HT receptors. We conducted this study to determine the efficacy of prophylactic Ondansetron and Ramosetron in preventing the incidence of postoperative nausea and vomiting in adults undergoing LSCS after carboprost under spinal anesthesia.

Results of our study showed that overall incidence of vomiting and need for rescue anti emetic was more in Ondansetron group in the first 3 hour and 24hrs post-operatively, and complete response in Ramosetron group (76%) is higher than Ondansetron group (56%) and is statistically significant (p value <0.023).

In conclusion, Ramosetron at an intravenous dose of 0.3 mg is safe and Well tolerated and more effective than 4 mg intravenous Ondansetron for antiemetic prophylaxis in adults undergoing LSCS under spinal anaesthesia after carbiprost injection and can be employed as routine antiemetic prophylaxis for PONV.

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