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The efficacy and safety of granisetron with ondansetron for the prevention of post-operative nausea and vomiting in patients undergoing cesarean section under spinal anesthesia

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ABSTRACT

Background: Spinal anesthesia often causes more post-operative nausea and vomiting (PONV). Cesarean-section patients have a significantly more PONV rate. Therefore, evidence-based knowledge about PONV prevention and care for high-risk individuals is urgently needed to reduce the consequences. **Aims and Objectives:** The aim of the study was to compare the efficacy and safety of granisetron with that of ondansetron in the prevention of PONV in patients undergoing cesarean section under spinal anesthesia. **Materials and Methods:** A total of 86 pregnant women with American Society of Anesthesiologists grade I–II scheduled for cesarean delivery under spinal anesthesia were enrolled. Patients were divided into two equal groups (n = 43): Ten minutes before spinal anesthesia, patients in group B (granisetron) received 2 mg granisetron intravenously diluted to 10 mL with normal saline, whereas patients in group A (ondansetron) received 4 mg ondansetron. **Results:** There was no significant difference between Groups A and B in terms of the number of vomiting episodes between 0 and 6 h. Group A had significantly more episodes of nausea after 2 h than Group B after 0–2 h. After 2–6 h, however, the nausea was similar in all groups. Of the patients in Group A, 4 (9.3%) required antiemetic medication, in Group B, it was 2 (4.7%). In Group A, 8 patients (18.6%) and 6 patients (14%) complained of headache and dizziness, respectively; in Group B, 3 patients (7.0%) and (0%), respectively. Dizziness was significantly more pronounced in Group A than in Group B. **Conclusion:** The results of the study show that granisetron (2 mg) was more effective than ondansetron (4 mg) in minimizing PONV episodes in women undergoing spinal anesthesia for cesarean section. There were no significant side effects and both drugs were comparatively safe.

Key words: Spinal Anaesthesia; Cesarean section; Granisetron; Shivering; Nausea; Vomiting

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INTRODUCTION

Ensuring the safety of mother and child is the main goal of obstetric anesthesia. Therefore, the choice of anesthesia and its correct administration are of crucial importance. For a long time, it was thought that general anesthesia for cesarean sections contributed to a higher incidence and severity of postpartum hemorrhage. In recent years, however, there has been a remarkable movement in favor of regional anesthesia, particularly spinal anesthesia.[1,2] General anesthesia is not recommended in favor of spinal anesthesia. Due to its simplicity, speed, simultaneous awareness of the mother and administration of the anesthesia, dense nerve block, reduced shivering, and low

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exposure of the fetus to drugs, spinal anesthesia is a safe and efficient anesthesia procedure for cesarean sections.[3] In addition, spinal anesthesia is much more economical compared to other regional anesthesia methods such as epidural anesthesia.[1] Post-operative nausea and vomiting (PONV) is a disadvantage of spinal anesthesia, despite its many purported advantages.[4,5] There is ample evidence that PONV has been shown to occur more frequently in women undergoing gynecologic or breast surgery, 80%–95% of whom receive minimal or no prophylactic antiemetic medication in the first 24 h after surgery.[6-8] PONV is an important factor in patient satisfaction and has a negative impact on the overall patient experience, particularly following cesarean section.[5]

Older, widely used antiemetics for the treatment of PONV were known to have unfavorable side effects, including drowsiness, dry mouth, dysphoria, hypotension, tachycardia, extrapyramidal reactions, dystonic symptoms, and agitation, leading to patient dissatisfaction. Although there are several antiemetic drugs on the market, no conventional antiemetic is 100% effective in preventing PONV, and combination drugs have many side effects.[5]

The incidence of PONV has not changed significantly even with the advent of new antiemetic medications, short-acting anesthetics, and minimally invasive surgical procedures. Antiemetic prophylaxis is now the recognized method for reducing PONV.[9,10]

Preventive antiemetic medication is not only beneficial but can also help patients at higher risk of PONV avoid hospitalization and additional care costs.[11] Traditional antiemetics, although tried, have their own drawbacks. Ondansetron, granisetron, tropisetron, and dolasetron are examples of the newer antiemetics used to treat and prevent PONV; they have none of these negative effects. Granisetron is a selective 5-HT3 antagonist and a relatively new antiemetic.[12] In the present study, the antiemetic effect of intravenous granisetron and ondansetron was compared for the prevention of PONV in cesarean section patients. Preventive use of these 5-HT3 receptor antagonists has been shown to increase patient satisfaction, shorten hospital stay and recovery time, and reduce the likelihood of unexpected hospital admissions.[13] It was therefore decided to compare the efficacy and safety of granisetron with that of ondansetron in the prevention of PONV in patients undergoing cesarean section under spinal anesthesia.

Aims

To compare the efficacy and safety of granisetron with that of ondansetron in the prevention of post-operative nausea and vomiting in patients undergoing caesarean section under spinal anaesthesia.

Objectives

1. To study and compare the incidence of post-operative nausea and vomiting between patients undergoing prophylaxis with granisetron and ondansetron.
2. To study and compare the side effects such as postoperative headache, dizziness, diplopia and shivering between granisetron and ondansetron groups.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Anesthesiology and the Department of Obstetrics and Gynaecology, Era's Lucknow Medical University and Hospital, Lucknow. Era's Lucknow Medical University is a tertiary care center with state-of-the-art infrastructure that primarily caters to the socioeconomically underprivileged suburban and rural population of Lucknow. The study included pregnant women with American Society of Anesthesiologists (ASA) grade I-II who were scheduled for cesarean delivery under spinal anesthesia. Patients with PONV, motion sickness, hyperemesis gravidarum, and pre-eclampsia, who had received antiemetics within 24 h before surgery, received methylergometrine and/or carboprost during surgery, and had a body mass index ≥30 were excluded.

After approval by the institution's ethics committee, a total of 86 patients with ASA I and II who met the eligibility criteria were included in the study. Subsequently, these patients were randomly divided into two equal groups of 43 patients each using computer-generated randomization: Patients in Group A (ondansetron group) received 4 mg ondansetron and patients in Group B (granisetron group) received 2 mg granisetron i.v. diluted to 10 mL with normal saline 10 min before spinal anesthesia.

Before the operation, each patient underwent an examination. Patients were not allowed to eat for at least 6 h before the operation. Written and informed consent was required for both the study and the anesthesia. After the patient was transferred to the pre-operative area of the operating room, intravenous access was established with an 18 G cannula, and administration of intravenous fluid (Ringer's lactate) was started at a rate of 20 mL/kg/h. 10 min before spinal anesthesia, the experimental drugs were administered intravenously. After the patient was taken to the operating room, the non-invasive blood pressure cuff, pulse oximeter probe, and electrocardiography electrodes were connected.

A 25-G Quincke-Babcock spinal needle was inserted between the L3 and L4 subarachnoid spaces while the patient was seated, following strict aseptic measures. Once

CSF free flow was confirmed, 12 mg of 0.5% hyperbaric bupivacaine was administered. Patients were placed in a horizontal supine position with a pillow under the head immediately after injection. Oxygen was administered to the patients through a face mask with a flow rate of 4–6 L/min. Alcohol swabs were placed bilaterally in the midclavicular line to measure the stinging and cold sensations to determine sensory blockade. The modified Bromage score was used to assess motor blockade immediately after sensory blockade assessment.

The following parameters were noted: Heart rate (HR), oxygen saturation, mean arterial pressure (MAP), diastolic blood pressure (DBP), systolic blood pressure (SBP), HR (DBP), and episodes of nausea and vomiting. The parameters were measured at the beginning of spinal anesthesia, 5 min after delivery, 10 min after the patient was transferred to the recovery room (RR), and every 2 h during the 6 h stay in the RR. For example baseline, 5, 10, 15, 25, 35, and RR, then 2, 4, and 6 h. After delivery, the operating gynecologist ordered the administration of an oxytocin injection. Treatment for hypotension included increasing the crystalloid infusion rate and administering intravenous ephedrine in 5 mg increments. Hypotension was defined as a blood pressure of <100 mmHg or a fall of more than 20% from baseline.

Atropine (0.5 mg intravenously) was used to treat bradycardia, which was defined as a HR of <50 beats/min. An intramuscular injection of diclofenac sodium (75 mg) was used for post-operative analgesia. In case of more than two episodes of vomiting and nausea lasting at least 15 min, an intravenous injection of 10 mg metoclopramide is administered as an emergency antiemetic.

Statistical analysis

The statistical analysis is performed using SPSS version 23.0. Data are presented as percentages (%) and mean (standard deviation). The Chi-square test is used to compare categorical variables between groups, whereas the independent t-test is used to analyze discrete variables. P<0.05 is considered significant.

RESULTS

The mean age, weight, and duration of surgery and frequencies of I and II ASA were comparable between Group A and Group B (Table 1).

Between 0 and 2 h, 19 (44.2 %) patients in Group A had no nausea, 17 (39.5 %) had one episode of nausea, and 7 (16.3 %) had two episodes of nausea. In Group B, on the other hand, 33 (76.7%) had no nausea and 10 (23.3%) had one episode of nausea in the same period. Statistically, there was a significant difference between the two groups (P=0.002). 40 (93.0%) of the patients in Group A had no nausea between 2 and 4 h and 3 (7.0%) had an episode of nausea. In contrast, in Group B, 39 (90.7%) had no nausea and 4 (9.3%) had an episode of nausea during the same period. Statistically, there was no significant difference between the two groups (P=0.693). Between 4 and 6 h, none of the patients in either group had a nausea episode (Table 2).

Between 0 and 2 h, the PONV score was 0, 1, and 2 in 19 (44.2%), 0 and 24 (55.8%) of the cases in Group A, and in 33 (76.7%), 4 (9.3%), and 6 (14%) of the cases in Group B, respectively. Statistically, this difference was significant (P=0.007). Between 2 and 4 h, the PONV score was 0, 1, and 2 in 37 (86%), 2 (4.7%), and 4 (9.3%) of the cases in Group A, and 39 (90.7%), 3 (7.0%), and 1 (2.3%) of the cases in Group B, respectively. Statistically, this difference was not significant (P=0.693). Between 4 and 6 h, the PONV score was 0 for all patients in both groups (Table 2).

Antiemetic treatment was required in 4 (9.3%) of the patients in Group A and 2 (4.7%) of the patients in Group B. Headache and dizziness were reported in 8 (18.6%) and 6 (14%) patients in Group A, compared with 3 (7.0%) and 0% patients in Group B. Statistically, the difference between the two groups was significant only for dizziness (P=0.011) (Table 3).

At baseline, mean DBP was 80.37±4.41 mmHg and 80.63±4.15 mmHg, respectively, in Groups A and B. The

Table 1: Baseline characteristics of the patients between Group A and Group B

Parameters	Group A (n=43)		Group B (n=43)		P-value
	Mean	±SD	Mean	±SD	
Age (years)	26.99	3.53	27.60	3.22	0.222
Weight (kg)	55.37	7.16	55.67	8.31	0.973
American Society of Anesthesiologists Grade					
Grade I	39	90.7	35	81.4	0.213
Grade II	4	9.3	8	18.6	
Duration of surgery (min)	36.26	4.39	37.47	4.99	0.236

SD: Standard deviation

Table 2: Comparison of post-operative episodes of vomiting in two study groups

Durations	No. of episodes	Group A (n=43)		Group B (n=43)		Statistical significance	
		No.	%	No.	%	χ^2	P
Vomiting							
0–2 h	0	19	44.2	37	86.0	17.546	0.001
	1	21	48.8	4	9.3		
	2	3	7.0	2	4.7		
2–4 h	0	39	90.7	42	97.7	2.111	0.349
	1	3	7.0	1	2.3		
	2	1	2.3	0	0		
4–6 h	0	43	100	43	100	0	1.000
	1	0	0	0	0		
	2	0	0	0	0		
Nausea							
0–2 h	0	19	44.2	33	76.7	12.584	0.002
	1	17	39.5	10	23.3		
	2	7	16.3	0	0.0		
2–4 h	0	40	93.0	39	90.7	0.156	0.693
	1	3	7.0	4	9.3		
	2	0	0	0	0		
4–6 h	0	43	100	43	100	0	1.000
	1	0	0	0	0		
	2	0	0	0	0		

Table 3: Comparison of post-operative antiemetic need and side effects in different groups

Variable	Group A (n=43)		Group B (n=43)		Significance of difference	
	No.	%	No.	%	"χ^2"	"P"
Rescue antiemetic need	4	9.3	2	4.7	0.716	0.397
Headache	8	18.6	3	7.0	2.606	0.106
Dizziness	6	14.0	0	0	6.450	0.011

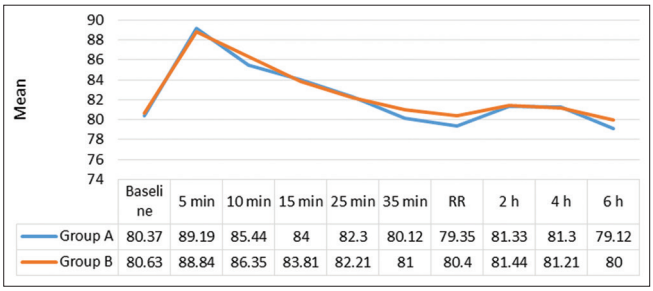


Figure 1: Diastolic blood pressure (mmHg)

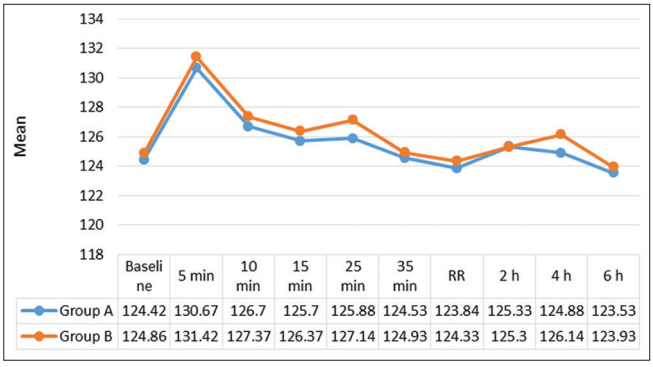


Figure 2: Systolic blood pressure (mmHg)

mean DBP was not significantly different from baseline to intraoperative and post-operative 6 h (Figure 1).

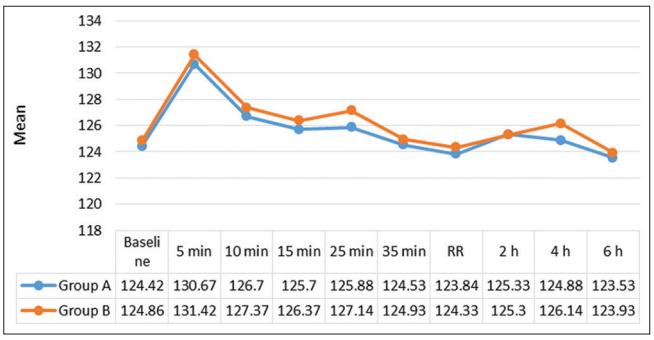
At baseline, the mean SBP was 124.42±8.09 in group A and 124.86±8.01 in group B. The mean SBP was not significantly different from baseline to intraoperative and post-operative 6 h (Figure 2).

At baseline, mean MAP was 124.42±8.09 mmHg in group A and 124.86±8.01 mmHg in group B. The mean MAP was not significantly different from baseline to intraoperative and post-operative 6 h (Figure 3).

At baseline, the mean HR was 78.02±3.78 bpm in Group A and 78.00±4.10 bpm in Group B. The mean HR was not significantly different from baseline to intraoperative and post-operative 6 h (Figure 4).

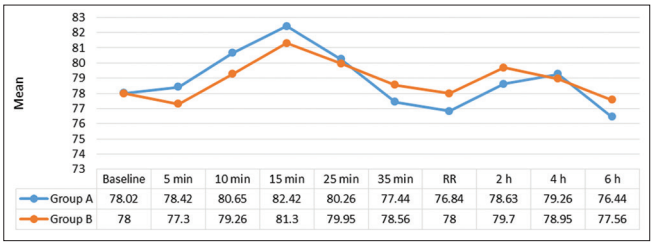
DISCUSSION

PONV in cesarean section deliveries is still common due to the adverse effects of conventional antiemetics.[10-12]



	Baseline	5 min	10 min	15 min	25 min	35 min	RR	2 h	4 h	6 h
Group A	124.42	130.67	126.7	125.7	125.88	124.53	123.84	125.33	124.88	123.53
Group B	124.86	131.42	127.37	126.37	127.14	124.93	124.33	125.3	126.14	123.93

Figure 3: Mean arterial pressure (mmHg)



	Baseline	5 min	10 min	15 min	25 min	35 min	RR	2 h	4 h	6 h
Group A	78.02	78.42	80.65	82.42	80.26	77.44	76.84	78.63	79.26	76.44
Group B	78	77.3	79.26	81.3	79.95	78.56	78	79.7	78.95	77.56

Figure 4: Heart rate (beats/min)

Recent advances in 5-HT3 receptor antagonists such as granisetron and ondansetron have been shown to have no side effects and are popular with surgical teams.[13] However, their relative efficacy in different clinical situations is less well documented. The aim of this study is to compare the efficacy of granisetron in different clinical situations.

In the present study, we found a significant difference between the two groups in the outcomes of vomiting, nausea, and PONV totals only in the early post-operative period (0–2 h), where granisetron outperformed ondansetron both in the occurrence of these events and in the higher severity of these events. In the subsequent follow-up intervals, no significant difference was observed between the two groups in terms of nausea, vomiting, and overall PONV scores. In fact, all serious PONV events occurred only in the first 2 post-operative h, and there was a consecutive decrease in these events in subsequent follow-up intervals. In the present study, no PONV event was detected in either group after 4 h post-operative interval. This means that both groups were effective in suppressing PONV beyond the 2-h post-operative period, while granisetron provided better control in the first 2 h after surgery.

According to the results presented by Hailu et al., multimodal PONV prophylaxis should be carried out in all obstetric patients undergoing cesarean section.[4] Due to the complicated pathophysiology of nausea and vomiting, research suggests that a multimodal strategy using a variety of antiemetic medications should be used and is most successful in preventing both intraoperative and PONV in cesarean section patients. Granisetron is known to have an excellent PONV suppressive effect as shown in different studies. Dasgupta et al.,[14] in their study reported a complete response in 80 and 82.5% of patients receiving granisetron at a dose of 40 μg/kg during the 0–4 and 4–24 h post-operatively, respectively.

In the present study, granisetron was found to be fully responsive in 86% and 97.7% of patients in the 0–2 and 2–4-h post-operative intervals, respectively, and fully effective in the 4–6-h period. As the duration of post-operative follow-up in the present study was limited to 6 h, we are not in a position to comment on the efficacy of granisetron for a post-operative period of up to 24 h. However, within the time frame of the study, our results for granisetron were comparable to previous studies[14] and we support their findings regarding the high efficacy of granisetron for the prevention of PONV. Although Parripati et al.,[15] found no significant difference in PONV scores between the granisetron and ondansetron groups for observations up to 24 h of the blockade in the 3 time periods 0–6 h, 7–12 h, and 13–24 h, they found that the incidence of PONV during the 7–12 h and 13–24 h periods was higher with granisetron (16% and 20%) compared to ondansetron (64% and 56%, respectively), demonstrating the superiority of granisetron over ondansetron as observed in the present study.

The differences in the blocked periods of post-operative evaluation and the total duration of follow-up have shown that the response patterns are slightly different in the different studies, yet the performance of granisetron and ondansetron at the given drug-dose combinations used in the present study has also shown clear superiority of granisetron over ondansetron in other studies.

In the study by Makker et al.,[16] who also used the same dose combinations of ondansetron and granisetron as in the present study, but evaluated the performance of the two drugs over two blocked post-operative intervals, namely, 0–3 h and 3–24 h, no significant difference was found between the two groups for the early (0–3 h) results, but reported that the ability of granisetron to completely contains PONV during the late (3–24 h) was significantly better than that of granisetron. Nikam et al.,[17] who reported their results over four post-operative time blocks, i.e., 0–6 h, 6–12 h, 12–18 h, and 18–24 h, found no significant difference between the two groups (for the same drug-dose combinations as in the present study) but noted that the performance of granisetron was significantly better than that of ondansetron in the 0–6 and 6–12 h post-operative block times. In another study, Chaudhari et al.,[18] also found no significant difference between the two drugs in the early post-operative period (0–6 h) but found significant differences between the two groups in

the late post-operative period (7–12 h) and reported that the performance of granisetron was better than that of ondansetron. In the present study, we did not include the results after the 6-h period because, according to the evidence available to date, the use of rescue antiemetics in patients with PONV episodes beyond the 6-h period is widespread, which could affect the performance of the preventive drugs we used. Considering the shorter overall duration of follow-up in the present study, the duration of blocked follow-up periods was also narrow, but within this narrow blocking of post-operative periods, we found that the performance of granisetron was better than that of ondansetron, which was also observed in previous studies that used the same drug-dose combinations but whose studies used different post-operative time blocks.[19,20]

In the present study, the need for emergency antiemetics was higher in the ondansetron group (9.3%) than in the granisetron group. Side effects such as headache and dizziness were also more common in the ondansetron group (18.6% and 14%) than in the granisetron group (7% and 0%), although the difference was only statistically significant for dizziness. In general, both drugs were reported to be well tolerated with no serious side effects. In their study, Anisha and Narayan[20] found side effects such as tremors, pain, nausea, and bradycardia in 0%–10% of patients in the ondansetron group and 10%–17% of patients in the granisetron group, although these were not statistically significant. In their study, Makker et al.,[16] and Mehta et al.,[19] reported headache and dizziness in 6.7%–10% in the ondansetron group and 6.7% and 6.7% in the granisetron group, respectively, and found no significant difference between the two groups. Although Nikam et al.,[17] found no significant difference between the two groups for individual side effects such as constipation and dizziness, they did find that headache was significantly more common in the ondansetron group (25%) than in the granisetron group (7.5%). Headache and dizziness are among the most frequently reported side effects of ondansetron, whereas granisetron is relatively safe in comparison.

Based on the results of the present study and its evaluation in light of the available evidence, there is an agreement with most of the available evidence supporting the use of granisetron over ondansetron for the prevention of PONV in patients undergoing surgery under spinal anesthesia. Further studies with a larger sample size are recommended to validate the results of the present study.

CONCLUSION

The results of the study showed that granisetron (2 mg) was more effective than ondansetron (4 mg) in reducing PONV episodes in women undergoing cesarean section under spinal anesthesia. Both drugs were relatively safe and no major complications occurred.

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Authors Contribution:
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