Original Research

A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND CLINICAL TRIAL FOR VALIDATING THE ENHANCED EFFECTIVENESS OF ONDANSETRON AND DEXAMETHASONE COMBINATION FOR PONV PROPHYLAXIS IN CAESAREAN SECTION WITH SPINAL ANAESTHESIA

Dr. Peter Engti[1], Dr. Deeshna A.[2], Dr. Snehlata Kumari[3], Dr. Bandana Mahanta[4]
[1]Assistant Professor, Department of Anaesthesiolgy, Diphu Medical College and Hospital, Diphu, Assam, India.
[2]Junior Consultant, Department of Anaesthesiology and Critical Care, Peerless Hospital, Guwahati, Assam, India.
[3]Assistant Professor, Department of Anaesthesiolgy, Pragjyotishpur Medical College and Hospital Guwahati, Assam, India.
[4]Professor & HOD, Department of Anaethesiology, Diphu Medical College and Hospital, Diphu, Assam, India.
Corresponding Author: Dr. Peter Engti
Assistant Professor, Department of Anaesthesiolgy, Diphu Medical College and Hospital, Diphu, Assam, India.

ABSTRACT

Background: Postoperative nausea and vomiting (PONV) has long been a common headache that accompanies caesarean section with spinal anaesthesia and leads to patient agitation, impaired recovery, and risk of comorbidities. The present study is done to establish the effectiveness of ondansetron, dexamethasone, and the combination in prevention of PONV in caesarean section patients of Diphu Medical College and Hospital, Assam.
Method: A total of 159 pregnant women, aged between 25 and 35 years, were randomly assigned into three groups (Group A, 4 mg dose; Group B, 8 mg dose; and Group C, Combination dose). The study employed a randomized, double-blind design with intraoperative and postoperative monitoring of nausea, vomiting, and key parameters.
Result: Results showed that the combination therapy (Group C) significantly reduced the incidence of both intraoperative (3.8%) and postoperative nausea (3.8%) compared to ondansetron alone (15.1% and 13.2%) and dexamethasone alone (41.5% for both). Notably, postoperative vomiting was absent in the combination group, whereas it occurred in 17% and 26.4% of patients in Groups A and B, respectively. Statistical analysis confirmed the significance of these findings ($p < 0.05$). Additionally, combination therapy demonstrated a lower frequency of side effects such as headache, dizziness, and rashes compared to monotherapy.
Conclusion: Based on the results, the combined ondansetron and dexamethasone approach exhibited stronger antiemetic activity over monotherapy, decreased random drug related adverse events and results in better PONV prophylaxis in caesarean sections under spinal anaesthesia.

Keywords: Caesarean Section, Spinal Anaesthesia, Postoperative Nausea and Vomiting (PONV), Ondansetron, Dexamethasone.

INTRODUCTION

Post operative nausea and vomiting is a commonly occurring clinical syndrome following surgical procedure performed under general and localized Anaesthesia, and also inclusive of obstetric interventions such as Caesarean section performed under spinal anaesthesia. Characterized by retching, nausea and vomiting due to activation of the vomiting centre in the brain stem via Chemoreceptor Trigger Zone (CTZ) mediated signalling upon receiving toxic or chemical stimulus (Chemotherapy or Anaesthetic drugs).

Similar signalling to the vomiting centre may also be raised due to spinal anaesthesia mediated hypotension that leads to irritation of the vegus nerve and ultimately sending rapid signal to the vomiting centre. Significantly higher frequency of overall incidence during C section may be attributable to factor such as use of uterotonics for effective management of post-partum haemorrhage besides spinal anaesthesia mediated hypotension and intrathecal or systemic opioids. Whatever the reason may be post operative nausea and vomiting is

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under spontaneous control but sometimes it is associated with the risk of complications such as pulmonary aspiration of gastric contents, wound dehiscence, oesophageal perforation, bilateral pneumothorax and subcutaneous emphysema. Apart from it, nausea and vomiting are also associated with significant delay in discharge from post anaesthesia care unit along with prolong hospital stay besides dehydration, severe electrolyte imbalance. Of the different factors involved in PONV previous studies suggests opioid premedication and use of anaesthetics as the cause of approximately 75-80% of the post operative nausea and vomiting (PONV) incidence.

With the advancement of modern medications, the incidence of PONV has significantly reduced over the past few years. Ondansetron, acts as a receptor antagonist to 5-hydroxy tryptamine type-3 (5-HT3) receptor present on gastrointestinal vegal afferent nerve terminal (peripheral effect), on CZT and nucleus tractus solitarius (NTS) in the dorsomedial medulla oblongata (central effect). By binding to the serotonin receptor (5-HT), ondansetron reduces afferent stimulation to the vomiting centre. (Andrews P.L. et.al, 1992).[1]

Dexamethasone, a synthetic glucocorticoid with potent anti-inflammatory and immune suppressive effect is also used as an anti-emetic during C-section with a probable inhibitory effect on prostaglandin biosynthesis and reduction in serotonin activity in in the gut. Centrally it acts on NTS of brain stem and there by altering neurotransmission involved in emesis (De Oliviera.G.S.et.al, 2013).[2] Monotherapy with ondansetron or Dexamethasone is associated with individual limitations and complications. Ondansetron is often associated with prolong QT interval and thereby increasing the risk of cardiac arrhythmias besides the other common side effects such as headache, dizziness, constipation etc. Apart from that, partial control of nausea due to spinal anaesthesia induced hypotension or visceral stimulation are the other serious limitation of its use in monotherapy (Balki.M.et.al, 2005; Tramer M.R. et.al, 1997; Gupta S.D. et.al, 2011).[3-5] Similarly, monotherapy with dexamethasone is often associated with maternal hyperglycaemia as it is a synthetic glucocorticoid and there by raising concern in diabetic or gestational diabetic patients. Owing to its immunosuppressive effect, delayed wound healing is another major complication associated with its use apart from perineal discomfort during intravenous administration.

A combination therapy of ondansetron and dexamethasone has been reported previously for enhanced anti emetic effect due to their complementary mode of action. Sane.S.et.al, 2015 reported the enhanced efficacy of the combination therapy against PONV in C-section with spinal anaesthesia. Data reported by Imeh.A.et.al, 2014 is also in agreement with it. Earlier Bhattarai.B.et.al, 2011[6] reported the enhanced efficacy of the combinatorial therapy for elective laparoscopic surgery also. While ondansetron acts as 5HT-3 receptor antagonist (Zhou.C.et.al, 2018)[7], dexamethasone acts as an inhibitor of serotonin (5HT) biosynthesis and there by inhibit central modulation of the vomiting centre in a synergistic way offering a broader range of anti-emetic coverage (Demirhan.A.et.al, 2013).[8] Additionally, this combinatorial approach also lowers the individual drug dose and thereby significantly reduce drug related side effects (Rajeeva.V.et.al, 1999; Bilgan.S.et.al, 2018 & Chilkoti.G.T.et.al,2025).[9-11]

Although the enhanced efficacy of the combinatorial anti-emetic therapy is well established, however patients' demographic factors like genetic variability, BMI, Ethnicity and individual susceptibility (Gan.T.J.et.al, 2020)[12] apart from anaesthetic approach significantly impact the treatment response and as such indicates the necessity of regional evaluation of the therapy. Karbi Anglong being a tribal dominate district of assam requires a formal investigation regarding the assessment of the efficacy of the combinatorial therapy, although supported by global evidences. This study focuses on analysing the effect of ondansetron and dexamethasone alone and applied in combination for treating PONV following C-section with spinal anaesthesia in Gynaecology and Obstetrics department of Diphu Medical College and Hospital, Diphu, Karbi Anglong, Assam.

MATERIAL AND METHOD

Patient Recruitment

A total of 159 prepartum pregnant women admitted to Gynaecology ward within the age range of 25-35, who were prescribed for caesarean section with spinal anaesthesia were recruited in the study after obtaining proper written informed consent dully signed either by the patient or by their attendee.

Patients with history of motion sickness, pregnancy induced hypertension, hypersensitivity to anti emetic drug were excluded from the study. Also, patients with glucose intolerance, gestational diabetes and who had taken anti emetic drug within 24 hours were also excluded. Only pregnant women of age group between 18-40 years, who were haemodynamically stable and with singleton pregnancy (≥37 weeks gestation), scheduled for elective lower segment Caesarean section (LSCS) under spinal anaesthesia were included in the study upon obtaining proper informed consent. While including the patients, their capability of understanding and reporting symptoms of nausea, vomiting, and pain were also kept under consideration. Following recruitment, the patients were randomly distributed into three groups of 53

patients in each. Group-A will receive ondansetron, 4mg alone, Group-B will receive Dexamethasone, 8 mg alone and Group-C will receive a combination of both (Ondansetron, 4mg and Dexamethasone, 8 mg).

Preparation of anti-emetic solutions

4 mg of Ondansetron was mixed with 5 ml normal saline and administered to group-A. For group-B, 8ml of Dexamethasone was mixed with 5 ml of normal saline and for group-C both the solution in similar amount was administered intravenously.

Method

Preoperative investigation was done one day prior to caesarean section and all the patients were given Ranitidine, 150 mg and were kept nil per oral for atleast 6-8 hours prior to surgery.

After shifting the patients to the operation theatre, normal saline infusion was started. For recording the baseline data regarding pulse rate, oxygen saturation (SaO2%), Blood pressure etc, monitors were applied and recorded in a non-invasive manner. 16-18G cannula was used for intravenous access using which 500 ml Ringer's lactate solution was infused at the rate of 20 ml/kg for 20-30 minutes prior to applying spinal anaesthesia. 5 ml of the prepared drug solution was poured into a syringe and to maintain double blindedness of the study, syringes were labelled as 'A', 'B', and 'C' and administered into respective group patients through intravenous route by the attending anaesthetist before applying spinal anaesthesia. For spinal anaesthesia patients were positioned sitting and following aseptic skin drapping and locating of L2-L3 or L3-L4 intervertebral space, the skin and the interspinous ligament was infiltrated with 2% lidocaine using 25G hypodermal needle. Subarachnoid blockage was performed using single bolus injection of 2.5 ml 0.5% Hyperbaric bupivacaine, administered using 25G spinal needle. Prior to surgical incision, the sensory level of spinal blockade was assessed using a pinprick method. Patients in whom adequate analgesia could not be achieved were excluded from the study and subsequently administered general anaesthesia. Non-invasive blood pressure (NIBP) was monitored at 3-minute intervals. Hypotension was defined as a systolic blood pressure below 100 mmHg or a reduction exceeding 20% from baseline values. Management of hypotension included increasing the rate of crystalloid infusion along with intravenous boluses of 50 µg phenylephrine. Following delivery of the fetus, 10 units of oxytocin were administered intramuscularly, and an additional 10 units diluted in 500 ml of 0.5% normal saline were infused at a rate of 125 ml/hour to facilitate uterine contraction. Oxygen was supplemented at the rate of 5L/min using nasal prong during the surgical procedure. Vital signs were recorded continuously at fixed interval. Assessment of nausea and vomiting was done throughout the surgical procedure continuously. Patients were questioned regarding emetic symptoms and discomfort every 3 minutes and were instructed to report any adverse events. Drug-related complications were monitored for the next 24-hour post operatively and recorded accordingly as intra operative and post operative nausea and vomiting. Rescue antiemetic therapy consisted of intravenous palonosetron 0.075 mg administered as a single dose over 10 seconds.

Collected data were analysed using SPPS version 25 (SPSS, Chicago, IL, USA). For comparing mean values ANOVA was performed while for discrete categorical data Fisher's exact test and Chi square test was performed. In all the statistical analysis, $p<0.05$ was considered statistically significant.

RESULTS

Analysis of sociodemographic profile of study population

The mean age (in years) of the patients included in group-A was 26.77±4.8, in group-B it was 26.89±4.2 and that in group-C was observed to be 28.36±4.69. The mean comparison exhibits non-significant mean age difference between the randomized groups. The average body weight (in Kg) of the patients also did not exhibit any significant in mean body weight between the groups. The mean body weight was recorded to be 64.58±5.6 in group-A, 64.96±6.47 in group-B and 65.79±6.5 in group-C ($P>0.05$) (Table:1).

Mean hight and BMI also exhibits a similar observation with non-significant mean difference between the randomized groups. The mean height (in CM) varies from 154.94±5.68 (in group-A) to 156.08±5.98 (in group-C) and the BMI ranges from 26.8±1.5(in group-A) to 27.06±2.94 (in group-C). Regarding ethnicity, non-tribal to tribal ratio changes from 18:35 in group-A to 15:38 in group-B and 14:39 in group-C; there by exhibiting an almost equal ratio of representation across the groups with more tribal patients recruited in the study. While majority of the study population was illiterate, the ratio of literate to illiterate also exhibits non-significant difference in ratio of representation across all the groups.

Analysis of the baseline parameters

Intraoperative rate of respiration (in Cycles/min) was 15±1.71in group-A and remains almost same in the post operative recovery phase with no significant difference in mean values and there by exhibiting an almost stable maintenance of the respiration rate throughout the clinical procedure. The observation was consistent with group-B and group-C.

Oxygen saturation (SaO_2%) was approximately 97-98 in both intraoperative and post operative condition for group-A although patients were consistently given oxygen through nasal prong. The oxygen saturation percentage was slightly higher in

group-B with intraoperative value of 98.66± 1.07 to 97.68± 1.13 post operatively (p=0.147). A similar observation was also exhibited by group-C. Thus, all the patients belonging to different test group exhibits an almost stable maintenance of oxygen saturation around 96-99% (Table 2).

Mean arterial pulse rate (bpm) decreases from 89±9.2 during intra operative stage to 84.87±9.31 in post operative condition in group-A. Although not significantly differed from intraoperative stage, but the difference is persistently observed across all the three groups. No episode of bradycardia was observed in any of the group. Intraoperative systolic blood pressure (mm of Hg) decreases significantly from 119.92± 11.23 to 114.64± 9.74 post operatively in group-A (P=0.001). Similarly, in group-Bit reduces from 120.66± 12.4 to 115.23± 10.7 (p=0.001) and in group-C, the value reduces from 119.96± 11.8 to 113.23± 17.7 (p=0.001). Slightly higher systolic BP was observed in group-B. Diastolic B.P. also exhibits a similar pattern with significant difference between intraoperative and post operative value.

Analysis of nausea and vomiting

For intraoperative nausea 15.1% patients from group-A and 41.5% patients from group-B exhibits intra operative nausea while group-C patients exhibit lowest incidence of 3.8%. Majority of patients from group-C (96.2%) did not exhibits symptoms of nausea which is higher than the observed frequency in group-A (84.91%) and group-B (58.5%). Intraoperative nausea was observed to be highest in group-B. The frequency difference among the group was found to be statistically significant upon performing fisher's exact test with χ^2 value of 24.72 and p=0.001.

A similar pattern was observed for postoperative nausea with 13.2% from group-A, 41.5% from group-B and as low as 3.8% patients from group-C experience post operative nausea. On the contrary 86.8% from group-A, 58.5% from group-B and 96.2% from group-C did not experience post operative nausea and the difference between the group was statistically significant (χ^2=26.046, p= 0.001). While group-A patients exhibit17% post operative vomiting and 26.4% by group-B patient, it was totally absent among group-C. Post operative vomiting was maximally observed in group-B and totally absent in group-C. Group comparison exhibits a statistically significant difference in frequency of both 'YES' and 'NO' category patient (χ^2=15.35, p= 0.001) across all group (Table 3).

Our observation clearly suggest that monotherapy is associated with significant risk of intra operative and post operative nausea and vomiting. Whereas a combination of both the drug exhibits an enhanced efficacy regarding control over PONV. Apart from that between ondansetron and dexamethasone, the later is comparatively less effective in subsiding PONV.

Analysis of post-operative side effect

Post operative headache was reported by 28.3% of patients in group-A which reduces to 17% in group-B and further reduced to 7.5% in group-C. This significant decrease in frequency (p=0.003) is attributable to the anti-emetic used. The observed result suggest headache as a common side effect, mostly associated with ondansetron followed by dexamethasone. As a side effect dizziness was found to be more closely associate with use of dexamethasone (64.2%) followed by ondansetron (49.1%). However, their combination therapy exhibits lower frequency (17%) (Table:4).

Post-operative rashes are observed to be appeared with almost similar frequency for both the monotherapy; however, the frequency reduces with combinatorial therapy. Similarly, other side effects like pruritic, flushing and coughing were also observed to be associated with monotherapy with highest frequency being observed in group-B patients. Another major side effect of steroid anti-emetic is insomnia, which was observed to be highest among group-B patients treated with a corticosteroid (dexamethasone, 43.4%) whereas the frequency was quite low with group-A (13.2%) patients. Moderate insomnia cases were reported from group-C (28.3%). The difference was statistically significant (χ^2=11.9, p=0.002).

Characteristics	Mean ± SD			P1 (Gr-A Vs Gr-C)	P2 (Gr-B Vs Gr-C)	P3 (Gr-A Vs Gr-B)
	Group-A ***(Ondansetron 4 mg), n=53***	**Group-B** ***(Dexamethasone 8 mg), n=53***	**Group-C** ***(Ondansetron 4 mg + Dexamethasone 4 mg), n=53***			
Age	26.77±4.8	26.89±4.2	28.36±4.69	0.079	0.103	0.900
Body Weight (in Kg)	64.58±5.6	64.96±6.47	65.79±6.3	0.314	0.488	0.752
Height (in CM.)	154.94±5.68	155.64±6.25	156.08±5.98	0.331	0.709	0.549
BMI (Kg/m2)	26.87±1.5	26.84±2.58	27.06±2.94	0.677	0.625	0.945
Ethnicity (Non-tribal/ Tribal)	18:35	15:38	14:39	NS	NS	NS

Literacy ratio (Literate/Non-literate)	12:41	10:43	19:34	NS	NS	NS

Table 1: Socio demographic profile of the study population

***P1** compares Group-A Vs Group-C; **P2** compares Group-B Vs Group-C; **P3** compares Group-A Vs Group-B; P<0.05 was considered statistically significant., NS-Non significant*

Parameters	**Mean ± SD**								
	Group-A (*Ondansetron 4 mg*), n=53		**P Value**	**Group-B (*Dexamethasone 8 mg*), n=53**		**P Value**	**Group-C (*Ondansetron 4 mg + Dexamethasone 4 mg*),**		**P Value**
	Intra-operative	**Post-operative**		**Intra-operative**	**Post-operative**		**Intra-operative**	**Post-operative**	
Respiratory rate (Cycle/min)	15±1.71	15.74±2.02	0.843	14.98±1.75	15.7±2.23	0.898	15.4±2.23	15.43±2.01	0.125
SaO2 (%)	96.68±1.03	97.68±1.33	0.142	98.66±1.07	97.68±1.13	0.147	96.68±1.07	97.68±1.13	0.47
Pulse Rate/min	89±9.2	84.87±9.31	0.065	88.28±7.34	84.43±7.15	0.061	88.49±6.89	84.34±7.07	0.100
Systolic blood pressure (mmHg)	119.92±11.23	114.64±9.74	**0.001**	120.66±12.4	115.23±10.7	**0.001**	119.96±11.8	113.23±17.7	**0.001**
Diastolic blood pressure (mmHg)	73.96±7.76	70.09±7.45	**0.001**	74.3±8.5	70.53±8.14	**0.001**	74.53±7.9	70.25±8.1	**0.001**

Table 2: Intraoperative and post operative baseline parameters of patients belonging to different group (Gr-A, Gr-B & Gr-C, N=53 in each group)

Nausea &Vomiting	**Group-A *(Ondansetron 4 mg), n=53, no. (%)***	**Group-B *(Dexamethasone 8 mg), n=53, no. (%)***	**Group-C *(Ondansetron 4 mg + Dexamethasone 4 mg), n=53, no. (%)***	**X^2 value**	**P value**
Intra operative nausea					
Yes	8 (15.1%)	22 (41.5%)	2 (3.8%)	24.726	**0.001**
No	45 (84.9%)	31 (58.5%)	51 (96.2%)		
Post operative nausea					
Yes	7 (13.2%)	22 (41.5%)	2 (3.8%)	26.046	**0.001**
No	46 (86.8%)	31 (58.5%)	51 (96.2%)		
Intra operative vomiting					
Yes	9 (17%)	14 (26.4%)	0 (0.00%)	15.351	**0.001**
No	44 (83%)	39 (73.6%)	53 (100%)		
Post operative vomiting					
Yes	6 (11.3%)	14 (26.4%)	0 (0.00%)	16.929	**0.001**
No	47 (88.7%)	39 (73.6%)	53 (100%)		

Table 3: Intraoperative and Postoperative nausea and vomiting frequency after using ondansetron, dexamethasone and their combination applied during C section

Post operative side effect		Group-A *(Ondansetron 4 mg), n=53, no. (%)*	Group-B *(Dexamethasone 8 mg), n=53, no. (%)*	Group-C *(Ondansetron 4 mg + Dexamethasone 4 mg), n=53, no. (%)*	X^2 value	P value
Headache	Yes	15 (28.3%)	9 (17%)	4 (7.5%)	7.889	**0.003**
	No	38 (71.7%)	44 (53%)	49 (92.5%)		
Dizziness	Yes	26 (49.1%)	34 (64.2%)	9 (17%)	2.504	**0.001**
	No	27 (50.9%)	19 (35.8%)	44 (83%)		
Rash	Yes	41 (77.4%)	42 (79.2%)	24 (45.3%)	17.54	**0.001**
	No	12 (22.6%)	11 (20.8%)	29 (54.7%)		
Pruritis	Yes	10 (18.9%)	14 (26.4%)	3 (5.7%)	8.298	**0.046**
	No	43 (81.1%)	39 (73.6%)	50 (94.3%)		
Flushing	Yes	2 (3.8%)	3 (5.7%)	2 (3.8%)	0.299	0.592
	No	51 (96.2%)	50 (94.3%)	51 (96.2%)		
Cough	Yes	8 (15.1%)	12 (22.6%)	9 (17%)	1.097	0.450
	No	45 (84.9%)	41 (77.4%)	44 (83%)		
Insomnia	Yes	7 (13.2%)	13 (43.4%)	15 (28.3%)	11.9	**0.002**
	No	46 (86.8%)	30 (56.6%)	38 (71.7%)		

Table 4: Postoperative side effect of ondansetron, dexamethasone and their combination applied during C section to prevent PONV

DISCUSSION

Post operative nausea and vomiting are the two major distressing conditions following C section under spinal anaesthesia. Owing to the efficacy issue of monotherapy with ondansetron or dexamethasone; A combinatorial therapy of the two were suggested with previous literary evidence. Szarvas et al, 2003 and Lopez olaondo et al, 1996[13,14] had suggested a reduced incidence of the complication with a combination of both the drug. A number of recent studies also corelates with the pattern reported by them. In spite of having global evidence in support of the combinatorial therapy, there is a need of regional assessment before routine practice mainly attributable to genetic diversity, ethnicity and individual susceptibility etc.

While non-significant difference in sociodemographic features ensures proper randomization during grouping of the study population, the blinded labelling of the drugs administered maintains the unbiasedness of the study. Findings of the study are also in agreement with the previous studies exhibiting majority of PONV prophylaxis failure occurred within 24 hours post operative in patients with dexamethasone monotherapy compared to those received the combination therapy.

In a similar study performed by Imeh A. et al, 2014[15] using ondansetron and metoclopramide for preventing PONV in a C section with epidural anaesthesia, reported that ondansetron offers better prophylaxis than the other besides enhanced patient comfort.

Better efficacy of combinatorial approach using ondansetron and midazolam was previously reported by Jabalameli et al. in 2012[16] when applied during C section with spinal anaesthesia. Replacing midazolam with dexamethasone in this study also exhibits a similar result. A supportive observation has also been reported by Habib et al, 2013.[17] In this study the frequency of occurrence of nausea and vomiting clearly differs among the three study groups. Of which, group-B experiencing highest incidence while group-C reported the lowest frequency. These statistically significant differences in frequency were suggestive of greater effectiveness of the combinatorial therapy. Probably diverse model of action that provide better prevention. Notably the complete absence of post operative vomiting in group-C further reinforces the said benefit of broader anti-emetic spectrum. This improved result is attributable to the complementary action of ondansetron (5HT-3 receptor blocker) and dexamethasone (inhibitor of 5HT synthesis); while maintaining the level of side effect within acceptable limits. Apart from better efficacy and acceptable limits of side effect caused, the similarity in baseline characteristics across the group further supports the reliability of the findings.

CONCLUSION

The present study demonstrates that combination therapy with ondansetron, 4mg and dexamethasone, 8mg is more effective than either drug used alone in preventing PONV. Patients receiving the combined regimen showed the lowest incidence of nausea and complete absence of postoperative vomiting. Overall, this study supports the use of ondansetron–dexamethasone combination therapy as a more reliable and effective strategy for PONV prophylaxis in cesarean section patients, with spinal anaesthesia. It also highlights the importance of

regional evaluation before adopting global clinical practices.

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Disclaimers

The views and conclusions expressed in this article are solely those of the authors and do not necessarily represent the views of their affiliated institutions. The authors are responsible for the accuracy and completeness of the information provided, but do not accept any liability for any direct or indirect losses resulting from the use of this content.

Conflict of Interests

The author declares no conflict of interest in this study both financially and non-financially.

Informed Consent

Patients were recruited in the study after obtaining Dully signed informed consent.

Ethical Approval

The study has the approval of the institutional ethical committee with ethical clearance certificate vide letter no: DMCH/EC/2022/105/120.

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