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Original Research Article

Effect of dexamethasone versus dexamethasone with granisetron in prevention of nausea and vomiting in caesarian section under spinal anesthesia: a randomized double blind study

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) are a common occurrence in patients undergoing caesarean section under spinal anaesthesia. It can lead to adverse events like pain, bleeding, dehydration, electrolyte imbalance, aspiration pneumonia etc.
Methods: This study was aimed at comparing the effectiveness of dexamethasone alone with dexamethasone with granisetron in prevention of PONV in patients undergoing caesarean section under spinal anaesthesia. This was a double blinded prospective randomized controlled trial conducted on 60 pregnant mothers undergoing elective caesarean section under spinal anaesthesia. One group of patients (n=30) received dexamethasone 8 mg intravenously whereas the other group received dexamethasone 8 mg plus granisetron 2 mg intravenously after baby was delivered and cord clamped. Patients were then observed for a period of 24 hrs postoperatively.
Results: Upon comparison of PONV score between both groups, at 0-2 hrs dexamethasone-granisetron (PONV 0=50%, 1=33.3%, 2=13.3%, 3=3.3%) showed better control than dexamethasone alone (PONV 0=40%, 1=36.7%, 2=16.7%, 3=6.7%). Similar results were seen at 2-24 hrs with dexamethasone-granisetron (PONV 0=83.3%, 1=16.7%, 2=0%, 3=0%) having better score than dexamethasone (PONV 0=66.7%, 1=26.7%, 2=3.3%, 3=3.3%). Need for rescue antiemetic was less in dexamethasone+granisetron (5 out of 30=16.7%) compared to dexamethasone (10 out of 30=33.3%). No major side effects were seen.
Conclusions: Our study shows that dexamethasone combined with granisetron is a safe and effective prophylactic antiemetic in pregnant ladies undergoing caesarean section under spinal anaesthesia, compared to monotherapy of dexamethasone.

Keywords: Caesarean section, Spinal anaesthesia, Post-operative nausea and vomiting

INTRODUCTION

Nausea and vomiting are very common problem in patients undergoing caesarean section under spinal anaesthesia. The prevalence is estimated to be 80%.[1] PONV is distressing for the patients as well as the doctors involved. It adds to the hospital cost of patient care. Bleeding, wound dehiscence, electrolyte imbalance, dehydration, aspiration pneumonia etc. are various complications associated with PONV.[2,3] Multiple studies are being conducted to find out an amicable solution to the problem. Hence understanding the neurophysiology, sorting out the risk factors and cumulating knowledge about various available antiemetics, is the need of the hour. Various drugs are

available for the management of PONV. There are 5HT3 receptor antagonists like granisetron, ondansetron. Corticosteroids like dexamethasone, methylprednisolone etc. are also useful in PONV. Anticholinergics such as scopolamine are used in PONV management. Histamine receptor antagonist like promethazine is also used as a remedy of PONV. Other available options are dopamine antagonist like metoclopramide, butylphenols like droperidol etc. Despite availability of various types of drugs, none of these drugs are 100% effective in management of PONV.

Stimulation of gastrointestinal and central pathways activate the chemoreceptor trigger zone in the area postrema and thus the vomiting center is activated.[4] Risk factors of PONV include younger age, female gender, nonsmoking status, better ASA status, previous history of PONV and motion sickness, anxiety, gastroparesis, type and duration of surgical procedure, decreased perioperative fluids, use of volatile anaesthetics, nitrous oxide, large dose neostigmine or intraoperative and postoperative opioids for pain management.[3,5-7]

Dexamethasone has been found to be effective and safe in prophylactic management of PONV.[1,8] It is also effective in preventing nausea and vomiting seen with epidural and intravenous opioids which are used for postoperative analgesia.[9] It is assumed that dexamethasone exerts its antiemetic action by activating glucocorticoid receptors in tractus solitarius. When compared with droperidol and saline for evaluation of prophylactic effect of dexamethasone on PONV, dexamethasone was effective in 68% cases in managing PONV.[10,11] Dexamethasone also have added benefit of being effective in post-operative pain management due to its anti-inflammatory property.[12]

Granisetron is a selective 5-HT3 receptor antagonist and a potent antiemetic. It binds specifically to the 5-HT3 receptors of vagal afferents of the digestive tract. As it blocks the receptors irreversibly, it acts as long acting and the need for rescue antiemetic is less.[2] Multiple studies have shown that Granisetron is more effective than another widely used 5HT3 blocker Ondansetron in preventing early as well as PONV.[13,14] It has also been found effective in managing intraoperative and postoperative shivering in spinal anaesthesia.[15]

Multimodal management of PONV is preferred because of the multiple mechanisms at play. A combination of dexamethasone with 5-HT3 receptor antagonists is likely the best antiemetic prophylactic regimen.[16,17] The combination dexamethasone and granisetron have been found to be more effective than monotherapy.[18-22]

Considering the distress caused by PONV to patients, it has been found that the prophylaxis of PONV with multimodal management increases patient satisfaction.[11] In this study, we compared the efficacy of dexamethasone monotherapy with combination therapy of dexamethasone and granisetron in management of PONV in women undergoing elective caesarean section under spinal anaesthesia as this study has not been undertaken in this part of the country and on this indigenous group of parturient mothers. The objective of this study is to evaluate the effectiveness of dexamethasone alone compared to dexamethasone and granisetron in prevention of PONV and to evaluate the prevalence of side effects between the two study groups.

METHODS

This randomized controlled trial study was conducted in the department of anesthesiology, regional institute of medical sciences, Imphal, a tertiary care hospital in Manipur, from October 2021-September 2023. Based on the previous study, the sample size was calculated.[5,9] Calculated sample size in each group was 28.51, assuming a 5% dropout rate, the final sample size was rounded up to 30 participants in each group. Sixty patients in total were recruited for this study. Ethical approval was obtained from the research ethics board in RIMS. Informed written consent was obtained from the respondents. Privacy and confidentiality of the participants have been maintained.

Inclusion criteria

Patients with ASA grade I and II (ASA-American society of anaesthesiology), age between 18 to 45 years undergoing elective caesarean section under spinal anaesthesia were included in this study.

Exclusion criteria

Patients with uncontrolled diabetes or hypertension, hyperemesis gravidarum or pre-eclampsia, hypersensitivity to 5-HT3 or dexamethasone, psychiatric disorder, on chronic steroid therapy or immunocompromised, history of motion sickness or PONV and patients who took antiemetic drugs 24 hrs. preoperatively were excluded from the study.

Patients were divided into two groups, group D (n=30) received 8mg of dexamethasone and group GD (n=30), received 2 mg of granisetron and 8 mg of dexamethasone. Computer generated randomization chart was used by generating the chart from the website www.randomization.com. The lowest integer was 1 and the highest was 60 and there were two blocks. After generating the randomization chart, patients were divided into two groups namely group D and group GD, by an independent allocator. Among the 60 patients of the total sample size, 30 patients were randomly allocated in each group following the randomized chart.

The principal investigator and the patients remained blind to the allocation. Independent variables were age (in years), weight (in kg), ASA I, II and duration of surgery (hours and minutes). Dependent variables were nausea, retching, vomiting, complete response, rescue antiemetic, HR, BP, SpO_2 and side effects.

Both the patient and the primary investigator were blinded. Preparation of the drugs were done by an anesthetist not directly involved in the study. For group D dexamethasone 8mg was diluted up to 5 ml with normal saline and administered intravenously after the baby was delivered and the cord clamped. For group GD 8 mg of dexamethasone and 2 mg of granisetron was diluted up to 5ml with normal saline and the drug was administered intravenously after the baby delivered and the cord clamped. The primary outcome of the study were incidences of PONV in the first 24 hours post operatively and usage of rescue antiemetics in first 24 hours postoperatively. The Secondary outcomes were any event of tachycardia or bradycardia, hypotension or hypertension, dizziness, headache, constipation, hypersensitivity to any of the drugs used. After obtaining the approval from the ethical committee, the patients were recruited for the study. A pre-operative visit was done a day before surgery and a good rapport was established and eligible patients fulfilling the inclusion criteria, without the exclusion criteria were informed about the study and consent was sought. The eligible patients read the informed consent. For those who could not read, a companion explained this to the patients. When the eligible patients gave consent to participate in the study, their written consent was taken. After they gave consent, they were enrolled for the study. All the patients included in this study kept fasting for 6 hours prior to the introduction of anaesthesia. In the pre-operative holding area, intravenous access was secure. All the patients were preloaded with 15 ml/kg of Ringers lactate solution over 15 minutes before the administration of spinal anaesthesia and baseline hemodynamic parameters such as blood pressure, heart rate, and oxygen saturation were recorded. On arrival to the operation theatre baseline monitoring including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation (SpO_2) was noted.

The study drugs were prepared by other anesthesiologists not involved further in the study. The principal investigator, who was blinded to the group allocation, administered the drug to the patient, who was also unaware of the drug she received. After the baby was delivered and the cord was clamped, the study drug was administered intravenously. Patients were followed up in the ward post operatively up to 24 hours. The follow-up of the patients in the first 2 hours was undertaken in the post-anaesthesia care unit (PACU) and thereafter (2-24 hrs), in the post-natal ward. During the first 2 hours in the PACU, vital signs such as heart rate, blood pressure, oxygen saturation were monitored every half hourly. All the patients were evaluated for PONV, rescue antiemetic and adverse effects of drugs during this period.

The evaluation of PONV were done by a four-point (0-3) scoring system.[7] PONV score 0=no nausea and no vomiting; score 1=complaining of nausea and retching; score 2=vomiting once or two times in 30 m; score 3=vomiting more than 2 times in 30 minutes. Injection metoclopramide 10 mg was used as a rescue antiemetic. Data was collected in predesigned proforma. Baseline information like age, weight, ASA grading, HR, BP, SpO_2, were recorded preoperatively. Postoperatively, the number of incidences of retching, nausea and vomiting, administration of rescue antiemetic, grades of PONV and the side effects were recorded in due time.

Statistical analysis was done by using SPSS version 21 software. Quantitative data like age, weight, number of patients requiring rescue antiemetic and hemodynamic parameters (HR, BP, SpO_2) were summarized in mean and SD and analyzed with student's t test.

Qualitative data like grades of PONV, ASA grading and side effects between two groups were analyzed with chi square test and $p<0.05$ was taken as statistically significant.

RESULTS

A total of 60 participants were included in the study (30 each intervention group). There were no participants who dropped out or lost to follow-up. Table 1 shows that the age and weight of the participants of both study group were comparable. Table 2 shows that, there was no significant difference of either systolic or diastolic blood pressure among the two groups. Table 3 shows that the study group of dexamethasone-granisetron injection had comparatively better PONV in both 0-2 hours and 2-24 hours of post operative period. For 0-2 hours, the incidence of nausea in dexamethasone-granisetron was 13.3% and the dexamethasone group was 33.3%.

At 2-24 hours, the incidence of nausea was 23.3% in dexamethasone-granisetron group and 50% in dexamethasone group, which is statistically significant with p=0.03. Retching was seen more (13 out of 30 participants) in dexamethasone group than dexamethasone-granisetron group (0 out of 30 participants). Vomiting was seen less in dexamethasone-granisetron group (3 out of 30) within 24 hours of post-operative than dexamethasone group (6 out of 30 participants) which is found to be statistically significant with a p=0.04.

Complete response was seen more in study group of dexamethasone-granisetron (21 out of 30 participants) than only 13 out of 30 participants in dexamethasone group which is found to be statistically significant (p=0.03) at 2-24 hours. Comparison of the study group by requirement of rescue antiemetic shows that dexamethasone-granisetron group required less rescue antiemetic (only 5 out of 30 patients, 16.7%) but 10 out of 30 participants (33.3%) required antiemetics in dexamethasone group. The side effects were very less in our study. Only two patients in dexamethasone group complained of headache whereas only one patient in dexamethasone-granisetron group complained of constipation.

Table 1: Comparison of age and weight of the participants (n=60).

Variables	Group	N	Mean	SD	Mean differences	P value
Age (in years)	Dexamethasone	30	26.50	6.252	1.33	0.36
	Dexamethasone-granisetron	30	27.83	5.670		
Weight	Dexamethasone	30	63.63	4.173	0.70	0.31
	Dexamethasone-granisetron	30	62.93	3.903		

Table 2: Comparison of post-operative blood pressure among study group.

Blood pressure	Group	N	Mean	SD
Systolic BP	Dexamethasone group	30	123.70	8.754
	Dexamethasone-granisetron group	30	125.20	9.375
Diastolic BP	Dexamethasone group	30	69.87	7.825
	Dexamethasone-granisetron group	30	67.63	14.146

Table 3: Comparison of post-operative nausea vomiting score.

Post-operative nausea vomiting (PONV) score		Study group		Total
		Dexamethasone (n=30) (%)	**Dexamethasone-granisetron (n=30) (%)**	
0 to 2 hours	0	12 (40)	15 (50)	0.40
	1	11 (36.7)	10 (33.3)	
	2	5 (16.7)	4 (13.3)	
	3	2 (6.7)	1 (3.3)	
2 to 24 hours	0	20 (66.7)	25 (83.3)	0.86
	1	8 (26.7)	5 (16.7)	
	2	1 (3.3)	0 (0)	
	3	1 (3.3)	0 (0.0)	

PONV score: 0-No nausea/vomiting, 1-complain, 2-once /twice in 30 minutes and 3->2 times in 30 minutes.

Table 4: Comparison of development of nausea post-operatively, (n=60).

Nausea (Present)	Study group		P value
	Dexamethasone (%)	**Dexamethasone-granisetron (%)**	
0 to 2 hours	10 (33.3)	4 (13.3)	0.06
2 to 24 hours	15 (50)	7 (23.3)	0.03

Table 5: Comparison of retching among the study group post-operatively, (n=60).

Retching (Present)	Study group		P value
	Dexamethasone (%)	**Dexamethasone-granisetron (%)**	
0 to 2 hours	3 (10)	0 (0)	-
2 to 24 hours	10 (33.3)	0 (0)	-

Table 6: Comparison of vomiting among the study group post-operatively, (n=60).

Vomiting (Present)	Study group		P value
	Dexamethasone (%)	**Dexamethasone-granisetron (%)**	
0 to 2 hours	3 (10)	1 (3.3)	0.30
2 to 24 hours	3 (10)	2 (6.7)	0.04

Table 8: Comparison of complete response after 24 hours of post-operative.

Comparison of response (Present)	Study group, n=60		P value
	Dexamethasone (%)	**Dexamethasone-granisetron (%)**	
0 to 2 hours	19 (63.3)	24 (80)	0.15
2 to 24 hours	13 (43.3)	21 (70)	0.03

Table 9: Comparison of the study group by requirement of rescue antiemetic, (n=60).

Rescue antiemetic	Study group	
	Dexamethasone (n=30) (%)	Dexamethasone-granisetron (n=30) (%)
Yes	10 (33.3)	5 (16.7)

Table 10: Number of patients with side effects.

Dexamethasone	Dexamethasone-granisetron
2 (Headache)	1 (Constipation)

DISCUSSION

PONV are a distressing and unpleasant event to patients after surgery. Multiple studies are being conducted to find a more effective solution for this problem. The incidence touches a peak of 75% to 80% in certain high-risk groups. Dexamethasone is a steroid derivative and an inexpensive, effective and safe drug. The mechanism of antiemetic effect of dexamethasone is poorly understood but it is postulated that it might work by activating glucocorticoid receptors in nucleus of tractus soliterius, nucleus of raphe and the area postrema. Demiharan et al found that dexamethasone at the dose of eight mg bolus was as effective as four mg ondansetron in preventing PONV after the LSCS.[1] A meta-analysis done by Mitchell et al shows that the dexamethasone is effective in PONV with the added advantage of decrease in the post operative pain also.[23]

Granisetron is a 5-HT antagonist with selectivity for 5-HT_3 receptor which are present in nucleus of tractus soliterius and chemoreceptor trigger zone (CTZ) area in CNS. It has been shown to be superior to other drugs in preventing acute, chronic and chemotherapy induced nausea and vomiting. The elimination half-life is 4-5 hrs after an intravenous injection, though it shows considerable inter-individual variation. A study done by Nikam et al found that granisetron at the dose of 2mg was very effective (80%) in prevention of PONV in patients undergoing total abdominal hysterectomy under spinal anaesthesia.[14] Mehta et al suggested that no drug was 100% effective in management of nausea and vomiting and they found granisetron to be more effective than ondansetron in late post-operative period.[2] In our study, we used 8 mg of dexamethasone for monotherapy and 2 mg of granisetron with 8 mg of dexamethasone for combination therapy. The effectiveness of combination therapy of 5-HT_3 inhibitor (ondansetron, granisetron, palonosetron, ramosetron) with dexamethasone have been evaluated in many studies as a treatment for PONV and chemotherapy associated nausea and vomiting as well. Similarly, in our study, we compared, dexamethasone monotherapy to combination of dexamethasone and granisetron for the prevention of PONV, on the indigenous population of Manipur. We did not include a placebo group as control in our study, in view of suggestion of Michels et al.[23] that states that if active drugs are available, placebo-controlled trials may be unethical because PONV is very much distressing for the patient. In our study, when we observed the incidence of nausea for the period of 0-2 hrs and 2-24 hrs post operatively, we found that dexamethasone-granisetron had lower incidences. Ten patients (33.3%) complained of nausea in dexamethasone group whereas only 4 patients (13.3%) complained in dexamethasone-granisetron group within 0-2 hrs postoperative. In 2-24 hrs, 15 patients (50%) in dexamethasone group and 7 patients (23.3%) in dexamethasone-granisetron group complained of nausea, which was significant with a p=0.03. Retching was absent in dexamethasone-granisetron group in 0-2 and 2-24 hrs hours whereas in dexamethasone group 3 patients complained at 2-24 hrs and 10 patients complained at 2-24 hrs. The incidence of vomiting at 0-2 hrs in dexamethasone group was 3 patients (10%) and in dexamethasone-granisetron group it was 1 (3.33%). For 2-24 hrs, incidence of vomiting was 3 (10%) and in dexamethasone group whereas it was 2 (6.7%) in dexamethasone-granisetron group, which was statistically significant with p=0.04. The total number of patients who had complete response in 0-2 hrs were 19 (63.3%) in dexamethasone and 24 (80%) in dexamethasone-granisetron group. For the period of 2-24 hrs, the incidence was 13 (43.3%) in dexamethasone group and 21 (70%) in dexamethasone-granisetron group, which was statistically significant with p=0.03. Overall PONV score for 0-2 hrs and 2-24 hrs were better in dexamethasone-granisetron group as compared to dexamethasone alone. Rescue antiemetic was required for 10 patients (33.3%) in dexamethasone group and for 5 patients (16.7%) in dexamethasone-granisetron group. Very few side effects were observed among the study groups such as only two patients complained of headache in dexamethasone group and one patient complained of constipation in dexamethasone-granisetron group. Singh et al studied on 86 patients undergoing caesarean section under spinal anaesthesia and compared the efficacy of granisetron 2 mg and ondansetron 4mg for prevention of post operative nausea and vomiting.[12] Their study concluded that granisetron was more effective than ondansetron. Kishor et al did a study on 150 patients undergoing laparoscopic cholecystectomy, comparing the effects of ondansetron 0.1 mg/kg, granisetron 0.04 mg/kg and granisetron with dexamethasone (0.04 mg/kg and 8 mg) for prevention of post operative nausea and vomiting.[21] They found that combination therapy with dexamethasone and granisetron IV used as prophylactic antiemetic was better than granisetron or ondansetron given IV alone with fewer side effects. Nanjundaswamy et al conducted study on 75 patients undergoing laparoscopic cholecystectomy, compared the effects of dexamethasone and dexamethasone with either granisetron or ondansetron and they found that the incidence of PONV was 16% in

dexamethasone-granisetron.[22] Complete response in dexamethasone-granisetron group after 24 hrs was 84% and no patient required rescue antiemetic. for dexamethasone group the PONV incidence was 68% whereas complete response was 32% and 3 patients required rescue antiemetic.

Our study also showed that dexamethasone with granisetron combination is better than dexamethasone alone as dexamethasone with granisetron shows lower PONV score, higher incidence of complete response and lesser side effects. The results of our study were comparable to the study done by Kishor et al and Nanjundaswamy et al.[21,22] Further study may be undertaken with different drug concentrations to see the effects with different dosage. Additional benefit of dexamethasone is its effect in better post-operative analgesia whereas granisetron has been found effective as rescue from intra as well as post-operative shivering.[24,25] These beneficial effects have not been explored in our study and further studies are required to evaluate this effect.

Limitations of this study are; it includes only elective LSCS under spinal anaesthesia and no other emetogenic surgeries like strabismus, bariatric surgery, laparoscopic cholecystectomy under general anaesthesia, our study was done on LSCS which is a short duration surgery. Hence the result may not be similar for longer duration surgery, surgical technique has not been specified as some interventions such as externalization of the uterus have been associated with higher incidences of nausea and vomiting both during and after the operation and in our study, we administered the study drugs only once which may not have sufficed for 24 hrs period and we have not evaluated that aspect.

CONCLUSION

This study showed that the combination therapy of intravenous granisetron 2 mg and dexamethasone 8 mg used as a prophylactic antiemetic is more effective than monotherapy of dexamethasone 8 mg alone in prevention of PONV in patients undergoing elective LSCS under spinal anaesthesia, without any major side-effect.

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