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Research Article

PROPHYLACTIC USE OF GRANISETRON FOR PREVENTION OF NAUSEA AND VOMITING DURING CESAREAN DELIVERIES: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

In this study, we investigated the efficacy of granisetron, a 5HT3 receptor antagonist, in preventing nausea and vomiting during cesarean deliveries performed under spinal anesthesia. A total of 160 pregnant women received either intravenous granisetron (40 mg/kg) or placebo after umbilical cord clamping (n = 80 each). Following spinal anesthesia, patients were monitored for nausea, vomiting, and adverse events for 24 hours. Granisetron achieved a complete response in 80% of patients immediately after spinal anesthesia, compared to 45% with placebo. From 4 to 24 hours post-anesthesia, the corresponding rates were 83.5% and 55% ($P < 0.06$). Adverse events did not significantly differ between the groups. Granisetron demonstrates efficacy in preventing emetic episodes during spinal anesthesia for cesarean delivery when administered prophylactically.

Keywords:- Granisetron, Nausea, Vomiting, Cesarean delivery, Spinal anesthesia**.**

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INTRODUCTION

It has been reported that over 67 percent of cesarean deliveries under spinal anesthesia are associated with nausea and vomiting [1, 2]. Surgical procedures can be complicated by nausea and vomiting after surgery (PONV). Postoperative complications include (i) aspiration of vomitus, (ii) dehydration and electrolyte disturbances, (iii) insufficient nutrition, and (iv) wound dehiscence. Current antiemetics include 5-HT3 (5-hydroxytryptamine-3) antagonists like ondansetron and granisetron. As a 5-HT3 receptor antagonist, granisetron has stronger and longer-lasting effects than ondansetron to treat nausea caused by cisplatin [3]. In patients undergoing general anesthesia, granisetron has been shown to prevent PONV [4]. Granisetron, dolosetron, and tropisetron have been studied in the Indian context less frequently than other 5-HT3 antagonists, and only granisetron has been studied for prevention of PONV during cesarean delivery. During cesarean delivery under spinal anesthesia, conducted a prospective, randomized, double-blind, placebo-controlled study to determine whether granisetron prevents PONV.

Methods

A written informed consent and ethical committee approval were obtained prior to conducting the study. In total, 80 women underwent elective cesarean deliveries aged 22–35 years. Using a random number table, all of the participants were randomly divided into two groups based on their age. Age and BMI were matched.

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The study excluded women with motion sickness, acid peptic diseases, post-delivery emesis, antiemetic meditation 24 hours prior to surgery, and chronic medical or surgical conditions complicating pregnancy. The Granisetron 40g/kg group received intravenous Granisetron and Group P received saline. After umbilical cord clamping, intravenous injections of the study agents were administered to the subjects. Anesthetists were blinded by preparing study medications in individual 5 ml syringes. Investigators and patients blinded to the study drug collected post-delivery data. Pregnancy parturients received 0.4 M sodium citrate (30 ml) orally as a prenesthetic. Induction of spinal anesthesia was preceded by intravenous hydration with lactated Ringer's solution 20 ml/kg. A parturient's heart rate, blood pressure, and oxygen saturation were monitored prior to spinal anesthesia. Two milliliters (10 mg) of 0.6percent hyperbaric bupivacaine were administered with 25 gauge lumbar puncture needle in right lateral decubitus position. During the procedure, a wedge was placed under the right hip in order to cause a 15° displacement of the left uterus. A face mask delivered 3l/min of oxygen. Pulse oximetry, NIBP, and ECG were continuously monitored during the procedure. After spinal injection, if systolic blood pressure decreased by 20% or less than 80 mmHg, ephedrine 5 to 10 mg intravenously were injected and/or additional intravenous fluids were given. A spinal block was confirmed with pinprick and cold sensation loss at T4–5. During umbilical cord clamping, syntocinon (10 units) was administered intravenously. Cesarean section was performed with low transverse skin incisions in all cases, and the uterus was repaired without the use of 1.0 Vicryl stitches in both layers. No repair of peritoneum visceral and parietal. Sheath and skin of the rectus were repaired. After delivery following uterine exteriorization or peritoneum manipulation, intravenous pethidine 0.5 mg/kg was permitted in both groups. Attending anesthesiologists were blinded to treatment type and recorded emetic episodes intraoperatively and postoperatively. The urge to vomit is accompanied by an unpleasant sensation. As a result of retching, the respiratory muscles contract laboriously, spasmodically, and rhythmically without releasing gastric contents. A forceful expulsion of gastric contents from the mouth is defined as vomiting. At least two episodes of emesis were treated with rescue antiemetics (ondansetron 4 mg). Retching and vomiting were treated equally. After each observation period, patients evaluated nausea severity numerically. Attending anesthesiologists recorded adverse effects during study period. Peptide 1.5 mg/kg was injected intramuscularly for postoperative analgesia.

Statistics

A v2 test and Student's t test were used to test differences between groups. A significance level of P 0.05 was used. A value is expressed as a mean ± SD range or number %.

Results

Tables 1 and 2 summarize patient profiles as well as information about surgery and operative management. Patient demographics and operative management were comparable between treatment groups. Following spinal anesthesia, 64 patients (80%) receiving granisetron and 36 patients (45%), receiving placebo, showed no signs of adverse reactions. In the granisetron group, 33 (82.5%) occurred and in the placebo group, 44 (55%) occurred. As shown in Table 3, patients who received granisetron after spinal anesthesia were significantly more likely to have a complete response (P / 0.02) than those who received placebo (P / 0.03).

Headaches, dry mouth and lips, dizziness, constipation, and myalgia have all been observed as adverse events but were not clinically significant. Table 4 shows that the adverse effects between the two groups were not different.

Table 1: Demographics of mothers

	Group G Granisetron (n = 80)	Group P Placebo (n = 80)
Age	26 ± 4.5	26 ± 3.1
Weight (kg)	57 ± 8.2	58 ± 9
Primigravida	56	58
Multigravida	24	22
ASA grade		
1	62	60
2	18	20
Systolic blood pressure at baseline (mmHg)	125.5 ± 9.1	125.5 ± 7.1
Differences are not significant		

PONV was reported in 20 patients (26 %) treated with granisetron and in 50 patients (63.5 %) treated with placebo.

Table 2: Details of the operation

	Group G Granisetron (*n* = 80)	Group P Placebo (*n* = 80)
Duration of surgery (min)	49.2 ± 9	47.7 ± 7
Exteriorized uterus (n)	72	70
Uterus exteriorized duration (minutes)	19 ± 6.4	19 ± 7.1
Ephedrine total (mg)	7.5	7.5
Pethidine intraoperatively administered to patients (n)	36	32
Consumption of pethidine intraoperatively (mg)	28± 5.1	54 ± 4
Consumption of pethidine postoperatively (mg)	232.5	233.5

Table 3: Spinal anesthesia response during the first four hours (0–4 h) and the next twenty hours (4–24 h)

	Group G Granisetron (n = 80)	Group P Placebo (n = 80)	p
0–4 h after spinal anesthesia			
Complete response (no PONV)	64	36	0.02
Nausea	10	28	
Vomiting	6	14	
Complete response (no PONV)	66	44	0.02
Nausea	8	22	
Vomiting	6	14	
Severity of nausea	0	0	
Overall cumulative incidences of PONV (0–24) h	20	50	0.002

Table 4: Effects adverse to health

	Group G Granisetron (n = 80)	Group P Placebo (n =80)
0–4 h after spinal anesthesia		
Headache	16	14
Dizziness	10	6
Constipation	4	4
Myalgia	2	2
4–24 h after spinal anesthesia		
Headache	14	14
Dizziness	6	6
Constipation	4	4
Myalgia	0	0

DISCUSSION

In the absence of prophylactic antiemetics, it has been found that certain symptoms of nausea and vomiting may occur during regional anesthesia for cesarean section [1]. These cases have complex etiologies for emetic symptoms. Women's labor periods are affected differently by spinal anesthesia than non-obstetric patients'. As a result of increased spinal canal pressure, as well as the acid-base balance and protein levels of cerebrospinal fluid (CSF), distribution of anesthetic drugs can be less predictable in the latter group [1]. PONV can be affected by factors such as perioperative hypotension, postoperative pain, and use of perioperative opioids, anesthetic technologies, and peritoneal traction [5-6]. Induction of spinal anesthesia may cause maternal hypotension, causing emesis to occur [7]. The disruption of abdominal viscera during a cesarean, as with other abdominal surgeries, may cause humoral substances to be released, including 5-HT [7], which can trigger emetic reflexes, especially in awake patients, through 5-HT3 receptors. In the emetic response, four major neurotransmitter systems are involved, namely. Cholinergic, histaminic (H1), muscarinic and 5HT3 dopaminergic receptors. In most cases, PONV is managed with antihistaminic, phenothiazine derivative, anticholinergic, and dopamine receptor antagonist medications that may cause sleepiness, dysphoria, restlessness, and tachycardia. 5HT3 receptor antagonists are highly effective drugs that have the ability to prevent and treat PONV without causing such side effects. Dolasetron, tropisetron, and ondansetron act as antagonists of 5HT3 receptors. The Indian market now

offers ondansetron and granisetron. Ondansetron and granisetron both have similar antiemetic efficacy, but granisetron is much less effective than ondansetron, according to a study [8]. Two milligrams of granisetron IV are equivalent to eight to sixteen milligrams of ondansetron IV. Granisetron prevents nausea and vomiting more effectively than ondansetron, which has a shorter half-life of 3 h. In addition, granisetron is a more selective 5-HT3 receptor antagonist. It is possible to prevent chemotherapy-induced vomiting with a 0.04 mg/kg IV dose. PONV prevention has been described as effective with a similar dose. Due to granisetron's longer elimination half-life than ondansetron, less frequent dosing is required [9]. After gynecological procedures in daycares, granisetron was used to prevent PONV. Granisetron is better than droperidol [10]. Granisetron prevents both intraoperative and postoperative emesis, unlike droperidol and metoclopramide, which prevent only intraoperative emesis. When cesarean deliveries were performed under spinal anesthesia, we studied granisetron's effects on nausea and vomiting.

CONCLUSIONS

In our study, the demographics and operative characteristics of each group were matched. In order to prevent and treat their hypotension, oxygen supplementation, left uterine displacement, and incremental doses of ephedrine were administered. Both groups experienced hypotension following spinal anesthesia and had to be given ephedrine to treat the hypotension. During the perioperative period, pethidine was prescribed for the control of perioperative pain, and similar amounts were consumed by patients. As a result, the study drug may have contributed to the differences in PONV incidence. According to our results, granisetron prevented vomiting and nausea during and after spinal anesthesia ($P < 0.01$), similar to previous study. Granisetron is much more expensive than other antiemetic options. Choosing an antiemetic should not be based solely on these costs, but also on the patient's outcome in the event of emesis. Therefore, granisetron prophylactic therapy after elective cesarean delivery is effective in preventing PONV.

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