Comparison of the Prophylactic Effect of Propofol, Dexamethasone and Ondansetron on Post-Operative Nausea and Vomiting in Elective Cesarean Section Under Spinal Anesthesia

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Received: 12 May 2021; Accepted: 23 Nov. 2021

Abstract- Nausea, and vomiting are common complications in women undergoing cesarean section with spinal anesthesia. This study aimed to compare the propofol, dexamethasone, and ondansetron effects on nausea and vomiting. In this double-blind, randomized clinical trial study, 120 women aged 15 to 35 years candidates for cesarean section under spinal anesthesia were enrolled. Patients were randomly divided into four groups (three-drug groups and control group). Patients received 0.05 mg/kg ondansetron (group O), 0.1 mg/kg dexamethasone (group D), 0.2 mg/kg propofol (group P) and normal saline in controls (group C). Nausea and vomiting in recovery and 6 hours after surgery compared between groups. In recovery and 6 hours after surgery, both nausea and vomiting were the highest in group C while they were lowest in group O. the frequency of nausea was 11(36.7%) in both recovery and 6 hours after surgery, and the frequency of vomiting was 12(40%) and 10(33.3%) in the recovery and 6 hours after surgery respectively. Among three drug groups, nausea and vomiting were higher in group D in both the recovery room and 6 hours after surgery. The frequency of vomiting was 10 (33.3%) and 5 (16.7%) in recovery and 6 hours after surgery in group D, respectively. These differences were statistically significant between the four groups (P<0.05). The preventive effect of dexamethasone is not very useful in both periods. Therefore, it can be recommended that in the short period after surgery, propofol has a beneficial effect in preventing postoperative nausea and vomiting.

Acta Med Iran 2021;59(12):713-719.

Keywords: Propofol; Dexamethasone; Ondansetron; Nausea; Vomiting; Cesarean section

Introduction

Nausea and vomiting have been reported in more than 80% of patients undergoing cesarean section with spinal anesthesia (1-3). Various factors such as the patient's mental status, type of surgery, visceral peritoneal traction, hypotension, use of hypnotics, and factors related to uterine manipulation can cause these complications (4-6). In these patients, nausea and vomiting cause minatory complications, and by preventing them, patients feel comfortable (7). Although in many cases, nausea and vomiting are self-limiting, in some cases, minatory complications such as aspiration, wound dehiscence, esophageal rupture, subcutaneous emphysema, and pneumothorax will occur (8). Nausea and vomiting also delay PACU discharge and increase the length of stay in the hospital (9). In cesarean section, prophylactic agents are usually prescribed after fetal umbilical cord ligation (10-12). Ondansetron is a selective 5-hydroxytryptamine three receptor antagonist and is very effective in preventing and treating nausea and vomiting due to chemotherapy or during and after surgery. This agent reduces nausea and vomiting caused by cesarean section, but this effect is not complete (13-15). In the study of Oliveria *et al*., they showed that in patients undergoing cesarean section under epidural anesthesia, vomiting

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occurred despite the prophylactic administration of 4 mg ondansetron (16). Dexamethasone has been introduced as a potent anti-nausea and an effective anti-inflammatory compound (17-20). The mechanism of this effect is unknown, but it can be due to prostaglandins' inhibition, producing anti-inflammatory factors and endogenous opioids reduction. (19,20). The anti-nausea and vomiting dose of this drug is 2.5 to 10 mg daily (21,22).

The choice approach in cesarean section surgery, is spinal anesthesia. This technique keeps the mother informed about the delivery process, although due to the mother's awakening during surgery, stress may be present. This stress during cesarean section is more than normal delivery (23-25). In these patients, after fetus removal, administration of sedative agents may be helpful. This overt stress can be due to misconception of unhealthy fetus after birth, Inability of the patient to move the legs, anesthesia-related shivering, and nausea and vomiting. Pregnant women experience different reactions to these stressful situations. Prescribing sedatives such as propofol and midazolam can help patients to be comfortable and reduce stress of fetus at birth (26,27). Although the efficacy of antiemetic therapy for prevention and treatment of PONV has been frequently studied, it is not well understood (28). Nausea and vomiting are two common and unpleasant complications of spinal anesthesia in patients undergoing cesarean section. Therefore, prophylactic administration of antiemetics has been recommended in these patients (16,29,30). Some of the medications prescribed to treat postoperative nausea and vomiting include 5-hydroxytryptamine antagonists (ondansetron and granisetron), dopamine receptor antagonists, and antihistamine compounds. However, some medications are associated with factors that limit their prescription. These include the extrapyramidal side effects of dopamine antagonists, the high cost of 5-hydroxytryptamine antagonists, and tachycardia and excessive sedation of antihistamine compounds (31-33). Many recent studies have evaluated the preventive effects of midazolam infusion on postoperative nausea and vomiting (34). Midazolam is a short-acting benzodiazepine that has recently been recommended for the prevention of postoperative nausea and vomiting as a pre and after induction of anesthesia dose and as an infusion in the postoperative period (35). Recently, sub-hypnotic doses (1 mg/kg/h) of propofol have been reported to be more effective than droperidol and metoclopramide in reducing nausea and vomiting during cesarean section under spinal anesthesia (33). Nausea and vomiting during surgery are accompanied by sudden contractions of the diaphragm and cause discomfort in patients and pressure on the abdominal viscera and increase the likelihood of visceral injury. Also, the risk of aspiration is high, especially in patients with a full abdomen if these complications occur. Benzodiazepines have benefits in the management of patients' nausea and vomiting by reducing dopamine in the cerebral chemoreceptor zone (36). Dexamethasone has been reported as a relatively inexpensive drug for controlling nausea and vomiting (37,12). Ondansetron has also been introduced as an effective drug in the prevention of this complication which is well tolerated by patients (38).

Considering the importance of preventing nausea and vomiting as the two most common complications during cesarean section under spinal anesthesia by the safest drug and considering that different results have been reported in previous studies, we decided to design this study to compare the preventive effects of the three drugs propofol, dexamethasone and ondansetron.

Materials and Methods

In this double-blind, randomized clinical trial study, after obtaining informed consent from patients, 120 pregnant patients aged 15 to 35 years ASA I, ASA II candidates for cesarean section under spinal anesthesia were randomly divided into four groups. Exclusion criteria were: patients with a history of antidepressants consumption, gastrointestinal disorders, motion sickness, weight over 100 kg, surgeries that lead to general anesthesia for any reason, hemorrhagic surgeries such as placenta previa and acrta, a history of previous allergies to ondansetron, propofol and dexamethasone, intraoperative hemodynamic disorders, preeclampsia, eclampsia and patients who have taken antiemetic drugs in the past 24 hours. In all patients, after transfer to the operating room, initial monitoring, including blood pressure, pulse oximetry, and electrocardiography, were performed, and after implantation of a suitable intravenous line, 15-20 ml/kg Ringer's serum was administered. After that, spinal anesthesia was performed for patients using 12.5 mg of hyperbaric bupivacaine and using spinal needle No. 25 in a sitting position. Oxygen therapy was performed with a 3 lit/min with the face mask. Blood pressure was measured every 2 to 3 minutes. If hypotension occurred more than 20% of basal blood pressure, the therapeutic intervention was performed by prescribing 5-10 mg of ephedrine, and these patients were excluded from the study. The used drugs in this study

were ondansetron 0.05 mg/kg (group O), dexamethasone 0.1 mg/kg (group D) and propofol 0.2 mg/kg (group P). These drugs were administered after the fetus's removal and the umbilical cord ligation. Patients were randomly divided into three intervention and control groups using random allocation computer software. By selecting the simple randomization method and entering the total determined sample size in this software, numbers were given to the patients and patients were entered based on generated computer numbers into four groups. Patients received 0.05 mg/kg ondansetron, 0.1 mg/kg dexamethasone, 0.2 mg/kg propofol and normal slain in O, D, P and control (group C) groups respectively. These administrations were done by an anesthesiologist who did not know the content of the study. Patients were followed up in recovery room and 6 hours after surgery for nausea and vomiting, and data were collected by checklists and analyzed. The study was approved by ethics committee of Urmia University of Medical Science with IR.UMSU.REC.1397.112 ID number and was registered in Iranian Registry of Clinical Trials website with IRCT20170408033280N3 number.

Statistical analysis

The values were presented as number (percent). The frequency of nausea and vomiting in recovery and 6 hours after surgery was compared using Chi-square test between four groups. Data analysis performed using SPSS software and *P* less than 0.05 considered as significant level.

Results

In this study, 120 pregnant women candidate cesarean section under spinal anesthesia (30 patients in each group) were analyzed at the end of the study.

Nausea in the recovery room and 6 hours after surgery

In recovery, the frequency of nausea was higher in group C than three-drug intervention groups. Among patients in the three-drug groups, group D had the highest nausea. There was no case of nausea in group O while its frequency was 1(3.3%), 5 (16.7%), 11 (36.7%) in the P, D, and C groups, respectively. There was a significant difference between the four groups in nausea ($P<0.001$). In a two-by-two comparison, there was a significant difference in nausea in the recovery room between O and D ($P=0.02$), O and C ($P=0.001$), D and C ($P=0.01$), P and C ($P=0.03$), D and P ($P=0.008$)

Six hours after surgery, like in the recovery room, the nausea was highest in the C and D groups. The frequency of nausea was 1 (3.3%), 7 (23.3%), 8 (26.7%), and 11 (36.7%) in the O, P, D, and C groups, respectively. Nausea had a significant difference between the four groups ($P=0.01$). In a two-by-two comparison, the frequency of nausea was statistically significant between O and D ($P=0.01$), O and C ($P=0.001$), O and P ($P=0.01$) groups. But there was no significant difference between P and D ($P=0.76$), P and C ($P=0.26$), and D and C ($P=0.45$) groups (Table 1).

Table 1. Comparing the frequency of nausea in the recovery and 6 hours after surgery between groups

Study groups	In recovery		6 hours after surgery	
	Yes*	No	Yes*	No
O	0(0.0%)[a]	30(100%)	1(3.3%)[a]	29(96.7%)
P	1(3.3%)[a]	29(96.7%)	7(23.3%)[b]	23(76.7%)
D	5(16.7%)[c]	25(83.3%)	8(26.7%)[b]	22(73.3%)
C	11(36.7%)[d]	19(63.3%)	11(36.7%)[b]	19(63.3%)
Total	17(14.2%)	103(85.8%)	27(22.5%)	93(77.5%)
p-trend¶		<0.001	0.01	

Compared using Chi-square test

*: The different letters indicate the statistical significance, and the same letters indicate no differences for two-by-two comparison

Vomiting in the recovery room and 6 hours after surgery

In the recovery room, 2 (6.7%), 3 (10%), 10 (33.3%), and 12 (40%) of patients had vomited in O, P, D, and C groups, respectively. The vomiting was a statistically significant difference between the four groups ($P=0.002$).

In a two-by-two comparison, the vomiting had a significant difference between O and D (*P*=0.002), O and C (*P*=0.002), D and P (*P*=0.02), P and C. (*P*=0.03), D and C (*P*=0.01) groups. But there was no significant difference between the O and P (*P*=0.64) groups.

Six hours after surgery, any patients had no vomiting in the O group while the C group and then the D group had the highest of vomiting as its frequency was 10 (33.3%), 5 (16.7%), 4 (13.3%) in C, D and P groups respectively. Vomiting was statistically significant between four groups 6 hours after surgery (*P*=0.005). In a two-by-two comparison, significant differences were observed between O and D (*P*=0.02), O and C (*P*=0.04), and O and P (*P*=0.03) groups. But there was no significant difference between P and D (*P*=0.71), P and C. (*P*=0.06), and D and C groups (*P*=0.13) (Table 2).

Table 2. Comparing the frequency of vomiting in the recovery and 6 hours after surgery between groups

Study groups	In recovery		6 hours after surgery	
	Yes*	No	Yes*	No
O	2(6.7%)[a]	28(93.3%)	0(0%)[a]	30(100%)
P	3(10%)[a]	27(90%)	4(13.3%)[b]	26(86.7%)
D	10(33.3%)[b]	20(66.7%)	5(16.7%)[b]	25(83.3%)
C	12(40%)[c]	18(60%)	10(33.3%)[bc]	20(66.7%)
Total	27(22.5%)	93(77.5%)	19(15.8%)	101(84.2%)
p-trend¶	0.002		0.005	

Compared using Chi-square test

*: The different letters indicate the statistical significance, and the same letters indicate no differences for two-by-two comparison

Discussion

Based on the results obtained in the comparison of the four groups in assessing the frequency of nausea and vomiting in recovery, the highest rate of nausea and vomiting was seen in group C, and the lowest rate of nausea and vomiting was observed in group O, while in group D the frequency of nausea and vomiting was higher than group P. In the comparison of groups P and O, there was a statistically significant difference in nausea and vomiting in the recovery room. There was no statistically significant difference between groups P and O in nausea and vomiting in the recovery room. Also, the frequency of nausea and vomiting in group O was less than in group D.

These results are consistent with the results of a study by Tarhan *et al*., in Turkey. In the results of their study, sub-hypnotic doses of propofol have an effective role in preventing nausea and vomiting after spinal anesthesia. To justify this, it can be stated that sub-hypnotic doses of propofol are effective in preventing postoperative nausea and vomiting, but the mechanism of this effect is unknown (33). In various studies on the prophylactic effect of propofol on nausea and vomiting after general anesthesia in gynecological and laparoscopic surgeries, propofol could not reduce the frequency of postoperative nausea and vomiting (39-45). However, in a study conducted by Numazaki *et al.*, On sub-hyponic doses of propofol, it was found that these doses are very effective in preventing nausea and vomiting after spinal anesthesia, which is clearly consistent with the results of our study (32). The main reason for this difference in the above studies may have been related to differences in the type of surgery, anesthesia technique, and duration of patient evaluation. The antiemetic mechanism of propofol is unknown, but propofol does not appear to have vagolytic effects (46). It is hypothesized that the sedative effect of sub-hypnotic doses of propofol is responsible for its antiemetic mechanism. Another suggested mechanism for the antiemetic effects of propofol is its anti-anxiety effects. However, this effect is not considered as the main mechanism. On the other hand, in a study conducted by Hamas *et al*., They concluded that propofol has brief antagonistic effects on 5-HT3 receptors. Despite all the above hypotheses, the antiemetic mechanism of propofol is unknown and needs further study (47).

In Kalani *et al*., study, it was stated that the role of dexamethasone and ondansetron in preventing nausea and vomiting after spinal anesthesia is the same and can be prescribed interchangeably (45). While in the results of our study, this role was much less for dexamethasone than for ondansetron, and there was a statistically significant difference in the ondansetron group compared to the dexamethasone group. In the dexamethasone group, the frequency of nausea and vomiting in the recovery room was more than in the ondansetron group. To justify this, we can refer to the study of Movafegh *et al*., that the results of this study indicate that the

administration of dexamethasone in patients under anesthesia with intrathecal meperidine is effective in reducing nausea and vomiting after spinal anesthesia (48). This prominent role of dexamethasone could be due to hormonal changes, patients 'age, patients' weight, duration of surgery, and, most importantly, intrathecal opioid use. In other words, their study found that dexamethasone was more prominent in preventing postoperative nausea and vomiting in patients undergoing spinal anesthesia with intrathecal opioids. In our study, spinal anesthesia was performed with the administration of intratechal bupivacaine without additive opioids. In the results of our study, the effect of these three drugs 6 hours after surgery was also compared. At this time, the results showed that the frequency of nausea and vomiting in the ondansetron group was the lowest, in the control group was the highest and the propofol and dexamethasone groups were significantly different from the ondansetron group. In other words, in the ondansetron group, this amount was much lower than in the propofol and dexamethasone groups. In justification of this matter, it can be said that perhaps due to the fact that the duration of action of propofol at a sub-hypnotic dose is short and the rapid metabolism of the drug reduces its postoperative effects, so the effect of propofol 6 hours after surgery It is not as big as the recovery phase and will be much less, which can be seen in the results of our study. However, the mechanism of ondansetron`s antiemetic effect is inhibition of 5 HT3 receptor. So, it can play its anti-emetic role for a longer period of time.

Obviously, more studies are needed to achieve more accurate results. Also, in our study, there was a significant difference between the ondansetron and dexamethasone groups 6-hours after surgery. Again, in the ondansetron group, the rate of nausea and vomiting was much lower than the dexamethasone group.

In conclusion, it can be said that during the recovery period, the effect of propofol on the prevention of postoperative nausea and vomiting is similar to ondansetron, while this effect is not seen 6 hours after surgery. On the other hand, the effect of dexamethasone in this prevention is not very useful in both periods. Therefore, it can be recommended that in the short period after surgery, propofol has a beneficial effect in preventing postoperative nausea and vomiting.

Acknowledgements

The authors appreciate statistical counselors of the Clinical Research Development Unit of Imam Khomeini Hospital, Urmia University of Medical Sciences.

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