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Сравнительная противорвотная эффективность метоклопрамида, ондансетрона и пиридоксина для профилактики тошноты и рвоты у пациенток, перенесших кесарево сечение в условиях спинномозговой анестезии

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РЕЗЮМЕ

Введение. Одним из осложнений после кесарева сечения является тошнота и рвота, особенно при проведении спинномозговой анестезии. Основные причины развития тошноты и рвоты сложны и могут быть связаны с хирургическим вмешательством, снижением артериального давления, возбуждением блуждающего нерва и введением окситоцина.

Цель – сравнение и оценка эффективности внутривенного введения ондансетрона, пиридоксина и метоклопрамида для профилактики рвоты у пациенток, перенесших кесарево сечение в условиях спинномозговой анестезии.

Материалы и методы. В данное исследование включены 100 беременных женщин на позднем сроке беременности без выраженной сопутствующей патологии, соответствующих I и II классу по шкале ASA. Пациентки случайным образом разделены на группы, принимающие три препарата, и контрольную группу. В каждой группе было по 25 пациенток: группа ондансетрона (4 мг внутривенно), группа метоклопрамида (10 мг внутривенно), группа пиридоксина (100 мг внутривенно) и группа плацебо или контрольная группа (физиологический раствор – 2 мл внутривенно). В ходе исследования фиксировали тошноту и рвоту, которые возникали во время операции и после нее, а также любые дополнительные побочные эффекты. Для статистического анализа данных была использована программа SPSS 20.0.

Результаты. Частота интра- и послеоперационной тошноты и рвоты была выше в группе плацебо (40% и 32%) по сравнению с группой ондансетрона (4% и 8%), метоклопрамида (8% и 16%) и пиридоксина (20% и 24%). Признаки расстройства ЖКТ были более выражены в группе пиридоксина по сравнению с группами метоклопрамида и ондансетрона. Частота тошноты и рвоты после операции была высокой в группе плацебо и статистически значимой по сравнению с группой ондансетрона (p = 0,0232), статистически значимой разницы с группами метоклопрамида и ондансетрона не было.

Заключение. Согласно результатам исследования, ондансетрон и метоклопрамид были более эффективны в снижении тошноты и рвоты, чем пиридоксин и плацебо. Ондансетрон показал наибольшую эффективность для профилактики как интра-, так и послеоперационной тошноты и рвоты.

Ключевые слова: противорвотная эффективность, метоклопрамид, ондансетрон, пиридоксин, кесарево сечение, спинномозговая анестезия

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Comparative antiemetic efficacy of metoclopramide, ondansetron and pyridoxine for the prevention nausea and vomiting in patients undergoing cesarean section under spinal anesthesia

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ABSTRACT

Introduction. One of the complications after Cesarean Section is nausea and vomiting, especially during spinal anesthesia. The main causes of nausea and vomiting are complex, and may be related to surgical intervention, decrease in blood pressure, vagal excitation, and oxytocin administration.

The objective was to compare and estimate the efficacy of intravenous injections of ondansetron, pyridoxine and metoclopramide in inhibiting emesis prophylactically in patients undergoing cesarean section under spinal anesthesia.

Materials and methods. This study included 100 pregnant females in the last term without significant concomitant pathology of ASA grades I and II. Patients were randomly allocated into three drug groups and a control group. Each group consisted of 25 patients: the ondansetron group (4 mg intravenously), the metoclopramide group (10 mg intravenously), the pyridoxine group (100 mg intravenously), and the placebo group or the control group (normal saline - 2 ml intravenously). During the study, nausea and vomiting occurred during and after surgery, in addition to any additional adverse effects. Statistical software (SPSS 20.0) was used for statistical data analysis.

Results. The incidence of intra- and postoperative nausea and vomiting was higher in the placebo group (40% and 32%) compared with the ondansetron group (4% and 8%), the metoclopramide group (8% and 16%), and the pyridoxine group (20% and 24%). Signs of gastrointestinal disorders were more pronounced in the pyridoxine group compared with the metoclopramide and ondansetron groups. The incidence of nausea and vomiting after surgery was high in the placebo group and statistically significant compared with the ondansetron group ($p = 0.0232$), there was no statistically significant difference with the metoclopramide and ondansetron groups.

Conclusion. According to the results of the study, ondansetron and metoclopramide were more effective in reducing nausea and vomiting than pyridoxine and placebo. Ondansetron was significantly more effective for prevention of both intra- and postoperative nausea and vomiting.

Keywords: *antiemetic efficacy, metoclopramide, ondansetron, pyridoxine, cesarean section, spinal anesthesia*

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Introduction

Pain and GIT upset as nausea and vomiting are considered the most common adverse signs that can occur before and post cesarean sections performed with spinal anesthetics, which are definitely stated in more than 66% of patients [16]. They can be caused by a variety of factors, including the surgery itself, anesthesia, and medications.

These unpleasant symptoms can cause discomfort, distress, and potentially lead to complications such as aspiration, dehydration, and delayed recovery, as well as an important defy to the operative surgeon, possibly prolonging the time of the process and increasing the risk of unintentional bleeding and surgical trauma [15, 31]. Thus, preventing these symptoms in patients undergoing cesarean section is crucial to ensure optimal surgical outcomes and to improve patient satisfaction. Cesarean section is a surgical procedure for women, refuge to it when there is a deficiency of progression in labor, in addition to further indications [26].

In most surgical patients, these symptoms are critical anesthesiological complications that are mainly related to postoperative complications. In addition to aspiration pneumonitis, airway obstruction and wound dehiscence are rare [34].

The dangerous aspects that form PONV involve sex, mainly in women, no smoking history, migraine, involuntary movement, vomiting and nausea next to surgery, age especially in young people, general anesthetics, previous history of abuse of medicines, general anesthesia, use of nitrous oxide, hypotension after surgery, general health of the patient, surgical period, and gynecological and abdominal operation [37].

Nausea and vomiting may be caused by hypotension or vagal reflexes caused by visceral handling. Oxytocic medications, such as Carboprost, Misoprostol or Methergine have strong emetogenic effects [17].

There are different drugs used for treating emesis, typically within classes of drugs include the Neurokinin-1 receptor (NK1R) antagonist drug, 5-Hydroxytryptamine3 (5HT3), corticosteroids, dopaminergic receptor drugs (D2R), anti-histamine drugs, and anti-cholinergic drugs [11, 12]. The differing in the undesired effects have been belonged to the diverse classes, 5-HT3antagonists cause constipation and headache; D2R antagonists cause sedation, arrhythmia, extrapyramidal symptoms and QT prolongation; Cortico-steroids increase serum glucose level, effect on immune responses and reduced wound curing; Anti-histamine drugs give rise to sleepiness, xerostomia and urinary complications; finally Anti-cholinergic drugs bring about xerostomia and visual disorders [11, 40]. Inadequate confirmation of undesired effects of NK_1R antagonists. However, some studies have shown that vertigo and headaches can occur [8].

Serotonin type 3 receptor antagonists like, ondansetron, granisetron, generally denoted as 'setrones', which obstruct 5-HT3 receptors in GIT in addition to central AP inhibition. These drugs are widely used for prophylaxis and treatment of PONV, ondansetron is widely used for avoidance GIT upset (nausea and vomiting) in chemotherapy or surgical operation. It affects the peripheral inhibition of the 5-HT3R in postrema as well as disables the vomiting center in the medulla oblongata, and centrally blocks serotonin in chemo-receptor trigger zones. Therefore, ondansetron is an effective drug for the treatment and prevention of PONV with few side effects [18].

Dopamine receptor antagonists are antiemetic that inhibit the enzyme adenyl cyclase, leading to a reduced quantity of neuronal c-AMP in the NTS and AP by antagonizing the D2 and D3 receptors [19]. The drugs include Metoclopramide, Droperidol, Haloperidol, and Amisulpride [23, 22]. The main undesirable effects are the propensity to induce QT elongation and malignant ventricular arrhythmias. Droperidol creates sleepiness [6].

Metoclopramide is a prokinetic medication that acts by increasing the stress of the low esophageal sphincter. Furthermore, it acts as a dopaminergic inhibitor in the chemoreceptor trigger zone and exerts serotonergic inhibition at higher doses [10]. As prophylaxis for PONV in non-obstetric operations, a 10 mg dose is used but does not have an antiemetic effect [14]. This dose was described to be harmless in parturients [25], and even if it passes through the placental barrier, it is not affected in neonates [3].

Pyridoxine (Vitamin B6), also known as pyridoxine, has been suggested as an adjunct therapy for managing pregnancy-induced nausea and vomiting, although its mechanism of action is not fully understood [21]. Vitamin B6 is available as the first pharmacotherapy for nausea, as it can recover from nausea together with fewer undesired effects [27]. In animal studies, pyridoxine was not teratogenic at a dose of 100 mg/kg [5]. Vitamin B6 recovers mild nausea but not vomiting, as reviews in some randomized trials have also shown in controlled studies [29]. The therapeutic mechanism for this is unknown, although there are hypotheses describing the prevention or management of Vit. B6, essential anti-nausea characteristics, and/or effects of antihistamines on nausea when given together in synergy [33]. Although the levels of this vitamin reduce as pregnancy progresses, the relationship between the concentration of vitamin B6 in the mother and the occurrence of nausea has not been established [35].

This study is significant because it compares the antiemetic efficacy of three different drugs for the avoidance of nausea and vomiting after spinal anesthetic cesarean section. It is an important topic due to signs of GIT distress, as nausea and vomiting are common side effects of cesarean section, and they can be very unpleasant and disruptive for patients. This research could help doctors to choose the most effective drug to avoid these symptoms in their patients.

The results of this study could help improve the care of patients who have undergone a cesarean section. By providing doctors with more information about the different antiemetic drugs, this research could help to ensure that patients receive the best possible treatment for nausea and vomiting.

In addition to the research questions listed below, this study could also explore other factors that may affect the efficacy of antiemetic drugs, such as the timing of administration, dose of the drug, and the patient's individual characteristics. The study also collected data on the quality of life of patients who received different antiemetic drugs to assess the impact of the drugs on the patient's overall well-being.

This research is likely to be of interest to a variety of stakeholders, including doctors, nurses, patients, and policymakers. The results of this study could help to improve the quality of care for patients who have undergone cesarean section, and could also inform future research on avoidance symptoms such as nausea and vomiting following the surgical procedure.

The findings of this study have the potential to provide respected insights into the obstetric anesthesia field and improve the care provided to cesarean section patients. By identifying the most effective antiemetic agent, healthcare providers can develop evidence-based protocols that reduce the occurrence of nausea and vomiting, enhance patient comfort, and facilitate smooth recovery following cesarean section performed under spinal anesthesia.

Objective. This study aimed to conduct a comparative analysis of the antiemetic activity of three medications, metoclopramide, ondansetron, and pyridoxine, to avoid intraoperative and postoperative nausea and vomiting (PONV) subsequent to spinal anesthesia, particularly for patients undergoing cesarean section. The study noted the number of emetic episodes (nausea, retching, and vomiting) during the intraoperative and postoperative periods as well as any adverse effects.

Materials and methods

The comparative clinical trial study was conducted at Al-Zahra Hospital in Al-Najaf city, Iraq, during the period from 1st of February to 1st of July 2023. The study was proposed and subsequently approved by the scientific council of anesthesia and intensive care of the Arabic board of medical specialists and permission from Al-Zahra Hospital.

Permission of the Ethics Committee. This work was approved by Ethical Committee Reviewer Board of the University of Kufa, Faculty of Pharmacy (No. 601 in 10th January 2023).

This study was a double-blind, randomized clinical trial. A total of 100 pregnant women between 20 and 35 years of age, ASA I, ASA II, and the need for cesarean births with spinal anesthetics at Al-Zahra Hospital were randomly divided into four groups.

Division of the groups:

At random division, four groups, each one with 25 pregnant patients.

Group I: (n = 25) I.V. inj., 10 mg of Metoclopramide

Group II: (n = 25) I.V. inj., 4 mg of Ondansetron

Group III: (n = 25) I.V. inj., 100 mg of Pyridoxine

Group IV: (n = 25) I.V. inj., 2 ml of Normal Saline (placebo)

Exclusion criteria. Patients with ASA score III or IV, eclampsia, pre-eclampsia, and pregnant women who had reserved antiemetic medications in the previous 24 hours, previous history of PONV, history of allergies to ondansetron, metoclopramide, and pyridoxine.

Statistical Analysis. The results are presented as numbers (percentage). The Chi-square test was used to compare the number of occurrences of the symptoms nausea and vomiting (N/V) in recovery and six hours after surgery in the four groups. Statistical analysis was performed using SPSS software, and statistical significance was set at $p < 0.05$. Categorical variables included the study group (treated group) and incidence of nausea and vomiting, which were used in this test.

Results

Table 1 and 2 show the frequency of nausea and vomiting after one hour for the four groups, and the occurrence of nausea and vomiting after six hours for the four groups, respectively.

Fisher's exact test. In this case, the p-value is 0.0232, which is less than the significance level of 0.05. This indicates that there was a significant association between the study group and vomiting. In other words, patients who received ondansetron were less likely to experience vomiting than those who received a placebo (table 3).

The p-value of 0.1706 for the chi-square test comparing metoclopramide to placebo for vomiting after surgery indicated that there was no statistically significant difference in the vomiting rates between the two groups. In other words, the data do not provide strong evidence that metoclopramide is more effective than placebo in preventing postoperative vomiting. It is important to note that the p-value of 0.1706 does not mean that metoclopramide is not effective. This means that the data do not provide strong evidence to support its effectiveness (table 4).

The p-value of 0.5202, the difference in the vomiting rates between the pyridoxine and placebo groups was not statistically significant. Therefore, it cannot be confidently concluded that pyridoxine is less likely to cause vomiting than placebo based on this information alone (table 5).

Table 1. **Frequency of nausea and vomiting after one hour for four groups**

Study group	Frequency of vomiting	Without vomiting	Frequency of nausea	Without nausea
Ondansetron	1(4%)	24 (96%)	2 (8%)	23 (92%)
Metoclopramide	3 (12%)	22 (88%)	4 (16%)	21 (84%)
Pyridoxine	5 (20%)	20 (80%)	6 (24%)	19 (76%)
Placebo	8 (32%)	17 (68%)	10 (40%)	15 (60%)
Total	17 (17%)	83 (83%)	22 (22%)	78 (78%)

Table 2. **Occurrence nausea and vomiting after six hours for four groups**

Study group	Frequency of vomiting	Without vomiting	Frequency of nausea	Without nausea
Ondansetron	1 (4%)	24 (96%)	1 (8%)	24 (96%)
Metoclopramide	2 (8%)	23 (92%)	3 (16%)	22 (88%)
Pyridoxine	2 (8%)	23 (92%)	4 (24%)	21 (84%)
Placebo	6 (24%)	19 (76%)	8 (40%)	17 (68%)
Total	11 (11%)	89 (89%)	16 (22%)	84 (84%)

Table 3. **Comparison with the frequency of vomiting between ondansetron and placebo after 1 hour**

Study group	With vomiting	Without vomiting	P value
Ondansetron	1 (4%)	24 (96%)	0.0232
Placebo	8 (32%)	17 (68%)	

Table 5. **Comparison with the frequency of vomiting between pyridoxine and placebo after 1 hour**

Study group	With vomiting	Without vomiting	P-value
Pyridoxine	5 (20%)	20 (80%)	0.5202
Placebo	8 (32%)	17 (68%)	

Table 6. **Comparison with the frequency of vomiting between ondansetron and metoclopramide after 1 hour**

Study group	With vomiting	Without vomiting	Total	P-value
Ondansetron	1 (4%)	24 (96%)	25 (100%)	0.6092
Metoclopramide	3 (12%)	22 (88%)	25 (100%)	

Table 7. **Comparison with the frequency of vomiting between ondansetron and pyridoxine after 1 hour**

Study group	With vomiting	Without vomiting	Total	P-value
Ondansetron	1 (4%)	24 (96%)	25 (100%)	0.1895
Pyridoxine	5 (20%)	20 (80%)	25 (100%)	

Table 8. **Comparison with the frequency of vomiting between metoclopramide and pyridoxine after 1 hour**

Study group	With vomiting	Without vomiting	Total	P-value
Metoclopramide	3 (12%)	22 (88%)	25 (100%)	0.7019
Pyridoxine	5 (20%)	20 (80%)	25 (100%)	

The *p*-value of 0.6092 for the chi-square test comparing ondansetron to metoclopramide for vomiting after surgery indicated that there was no statistically significant difference in the rates of vomiting between these two groups. In other words, the data do not provide strong evidence that ondansetron or metoclopramide is more effective than others in preventing vomiting after surgery (table 6).

According to the *p*-value, ondansetron was more effective than pyridoxine in preventing vomiting after surgery. The *p*-value of 0.1895 for the chi-square test comparing ondansetron to pyridoxine indicated that there was a non-significant difference in the rates of vomiting between these two groups. In other words, the data indicate that ondansetron is not superior to pyridoxine in preventing postoperative vomiting (table 7).

The *p*-values of 0.7019 suggests that there may not be a statistically significant difference between the two groups, which suggests that the observed differences in vomiting rates between the two groups could be due to random chance rather than a true effect of the treatments. In other words, there is no strong evidence to conclude that one treatment is more effective than the other in preventing vomiting (table 8).

Discussion

Intra- and postoperative nausea and vomiting (IONV and PONV) are frequent because they can be adverse to pregnant women undergoing cesarean delivery (CD) with neuraxial anesthesia. The incidence of IONV differed among diverse studies, with rates of 60–80% being stated [4].

There are multiple causes of IONV, including progesterone, which is decreased in a low esophageal sphincter tone, increased pressure inside the gastric [25], uterine exteriorization, visceral motivation, decline in blood pressure, and use of neuraxial opioids [31].

The occurrence of emetic signs is elevated during pregnancy because of an increase in progesterone concentration, which is considered a reason for relaxation of the smooth muscle, diminution in lower esophageal sphincter tone, lowering of gastrointestinal motility, and excess intestinal secretion [38]. The reason for IONV is intricate; it can be due to surgical stimuli, reduced blood pressure, vagal stimulation, and oxytocic medications. Demographic data and anesthetic methods can also play a role [4]. Cesarean section achieved underneath local anesthetics has been widely popular owing to improved patient satisfaction, enhanced fetal state during birth, and enhanced safety to the mother [30, 32]. Furthermore, when these females give spinal anesthetics used for cesarean section, a danger of IONV and next to delivery emetic signs may be associated with a reduction in blood pressure after post-induction that may cause brainstem hypoxia and motivation of the vomiting center [9].

The aim of this study was to identify a highly efficient antiemetic drug to reduce the incidence of intra- and postoperative nausea and vomiting in 100 female patients who underwent cesarean section under spinal anesthesia. Metoclopramide, ondansetron, and pyridoxine, and control groups were compared to avoidance the (nausea and vomiting) in cesarean section patients who were administered spinal anesthetics.

The outcomes that were obtained from the comparison between the four groups in evaluating the frequency of nausea, vomiting (N/V) during recovery, and 6 hours after surgery showed that the maximum rate N/V was realized in the placebo or control group, while the lowermost rate N/V was detected in the ondansetron group. The statistically significant difference in N/V ($p = 0.0232$) was less than 0.05. A p-value of less than 0.05 is commonly considered to be statistically significant. This indicates that there is < 5% opportunity for the detected difference in the rates of vomiting between the two groups to be due to chance, while there was no statistically significant difference between ondansetron, meteclopromide and pyridoxine groups that have high frequency N/V when compared with other treated groups. Although there was no statistically significant reduction in the rate of PONV in different groups, these outcomes are compatible with those found in the study by Afsargharehbagh et al., who found that ondansetron did not possess any advantage over metoclopramide in decreasing post cesarean signs (nausea and vomiting) [2].

Ondansetron is the favorable among group of antiemetic drug. This outcome is consistent with the outcome of García – Miguel, where ondansetron and metoclopramide significantly decreased the N/V rate when matched to the placebo; nevertheless, the ondansetron and metoclopramide groups showed no significant difference [13]. In comparison with Krobbuaban et al., it was found nearly results, which determined that ondansetron, when used prophylactically in pregnant women suffering from cesarean section, showed more efficacy than metoclopramide for avoiding PONV in similar conditions [24]. At doses ranging from 4 mg to 8 mg, ondansetron has an antiemetic effect. However, the 4 mg dose, which represents the lowest effective dose of ondansetron, is the usual dose used to avoid PONV, as emphasized in numerous clinical studies. Dershwitz et al. surveyed six diverse ondansetron doses for PONV avoidance and suggested that the dose of 4 mg has the antiemetic effect [7]. The survey by Abouleish et al. stated that the 4 mg dose of ondansetron throughout the cesarean section significantly diminished the incidence of emetic symptoms as compared with the placebo [1]. The current study also indicated that the use of 4 mg ondansetron and the outcomes observed in this group were comparable to those reported in previous studies.

Another study established that ondansetron injection resulted in a decline in the occurrence of postoperative nausea and vomiting compared with metoclopramide [39]. However, no significant difference was observed in palonosetron as an anti-nausea effect when compared to ondansetron and metoclopramide [36]. There was no specific indication of pyridoxine to avoidance (nausea and vomiting) in pregnant women with cesarean section beneath spinal anesthesia in the provided abstracts.

The survey by Zahedi et al. was matched with ondansetron and metoclopramide efficacy, which established that metoclopramide has high activity as an antiemetic medication [41]. Norouzi A. indicated that ondansetron has an effective function in governing N/V subsequent to the cesarean section [28].

In comparison with to the outcomes that described by Zahedi H. et al. [41], stated alike effective property for two medications in avoiding N/V whereas A.Imeh et al. institute superior efficacy as antiemetic by ondansetron [20].

Conclusion

Ondansetron and metoclopramide were more effective in reducing IONV than pyridoxine or placebo. Ondansetron was significantly more effective in reducing PONV; therefore, it is the most effective medication for preventing both IONV and PONV. More research is needed to confirm this finding, using a larger sample size and a more precise design. It is essential to interpret these results with caution and consider other factors, such as the study design and sample size.

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