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The Incidence and Risk Factors of Intra-operative Nausea and Vomiting after Cesarean Section under Spinal Anesthesia

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Abstract-- *Background: Nausea and vomiting is a common postoperative complication after general anesthesia, while spinal anesthesia may be associated with intra-operative nausea and vomiting (IONV), as well. Several factors affect the incidence of IONV that have to be considered for prevention of this complication. Considering the racial differences in the incidence of IONV, and different drug efficacy and adverse effects, we aimed to determine the incidence and risk factors of IONV in patients undergoing cesarean sections (C/S) under spinal anesthesia in an Iranian population.*

Methods: This cross-sectional study was conducted on 500 pregnant women who underwent C/S under spinal anesthesia. The collected data included demographics (age, educational level, body mass index [BMI], and number of pregnancies), history of gastrointestinal diseases, migraine headaches, anxiety (evaluated by Beck Anxiety Inventory), hypertension, nausea and vomiting (N/V) and vaginal bleeding during pregnancy, and NPO state, as well as the type and dosage of spinal anesthetic, use of ephedrine for blood pressure control, needle size, and sex of the neonate.

Results: There was a significant association between IONV and hyperemesis, anxiety, ephedrine use, and eclampsia ($P<0.05$), while there was no significant association between IONV and the rest of variables ($P>0.05$). Backward logistic regression indicated that ephedrine usage, history of hyperemesis, eclampsia, and anxiety were independently and significantly associated with IONV.

Conclusions: Appropriate treatment of conditions that are associated with IONV before C/S, including ephedrine usage, history of hyperemesis, eclampsia, and anxiety, can be effective in preventing this annoying complication.

Keywords--- *Anesthesia, spinal; Cesarean section; Postoperative nausea and vomiting; Postoperative complications.*

I. INTRODUCTION

Postoperative Nausea and Vomiting (PONV) is one of the most common complications of surgery and anesthesia, which patients experience not only after surgery, but also after discharge that can prolong the hospitalization period

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and increase the costs as well as disturbing the patients [1]. Without prophylactic intervention, PONV occurs in a high percentage of patients that varies based on several factors, including patients' sex, duration of surgery and anesthesia, different surgical and anesthetic techniques, and use of drugs, as well as history of diseases, including migraine, anxiety, etc. [2].

Female sex is known as a factor associated with higher risk of PONV and pregnant women suffer from severe N/V during pregnancy due to predisposition by pregnancy hyperemesis that impairs their quality of life [3]. As most cases are not well diagnosed and treated, most pregnant women hope to get rid of this problem after child birth [4], but C/S under spinal anesthesia is associated with additional risk of intra-operative nausea and vomiting (IOPV), as well as PONV, which will add to their discomfort and highlights the necessity of appropriate management of this complication [5].

Based on the pathogenesis suggested, stimulation of the chemoreceptor trigger zone (CTZ) in medulla by dopamine, opioid, histamine, acetylcholine, and 5-hydroxytryptamine type 3 (5-HT3) causes N/V [6]; accordingly, several anti-emetics have been proposed to control this complication, including anticholinergics, anti-dopaminergics, anti-histaminergics, and anti-serotonergics [7]. Several studies have compared the efficacy of the suggested medications [8, 9], while there is no widely-accepted protocol and N/V is still a disturbing complication for patients undergoing general surgical procedures [10]. Therefore, evidence suggests a combinational treatment [11], as well as management of preventable risk factors [5]. In addition, the efficacy of medications for IOPV and PONV after C/S seems to be different than that of general surgery [12]. Therefore, paying attention to factors associated with N/V in women undergoing C/S under spinal anesthesia is of great importance.

Considering the importance of N/V in women undergoing C/S under spinal anesthesia, beside racial difference in the incidence of PONV [13], and different efficacy and adverse effects of drugs, such as opioids, in different ethnicities [14], as well as the fact that this issue has not been investigated in Iran, this study aimed to determine the incidence and risk factors of PONV in C/S under spinal anesthesia.

II. Patients and Methods

2.1. Study design

This cross-sectional study investigated pregnant women who underwent C/S under spinal anesthesia at educational center of Zeinabieh Hospital, Shiraz, from 2015-2016. First, the study protocol of was approved by the Ethics Committee of Shiraz University of Medical Sciences. Before recruitment of participants, the design and objectives of the study were explained to all participants and they were explained that their information would be kept confidential and analyzed without names and only for the purpose of this study. They were clarified that they were free to leave the study whenever they wished to. Then, written informed consent was obtained from those who were willing to participate in the study.

The sample size was calculated based on the prevalence of 10% according to the study by Serajuddin and colleagues [15], considering type I error (α error) = 0.05 and test power of 80% with 2% maximum difference at 441 participants, therefore, for higher accuracy, 500 patients were considered as the final sample size.

The inclusion criteria consisted of pregnant women who underwent elective C/S under spinal anesthesia at Zeinabieh Hospital, Shiraz, from 2015-2016, who did not use anti-emetics during the past 24 hours. Any patient who required changing spinal to general anesthesia (failed spinal anesthesia or requiring venous anesthesia) and patients with abnormal vaginal bleeding were excluded from the study.

The spinal anesthesia was performed by a single anesthesiologist by spinal needle size 24-25 (according to patient's body) in sitting position through L4-L5 space. Then, 0.5% bupivacaine (Milan Co., France) and 5% lidocaine (Alhavi Co., Iran) were injected through the needle in the spinal space. The amount of each drug was estimated by the anesthesiologist based on the operation's duration. After spinal anesthesia, the patient was laid in supine position with tilting the operating table to left for prevention of hypotension syndrome. After prep & drep, the C/S was performed by the gynecologist through horizontal lower abdominal incision. During anesthesia and the surgery, patients' vital signs as well as electrocardiogram (ECG), pulse oximetry, and non-invasive blood pressure (NIBP) were monitored. Then, the patients were relocated to PACU (post-anesthesia care unit) for recovery.

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Before entering the operating theater, the researcher collected the following data, based on the researcher-made checklist: demographics (including age, educational level, height and weight [essential for calculation of body mass index (BMI)], and number of pregnancies), history of gastrointestinal diseases including gastroesophageal reflux disease (GERD), migraine headaches, and disease during pregnancy including pre-eclampsia (defined as blood pressure >140/90 mmHg and positive urinary protein, with or without abdominal pain and visual signs such as headache and blurred vision, hyperemesis (defined as N/V leading to hospitalization), and vaginal bleeding during pregnancy, as well as NPO state and duration of overnight fasting before C/S.

Patients' NIBP was measured in lying position from the left hand with Novin device model 1800 once at entrance to the operating theater and once 15 minutes later and recorded in the checklist.

Ephedrine was used for management of hypotension after spinal anesthesia as a risk factor of N/V, by anesthesiologist's consult, when she observed > 20% decrease in BP.

For assessing the level of anxiety, the researcher used Persian version of Beck Anxiety Inventory with confirmed validity and reliability [16], which includes 21 questions on anxiety symptoms the patient experienced during the a week earlier, scored based on a four-point Likert scale from 0 to 3 (0=not at all, 1=mild, 2=moderate, and 3=severe), with a total score ranging from 0 to 63. A total score of 0-7 indicates no or least anxiety, 8-15 shows mild, 16-25 moderate, and 26-63 severe anxiety. First, the researcher explained the Inventory and how to answer the questions to the participants; then, he asked the patient to complete the inventory and stayed by the patient, so that she can freely ask any questions they might have. If the patient was illiterate, the researcher read the questions for the patient and recorded her answers on the inventory sheet for the patient. Then, the researcher checked that all questions have been answered and calculated the patient's anxiety score and recorded it in the data collection checklist of the relevant patient.

At the operating theater, the researcher completed the data collection checklist with the following information: type and dosage of spinal anesthetic, use of ephedrine for blood pressure control and the dosage, needle size, and sex of the neonate.

Nausea and vomiting was assessed during the surgery and reported as having N/V (mild, moderate, and severe) or not [17].

2.2. Statistical analysis

Results were presented as mean ± standard deviation (SD) for quantitative variables and were summarized by frequency (percentage) for categorical variables. Kolmogorov-Smirnov test was used to assess the normal distribution of data. For comparing the incidence of N/V between categorical variables, odds ratio (OR) and 95% confidence interval (CI) Chi square test was used and backward logistic regression test was used to determine the association between risk factors and N/V. For statistical analysis, SPSS software for Windows version 21.0 (IBM Corp. 2012. Armonk, NY: IBM Corp.) was used. P values of 0.05 or less were considered as statistically significant.

III. Results

Of the total participants (500 pregnant women), mean and standard deviation (SD) of the patients' age was 30.688±5.914 years. 42 (4.3%) were illiterate, 97 (19.4%) had elementary school, 114 (22.8%) had secondary school, 29 (8.8%) had high school education, 145 (29%) had high school diploma, 28 (5.6%) had associate's degrees, 44 (8.8%) had bachelor's degrees, and 1 (2.0%) had higher than bachelor's degree. Mean BMI was 30.388±5.01 kg/m2.

Assessment of medical history of patients revealed that 371 (74.2%) had a positive history of operation, 289 (57.8%) had previous anesthesia, 51 (10.2%) had migraine headaches, and 59 (11.8%) had digestive disease, while 81.8% (N=409) declared no history of known diseases. During pregnancy, 49 (8.9%) had hyperemesis, 42 (8.4%) had eclampsia, 40 (8%) had bleeding in the first trimester, 4 (0.8%) in the second trimester, and 5 (1%) in the third trimester.

Most participants (88%) did not use any medications, while 24 (4.8%) used levothyroxine, 10 (2%) used insulin, 2 (0.4%) used clomiphene, and 1 person (0.2%) used each of the following: alprazolam, aspirin, carbamazepine, fluoxetine, methadone, methimazole, methyldopa, ranitidine, serotonin, and warfarin.

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Systolic blood pressure at entrance to the operating theater was ≥140 mmHg in 92 patients (18.4%) and after 15 minutes in nine patients (1.8%). Diastolic blood pressure at entrance to the operating theater was ≥90 mmHg in 84 (16.8%) and after 15 minutes in 14 patients (2.8%). During the procedure, 394 (78.8%) received Marcaine and 106 (21.2%) received lidocaine, 302 (60.4%) received ephedrine, and 183 (36.6%) received opioids. Finally, 275 (55%) neonates were boys and 225 (45%) were girls. 362 patients (72.4%) had no N/V, 89 (17.8%) had mild, 42 (8.4%) had moderate, and 7 (1.4%) had severe N/V.

Categorical variables			Nausea and vomiting		OR (95% CI)	P value
			Yes	No		
History of diseases before and during pregnancy	Underlying disease	yes	29 (31.9%)	62 (68.1%)	1.287	0.189
		no	109 (26.7%)	300 (73.3%)		
	Migraine	yes	13 (25.5%)	38 (74.5%)	0.887	0.432
		no	125 (27.8%)	324 (72.2%)		
	Digestive disease	yes	17 (28.8%)	42 (71.2%)	1.070	0.466
		no	121 (27.4%)	320 (72.6%)		
	Hyperemesis	yes	21 (42.9%)	28 (57.1%)	2.141	0.01
		no	117 (25.9%)	334 (74.1%)		
	Eclampsia	yes	18 (42.9%)	24 (57.1%)	2.113	0.019
		no	120 (26.2%)	338 (73.8%)		
	Vaginal bleeding	yes	13 (26.5%)	36 (73.5%)	0.942	0.505

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		o	125 (27.7%)	326 (72.3%)		
	History of operation	es	100 (27%)	271 (73%)	0 .679	0.750
Past medical history		o	38 (29.5%)	91 (70.5%)		
	History of anesthesia	es	80 (27.7%)	209 (72.3%)	0 .679	0.847
		o	58 (27.5%)	153 (72.5%)		
	Positive history of drugs	es	57 (31.1%)	126 (68.9%)	1 .318	0.107
		o	81 (25.6%)	236 (74.4%)		
(Pre-)Surgical conditions	Type of anesthetics	arcaine	102 (25.9%)	292 (74.1%)	0 .679	0.065
		idocaine	36 (34%)	70 (66%)		
	NPO	es	83 (29.5%)	198 (70.5%)	0 .679	0.407
		o	55 (25.1%)	164 (74.9%)		
	The needle size	3	19 (22.4%)	66 (77.6%)	0 .716	0.145
		5	119 (28.7%)	296 (71.3%)		
	Ephedrine use	es	98 (32.5%)	204 (67.5%)	1 .898	0.002

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		o	40 (20.2%)	158 (79.8%)		
Neonate's sex		oy	76 (27.6%)	199 (72.4%)	1 .0004	0.533
		irl	62 (27.6%)	163 (72.4%)		

Table 1: Comparison of categorical variables between patients with and without nausea and vomiting

Comparing the qualitative variables between patients with and without IONV, as demonstrated in table 1, revealed a significant association between IONV and history of hyperemesis (OR=2.14, P=0.01), ephedrine use (OR=1.89, P=002), and pre-eclampsia (OR=2.11, P=0.01), while there was no significant association between IONV and the rest of categorical variables, including history of diseases, operation, anesthesia, needle size, neonate's sex, NPO state, vaginal bleeding during pregnancy, and type of spinal anesthetic used (P>0.05). Mean anxiety level was 7.108±0.630 in patients with N/V and 6.135±0.419 in patients without N/V (P=0.0037).

The educational level of patients and hypotension were not statistically different between patients with and without IONV (P=0.369 and 0.141, respectively). Comparison of the incidence of N/V between patients who received Marcaine (P=0.966) and those who received lidocaine (P=0.065) indicated no statistically significant difference (25% vs. 34%, respectively).

	Nausea and vomiting		P value
	Yes Mean ± SEM	No Mean ± SEM	
BMI	30.401 ± 0.414	30.383 ± 0.266	0.970
Age, years	31.224 ± 0.569	30.483 ± 0.293	0.534
Number of pregnancies	1.823 ± 0.069	1.822 ± 0.069	0.806
Marcaine dose, mg	9.152 ± 0.195	9.323 ± 0.512	0.966
Lidocaine dose, mg	59.611 ± 1.692	59.728 ± 0.891	0.966
Anxiety score	7.108 ± 0.630	6.135 ± 0.419	0.037
Systolic pressure at entrance, mmHg	128.050 ± 1.355	127.278 ± 0.687	0.875
Diastolic pressure at entrance, mmHg	79.797 ± 1.007	79.922 ± 0.495	0.447

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Systolic pressure after 15 min, mmHg	105.550 ± 1.263	106.732 ± 0.674	0.297
Diastolic pressure after 15 min, mmHg	64.789 ± 0.929	65.477 ± 0.528	0.241
Duration of fasting, hours	10.550 ±0.622	9.672 ±0.243	0.407

Table 2: Comparison of categorical variables between patients with and without nausea and vomiting

Comparing the quantitative variables between patients with and without IONV, as demonstrated in table 2, revealed no significant association in none of the variables, including BMI, educational level, number of pregnancies, and systolic and diastolic blood pressure at entrance to the operating theater and after 15 minutes. Only, the anxiety level was statistically higher in patients with nausea and vomiting (P=0.037) (Table 2). Comparison of variables between patients with and without nausea and vomiting is shown in figure 1.

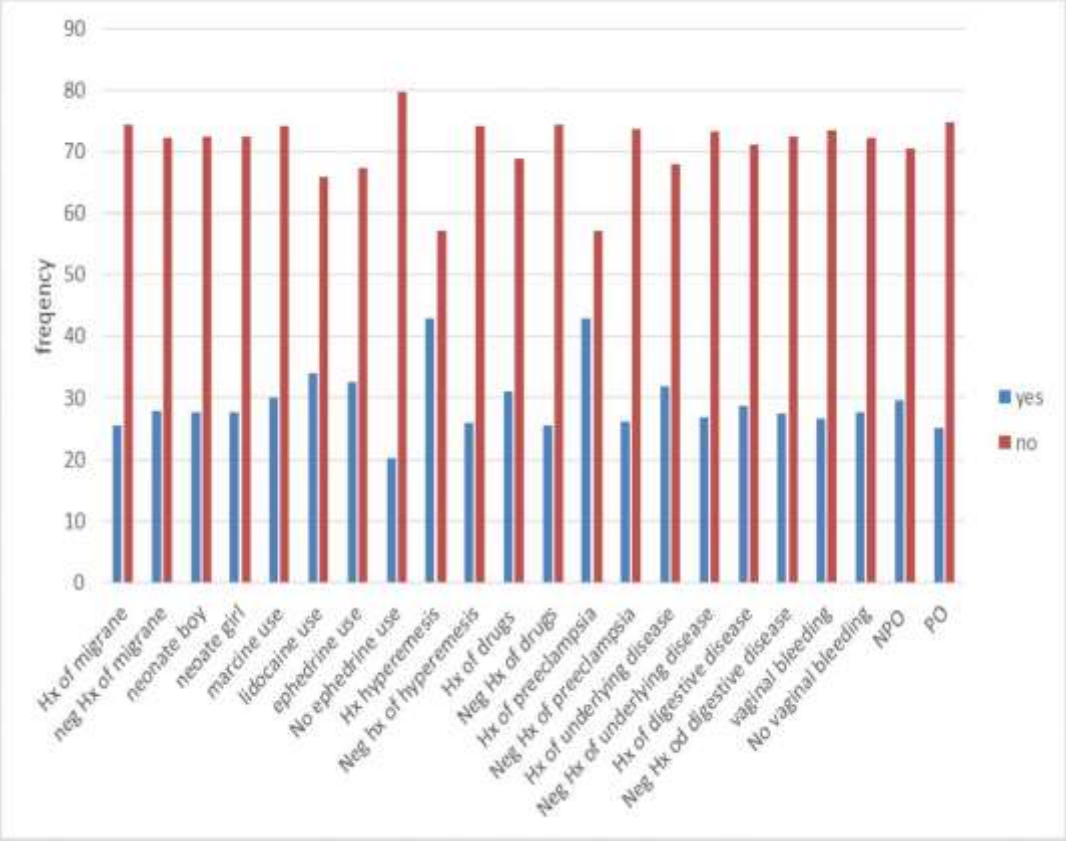

Figure 1: Comparison of variables between patients with and without nausea and vomiting

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Backward logistic regression indicated that ephedrine use (OR=1.862, 95%CI: 1.215-2.852, P=0.004), history of hyperemesis (OR=2.026, 95%CI: 1.098-3.739, P=0.024), and pre-eclampsia (OR=2.036, 95%CI: 1.057-3.923, P=0.034), were independently and significantly associated with IONV.

IV. Discussion

Nausea and vomiting is a troublesome experience that occur not only after surgery in patients under spinal anesthesia, but also during the procedure, which leads to patients' discomfort. In this study, we evaluated the incidence and risk factors of IONV at a referral hospital in Shiraz. The results showed that of 500 patients, 362 (72.4%) had no nausea and vomiting, 89 (17.8%) had mild, 42 (8.4%) had moderate, and 7 (1.4%) had severe nausea and vomiting.

The incidence of IONV in patients undergoing C/S under spinal anesthesia is reported differently in various studies, for example its incidence was about 7% in African population [18], which is much less than the present study (about 28%). This difference is due to the fact that the incidence of IONV in patients undergoing C/S under spinal anesthesia depend on various factors, especially patients' demographics, including race/ethnicity that strongly affect IONV. Therefore, it is essential to study this issue in Iranian population to be comparable to our study, while as far as the authors are concerned, this study is the first to study IONV in patients undergoing C/S under spinal anesthesia in Iranian women.

In another study, the efficacy of four drug regimens were compared for prophylaxis of IONV in patients undergoing C/S under spinal anesthesia and the combination of tropisetron 2 mg and metoclopramide 20 mg was suggested as the most appropriate combination, which could reduce the incidence of IONV from about 63% to about 25% [4]. In the present study, no prophylaxis was used for patients and the incidence of IONV was close to the group with combinational therapy in this study [4]. Other studies have reported its incidence as high as 80% [19], which is much higher than that of the present study. These variations in the incidence of IONV in patients undergoing C/S under spinal anesthesia can be due to several reasons, such as hypotension and cardiac output during surgery, while the etiology of IONV is suggested to be multifactorial and is not well understood [20].

Several studies have addressed risk scores of PONV [21, 22], nevertheless, the risk factors of IONV has to be further evaluated. It is generally suggested that the pathophysiology of IONV is different from PONV, which are reduced lower esophageal sphincter tone due to progesterone, hypotension, and increased intra-gastric pressure [23]. Accordingly, the choice of drug is also different in IONV from PONV, for example 10 mg metoclopramide has no effect on PONV in patients undergoing non-obstetric surgery under general anesthesia, but evidence suggests that it is effective in IONV in patients undergoing C/S under spinal anesthesia [12]. Several studies have compared the efficacy of different medications in prophylaxis and treatment of IONV in patients undergoing C/S under spinal anesthesia [24-27], but few studies have focused on the factors associated with this complication [4]. Some studies mention a number of factors during their analysis of different drug regimens [12]. In the present study, we also tried to investigate the possible variables that can have a significant effect on IONV in these patients in order to be able to prevent this complication by management of the effective variables.

The results of analysis of several factors indicated ephedrine use, history of hyperemesis, eclampsia, and anxiety as independent factors associated with IONV, while other factors, such as age, BMI, educational level, number of pregnancies, and blood pressure in the operating theater, history of underlying diseases, and vaginal bleeding during pregnancy, needle size, and dosage of spinal anesthetic, and neonate's sex had no significant effect on its incidence. The association of ephedrine with IONV could be due to the fact that ephedrine was administered in patents with hypotension, who might have IONV due to their hypotension, not due to the administration of ephedrine. However, according to the results, history of hyperemesis and eclampsia, as well as anxiety were important risk factors associated with IONV. Few studies have evaluated the factors associated with IONV in patients undergoing C/S under spinal anesthesia, but as far as the authors are concerned, this study was the first to evaluate a combination of various factors. Voigt and colleagues reported that patients' age, smoking status, duration of surgery, intra-operative hypotension, bradycardia, postoperative opioids and pethidine, and oxytocin had no statistically significant effect on IONV in 308 patients undergoing C/S under spinal anesthesia [4], which is consistent to the results of the present study. Similarly,

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in the study by Morino and colleagues, age, parity, previous C/S, smoking, motion sickness, and duration of surgery did not have a significant effect on the incidence of IONV in 258 patients undergoing C/S under spinal anesthesia, while they stated hypotension as the only significant factor [28]. Furthermore, the results of studies in other populations may not be comparable to our results, due to the effect of race/ethnicity on IONV in patients undergoing C/S under spinal anesthesia.

One of the unique findings of the present study is the association between anxiety (examined by Beck Anxiety Inventory) and IONV, which as far as the authors are concerned, has not been evaluated in patients undergoing C/S under spinal anesthesia. Research on the effect of pre-operative anxiety on PONV has resulted in different outcomes. Van der Bosch measured anxiety by the Spielberger State-Trait Anxiety Inventory and the Amsterdam Preoperative Anxiety and Information Scale, but they reported that adding anxiety to the logistic regression could not increase the area under curve and concluded that the effect of other predictors might have been stronger than anxiety [29]. Another study by Atanasova and Hinev measured pre-operative anxiety by State-Trait Anxiety Inventory Short-form (STAI S-form) and Visual Analogue Scale (VAS) and concluded that high pre-operative anxiety is associated with higher incidence of early postoperative nausea and vomiting [30], but the results of the above-mentioned studies cannot be easily compared with the present study, due to the differences in the pathophysiology of IONV and PONV and different surgical conditions, as well as different tools used for the measurement of anxiety. In the present study, pre-operative anxiety could predict IONV in patients undergoing C/S under spinal anesthesia, therefore, it is suggested to evaluate and manage anxiety before C/S in these patients.

The limitations of the present study included the cross-sectional design of the study, which made the assessment of patients in follow-up impossible, although the prospective design of the study limited measurement and diagnostic bias. Furthermore, we had no control group and were also ethically unable to prevent patients from taking antiemetics to assess the pure effect on N/V.

V. conclusion

Tvaluation of a variety of variables in 500 patients undergoing C/S under spinal anesthesia by logistic regression indicated ephedrine, hyperemesis, eclampsia, and anxiety as independent and significant factors associated with IONV. Therefore, appropriate management of these conditions can be an effective measure to prevent this annoying complication.

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