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Effect of Propofol on Postoperative Nausea and Vomiting in Patients Undergoing Elective Cesarean Section under Spinal Anesthesia: A Randomized Clinical Trial

Atif Nazir, Ayesha Shahid, Atiya Chaudhry, Syed Makarram Ahmed Bukhari, Azher Munir, Meamoona Shabbir

ABSTRACT

Objective: To analyze anti-emetic effect of sub-hypnotic dose of Propofol in patients undergoing cesarean section.

Study Design and Setting: Prospective, Interventional Randomized Clinical trial done at PAF Hospital Islamabad, from 1st August 2021 to 31st January 2022.

Methodology: A total of 60 patients undergoing elective cesarean under spinal anesthesia were selected for the study. Selected patients were randomly allocated either of the two groups. Patients included in the Group A received sub hypnotic intravenous dose of Propofol as per their body weight, whereas the Group B patients received intravenous saline (0.9%). Postoperative nausea and vomiting was assessed during patients' PACU stay of 1 hour using the subjective feelings of the patients. If the patient complains of vomiting in PACU, an intravenous dose of 10mg Metoclopramide was given as rescue antiemetic.

Results: Mean age of patients was 30.73±4.51 years. APFEL score 3 was observed in 15 (50.0%) in group A and 15 (50.0%) in group B. Score 4 was observed in 4 (13.3%) in group A and 08 (26.7%) in group B(p-value 0.33).Vomiting was observed in 06 (20.0%) in group A and 24 (80.0%) in group B respectively(p-value of <0.01).Nausea was found in 08 (26.7%) in group A and 25 (83.3%) in group B (p-value <0.01).

Conclusion: Propofol in sub-hypnotic dose is effective in the prevention of postoperative nausea and vomiting in patients undergoing cesarean section under spinal anesthesia.

Key words: Elective cesarean, Postoperative nausea and vomiting, Propofol, Spinal anesthesia

How to cite this Article:
Nazir A, Shahid A, Chaudhry A, Bukhari SMA, Munir A, Shabbir M. Effect of Propofol on Postoperative Nausea and Vomiting in Patients Undergoing Elective Cesarean Section under Spinal Anesthesia: A Randomized Clinical Trial. J Bahria Uni Med Dental Coll. 2025;15(2):97-102 DOI: https://doi.org/10.51985/JBUMDC2024488

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Received: 11-12-24
Accepted: 27-03-25
1st Revision: 24-12-24
2nd Revision: 18-03-25
3rd Revision: 25-03-25

INTRODUCTION:

Lower segment cesarean section remains the most commonly performed surgical procedure in obstetric population worldwide.[1] Spinal anesthesia is the choice of anesthesia in majority of cases owing to its safety and fast speed of recovery. Nausea and vomiting in postoperative period is an unpleasant experience, often described as side effect of anesthesia and surgery. It is very common in women undergoing spinal anesthesia for cesarean section. Incidence of nausea and vomiting after cesarean section may vary from 35 to 60% and is different in varying age groups. After postoperative pain, it is the next most common complain after surgery.[2] It is one of the major concerns in Post Anesthesia Care Units after lower segment cesarean section. The etiology of nausea and vomiting in postoperative period is multifactorial and is divided into patient factors, intra operative and post-operative factors. Various patient factors are obesity, female gender, non-smoking, history of postoperative nausea and vomiting, motion sickness as well as genetic predisposition. Surgical factors involves nature, site and duration of surgery. Anesthetic factors are type of anesthesia, use of opioids, inhalational agents and nitrous oxide. Literature shows that a 30-minute increase in surgical time can increase the incidence of nausea and vomiting by

60%. As duration of surgery prolongs, use of drugs like narcotics, sedatives and inhalational agents increases. These drugs tend to stimulate the chromaffin cells in gastric mucosa resulting in release of neurotransmitters and activation of vagus nerve. This initiates the vomiting reflex through chemoreceptor trigger zone in medulla. Smoking is a protective factor for postoperative nausea and vomiting. Tobacco contains nicotine and polycyclic aromatic hydrocarbons. They have the ability to decrease nerve receptor function. They cause activation of cytochrome P-450 and increase tolerance of body for narcotics.[3]APFEL scoring is based on four independent factors named female gender, non-smoking, opiods, history of postoperative nausea and vomiting or motion sickness. Each variable carries 1 score. APFEL score ranges from 0,1,2,3 to 4 predicting the possibility of developing postoperative nausea and vomiting as approximately 10%, 20%, 40% or 80%.[4]

Incidence of postoperative nausea and vomiting (PONV) in cesarean section was 24% and 14% respectively as quoted in literature search .[5]Postoperative nausea and vomiting increases the risk of dehiscence of wound, postoperative bleeding, aspiration of gastric contents causing pneumonitis, dehydration due to fluid loss, electrolyte imbalance and delay in starting oral feeding. It increases duration of hospital stay thus causing financial burden for patients. Patients reported that postoperative nausea and vomiting is even more troublesome than postoperative pain. Though difficult to completely avoid postoperative nausea and vomiting, it can be significantly reduced by opting multimodal non-opioid based analgesia, total intravenous anesthesia technique and using antiemetic prophylaxis as part of premedication [6]. Review of literature shows use of both medication and as well as non-medication therapies. Various drugs used are ondansetron, metoclopramide, droperidol while non medication therapy includes ginger, acupressure and acupuncture.[7]Propofol (2,6-diisopropylphenol) is used as intravenous induction agentin general anesthesia. It has relatively fast onset of action and short duration. In addition to its use as induction agent it has got antiemetic and antipruritic effects. However, its mechanism of action for antiemetic role is still not clear. Propofol has anti-emetic effects at sub hypnotic dose both in bolus or continuous infusion form in susceptible individual, however the exact mechanism of this effect is yet not known. [8]

The antiemetic actions of Propofol have been shown in previous investigations, whether administered as a bolus dosage or as a continuous intravenous infusion.[9] In addition, very few clinical trials strengthen the evidence that Propofol when given as infusion in a low dose (1.0 mg/kg/h) is effective in prevention of postoperative nausea and vomiting in patients undergoing cesarean section. But they did not mentioned treatment specifics for the pregnant patients who had acute nausea and vomiting, nor did they analyze the neonatal behavior linked with postoperative nursing in the case of the other women. A continuous intravenous infusion of Propofol, in conjunction with small bolus doses for immediate control, was expected to be beneficial and safe in reducing the incidence of postoperative nausea and vomiting in parturients after cesarean delivery as compared to a control group receiving placebo.[10]This study aims to evaluate the effectiveness of Propofol in reducing postoperative nausea and vomiting (PONV) in parturients undergoing cesarean sections under spinal anesthesia, as current literature lacks sufficient evidence on its efficacy in this setting in Pakistan. Given the high incidence of PONV and its negative impact on patient recovery, this study will assess whether Propofol can serve as a viable alternative to conventional antiemetic treatments.

METHODOLOGY:

The study was conducted as a prospective interventional randomized clinical trial at PAF Hospital Islamabad affiliated with Fazaia Medical College (IRB no CPSP/REU/ANS-2020-137-2419dated 30th April 2021) from 1st August 2021 to 31st January 2022.The study was registered with ClinicalTrials.gov No NCT05071794. Patients undergoing elective lower segment cesarean section under spinal anesthesia were recruited for the study. A total of 60 patients were included in the study while dividing them in two groups of 30 patients each. Sample size was calculated by using WHO calculator, taking population percentage 8.7%, test value of population proportion 93.9%, level of significance 5% and power of test as 95%[11]The participants included parturients aged between 18 – 50 years, ASA[12] status II and gestational age more than 37 weeks, planned for elective lower segment cesarean section under spinal anesthesia. Exclusion criteria were ASA Class III and above, allergy to Propofol, patients who refused for spinal anesthesia and anti-emetic drug was administered 24 hours before surgery. Patients included in the study were thoroughly counseled about the procedure, drugs used and significance of antiemetic drugs. Informed written consent as per hospital policy was taken from all the patients included in this trial. Patients were divided in group A and B by table of random numbers. All the patients were kept NPO for 8 hours before surgery. Baseline investigations including blood CP, blood sugar random, liver and renal function test as well as hepatitis screening and coagulation profile was done. Using aseptic measures patients were cleaned and draped for spinal anesthesia in sitting position. Interspinous space was identified and infiltrated with injection lignocaine plain 2%.Spinal anesthesia was administered with injection Bupivacaine hyperbaric 12 mg at space L3-L4. Standard vital monitoring including BP, heart rate, oxygen saturation and ECG was done. Preloading was done with infusion ringer lactate 500 ml. Vital signs' monitoring was done at every 5 minutes interval. Intraoperative hypotension was treated with boluses of injection Phenylephrine 50ug intravenously. Intraoperative bradycardia was managed with injection Atropine 0.5 mg

intravenously. At the time of delivery of baby injection Oxytocin was given as 10 IU followed by infusion of 40 IU in normal saline. Baby was resuscitated by a registrar from the pediatrics' department. Patients included in the Group A received sub hypnotic IV dose of Propofol[13] as per their body weight i.e. 0.5mg/kg whereas the Group B patients received 5 ml saline (0.9%) 10-15 min before end of procedure. Patients were monitored for level of sedation and oxygen saturation. Purposeful verbal response to commands was followed and maintained in all patients. At the end of surgery patients were transferred to recovery room. Nausea and vomiting in postoperative period was assessed by a registrar anesthetist who was blinded for study during stay of patients in post anesthesia care unit. Patients were followed in recovery room for 1 hour. Nausea was defined as subjective uncomfortable feeling of retching and vomiting was defined as forceful expulsion of gastric contents. If episodes of nausea and vomiting were more than 2 minutes apart they were considered as independent events. The findings including demographic data and APFEL scoring[14]were recorded in the Study Performa. APFEL scoring includes female gender, non-smoking, history of postoperative nausea and vomiting, and motion sickness. Each variable was assigned 1 score and scoring varying from 0-4 were recorded. If the patient complained of vomiting in PACU, an IV dose of 10mg Metoclopramide was given as rescue anti-emetic. Relief was considered if more than 50% of symptoms were relieved as documented by patients. Data was collected and analysis was done on SPSS version 25.Mean ± SD was calculated for age. Frequency was calculated for categorical data like APFEL scoring. Frequency was calculated for nausea and vomiting in both groups. P value was calculated for all the variables and less than 0.005 was considered significant.

RESULTS:

Demographic profile regarding age and APFEL scoring is shown in table 1 that show statistically no significant difference among both groups with p value 0.12 and 0.33 respectively. Frequency of postoperative nausea and vomiting was compared among both groups (table 2) that show statistically significant difference (p value 0.01) with less postoperative nausea and vomiting in Propofol group in comparison to placebo group. Stratification was done regarding age by dividing patients in age groups 18-30 years and 31-42 years. There was statistically significant difference in frequency of postoperative nausea and vomiting in both groups considering age. When stratification was done regarding APFEL scoring there was significant difference in frequency of nausea and vomiting in postoperative period in both groups with APFEL scoring 2 and 3, however this difference was statistically insignificant in patients with APFEL scoring 4 that shows that high APFEL scoring is a significant risk factor regarding postoperative nausea and vomiting. (table 3)

Table 1. Demographic profile regarding age in years (mean ± SD) and APFEL scoring

	Group A (n=30)	Group B (n=30)	P-value
Age (years) ± SD	31.63 ± 3.73	29.83 ± 5.09	0.12
APFEL score 2	11 (36.7%)	07 (23.3%)	0.33
APFEL score 3	15 (50.0%)	15 (50.0%)	
APFEL score 4	04 (13.3%)	08 (26.7%)	

Table 2. Frequency of nausea and vomiting and rescue antiemetic

		Groups		P-value
		Group A (N=30)	Group B (N=30)	
Vomiting	**Yes**	06 (20.0%)	24 (80.0%)	0.01
Nausea	**Yes**	08 (26.7%)	25 (83.3%)	**0.01**

Table 3. Stratification regarding age and Apfel scoring with complaint of nausea and vomiting

		Group A (N=13)	Group B (N=17)	P value
Age: 18-30 years	**Nausea**	04 (30.8%)	15 (88.2%)	<0.01
	Vomiting	04 (30.8%)	15 (88.2%)	<0.01
Age: 31-42 years	**Nausea**	04 (23.5%)	10 (76.9%)	<0.01
	Vomiting	02 (11.8%)	09 (69.2%)	<0.01
APFEL score 2	**Nausea**	0	03 (42.9%)	0.02
	Vomiting	0	03 (42.9%)	0.02
APFEL score 3	**Nausea**	04 (26.7%)	15 (100%)	<0.01
	Vomiting	03 (20.0%)	14 (93.3%)	<0.01
APFEL score 4	**Nausea**	04 (100.0%)	07 (87.5%)	0.46
	Vomiting	03 (75.0%)	07 (87.5%)	0.58

DISCUSSION:

Gan et al. performed a trial and established that plasma concentrations of 343 ng/mL and 592 ng/mL of Propofol reduced incidence of nausea upto 50% and 90% patients, respectively. He used a computer-assisted continuous infusion device in the post anesthesia care unit.[15] Moreover he found that 20 mg Propofol was effective for treatment of postoperative nausea and vomiting with shorter post anesthesia care unit stay and higher degree of patient satisfaction. Review of literature shows various studies done on antiemetic potential of Propofol. Mohammad MJ conducted a randomized trial to observe antiemetic efficacy of Propofol in patients undergoing cesarean section. He divided patients in two groups. First group received Propofol as continuous infusion while the second group received normal saline as placebo. He found that there was statistically significant difference in incidence of postoperative nausea (p value 0.003) and vomiting (p value 0.014) in Propofol group as compared to placebo group. Moreover, the requirement of rescue antiemetic was lower in Propofol group than placebo. The results of this study were the same as our trial.[16]

Sprung J retrospectively collected data on patients who underwent procedure under general anesthesia and analyzed whether use of Propofol in intraoperative period was associated with decrease need of rescue antiemetic. He found that those patients who receive Propofol as bolus or as infusion intraoperatively, had less incidence of nausea and vomiting. While there was no significant difference in recovery time in PACU when compared with those patients who didn't receive Propofol intraoperatively however, this effect was dose dependent with no added advantage in dose more than 100ug/kg/ min was noted. Antiemetic effect of Propofol was independentof the type of volatile agent used in surgery, duration of procedure and prophylactic use of antiemetics. At the end of this trial he concluded that intraoperative use of Propofol infusion in volatile based anesthesia not only reducesthe incidence of postoperative nausea and vomiting but this practice can be improvised depending upon patient specific as well as procedure specific factors. Results of this trial were same as our trial however we didn't measure dose dependent effect of propofol.[17]

Pang QY conducted a meta analyses of randomized clinical trials in patients undergoing breast surgeries. He found that those patients who received Propofol based anesthesia had higher requirement of rescue analgesics as compare to inhalational anesthetics, however incidence of postoperative nausea and vomiting as well as rescue antiemetics was significantly less in Propofol group than the inhalational group. This meta-analysis also demonstrated that Propofol has tendency to preserve nature killer cell cytotoxicity, decrease interleukin 6 levels, decrease neutrophil to lymphocyte ratio as well as increase in 2 years' survival rate. However, these long term effects of Propofol need trials to be done on large population.[18]Antiemetic effect of Propofol was also studied in procedures outside the operation theatre. Sakanoue H observedthe incidence of postoperative nausea and vomiting with Propofol infusion in patients undergoing catheter ablation for atrial fibrillation. He found that although Propofol has significant antiemetic effect, however APFEL scoring had low accuracy in predicting incidence of nausea and vomiting after Propofol infusion. This is in contrast to our results where Propofol has significant antiemetic effect in patients with APFEL score of two and three, however results were not significant with APFEL score of 4, indicating that high APFEL score is itself a very high risk factor for nausea and vomiting in postoperative time. [19]

Kampo S conducted a prospective double blind study on patients undergoing cesarean section. He selected 345 parturients and randomly divided them in three groups. All patients underwent cesarean section under spinal anesthesia. One group was given injection Propofol 0.5 mg/kg, second group was given injection Metoclopramide 10 mg and third was placebo group that received normal saline.Patients were followed in recovery room for nausea and vomiting and requirement of rescue analgesia. 10 patients in Propofolgroup, 8 patients in metoclopramidegroup while 108 patients in placebo group experienced postoperative nausea and vomiting. Statistically there was no significant difference in incidence of nausea and vomiting in Propofol and metoclopramide group however when compared to placebo group this difference was statistically significant. Moreover, the requirement of rescue antiemetic was 10%, 37.5% and 97.2% inPropofol, metoclopramide and placebo group respectively.This shows that the requirement of rescue antiemetic was low in Propofol group as compared to metoclopramidegroup. The incidence of postoperative pruritus is also less in Propofol group as compared to placebo. Results of this study are similar to our trial however we didn't measure need for rescue antiemetic as well as postoperative pruritus in our study.[11]

Acharya SA performed a comparative study in patients undergoing laparoscopiccholecystectomy. He compared ondansetron, ramosetron and subhypnotic dose of Propofol and observed patients for nausea and vomiting in postoperative period .He selected 120 patients planned for cholecystectomy and divided them in three equal groups. Group 1 was given ondansetron 4 mg, group 2 was given ramosetron 0.3 mg and group 3 was given Propofol 0.5mg/kg. All patients were given general anesthesia as per standard protocol. Study drugs were given at the time of removal of umbilical ports. Patients were followed in postoperative period for nausea and vomiting. He observed that in first 6 hours postoperatively the difference in incidence of vomiting was statistically insignificant, however from 6-24 hours the incidence of vomiting was much high in Propofol group as compared to other two groups. The incidence of nausea was more or less same in all groups. Results of this trial are same as our study as percentage of vomiting is same as in our study. However, in our study we have compared Propofol with placebo rather than any other anti-emetic. [13]

Bansal T performed a prospective double blind study on patients who underwent elective laparoscopic surgeries under general anesthesia.70 patients were included in this study divided intwo groups of 35 each. After induction of anesthesia one group was given Propofol infusion as maintenance of anesthesia and other group was given combination of Propofol with sevoflurane for maintenance of anesthesia. Incidence of postoperative nausea and vomiting was 33% in Propofol group and 38.7% in combination group that shows statistically no significant difference. Need for rescue antiemetic was 11 in Propofol group and 12 in combination group that was also statistically insignificant. Since there was no placebo group in this study so this trial doesn't measure antiemetic efficacy of Propofol alone.[20]

Zhao TUM conducted a trial on patients undergoing gastroscopy. He selected 112 patients and divide them in two groups. Group C was given Ciprofol 0.4 mg/kg and group P was given Propofol 1.5 mg/kg. Both groups were

augmented with Alfentanil 7 mcg/kg. Patients were discharged after procedure and were followed on telephone for postoperative nausea and vomiting after 24 hours. He found that although both Propofol and Ciprofol could prevent nausea and vomiting, antiemetic effect of Propofol was superior to Ciprofol with p value 0.042.[21]

Admabb BA performed a clinical trial on pregnant patients undergoing cesarean sections. He selected 100 patients who were planned to undergo elective cesarean delivery. He collected data on form that included patient history, anesthesia monitoring chart and standard check list. He analyzed that in his study population patients at low, medium and high risk of postoperative nausea and vomiting were 21%, 33% and 25% respectively. He emphasized on SAMBA guidelines that stated stratification of risk of postoperative nausea and vomiting, baseline risk reduction strategies, no prophylaxis in patients with low risk of postoperative nausea and vomiting, administering 1-2 pharmacological interventions in medium risk and more than two agents in high risk patients. Those patients who did not receive preemptive antiemetic or failed to respond to prophylactic antiemetic should be addressed urgently and every setup should establish some local guidelines for prevention of postoperative nausea and vomiting. He documented that in clinical practice there is a significant performance gap in prevention of postoperative nausea and vomiting. Adherence to SAMBA guidelines may provide a significant tool in prevention of postoperative nausea and vomiting.[22]

Hence prevention of postoperative nausea and vomiting after cesarean section needs both prophylactic as well as therapeutic measures. Prophylactic measures include adequate fasting, head up positioning of patient and prophylactic antiemetic well before surgery. Therapeutic measures include administering right choice of antiemetic well in time and it should be rationalize according to patients need and known risk factors.

CONCLUSION:

When compared with placebo, intravenous administered sub-hypnotic dose of Propofol has shown significant anti emetic activity for prevention of postoperative nausea and vomiting in patients undergoing cesarean section under spinal anesthesia however this effect was not significant in patients with high APFEL scoring.

Authors Contribution:
Atif Nazir: Concept & Design of study drafting, revisiting critically, data analysis, final approval of version
Ayesha: Concept & Design of study, drafting, final approval of version
Atiya Chaudhry: Concept & Design of study, drafting
Sayed Makarram Ahmed Bukhari: Concept & Design of study, data analysis
Azher Munir: Concept & Design of study, data analysis
Meamoona Shabbir: Concept & Design of study, data analysis

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