

To Compare the Efficacy of Bolus Dose of Propofol versus Control in Patients Undergoing Elective Cesarean Section under Spinal Anesthesia

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ABSTRACT

Objective: The compare the efficacy of bolus dose of Propofol versus control in patients undergoing elective cesarean section under spinal anesthesia.

Study Design: Randomized controlled trial study

Place and Duration of Study: This study was conducted at the Department of Anesthesia, Dow University of Health Sciences and Civil Hospital, Karachi from 1st January 2018 to 30th June 2018.

Materials and Methods: All women aged 18-38 years presented with full-term, para 0-5, weight between 50–75 kg, ASA class I & II underwent elective cesarean section under spinal anesthesia were included. Participants were randomly allocated equally to the control group (Group C) or Propofol groups (Group P) using a lottery method. Efficacy was labeled as positive if there was no vomiting intraoperatively.

Results: Mean age of the women was 32.89 ±4.03 years. The mean weight, height, and BMI of the women were 60.07±5.12kg, 1.54±0.06m, and 26.98±5.15kg/m² respectively. Efficacy was found 42 (93.3%) significantly higher among women with propofol as compared to placebo 30 (66.7%) (p=0.002).

Conclusion: The efficacy of bolus dose of propofol was found higher among control in patients undergoing elective cesarean section under spinal anesthesia.

Key Words: Efficacy, Propofol, Elective caesarean section, Spinal anaesthesia

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INTRODUCTION

Spinal anaesthesia has established itself as the primary anaesthetic option for caesarean section¹ because it is both safe and quick². Despite the fact that this procedure is generally regarded safe, it is associated with a few distinct but severe side effects, the most notable of which is post-operative nausea and vomiting (PONV)²⁻³. While caesarean delivery is common, it can occur in as many as 50 percent to 80 percent of women who give birth if no prophylactic antiemetic is taken during the pregnancy.

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The use of prophylactic antiemetics in patients undergoing caesarean delivery is therefore recommended⁴⁻⁵.

There are several medications available to treat post-operative nausea and vomiting (PONV), such as 5-HT₃ antagonists (ondansetron and granisetron), dopamine antagonists, and antihistamines, that are utilised in the United States.

On the other hand, the disadvantages of each of these treatments include the high cost of 5-HT₃ antagonists, the possibility of extrapyramidal symptoms from dopamine receptor antagonists, excessive sedation from antihistamine drugs, and tachycardia from antihistamine medications^{6,7}.

When propofol was administered at a subhypnotic dose (1.0 mg/kg/hr) during spinal anaesthesia for caesarean section, the results showed that it was effective in reducing gastrointestinal symptoms⁸. Propofol was administered at a subhypnotic dose (1.0 mg/kg/hr) in several studies, with the findings demonstrating that it was effective in decreasing gastrointestinal symptoms during caesarean section. When administered with propofol, the reported incidence of vomiting was 3.3 percent and 23.3 percent, respectively⁹, while the reported incidence in the control group was 23.3 percent and 3.3 percent.

A plasma concentration of 1000 ng/mL propofol administered during caesarean section, as compared to placebo, significantly reduced the incidence of post-delivery nausea, but had no influence on the incidence of retching or vomiting episodes occurring during the procedure, according to Niu et al¹⁰.

A clinical trial conducted by Rosillo-Meneses et al to compare the efficacy of propofol versus ondansetron in the prevention of postoperative nausea and vomiting in nasal surgery revealed that there is no statistically significant difference between the two drugs in terms of protection, leading to the conclusion that administering propofol or ondansetron for postoperative antiemetic prophylaxis is equally effective¹¹.

In addition, despite an extensive search, no local studies on propofol administered intraoperatively for the prevention of vomiting in patients undergoing elective caesarean section under spinal anaesthesia have been located. If the efficacy of propofol is revealed to be greater than expected as a consequence of this experiment, it is hoped that it will be used in the future to avoid vomiting in patients undergoing elective caesarean section under spinal anaesthesia in the future.

MATERIALS AND METHODS

This randomized controlled trial was conducted at the Department of Anesthesia, Dow University of Health Sciences and Civil Hospital, Karachi from 1st January 2018 to 30th June 2018. The participants in this study were 90 full-term pregnant women ranging in age from 18 to 38 years, with an ASA class I or II and who underwent elective caesarean delivery under spinal anaesthetic. Ineligible patients included those who had any obstetric complication such as eclampsia or gestational diabetes that was evident from their history and medical records, patients who had evidence of foetal compromise, patients who had acute gastroenteritis, gastroenteritis with hepatitis, or patients who had received any antiemetic within 24 hours of the study's start. Patients who had received any antiemetic within 24 hours of the study's start were also excluded. After explaining the potential risks and advantages of the research medicine, patients were asked to sign an informed written permission form. Through the use of a lottery system, participants were assigned evenly to either the control group (Group C) or the propofol group (Group P).

Propofol 2ml (20 mg) bolus was administered to patients in group P, and normal saline 2ml bolus was administered to those in group C. Immediate intravenous administration of propofol was initiated following acclimation of the umbilical chord. A supervisor was there to oversee the entire operation, which was completed entirely by the researcher. In the event of two or more episodes of emesis during surgery, an antiemetic (metoclopramide 10 mg) was given. If there was no vomiting throughout the operation, the

efficacy was considered to be good (from the administration of the drug to the last stitch). An annexure contains a proforma on which this information, as well as age, parity, length of operation, and BMI, was entered. SPSS-21 was used to conduct the statistical tests. The chi-square test was used to evaluate the efficacy of the two groups. The significance level was set at 0.05.

RESULTS

The majority of the women in both the propofol and placebo groups were over 30 years old, with 39 (86.7%) and 37 (82.2 %) respectively. Many cases in both the propofol and placebo groups had a BMI of less than 30 kg/m².

Table No.1: Baseline Details of all the included patients

Variable	Propofol group (n=45)	Placebo group (n=45)
Age (years)		
<30	6 (13.3%)	8 (17.8%)
>30	39 (86.7%)	37 (82.2%)
Body mass index (kg/m ²)		
≤30	28 (62.20%)	24 (53.30%)
>30	17 (37.80%)	21 (46.70%)
Duration of surgery (minutes)		
<40	19 (42.20%)	17 (37.80%)
>40	26 (57.80%)	28 (62.20%)
Parity		
Nulliparous	3 (6.70%)	11 (24.40%)
Primiparous	13 (28.90%)	22 (48.90%)
Multiparous	29 (64.40%)	12 (26.70%)
ASA Score		
I	18 (40%)	29 (64.40%)
II	27 (60%)	16 (35.60%)

Table No.2: Comparison of efficacy with respect to group (n=100)

Group	Efficacy		P value
	Yes	No	
Propofol	42 (93.3%)	3 (6.7%)	0.002
Placebo	30 (66.7%)	15 (33.3%)	

The average surgery time was 42.2±4.9 minutes. Maximum number of the patients in both the propofol and placebo groups were awake for more than 40 minutes. Many cases in the propofol group were multiparous 29 (64.4%), while higher number of the women in the placebo group were primiparous 22 (48.9%). The majority of the cases in the propofol group (60%) were given ASA level I, whereas the in the placebo group (64%) were given ASA status II (Table 1).

Efficacy was found 42 (93.3%) significantly higher among women with propofol as compared to placebo 30 (66.7%) (p=0.002) (Table 2).

DISCUSSION

To overcome post-operative nausea and vomiting (PONV) many treatments has been tried, such as 5-HT₃ antagonists (ondansetron and granisetron), dopamine receptor antagonists and antihistamine drugs. However, each has some drawbacks, i.e. cost effectiveness, sedation etc.

Some authors have used an infusion of propofol with a sub hypnotic dose (1.0 mg/kg/hr) and found that it was effective in the prevention of emetic symptoms during spinal anesthesia for cesarean section.⁸ Incidence of vomiting with propofol has been reported as 3.3% and respectively while for the control group as 23.3% respectively.⁹ In our study efficacy was found 42 (93.3%) significantly higher among women with propofol as compared to placebo 30 (66.7%).

In one study it has been associated with more maternal hypotension, possibly increased risk of maternal awareness, and worse Apgar scores in the neonate when compared with thiopentone. Other studies however have shown no difference. No studies have shown the superiority of propofol. Ketamine has a place in the management of the hypovolaemic obstetric patient requiring cesarean section and experience and confidence with this drug is likely to be far greater in many under-resourced areas than in the UK. A major advantage of propofol is the expected rapid emergence from anesthesia.¹²⁻¹⁵ The antiemetic actions of propofol have been demonstrated in previous investigations¹⁶⁻¹⁷ with either a bolus dose or a continuous infusion. Furthermore, only a small number of clinical trials have proven that infusion of propofol at a modest dose (1.0 mg/kg/h) is useful in the prevention of nausea and vomiting during and after cesarean section¹⁸.

Numazaki et al¹⁹ came to the conclusion that a subhypnotic dose of propofol 1.0 mg/kg/h reduces the incidence of post-delivery nausea and vomiting in parturients undergoing cesarean delivery without excessive sedation, and that it is a more effective antiemetic than traditional antiemetics (droperidol and metoclopramide) for reducing the severity of nausea and vomiting²⁰. There are no definitive explanations for how propofol prevents intraoperative and post-delivery emesis; however, according to Smith et al²¹, there is a possibility that propofol has direct antiemetic properties, and that reduced levels of serotonin in the area postrema are associated with these antiemetic properties, as determined by Cechetto et al²². Thirteen percent of the propofol group vomited, according to Gan et al²³, indicating that propofol has direct depressive effects on the chemoreceptor trigger zone, the vagal nuclei, and other brain regions associated with nausea and vomiting.

CONCLUSION

In patients undergoing elective caesarean delivery under spinal anaesthesia, the efficacy of a bolus dosage of propofol was found to be higher than in the control group.

Author's Contribution:

Concept & Design of Study: Iftikhar Shah
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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