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Effect of Prophylactic Propofol and Metoclopramide on Post-operative Nausea and Vomiting after Cesarean Section at Dilla University Referral Hospital, South Ethiopia: A Prospective Cohort Study

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ABSTRACT

BACKGROUND: Postoperative Nausea and vomiting are some of the common complications of spinal anaesthesia after Caesarean delivery (CD) with an incidence of 50-80% without prophylactic antiemetic. This study aim of this study was to assess the Prophylactic efficacy of Propofol and Metoclopramide on reducing Postoperative Nausea and Vomiting in patients who undergo cesarean section under spinal anesthesia.

MATERIALS AND METHODS: An institutional-based Prospective cohort study was employed. Two equal groups of 80 adult females aged 18- 65 years were scheduled for elective cesarean under spinal anaesthesia and metoclopramide as a non-exposed group. Nausea severity, all episodes of PONV during the first 24 h after anaesthesia were recorded and assessed using the Mann-Whitney U test for 24hrs. The chi-square test was used to analyze the homogenous categorical independent variables between these two groups and a p-value less than 0.05 was considered as statistically significant.

RESULT: The incidence of PONV significantly lower in the Propofol group than that of the metoclopramide group (32.5 vs 64.9 %) at 0-6 hours (p = 0.005). The comparisons of the groups for the number of patients with PONV showed a significant difference at 0-6 hours, however there were no statistically significant differences at 6-12 as well as 12-24 hours.

CONCLUSION: The administration of a prophylactic dose of Propofol reduced the incidence of postoperative nausea and vomiting in patients undergoing cesarean section Superior to metoclopramide and during the first 6 hours. Further study with adequate sample size, we recommended.

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KEYWORDS

Postoperative; Vomiting; Nausea; Cesarean section

ABBREVIATIONS

DURH: Dilla University Referral Hospital; NRS: Numerical Pain Rating Scale; ASA: American Association of Anesthesiologists; BP: Blood Pressure; HR: Heart Rate; IQR: Interquartile Range; IRB: Institutional Review Board; LA: Local Anesthetics; MAP: Mean Arterial Pressure; MOPS: Modified Objective Pain Score; PONV: Postoperative Nausea and Vomiting; POP: Postoperative Pain; RCT: Randomized Control Trial; SD: Standard Deviation; WHO: World Health Organization

INTRODUCTION

Postoperative nausea and vomiting is a common postoperative unpleasant and distressful experience among major abdominal, gynecological surgery with incidences of up to 54% and 71% vomiting &nausea respectively. PONV primarily occurs within 24 hours can lead to significant morbidity, unexpected hospital admission of surgical outpatients by reducing patient comfort, delayed discharge from the hospital, and an increase in costs [1].

Nausea and vomiting are initiated by gynecologic intra-abdominal mass because this mass stimulates the emetogenic receptors found within the intraluminal surface of the stomach [2]. A preoperative condition such as sex, History, Smoking, intraoperative anaesthesia drugs, Duration of surgery, and duration of anaesthesia and post-operative factors like Pain, Opioids, Hypoglycemia, Hypoxemia, Oral intake has a role for PONV [3].

Recently serotonin antagonist such as ondansetron is the most popular agent used for the prevention and treatment of PONV. Another cost-effective antiemetic such as Metoclopramide and Dexamethasone has also been shown to be an effective anti-emetic drug used for the prevention of PONV in patients undergoing surgery [4]. The discovery was continued and the incidence of anaesthetic death secondary to vomiting and aspiration was more than 10 present [5-7].

The exact mechanism by which Propofol acts as an antiemetic remains unclear, However, It has been postulated that antiemetic effects of Propofol may be as an antagonist of the 5-HT3 receptor [8-10].

Metoclopramide is a generic inexpensive drug. It is currently rarely used in the UK for the management of nausea and vomiting associated with neuraxial anaesthesia, possibly due to a perceived lack of efficacy. On the other hand, some centres in North America use it regularly for this purpose. At higher doses (0.2 mg/kg), metoclopramide is associated with extrapyramidal reactions such as akathisia and motor restlessness. None of the antiemetics currently available is entirely effective, perhaps because most of them act through the blockade of one receptor [4].

Although several investigations have demonstrated that prophylactic therapy with droperidol or metoclopramide reduces the incidence of emetic symptoms in cesarean patients under spinal anaesthesia [11-14]. However, these drugs occasionally cause other undesirable adverse effects, such as excessive sedation, restlessness, dystonic reactions, and extrapyramidal signs [15].

Therefore, the main intent of this prospective cohort study was to assess the prophylactic effect of Propofol and Metoclopramide on post-operative Nausea and Vomiting in patients undergoing elective cesarean section surgery under spinal anaesthesia in a resource-restricted setting.

MATERIALS AND METHODS

Study Area

The study was conducted in the Dilla University Referral Hospital, which is found in Dilla Town, Gedeo Zone, on the main road from Addis Ababa to Kenya, 360 km south of Addis Ababa, and 90 km south of Hawassa (capital of SNNPR). It is one of the public university hospitals providing health services to more than 4 million population of Gedeo Zone and neighboring catchment areas of Sidama and Oromia Region with 500 hospital beds.

Study Design and Period

The study was conducted from January 25th, 2018 to September 22nd, 2019 G.C at Dilla University Referral Hospital. The study design was a prospective cohort study.

Source Population

The source population was all mothers who gave birth by elective cesarean section under spinal anesthesia in DURH.

Study Population

The study population included mothers who gave birth by elective caesarian section under spinal anesthesia at DURH during the study period.

Inclusion Criteria

Term pregnant patients undergoing elective cesarean section surgery under spinal anaesthesia

1. ASAI, and ASA II
2. Age ≥18 years

Exclusion Criteria

1. Allergy to the study drugs
2. Patients with a prior history of motion sickness or PONV
3. History of alcohol or substance abuse
4. History of smoking, those who have received drugs with antiemetic properties
5. Opioids within 24 hours before surgery were excluded from the study

Sample Size

The sample size was calculated using G-power version 3.1. The effect size was determined from the previous alpha value of 0.05, and a power of 80% the total sample size of 80 was determined. With a 1:1 allocation ratio of 40 in each group.

Sampling Procedure

According to Dilla University, a five-month consecutive report showed 280 patients undergo an elective cesarean section. After doing situational analysis, simple random techniques using the lottery method were employed to obtain a sample of daily cases posted ahead of the operation day. Participants were prospectively followed based on whether they were exposed to either of the two treatments, Propofol or Metoclopramide.

Data Collection Procedures

Structured questionnaires were used to gather information from the patient's chart and mothers who underwent a cesarean section. Informed consent was taken, after descriptions of the objectives of the study were informed of the patients. After preoperative preparation done participants who fulfilled the inclusion criteria; baseline vital signs, spinal anaesthesia block, incision time was documented by a trained anaesthetist. Baseline vital signs were measured every 05 minutes before the study drugs were administered. Post bock vital signs were measured 10 minutes after skin incision, then, the ability to maintain value as compared to values before incision indicates successful spinal anaesthesia. Vital signs were recorded on admission to the PACU and then every 30 minutes till the patient was discharged to the ward.

According to Habtemariam M, et al. 2020, postoperative emetic episodes and severity (nausea and vomiting) experienced by the patients was assessed using the Numerical Rating Scale (NRS). It is a valid severity of

nausea assessment tool that involves asking a patient to rate their nausea feeling from 0-10 (11-point scale) with the understanding that 0 is equal to no nausea and 10 equals to severe nausea. Accordingly, those who score NRS greater than 3 indicated moderate nausea. Those patients who had a score greater than 3 were given rescue antiemetic with IV 4mg ondansetron. Patients were observed trained nurses & the NRS score was documented at PACU, 2^{nd}, 4^{th}, 8^{th}, 12^{th}, and 24^{th} postoperative hour. Total antiemetic consumption, duration of action, and adverse effects were documented when it was reported within 24 hours postoperatively. Completeness of the data was cross-checked for completeness and consistency every day.

Statistical Analysis

Data were entered into Epi-Info version 7 and transfer to SPSS version 20 .0 for analysis. Descriptive statistics were applied to see a pattern of data. The normality test was checked by using the Shapiro-Wilk and Kolmogorov-Smirnov however, the data were not normally distributed. Mann- Whitney U test was used for analysis. Chi-square (x2) tests were used to analyze the homogenous categorical independent variables and the incidence of PONV between these two groups and the data were homogeneous as tested by Levine's test of equality of variance. Normally distributed data are presented as mean ± SD, and non-normal equivalent is presented as median (interquartile range) and Frequency and percentage were used to describe a categorical variable, and statistical differences between groups were tested by using the chi-square test or Fisher exact. AP-value of less than 0.05 was considered as statistically significant.

Operational definitions

Anaesthesia: pharmacology induces loss of conscious, reflex, sensation, memory and free from pain. Anti-emetic request: if patients ask anti-emetic drugs any time within 24 hours postoperatively when they feel nausea or vomiting.

Duration of anaesthesia

Time is the interval from loss of consciousness to spontaneous recovery of consciousness in minutes after a surgical procedure.

Duration of surgery

Time interval from skin incision to closure in minutes.

Elective surgery

Surgery done before on the set of any complication that might constitute urgent indication.

Late postoperative time

Time considered from six hours of patient reached to post-anaesthesia care unit to twenty-four hours.

Hypotension

A drop in blood pressure more than 20% of baseline or any systolic blood pressure less than 80mmHg that occurs intraoperatively or postoperatively.

Bradycardia

A pulse rate of less than 60 beats per minutes.

Tachycardia

A pulse rate greater than 100 beats per minutes.

Nausea

An unpleasant sensation associated with the urge to vomit, which is the forceful ejection of liquid or semisolid stomach contents.

NRS

Valid nausea/vomiting intensity assessment tool that involves asking a patient to rate his or her nausea intensity from 0-10(11 point scale) with the understanding that 0 is equal to no nausea and 10 equal to the worst possible nausea.

Postoperative nausea and vomiting

Any nausea, retching or vomitus occurring in the first 24 hours after surgery.

Retching

Laboured spasmodic, rhythmic contraction of the respiratory muscles without the expulsion of gastric contents.

Vomiting

Forceful expulsion of gastric or intestinal contents through the mouth.

Ethical Consideration

Ethical clearance was obtained from the IRB of Dilla University College of Health Sciences and Medicine before the start of the study. Data collector obtained informed written consent from each participant. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. Participant's involvement in the study was voluntary bases, and participants who were not willing to participate in the study and those who wish to quit their participation at any stage were informed to do so without any restriction. The study was registered at Research Registry with the unique identifying number UIN of research registry 5931.

Variable Name	Propofol n = 40	Metoclopramide n = 40	P-value
Age (years)*	26.8±6*	28.03±7.7*	0.45
ASA status			0.72
ASA I (n, %)	35(88.9)	36 (91.7)**	
ASA II (n, %)	5(11.1)	4 (8.3)	
Gestational age (wks.)	34 ± 12.5	34.4 ± 12.6	0.96
Weight (kg)	58.7 ± 5	57.5 ± 4	0.34
Height (cm)*	160.6 ± 4.9	159.5 ± 3.7	0.99
BMI#	26 (26-28)	26 (24-28)	0.27
Operative characteristics			
Duration of uterus exorcised (min.)	4.5 ± 1.5	4.4 ± 1.9	0.84
Duration of Surgery (min.))*	41.2 ± 5.3	44.2 ± 10.2	0.12
Intraoperative blood loss(ml)	290.7 ± 11.3	290.8 ± 18.5	0.96

Table 1: Demographic and operative characteristics. **Note:** NB * Mean and Standard deviation, **Median and IQR, Mann: Whitney U test, chi-square test (x^2) was used, p-value < 0.05 considered statistically significant.

Variable Name	Propofoln = 40	Metoclopramide n = 40	P- value
Systolic, mmHg			
Before anesthesia (baseline)	123.3+13.7	116.9+11.6	0.29
After study drug administration	107.2+24.5	114.6+9.6	
Diastolic, mmHg			
Before anesthesia (baseline)	76.83+10.04	73.01+10.2	0.95
After study drug administration	69.9+8.6	71.9+7.6	
Pulse Rate, beat/min			
Before anesthesia(baseline)	100.9+13.9	99.4+14.5	0.62
After study drug administration	94.7+15.8	95.2+14.4	
SPO2(%)			
Before study drug administration	95.9+1.01	5.6+0.9	
After study drug administration	95.8+1.01	95.5+0.93	
Respiratory rate (breath/minute)			
At recovery room			
	18(2) **	18(1) **	0.74
Post-operative shivering(n, %)	3(7.5)	1(2.5)	0.31

Table 2: Post-operative hemodynamic response and shivering between groups. **Note:** NB* Mean and Standard deviation, **Median and IQ. Number (%), Mann - Whitney U test was used, p-value < 0.05 considered statistically significant.

RESULTS

Demographic and Perioperative Characteristics

Eighty patients (40 patients in each group) were analyzed based on whether they received propofol or metoclopramide after cesarean section at the end of the surgery. There was no statistically significant difference between the two groups in demographic and perioperative characteristics such as age, gestational age, ASA classification, and perioperative characteristics such as

estimated blood loss, duration of surgery, and duration of the uterus exorcised (P >0.05) as shown in (Table 1).

The hemodynamic response between groups

There was no significant difference in mean heart rate, mean systolic blood pressure, and diastolic blood pressure at PACU, 30 minutes, 1st hour 2nd, 6th, 12th, and 24th hours of postoperative time between the groups. Regarding postoperative complications, none of the patients had hypotension, bradycardia, and respiratory depression while 3 (7.5%) patients in the Propofol group and 1(2.5%) patients in the metoclopramide group experienced shivering in the post-operative period which shows a non-statistically significant difference as shown in (Table 2) below.

Incidence and severity of postoperative nausea and vomiting

The overall incidence of PONV significantly lower in the Propofol group than that of the metoclopramide group (32.5% and 64.9 %), respectively), in the first 6 hours (p = 0.01). However, there were no statistically significant differences at 6-12, or 12-24 hours (Figure 1).

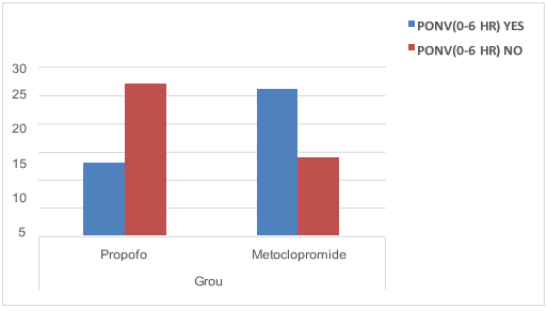

Figure 1: Post-operative nausea and vomiting between groups.

The incidence of nausea alone during the first six hours was significantly lower in patients who received propofol (22.5% and 45%) (P = 0.01). Similarly, the incidence of vomiting was a higher metoclopramide group when compared to the propofol group (10% and 38.9%, respectively) (p=0.02). The severity of nausea was greater in the metoclopramide group; 7 patients (13.89%) experienced severe nausea versus no episodes in the propofol group (Figure 2).

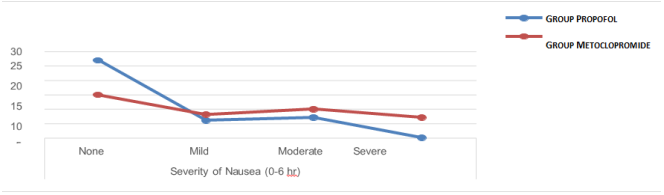

Figure 2: Severity of Nausea between groups.

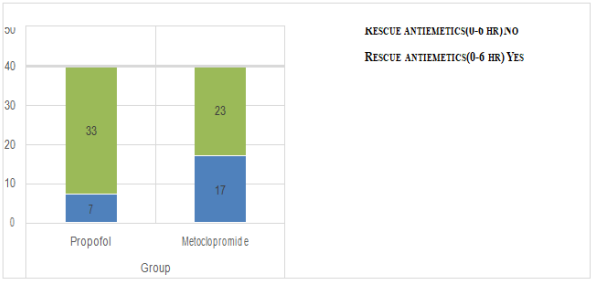

Figure 3: Requirements of rescue antiemetics between groups.

During the first postoperative six hours, there were fewer patients required to rescrescuei-emetic in the Propofol group the Metoclopramide group (12.5% vs 47.5%). It was found that there was a spastically significant difference up to 6 hours (p = 0.02) while no significant difference was noticed between 6-12 hours and 12-24 hour interval.

DISCUSSION

Our study shows that the incidence of postoperative nausea and vomiting after spinal anesthesia was significantly lower in the propofol group 32.5% compared to Metoclopramide 62.9%. A high incidence of PONV during spinal anaesthesia for cesarean section was demonstrated in our study consistent with other studies that demonstrated a reduction in the incidence of PONV in the first six hours [17]. However, the incidence of PONV was comparatively high in our study. This difference could be explained by the small sample size in our study. On the other hand, in line with previous studies parturient who received a low dose of propofol after delivery and clamping of the umbilical cord experienced less nausea and vomiting compared to parturient who received Metoclopromide [11,13]. Besides, at these sub

hypnotic doses, no significant depressant effects on respiration or hypotension were observed, which provided acceptable prophylactic effect throughout the surgery and postoperatively as well [16].

A study done by Rudra and his colleagues [18] found that propofol at sub hypnotic doses (1 mg/kg) in women undergoing cesarean delivery under spinal anaesthesia resulted in no reported episodes of nausea or vomiting in the intraoperative or post-delivery period. A prospective randomized double- blind study [19], in patients undergoing middle ear surgery, reported that the comparison of groups for nausea showed significant difference at 0-4 hours, but not at 4-12 and 12-4 hour, comparable observations were made in our study (p = 0.02) [20].

In contrary to our result, a study done by Nesek-Adam et al. & Khalaj et al. [4] found that 10mg metoclopramide is not effective as a prophylactic antiemetic in preventing PONV and Their result showed that (49.1% & 45%) incidence of PONV in the metoclopramide group respectively. The incidence of nausea alone was significantly lower in the propofol group than that of the metoclopramide group (p=0.02). This finding was highly comparable to other studies.

Our study also showed that the incidence of vomiting alone in the Propofol group was significantly lower than that of the metoclopramide group (p = 0.02) while this difference was not significant at 12-24 hours, which is reported by some studies however, a study was done by Shahriari et al. [18] contradict with our result they found a significant difference in the incidence of PONV b/n dexamethasone (8mg) & combination of dexamethasone (8mg) & metoclopramide (10mg) group. In this study incidence of nausea at recovery was 20% with metoclopramide, 16% with dexamethasone and 8% with the combination & the incidence of vomiting was 20%, 4%, 4%, and 0% respectively in the 4 groups. This difference may be due to the type of surgery & they have also used propofol for induction since the propofol has an antiemetic effect & it could affect the result [21].

Our study showed that, in patients who received propofol, the incidence of nausea and vomiting, reduced significantly without more sedation or respiratory depression. On the contrary Jelting et al. didn't find a significant difference in the incidence of nausea and vomiting when sub hypnotic doses of propofol or metoclopramide were used for gynecological surgeries [22]. This difference could be due to the time of drug delivery, which may affect the result because metoclopramide has a short duration of its antiemetic effect & it was more efficacious when administered at the end of anaesthesia than when given at its induction. In our case we were administered at the induction of anaesthesia [23].

The use of prophylaxis combination therapy against PONV has shown to have superior efficiency to monotherapy and should be adopted in patients at higher-risk score for PONV. The use of Metoclopramide in combination with other agents has not been found to decrease the incidence of PONV more than monotherapy [12,23]. Fuji et al. perhaps we compare propofol and metoclopramide we found comparable results with studies, who evaluated the difference between combination therapy and monotherapy as antiemetic for gynecological surgery [11, 19]. A study in Turkey [24] reported that patients given propofol had significantly less rescue antiemetic requirements than those in a metoclopramide group in the first 6 h of postoperative (4 and 13 patients respectively; P=0.01) in line with our study. They also showed that there were no significant differences among the groups of 12-24 h in terms of total antiemetic drug consumptions. Whereas, regarding the number of patients that need rescue anti-emetics, our result (0.42) was also compared with other studies [25].

In line with our study, Shahriari et al. reported that there were no significant documented adverse effects such as hypotension, apnea and a decrease in oxygen saturation in the propofol group, a possible explanation for this result might be we used the small and safe dose of propofol (30 mg). This dose has been used in previous studies with the effect of reducing PONV without any complications [4,21,24,25].

Strength

Study participants were homogenous.

LIMITATION

The limitations of this study mainly emerged from the observational nature and also Small Sample size of the study participant. Also, the study does not assess patient satisfaction.

DATA AVAILABILITY

Data used to support the findings of this study are available on request.

ETHICAL APPROVAL

Ethical clearance was obtained from the IRB College of Health Sciences and Medicine before the start of the study.

CONSENT

Informed written consent was obtained from each participant by the data collector. The objective of the study was explained to each of the participants. Confidentiality was maintained at all levels of the study. Participant's involvement in the study was by voluntary bases, and participants who were not willing to participate in the study and those who wish to quit their participation at any stage was informed to do so without any restriction.

DISCLOSURE

The funding body had no role in the design of the study and collection, analysis, and interpretation of data, and writing of the manuscript.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interests.

AUTHORS' CONTRIBUTIONS

Sleshi Hailu has made substantial contributions to conception, design, analysis, and interpretation of data, and participated in the critical review and editing of the manuscript drafts for scientific merit and depth. Nugusu Ayalew helped with substantial intellectual contributions to conception, design, and acquisition of data, analysis, and interpretation of data, as well as on preparing the manuscript for this study. Zemedu Aweke, Alem Esekeziya and Million Habetemariam were involved in analysis, interpretation of data, and drafting the manuscript and revising it critically for important intellectual contents. All authors are responsible for the contents, have contributed substantially to the drafting, and have approved the final version.

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CONCLUSION

In conclusion, administration of sub hypnotic intravenous doses of Propofol (30 mg) as prophylaxis after spinal anaesthesia for elective cesarean section achieved better postoperative antiemetic as shown by lower nausea severity scores, total antiemetic consumption, and longer time to the rescue antiemetic request in the first 24 hours postoperatively compared to the metoclopramide group. We recommend an additional randomized controlled study with a large sample size.

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