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Comparative evaluation of effect of Ondansetron and Ondansetron with dexamethasone for prevention of nausea, vomiting & shivering in patient of caesarean section under spinal Anesthesia

Dr. Nipa N Desai[1], Dr. Smitul Dave[2], Dr. Nirupama Sunasara[3], Dr. Nirav Prajapati[4]
[1] Tutor, Department of Anesthesiology, SMT SCL Hospital, Ahmedabad, Gujarat, India
[2] 2nd Year Resident, Department of Anesthesiology, SMT SCL Hospital, Ahmedabad, Gujarat, India
[3, 4] 1st Year Resident, Department of Anesthesiology, SMT SCL Hospital, Ahmedabad, Gujarat, India

Abstract
Background: Nausea and vomiting after cesarean section is reported in more than 66% of cases due to sudden contraction in diaphragm and manupulation and stretching of abdominal viscera. Similarly due to redistribution of blood flow shivering occurs in spinal anaesthesia. Nausea and vomiting resulted in different problems such as delayed discharging from post anesthesia care unit, high length of hospital stay, high risk of aspiration, and serious problems.
Objectives: This study aims at evaluating the efficacy of Ondansetron and Ondansetron with Dexamethsone for prevention of nausea, vomiting & shivering in patient of caesarean section under spinal anesthesia
Materials and Methods: Total 100 patients of age group 18to 35 years of ASA grade I /II were selected. Patients were randomly divided into two groups (n=50). In Group O inj. Ondansetron {4mg} and in Group OD inj. Ondansetron 4mg + inj. Dexamethasone 8mg was given. During the post-delivery period, nausea, vomiting and shivering episodes were recorded.
Results: There was significant difference in the incidence of nausea and vomiting between the groups (p value= 0.027).
Conclusion: Our study concluded that combined use of ondansetron 4mg and dexamethasone 8mg is effective in controlling PONV in CS after spinal anesthesia as compared to ondansetron 4 mg alone.

Keywords: ondansetron, dexamethasone, nausea, vomitingc, cesarean section

Introduction

World wise most common obstetric surgery is cesarean section [1]. Spinal anaesthesia is used for cesarean section as safe, easy and quick technique [2]. Nausea and vomiting after cesarean section is reported in more than 66% of cases [3, 4] due to sudden contraction in diaphragm and manupulation and stretching of abdominal viscera [5]. Similarly due to redistribution of blood flow shivering occurs in spinal anaesthesia [6]. Although in most cases nausea and vomiting are controlled spontaneously, sometimes it can result in complications such as aspiration, suture dehiscence, esophageal rupture, subcutaneous emphysema, and pneumothorax [7]. Nausea and vomiting resulted in different problems such as delayed discharging from post anesthesia care unit, high length of hospital stay, high risk of aspiration, and serious problems. Dexamethasone has been introduced, an inexpensive and widely available drug to control nausea and vomiting. Similarly ondansetron, selective antagonist of the 5-hydroxytryptamine3 (5-HT3), is considered as an effective drug for prevention and treatment of nausea and vomiting that is well controlled by the patients. Routinely we use Ondansetron as a premedication for prevention of nausea and vomiting during spinal anesthesia. But it is not sufficient for prevention of nausea and vomiting. Different studies have been done for comparision of the effect of Ondansetron and Dexamethasone in prevention of nausea and vomiting. In our study we compared the clinical efficacy of combination of Ondansetron and Dexamethasone with Ondansetron alone for prevention of nausea, vomiting and shivering.

Aims and Objectives

- To compare the incidence of nausea and vomitting
- Hemodynamic stability
- Shivering
- Side effects

Materials and Methods

In a double-blind, randomized, controlled trial study, 100 pregnant patients of age group 18 to 35 yrs old, ASA class I and II, posted for elective/emergency caesarean section, having no history of known physical and mental illnesses, and any history of taking pain killers and anti-depressants, sleeping pills and psychotropics. Were selected. The patients were randomly divided into two equal groups of 50 patients.

Exclusion Criteria

1) not NBM
2) weighing more than 100 kg
3) lack of appropriate communication with patients for evaluating postoperative nausea and vomiting
4) need for hospitalization in the ICU after surgery
5) Any previous history of allergy to Ondansetron or Dexamethasone.
6) infection, diabetes, glaucoma, preeclampsia, eclampsia, a psychiatric disorder
7) patients who took an antiemetic agent in the last 24 hours

Patients were randomly divided into two groups (group O and group OD). Group O received 4 mg of Ondansetron, while

group OD received 4 mg of Ondansetron and 8 mg of Dexamethasone (As a pre medication before giving spinal anesthesia). Incidence of nausea and vomiting, blood pressure, heart rate, O_2 saturation and respiratory rate and shivering of each patient were recorded after spinal anesthesia and postoperatively for 12 hours.

Antiemetic medicines were provided in the form of syringes containing 5 ml of normal saline solution and were injected by a second party who was unaware of what the syringes contain.

Solutions were prepared as follows: For Group O (50 patients), 4 ml ondansetron was added to 5 ml diluted normal saline, for Group OD, 2 syringes (1 having 5 ml normal saline and 8 ml dexamethasone and other having 5 ml normal saline with 4 ml ondansetron) were prepared and injected as premedication.

At the operating room, initially, standard monitorization that included electrocardiogram, noninvasive arterial blood pressure measurement and pulse oximetry was applied to all patients. All patients received 15-20 mL/kg (1500 ml maximum) normal saline before the intervention. Spinal anesthesia was performed using a 25-gauge spinal needle while the patient is in the sitting position, through the L3-4 inter space (or alternatively through the L2-3 or L4-5 interspaces) and 2 mL (depending on patients height) of 0.5% heavy bupivacaine was administered to the subarachnoid space. Patients were then moved to supine position, and to prevent spinal anesthesia induced hypotension, patients were infused normal saline at a rate of 125 ml/hr, operation table was given a 15-20 degrees left lateral tilt to decrease the aortocaval compression caused by the uterus. Oxygen was delivered to all patients at a rate of 2-3 L/ min via a face mask. Before the surgical incision, the level of sensorial blockage was evaluated by pinprick test, and the highest level of blockade was determined. Patients in whom the level of analgesia was insufficient were excluded from the study, and were given general anesthesia. Non-invasive blood pressure measurements were obtained from each patient at 1-3 min intervals, and in case of hypotension blood pressure measurement intervals were shortened to 1 min.

Mephentermin was given if hypotension (20% drop in baseline) occurred during the operation and Atropine was given for bradycardia (20% drop in baseline) was planned. After delivery of the fetus, 10 units of oxytocin/500 mL 0.9% normal saline administered at a rate of 125mL/hour to increase the uterine contractility.

During the post-delivery period, nausea, vomiting and shivering episodes were recorded. Drug related complications were recorded during the intra and post operative period for 12 years.

Statistical Analysis

Data were analyzed and unpaired t test was performed for comparison of two groups. A p-value less than 0.05(p value <0.05) was considered statistically significant.

Results and Observation

A total of 100 patients were initially included in the study. The Study groups were compared with respect to Demographic parameters, nausea, vomiting and shivering.

Levels of the sensorial blockade of the 100 patients were sufficient for the surgical procedure and were between T5 and T6 with no significant difference between the groups. All patients included in the study had an uncomplicated CS.

There were no significant differences between the groups in terms of demographic parameters as shown in table 1.

Table 1: Demographic Data.

Demographic Criteria	Group o	Group od
Age (years)	30.36±6.15	31.4±6.3
Weight(kgs)	74±12	79±14
Gestational age(weeks)	37±1	37±1

Values are expressed as means ±SD.

Only 6 patient from Group OD exhibited nausea and vomiting while 15 patients in group O had nausea and vomiting as shown in Table 2. There was no significant difference in the incidence of shivering in both the groups as shown in Table 3. Extrapyramidal side effects or cardiac arrhythmias and bradycardia occurred in none of the patient. A total of 9(9%) patients in both groups had hypotension. None of the patients in the two groups experienced increase in respiratory rate, oxygen saturation drop and oxygen desaturation drop after spinal anesthesia.

Table 2: Incidence of nausea and vomiting.

	YES (n=50)	NO (n=50)	P value
Group o	15	35	0.027
Group od	06	44	

n= number of patients.

Table 3: Incidence of shivering

	Yes (n=50)	No (n=50)	P value
Group O	22	28	0.216
Group OD	16	34	

n= number of patients.

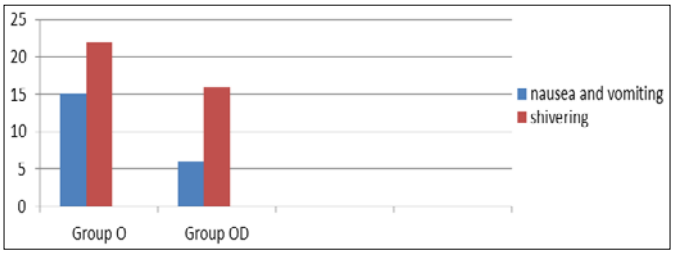

Fig 1

Discussion

This randomized, prospective, double blind study demonstrated that combined use of ondansetron 4 mg with dexamethasone 8 mg for the prevention of nausea and vomiting is more effective when compared with the ondansetron alone.

The precise etiology of nausea and vomiting remains unknown and various factors have been implicated. Hypotension is probably the most important cause that occurs during CS under spinal anesthesia. Hypotension can induce the emetic symptoms by leading to cerebral hypoperfusion[8]. Prevention of hypotension is therefore important for the prevention of nausea and vomiting. We tried to take the

necessary measures to prevent hypotension in all of our patients.

In our study we especially evaluated the incidence of post delivery IONV. Because the nausea and vomiting before the delivery period is especially related with spinal anesthesia induced hypotension which can be prevented, we thought that it would be better to investigate the nausea and vomiting in the post delivery period which is more difficult to control.

Although majority of hypotension during spinal anesthesia for CS occur before the delivery period, none of our patients experienced hypotension during this period as a result of adequate preventive measures. All of the hypotension cases in our study occurred after the delivery period. All patients developing hypotension also showed emetic symptoms sequentially, which resolved simultaneously within a short time with the correction of hypotension.

The baseline characteristics and intraoperative managements of all patients in the groups were similar in our study. The surgical procedure was less than one hour in all of the cases.

Ondansetron is a potent antiemetic agent which has been effectively used for the control of IONV and PONV. In clinical practice, it is commonly used at a dose of 4 mg intravenously [9-13]. Dershwitz *et al*. studied 6 different doses of ondansetron for the prevention of PONV and they recommended the 4 mg dose as a result of their study [11]. Abouleish *et al*. found that use of 4 mg ondansetron during CS decreased the occurrence of the emetic symptoms significantly when compared with the placebo (%36 vs. %58) [9]. In our study we also used ondansetron at a dose of 4 mg and the emetic symptoms observed in Group O was similar to the previous studies.

Combined use of antiemetics can act from several different ways in controlling nausea and vomiting symptoms, and therefore can be more effective than using single agents [14]. In our study we investigated the efficacy of 4 mg ondansetron alone or in combination with dexamethasone 8mg + 4mg ondansetron for the control of nausea and vomiting. Since these 2 agents act by different antiemetic mechanisms, we did not decrease the dosage of each agent during combined therapy. Incidence of nausea and vomiting in Group OD was significantly lower from the group O which was statistically significant.

Conclusion

Ondansetron and Dexamethasone, if given before spinal anaesthesia, prevents the nausea, vomiting and shivering more effectively than Ondansetron alone without any significant side effects.

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