Efficacy of Ramosetron and Ondansetron for Prevention of Nausea and Vomiting after Caesarean Section under Spinal Anaesthesia

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ABSTRACT

BACKGROUND
Spinal anesthesia has been shown to be easy, rapid and safe technique for caesarean section. Both Ramosetron and Ondansetron are increasingly being used for prevention and treatment of nausea and vomiting. We wanted to evaluate the efficacy of Ramosetron and Ondansetron in prevention of nausea and vomiting intraoperatively and postoperatively in LSCS patients under spinal anesthesia.

METHODS
This was a randomized, double blind study conducted among 60 female patients. They received either Ondansetron (4 mg) or Ramosetron (0.3 mg) intravenously 10 minutes before administration of spinal anesthesia. All patients were subjected to elective caesarean section under spinal anesthesia. They were randomly allocated into two groups namely control group (A) 30 patients who received Inj. Ondansetron 4 mg/IV and study group (B) of 30 patients who received Ramosetron 0.3 mg/IV. The patients were observed intraoperatively, in the recovery room and the ward up to 24 hours for episodes of nausea and vomiting. Rescue antiemetic was given if PONV score 2 was recorded. Side effects such as dizziness, headache, sedation or extrapyramidal reaction were noted.

RESULTS
Nausea and vomiting were noticed in 33.3% of the control group compared to 20% of the study group. Rescue antiemetic with PONV score 2 was given to 13.3% and 6.66% of the control and study groups respectively. Side effects were minimal with satisfaction expressed by 60% of control and 80% of the study population.

CONCLUSIONS
Ramosetron is quite effective to prevent nausea and vomiting in LSCS patients under spinal anaesthesia. It reduces the incidence of nausea and vomiting intraoperatively and in the immediate postoperative period with minimal side effects and with good patient satisfaction.

KEYWORDS
Spinal Anaesthesia, Caesarean Section, Ramosetron, Ondansetron, Post-Operative Nausea and Vomiting
Caesarean section under spinal anaesthesia has become increasingly popular in recent years and is a commonly performed surgical procedure. Regional anaesthesia is used in about 80% of patients compared to 20% of general anaesthesia. Consciousness allows the patients to enjoy early immediate contact with the newborn child. The procedure may be associated with various important problems, like arterial hypertension, headache, insufficient anaesthesia and psychologic distress. A common problem in caesarean section is intra and postoperative nausea and vomiting under regional anaesthesia.

About 72% of patients are afraid of nausea and vomiting and 71% feel significant discomfort. Previous reports suggest both nausea and vomiting as frequent phenomenon, with the incidences up to 80%. The major risk factors for nausea and vomiting during or after spinal anaesthesia in caesarean section is arterial hypotension due to blockade of the sympathetic nervous system. Critical anesthesiologic complications such as airway obstruction, aspiration pneumonitis and wound dehiscence are rare and mainly related to postoperative nausea and vomiting in general surgical patients.

Nausea and vomiting may be influenced by hormonal changes in pregnancy, which alter the sphincter tone of the esophagus and the stomach and the activity of small bowel and esophagus, as well as adverse effects of uterotonic drugs, intraoperative manipulation of the uterus and psychological distress aggravated by insufficient anaesthesia.

We wanted to evaluate the efficacy of Ramisetron as compared to Ondansetron in the prevention of nausea and vomiting in LSCS patients under spinal anaesthesia in the intraoperative and 24 hours postoperative period.

This was a comparative, clinical randomized, double blind study. The study was done at Murshidabad Medical College and Hospital for one year from July 2016 to June 2017. Sixty female patients were divided equally into two groups. Gr. A Ondansetron (4 mg) and Gr. B study group Ramisetron (0.3 mg). The drugs were given intravenously 10 minutes before the administration spinal anaesthesia. All the patients were subjected to elective caesarean section under spinal anesthesia, the patients with H/O Diabetes mellitus, allergic to local anesthetic, hepatic disorders and those taking antiemetic medication were excluded from the study. After pre-anesthetic evaluation and investigations, the patients were explained about the procedure. Informed consent was taken. Baseline vital parameters were recorded. All the patients were preloaded with RL10 ml/kg to prevent intraoperative hypotension followed by nausea and vomiting. All patients were given premedication with Midazolam 3.75 mg orally 1 hr. before transfer to the operation theatre. Spinal anaesthesia was induced in sitting position between L3/L4 with 0.5% hyperbaric bupivacaine with 25/26G spinal needle. Dosage depended on the body height. With body height of 150 cms the dose administered was 1.8 ml bupivacaine 0.5%. An additional 0.2 ml bupivacaine dosage was administered for every 5 cms of increased height. The patients were observed intraoperatively in the recovery room and in the ward upto 24 hrs. Episode of nausea and vomiting or retching were evaluated on 3-point PONV score (0 - no nausea and vomiting, 1 - episode of nausea, 2 - retching, vomiting).

There was a total of 60 patients in the study, with 30 patients in each group. The demographic data with respect to age, height and weight were comparable in both groups. (Table 1) There was no statistically significant difference with respect to duration of surgery and duration of anesthesia in both the groups. PONV score in the control and study groups are shown in table II. In spite of pre-anesthetic anti-emetics, scores 1-2 was noticed is 13 (43.3%) & 6 (20%) of patients in the control and study populations respectively. Rescue antiemetic was given with PONV score 2 in 4 & 2 cases (13.3% and 6.6%) of group A (control group) and group B (study group) respectively. Table 3 shows episodes of vomiting is the two groups within 6 hours and 6-24 hours of operation. In the early postoperative period (within 6 hours) nausea and vomiting was noticed was 36.6 of control group compared to 16.6% of the study group. After 6 hours the incidence was 6.66% vs 3.33% in control and study groups respectively. PONV score 0 (no nausea and vomiting) was observed in 56.6% in control group and 80% in study group. PONV score 2 (episodes of retching, vomiting) was 13.33% in control and 6.66% in study group. Table 4 shows the side effects of antiemetic drugs used. About half of the patients in each group had minimal side effects like dizziness and sedation. Dizziness was 36.6% in control group and 30% in the study group. Satisfaction of the patients are shown in table 5. Sixty percent of the control group were satisfied compared to 80% of the study group.
The study was conducted to find a highly efficient antiemetic and anaesthetic procedure to reduce the incidence of intra and postoperative nausea and vomiting in female patients subjected to caesarean section under spinal anaesthesia. The study was conducted on the background that an optimal perioperative patient comfort is of outstanding interest and nausea and vomiting with average incidence of 30% is rated as one of the most undesirable events in the context of surgery and anaesthesia. Therefore, every attempt should be made, especially in the context of birth, to avoid this complication, which is an unpleasant adverse effect, but also may cause severe complications such as wound dehiscence, dehydration, aspiration or pneumothorax. There were no definite study performed regarding comparison of Ramosetron and Ondansetron in LSCS patients under spinal anaesthesia, in our population.

In our study, we observed 60 patients for episodes of nausea and vomiting in LSCS patients under spinal anaesthesia, following preoperative antiemetics. Ramosetron is recently developed selective 5HT3 receptor antagonist. It shows significantly greater affinity for 5HT3 receptors, resulting in more potent, longer receptor antagonizing effects compared to older 5HT3 antagonist. Ramosetron is more potent and has longer duration of action than Granisetron in the prevention of emesis after cisplatin therapy and prevention of PONV. Choi and Colleagues reported that Ramosetron IV was better than Ondansetron IV in reducing the severity of nausea, incidence of vomiting and need for postoperative antiemetic (at 6-24 hrs) following caesarean section under spinal anaesthesia. PONV score was 0 in 80% patients in study group (Ramosetron group) compared to 66% patients in control group (Ondansetron group) in our study. It suggests that Ramosetron is quite effective in controlling nausea and vomiting in both intraoperative and postoperative period, Fuji et al reported that Ramosetron is effective in preventing PONV after major gynaecological surgery. In our study Ramosetron 0.3 mg was effective in reducing the incidence of PONV (80% in Ramosetron group versus 56.66% in Ondansetron group). Kim et al performed similar study in gynaecological surgery and have observed similar results as well. Rescue dose with PONV score of 2 was required in 6.66% of study population compared to 13.3% of control group. The most frequently reported adverse effects of 5HT3 receptor antagonists are dizziness and headache. Adverse events were mild and in our study were dizziness and sedation in both study and control group. Satisfaction were expressed by 80% of study population compared to 60% of the control group. There were differences in findings of different parameters through statistically not significant. It may be due to small study population.

## DISCUSSION

The study was conducted to find a highly efficient antiemetic and anaesthetic procedure to reduce the incidence of intra and postoperative nausea and vomiting in female patients subjected to caesarean section under spinal anaesthesia. The study was conducted on the background that an optimal perioperative patient comfort is of outstanding interest and nausea and vomiting with average incidence of 30% is rated as one of the most undesirable events in the context of surgery and anaesthesia. Therefore, every attempt should be made, especially in the context of birth, to avoid this complication, which is an unpleasant adverse effect, but also may cause severe complications such as wound dehiscence, dehydration, aspiration or pneumothorax. There were no definite study performed regarding comparison of Ramosetron and Ondansetron in LSCS patients under spinal anaesthesia, in our population.

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### CONCLUSIONS

Inj. Ramosetron 0.3 mg IV is much more effective for prevention of postoperative nausea and vomiting in LSCS patients under spinal anaesthesia. Ramosetron seems to be useful alternative and relatively safe drug for effective antiemetic prophylaxis. It improves the PONV score, reduces nausea and improves patient satisfaction, with very mild side effects.

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### REFERENCES


