British Journal of Anaesthesia **103 (4):** 549–53 (2009)
doi:10.1093/bja/aep209 Advance Access publication August 21, 2009

BJA

Comparison of ramosetron with ondansetron for prevention of postoperative nausea and vomiting in patients undergoing gynaecological surgery

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Background. Ramosetron is a new selective 5-hydroxytryptamine type 3 (5-HT_3) receptor antagonist that reportedly has more potent antiemetic effects compared with other 5-HT_3 receptor antagonists. The purpose of this study was to evaluate the efficacy of ramosetron for the prevention of postoperative nausea and vomiting (PONV) with that of ondansetron or placebo in high-risk patients undergoing gynaecological surgery.

Methods. In this prospective, randomized, double-blinded, placebo-controlled study, 162 healthy patients who were undergoing gynaecological operation under general anaesthesia using sevoflurane were enrolled. Patients were divided into three groups: the ramosetron group (0.3 mg i.v.; n=54), the ondansetron group (8 mg i.v.; n=54), and the placebo group (normal saline i.v.; n=54). The treatments were given before the end of surgery. The incidence of PONV, severity of nausea, and the use of rescue antiemetic requirements during the first 24 h after surgery were evaluated.

Results. The incidence of nausea was lower in the ramosetron (50%) and ondansetron (44%) groups compared with the placebo group (69%) ($P<0.05$). In addition, the incidence of vomiting was lower in both the ramosetron (17%) and the ondansetron (20%) groups than in the placebo group (44%) during the first 24 h after surgery ($P<0.05$). The visual analogue scale score for nausea was also lower in the ramosetron and ondansetron groups compared with the placebo group ($P<0.05$). The proportion of patients requiring rescue antiemetics was significantly lower with ramosetron (15%) when compared with the placebo group (41%) during the 24 h after surgery ($P<0.05$). However, there were no significant differences in the incidence of nausea and vomiting, severity of nausea, and required rescue PONV between the ramosetron and the ondansetron groups.

Conclusions. Ramosetron 0.3 mg i.v. was as effective as ondansetron 8 mg i.v. in decreasing the incidence of PONV and reducing nausea severity in female patients during the first 24 h after gynaecological surgery.

Br J Anaesth 2009; **103**: 549–53

Keywords: antiemetics, ondansetron; antiemetics, ramosetron; PONV; vomiting, antiemetics

Accepted for publication: May 22, 2009

Postoperative nausea and vomiting (PONV) is one of the most common and distressing complications after anaesthesia and surgery, and may lead to serious postoperative complications. The overall incidence of PONV has been reported to be between 20% and 30%, but can increase up to 80% in high-risk patients. Patients undergoing gynaecological surgery have been associated with high risk for developing PONV.[1 2]

For PONV prevention, selective serotonin 5-hydroxytryptamine type 3 (5-HT_3) receptor antagonists are considered one of the first-line therapy because of their efficacy and few side-effects compared with other antiemetics.[3] Most research on the 5-HT_3 receptor antagonists has been on ondansetron, and its antiemetic efficacy has been well established in chemotherapy-induced emesis and the prevention and treatment of PONV.[4–7]

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Ramosetron is a recently developed selective 5-HT_3 receptor antagonist. It exhibits significantly greater binding affinity for 5-HT_3 receptors with a slower dissociation rate from receptor binding, resulting in more potent and longer receptor antagonizing effects compared with older 5-HT_3 receptor antagonists.[8 9]

It was reported that ramosetron is more potent with a longer duration of action than granisetron in the prevention of emesis after cisplatin chemotherapy, and in the prevention of PONV.[10–12] However, there are few reports about the antiemetic effect of ramosetron compared with ondansetron for prevention of PONV. Choi and colleagues[13] reported that ramosetron i.v. was superior to ondansetron i.v. in reducing the severity of nausea, incidence of vomiting, and the use of rescue antiemetics at 6–24 h after operation in patients who had undergone lumbar spine surgery, but this study was not placebo-controlled. However, the antiemetic efficacy of ramosetron i.v. to prevent PONV compared with that of ondansetron i.v. or placebo in patients undergoing gynaecological surgery has not yet been reported.

Therefore, we designed this prospective, randomized, double-blind, placebo-controlled study to evaluate the efficacy of ramosetron for preventing PONV compared with that of ondansetron or placebo in high-risk patients undergoing gynaecological surgery during the first 24 h after surgery.

Methods

An approval was obtained from IRB before study commencement. After receiving written informed consent, 162 female healthy patients, aged 21–71 yr, undergoing elective gynaecological surgery were enrolled in this randomized, placebo-controlled, double-blinded study. The duration of surgery ranged 35–190 min and the patient underwent hysterectomy, ovarian cystectomy, and salpingo-oophorectomy.

Exclusion criteria were pregnancy, body weight more than 30% above the ideal body weight, vomiting or retching within 24 h before the operation, administration of antiemetics or steroids or psychoactive medications within 24 h before the operation, and respiratory, cardiovascular, renal, hepatic, endocrine, gastrointestinal, or neurological disease. Patients were asked to provide a detailed medical history and patient characteristic information, including age, weight, and any history of PONV, motion sickness, or smoking.

Patients were randomly allocated to receive one of the three study medications according to a computer-generated randomized number table: ramosetron group, ramosetron 0.3 mg i.v.; ondansetron group, ondansetron 8 mg i.v.; and placebo group, saline i.v. The envelopes were opened before induction of anaesthesia by a trained nurse not involved in the study. The nurse then prepared the appropriate study medication diluted to 4 ml in identical syringes, and administered ~30 min before the end of surgery. All patients, investigators collecting the postoperative data, and nurses involved in the postoperative care of patients were blinded to the randomization.

A standardized anaesthesia regimen was followed. All patients received midazolam 3–5 mg i.m. for premedication 30 min before surgery. General anaesthesia was induced with propofol 2 mg kg^{-1} and fentanyl 2–3 μg kg^{-1}. Rocuronium 0.6 mg kg^{-1} was administered to facilitate tracheal intubation. Anaesthesia was maintained with sevoflurane (0.5–5%) and nitrous oxide (50%). At the end of surgery, residual neuromuscular block was reversed with pyridostigmine (0.2 mg kg^{-1}) and glycopyrrolate (0.005 mg kg^{-1}) in all patients. The study medication (ondansetron, ramosetron, or saline) was administered i.v. ~30 min before the end of surgery. For postoperative pain control, patients were administered fentanyl using i.v. patient-controlled analgesia (bolus dose fentanyl 15 μg, lockout interval of 5 min, and no background infusion). After surgery, patients were observed in the postanaesthetic care unit (PACU) before ward transfer when stable.

The incidence of PONV, severity of nausea, and the need for rescue antiemetics were evaluated for 24 h after surgery, divided into two intervals: 0–6 and 6–24 h. Patients were monitored every 15 min in the PACU and every 2 h in the ward except when sleeping. An episode of vomiting was defined as either vomiting (expulsion of stomach contents) or retching (an involuntary attempt to vomit but not productive of stomach contents). The intensity of nausea episode was assessed using a 100 mm visual analogue scale (VAS) (0, none; 100, maximum). Patients were asked to evaluate their maximal degree of nausea during the interval assessments. When moderate or severe nausea (VAS score >50) or vomiting was present, patients were asked if they required rescue antiemetics. Rescue medication for PONV (metoclopramide 10 mg as an initial rescue drug, ondansetron 4 mg as a second rescue drug) was administered upon patient request or complaint of established nausea (VAS score >50) or vomiting. To minimize suffering from PONV, patients were informed and educated on how to request treatment when PONV occurred before, after surgery, or both. Adverse events were evaluated and recorded by the investigator during the entire observation period. Patients were also asked to rate their overall satisfaction with the anaesthetic experience on a three-point scale (satisfied, neutral, and dissatisfied) 24 h after surgery completion.

The primary outcome measure of this study was the incidence of nausea and vomiting during the first 24 h after operation, and the secondary outcome measures were the severity of nausea, need for rescue medication, and patient satisfaction.

Sample size was predetermined using a power analysis to achieve an 80% chance (β=0.2) of detecting a 40%

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