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ORIGINAL RESEARCH

Ramosetron versus ondansetron for the prevention of post-operative nausea and vomiting in high-risk patients

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Abstract

Background: Post-operative nausea and vomiting (PONV) is a common complaint, with an incidence of up to 80% in high-risk patients. The present study was conducted to compare ramosetron with ondansetron for the prevention of post-operative nausea and vomiting in high-risk patients.

Materials & Methods: 100 adults undergoing surgeries of both genders were divided into 2 groups of 50 each. Group I received ramosetron 0.3 mg and group II received ondansetron 8 mg, 30 min before the end of surgery. The incidence of PONV, severity of nausea and need for rescue antiemetic were recorded over the next 24 hours.

Results: Group I had 26 males and 24 females and group II had 25 males and 25 females. Nausea was seen in 36% and 39%, retching in 9% and 16%, emesis in 13% and 10% and rescue anti- emetic in 24% and 30% in group I and II respectively. The difference was significant (P < 0.05). Nausea was none in 45% in group I and 70% in group II, mild in 30% in group I and 20% in group II and normal in 25 % in group I and 10% in group II. The difference was significant (P < 0.05).

Conclusion: Both Ramosetron 0.3 mg and ondansetron 8 mg were equally effective in reducing the incidence of PONV in high- risk patients.

Key words: ramosetron, ondansetron, nausea and vomiting

Introduction

Post-operative nausea and vomiting (PONV) is a common complaint, with an incidence of up to 80% in high-risk patients. This is despite the availability of several medications for prophylaxis and treatment of PONV. PONV is distressing and potentially detrimental to a patient's recovery as it can result in wound dehiscence, bleeding, aspiration of gastric contents, electrolyte imbalances, and delayed hospital discharge. 2

Selective serotonin [5 hydroxytryptamine type 3 (5 HT3)] receptor antagonists are considered first line in the prevention of PONV, due to their proven efficacy and favourable side-effect profile. Most research has been conducted on ondansetron, and its efficacy is well-established. Ramosetron is a selective 5-HT3 antagonist. It exhibits a higher affinity for the receptors with a slower dissociation, resulting in a longer duration.³

Many patients experience mild to moderate pain or even excruciating pain during propofol injection. Numerous studies have been conducted to know the better among them for

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prevention of post-operative nausea and vomiting (PONV) but less for reducing propofol-induced pain. A,5 Ondansetron has been proved to have a local anaesthetic effect, other than antiemetic property. Ramosetron is one of the potent 5-HT3 antagonist commonly used as an antiemetic and has been found to be effective in prevention of early PONV compared to ondansetron. The present study was conducted to compare ramosetron with ondansetron for the prevention of post-operative nausea and vomiting in high-risk patients.

Materials & Methods

The present study comprised of 100 adults undergoing surgeries of both genders. All gave their written consent for the participation in the study.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 50 each. Group I received ramosetron 0.3 mg and group II received ondansetron 8 mg, 30 min before the end of surgery. The incidence of PONV, severity of nausea and need for rescue antiemetic were recorded over the next 24 hours. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

Results

Table I: Distribution of patients

| Groups | Group I | Group II |
|--------|-------------------|------------------|
| Drug | ramosetron 0.3 mg | ondansetron 8 mg |
| M:F | 26:24 | 25:25 |

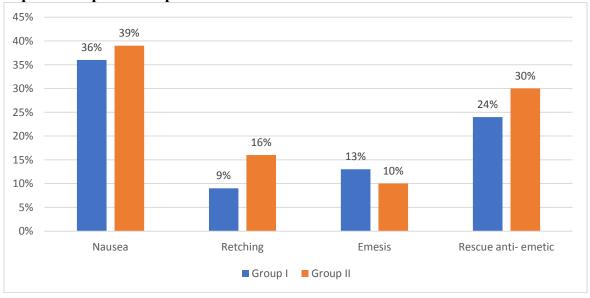
Table I shows that group I had 26 males and 24 females and group II had 25 males and 25 females.

Table II: Comparison of parameters

| Parameters | Group I | Group II | P value |
|---------------------|---------|----------|---------|
| Nausea | 36% | 39% | 0.12 |
| Retching | 9% | 16% | 0.04 |
| Emesis | 13% | 10% | 0.05 |
| Rescue anti- emetic | 24% | 30% | 0.04 |

Table II, graph I shows that nausea was seen in 36% and 39%, retching in 9% and 16%, emesis in 13% and 10% and rescue anti- emetic in 24% and 30% in group I and II respectively. The difference was significant (P < 0.05).

Graph I: Comparison of parameters



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Table III: Severity of nausea

| Nausea | Group I | Group II | P value |
|--------|---------|----------|---------|
| None | 45% | 70% | 0.01 |
| Mild | 30% | 20% | |
| Normal | 25% | 10% | |

Table III shows that nausea was none in 45% in group I and 70% in group II, mild in 30% in group I and 20% in group II and normal in 25% in group I and 10% in group II. The difference was significant (P< 0.05).

Discussion

For PONV prevention, selective serotonin 5- hydroxytryptamine type 3 (5-HT3) receptor antagonists are considered one of the first-line therapy because of their efficacy and few side-effects compared with other antiemetics. Most research on the 5-HT3 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. The present study was conducted to compare ramosetron with ondansetron for the prevention of post-operative nausea and vomiting in high-risk patients

We found that group I had 26 males and 24 females and group II had 25 males and 25 females. Kim et al¹² in their 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, the ondansetron group and the placebo group. 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%). 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. The visual analogue scale score for nausea was also lower in the ramosetron and ondansetron groups compared with the placebo group. 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. 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.

We found that nausea was seen in 36% and 39%, retching in 9% and 16%, emesis in 13% and 10% and rescue anti- emetic in 24% and 30% in group I and II respectively. Agarkar et al¹³ in their study 206 patients with at least two risk factors for PONV were randomised to receive ramosetron 0.3 mg or ondansetron 8 mg, 30 min before the end of surgery. The incidence of PONV, severity of nausea and need for rescue antiemetic were recorded over the next 24 h. Primary outcome was the incidence of PONV. Secondary outcomes included severity of nausea and need for rescue. The incidence of PONV was found to be 35% in the ramosetron group as opposed to 43.7% in the ondansetron group (P = 0.199). Need for rescue antiemetic was 23.3% in the ramosetron group and 32% in the ondansetron group (P = 0.156) in the 24 h following surgery.

We found that nausea was none in 45% in group I and 70% in group II, mild in 30% in group I and 20% in group II and normal in 25 % in group I and 10% in group II. Tramer et al ¹⁴ in their study fifty-three trials were found that had data from 7,177 patients receiving 24 different ondansetron regimens and from 5,712 controls receiving placebo or no treatment. Average early and late PONV incidences without ondansetron were 40% and 60%, respectively. There was a dose response for oral and intravenous ondansetron. Best number-needed-to-treat to prevent PONV with the best documented regimens was between 5 and 6.

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This was achieved with an intravenous dose of 8 mg and an oral dose of 16 mg. Antivomiting efficacy was consistently better than antinausea efficacy. Efficacy in children was poorly documented. Ondansetron significantly increased the risk for elevated liver enzymes (number-needed-to-harm was 31) and headache.

The limitation the study is small sample size.

Conclusion

Authors found that Both Ramosetron 0.3 mg and ondansetron 8 mg were equally effective in reducing the incidence of PONV in high- risk patients.

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