Comparison of Antiemetic Effect of Ramosetron with Ondansetron in the Patients Undergoing Microvascular Decompression with Retromastoid Craniotomy

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Directed by Professor Kyeong Tae Min

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ABSTRACT

Comparison of Antiemetic Effect of Ramosetron with Ondansetron in the Patients Undergoing Microvascular Decompression with Retromastoid Craniotomy

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(Directed by Professor Kyeong Tae Min)

Background: Microvascular decompression (MVD) with retromastoid craniotomy (RMC) has an especially high risk of postoperative nausea and vomiting (PONV). In this study, we compared the efficacy of ramosetron and ondansetron on PONV in patients undergoing RMC.

Methods: Using a balanced anesthesia with sevoflurane in air and remifentanil infusion, ondansetron 8 mg (group O, n = 31) or ramosetron 0.3 mg (group R, n = 31) was administered at the dural closure. The frequency and severity of PONV and required rescue medications and frequency of side effects were measured at post anesthetic care unit (PACU), 6, 24 and 48 hours postoperatively. Independent t-tests and Chi-square test or Fisher's exact test were used for statistical analyses. Binary logistic regression was used to calculate OR (95% CI). For multiple comparisons,

Bonferroni correction was used.

Results: There were no differences in demographic data between groups except a slightly longer anesthetic duration of group R (p = 0.01). The overall postoperative 48 hour incidence of nausea and vomiting was 90.3% and 61.3% (group O) and 87.1% and 54.8% (group R), respectively. There were no statistical differences of any measured variables between groups at measured intervals, but patients of group R were in trends of less severe degree of nausea (OR = 0.30; 95% CI, 0.10-0.85; adjusted p = 0.08) and lower incidence of dizziness (OR = 0.34; 95% CI, 0.12-0.96; adjusted p = 0.16) between 6 and 24 hours.

Conclusions: The antiemetic efficacy of ramosetron alone was not satisfactory and superior to that of ondansetron in patients undergoing MVD with RMC for at least 48 hours after surgery.

Key words : microvascular decompression, postoperative nausea and vomiting, ramosetron

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I. INTRODUCTION

Among high-risk patients undergoing craniotomy for postoperative nausea and vomiting (PONV), infratentorial craniotomy has been suggested as an additional independent risk factor.[1,2] Recent retrospective studies have reported that microvascular decompression (MVD) is an especially strong risk factor for PONV among craniotomy patients, with reported odds ratios ranging from 5.38[3] to 6.7[4]. According to another retrospective study, the incidence of PONV after MVD with retromastoid craniotomy (RMC) is greater than 60%[1] within postoperative 24 hours despite the use of the ondansetron. Meta-analysis on the antiemetic efficacy of ondansetron after craniotomy[5] revealed that ondansetron significantly reduced nausea and vomiting in adult patients by 22% and 57%, within 24 hours after surgery, respectively, but was not effective between 24 and 48 hours after surgery. On the other hand, a randomized prospective double-blind study[6] found that nausea after infratentorial craniotomy exhibited a bimodal pattern up to 48 hours, suggesting that

prophylactic antiemetic treatment for PONV is needed up to 48 hours postoperatively. Therefore, ramosetron, a selective 5-HT_3 receptor antagonist with a higher affinity and a longer duration of action than ondansetron,[7] may be more appropriate than ondansetron in complete response and incidence of PONV until 48 hours after surgery in some patients at high risk for PONV.[8,9]

The purpose of this study was to compare the antiemetic efficacy of ramosetron with that of ondansetron up to 48 hours after surgery in patients undergoing MVD with RMC.

II. MATERIALS AND METHODS

Materials

After institutional review board approval (4–2010–0242) and written informed consent, 64 adult patients aged 20–75 years and with an American Society of Anesthesiologists physical status I or II who were scheduled for MVD with RMC, were included in this prospective study. Exclusion criteria included patients with ASA physical status III or IV, pregnancy, having undergone chemotherapy or ventriculo-peritoneal shunt insertion, allergy to ondansetron or ramosetron, antiemetic therapy within 24 hours before the operation, systemic steroid therapy within 24 hours before the operation or up to 48 hours during the postoperative period, emergency operation, cardiovascular disease, respiratory disease, renal disease, hepatic disease or Glasgow Scale Score < 13 points.

Methods

Patients were randomly allocated to receive ondansetron (group O) or ramosetron (group R) according to a computer grouping program. None of the patients received premedication, and all were asked to provide a detailed medical history and current list of medications. Pulse oximetry, EKG, non-invasive blood pressure and end tidal CO_2 were continuously monitored in the operating room.

General anesthesia was induced with a bolus of propofol 2.0 mg/kg and remifentanil 0.5–1 μg/kg. Rocuronium 0.8 mg/kg was administered for endotracheal

intubation. Anesthesia was maintained with sevoflurane (age adjusted 0.6–0.9 MAC) in air along with 50% oxygen, supplemented with remifentanil infusion at 0.05–0.2 μg/kg/min. Controlled ventilation was performed to maintain end tidal CO_2 of 32–35 mmHg during the surgery.

At the onset of dural closure, ondansetron 8 mg or ramosetron 0.3 mg was administered intravenously. The study medication was prepared by one of investigator (Ha, SH) in identical 5 ml syringes and administered in an equal volume of 4 ml (ramosetron was prepared with 2 ml of normal saline). The other investigators and observers were unaware of which drug was being administered to the patient. Fentanyl 50 μg was administered during skin closure for postoperative analgesia. At the end of the surgery, sevoflurane and remifentanil infusion were discontinued. After adequate reversal of neuromuscular blockade with glycopyrrolate 0.2 mg and pyridostigmine 0.2 mg/kg, all patients were extubated and observed in the post anesthetic care unit (PACU) for approximately one hour before trasferring to general ward.

Investigators who were unaware of the patient treatment groups evaluated the occurrence and severity of nausea, occurrence of vomiting, pain intensity and requirements of rescue antiemetic or analgesic at PACU, at intervals of 1–6 hours, 6–24 hours and 24–48 hours after surgery. The occurrence of side effects of 5-HT_3 antagonist such as dizziness and sedation were also assessed. Nausea was defined as a subjectively unpleasant sensation associated with awareness of the urge to vomit,

while an emetic episode was defined as a single episode of vomiting (the forceful expulsion of gastric contents through the mouth). Retching, (expulsive movement of the stomach muscles without expulsion of stomach contents) was also considered as vomiting. The intensity of nausea was graded using a verbal 11-point rating scale, with 0 indicating no nausea and 10 indicating worst nausea. The severity of nausea was graded according to verbal rating scale scores: no (0), mild (1–3), moderate (4–6) and severe (7–10). Metoclopromide 10 mg was given intravenously as rescue antiemetic when the patient asked to be treated for nausea or vomited more than twice within a 15 minutes period. Pain intensity scores were measured on a visual analog scale in cm, ranging from 0 (no pain) to 10 (worst pain imaginable). Patients received tramadol 50 mg intravenously if they complained of pain greater than 5 on the visual analog scale.

Sample Size and Statistical Analyses

This prospective investigation was performed as a preliminary study in nature because there were no previous reports about antiemetic efficacy either with ondansetron or ramosetron in patients undergoing MVD with RMC. Thus, authors intended to include at least 30 patients in each group to pass the normality test. For statistical analysis, Independent two sample t-test and Chi-square or Fisher's exact test were performed to compare continuous and categorical data, respectively. Binary logistic regression was used to calculate odd ratio (95% confidence interval). All tests

were two-sided and *p*-values were adjusted using Bonferroni correction for multiple comparison. All analyses were performed using IBM SPSS statistics v20 (USA).

III. RESULTS

Sixty two patients (31 patients in each group) among 64 patients enrolled were analyzed because two patients (1 in group O and 1 in group R) violated the experimental protocol. Demographic data showed no statistical significance between two groups, but anesthetic duration in group R was longer than that in group O (231.1 ± 41.0 minutes vs. 261.4 ± 53.3 minutes, $p = 0.01$) (Table 1).

The overall incidence of nausea and vomiting during postoperative 48 hours were 90.3% and 61.3% in group O and 87.1% and 54.8% patients in group R, respectively. Almost 80% of patients regardless of group required a rescue antiemetic. All the measured variables were not different statistically between two groups at any measured intervals (Table 2 and 3). However, between 6 and 24 hours of postoperative period, more patients in group O were in trends of experiencing moderate to severe nausea (58.1% vs. 29.0%; OR = 0.30; 95% CI, 0.10-0,85; adjusted $p = 0.08$) and dizziness (54.8% vs. 29.0%; OR = 0.34; 95% CI, 0.12-0.96; adjusted $p = 0.16$) compared with those in group R.

TABLE 1. Demographic Data

	Group O n = 31 (%)	**Group R** n = 31 (%)	***p*-value**
Age (yr)	53.5 ± 9.7	52.6 ± 9.7	0.66
Sex (M/F)	9/22	9/22	>0.99
Height (cm)	159.5 ± 8.5	158.6 ± 7.8	0.68
Weight (kg)	60.4 ± 9.7	59.6 ± 9.4	0.75
ASA PS, I/II	22/9	24/7	0.56
Anesthesia time (min)	231.1 ± 41.0	261.4 ± 53.3	0.01
Operation time (min)	164.5 ± 42.7	181.0 ± 33.7	0.10
Remifentanil administered (μg)	1,083.9 ± 291.1	1,125.8 ± 314.1	0.59
Hypertension	8 (25.8)	6 (19.4)	0.54
DM	3 (9.7)	4 (12.9)	>0.99
Smoking	3 (9.7)	1 (3.2)	0.61
History of motion sickness	7 (22.6)	6 (19.4)	0.76
History of PONV	1 (3.2)	2 (6.5)	>0.99

Data are mean ± SD or number of patients (%). Group O, ondansetron group; Group R, ramosetron group; ASA PS, American Society of Anesthesiologists Physical Status; DM, diabetes mellitus; PONV, postoperative nausea and vomiting.

Table 2. Incidence of Nausea, Vomiting, and Required Antiemetics

	Group O n = 31 (%)	Group R n = 31 (%)	OR (95% CI)	*p*-value	Adjusted *p*-value
Nausea					
PACU	23 (74.2)	20 (64.5)	0.63 (0.21-1.88)	0.41	>0.99
1–6 h	19 (61.3)	22 (71.0)	1.54 (0.54-4.46)	0.42	>0.99
6–24 h	23 (74.2)	17 (54.8)	0.42 (0.15-1.23)	0.11	0.44
24–48 h	17 (54.8)	11 (35.5)	0.45 (0.16-1.26)	0.13	0.52
Nausea severity					
PACU (no~mild/mod~severe)	15/16	19/12	0.59 (0.22-1.62)	0.31	>0.99
1–6 h (no~mild/mod~severe)	19/12	23/8	0.55 (0.19-1.62)	0.28	>0.99
6–24 h (no~mild/mod~severe)	13/18	22/9	0.30 (0.10-0.85)	0.02	0.08
24–48 h (no~mild/mod~severe)	23/8	27/4	0.43 (0.11-1.60)	0.20	0.80
Vomiting					
PACU	6 (19.4)	5 (16.1)	0.80 (0.22-2.96)	0.74	>0.99
1–6 h	4 (12.9)	7 (22.6)	1.97 (0.51-7.56)	0.32	>0.99
6–24 h	13 (41.9)	9 (29.0)	0.57 (0.20-1.63)	0.29	>0.99
24–48 h	5 (16.1)	3 (9.7)	0.56 (0.12-2.57)	0.71	>0.99
Required rescue antiemetics					
PACU	11 (35.5)	9 (29.0)	0.74 (0.26-2.17)	0.59	>0.99
1–6 h	16 (51.6)	21 (67.7)	1.97 (0.70-5.52)	0.20	0.80
6–24 h	14 (45.2)	11 (35.5)	0.67 (0.24-1.85)	0.44	>0.99
24–48 h	11 (35.5)	11 (35.5)	1.00 (0.35-2.83)	>0.99	>0.99

Data are number of patients (%). PACU, post anesthetic care unit; h, hours; mod, moderate.
OR, odd ratio; CI, confidence interval. *p*-value was analyzed using Chi-square test (Fisher's exact test).
Adjusted *p*-value was taken after multiple comparison with Bonferroni correction.

Table 3. Pain Score and Required Rescue Analgesics

	Group O n = 31(%)	Group R n = 31(%)	OR (95% CI)	*p*-value	Adjusted *p*-value
Pain score					
PACU	5.23 ± 2.64	5.03 ± 2.50	0.87 (0.36-2.08)	0.77	>0.99
1–6 h	5.10 ± 2.5	4.23 ± 2.36	0.50 (0.20-1.20)	0.16	0.64
6–24 h	3.32 ± 1.72	3.00 ± 1.81	0.73 (0.30-1.76)	0.47	>0.99
24–48 h	2.19 ± 1.64	2.13 ± 1.38	0.90 (0.37-2.20)	0.87	>0.99
Required rescue analgesics					
PACU	9 (29.0)	10 (32.3)	1.16 (0.40-3.43)	0.78	>0.99
1–6 h	21 (67.7)	20 (64.5)	0.87 (0.30-2.48)	0.79	>0.99
6–24 h	20 (64.5)	15 (48.4)	0.52 (0.19-1.43)	0.20	0.8
24–48 h	10 (32.3)	10 (32.3)	1.00 (0.35-2.90)	>0.99	>0.99

Data are mean ± SD or number of patients (%). PACU, post anesthetic care unit; h, hours; OR, odd ratio; CI, confidence interval.

p-value was analyzed using Chi-square test (Fisher's exact test) and Independent two sample t-test. Adjusted *p*-value was taken after multiple comparison with Bonferroni correction.

IV. DISCUSSION

This prospective randomized observer-blinded preliminary study was performed to compare the antiemetic efficacy of ramosetron compared with that of ondansetron in patients undergoing MVD with RMC until 48 hours after surgery, because such patients are at a higher risk for PONV than patients undergoing supratentorial craniotomy.[1,3,4] Unfortunately, although ramosetron had a trend of reducing the degree of nausea severity and incidence of dizziness between 6 and 24 hours compared with ondansetron, the antiemetic efficacy of ramosetron was not satisfactory and was comparable to that of ondansetron up to 48 hours after surgery.

The ondansetron group in this study exhibited a higher overall incidence of nausea (90.3%) and vomiting (61.3%) in patients undergoing microvascular decompression compared with a retrospective meta-analysis of craniotomy in adult patients.[5,10] In fact, retrospective analysis may underestimate the incidence of PONV unless patients complained of a mild degree of nausea. As findings of a secondary aim of this study that how long antiemetic medications should be given prophylactically for these patients, many patients in both group still nauseated (54.8% and 35.5%) and vomited (16.1% and 9.7%) between 24 and 48 hours and these patients may require antiemetic regimen at least until postoperative 48 hours. Our results were comparable with the previous study with infratentorial craniotomy[6], in which almost 50% of patients experienced nausea and 20% of patients vomited during 48 hours of postoperative period despite use of ondansetron 8 mg.

Being comparable to the controversy regarding the effects of ondansetron on PONV after craniotomy in adult patients,[5,10] ramosetron, a selective serotonin 5-HT_3 receptor antagonist, with a higher affinity to that receptor and a longer duration of action than ondansetron, was not sufficient in preventing PONV in patients undergoing MVD with RMC, as 87.1% and 54.8% of patients experienced nausea and vomiting up to 48 hours after surgery, respectively. Nevertheless, ramosetron showed a tendency of reducing the severity of nausea (OR = 0.30; 95% CI, 0.10-0.85; adjusted p = 0.08) and frequency of dizziness (OR = 0.34; 95% CI, 0.12-0.96; adjusted p = 0.16) between 6 and 24 hours after surgery. In addition, although not statistically significant, the incidence of nausea and vomiting with ramosetron was less than ondansetron between 24 and 48 hours after surgery. These results suggest that ramosetron alone may be too weak to prevent PONV in extremely high risk patients, although a better antiemetic effect of ramosetron compared with ondansetron was evident in less susceptible surgical circumstances up to 48 hours postoperatively.[7]

Perhaps another conflicting issue may exist regarding the antiemetic efficacy of 5-HT_3 antagonists. A randomized double-blind study for supratentorial craniotomy[11] found that the combination of ondansetron 4 mg and granisetron 1 mg is comparably effective in preventing emesis compared with placebo control for 24 hours postoperatively, while neither drug alone effectively prevented nausea. Likewise, Fabling et al.[12] found that ondansetron was able to reduce the nausea but not emesis in a study of supratentorial craniotomy.

Although ramosetron is superior to ondansetron in preventing PONV in patients undergoing other highly susceptible surgical circumstances such as lumbar spine surgery[8] or unilateral total knee replacement[9], we did not observe a satisfactory antiemetic effect with ramosetron in patients undergoing MVD with RMC. Thus, we could consider possible reasons why MVD with RMC is associated with significantly increased and prolonged risk of PONV compared with supratentorial craniotomy as well as other surgical procedures. As suggested by Eberhart et al.[13], blood clots or air around the surgical sites might trigger the nearby area postrema locating in vomiting center. Specifically, pneumocephalus is an unavoidable sequela of craniotomy[14] and may trigger the area postrema. Thus, reduction rate of pneumocephalus after craniotomy may provide insights as to why an antiemetic plan should be in place during the first 48 hours after surgery, as it resolves by 31% per day after craniotomy.[14] Interestingly, a prophylactic transdermal scopolamine patch administered preoperatively is associated with decreased PONV (OR = 0.3, p = 0.001) after MVD surgery[1].

There are several possible limitations of this study. First, we did not compare the antiemetic efficacy of ramosetron with that of placebo control, as a study design with a placebo control group would be inappropriate because the subjects were at an extremely high risk for PONV; almost 90% of patients experienced some degree of nausea, and more than 50% of patients vomited even though having taken either ondansetron or ramosetron. Secondly, we did not evaluate the antiemetic efficacy of

5-HT_3 antagonists combined with dexamethasone.[2,15] We also excluded the patients administered dexamethasone during perioperative period, because our institutional protocol regarding intraoperative brainstem auditory evoked potential (iBAEP) and facial electromyography recommends dexamethasone in cases of prolonged latency or decreased amplitude of wave V of iBAEP.[16] Thirdly, the anesthetic duration in group R lasted a little bit longer than that in group O (261.4 ± 53.3 minutes vs. 231.1 ± 41.0 minutes, $p = 0.01$); however, we considered that the small difference of 30 minutes would not significantly affect the antiemetic efficacy of ramosetron. Lastly, the sample size of our study may have been too small to sufficiently detect clinically significant differences between ramosetron and ondansetron; however, clinical trials for especially high risk patients for PONV should be enrolled as few patients as possible because severe nausea or vomiting after craniotomy is associated with higher morbidity and mortality as well as higher medical expenses. Therefore, this prospective study was performed preliminary in nature with at least 30 sample size in each group to pass the normality test.

V. CONCLUSION

In conclusion, this prospective preliminary observer-blind study of MVD with RMC may suggest some clinical implications. The antiemetic efficacy of ramosetron as a single agent was not satisfactory compared with ondansetron in patients undergoing MVD with RMC until postoperative 48 hours. Thus, a multimodal antiemetic approach may be necessary for at least 48 hours after surgery.

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ABSTRACT(IN KOREAN)

유양돌기 후방 개두술로 미세혈관감압술을 시행받은 환자에서 Ramosetron과 Ondansetron의 항구토 효과에 대한 비교

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하상희

배경: 유양돌기 후방 개두술로 미세혈관감압술을 시행받는 환자는 다른 수술에 비해 수술 후 오심 및 구토 (PONV)의 고위험군이다. 본 연구에서는 유양돌기 후방 개두술로 미세혈관감압술을 시행받은 환자에서 ramostron과 ondansetron의 항구토 효과를 비교해 보고자 한다.

방법: 전신마취 하 수술을 진행하였고, 경막을 닫을 때 ondansetron (8 mg, O군, n = 31)또는 ramosetron (0.3 mg, R군, n = 31)을 투여하였다. 회복실, 수술 후 6시간, 24시간, 48시간 네 시점에서 PONV의 빈도와 정도, 수술 후 투여된 항구토제, 항구토제의 부작용을 조사하였다. 통계학적 분석을 위해 Independent t-tests와 Chi-square test 혹은 Fisher's exact test를 사용하였다. 다중 비교를 위해 Bonferroni 검정법을 사용하였다.

결과: Demographic data에 있어 R군에서 약간 길어진 마취시간($p = 0.01$)

외에는 통계학적으로 유의한 차이는 없었다. 수술 후 48시간동안 오심과 구토의 전체 발생률은 O군에서 각각 90.1%와 61.3%, R군에서 87.1%와 54.8%였다. 수술 후 6시간에서 24시간 사이에 R군에 비해 O군에서 중등도의 오심을 더욱 호소하는 경향을 보였고(58.1% vs 29.0%, OR = 0.30; 95% CI, 0.10−0.85; adjusted p = 0.08), 어지러움의 발생률이 더 높았다(54.8% vs 29.0%, OR = 0.34; 95% CI, 0.12−0.96; adjusted p = 0.16).

결론: 유양돌기 후방 개두술로 미세혈관감압술을 시행받은 환자에서 수술 후 48시간 동안 ramosetron 단독의 효과는 만족스럽지 못했고, ondansetron과 비교해서도 더 우월하지 않았다.

핵심되는 말 : ramosetron, 수술 후 오심 및 구토, 미세혈관감압술