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ORIGINAL RESEARCH REGIONAL ANESTHESIA

Comparison of haloperidol and ondansetron in reducing the incidence of postoperative nausea and vomiting in patients undergoing subarachnoid block

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ABSTRACT

Background: Postoperative Nausea and Vomiting (PONV) is a common complication that disrupts patient recovery and increases healthcare costs. Effective management is crucial. This study compares the effectiveness of intravenous haloperidol and ondansetron in reducing PONV in patients undergoing Sub Arachnoid Block (SAB) anesthesia.

Methodology: A true experimental study using a double-blind randomized prospective cohort method was conducted at RSUP H. Adam Malik Medan and Rumah Sakit Umum Haji Medan to compare the effects of intravenous haloperidol and ondansetron on PONV in RA-SAB patients.

Result: The average age in the haloperidol group was 34.9 ± 2.03 years, while in the ondansetron group, it was 33.25 ± 2.39 years. Differences were observed in body weight, height, and BMI between the two groups. The incidence of PONV was significantly lower in the haloperidol group (2.5%) compared to the ondansetron group (30%) (P = 0.001). Conclusion: Intravenous haloperidol is more effective in reducing PONV incidence compared to ondansetron in RA-SAB patients.

Keywords: Postoperative Nausea and Vomiting (PONV), Haloperidol, Ondansetron, Sub Arachnoid Block (SAB).

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1. INTRODUCTION

Postoperative Nausea and Vomiting (PONV) is a common postoperative complication that can affect patient comfort, prolong recovery, increase healthcare costs, and elevate the risk of further complications such as infection and deep vein thrombosis (DVT).[1-4]

The global prevalence of PONV varies widely, reaching up to 70–80% in high-risk patients, including females, those with a history of PONV or motion sickness, and patients receiving general anesthesia and opioids.[2-7]

Regional anesthesia, such as subarachnoid Block (SAB), tends to reduce the incidence of PONV compared to general anesthesia; however, the risk remains present. Chekol et al. reported that Intraoperative Nausea and Vomiting (IONV) occurred in 36.8% of patients who received spinal anesthesia.[7] SAB is popular due to its effectiveness, safety, and additional benefits, such as profound analgesia, reduced intraoperative blood loss, and faster postoperative recovery.[8,9] Nevertheless, PONV continues to be a clinical challenge even among SAB patients.

Antiemetic agents such as haloperidol and ondansetron have been widely used for the prevention and treatment of PONV. Haloperidol exerts its antiemetic effect by blocking dopamine receptors, while ondansetron works by antagonizing 5-HT3 serotonin receptors, both proving effective in

suppressing nausea and vomiting.[8-10] Ondansetron has shown approximately 40% effectiveness in preventing PONV compared to 20% with placebo.[11]

However, direct comparative studies evaluating the efficacy of intravenous haloperidol and ondansetron specifically in SAB patients are still limited. Moreover, ondansetron is known to carry a risk of QT interval prolongation, particularly in patients with existing risk factors.[12] Therefore, this study aims to compare the effectiveness of intravenous haloperidol and ondansetron in preventing PONV among patients undergoing surgery with SAB, and to provide a scientific basis for the selection of optimal antiemetic therapy.[13] The findings are expected to support the development of standardized protocols for PONV management and enhance the quality of postoperative care.

2. METHODOLOGY

2.1. Study Design

This study was a true experimental design using a double-blind randomized prospective cohort method. It aimed to compare the intraoperative intravenous administration of haloperidol and ondansetron in reducing the incidence of postoperative nausea and vomiting (PONV) among patients undergoing regional anesthesia Sub Arachnoid Block (RA-SAB). The study was conducted at RSUP H. Adam Malik Medan and Rumah Sakit Umum Haji Medan after obtaining ethical approval. (Number: 1511/KEPK/USU/2024)

2.2. Population and Samples

The target population comprised patients undergoing elective surgery under RA-SAB at the two hospitals. Inclusion criteria were: male patients aged 18–60 years, non-smokers, undergoing surgical procedures involving the gastrointestinal, pelvic, genital, perineal, or urologic regions in supine position, and having stable hemodynamic status. Exclusion criteria included the use of combined spinal and epidural anesthesia, history of allergy to haloperidol or ondansetron, presence of systemic infection, neuropathy, coagulopathy, severe anxiety or psychiatric conditions, neuromuscular disorders, hormonal imbalances, gastritis, or pregnancy. Subjects were also excluded if complications arose (e.g., shock), if general anesthesia had to be used due to block failure, or if surgery duration extended abnormally. The sampling technique used was non-probability consecutive sampling, enrolling all eligible patients sequentially until the sample size was achieved. Sample size was calculated using a cohort risk-based formula with $\alpha = 5\%$, $Z\alpha = 1.96$, $Z\beta = 0.84$, and prior proportion (P1) estimates based on previous studies.

2.3. Study Instruments

The instrument used for this study was a structured and validated questionnaire adapted from the Simplified Postoperative Nausea and Vomiting Impact Scale developed by Myles and Wengritzky (2012). The instrument had been previously tested for validity and reliability ($P < 0.0005$). It comprised two main items:

1. The frequency of vomiting or dry retching, scored from 0 (none) to 3 (≥3 episodes), and
2. The degree to which nausea interfered with daily activities.

2.4. Data Collection

Data collection was performed during surgery and continued for 24 hours postoperatively. Participants were randomly assigned into two groups: the haloperidol group and the ondansetron group. Each subject received the respective antiemetic intravenously during the intraoperative period. Both patients and clinical observers were blinded to group assignment. Observations included the incidence of nausea, vomiting, and any side effects such as sedation or dizziness.

2.5. Data Analysis

Data analysis was conducted using SPSS version 26.0. The Shapiro-Wilk test was applied to assess the normality of data distribution. Continuous variables were expressed as mean ± standard deviation or median with interquartile range, depending on data distribution. Differences between groups were analyzed using independent t-tests or Mann–Whitney U tests for continuous data, and Chi-square tests for categorical variables. A P-value less than 0.05 was considered statistically significant.

3. RESULTS

A total of 40 male patients were enrolled in the study and randomly assigned into two equal groups: intravenous haloperidol group (n=20) and intravenous ondansetron group (n=20). All participants were male (100%). The mean age in the haloperidol group was 34.9 ± 2.03 years, compared to 33.25 ± 2.39 years in the ondansetron group ($P = 0.601$). Patients in the haloperidol group had a lower mean weight (66.35 ± 2.46 kg) and height (169.05 ± 2.64 cm) than those in the ondansetron group (74.65 ± 3.36 kg and 173.35 ± 2.12 cm, respectively). The average Body Mass Index

(BMI) was 23.39 ± 0.96 in the haloperidol group and 25.00 ± 1.40 in the ondansetron group.

In terms of APFEL risk score distribution, the haloperidol group had more patients in the low-risk category (score 0–1), accounting for 16 patients

(40%), and 4 patients (10%) in the mild-to-moderate risk category (score 2).

No patients in this group were classified as high or very high risk. In contrast, the ondansetron group had 10 patients (25%) in the low-risk group, 2 patients (5%) with moderate risk, and 8 patients (20%) classified as high (score 3) or very high risk surgery with Sub Arachnoid Block (RA-SAB). .

A significant difference was found in the incidence of PONV between the two treatment groups. In the haloperidol group, only 1 patient (2.5%) experienced PONV, while in the ondansetron group, 12 patients (30%) developed PONV. Conversely, 19 patients (47.5%) in the haloperidol group had no PONV, compared to only 8 patients (20%) in the ondansetron group. The difference was statistically significant (P = 0.001), indicating that intravenous haloperidol was more effective than ondansetron in reducing the occurrence of PONV.

The calculated relative risk (RR) of developing PONV in patients receiving haloperidol was 0.083, with a 95% confidence interval ranging from 0.05 to 0.13. This means that patients who received haloperidol had an approximately 91.7% lower risk of developing PONV compared to those who received ondansetron. These results clearly indicate that intravenous haloperidol is significantly more effective in reducing PONV than intravenous ondansetron in male patients undergoing surgery under subarachnoid block (RA-SAB).

Table 1: Patient characteristics and APFEL score distribution

Parameter	Haloperidol group	Ondansetron group	P-value
Gender			
Male	20 (100)	20 (100)	-
Female	0 (0)	0 (0)	
Age (years)	34,9 ± 2,03	33,25 ± 2,39	0,60[1]
Body weight (kg)	66,35 ± 2,46	74,65 ± 3,36	0,54[1]
Height (cm)	169,05 ± 2,64	173,35 ± 2,12	0,21[1]
BMI (kg/m²	23,39 ± 0,96	25 ± 1,4	
APFEL Score			
Low Risk (Score 0-1)	16 (40)	10 (25)	
Mild-Moderate Risk (Score 2)	4 (10)	2 (5)	0,31[2]
High Risk (Score 3)	0 (0)	4 (10)	
Very High Risk (Score 4)	0 (0)	4 (10)	

[1] Independent T-test; [2] Mann-Whitney U Test ' P < 0.05 was significant

4. DISCUSSION

This study aimed to evaluate the effectiveness of intravenous haloperidol compared to ondansetron in reducing the incidence of Postoperative Nausea and Vomiting (PONV) in male patients undergoing The results showed that PONV occurred in only 1 patient (2.5%) in the haloperidol IV group, while 12 patients (30%) in the ondansetron IV group experienced PONV. This difference was statistically significant with a p-value of 0.001. The Relative Risk (RR) for PONV in the haloperidol group was 0.083, with a 95% Confidence Interval (CI) ranging from 0.05 to 0.13, indicating that intravenous haloperidol was significantly more effective in preventing PONV.

These findings are supported by the pharmacological mechanism of haloperidol, which acts as a dopamine D2 receptor antagonist in the chemoreceptor trigger zone (CTZ). The low incidence of PONV in this group is consistent with prior research by Schmidt, (2020) and Ju et al., (2023) highlighting haloperidol's antiemetic effects.[1,6] The study results also reinforce evidence from other clinical trials suggesting that low-dose haloperidol (≤ 2 mg) is safe and effective when used for short-term prophylaxis of nausea and vomiting.

Meanwhile, ondansetron, a 5-HT3 receptor antagonist, showed a higher rate of PONV in this study, which may be partially explained by the higher APFEL risk score distribution in the ondansetron group in earlier studies by Johansson et al. (2021) and Chekol et al. (2021).[7,10] Specifically, the ondansetron group had 4 patients (10%) in the high-risk (score 3) category and 4 patients (10%) in the very high-risk (score 4) category, while the haloperidol group had none (0%) in these categories. This suggests that baseline PONV risk factors may have influenced the outcomes despite ondansetron's recognized efficacy.

Table 2: Incidence of postoperative nausea and vomiting (PONV)

Group	PONV	PONV No	*Mean ± SD*	*P*-value	Relative Risk (RR)
Haloperidol	1 (2.5%)	19 (47.5%)	23.40 ± 4.28	0.001	0.083 (95% CI: 0.05–0.13)
Ondansetron	12 (30%)	8 (20%)	25.20 ± 6.26	–	–

Data presented as n (%) or mean ± SD

Another important aspect is safety. In the haloperidol group, 1 patient (5%) experienced mild sedation, but no extrapyramidal symptoms, bradycardia, dizziness, or allergic reactions were reported by Kwak, (2017) and Yu, et al., (2019).[12,13] similarly, no adverse effects were observed in the ondansetron group. These findings support previous literature reporting that low-dose haloperidol is generally well tolerated and does not frequently result in adverse neurologic effects, particularly when used in small, single doses.

This study also demonstrated hemodynamic stability in both treatment groups, with no significant intraoperative complications requiring intervention.[3,8] Therefore, both drugs can be considered hemodynamically safe for patients undergoing RA-SAB, although haloperidol appears superior in preventing PONV under the specific conditions of this study.

However, this study has several limitations. First, it only included male patients, which may limit generalizability, as females generally have a higher incidence of PONV. Second, the sample size (n=40) was relatively small, potentially limiting the ability to detect rare side effects. Third, the study did not evaluate other relevant postoperative outcomes such as pain scores, time to mobilization, or patient satisfaction, which could provide a more comprehensive assessment of recovery quality.

Given the favorable outcomes observed with haloperidol, future research should consider larger, multi-center studies, include female patients, and assess combination antiemetic regimens. Furthermore, incorporating cost-effectiveness analyses and patient-reported outcomes will be valuable in guiding clinical decision-making.

5. CONCLUSION

This study demonstrated that intravenous haloperidol is significantly more effective than intravenous ondansetron in reducing the incidence of Postoperative Nausea and Vomiting (PONV) in male patients undergoing surgery with Sub Arachnoid Block (RA-SAB). The incidence of PONV was substantially lower in the haloperidol group (2.5%) compared to the ondansetron group (30%), with a statistically significant (P = 0.001) and a relative risk (RR) of 0.083; 95% CI: 0.05–0.13. In addition to its superior efficacy, haloperidol was well tolerated, with only one mild case of sedation reported and no serious adverse events in either group. These findings suggest that haloperidol 1–2 mg IV may serve as an effective and safe alternative to ondansetron for PONV prevention, particularly in settings with limited resources or in patients at low to moderate risk.

6. LIMITATIONS

However, due to the study's limited sample size and focus on male patients, further research with larger, gender-balanced populations and diverse surgical settings is recommended to confirm these findings and support broader clinical application. Future studies should also evaluate long-term safety, cost-effectiveness, and patient satisfaction outcomes.

7. Data availability

Numerical data generated during this study in available with the authors/

8. Conflicts of interest

All authors declare no conflict of interest.

9. Author contribution

RR: the study conception and design, data collection, statistical analysis, interpretation of results, and drafting of the manuscript.
.APL: provided academic supervision, assisted in methodology validation, and critically revised the manuscript for important intellectual content

MI: the refinement of the study design, literature review, and final review of the manuscript before submission.

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