

The Effect of Intranasal Dexamethasone in Preventing Postoperative Nausea and Vomiting Among Children Having Laparoscopic Surgery: A Randomized Controlled Trial

Hamidreza Shetabi¹, Amir Shafa^{1*}, Mehrdad Norouzi¹, Zahra Rahimi¹, Ali-Mohammad Bameri²

¹Anesthesiology and Critical Care Research Center, Department of Anesthesiology, Isfahan University of Medical Sciences, Isfahan, Iran.

²Anesthesiology and Critical Care Research Center, General Medicine, Isfahan University of Medical Sciences, Isfahan, Iran.

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ABSTRACT

Background: After laparoscopic surgery, children often experience postoperative nausea and vomiting (PONV), a common issue that can affect up to 70% of patients if no preventive steps are taken. While dexamethasone administered through an IV has been thoroughly studied for preventing PONV, there's much less information available about using it nasally. This study set out to explore how effective intranasal dexamethasone is and how long its benefits last in reducing PONV in pediatric patients.

Methods: In our study, we split 116 children aged 2 to 15 years, all preparing for laparoscopic surgery, into two groups after anesthesia started: one group (IND) received intranasal dexamethasone at a dose of 0.2 mg per kg, while the other group (INS) was given normal saline as a placebo. The main focus was on PONV rates over the initial 24 hours postoperatively.

Results: In the first 24 hours, PONV hit 24.1% in the dexamethasone arm compared to 46.6% in saline (odds ratio 0.38, 95% CI from 0.20 to 0.70; $p=0.002$). The onset of first nausea or vomiting came later, and fewer kids needed backup antiemetics (21% vs. 40%). Post-anesthesia care unit (PACU) time was cut by about 18 minutes on average in the IND group (95% CrI -30 to -7). Parents gave higher marks for satisfaction, with 81% rating 4 or above versus 55% in INS.

Conclusion: Intranasal dexamethasone reduces nausea and vomiting after laparoscopic surgery in children within the first 24 hours. Intranasal dexamethasone administration is a useful option for preventing PONV in children.

Introduction

Postoperative nausea and vomiting (PONV) is a distressing complication following pediatric anesthesia, with a frequency of occurrence in children ranging from approximately 30% in non-elective surgeries to 80% in procedures such as ENT or laparoscopic surgeries [1-2]. In children, PONV is not

only considered uncomfortable but also a factor in delayed oral intake, increased need for analgesics, unplanned readmissions, and decreased parental satisfaction, which imposes a clinical and economic burden on perioperative services [1,3]. Laparoscopic surgery in children carries particular risk for PONV because of pneumoperitoneum, visceral manipulation, and often longer anesthetic exposure, making effective prophylaxis a high priority in pediatric perioperative

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*Corresponding author.

E-mail address: shafa_amir@yahoo.com

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planning [2-3]. Dexamethasone, a glucocorticoid with proven antiemetic properties, occupies a central role in multimodal PONV prophylaxis. Multiple randomized trials and meta-analyses in pediatric and adult populations have demonstrated that a single perioperative dose of dexamethasone reduces PONV incidence and the need for rescue antiemetics, without a consistent signal for increased surgical-site infection when used in single doses [4–7]. In children, preoperative dexamethasone has been associated with clinically meaningful absolute risk reductions in PONV across a variety of procedures, and it is a recommended agent within contemporary consensus guidelines for PONV management [3,5,8]. Nevertheless, most of the high-quality evidence pertains to intravenous administration; alternative routes that are less invasive and more suitable for pediatric use, such as intranasal delivery, remain understudied.

Intranasal delivery of medications has clear practical advantages in pediatrics: it avoids venipuncture, is rapid to administer, and supplies a route that may yield both local and systemic absorption via the highly vascular nasal mucosa [9]. Recent pharmacokinetic investigations comparing intranasal and intravenous dexamethasone report substantial systemic bioavailability after intranasal dosing and a T_{max} compatible with perioperative prophylaxis, supporting physiological plausibility for an antiemetic effect via the intranasal route [6]. Moreover, a limited number of clinical studies have begun to evaluate intranasal dexamethasone for postoperative symptoms in children; early randomized evidence suggests potential benefit but is sparse, small in scale, and heterogeneous in endpoints and patient populations [6,10].

Important gaps in knowledge therefore remain. First, the time course of intranasal dexamethasone's antiemetic efficacy across clinically relevant postoperative windows (early: 0–6 h; intermediate: 6–12 h; late: 12–24 h) has not been rigorously characterized in pediatric laparoscopic populations. Second, previous studies have focused largely on intravenous dosing; direct comparisons or robust, adequately powered RCTs of intranasal administration in children are limited. Finally, there is a need to integrate modern analytic approaches (including hierarchical and Bayesian models) to quantify treatment effects while accounting for age, surgical type, and other confounders that influence PONV risk in pediatrics [3,11]. In order to fill in these gaps, we investigated the standard of these medications on children (undergoing elective laparoscopic surgery) by conducting a randomized, double-blind, clinical trial aimed at estimating the effects of a single intraoperative dose of dexamethasone (0.2 mg/kg) intranasally on the rates and intensities of postoperative nausea and vomiting (PONV). We sequentially evaluated the participants in PONV at 2, 6, 12, and 24 hours after surgery. The trial was designed to include an adequate sample size to achieve a clinically meaningful decrease in PONV,

included a stratified random assignment by age and type of operation, and was based on which the choice of analysis plan to assess and reproduce a dependable and generalizable estimate of the effect of treatment was made. This approach aligns with current guideline recommendations for multimodal and risk-adjusted prophylaxis while exploring a child-friendly, non-invasive route of administration that could broaden options for pediatric anesthesia practice [3-4,6,10].

Methods

Study Design

This study was conducted as a prospective randomized double-blind placebo-controlled clinical trial at the Imam Hossein Pediatric Surgery Center, affiliated with Isfahan University of Medical Sciences. The protocol was in accordance with the CONSORT guidelines for randomized clinical trials. The study was registered with the Iranian Clinical Trials Center under the code IRCT20180416039326N24. The study has ethical approval from Isfahan University of Medical Sciences with the code IR.MUI.MED.REC.1403.144. Informed written consent was also obtained from parents or legal guardians, and, if necessary, from children over 7 years of age.

Participants

Eligible participants were children aged 2–15 years scheduled for elective laparoscopic surgery under general anesthesia. Procedures included laparoscopic appendectomy, hernia repair, and diagnostic laparoscopy.

Inclusion criteria included ASA physical status I–II, surgical duration expected between 30 and 120 minutes, and no evidence of nasal obstruction on physical examination. Also known allergy or contraindication to corticosteroids, prior immunosuppressive therapy or chronic corticosteroid use, history of motion sickness or prior severe PONV requiring hospitalization, developmental delay or neurological conditions impairing reliable assessment of nausea, and upper respiratory tract infection or nasal obstruction at the time of surgery were excluded.

Randomization and Blinding

Participants were randomly assigned in a 1:1 ratio to receive intranasal dexamethasone or saline. Randomization was stratified by age group (2–6, 7–11, 12–15 years) and surgical type (appendectomy vs. other laparoscopic procedures) using computer-generated permuted blocks of variable sizes (4–8). Similar disposable syringes containing either saline or dexamethasone were supplied by the operating room pharmacy; they were simply marked with the patient study ID. Intranasal dexamethasone or a placebo was administered to participants at random in a 1:1 ratio.

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Intervention

Children in the intervention group received intranasal dexamethasone at 0.2 mg/kg (maximum 8 mg) immediately after induction of anesthesia. This dose was selected based on pharmacokinetic data demonstrating high systemic bioavailability (75.8%) for intranasal dexamethasone in adults (6), with the goal of achieving systemic exposure comparable to or greater than the effective intravenous dose of 0.1–0.15 mg/kg used for PONV prophylaxis in children. The control group received an equivalent volume of sterile 0.9% saline intranasally. The control group received an equivalent volume of 0.9% sterile saline intranasally. All patients underwent standard general anesthesia with propofol and fentanyl, maintained with sevoflurane and atracurium. Intraoperatively, morphine 0.1 mg/kg was used as an analgesic. In case of severe vomiting or nausea, ondansetron was administered in the post-anesthesia care unit (PACU) or in the inpatient ward according to current pediatric PONV guidelines [12–14]. A standard protocol using acetaminophen and ibuprofen was used for postoperative pain relief, with morphine reserved for rescue analgesia only.

Primary Outcome

The primary endpoint was the presence of PONV at any time during the 24-hour postoperative period. PONV was evaluated at predefined time points (2, 6, 12, and 24 hours). The severity of nausea was assessed using the Pediatric Nausea Assessment Scale (PNAS), a validated 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe) [15]. To ensure consistent and reliable assessment across the pediatric age range, the operationalization of the PNAS was age-adapted. For children aged 7 years and older who could provide a self-report, the score was primarily based on the child's verbal description of their nausea, guided by a standardized script (e.g., "Do you feel sick to your stomach?"). For non-verbal children or those under the age of 7, the PNAS score was determined by a trained nurse observer based on a predefined set of objective and behavioral signs. These signs included: observed episodes of retching or gagging without emesis, persistent pallor, reports of refusal to take oral fluids or food despite encouragement, increased and persistent crying or irritability not

attributable to pain (as assessed by the primary nurse), and observable signs of diaphoresis. The observing nurse integrated these observations to assign a single PNAS score. All nursing staff involved in postoperative assessment received standardized training on this protocol prior to the commencement of the study to enhance inter-rater reliability. While every effort was made to distinguish nausea-specific signs from those of pain (e.g., by consulting the primary nurse's pain assessment and the analgesic administration record), we acknowledge the potential for confounding in this patient population.

Secondary Outcomes

Time to first PONV episode, analyzed using Kaplan–Meier survival methods. Rescue antiemetic requirement, defined as the administration of ondansetron 0.1 mg/kg IV. Postoperative recovery profile including duration of post-anesthesia care unit (PACU) stay and readiness for discharge, measured using validated Aldrete and modified Steward recovery scores. Parents shared how satisfied they were with their child's care a day after surgery, using a Likert scale, a simple scale from 1 to 5, where 1 meant "very dissatisfied" and 5 meant "very satisfied." We also kept a close eye out for any side effects during the first 24 hours after surgery, such as nose irritation, headaches, high blood sugar (above 150 mg/dL), or any other issues that might be linked to steroid use, and carefully noted them down. Morphine use, including: Proportion of children receiving morphine, stratified by age group. Cumulative morphine dose administered in each group. Timing of first morphine administration, analyzed as a time-to-event outcome. The sample size calculation was performed a priori for the primary outcome of cumulative PONV incidence over the 24-hour postoperative period. The assumptions were based on a systematic review of pediatric laparoscopic studies and randomized trials of dexamethasone for PONV prophylaxis [14–16], which indicated a baseline (placebo) PONV incidence of approximately 45%. We defined a clinically meaningful absolute risk reduction of 25%, corresponding to an expected PONV incidence of 20% in the intervention group. Using these parameters (control proportion $P_1 = 0.45$, intervention proportion $P_2 = 0.20$), the minimum required sample size was calculated using the standard formula for comparing two independent proportions (two-sided chi-square test), with an alpha (α) error of 0.05 and a power ($1-\beta$) of 80%. This calculation yielded a requirement of 52 patients per group.

Statistical Analysis

We utilized R (version 4.2.1) to perform all analyses. For the main outcome (cumulative 24-hour PONV incidence), the estimated odds ratio (OR) with 95% confidence interval (CI) was calculated based on a

frequentist logistic regression model. We also performed a secondary analysis of PONV incidence at the 2, 6, 12, and 24-hour time points using a Bayesian hierarchical logistic regression model.

This model included a fixed effect for treatment group and time point (as a categorical factor), with a random intercept for patient ID to account for repeated measurements.

The model utilized weakly informative priors: a normal distribution with a mean of 0 and a standard deviation of 2.5 for fixed-effects coefficients and exponential distributions with a rate of 1 for the standard deviation of random intercepts.

Posterior distributions were sampled through Markov Chain Monte Carlo (MCMC), incorporating 4 chains of 10,000 iterations with a 5,000-iteration warm-up. Model convergence was confirmed by ensuring all R-hat statistics were ≤ 1.01 . Results from the Bayesian analysis are reported as posterior median ORs with 95% credible intervals (CrIs) and the posterior probability $P(\text{OR} < 1)$. Description of analyses for continuous outcomes (PACU stay, morphine dose), categorical outcomes (parental satisfaction, discharge readiness), time-to-event analyses, and PNAS scores.

The adequacy of the sample size for Bayesian inference was confirmed through simulation studies as described in the Sample Size Estimation section.

Results

Participant Flow and Baseline Characteristics. A complete screening was performed on a total of 128 children, out of which 116 were eligible after applying the criteria and then randomly assigned to the groups: 58 in the dexamethasone group and 58 in the placebo group. All the subjects attended the postoperative follow-up at the end of 24 hours. Baseline demographics and surgical characteristics are summarized in (Table 1). The two groups were comparable in terms of age, gender, body weight, ASA status, and laparoscopic surgery type and operation time. Main outcome: PONV incidence, the overall occurrence of PONV within 24 h was 24.1% in patients who received dexamethasone and 46.6% in those receiving placebo. Frequentist logistic regression of the primary outcome, 24-hour PONV incidence, showed an OR of 0.38 (95% CI 0.20–0.70), $p = 0.002$, in favor of dexamethasone. A preplanned secondary analysis of PONV incidence at specific time points revealed a time-dependent treatment effect. A preplanned secondary analysis of the incidence of PONV at individual time points revealed a time-dependent treatment effect. The protective action was strongest at the 6-hour measurement (OR 0.32, 96% $P(\text{OR} < 1)$), remained significant at 12 hours (OR 0.35, 95% $P(\text{OR} < 1)$), and was still present but weaker by 24 hours (OR 0.44, 92% $P(\text{OR} < 1)$) (Table 2). This data is a picture of a very strong early effect that progressively weakens over the 24 hours.

Table 1- Baseline Characteristics of Study Participants

Characteristic	Overall (n=116)	Dexamethasone (n=58)	Placebo (n=58)	95% CI (Overall)	P value
Age (years)	8.7±3.8	8.5±3.7	8.8±3.9	7.96–9.34	0.78
Weight (kg)	28.2±10.1	28.4±9.8	27.9±10.3	26.32–29.98	0.81
Female sex	51 (44.0)	26 (44.8)	25 (43.1)	35.0–53.0	0.88
ASA physical status I–II	81 (69.8)	41 (70.7)	40 (69.0)	61.5–78.1	0.91
Surgery type:	71 (61.2)	35 (60.3)	36 (62.1)	52.3–70.1	0.82
Appendectomy					
Surgery type: Other laparoscopic	45 (38.8)	23 (39.7)	22 (37.9)	29.9–47.7	0.82
Operation time (min)	66.6±18.0	66.2±17.9	66.9±18.1	63.3–69.8	0.66
Recovery time (min)	50.0±15.1	50.1±15.2	49.8±14.9	47.2–52.7	0.60

Baseline characteristics presented as mean \pm SD or n (%). Groups compared by t-tests (continuous) or χ^2 tests (categorical). Overall estimates shown with 95% CIs. ASA = American Society of Anesthesiologists; CI = confidence interval; SD = standard deviation.

Table 2- Secondary analysis of PONV incidence at specific postoperative time points

Time point	Dexamethasone, n (%)	Placebo, n (%)	Bayesian Median OR (95% CrI)	P(OR < 1) (%)	Frequentist P value
2 hours	5 (8.6)	12 (20.7)	0.37 (0.15–0.78)	94	0.032
6 hours	7 (12.1)	17 (29.3)	0.32 (0.14–0.70)	96	0.018
12 hours	9 (15.5)	21 (36.2)	0.35 (0.16–0.78)	95	0.021
24 hours	12 (20.7)	24 (41.4)	0.44 (0.21–0.88)	92	0.035

Secondary analysis of PONV incidence at specific time points. The Bayesian hierarchical logistic regression model (see Methods for specifications), which accounted for repeated measures within patients via a random intercept, estimated posterior median ORs, 95% CrIs, and posterior probability $P(\text{OR} < 1)$. Frequentist P values are provided from a corresponding mixed-effects logistic regression model as a sensitivity analysis. CrI = credible interval; OR = odds ratio

Secondary Outcomes

Antiemetic Use: Fewer children in the dexamethasone group required rescue antiemetics (10.3% vs. 34.5%; Bayesian OR 0.23, 95% CrI 0.09–0.52, $P(\text{OR}<1)=97\%$). The median time to the first rescue antiemetic dose was delayed with dexamethasone (15 hours, 95% CrI 12–19) vs. placebo (7 hours, 95% CrI 5–10). Postoperative recovery profile: The mean PACU stay was shorter in the dexamethasone group (62 ± 12 min) compared with the placebo (80 ± 15 min), with a mean difference of 18 min; 95% CrI from -30 to -7 ; $p = 0.002$. Time to discharge readiness was also reduced, consistent with faster recovery scores. Parental satisfaction was higher in the dexamethasone group, with 81% rating satisfaction $\geq 4/5$ vs. 55% in the placebo group. The ordinal logistic regression showed that dexamethasone had a cumulative OR of 2.9, 95% CrI 1.4–6.1, $p = 0.004$. **Morphine Use:** The proportion of children receiving morphine was 24% in the dexamethasone group and 28% in the placebo group. The Bayesian analysis yielded an odds ratio of 0.81, but the 95% credible interval was wide (0.35 to 1.80). This indicates that the findings could be compatible with both a clinically meaningful reduction and an increase in the need for morphine. This study likely suffered from a lack of power for this outcome. The cumulative morphine dose (0.045 ± 0.01 mg/kg vs 0.048 ± 0.01 mg/kg, $p = 0.45$), as well as the time to first morphine administration (Kaplan-Meier analysis, $p = 0.52$), did not demonstrate significant differences. Age was also analyzed as a potential variable; however, we did not find evidence of a clinically relevant interaction between age group and treatment. **Adverse Events:** No serious adverse events were observed in either group. Three (5%) children in the dexamethasone group and 1

child (2%) in the placebo group developed mild nasal irritation (OR 2.6, CrI 95%: 0.25–27.0; $p = 0.41$). No cases of headache, hyperglycemia, or steroid-related complications were reported (Table 3).

Discussion

This randomized, double-blind, placebo-controlled trial demonstrates that a single perioperative dose of intranasal dexamethasone (0.2 mg/kg) significantly reduces the incidence and severity of postoperative nausea and vomiting (PONV) in children undergoing laparoscopic surgery. Our findings are robust, supported by both frequentist and Bayesian analytical frameworks, which collectively indicate a clinically meaningful benefit. The observed reduction in the 24-hour cumulative PONV incidence from 46.6% to 24.1% with intranasal dexamethasone aligns with the established efficacy of intravenous dexamethasone for PONV prophylaxis [4,7,17]. This study, however, extends the evidence base by confirming that the intranasal route, with its high systemic bioavailability [6], provides effective systemic antiemetic action. A particularly compelling finding was the significant delay in the time to the first PONV episode, with a median of 24.0 hours in the intervention group versus 6.5 hours in the placebo group. This more than threefold prolongation of the nausea- and vomiting-free period is a critical patient-centered outcome that enhances early recovery comfort. Our time-course analysis provides a nuanced profile of the drug's efficacy. The protective effect was most potent within the first 6 hours postoperatively, corresponding with the period of highest emetic risk during emergence and early recovery.

Table 3- Secondary Outcomes, Morphine Use, and Adverse Events

Outcome	Dexamethasone (n=58)	Placebo (n=58)	Effect Estimate (95% CI or CrI)	P value or P (Effect)
Rescue antiemetic use ≤ 24 h	6 (10.3%)	20 (34.5%)	OR: 0.23 (0.09 to 0.52) Bayesian $P(\text{OR}<1) = 97\%$	0.001
Time to first PONV (h)	24.0 (18.0 - 24.0)	6.5 (4.0 - 12.0)	HR: 0.42 (0.25 to 0.69)	<0.001
Time to first rescue antiemetic (h)	15.0 (10.0 - 22.0)	7.0 (4.0 - 12.0)	HR: 0.40 (0.22 to 0.75)	0.003
PACU stay (min)	62 ± 12	80 ± 15	MD: -18 (-30 to -7)	0.002
Discharge ready ≤ 6 h	48 (82.8%)	36 (62.1%)	OR: 2.9 (1.3 to 6.8)	0.012
Parental satisfaction $\geq 4/5$	47 (81.0%)	32 (55.2%)	cOR: 2.9 (1.4 to 6.1)	0.004
Proportion receiving morphine	14 (24.1%)	16 (27.6%)	OR: 0.81 (0.35 to 1.80) Bayesian $P(\text{OR}<1) = 67\%$	0.600
Cumulative morphine dose (mg/kg)	0.045 ± 0.01	0.048 ± 0.01	MD: -0.003 (-0.011 to 0.005)	0.450
Mild nasal irritation	3 (5.2%)	1 (1.7%)	OR: 2.6 (0.25 to 27.0)	0.410

Data are presented as n (%), mean \pm standard deviation (SD), or median (interquartile range, IQR). Effect estimates are presented as Odds Ratio (OR), Cumulative Odds Ratio (cOR), Hazard Ratio (HR), or Mean Difference (MD) with 95% Confidence Interval (CI) or 95% Credible Interval (CrI). Bayesian posterior probabilities $P(\text{Effect})$ are reported for prespecified Bayesian analyses. PACU = post-anesthesia care unit.

This timing is physiologically plausible, as it aligns with the expected peak plasma concentration (Tmax) after intranasal administration [6].

The effect remained substantial at 12 hours but showed clear attenuation by 24 hours, consistent with the drug's elimination half-life. This temporal pattern is crucial for clinical strategy: intranasal dexamethasone serves as an excellent foundational agent for early prophylaxis but should be integrated into the multimodal regimens advised by current consensus guidelines [1,3] to ensure coverage over the entire 24-hour postoperative period, potentially by combining it with longer-acting antiemetics.

The intervention also led to a marked reduction in the need for rescue antiemetics, from 34.5% in the placebo group to 10.3% with dexamethasone (OR 0.23). This substantial decrease underscores the intervention's capacity to not only prevent but also mitigate the severity of PONV, thereby reducing the burden on nursing staff and streamlining postoperative care.

A key practical advantage of the intranasal route in pediatric anesthesia is its non-invasive nature. It avoids the distress and logistical challenges of preoperative venipuncture, can be administered rapidly after anesthetic induction, and integrates seamlessly into the perioperative workflow [9, 18].

These features may improve adherence to PONV prophylaxis protocols and support a shift toward more patient-centered care, particularly in children. The significantly higher parental satisfaction in the intervention group (81% vs. 55%) likely reflects this combination of reduced patient distress and improved clinical outcomes.

Contrary to some studies on intravenous dexamethasone, we did not find conclusive evidence for a statistically significant opioid-sparing effect. Morphine consumption was low in both groups, likely due to our standardized multimodal analgesic regimen of scheduled acetaminophen and ibuprofen.

The observed difference in the proportion of children receiving morphine was not significant, and the confidence intervals were wide, indicating substantial uncertainty. Therefore, while a potential indirect benefit through improved comfort remains plausible, our study cannot confirm a meaningful effect on opioid requirements.

The application of Bayesian analysis enriched our interpretation by providing direct probabilistic statements about treatment efficacy. For instance, the posterior probability of dexamethasone reducing PONV risk exceeded 92% at all assessed time points and was 97% for reducing rescue antiemetic use.

This approach complements frequentist statistics by quantifying the probability of the effect given the observed data, which can be more intuitive for clinicians weighing the evidence for implementation [11,19].

Limitations

Several limitations of our study warrant consideration. First, the single-center design may affect the generalizability of our findings, as results can be influenced by local surgical and anesthetic practices. Second, the assessment of nausea in younger, nonverbal children, despite using a validated scale (PNAS) with standardized training, remains challenging. Reliance on behavioral proxies such as irritability or pallor introduces a risk of measurement bias, as these signs are non-specific and can be confounded by pain or emergence of delirium. Although we attempted to mitigate this by cross-referencing pain assessments, future studies would benefit from a formal inter-rater reliability assessment. Finally, while the sample size was adequate for our primary analysis, the study was likely underpowered to detect smaller effects on secondary outcomes like morphine consumption.

Conclusion

Intranasal dexamethasone is an effective, well-tolerated, and practical non-invasive option for PONV prophylaxis in children undergoing laparoscopic surgery, providing robust protection especially within the first 12 hours postoperatively. Its efficacy profile and ease of administration position it as a valuable component of multimodal antiemetic strategies in pediatric anesthesia. Future research should include multicenter trials directly comparing the intranasal and intravenous routes to establish their relative efficacy, cost-effectiveness, and roles within comprehensive pediatric PONV management protocols.

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