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Comparison of Propofol and Fentanyl for Preventing Emergence Agitation Following Sevoflurane Anesthesia in Pediatric Patients: A Single-Center Study in Bangladesh

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Abstract

Background: Emergence agitation (EA) is a common phenomenon observed in pediatric patients following general anesthesia. This study aimed to assess the efficacy of propofol and fentanyl in preventing EA and to compare their associated complications or side effects. **Methods:** This prospective randomized observational comparative study was conducted at Dhaka Medical College Hospital from July 2013 to June 2014. The study aimed to evaluate the effects of propofol and fentanyl on EA in children aged 18 to 72 months undergoing circumcision, herniotomy, and polypectomy operations. Ninety children were included in the study, with 45 in each group. Patients with psychological or neurological disorders were excluded. Various parameters including age, sex, weight, American Society of Anesthesiologists (ASA) class, duration of anesthesia, Saturation of Peripheral Oxygen (SPO_2), heart rate (HR), respiratory rate (RR), Pediatric Anesthesia Emergence Delirium (PAED) score, duration of post-anesthesia care unit (PACU) stay, incidence of laryngospasm, nausea, vomiting, and rescue drug requirement were compared between the two groups. **Results:** Age, sex, weight, ASA class, and duration of anesthesia were comparable between the two groups. Perioperative

SpO_2 and HR were similar in both groups. However, the PAED score was significantly higher in the fentanyl group during all follow-ups except at 30 minutes postoperatively. The mean duration of PACU stay was significantly longer in the fentanyl group. Although the incidence of laryngospasm was higher in the fentanyl group, it was not statistically significant. Conversely, nausea or vomiting was significantly higher in the fentanyl group. The requirement for rescue drugs was significantly higher in the fentanyl group compared to the propofol group. **Conclusion:** Both propofol and fentanyl were effective in preventing emergence agitation in pediatric patients undergoing various surgical procedures under sevoflurane anesthesia. However, propofol demonstrated a better safety profile with fewer incidences of nausea, vomiting, and rescue drug requirements compared to fentanyl.

Keywords

Emergence Agitation (EA), General Anesthesia, Propofol, Fentanyl, Pediatric Patients, Pediatric Anesthesia Emergence Delirium (PAED) Score, Bangladesh

1. Introduction

Emergence agitation (EA) in children after sevoflurane anesthesia is a common postoperative problem, with an incidence ranging up to 80% [1]. Approximately 4 million children undergo anesthesia each year, and EA has been identified as a significant issue in children recovering from anesthesia, with reported incidences ranging between 10 - 80% [2]. The administration of inhaled anesthetic agents, such as sevoflurane, is associated with a high incidence of emergence agitation in young children. It is uncertain whether this phenomenon is due to the direct pharmacological action of these agents or if the rapid awakening induced by these drugs mitigates postoperative excitement. The increased utilization of sevoflurane in developing countries has led to a rise in emergence agitation (EA), a postoperative behavioral disorder first described in the early 1960s [3]. EA manifests as crying, excitation, agitation, and delirium during the early stages of emergence from anesthesia in children [4].

It is a multifaceted phenomenon with proposed etiological factors including surgical, patient-related, and anesthesia-related factors such as rapid emergence due to the low blood solubility of sevoflurane [5]. With sevoflurane or desflurane anesthesia, the incidence of EA varies widely between 2% and 80%, depending on the scoring system and anesthetic technique used, and is more frequently observed in preschool children [6] [7]. Despite its spontaneous resolution, EA is considered a potentially serious complication due to the risks of self-injury and the stress it causes caregivers and families. The incidence and severity of EA were evaluated using the Pediatric Anesthesia Emergence Delirium (PAED) scale, and factors such as time to recovery and the incidence of nausea/vomiting

were assessed.

Aono *et al*. [8] demonstrated in 1997 that preschool boys aged 2 - 6 years have a higher rate of EA compared to schoolboys, which was attributed to rapid awakening and psychological immaturity. Additionally, Martini's commentary suggests a role of brain maturation and physiological development in the susceptibility of young children to delirium [9]. Pain is a major risk factor for EA, and the high incidence of EA associated with sevoflurane has prompted numerous studies evaluating its incidence following inhalation and intravenous anesthetics. Sevoflurane is not the only anesthetic implicated in agitation; desflurane and isoflurane have also been shown to have comparable incidences ranging between 50% and 80% [10]. However, most studies indicate that sevoflurane causes more agitation [11].

Various strategies have been proposed to decrease the incidence and severity of EA, including administering sedative medication before induction, altering the maintenance technique of anesthesia, or administering pharmacological agents at the end of anesthesia [7] [12] [13]. Among these strategies, administering pharmacological agents at the end of anesthesia is considered the most convenient and easily applicable method in clinical settings. Fentanyl, a potent opioid receptor agonist, is widely used and appears to be effective in preventing EA.

Propofol, characterized by its ultra-short-acting nature and belonging to the nonbarbiturate, nonbenzodiazepine class, boasts a rapid onset of action [14] [15]. It serves as a commonly employed intravenous agent for sedation, as well as for the induction and maintenance of anesthesia. Additionally, it can be administered at the conclusion of a procedure or examination to mitigate the occurrence and intensity of emergence agitation [16]. Propofol, widely administered to over 40 million patients, boasts a remarkable safety record. However, notable complications have been reported, the most severe being the "propofol-infusion syndrome," primarily observed in pediatric patients receiving high-dose propofol infusions [17]. The propofol-infusion syndrome, albeit rare, is characterized by severe metabolic acidosis, rhabdomyolysis, and cardiovascular collapse, often fatal, especially in children receiving prolonged high-dose infusions. Mechanistically, propofol may impair mitochondrial function, leading to mitochondrial myopathies-like symptoms [17]. Furthermore, propofol's emulsion contains a significant fat load, potentially leading to hyperlipidemia with prolonged use. Monitoring lipid profiles, particularly after 72 hours of propofol administration, is recommended to mitigate hypertriglyceridemia-associated risks, including pancreatitis. Additionally, propofol can cause green discoloration of urine and skin due to the production of a phenolic green chromophore [17] [18]. Given these risks, caution is advised, particularly in pediatric patients and those receiving prolonged high-dose infusions. Monitoring triglyceride and creatine kinase levels, along with arterial acid-base status, is crucial in patients receiving extended high-dose propofol infusions to detect early signs of complications [17]. However, several studies have suggested that a single administration of 1 mg kg^{-1} of propofol at the discontinuation of anesthesia is effective in reducing

EA without delaying discharge from the PACU in children receiving sevoflurane anesthesia for induction and maintenance [14]. With the widespread adoption of propofol, there has been a resurgence of interest in studying cognitive recovery following sedation. Not only does propofol sedation enhance patient satisfaction, but it also facilitates a swifter recovery period, all while maintaining a comparable complication profile to standard sedation protocols [19]. Moreover, findings from several studies indicate that female patients tend to awaken more rapidly from propofol anesthesia. A previous study involving propofol and remifentanil suggested that female patients might experience a more rapid decline in plasma propofol levels during emergence. Consequently, differences in propofol kinetics, at least partially, could account for the faster emergence observed in women. Another plausible explanation for this phenomenon could be a lower sensitivity to propofol among women, suggesting a pharmacodynamic difference [20] [21].

Kim *et al*. [22] compared the effects of propofol and fentanyl on EA and found that nausea and vomiting were significantly more frequent in the fentanyl group than in the propofol group. Although both propofol and fentanyl can be administered at the end of sevoflurane anesthesia to reduce the incidence and severity of EA, it has not been determined which agent is more efficacious.

The outcome of this study is expected to ensure satisfactory intraoperative and postoperative analgesia, reduce nausea, vomiting, sedation, respiratory depression, and associated risks, and improve overall outcomes, including reduced self-injury, parental anxiety, and satisfaction. It is also expected to be a cost-effective procedure by reducing the duration of post-anesthesia care unit stay. This study aims to evaluate the effects of propofol in preventing EA at the end of sevoflurane anesthesia in children [7] [12] [13].

2. Materials and Methods

The study, a prospective randomized observational comparative study, was conducted at the Department of Anaesthesia, Analgesia, and Intensive Care Unit (ICU) of Dhaka Medical College Hospital, Dhaka, from July 2012 to June 2014. Its primary aim was to evaluate the efficacy of propofol in preventing postoperative emergence agitation (EA) in children, with specific objectives including assessing propofol's effects on EA and potential side-effects, examining fentanyl's impact on EA and associated side-effects, and comparing the postoperative stay between propofol and fentanyl recipients. The study population comprised American Society of Anesthesiologists (ASA) -I or II classification patients aged 18-72 months of both genders undergoing circumcision, herniotomy, and polypectomy operations. Patients were randomized into two groups: Group I received Inj. propofol after general anaesthesia with sevoflurane, and Group II received Inj. fentanyl after general anaesthesia with sevoflurane. Inclusion criteria included ASA I or II classification, age 18 - 72 months, and both genders, while exclusion criteria involved psychological/neurological disorders, extreme agitation, and drug hypersensitivity. Ethical clearance was obtained from the ethical

committee of the institute, and data collection proceeded with the acquisition of consent from the patients' legal guardians. Data collection involved gathering demographic, clinical, and outcome variables, including the Pediatric Anaesthesia Emergence Delirium (PAED) score. Statistical analysis utilized Statistical Package for the Social Sciences (SPSS) for mean calculations, Chi-Square/Fisher's exact test for categorical variables, and Student Unpaired t-test for continuous variables, with a significance level set at $p < 0.05$.

3. Results

Table 1 presents an overview of the demographic characteristics of the patients, while Figure 1 illustrates the distribution of respondents according to their age groups in both group I and group II. In both groups, a substantial proportion of patients were aged over 48 months, with 37.8% and 40.0% in group I and group II, respectively. The mean age was 45.5 ± 15.9 months in group I and 47.3 ± 15.5 months in group II. Male patients predominated in both groups, comprising 73.3% in group I and 66.7% in group II. Female patients constituted 26.7% in group I and 33.3% in group II. In terms of weight distribution, 46.7% of patients in group I and 51.1% in group II had a weight between 18 - 20 kg. The mean weight was 20.2 ± 2.5 kg in group I and 19.9 ± 30.0 kg in group II. The majority of patients in both groups were classified as ASA 1, with 66.7% in group I and 73.3% in group II. The mean duration of anesthesia was comparable between the two groups, with 56.4 ± 8.7 min in group I and 56.9 ± 9.0 min in group II, showing no statistically significant difference ($p > 0.05$).

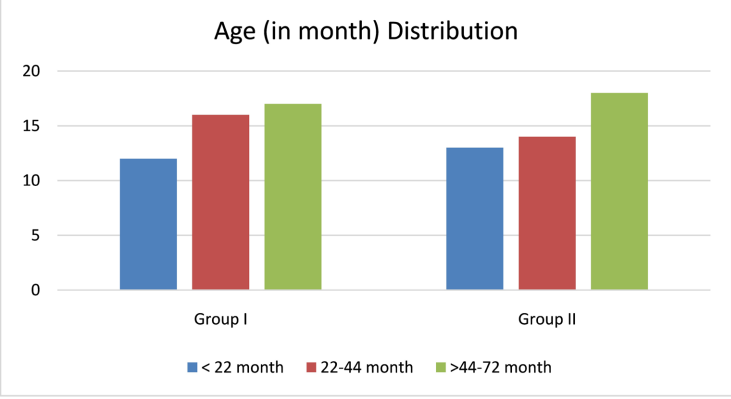

Figure 1. Distribution of respondents according to age groups in group I and group II.

Table 1. Demographic characteristics of study participants (N = 90).

Demographic Parameters	Respondents (N = 90)		*P* value
	Group I $n_1 = 45$	Group II $n_2 = 45$	
[a]Age (Months)			
Mean Age, ± SD	45.5, ± 15.9	47.3 ± 15.5	0.588^{ns}
(Minimum, Maximum)	(24, 72)	(24, 72)	
[b]Sex	f (%)	f (%)	

Continued

Male	33 (73.3)	30 (66.7)	0.490[ns]
Female	12 (26.7)	15 (33.3)	
ASA	30 (66.7)	33 (73.3)	0.490[ns]
1	15 (33.3)	12 (26.7)	
2			
[b]Duration of Anaesthesia (Min)			
Mean, ± SD	56.4 ± 8.7	56.9 ± 9.0	0.789[ns]

N = Total number of respondents; n_1 = Respondents in group A, and n_2 = Respondents in group B; ns = Not significant; SD = Standard Deviation; Data were presented as frequency (f) and mean ± SD. Figures in the parentheses denote the corresponding %. Statistical analysis was done by [A] Chi-square test and [B] independent t-test. *p*-value ≤ 0.05 was considered significant.

Table 2. Comparison of surgeries between two groups of study patients.

[a]Name of Surgical Intervention	Respondents (N = 90)		
	Group I f (%) n_1 = 45	Group II f (%) n_2 = 45	*P* value
Circumcision	15 (33.3)	13 (28.9)	
Herniotomy	21 (46.7)	18 (40.0)	0.481 [ns]
Polypectomy	9 (20.0)	14 (31.1)	

N = Total number of respondents; n_1 = Respondents in group I, and n_2 = Respondents in group II; ns = not significant; Data were presented as frequency (f); Figures in the parentheses denote the corresponding%. Statistical analysis was done by [a] Chi-square test. *p*-value ≤ 0.05 was considered significant.

Table 3. Intra-operative clinical characteristics of the patients.

[a]Intraoperative Parameters	Respondents (N = 90)		
	Group II f (%) n_1 = 45	Group II f (%) n_2 = 45	*P* value
Mean, ± SD of Saturation of Peripheral Oxygen (SPO_2)	97.6 ± 1.3	97.3 ± 1.4	1.0537[ns]
Mean, ± SD of Heart Rate /min	114.9 ± 3.0	115.4 ± 2.6	0.8451[ns]

N = Total number of respondents; n_1 = Respondents in group I, and n_2 = Respondents in group II; ns = significant; Data were presented as mean ± SD. Statistical analysis was done by [a] independent t-test. *p*-value ≤ 0.05 was considered significant.

Table 2 presents the distribution of operations among study patients. Circumcision was performed on 15 (33.3%) patients in group I and 13 (28.9%) in group II. Herniotomy was observed in 21 (46.7%) patients in group I and 18 (40.0%) in group II. Additionally, polypectomy was conducted on 9 (20.0%) patients in group I and 14 (31.1%) in group II. No statistically significant difference ($p > 0.05$) was observed between the two groups.

Table 3 presents the intra-operative clinical characteristics of the respondents,

including the mean and standard deviation of SPO_2 and heart rate, which were analyzed and found to be not statistically significant.

Table 4 displays the PAED score of study patients at various time intervals. At 0 minutes, the mean PAED score was 12.4 ± 1.4 in group I and 14.3 ± 1.2 in group II. At 5 minutes, the mean PAED score was 9.8 ± 1.8 in group I and 12.6 ± 0.9 in group II. Similarly, at 10, 15, 20, and 25 minutes, the mean PAED scores were 9.2 ± 1.8 vs. 10.5 ± 1.6, 9.3 ± 1.9 vs. 10.8 ± 1.4, 5.7 ± 1.69 vs. 7.5 ± 1.4, and 4.1 ± 1.1 vs. 5.1 ± 1.1 in groups I and II, respectively. These differences were statistically significant ($p < 0.05$) between the two groups.

Table 5 illustrates the postoperative clinical parameters of the patients, including SPO_2, HR, and RR. Meanwhile, Table 6 depicts the distribution of the study patients by Post Anesthesia Care Unit (PACU) duration. Notably, only the PACU duration was found to be statistically significant.

Table 4. PAED Score of Study Patients during post operative period at different interval.

[a]PAED Score during Postoperative Period (Mean, ± SD)	Respondents (N = 90)		
	Group II f (%) $n_1 = 45$	Group II f (%) $n_2 = 45$	*P* value
On arrival in post operative ward	12.4 ± 1.4	14.3 ± 1.2	0.001[s]
5 minutes	9.8 ± 1.8	12.6 ± 0.9	0.001[s]
10 minutes	9.2 ± 1.8	10.5 ± 1.6	0.001[s]
15 minutes	9.3 ± 1.9	10.8 ± 1.4	0.001[s]
20 minutes	5.7 ± 1.9	7.5 ± 1.4	0.001[s]
25 minutes	4.1 ± 1.1	5.1 ± 1.1	0.001[s]
30 minutes	3.2 ± 1.1	3.4 ± 0.8	0.509[ns]

N = Total number of respondents; n_1 = Respondents in group I, and n_2 = Respondents in group II; s = significant, ns = not-significant; Data were presented as mean ± SD. Statistical analysis was done by [a] independent t-test. *p*-value ≤ 0.05 was considered significant.

Table 5. Post operative clinical parameters of the patients (n = 90).

[a]Variable Related to Post Operative Clinical Parameter	Respondents (N = 90)		
	Group-I (n = 45)	**Group-II** (n = 45)	*P* value
Mean, ± SD of Saturation of Peripheral Oxygen (SPO_2)	97.9 ± 1.4	97.3 ± 1.5	1.959[ns]
Mean, ± SD of Heart Rate (per Min)	114.4 ± 3.0	114.8 ± 2.9	0.643[ns]
Mean, ± SD of Respiratory Rate (per Min)	23.3 ± 2.3	24.3 ± 3.1	1.739[ns]

N = Total number of respondents; n_1 = Respondents in group I, and n_2 = Respondents in group II; s = significant, ns = not-significant; Data were presented as mean ± SD. Statistical analysis was done by[a] independent t-test. *p*-value ≤ 0.05 was considered significant.

Table 6. Distribution of the study patients by PACU duration. (n = 90)

[a]PACU Duration (Minute)	Respondents (N = 90)		
	Group-I (n = 45)	**Group-II** (n = 45)	*P* value
Mean, ± SD	47.0 ± 8.4	53.6 ± 11.0	0.001[s]

N = Total number of respondents; n_1 = Respondents in group I, and n_2 = Respondents in group II; s = significant, ns = not-significant; Data were presented as mean ± Standard Deviation (SD). Statistical analysis was done by [a] independent t-test. *p*-value ≤ 0.05 was considered significant; PACU = Post Anaesthesia Care Unit.

Table 7. Comparison of postoperative complications between two groups of study patients.

Post Operative Complications	Respondents (N = 90)		
	Group I f (%) n_1 = 45	Group II f (%) n_2 = 45	*P* value
Laryngospasum			
Present	1 (2.2%)	2 (4.4%)	0.500 [ns]
Absent	44 (97.8%)	43 (95.6%)	
Nausea or Vomiting			
Present	3 (6.7%)	18 (40%)	0.010 [s]
Absent	42 (93.3%)	6 (27.27)	

N = Total number of respondents; n_1= Respondents in group I, and n_2= Respondents in group II; ns = not significant, s = significant; Data were presented as frequency (f); Figures in the parentheses denote the corresponding %. Statistical analysis was done by [A] Chi-square test. *p*-value ≤ 0.05 was considered significant.

Table 7 presents the postoperative complications observed among the patients. Laryngospasm occurred in 1 patient (2.2%) in group I and 2 patients (4.4%) in group II. Nausea or vomiting was reported in 3 patients (6.7%) in group I and 18 patients (40.0%) in group II. The incidence of nausea or vomiting was statistically significant ($p < 0.05$) between the two groups. However, other postoperative complications did not exhibit statistically significant differences ($p > 0.05$) between the two groups.

Table 8 illustrates the administration of rescue drugs among the study participants. In group I, 3 patients (6.7%) received rescue drugs, whereas in group II, 18 patients (40.0%) required rescue drugs. This disparity between the two groups was statistically significant ($p < 0.05$).

Table 8. Distribution of rescue drug administration among study groups.

[A] Rescue Drugs Received	Respondents (N =90)		
	Group I f (%) $n_1 = 45$	Group II f (%) $n_2 = 45$	*P* value
Yes	3 (6.7%)	18 (40%)	0. 001[s]
No	42 (93.3%)	27 (60%)	

N = Total number of respondents; n_1 = Respondents in group I, and n_2 = Respondents in group II; s = significant; Data were presented as frequency (f); Figures in the parentheses denote the corresponding %. Statistical analysis was done by [A]Chi-square test. *p*-value ≤ 0.05 was considered significant.

4. Discussion

In the current study, a considerable portion of patients in both groups were aged over 48 months, comprising 37.8% in group I and 40.0% in group II, with mean ages of 45.5 ± 15.9 months and 47.3 ± 15.5 months, respectively. These findings closely correspond to previous research by Aouad *et al*. [12], Cravero *et al*. [11], and Cohen *et al*. [14], where no statistically significant differences in mean age were noted between the groups (p > 0.05).

Moreover, a predominance of male patients was observed in both groups, constituting 73.3% and 66.7% in group I and group II, respectively, with no statistically significant difference between them (p > 0.05). This observation aligns with findings reported by Cohen *et al*. [5] [14], and Cravero *et al*. [23], consistent with the current study. However, it is noteworthy that Cravero *et al*. [11] and Aouad *et al*. [12] reported a female predominance in both groups in their studies.

Regarding weight, the mean weight was 20.2 ± 2.5 kg in group I and 19.9 ± 30.0 kg in group II, with no statistically significant difference observed (p > 0.05). Comparable results were reported by previous studies, including Aouad *et al*. [12], Cohen *et al*. [5] [14], and Cravero *et al*. [23], indicating no significant differences (P > 0.05) in weight between the study groups.

Additionally, it was noted that more than two-thirds (66.7%) of patients in group I and 73.3% in group II had ASA class I, with no statistically significant difference observed between the groups (p > 0.05), consistent with the findings of Dalens *et al*. [24]. Analysis of surgical procedures revealed no significant differences between the groups, with circumcision, herniotomy, and polypectomy being performed at similar rates in both groups (p > 0.05).

The mean duration of anesthesia was 56.4 ± 8.7 minutes in group I and 56.9 ± 9.0 minutes in group II, with no statistically significant difference between the two groups (p > 0.05). This is consistent with findings from previous studies conducted by Cravero *et al*. [11], where the mean duration of anesthesia was 63.0 ± 30.0 minutes in group I and 67.0 ± 33.0 minutes in group II, and by Dalens *et al*. [24], who observed mean durations of 51.78 ± 13.38 minutes and 53.94 ± 18.61 minutes in group I and group II, respectively. Similarly, other studies by

Cohen *et al*. [5] [14], and Cravero *et al*. [23], reported comparable results regarding the duration of anesthesia, in line with the present study.

In the present study, intraoperative SpO_2 and heart rate (HR) were similar between the two groups, consistent with the findings reported by Tesoro *et al*. [25].

The Pediatric Anaesthesia Emergence Delirium (PAED) scale, as proposed by Sikich *et al*. [26], stands as a robust and reliable measure, minimizing potential measurement errors in the assessment of emergence agitation. Sikich *et al*. [26], set a threshold score of 10 to indicate the presence of emergence agitation. In the present study, the PAED scores exhibited a noteworthy pattern, with significantly higher scores observed in group II across all follow-up intervals, except at the 30-minute mark where the difference, although higher in group II, did not reach statistical significance ($p > 0.05$). These findings closely mirror those reported by Kim *et al*. [22] and Aouad *et al*. [12], where a similarly heightened PAED score was consistently noted among patients in group II.

During the postoperative period in this study, there were no statistically significant differences ($p > 0.05$) observed in SPO_2, HR, and RR between the two groups. This is consistent with the findings reported by Kim *et al*. [15], who similarly recorded heart rate, respiratory rate, and SpO_2 at regular intervals and found comparable results. Additionally, the mean duration of post-anesthesia care unit (PACU) stay was significantly ($p < 0.05$) longer in group II compared to group I, as observed in our study and supported by Kim *et al*. (2013), although these differences were deemed clinically insignificant. In terms of postoperative complications, while laryngospasm was higher in group II without statistical significance ($p > 0.05$), nausea or vomiting was significantly ($p < 0.05$) more common in group II, consistent with the findings of Kim *et al*. (2013) and supported by previous studies by Dalens *et al*. [24] and Cohen *et al*. [5]. Furthermore, the incidence of rescue drug administration was significantly ($p < 0.05$) higher in group II, in line with the findings of Kim *et al*. [22] and consistent with our study's results.

5. Conclusion

This study demonstrates that propofol effectively prevents emergence agitation following sevoflurane anesthesia in children, suggesting its potential utility in clinical practice. However, the study has several limitations. Firstly, the study population was limited to one hospital in Dhaka city, which may not fully represent the diversity of the country. Secondly, the study duration was relatively short. Additionally, although the study was conducted a few years ago, it remains a topic of concern, highlighting the enduring relevance of the findings. The small sample size may also limit the generalizability of the findings, warranting further investigation with larger cohorts. Furthermore, the efficacy of propofol and fentanyl may vary depending on the type of surgery, thus necessitating exploration across different surgical procedures. Exclusion of children

with severe preoperative anxiety and the lack of follow-up after discharge are notable limitations. Despite these constraints, the study affirms propofol's advantage over fentanyl in reducing nausea or vomiting during the recovery period. Recommendations for future research include conducting studies with larger patient cohorts to validate the findings and exploring the effects of propofol on emergence agitation across various surgical procedures.

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Authors' Contributions

The first author spearheaded the conceptualization and design of the study, meticulously collected data from the hospital, conducted data analysis, and drafted the manuscript. The second author played a pivotal role in manuscript preparation, providing critical analysis of the study. All authors collaborated in interpreting the findings and have collectively endorsed the final version of the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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