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Association between pre-procedural anxiety and vomiting in children who undergo procedural sedation and analgesia in the emergency department

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Abstract

Introduction Children presenting to the emergency department (ED) often require procedural sedation and analgesia (PSA) prior to procedures. Although ketamine is used widely for PSA safely, there is a risk of adverse effects. Among them, vomiting is significant as it occurs in about 10% of patients and can potentially endanger the airway. Because there is evidence that post-operative complications might be due to anxiety prior to the operation, this study aims to investigate the association between pre-procedural anxiety and vomiting in the ED.

Methods In this cohort study, a convenient sample of children aged 2 to 14 years who were a candidate for PSA with ketamine in the ED were enrolled. Anxiety was evaluated using the short version of the modified Yale preoperative anxiety scale (mYAS). Vomiting was recorded during the period of hospitalization in the ED and 24 h after discharge by a phone call. Association between anxiety level and vomiting was analyzed using the independent samples t-test and multivariable logistic regression was used to control for covariates.

Results 102 children were enrolled and 93 were included in final analysis. The mean age of participants was 3.95 ± 1.79 years and 55.9% were male. According to the mYAS, the mean score of anxiety was 48.67 ± 21.78 in the waiting room and 59.10 ± 23.86 in the operating room. The mean score of anxiety was 58.3±25.3 and 51.0±20.7 in the vomiting and non-vomiting groups, respectively. At least one episode of vomiting was reported in 23 children of which, 19 took place in the hospital and 4 after discharge. No significant association was observed between pre-procedural anxiety and the occurrence of vomiting. On univariate regression model, the odds ratio of the association between mean anxiety and vomiting was 1.02 (CI 95%: 0.99–1.04) (*P*-value: 0.16). On the multivariable logistic regression model, after adjusting for all the covariates, the odds ratio was 1.03 (CI 95%: 1.0–1.05) (*P*-value: 0.05).

Conclusion The present study showed that anxiety before procedural sedation and analgesia with ketamine in children was not associated with the incidence of vomiting.

Keywords Children, Vomiting, Anxiety, Ketamine, Procedural sedation and analgesia

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Introduction

Children presenting for diagnostic or therapeutic procedures in the emergency department (ED) often experience pain and anxiety. If these stresses remain untreated, they are susceptible to acute and long-term consequences such as post-traumatic stress disorder [1, 2]. Procedural sedation and analgesia (PSA) is recommended to control the pain and anxiety, allowing safe completion of both invasive and noninvasive procedures [3].

Vomiting is a consequential condition that may occur during or after PSA as a side effect of sedative agents such as ketamine, building the challenge of potentially compromising the airway [4]. Several studies have attempted to find predictors of this adverse effect but showed inconsistent results. Of note, these studies used demographics and simple variables as potential predictors.

There is some evidence that post-operative complications might be due to anxiety prior to the operation [5, 6]. There is currently no study on the impact of preoperative anxiety on vomiting in the ED. This study was conducted to investigate the association between preoperative anxiety and vomiting during and after PSA in the ED.

Methods

Study design and setting

This was a single center, prospective observational study, which took place between August 2019 and May 2020 at Imam Khomeini Hospital Complex (IKHC), Tehran University of Medical Sciences. The ED of the IKHC is an academic center in Tehran, Iran with 24/7 emergency care available. This center has a census of 65,000 patients annually and includes an outpatient operating room with about 50 pediatric patients who undergo PSA each month.

This study was approved by the institutional review board with the registration code of IR.TUMS.IKHC.REC.1397.225 (by Tehran University of medical sciences) and conducted in accordance with the Declaration of Helsinki. All participants had written informed consent for using their medical records for research purposes. The consents were obtained from the parents or legal guardians.

Selection of participants

In this cohort study, a convenient sample of children aged 2 to 14 years who were a candidate for PSA with intramuscular ketamine in the ED were enrolled. Exclusion criteria included: children who received any other sedatives, did not give consent (either by their parents or themselves), children with decreased consciousness, mental retardation, gastrointestinal diseases, head trauma, any other diseases which would potentially cause vomiting, or previous enrollment in the study.

Methods and measurements

During the study period, PSA was performed by emergency physicians in the ED via intramuscular administration of ketamine. According to the study site protocol, all the patients should receive 4 to 5 mg/kg ketamine IM for the PSA. The procedure in the OR and the PSA were conducted at the discretion of the emergency physician. According to the institution policy, no patient would receive any antiemetic prophylactically. One of the authors (EM) collected data on initial examination during her shifts, which were random in days and nights and also in days of the week. Demographic and clinical characteristics of children including age, sex, number of previous ED procedures, procedure type, shift time, and waiting time were collected using data collection sheets. The time of shift was recorded as morning (8 am to 1 pm), evening (1 pm to 8 pm), and night (8 pm to 8 am) shifts. Waiting time for patients was logged and defined as the time between ED registration and the start of the procedure. Patients were categorized to less than one hour, between one and three hours, or more than three hours.

Anxiety was evaluated in the study population using the short version of the modified Yale preoperative anxiety scale (mYPAS), which is the standard tool for assessing child anxiety during induction of anesthesia [7]. This instrument evaluates anxiety in children using 27 items in five domains (activity, vocalization, emotional expressivity, state of apparent arousal, and use of parents). Each item has a Likert-type response. The items were rated from 1 to 4 or 1 to 6 (depending on the item) with higher scores indicating higher severity within that item. The final score ranges from 23 to 100 with higher values indicating higher anxiety. Children with a score of 40 or greater are categorized into the high anxiety group. The researcher (EM) applied the mYPAS in two different periods; during the waiting time (in the waiting area) and in the operating room before the PSA.

Outcome

Incidence of vomiting was the outcome of interest and was defined as retching and/or vomiting [8]. It was assessed in two periods of time; in hospital after ketamine administration until discharge by the researcher, and at home during a 24-hour follow-up by phone call after discharge. Families who did not respond were called on 3 different days before considering them lost to follow up.

Statistical analysis

Normally distributed continuous variables were described as mean with standard deviation. Categorical variables were presented as numbers (percentage) and compared by the chi-square test. Anxiety level

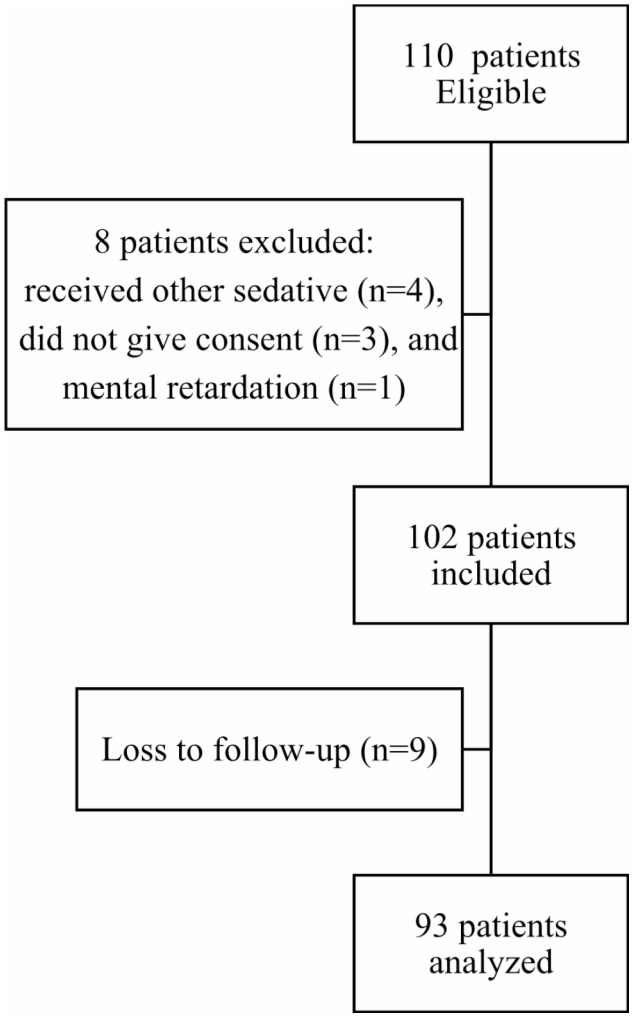

Fig. 1 Study flow diagram

association with vomiting was analyzed using the independent samples t-test. We used multivariable logistic regression to assess the association after controlling other covariates to assess the association between anxiety in different settings and vomiting. For sample size calculation, we considered a frequency of 10% vomiting among children who undergo PSA [9]. To reach power of 80%, a sample size of 70 cases was needed for two-sided alpha level of 0.05. Considering the drop outs and exclusion, 110 patients were considered as the final sample size. Data analyses were done using IBM SPSS Statistics for Windows, version 25.0 (Armonk, NY: IBM Corp.). Statistical significance was considered as *P*-value less than 0.05. To avert risk of multiplicity, we used Bonferroni correction of the *P*-value to less than 0.01 for logistic regression test results.

Table 1 Demographics and clinical characteristics of study population

Age (Years) (Mean ± SD)		3.95±1.19
Sex (Male) (%)		50 (53.8%)
Presentation shift (%)	Morning (8 am to 1 pm)	5 (5.4%)
	Evening (1 pm to 8 pm)	21 (22.6%)
	Night (8 pm to 8 am)	67 (72.0%)
Waiting Time (%)	<1 h	41 (44.1%)
	1–3 h	33 (35.5%)
	> 3 h	19 (20.4%)
Procedure type (%)	Face laceration other than oral cavity	41 (44.1%)
	Palate laceration	17 (18.3%)
	Laceration in other Sites of Oral Cavity	18 (19.4%)
	Non facial laceration	9 (9.7%)
	Orthopedics	8 (8.6%)
Previous history of procedure in the ED (%)	None	81 (87.1%)
	Once	3 (3.2%)
	Twice	9 (9.7%)

Data are presented as mean ± standard deviation and numbers

Results

In this study, 110 patients were eligible and 8 were excluded. Of 102 included children, for 9 patients, we did not receive any answer from the follow up call, leaving 93 patients for final analysis (Fig. 1). Mean age of participants was 3.95 ± 1.19 years and 53.8% were male. 72% of patients presented to the ED during the night shift (8 pm to 8 am). Of note, the waiting time (from admission to the PSA) was less than one hour for 41 (44.1%) patients and 1–3 h for 33 (35.5%) patients. 34 patients presented to the ED for laceration in the oral cavity (17 on the palate and 18 on other sites of the oral cavity), 41(44.1%) presented with laceration on other facial sites, and 9 (9.7%) on other parts of their body.

According to the mYPAS, the mean score of anxiety was 47.9 ± 22.0 in the waiting room and 57.6 ± 24.01 in the operating room of ED. The mean score of anxiety was 58.3±25.3 in the vomiting group and 51.0±20.7 in the non-vomiting group. 57% and 72% of children in the waiting area and in the OR had high levels of anxiety (mYPAS ≥ 40), respectively. Overall, 23 children experienced vomiting; 19 children only in the hospital, 4 cases vomited after discharge, and 2 children vomited in both periods (Table 1).

Table 2 and supplementary Table 1 show the association of vomiting with demographic variables and anxiety level in the waiting or operating room. There was no significant association between the incident of vomiting and anxiety level in either locations. On univariate regression model, the odds ratio of the association between mean anxiety and vomiting was 1.02 (CI 95%: 0.99–1.04) (*P*-value: 0.16). On the multivariable logistic regression model, after adjusting for all the covariates, the odds ratio

Table 2 Anxiety and vomiting association among study population

			Vomiting		
			Yes (*N* = 23)	No (*N* = 70)	*P*-value
Mean anxiety			58.3±25.3	51.0±20.7	0.21
Anxiety in Waiting Room			53.0±24.8	46.3±21.0	0.21
Anxiety in Operating Room			63.7±28.3	55.6±22.4	0.22
Age			4.4±1.9	3.8±1.8	0.25
Sex	Female		10	33	0.81
	Male		13	37	
Shift	Morning (8 am to 1 pm)		1	4	0.75
	Evening (1 pm to 8 pm)		4	17	
	Night (8 pm to 8 am)		18	49	
Waiting Time (Hours)	<1		11	30	0.26
	1–3		10	23	
	> 3		2	17	
Procedure Type	Laceration	Palate	4	13	0.84
		Other Sites of Oral Cavity	6	12	
		Other Sites of Face	10	31	
		Other Sites of Body	2	7	
	Orthopedic		1	7	
History of a procedure	None		19	62	0.76
	Once		1	2	
	Twice		3	6	

Data are presented as mean ± standard deviation and numbers

was 1.03 (CI 95%: 1.0–1.05) (*P*-value: 0.05). The other results are provided in supplementary Table 2.

Discussion

This study aimed to investigate the association between pre-procedural anxiety and the incidence of vomiting. While anxiety was higher in patients with vomiting, this study did not show significant association between anxiety levels before PSA and vomiting among children.

Hospital environments can generate anxiety and fear in children, especially in the ED [10, 11]. Reasons include separation anxiety, threatening and unfamiliar environments, and invasive and painful procedures commonly performed [12]. Children express anxiety in different ways; while they might verbalize their fears, they might also show behavioral changes such as crying and agitation [13]. In addition to ethical considerations, it is critical that anxiety is controlled. There is evidence that unattended anxiety after surgical procedures may result in high postoperative pain, delays in hospital discharge, and maladaptive behavior [14]. Additionally, it may cause irritability resulting in difficulties achieving the desired level of sedation with the need for higher doses of sedative agents [15]. Furthermore, anxious patients are more prone to behavioral changes after surgery such as sad dreams, disobeying parents, and separation anxiety [16].

Ketamine is widely used by emergency physicians for PSA in children. While this medication has a good safety profile, several adverse effects can ensue. The prevalence of adverse effects is 5–10%, with vomiting being the most prevalent [17]. As mentioned, some studies in adults showed evidences on the association between anxiety levels and postoperative vomiting in non-ED settings. Interestingly, there are even suggested mechanisms for this association such as excessive air swallowing by anxious patients [18]. The contrasting results of previous studies in non-ED setting can be explained by variations in study populations, anxiety measurement tools, and vomiting definition. To the best of our knowledge, our study was the first to examine the association between preoperative anxiety in the ED and the occurrence of vomiting after ketamine administration. For this purpose, we used standard tools and definitions. There are a few findings that are worth to mention; first, the rate of vomiting was higher than in previous studies. While the rate has been reported variably by many studies, even higher than 20% [19], we cannot exclude the risk of random error. Second, anxiety level in our study was higher than a previous study [20]. This might be due to several factors such as high proportion of patients presenting in the night shift. Furthermore we considered additional variables (e.g., waiting time), which could potentially affect the association. However, our study overall did not show any association and the results were similar after controlling for potential confounders including age, sex, procedure type and time, waiting time, and previous history of procedure. Although previous studies in other settings were not consistent, our study was in line with two studies on children in a hospital setting, in which there was no predictive value for anxiety [6, 21].

This study had some limitations. Firstly, demographic and clinical characteristics data were extracted based on the self-report of the participants and as a result, there was missing data. This is especially important in regard to the retching and vomiting occurrence after discharge, where parents might have missed reporting episodes. This can cause differentiated information bias with some changes in the estimation of the true effect. Secondly, this was a single-center study, and more multi-center studies with various populations are needed to confirm these findings.

In conclusion, while it is prudent to reduce anxiety in children, this study did not show that severity of this condition before PSA in children was associated with risk of vomiting during the hospital stay or after discharge.

Abbreviations

ED	Emergency department
IKHC	Imam Khomeini Hospital Complex
mYPAS	Modified Yale preoperative anxiety scale
PSA	Procedural sedation and analgesia

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12873-024-01097-5.

Supplementary Material 1

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None.

Author contributions
EM involved in data collection and protocol development, SHSHD oversees the study conduction and drafted the manuscript, SY provided critical comments to the manuscript draft, MJ involved in study design and analysis, SM participated in data curation and drafting, and HM conceived the study and formally analyzed the data.

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None.

Data availability
The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was approved by the institutional review board with the registration code of IR.TUMS.IKHC.REC.1397.225 (by Tehran University of medical sciences) and conducted in accordance with the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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