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ORIGINAL ARTICLE / ÖZGÜN ARAŞTIRMA MAKALESİ

Pediatric Procedural Sedation and Analgesia with Ketamine and Adverse Events in the Emergency Department

Ketamin ile Pediatrik Girişimsel Sedasyon Analjezi ve Acil Serviste Gelişen İstenmeyen Olaylar

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ABSTRACT

Aim: Procedural Sedation and Analgesia (PSA) is crucial in pediatric emergency care to minimize discomfort, enhance procedural success, and improve satisfaction for both healthcare providers and caregivers. This study aims to evaluate the characteristics of pediatric patients who received ketamine for PSA in the emergency department (ED) and to assess associated adverse events.

Material and Methods: This prospective observational study analyzed collected data from pediatric patients (3 months–18 years) who underwent ketamine-based PSA in the ED between June 21 and September 17, 2021. Data included demographics, nutritional status, ketamine dosing, oxygen support needs, and vital signs (e.g., blood pressure, oxygen saturation, respiratory rate, heart rate, end-tidal CO_2). Sedation levels (Ramsey Scale) and adverse events such as hypoxemia, apnea, hypercarbia, hiccups, hypersalivation, muscle twitching, vomiting, and transient apnea were recorded pre-, intra-, and post-procedure.

Results: Sixty pediatric patients (mean age: 3.5 ± 1 years; 46 males, 76.7%) were included. Most (98.3%) were ASA I, with one (1.7%) classified as ASA II. No significant differences were noted in vital signs except for increased systolic and diastolic blood pressure. Adverse events included agitation (16.7%), hiccups (11.7%), muscle twitching (10%), hypersalivation (8.3%), vomiting (3.3%), clonus (1.7%), transient apnea (1.7%), and nystagmus (1.7%). No severe complications occurred.

Conclusion: Although adverse events may occur during pediatric PSA with ketamine, serious events are rare. Ketamine demonstrates a favorable safety profile with no serious adverse events, confirming that single-agent PSA is a reliable practice in the pediatric ED when managed with appropriate clinical vigilance.

Keywords: Ketamine, ETCO2, sedation, emergency department, pediatric patient

ÖZ

Amaç: Pediatrik acil bakımda girişimsel sedasyon ve analjezi (GSA), hastanın rahatsızlığını azaltmak, girişim başarısını artırmak ve hem sağlık çalışanları hem de bakım verenler açısından memnuniyeti yükseltmek açısından kritik öneme sahiptir. Bu çalışma, acil serviste (AS) ketamin ile GSA uygulanan pediatrik hastaların özelliklerini değerlendirmeyi ve ilişkili advers olayları incelemeyi amaçlamaktadır.

Gereç ve Yöntem: Bu prospektif gözlemsel çalışma, 21 Haziran–17 Eylül 2021 tarihleri arasında AS'de ketamin temelli GSA uygulanan 3 ay–18 yaş arası pediatrik hastalardan prospektif olarak toplanan verilerin analizine dayanmaktadır. Demografik özellikler, beslenme durumu, ketamin dozları, oksijen desteği gereksinimi ve kan basıncı, oksijen satürasyonu, solunum hızı, kalp hızı ve end-tidal CO_2 gibi vital bulgular kaydedildi. Sedasyon düzeyleri (Ramsey Sedasyon Skalası) ile hipoksemi, apne, hiperkapni, hıçkırık, hipersalivasyon, kas seğirmesi, kusma ve geçici apne gibi advers olaylar girişim öncesi, sırası ve sonrasında değerlendirildi.

Bulgular: Toplam 60 hasta çalışmaya dahil edildi (ortalama yaş: 3,5 ± 1 yıl; 46 erkek, %76,7). Hastaların çoğu (%98,3) ASA I, yalnızca biri (%1,7) ASA II olarak sınıflandırıldı. Vital bulgularda sistolik ve diyastolik kan basıncı artışı dışında anlamlı bir değişiklik gözlenmedi. Advers olaylar arasında ajitasyon (%16,7), hıçkırık (%11,7), kas seğirmesi (%10), hipersalivasyon (%8,3), kusma (%3,3), klonus (%1,7), geçici apne (%1,7) ve nistagmus (%1,7) yer aldı. Ciddi komplikasyon saptanmadı.

Sonuç: Ketamin ile pediatrik GSA sırasında advers olaylar görülebilse de ciddi komplikasyonlar nadirdir. Ketamin, ciddi yan etki olmaksızın olumlu bir güvenlik profili sergilemekte olup, uygun klinik gözetimle yönetildiğinde tek ajanlı PSA'nın pediatrik acil serviste güvenilir bir uygulama olduğunu doğrulamaktadır.

Anahtar Kelimeler: Ketamin, $ETCO_2$, sedasyon, acil servis, pediatrik hasta

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Introduction

Painful and invasive procedures required in pediatric patients presenting to the emergency department (ED) can cause significant fear, agitation, and anxiety for both the patient and their families. Procedural Sedation and Analgesia (PSA) serves as a critical intervention to mitigate patient agitation, enhance the efficiency and quality of the procedure, and improve satisfaction among healthcare providers and caregivers (1). Consequently, PSA has become a routine practice in EDs, particularly for pediatric populations, as it reduces both psychological and physical trauma, enabling the performance of interventions in a safer and more effective manner (2).

Despite its benefits, PSA is not without risks. It requires meticulous preparation and expertise due to the potential for adverse events and complications. Therefore, PSA should be administered in controlled environments equipped with the necessary infrastructure, personnel, and materials. Patients undergoing PSA must be safeguarded within a comprehensive safety framework. Ensuring that all essential equipment is readily available and functional, and that the healthcare team is competent in managing potential complications, is paramount.

This study presents a retrospective analysis of prospectively collected data from pediatric patients who received ketamine for PSA in the ED. In this study, adverse events occurring after ketamine administration during minor procedures were specifically evaluated.

Material and Methods

This study was designed as a prospective observational study. Data were collected from pediatric patients who presented to the ED of Akdeniz University Hospital between June 21, 2021, and September 17, 2021, and underwent PSA with ketamine in real-time using a standardized data collection form specifically designed for this study. Following the completion of the data collection period, the gathered information was systematically analyzed. Ethical approval for the study was obtained prior to its initiation (Akdeniz University School of Medicine Clinical Research and Ethical Committee, approval date: November 10, 2021; approval number KAEK-797). Written informed consents were obtained from all of the participants' parents.

The study included patients aged 3 months to 18 years who required PSA with ketamine. Ketamine was administered via the intravenous (IV) route at a standard dosage range of 1–2 mg/kg. In all cases, the medication was carefully titrated, starting with a minimum of 1 mg/kg, and adjusted based on the patient's clinical response and the depth of sedation required for the procedure. Exclusion criteria were as follows: American Society of Anesthesiologists (ASA) physical status ≥ III, respiratory disorders, hypersensitivity to ketamine, acute narrow-angle glaucoma or other conditions causing increased intraocular pressure, inability to protect the airway (e.g., patients requiring intubation), obstructive cerebrospinal fluid disorders (e.g., head trauma, central congenital anomaly, or intracranial mass), porphyria, hyperthyroidism, prior history of poorly controlled epilepsy, ingestion of clear fluids within 1 hour or solid food within 3 hours, and refusal of parental consent for study participation.

Data collection included patient demographics (age, sex, weight, height, and allergy history), nutritional status (time since last solid food and clear liquid intake), oxygen support requirements, and the nature of the injury or indication for PSA. Vital signs, including blood pressure, oxygen saturation, respiratory rate, rhythm, heart rate, end-tidal carbon dioxide (ETCO2), level of consciousness, and sedation level (measured using the the Ramsey Sedation Scale), were recorded at baseline, every 5 minutes during the procedure, and every 10 minutes after the procedure. Information on ketamine dosing (initial dose and any additional dosing requirements) was also documented.

ETCO2 levels were measured using a Capnostream™20p Portable Bedside Monitor (Medtronic Parkway, Minneapolis, MN 55432-5640 USA). The monitoring team consisted of assistants who were not involved in the sedation procedures.

Sedation success was defined as the successful completion of the intended procedure under ketamine sedation. The depth of sedation was assessed clinically by the performing physician based on the patient's response to stimuli and muscle relaxation, ensuring an adequate level for the specific intervention. The Ramsey Sedation Scale was measured pre-, intra- and post-procedure.

Adverse events were systematically evaluated and included hypoxemia (oxygen saturation <90%), apnea (absence of spontaneous respiration for 30 seconds or lack of a visible CO2 waveform), hypercarbia (ETCO2 >50 mmHg or a >10% increase from baseline), laryngospasm, stridor, paradoxical abdominal breathing, aspiration, and the need for airway interventions (e.g., jaw thrust maneuver, bag-valve-mask ventilation, oxygen supplementation, or endotracheal intubation). Adverse events such as bradycardia, nausea, dysphoria, rash, injection site reaction, need for airway repositioning, hallucinations, hiccups, hypersalivation, hypotension, pleasant dreams, nightmares, muscle hypertonicity or twitching, pruritus, clonus, vomiting, nystagmus, seizures, euphoria, rigidity, and the need for verbal or physical stimulation were also assessed.

Statistical Analysis

The study data were analyzed using SPSS version 16.0 (SPSS Inc., Chicago, IL). Continuous variables were expressed as mean ± standard deviation, while categorical variables were

presented as percentages. Variables that did not follow a normal distribution were summarized using the median and interquartile range. The Friedman test was used to compare heart rate, oxygen saturation, $ETCO_2$, and blood pressure measurements. The Wilcoxon test was performed to test the significance of pairwise differences using Bonferroni correction. A p value< 0.05 was accepted as statistically significant.

Results

A total of 60 pediatric patients who underwent PSA between June 21, 2021, and September 17, 2021, were included in the study. The mean age of participants was 3.5 ± 1 years, with 46 (76.7%) being male and 14 (23.3%) female. The mean weight of the patients was 16 ± 5 kg. Allergy history was absent in 56 patients (93.3%), while 4 patients (6.7%) had a documented allergy. Adherence to the recommended fasting periods for solids and clear liquids, as per the guidelines, was confirmed in all cases. Oxygen support therapy was required in 19 patients (31.7%), while 41 patients (68.3%) did not need oxygen supplementation. Of the study population, 59 patients (98.3%) were classified as ASA I, and 1 patient (1.7%) as ASA II.

IV access was established in all cases, and ketamine was administered via the IV route at a standard dosage range of 1–2 mg/kg exclusively through IV titration to achieve the desired level of sedation. Second doses of ketamine were unnecessary in 10 patients (16.7%), while 50 patients (83.3%) required an additional dose. All patients in the study received ketamine for sedation and analgesia. The mean dose of ketamine administered was 1.6 ± 0.6 mg/kg (26.5 ± 10 mg, with a median dose of 25 mg). Rhythm assessments before, during, and after the procedures indicated no abnormalities, with regular rhythms documented throughout.

The depth of sedation showed a statistically significant change throughout the procedure (p<0.001). The mean Ramsey Sedation Scale (RSS) score increased from a baseline of 1.38 ± 0.49 to a peak of 5.66 ± 0.98 during the intervention, indicating the achievement of deep sedation. During the recovery phase, RSS scores progressively decreased, reaching a mean of 2.13 ± 1.30 at the final observation point, signifying a safe return to baseline neurological status.

Pre-procedure vital signs included a mean systolic blood pressure (SBP) of 117 ± 14.97 mmHg, diastolic blood pressure (DBP) of 74.2 ± 11.99 mmHg, heart rate of 122 ± 23.31 bpm, ETCO2 of 37.13 ± 4.8 mmHg, oxygen saturation of 99.3 ± 1.03%, and respiratory rate of 25 ± 14.76 breaths per minute. During the procedure, vital signs were recorded every five minutes and every 10 minutes after the procedure. There were no statistically significant differences in heart rate (p=0.14), ETCO2 (p=0.07), oxygen saturation (p=0.69), or respiratory rate (p=0.76) when comparing pre-, intra-, and post-procedure values.

However, statistically significant increases in SBP were observed between pre-procedure measurements and the third (p=0.01) and fourth (p=0.037) intra-procedure measurements, as well as between the first and third intra-procedure measurements (p=0.04). Similarly, DBP values measured pre-procedure and during the second (p=0.01), third (p=0.01), fourth (p=0.02), and fifth (p=0.03) intra-procedure intervals showed significant differences, with higher values observed during the procedure.

In one patient, oxygen saturation dropped below 90%, and the $ETCO_2$ level rose above 50 mmHg. After verbal and physical stimulation, the issue was resolved. In another patient, the $ETCO_2$ level increased to 56 mmHg, and the problem was resolved spontaneously. The adverse events observed in the study are detailed in Table 1.

Adverse Events	Number (%)
Agitation	10 (16.7)
Hiccups	7 (11.7)
Muscle twitching	6 (10.0)
Hypersalivation	5 (8.3)
Vomiting	2 (3.3)
Clonus	1 (1.7)
Temporary Apnea	1 (1.7)
Nystagmus	1 (1.7)
Decrease in oxygen saturation	1 (1.7)
Nausea	2 (3.3)
Bradycardia	None
Dysphoria/ Euphoria	None
Injection site reaction/ Itching/Rash	None
Hallucination/Pleasant dreams/ nightmares	None
Hypotension	None
Laryngospasm	None
Rigidity /Muscle hypertonicity	None
Seizure	None

Table 1. Adverse Events detected during PSA with Ketamine

Discussion

As a result of our study, we can conclude that adverse events (AEs) are commonly observed in pediatric patients undergoing PSA with ketamine in the ED. However, we did not detect any serious adverse events (SAEs) in our study population. During the PSA, no significant differences were observed in heart rate, oxygen saturation, or $ETCO_2$ values. A significant difference was found when comparing the pre-procedure and first measurements with the third and fourth measurements, indicating that the sedative effect of ketamine was diminishing and suggesting the need for an additional dose.

In contrast to some prospective studies conducted in pediatric emergency departments, our study did not observe high rates of hypopneic hypoventilation. For instance, prior research involving intravenous ketamine—often combined with midazolam—reported that 50% of subjects experienced $ETCO_2$ levels below 30 mmHg and

significant oxygen desaturation (3). It appears that the lower oxygen saturation reported in such studies may be attributed to the concurrent use of midazolam, as an increase in the variety of drugs used for sedation is known to be associated with a higher frequency of adverse events (4). Our findings align with large-scale datasets of over 22,000 pediatric sedations, which conclude that while the incidence of SAEs is low (1.77%), medication combinations like benzodiazepines or propofol significantly increase the risk compared to ketamine alone (4).

Furthermore, our results regarding respiratory stability are supported by randomized studies showing that hypercarbia ($ETCO_2$ > 50 mmHg) is rarely observed in patients sedated with ketamine, occurring more frequently in fentanyl-midazolam combinations (5). These findings suggest that sedation and analgesia with ketamine are safe and that additional monitoring with $ETCO_2$ may not provide significant added value in these patients(5). We believe the lower frequency of $ETCO_2$-related adverse events in our study can be attributed to our use of ketamine as a single agent, confirming that the impact on oxygenation and ventilation is minimal when PSA is administered with ketamine alone.

The safety profile observed in our cohort is also consistent with long-term retrospective reviews. For example, a seven-year review of pediatric ketamine sedation in a UK emergency department reported no major or sentinel adverse events, with an overall AE rate of 9.8% consisting mostly of minor complications like agitation (6). In our study, the most common minor adverse event was similarly agitation during recovery, which typically resolved without additional medication through family support. While other studies with larger populations have reported varying rates of vomiting (1.1%) or transient apnea (0.6%), these differences may stem from variations in monitoring protocols or the exclusion of certain minor events (7).

Interestingly, while some studies highlight hypersalivation or nystagmus as the most common occurrences (8), we found that hiccups were the most frequent event after recovery agitation, followed by muscle twitching. Systematic reviews of pediatric PSA in the ED further emphasize that while vomiting and agitation are common, the need for serious intervention like bag-valve-mask ventilation remains rare (5.0 per 1000 sedations) (9). Finally, evidence from over 6,000 pediatric cases confirms that the use of ketamine alone results in the lowest incidence of SAEs (0.4%) (10). In light of this information, our study reinforces that PSA with ketamine in the ED is a safe and effective practice with a manageable adverse event profile.

It is important to note that physiological parameters in children are highly age-dependent. In our study, we analyzed numerical changes over time to detect subtle shifts during sedation. While these numerical values vary across age groups, the primary focus was on the intra-individual trend.

Our findings have several practical implications for emergency physicians. First, the absence of SAEs in our cohort reinforces the reliability of ketamine for routine procedural sedation in the ED, suggesting that it remains a high-safety-profile agent for pediatric populations. Second, the stability of heart rate and oxygen saturation observed here provides clinical reassurance regarding respiratory safety, particularly when ketamine is used as a single agent. This suggests that the risk of significant respiratory depression is minimal, contrasting with the higher risks often associated with multi-drug sedation regimens. Finally, these results have implications for monitoring strategies; while continuous clinical vigilance is mandatory, our data support the perspective that routine $ETCO_2$ monitoring may not be indispensable for all low-risk pediatric patients undergoing ketamine-only PSA. Collectively, these insights suggest that a streamlined, single-agent ketamine protocol can be both safe and efficient for managing common pediatric procedures in a busy emergency department environment.

Limitations

Our study has several limitations: primarily, its single-center design and relatively small patient population, which may limit the generalizability of the findings. Due to these constraints and the absence of a formal a priori power analysis, the study may be underpowered to detect rare SAEs that are known to occur infrequently in larger cohorts. However, a significant strength of our methodology is that patient follow-up during the PSA was conducted by observers independent of the clinicians performing the procedure. This independent monitoring enhances the reliability of our data and is valuable in demonstrating the full spectrum of adverse events—including those without immediate clinical significance—that occurred in this specific patient population. Lastly, although we analyzed vital signs as continuous numerical data to monitor real-time trends, we did not categorize these values into age-adjusted groups (e.g., bradycardia or tachycardia based on specific age percentiles). While our intra-individual analysis accounts for baseline differences, future studies with larger cohorts could benefit from age-stratified categorical reporting to further enhance clinical interpretability. Consequently, while the sample size is small, the objectivity of our observations provides a transparent reflection of ketamine-only sedation safety in routine ED practice.

Conclusion

Although adverse events may occur during pediatric PSA with ketamine, SAEs are rare. Ketamine provides profound analgesia, sedation, and amnesia, maintains cardiovascular

stability, and has a rapid onset of action. The evidence gathered from this and previous studies shows that PSA can be safely administered with appropriate equipment and preparation in the ED. Studies with large patient numbers are needed for generalizable detailed results.

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Data Availability Statement: The datasets generated and analyzed during the current study are not publicly available due to patient confidentiality and data protection regulations. However, the data can be made available upon reasonable request and with appropriate justification from the corresponding author, subject to ethical and legal considerations.

Authors' Contribution MB: Conceptualization; Data curation; Investigation; Methodology; Project administration; Validation; Visualization; Writing—original draft; Writing—review & editing. Sİ: Investigation; Supervision; Project administration; Writing—original draft; Writing—review & editing. EG: Conceptualization; Methodology; Project administration; Formal analysis; Supervision; Writing—original draft; Writing—review & editing.

Ethical Approval: The study was authorized, and the need for informed permission was exempted by the Akdeniz University School of Medicine Clinical Research and Ethical Committee, Approval date: November 10, 2021; Approval number KAEK-797.

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