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Short Communication

Safety, Efficacy, and Clinical Outcomes of a Combined Sedation Protocol in Pediatric Dental Procedures: A Two-Year Retrospective Study

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Abstract
Pediatric dental procedures often present significant challenges, particularly in young and medically compromised patients requiring behavioral management and extensive dental treatment. Sedation techniques are widely used to facilitate safe and effective dental care in pediatric populations. This study aimed to evaluate the safety, efficacy, and clinical outcomes of a combined sedation protocol in pediatric dental treatment. A retrospective study was conducted over two years, including 577 pediatric patients aged 2–14 years treated at a single center in Libya. The sedation protocol consisted of ketamine, midazolam, propofol, morphine, tranexamic acid, and dexamethasone. Dental procedures performed under sedation included pulpotomy, pulpectomy, root canal treatment, tooth extraction, glass ionomer restorations, stainless steel crowns, and zirconia crowns. The protocol demonstrated a high success rate exceeding 98%, with minimal complications. Vomiting was the most commonly reported adverse event, occurring in approximately 2% of cases, while recovery time ranged between 30 and 45 minutes. No serious adverse events, such as respiratory depression or hemodynamic instability, were observed during the study period. These findings suggest that the combined sedation approach provides a safe, effective, and clinically reliable option for pediatric dental procedures, particularly in medically compromised children, including patients with autism spectrum disorder, and in resource-limited settings.
Keywords. *Pediatric Dentistry, Sedation, Ketamine, Autism Spectrum Disorder, Dental Caries*

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Introduction

Dental caries is one of the most prevalent diseases among children worldwide. Managing pediatric patients, especially those with special healthcare needs, is challenging. Sedation provides a controlled and safe environment for delivering dental care. However, limited data are available from Libya regarding sedation protocols in pediatric dentistry. This study provides one of the largest retrospective analyses of pediatric dental sedation in Libya [1,2].

Materials and Methods

Study design, setting, and duration

A retrospective study was conducted over a two-year period at Al-Kamal Private Dental Hospital, Misurata, Libya. Sample: 577 pediatric patients aged 2–14 years, ASA I and ASA II.

Ethical Considerations

Ethical approval was obtained from the institutional review board. All procedures were conducted according to the Helsinki Declaration (1964, revised 2000). Informed consent was obtained from parents or guardians.

Sedation Protocol

After adequate initial sedation was achieved using intramuscular ketamine (4 mg/kg) and midazolam (0.15 mg/kg) to reduce anxiety and facilitate patient cooperation, peripheral intravenous access was established to facilitate the administration of propofol, morphine, tranexamic acid, and dexamethasone. Propofol (MAC sedation): Initiation Slow injection: 0.5 mg/kg administered over 3-5 min; titrate to clinical response.

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Maintenance: Intermittent bolus method: Administer 10-20 mg increments and titrate to the desired level of sedation. Morphine 0.1 mg/kg. Tranexamic acid 10 mg/kg. Dexamethasone 0.2 mg/kg.

Monitoring

Continuous monitoring of vital signs.

Procedures

Dental procedures performed under sedation included restorative, endodontic, and surgical procedures such as pulpotomy, pulpectomy, root canal treatment (RCT), glass ionomer restorations, tooth extraction, stainless steel crowns (SSC), and zirconia crowns.

Statistical Analysis

Data were analyzed using SPSS version 25 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± SD, while categorical variables were presented as frequencies and percentages. Comparisons between categorical variables were performed using the Chi-square test. A p-value < 0.05 was considered statistically significant.

Results

A total of 577 pediatric patients aged 2–14 years were included in this study. The gender distribution was nearly equal, with 297 males (51.5%) and 280 females (48.5%). The majority of patients were medically healthy (93.4%), while 38 patients (6.6%) were classified as medically compromised. The demographic characteristics of the study population are summarized in (Table 1). The combined sedation protocol demonstrated a high success rate exceeding 98%, indicating its effectiveness in facilitating pediatric dental procedures. No statistically significant difference in success rates was observed between male and female patients ($p > 0.05$). The incidence of complications was minimal. Vomiting was the most commonly observed adverse event, occurring in approximately 2% of cases. No significant association was found between complication rates and patient health status ($p > 0.05$). The recovery time ranged between 30 and 45 minutes in most patients, reflecting a rapid recovery profile associated with the protocol. No serious adverse events, such as respiratory depression or hemodynamic instability, were reported during the study period. Overall, the findings indicate that the sedation protocol was well tolerated and effective across a broad pediatric population, including medically compromised patients.

Table 1. Demographic characteristics of the study population

Variable	Number	Percentage
Male	297	51.5%
Female	280	48.5%
Healthy	539	93.4%
Medically compromised	38	6.6%

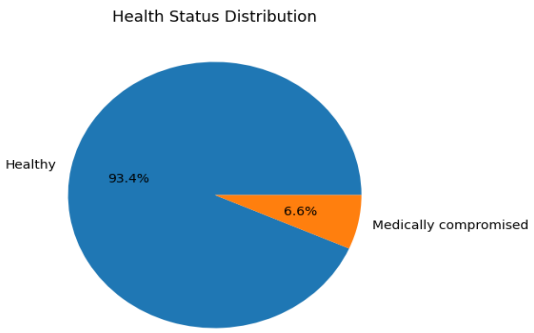

Figure 1. Distribution of healthy and medically compromised pediatric patients included in the study

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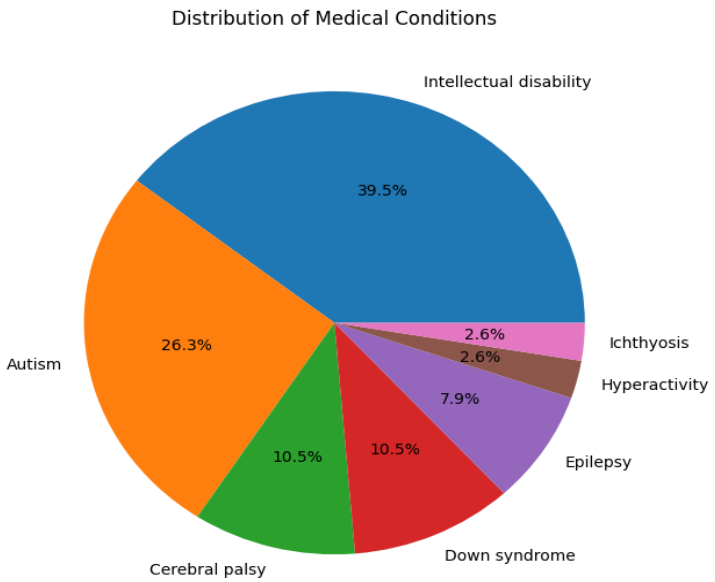

Figure 2. Distribution of medically compromised pediatric patients according to underlying medical conditions

Discussion

This study demonstrates that the combined sedation protocol is highly effective and safe for pediatric dental procedures, with a success rate exceeding 98%. This success rate is comparable to previously reported rates ranging between 95% and 99% in pediatric sedation studies, highlighting the reliability of multimodal sedation approaches in clinical practice [1,3]. The pharmacological combination used in this protocol provides synergistic effects that enhance both safety and efficacy. Ketamine is well known for preserving airway reflexes and providing adequate analgesia, making it particularly suitable for pediatric sedation [5]. Midazolam contributes to anxiolysis and improves patient cooperation, while propofol offers a rapid onset and short recovery duration, facilitating efficient clinical workflow [6,7]. This combination has been widely supported in pediatric sedation guidelines and clinical practice [2].

The low incidence of complications observed in this study further supports the safety profile of the protocol. Vomiting, which was the most commonly reported adverse event, occurred in approximately 2% of cases. This is consistent with reported complication rates in large-scale pediatric sedation studies, where adverse event rates typically range between 1% and 5% [8]. The recovery time observed in this study (30–45 minutes) is also consistent with previous reports of propofol-based sedation protocols, where recovery times generally range between 20 and 60 minutes [7,9]. These rapid recovery characteristics are particularly advantageous in high-volume clinical settings. Importantly, the protocol was effective in medically compromised patients, which further supports its clinical applicability across diverse pediatric populations. Similar findings have been reported in studies focusing on sedation in children with special healthcare needs [3,10].

Despite these strengths, this study has several limitations. The retrospective design may introduce selection bias and limit the ability to establish causal relationships. Additionally, the absence of a control group restricts direct comparison with alternative sedation techniques. Future prospective randomized studies are recommended to further validate these findings and optimize sedation strategies in pediatric dentistry [11]. Overall, the findings of this study are consistent with current pediatric sedation guidelines and reinforce the clinical utility of combined sedation protocols in improving treatment outcomes and patient safety [2,12].

Conclusion

The combined sedation protocol demonstrated a high level of safety and efficacy in pediatric dental procedures, with high success rates, minimal complications, and rapid recovery. It represents a reliable and clinically effective approach for managing pediatric patients, including those with medical complexities.

Authors' Contributions

Jamal A. Abu Dina contributed to study design, anesthesia protocol implementation, data analysis, and manuscript drafting. Kamal A. Sepsi contributed to supervision and revision. Ghadi R. Abolamdi, Sumeia

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A. Salem, and Wala H. Abdalla contributed to data collection and clinical work. All authors approved the final manuscript.

Conflict of Interest

The authors declare no conflict of interest.

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