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RESEARCH ARTICLE

Comparative Efficacy and Safety of Ketamine-Dexmedetomidine (Ketodex) Versus Ketamine-Propofol (Ketofol) for Procedural Sedation in Pediatric Patients

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ABSTRACT

Background: Pediatric procedural sedation requires safe, effective agents to ensure patient comfort while maintaining physiological stability. Combinations such as ketamine-dexmedetomidine (Ketodex) and ketamine-propofol (Ketofol) are increasingly utilized to balance the desirable effects of each component while mitigating their respective side effects.

Objective: This review aims to compare the safety and efficacy of Ketodex and Ketofol for procedural sedation in children aged 0–12 years.

Methods: A narrative synthesis of available clinical evidence, including meta-analyses and randomized controlled trials, was conducted to evaluate respiratory safety, hemodynamic stability, and recovery profiles.

Results: Comparative analysis demonstrates that Ketodex is associated with a significantly lower risk of respiratory depression, making it a safer option for patients with anticipated airway challenges. Conversely, Ketofol is consistently associated with a shorter recovery and discharge time, providing an advantage in fast-track surgical or procedural settings. Both combinations demonstrate similar hemodynamic stability, clinician satisfaction, and incidence of common adverse events such as nausea or vomiting.

Conclusion: The choice between Ketodex and Ketofol should be personalized based on the clinical priority, with Ketodex favored when respiratory safety is paramount and Ketofol preferred when rapid recovery and discharge are the primary objectives.

Keywords: Ketodex, Ketofol, pediatric procedural sedation, respiratory safety, recovery time, ketamine, dexmedetomidine, propofol, pediatric surgery.

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Introduction

Pediatric procedural sedation remains a complex clinical undertaking, primarily due to the physiological and psychological developmental variations inherent in children ranging from infancy to early adolescence. Children possess a heightened sensitivity to airway obstruction and are more susceptible to the adverse effects of sedative agents, including respiratory depression and paradoxical reactions. Traditional single agent approaches, such as the use of ketamine alone for its dissociative and analgesic properties, are frequently limited by emergence agitation, excessive secretions, and unpredictable recovery times. Conversely, propofol provides rapid onset and recovery but is notoriously associated with dose dependent hypotension and respiratory suppression, while dexmedetomidine, though hemodynamically favorable and minimally suppressive to the respiratory drive, often suffers from a slow onset and prolonged sedative effects. Consequently, the clinical search for an ideal sedative regimen has shifted toward balanced combination therapy, designed to synergistically maximize efficacy while minimizing the detrimental side effects of individual pharmacologic agents. The utilization of ketamine in conjunction with propofol, referred to as ketofol, and ketamine in combination with dexmedetomidine, known as ketodex, represents a significant evolution in pediatric practice, as these regimens are specifically formulated to offset the negative cardiovascular and respiratory profiles of their constituent drugs[1,2]. By integrating these agents, clinicians aim to achieve a state of deep yet stable sedation that preserves vital airway reflexes, which is critical in pediatric cardiac catheterization, diagnostic imaging, and minor surgical procedures where patients are at high risk for physiological instability[3,4]

Comparative Clinical Efficacy and Safety Profiles

The debate regarding the optimal combination for children aged 0–12 years often centers on the critical trade-off between respiratory safety and the speed of patient recovery. Systematic reviews and randomized controlled trials have consistently revealed that while both ketodex and ketofol provide excellent sedation and maintain hemodynamic stability, their individual safety profiles vary based on the

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pharmacology of their adjuvants[5,6] The primary advantage of ketodex lies in its superior respiratory safety profile. Dexmedetomidine functions through alpha 2 adrenergic agonism, which provides sedation without significantly depressing the central respiratory drive; when combined with ketamine, it facilitates a robust sedation profile that effectively avoids the apnea and oxygen desaturation often observed with propofol-based regimens[7,8] Research has indicated a statistically significant lower risk of respiratory depression in pediatric patients managed with ketodex, making this combination particularly suitable for children with difficult airways or those undergoing procedures prone to airway manipulation[9,10] In stark contrast, ketofol is favored in clinical scenarios where rapid patient throughput and early discharge are mandatory. The pharmacokinetics of propofol ensure a swift emergence from the sedative state, leading to a significantly shorter recovery time compared to the prolonged sedation typically observed with dexmedetomidine. Despite these differences, both combinations have been reported to provide comparable levels of clinician satisfaction and have shown no statistically significant disparity in the incidence of common complications like nausea, vomiting, or emergence agitation across diverse pediatric cohorts[11,12]. Ultimately, the selection between these strategies requires a nuanced clinical judgment that prioritizes the most urgent patient need: the safety of the airway in the context of ketodex or the clinical efficiency and rapid discharge offered by ketofol [13,14]

Objective: Comparative Performance of Sedation Regimens

The primary objective of this systematic evaluation is to rigorously compare the clinical performance, safety profiles, and recovery characteristics of the ketamine-dexmedetomidine (Ketodex) and ketamine-propofol (Ketofol) combinations in the pediatric population aged 0–12 years. By synthesizing evidence from multiple randomized controlled trials and meta-analytic data, this study seeks to delineate the specific clinical scenarios where one regimen provides a distinct advantage over the other. The investigation focuses on several key outcome measures, including the incidence of respiratory depression, hemodynamic stability, sedation depth, recovery time, and overall clinician and parental satisfaction[4,13]

Methods

Systematic Approach

To ensure the integrity and comprehensiveness of this comparative evaluation, a rigorous search strategy was employed across major academic databases, including PubMed, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL). These databases were selected for their extensive coverage of clinical literature concerning anesthesia, pediatric medicine, and pharmacology. The search strategy utilized a combination of Medical Subject Headings (MeSH) and free-text keywords, such as “pediatric procedural sedation,” “ketodex,” “ketofol,” “ketamine-dexmedetomidine,” “ketamine-propofol,” and “children,” to identify all relevant research published from inception through the present date. This systematic approach ensures that the analysis is grounded in the most current and verified clinical data available within the scholarly domain.

Inclusion and Exclusion Criteria

The selection of studies for this review was guided by strict inclusion and exclusion criteria designed to ensure homogeneity and high-quality evidence. Inclusion criteria were restricted to randomized controlled trials (RCTs) involving pediatric patients within the age range of 0 to 12

years who required sedation for diagnostic, therapeutic, or surgical procedures[15,16] Studies were included only if they provided a direct comparison between intravenous ketamine-dexmedetomidine (ketodex) and ketamine-propofol (ketofol) and reported key clinical outcomes such as respiratory events, hemodynamic status, and recovery metrics[17,18] Conversely, studies were excluded if they utilized non-intravenous routes of administration—such as intranasal, intramuscular, or oral—to ensure comparability of pharmacokinetics and clinical impact. Furthermore, research that failed to report the pre-specified primary or secondary safety and efficacy outcomes, or studies involving patients with complex comorbidities—such as American Society of Anesthesiologists (ASA) physical status classification of III or greater—were excluded to minimize confounding variables and maintain a focus on the target population of generally healthy pediatric patients undergoing routine procedures[19]

Clinical Outcome Measures: A Comparative Assessment

The clinical efficacy and safety of Ketodex and Ketofol are typically evaluated through several key outcome measures that directly influence patient care and operational efficiency. Respiratory safety serves as a primary metric, with extensive clinical evidence demonstrating that Ketodex is associated with a significantly reduced risk of respiratory depression compared to Ketofol. This difference is largely attributed to the pharmacodynamics of dexmedetomidine, which provides sedative effects while preserving the physiological respiratory drive, whereas propofol, a core component of Ketofol, possesses a well-documented potential for dose-dependent respiratory suppression and apnea. Consequently, Ketodex is frequently preferred in clinical settings where the pediatric patient's airway is identified as a high-risk area, such as during complex cardiac catheterization or prolonged diagnostic imaging procedures

Conversely, recovery time is a critical operational outcome that heavily favors Ketofol. Clinical data consistently indicate that Ketofol facilitates a much faster emergence from sedation, allowing for earlier discharge and improved patient turnover in ambulatory surgical centers and procedural suites[20]. While the recovery process with Ketodex is reliably effective, it is often prolonged, a factor that must be weighed against its safety advantages [15]. Hemodynamic stability remains high in both cohorts, as both combinations are adept at balancing the sympathomimetic effects of ketamine against the cardiovascular profile of the adjunct sedative, resulting in minimal incidence of clinically significant hypotension or bradycardia. Furthermore, clinician satisfaction remains high for both regimens, reflecting their utility and reliability in pediatric procedural sedation . Despite the differences in recovery profiles, both regimens exhibit comparable rates of minor adverse events, including nausea, vomiting, and emergence agitation, which suggests that the choice between these combinations is primarily driven by the priority of respiratory protection versus the need for rapid recovery kinetics.

Pharmacologic Basis and Synergy

Foundations of combination sedation

The clinical efficacy of ketamine-based combination therapy is fundamentally rooted in the distinct pharmacological profiles of ketamine and its adjuncts. Ketamine functions as a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist, which confers its well-established dissociative and potent analgesic properties. By inducing a state of dissociative anesthesia, ketamine enables patients to undergo surgical or diagnostic procedures without the emotional or sensory perception of pain, while notably preserving spontaneous respiratory efforts and protective airway reflexes . Despite these advantages, the use of ketamine as a sole agent is often constrained by undesirable side effects, such as emergence agitation, excessive sialorrhea, and tachycardia, which necessitate the addition of complementary sedative agents to refine the overall procedural experience[4-6]Dexmedetomidine, acting as a highly selective alpha-2 adrenergic receptor agonist, provides an ideal pharmacological complement due to its unique combination of sedative and analgesic effects, coupled with an exceptional airway preservation profile. Unlike many traditional sedative agents that cause significant respiratory depression, dexmedetomidine maintains a sedated state with minimal impact on the central respiratory drive, which is vital for maintaining physiological homeostasis in high-risk pediatric patients[3-5] Its sympatholytic action further contributes to cardiovascular stability by attenuating the stress response to surgical stimuli and reducing the incidence of tachycardia often triggered by ketamine. This synergistic integration—combining the robust analgesic and dissociative power of ketamine with the calm, airway-protective, and hemodynamically stabilizing characteristics of dexmedetomidine—creates a balanced sedative regimen. This combination is particularly well-suited for pediatric patients whose physiological vulnerability requires both effective pain management and the highest margin of respiratory safety throughout the duration of the procedure.

Synergy and Counteraction of Adverse Effects

The clinical utility of combination sedation strategies in pediatric patients is defined by the deliberate, evidence-based integration of agents to neutralize their respective limitations. Propofol is a highly effective sedative that provides both rapid onset and rapid recovery; however, its clinical application is fundamentally restricted by a dose dependent risk of hypotension and respiratory depression. When administered in the ketofol combination, the sympathomimetic profile of ketamine serves as a critical pharmacological counterweight. Ketamine's inherent capacity to stimulate the sympathetic nervous system, characterized by its positive inotropic and chronotropic effects, effectively mitigates the cardiovascular suppression typically induced by propofol, thereby stabilizing mean arterial pressure and heart rate during induction.[3,4]

This balanced interaction also extends to mitigating the adverse phenomena associated with ketamine monotherapy, particularly emergence agitation, which can be distressing for pediatric patients and their caregivers. Both propofol and dexmedetomidine exert profound sedative effects that dampen the dissociative manifestations and central nervous system excitation triggered by ketamine, leading to a smoother and more tranquil emergence from sedation . By achieving a state where the total dosage of each individual component can be reduced, these combinations minimize the occurrence of agent specific toxicities while preserving the necessary depth of sedation[4,5]. This synergistic pharmacologic approach effectively streamlines the procedural experience, as it allows for the stabilization of hemodynamics with ketofol and the enhancement of respiratory safety with ketodex, ensuring that clinicians can tailor their management strategy to the specific clinical requirements and physiological status of each child.

Clinical Outcomes: Comparative Analysis

Analysis of Sedation Regimens

The selection between ketamine-dexmedetomidine (ketodex) and ketamine-propofol (ketofol) for pediatric procedural sedation is guided by a systematic evaluation of their distinct clinical outcomes, particularly regarding safety and recovery profiles. A preponderance of evidence indicates that ketodex offers a significantly superior respiratory safety margin, which is a critical consideration in the 0–12 age demographic where airway vulnerability is a primary concern [8,13]. Randomized clinical trials and meta-analyses consistently confirm that patients undergoing sedation with ketodex experience a lower incidence of respiratory depression, apnea, and the subsequent requirement for airway intervention compared to those receiving ketofol . This finding is attributed to the fact that dexmedetomidine facilitates sedation without compromising the central respiratory drive, whereas propofol, a core component of ketofol, is known for its dose dependent potential to suppress respiratory function[10,11]

While ketodex excels in respiratory safety, the recovery profile distinctly favors ketofol, which is frequently preferred in environments demanding rapid patient throughput, such as ambulatory surgery units and diagnostic imaging centers. The pharmacological characteristics of propofol facilitate a more predictable and rapid emergence from the sedated state, which correlates with significantly shorter recovery and discharge times

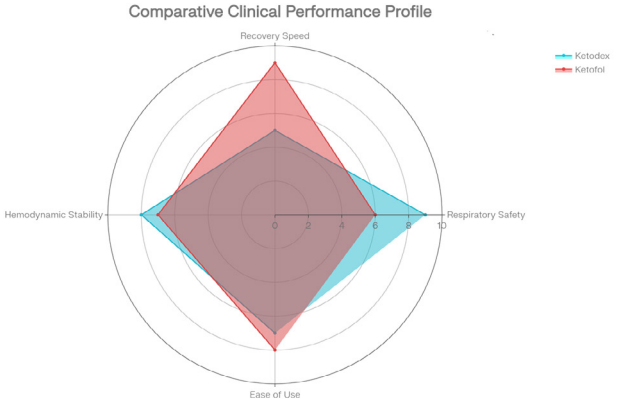

Fig 1: Comparative clinical performance profile

Table 1: Parameters and drugs

Parameter	*Ketamine + Dexmedetomidine (Ketodex)*	*Ketamine + Propofol (Ketofol)*
Primary Advantage	Superior respiratory safety	Rapid recovery kinetics
Respiratory Safety	High (maintains spontaneous breathing)	Moderate (risk of dose-dependent depression)
Recovery Speed	Slower	Faster
Ideal Patient Profile	High-risk airway / Prolonged procedures	Short-stay / Ambulatory procedures
Common Side Effects	Bradycardia	Hypotension

compared to the more prolonged sedation associated with dexmedetomidine. Hemodynamic stability, however, remains remarkably comparable between the two regimens, as both combinations leverage the balance between ketamine's sympathomimetic actions and the cardiovascular profile of the adjunct sedative to maintain mean arterial pressure and heart rate.

Regarding the incidence of adverse events, both ketodex and ketofol demonstrate similar clinical performance, with no statistically significant differences in the rates of emergence agitation, nausea, or vomiting[16]. While dexmedetomidine is occasionally associated with a higher incidence of transient bradycardia, and propofol-based regimens may be linked to infrequent mild hypotension, these cardiovascular effects are typically manageable and rarely impact clinical outcome[17]. Ultimately, clinicians must weigh the respiratory protective benefits of ketodex against the superior recovery efficiency of ketofol when tailoring sedation management to individual pediatric patient needs and procedure-specific requirements [18].

Discussion

Clinical Decision Making: Tailoring Sedation for Pediatric Patients.

The clinical decision to implement either ketodex or ketofol for pediatric procedural sedation necessitates a meticulous assessment of the specific risks and operational requirements inherent to the procedure and the patient's physiological status. Ketodex is primarily indicated for scenarios where respiratory safety is the foremost priority, particularly in patients identified as having a high risk for airway obstruction or those undergoing procedures that involve manipulation of the upper airway. Because dexmedetomidine does not depress the ventilatory drive, it provides a stable sedative environment that significantly reduces the necessity for airway interventions, making it an ideal choice for children with complex anatomical considerations or those requiring long-duration procedures in settings like cardiac catheterization or advanced diagnostic imaging [20]

Conversely, ketofol is strategically favored for clinical practices that emphasize rapid recovery and early patient discharge, such as day-case surgical centers, minor dental extractions, and rapid diagnostic workflows. The rapid emergence profile of propofol allows for an efficient transition from the procedural state to consciousness, which minimizes the total duration of stay and enhances operational turnover[19]. While clinicians must exercise heightened vigilance regarding respiratory monitoring in ketofol patients due to propofol's known potential for dose-dependent respiratory suppression, the combination with ketamine provides sufficient hemodynamic buffering to ensure that the procedural experience remains stable and effective.

Ultimately, the choice between these two combinations is rarely binary but rather a calculated selection based on a multi-factorial clinical assessment that includes the expected duration of the procedure, the anticipated level of pain, and the specific airway profile of the pediatric patient (). Clinicians should leverage the superior respiratory safety profile of ketodex for higher-acuity, long-duration cases, whereas the efficiency of ketofol should be utilized for streamlined, short-stay procedures to optimize both clinical outcomes and patient throughput[4-6]. By adopting a personalized approach to sedation selection, practitioners can maximize the therapeutic benefits of these potent combinations while minimizing the associated risks for pediatric patients across the 0–12 age demographic.

Patient Selection and Variability in Pediatric Cohorts

The pediatric population aged 0 to 12 years encompasses a wide spectrum of developmental stages, each presenting unique physiological considerations for procedural sedation. Infants and younger children typically possess higher metabolic rates, greater oxygen consumption, and airway anatomical differences—such as a larger tongue and more compliant chest wall—that render them more prone to hypoxemia during sedation compared to older children[1,2]. Consequently, patient selection for ketamine-based combinations requires an appreciation of this developmental variability, as the depth of sedation and the tolerance for adjuvant medications may differ significantly between a neonate and a pre-adolescent patient[2-4]. Clinicians must account for these maturation-dependent pharmacodynamic responses, ensuring that titration protocols are strictly adjusted to the patient's weight, age, and individual baseline physiological status to prevent over-sedation or inadequate analgesia[3,16]

Limitations of Current Evidence

Despite the robustness of comparative research, the current body of literature is limited by notable heterogeneity in study methodologies, which complicates the standardization of clinical practice. There is significant variation in the dosage regimens utilized across randomized controlled trials, with different dosing ratios for ketodex and ketofol, making it difficult to establish a single universal guideline for clinical

application[9,13]. Furthermore, the clinical evidence is derived from highly diverse procedural environments—including cardiac catheterization, magnetic resonance imaging (MRI), upper gastrointestinal endoscopy, and dental surgery—each of which imposes different demands on the sedative regimen regarding pain control, duration, and patient immobility. Because the physiological response to these combinations can be influenced by the specific type of surgical or diagnostic stimulus, findings from one procedural context may not be perfectly generalizable to another.[10,12] Additionally, the lack of large-scale, multicenter trials specifically focusing on the youngest end of the 0–12 age spectrum remains a gap in the literature, often resulting in small sample sizes that may lack the power to detect rare but serious adverse events [15,17,18];20]). Future investigations should prioritize standardization of dosage and rigorous procedural categorization to refine these promising combination strategies for the diverse needs of the paediatric population.

Conclusion

In summary, the implementation of ketamine-based combination therapy represents a pivotal advancement in pediatric procedural sedation, offering clinicians versatile tools to manage children aged 0 to 12 years with safety and precision. Both ketamine-dexmedetomidine (ketodex) and ketamine-propofol (ketofol) have proven effective in providing the necessary depth of sedation, analgesia, and hemodynamic stability required for a wide array of surgical and diagnostic interventions[9,13]. The clinical utility of these combinations is defined by their distinct pharmacodynamic advantages: ketodex stands as the preferred strategy for preserving airway integrity in high-risk pediatric populations, whereas ketofol is indispensable for fast-track clinical settings where rapid emergence and efficient throughput are the primary operational objectives[1,5,6]

To optimize clinical outcomes, personalized sedation strategies should be adopted, shifting away from a one-size-fits-all approach toward a model of targeted patient and procedure-specific care. Clinicians are encouraged to conduct a comprehensive pre-procedural risk assessment, explicitly evaluating the patient's airway profile, the expected duration and stimulation intensity of the procedure, and the necessity for rapid recovery[3,14,16]. For complex, longer-duration procedures—such as cardiac catheterization—where maintaining a patent airway without mechanical intervention is critical, ketodex is highly recommended[2,5]. Alternatively, for short-stay ambulatory procedures like dental extractions or imaging sessions where time-to-discharge is a priority, ketofol provides the optimal balance of efficacy and recovery kinetics[4,12,7]. By integrating these evidence-based choices into routine practice, while remaining vigilant for agent-specific adverse effects such as bradycardia in the ketodex group or transient hypotension in the ketofol cohort, practitioners can significantly enhance the safety and quality of pediatric procedural sedation[10,11,15,19,20,17,18]

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