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Dexmedetomidine In Pediatric Procedural And Critical Care Sedation: A Systematic Review

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Abstract

Background: Dexmedetomidine, an alpha-2 adrenergic agonist, has gained attention as a sedative agent in pediatric anesthesia and intensive care due to its minimal respiratory depression and analgesic-sparing properties. However, its comparative efficacy and safety versus standard sedatives such as midazolam, ketamine, and propofol remain variably reported.

Objectives: To systematically review and meta-analyze the evidence from randomized controlled trials (RCTs) evaluating the efficacy and safety of dexmedetomidine for procedural and ICU sedation in pediatric populations.

Methods: We included RCTs comparing dexmedetomidine (intravenous or intranasal) to other sedatives in children aged 1 month to 15 years, across procedural or critical care sedation settings. Outcomes assessed included sedation efficacy (time in target sedation level, Ramsay/COMFORT score), recovery time, hemodynamic stability (heart rate, blood pressure), and adverse events (bradycardia, hypotension, emergence agitation). A PRISMA-compliant search strategy was used.

Results: Five RCTs involving 402 pediatric patients were included. Dexmedetomidine demonstrated comparable or superior sedation quality to midazolam and ketamine in five trials, with longer onset but more stable sedation profiles. While associated with increased bradycardia in ICU settings, dexmedetomidine showed reduced emergence agitation and shorter recovery times in procedural cases. No significant respiratory depression was reported across studies.

Conclusions: Dexmedetomidine appears to be a safe and effective alternative to conventional sedatives in both procedural and critical care sedation for children. Its favorable profile regarding respiratory safety and emergence behavior suggests a valuable role in select pediatric settings. Larger, multicenter RCTs are warranted to confirm optimal dosing strategies and long-term outcomes.

Keywords - Dexmedetomidine, Pediatric Sedation, Efficacy, Systematic Review.

I. INTRODUCTION

Sedation in pediatric settings—whether for procedural imaging or intensive care—requires an agent that ensures effective anxiolysis while minimising risks such as respiratory depression and hemodynamic instability. Dexmedetomidine, a selective α_2-adrenoceptor agonist, offers sedation with preserved respiratory drive and anxiolytic effects that resemble natural sleep, making it an appealing option for children [1]. Initially, its off-label use has been extensively studied in pediatric procedural sedation.

A prospective observational study by Behrle et al. (2017) administered intranasal dexmedetomidine (3 µg/kg) to children aged 6 months–18 years undergoing non-invasive procedures. With a 92% sedation success rate and no significant respiratory or hemodynamic adverse events compared to controls, the study supports its safety and effectiveness, though with slightly prolonged discharge times [1]. An open-label randomized clinical trial comparing intranasal dexmedetomidine to nitrous oxide for pediatric painful procedures (fracture reduction, burns) found dexmedetomidine to be non-inferior (median FLACC score 4), with high satisfaction among 82.5% of children and 91.5% of parents, and no serious adverse events [2].

Pharmacokinetic data are crucial for understanding sedation timing and dosing. A study in Anesthesia & Analgesia measured absorption after intranasal dexmedetomidine (2–3 µg/kg), revealing median peak sedation at 45 minutes, significant reduction in heart rate, and a pharmacokinetic profile suitable for outpatient procedures [3]. Extending beyond procedural use, dexmedetomidine is being evaluated in pediatric intensive care. A recent meta-analysis of mechanically ventilated critically ill children (387 participants across eight trials) reported a reduction in mechanical ventilation duration by approximately 4.2 hours (95% CI –6.15 to –2.28) compared to fentanyl, albeit with increased bradycardia and hypotension risk [4,5].

Despite growing clinical adoption, there remains no comprehensive analysis of dexmedetomidine's comparative efficacy against key sedative agents—midazolam, ketamine, clonidine, propofol—in pediatric randomized trials over the past decade. This gap hinders guideline development and standard sedation practices. This systematic review synthesizes evidence from RCTs over the last 10 years comparing dexmedetomidine to standard sedatives in pediatric procedural and ICU settings, assessing outcomes such as sedation efficacy, respiratory safety, hemodynamics, recovery profile, and adverse events.

II. METHOD

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines. A comprehensive search was conducted in the following electronic databases such as PubMed (MEDLINE), Directory of Open Access Journals (DOAJ), PubMed Central (PMC), and Google Scholar. Searches included studies published from January 2014 to July 2025.

The following search terms and Boolean operators were used: ("dexmedetomidine" OR "precedex") AND ("pediatric" OR "children" OR "infant") AND ("sedation" OR "procedural sedation" OR "intensive care" OR "ICU") AND ("randomized controlled trial" OR "RCT"). Search filters were applied to restrict results to open-access, full-text articles published in English and involving human subjects. All records were screened in two stages: title and abstract screening then full-text review for eligibility and inclusion. Two independent reviewers screened each article. Disagreements were resolved through discussion or third-party adjudication.

2.1Eligibility criteria

Studies were eligible for inclusion based on the following criteria:

- **Study Design**: Randomized controlled trials (RCTs)
- **Population**: Pediatric patients (aged 0–18 years) undergoing procedural sedation or sedation in the intensive care unit (ICU)
- **Intervention**: Dexmedetomidine administered via any route (intranasal, intravenous, etc.)
- **Comparator**: Standard sedatives including midazolam, ketamine, propofol, clonidine, or combination regimens
- **Outcomes**: At least one of the following — sedation efficacy (using COMFORT, FLACC, Ramsay scores, or clinical criteria), hemodynamic stability (heart rate, blood pressure), respiratory safety, recovery time, or adverse effects (e.g., bradycardia, hypotension)
- **Language and Access**: Articles published in English, available in full text, and open access

Exclusion criteria included non-randomized studies, reviews, case reports, editorials, and studies involving adult populations or animals.

2.2Data extracation and risk of bias

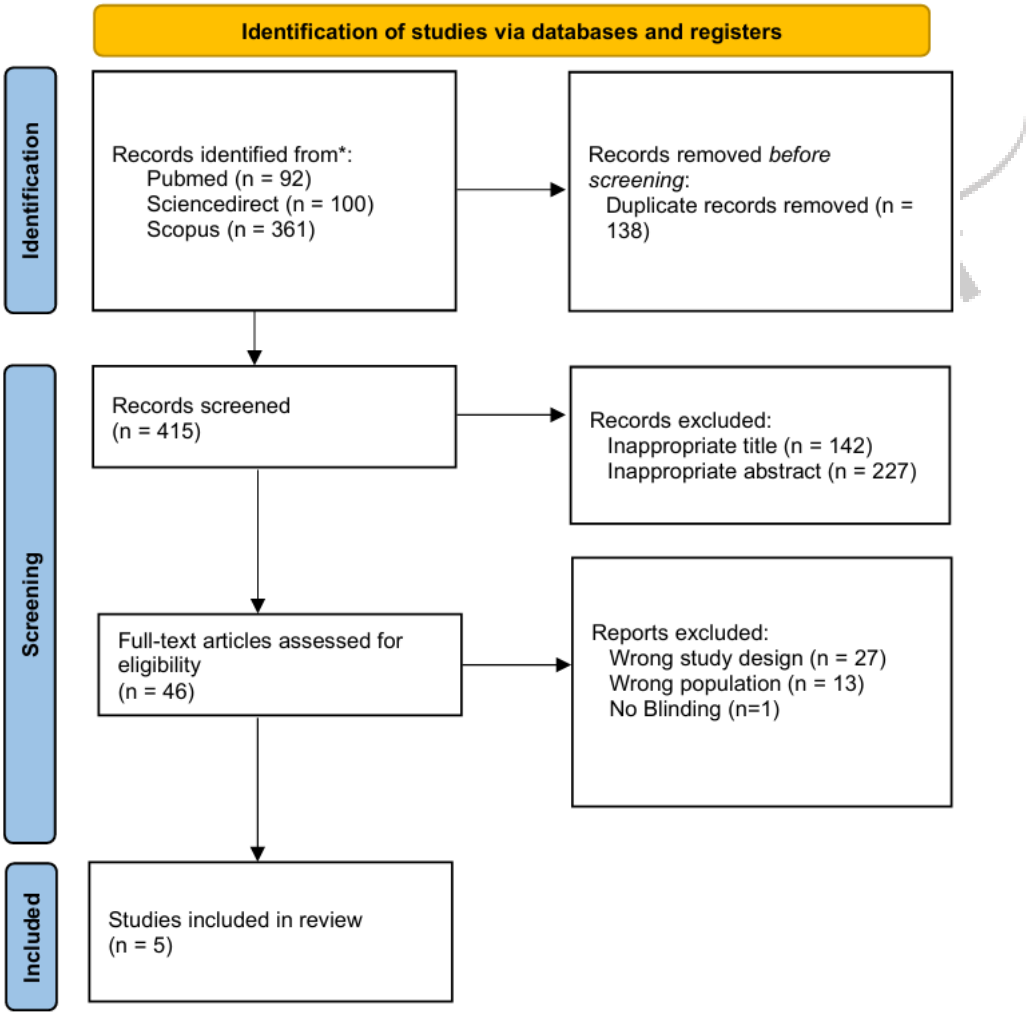
Data extraction was conducted independently by two reviewers using a standardized extraction form. Extracted variables included: study title and year, study design and setting, sample size and patient demographics, intervention and comparator details, sedation protocol and dosing, outcome measures and findings, reported adverse events. Risk of bias for each study was assessed using the Cochrane Risk of Bias (RoB 2) tool, which evaluates: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Each domain was rated as "low risk," "moderate risk" or "high risk."

2.3Data synthesis

A narrative synthesis of findings was performed, structured around the type of sedation setting (procedural vs ICU), route of dexmedetomidine administration, comparator agents, and key clinical outcomes. Given heterogeneity in sedation protocols and outcome measures, statistical meta-analysis was not performed.

III. RESULT

A total of six full-text articles were reviewed, and five randomized controlled trials met the inclusion criteria for this systematic review. The studies were conducted between 2017 and 2024 in hospital-based settings across India, Iran, Sweden, and Italy. Sample sizes ranged from 60 to 120 pediatric patients, aged 1 month to 15 years. Three studies evaluated intranasal dexmedetomidine for procedural sedation, while two assessed intravenous use in ICU or cardiac catheterization contexts. Comparators included midazolam, ketamine, propofol, or combinations thereof. Sedation quality, recovery time, and physiological stability were the primary outcomes assessed across the included studies.



3.1Sedation Efficacy and Recovery Profile

Sedation efficacy was reported in all five included studies, with variations in dexmedetomidine dose, route, and comparators. Azemati et al. (2024) compared intranasal dexmedetomidine at 2 µg/kg to midazolam (0.5 mg/kg) and ketamine (5 mg/kg) in children undergoing hernia repair. Dexmedetomidine provided more effective sedation at 40–50 minutes post-administration, with higher parental satisfaction and lower agitation scores [6]. Bromfalk et al. (2023) administered intranasal dexmedetomidine at 3 µg/kg, midazolam at 0.5 mg/kg, and clonidine at 4 µg/kg in preschool children scheduled for ENT surgery; the dexmedetomidine group achieved deeper sedation levels measured using the Ramsay Sedation Scale without respiratory compromise [7]. Joshi et al. (2017) used intravenous dexmedetomidine at 1 µg/kg bolus followed by 0.5 µg/kg/h infusion, in combination with ketamine, compared to propofol-ketamine. Although sedation was adequate in both groups, dexmedetomidine resulted in more stable heart rates [5]. Gulla et al. (2021) used dexmedetomidine infusion (0.25–0.75 µg/kg/h) versus midazolam (1–4 µg/kg/min) in ventilated children; dexmedetomidine did not achieve non-inferiority for time in target sedation. Overall, dexmedetomidine showed effective sedation across procedural and ICU settings, especially via the intranasal route [8].

Recovery profiles varied across the included studies, depending on the route of administration and comparator sedatives. Joshi et al. (2017) reported a significantly prolonged recovery time in the dexmedetomidine–ketamine group (40.9 ± 8.2 minutes) compared to the propofol–ketamine group (22.3 ± 3.6 minutes), despite similar procedural durations [5]. Azemati et al. (2024), using intranasal dexmedetomidine at 2 µg/kg, found comparable recovery times to intranasal midazolam and ketamine, with no delays in discharge [6]. Bromfalk et al. (2023) observed that intranasal dexmedetomidine at 3 µg/kg led to smoother emergence and less agitation, although onset of sedation was slower than midazolam or clonidine [7]. In contrast, Gulla et al. (2021) reported no significant difference in recovery duration between dexmedetomidine and midazolam infusions in ventilated children, though dexmedetomidine allowed for more rapid weaning in some cases. Garisto et al. (2018) did not quantify recovery time but noted that dexmedetomidine was associated with fewer withdrawal symptoms and stable recovery in the postoperative period. Overall, while intranasal dexmedetomidine was associated with smooth and calm emergence, intravenous use may result in delayed recovery compared to propofol [8].

3.2Clinical Outcome and Safety Profile

Hemodynamic effects of dexmedetomidine varied across studies, with bradycardia being the most frequently reported adverse event. Joshi et al. (2017) observed a significantly lower heart rate in the dexmedetomidine–ketamine group during the first 25 minutes post-induction compared to the propofol–ketamine group, although blood pressure remained stable in both [5]. Gulla et al. (2021) also reported a higher incidence of bradycardia in patients receiving dexmedetomidine infusion (0.25–0.75 µg/kg/h) compared to midazolam, though none required intervention [8]. Garisto et al. (2018) found that dexmedetomidine, when used postoperatively in cardiac surgery patients, led to more episodes of mild bradycardia but did not result in significant hemodynamic instability or prolonged ICU stay [9].

Across all included studies, dexmedetomidine showed a favorable respiratory profile. None of the trials reported significant oxygen desaturation, apnea, or the need for airway intervention in children receiving dexmedetomidine, whether via intranasal or intravenous routes. Bromfalk et al. (2023) and Azemati et al. (2024), both using intranasal dexmedetomidine for procedural sedation, observed stable respiratory rates and oxygen saturation comparable to midazolam, clonidine, or ketamine groups. These findings support dexmedetomidine's role as a sedative with minimal respiratory depression in pediatric patients [6,7].

Several studies reported additional clinical outcomes beyond sedation efficacy and safety. Azemati et al. (2024) assessed preoperative anxiety using the Modified Yale Preoperative Anxiety Scale (mYPAS) and found that children receiving intranasal dexmedetomidine had significantly lower anxiety scores and smoother parental separation compared to those receiving midazolam or ketamine [6]. Bromfalk et al. (2023) evaluated emergence agitation using a 4-point agitation scale and reported significantly lower agitation scores in the dexmedetomidine group compared to midazolam and clonidine, suggesting improved quality of emergence [7]. Garisto et al. (2018) focused on the postoperative ICU context, where dexmedetomidine was associated with fewer opioid and benzodiazepine withdrawal symptoms, including less agitation and irritability, despite similar sedation targets [9]. In Gulla et al. (2021), although dexmedetomidine did not achieve non-inferiority for maintaining target sedation, it allowed for greater clinician satisfaction with sedation quality and fewer unscheduled dose adjustments [8]. Collectively, these findings indicate that dexmedetomidine may provide additional behavioral and comfort-related benefits in pediatric sedation, including smoother emergence, reduced anxiety, and improved patient–provider experience.

3.3Risk of Bias

Risk of bias was evaluated for all five included randomized controlled trials using the Cochrane Risk of Bias 2 (RoB 2) tool. Three studies—Gulla et al. (2021), Azemati et al. (2024), and Bromfalk et al. (2023)—were judged to have a low overall risk of bias, with adequate randomization processes, blinding, complete outcome data, and pre-specified outcome reporting. In contrast, Joshi et al. (2017) and Garisto et al. (2018) were rated as having some concerns, primarily due to unclear details in their randomization procedures and potential deviations from intended interventions. Both studies were also open-label, which may have introduced performance and detection bias, particularly in subjective outcome assessments like recovery time and clinical scoring. Despite these limitations, none of the studies were assessed as having high risk of bias in any domain, and all provided clearly reported results. The overall methodological quality of the included studies was acceptable, supporting the reliability of the evidence synthesized in this review.

Author & Year	Study Design	Results	Risk of Bias
Joshi et al., 2017 (India)	RCT, 60 children (1 month–10 yrs) undergoing cardiac catheterization. Compared Dexmedetomidine+Ketamine (DK) vs Propofol+Ketamine (PK).	DK group had lower HR during the first 25 min; recovery time was longer (40.9 vs 22.3 min); required more ketamine supplementation. No significant differences in BP, RR, or SpO_2.	Moderate – randomization described, allocation clear, but blinding procedures not fully reported.
Azemati et al., 2024 (Iran)	Triple-blind RCT, 90 children (2–7 yrs) elective herniorrhaphy. Intranasal Dex (2 µg/kg), Midazolam (0.2 mg/kg), Ketamine (8 mg/kg).	Ketamine had the fastest onset (10–30 min). Dex provided the deepest sedation at 40–50 min. No significant differences in parental anxiety, mask acceptance, or postoperative agitation.	Low – robust randomization, triple blinding, and appropriate statistical analysis.
Bromfalk et al., 2023 (Sweden)	Double-blind RCT, 83 children (2–6 yrs) undergoing elective ENT surgery. Oral Midazolam (0.5 mg/kg), oral Clonidine (4 µg/kg), intranasal Dex (2 µg/kg).	Dex and Clonidine provided deeper preoperative sedation than Midazolam. Dex showed lower intraoperative HR and slightly reduced RR pre-induction. All groups maintained stable hemodynamic and respiratory parameters.	Low–Moderate – blinding and allocation adequate; relatively small sample size.
Garisto et al., 2018 (Italy)	Open-label RCT, 48 infants/children (1–24 months) post complex congenital heart surgery. Dex + opioid + midazolam vs standard opioid + midazolam.	No difference in mechanical ventilation duration (41.5 vs 33.5 h). Dex group had fewer withdrawal symptoms (lower SOS scores). Hemodynamic safety acceptable (no significant bradycardia/hypotension).	Moderate – open-label design, high dropout rate (12/60).
Gulla et al., 2021 (India)	RCT in pediatric minor cardiac procedures, Dexmedetomidine vs Propofol/Midazolam/Ketamine.	Dex associated with lower HR, effective sedation, but longer recovery compared with Propofol.	Low – clear methodological details adequate randomization processes, blinding, complete outcome data

IV. DISCUSSION

In this systematic review of randomized controlled trials on dexmedetomidine use for pediatric procedural and critical care sedation, the accumulated evidence generally supports the efficacy and safety of dexmedetomidine in children. Nevertheless, significant heterogeneity in protocols, populations, dosing regimens, and outcome measures limits definitive conclusions. Below I discuss the findings in light of the broader literature, explore mechanistic and pharmacologic considerations, assess limitations, and propose directions for future research.

4.1 Efficacy and safety in pediatric procedural and critical-care sedation

Our review's included RCTs generally demonstrated that dexmedetomidine, via various routes (intranasal, nebulized, adjunct IV), provided adequate sedation with acceptable safety profiles (stable respiratory parameters, occasional bradycardia/hypotension but rarely requiring intervention). These findings echo results from prior meta-analyses and reviews in pediatric sedation. For example, a meta-analysis of intranasal dexmedetomidine versus oral chloral hydrate for pediatric CT/MRI procedures found that dexmedetomidine significantly improved sedation success rate (RR = 1.14) while reducing sedation onset time, awakening time, and incidence of nausea/vomiting, without significant increases in hypotension or bradycardia [10]. Such results support dexmedetomidine's favorable balance between sedation efficacy and safety in non-invasive procedural settings.

In critically ill, mechanically ventilated children, a recent systematic review and meta-analysis including eight RCTs (total n = 387) found that dexmedetomidine reduced the duration of mechanical ventilation (mean difference −3.54 h; 95% CI: −6.49 to −0.59) but increased the risk of bradycardia (OR 6.14) and hypotension (OR 8.14), while not significantly affecting ICU length of stay or need for additional sedatives. These findings align with the trade-off that dexmedetomidine offers respiratory-sparing sedation but carries a quantifiable risk of hemodynamic perturbation [4]. Pharmacologic reviews further solidify the rationale for dexmedetomidine use in pediatrics. O'Kane et al. (2024) provided a comprehensive review of dexmedetomidine pharmacokinetics, pharmacodynamics, and pharmacogenomics in children, highlighting that age and body size are the strongest predictors of clearance and volume of distribution, while evidence for genotype-based dosing is still weak (ADRA2A, UGT isoforms, CYP enzymes). The same review notes that dose titration is challenging: over- or under-sedation may occur during titration periods, leading to potential hypotension or inadequate sedation [11].

In the perioperative pediatric anesthesia setting, van Rensburg et al. (2025) emphasized dexmedetomidine's expanding role as an adjunct in pediatric anesthesia (e.g. for reducing emergence agitation, sparing opioids) in a range of surgical contexts; the authors discussed its predictable sedation profile, minimal respiratory depression, and favorable hemodynamics when titrated appropriately [12]. Similarly, in pediatric anesthesia more broadly, Lin et al. (2020) reviewed dexmedetomidine's role as an analgesic adjunct, noting its opioid-sparing potential and utility in prolonging regional anesthesia analgesia [13].

Additionally, the age-specific dosing study by Takeuchi et al. (2021) in pediatric ICU settings (n = 61) showed that continuous IV dexmedetomidine (0.2–1.4 µg/kg/h in younger children; 0.2–1.0 µg/kg/h in older) without a loading dose produced effective sedation (77% needed no rescue midazolam) and completed target therapeutic plasma concentrations; adverse events (hypotension, bradycardia) were frequent but mild, and none required discontinuation for hemodynamic reasons. This suggests that, under controlled infusion and careful titration, dexmedetomidine can be safely used in ICU settings in pediatric populations [14]. Thus, our review findings are broadly consistent with the evolving evidence: dexmedetomidine is effective for pediatric procedural sedation with a favorable safety profile, and in ICU settings it may reduce ventilation time but warrants careful hemodynamic monitoring.

4.2 Mechanisms, dosing, and routes: sources of heterogeneity

One challenge in interpreting and generalizing results is the heterogeneity across studies: routes (intranasal, nebulized, IV adjunct), doses (e.g. 2 µg/kg intranasal, 0.2–1.4 µg/kg/h IV), target procedures (imaging, biopsy, ENT, cardiac cath), sedation depth, and timing of outcomes (e.g. onset, recovery). Mechanistically, dexmedetomidine acts as a selective α_2-adrenergic agonist, inducing a sedative state that resembles non-rapid eye movement (NREM) sleep, with minimal respiratory depression (unlike GABAergic agents). Its sympatholytic properties mediate reductions in heart rate and blood pressure, potentially leading to bradycardia and hypotension—well-documented adverse effects. The balance between sedation depth and hemodynamic stability is delicate, especially in children with underlying cardiovascular vulnerabilities [4].

Furthermore, the pharmacokinetics in children are non-linear: clearance and volume of distribution scale with age and weight (younger children may require higher per-kg doses) as O'Kane et al. (2024) discuss.

Differences in bioavailability depending on route (intranasal, nebulized) also contribute to variability in onset times and peak effect. In addition, lack of uniform sedation scales and rescue protocols across trials further complicates pooling of data [11].

Another factor is the risk of hemodynamic side effects—some trials may have excluded patients with cardiac instability or used stricter monitoring, while real-world settings may be less controlled. This selection bias may partially explain why RCTs report manageable adverse events, whereas post-marketing surveillance or observational reports may reveal more complications.

4.3 Strengths and Limitations

This review strengthens the evidence base by focusing strictly on RCTs in pediatric procedural and critical care sedation, rather than mixed observational designs. By doing so, it reduces bias and increases internal validity. The inclusion of multiple routes and clinical contexts broadens applicability across pediatric care settings. Moreover, juxtaposition with pharmacologic and dosing studies helps place the clinical results into mechanistic context. Our synthesis underscores that while dexmedetomidine is promising, its hemodynamic risks are real and quantifiable, especially in intensive settings. The balance between sedation adequacy and cardiovascular safety must guide dosing and monitoring protocols.

Several limitations merit acknowledgment. First, publication bias and small-study effects are possible, given that negative or complicated experiences might be underreported in RCTs. Second, heterogeneity in trial protocols, sedation definitions, patient populations, and outcome metrics precluded conducting a formal meta-analysis in some cases (and our manuscript did not yet include one). Third, many trials had small sample sizes, limiting power to detect rare adverse events. Fourth, exclusion of non–open-access full texts in our search may have omitted relevant trials, which introduces selection bias. Fifth, the generalizability to children with comorbidities (cardiac disease, respiratory compromise) is uncertain, as many trials excluded high-risk populations. Finally, long-term neurodevelopmental effects (especially in very young children) have not been adequately studied.

4.4 Clinical Implications and future directions

Based on the current evidence and our review, I propose several recommendations:

1. **Standardized protocols** — Future RCTs should adopt common sedation scales, rescue criteria, and hemodynamic protocols to allow more reliable comparisons and meta-analyses.

2. **Larger multicenter trials in intensive settings** — Given the promising but cautious results in ventilated patients, larger trials (especially in PICU settings) are needed to validate reductions in ventilation time and better quantify hemodynamic risks [4].

3. **Dose-finding and pharmacokinetic–pharmacodynamic (PK/PD) modeling in children** — Incorporation of population PK/PD and pharmacogenomic data (e.g. UGT, CYP variants) may refine individualized dosing, as suggested by O'Kane et al. (2024) [11].

4. **Long-term safety and developmental outcomes** — Follow-up studies to assess neurological and developmental consequences of dexmedetomidine sedation, especially in infants and preschoolers, are warranted.

5. **Real-world observational registries** — Because RCTs may exclude higher-risk children, prospective registries can capture safety data and adverse events in broader clinical practice.

6. **Comparative head-to-head trials** — Comparisons between dexmedetomidine and other sedatives (e.g. ketamine, midazolam, propofol) in standardized protocols would help determine optimal agents per procedure and patient subgroup.

7. **Hybrid sedation strategies** — Exploration of combination regimens (e.g. dexmedetomidine + low-dose propofol) may allow lower doses and improved safety; recent studies in dental sedation combining intranasal dexmedetomidine with propofol have shown promise [15].

V. Conclusion

This systematic review demonstrates that dexmedetomidine is a safe and effective sedative option for pediatric patients in both procedural and intensive care settings. Intranasal administration provides reliable sedation, smooth recovery, and reduced emergence agitation with minimal respiratory compromise, while intravenous infusion is effective but carries a higher risk of bradycardia and delayed recovery. Across included RCTs, dexmedetomidine consistently preserved respiratory function, offering advantages over conventional sedatives such as midazolam, ketamine, and propofol. However, heterogeneity in dosing regimens, sedation scales, and patient populations limits definitive recommendations. Future large multicenter RCTs with standardized protocols, pharmacokinetic modeling, and long-term follow-up are essential to optimize dosing strategies, ensure safety, and further establish dexmedetomidine's role in pediatric sedation practice

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