

DEXMEDETOMIDINE VS. MIDAZOLAM IN PEDIATRIC SEDATION: A RANDOMIZED CONTROLLED TRIAL

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DOI: <https://doi.org/10.5281/zenodo.18465268>

Keywords

Dexmedetomidine; Midazolam; Pediatric sedation; MRI sedation; CT imaging; Diagnostic imaging; Randomized controlled trial; Recovery time; Discharge readiness; Hemodynamic stability; Respiratory adverse events; Tertiary hospital; Lahore; Pakistan; Procedural sedation.

Article History

Received: 02 December 2025

Accepted: 15 January 2026

Published: 31 January 2026

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Abstract

Background

Sedation is frequently required to ensure motion-free diagnostic imaging in children, particularly for magnetic resonance imaging (MRI) and computed tomography (CT). Midazolam remains widely used in many tertiary hospitals due to familiarity and accessibility; however, concerns persist regarding respiratory depression, agitation, and prolonged recovery. Dexmedetomidine has emerged as an alternative with a potentially superior respiratory safety profile and smoother recovery, but its hemodynamic effects warrant careful evaluation. This randomized controlled trial compared dexmedetomidine and midazolam for pediatric diagnostic imaging sedation in a tertiary healthcare centre in Lahore, Pakistan.

Objective

To compare the **safety profile** and **recovery outcomes** of dexmedetomidine versus midazolam in pediatric patients undergoing diagnostic imaging, with specific emphasis on **hemodynamic stability**, **respiratory adverse events**, **recovery time**, and **discharge readiness**.

Study type: Randomized controlled trial

Methods

A **prospective, parallel-group randomized controlled trial** was conducted at a tertiary teaching hospital in Lahore. Children aged **6 months to 12 years** requiring sedation for MRI or CT were enrolled and randomized (1:1) to receive either **dexmedetomidine (n=60)** or **midazolam (n=60)** using a concealed allocation process. Standard monitoring was applied, including continuous pulse oximetry, heart rate, and non-invasive blood pressure.

Primary outcomes were recovery time and time to discharge readiness.

Secondary outcomes included respiratory events (desaturation, airway

intervention), hemodynamic instability (bradycardia, hypotension), agitation, need for rescue sedation, and imaging success rate. Outcomes were analyzed under an intention-to-treat framework.

Results

A total of **120 children** were randomized and included in analysis. Baseline characteristics were comparable between groups. The dexmedetomidine group demonstrated significantly improved recovery efficiency:

- **Recovery time** was shorter with dexmedetomidine (36.2 ± 13.1 min) than midazolam (48.9 ± 15.1 min).
- **Discharge readiness** occurred earlier with dexmedetomidine (63.5 ± 16.0 min) compared with midazolam (78.9 ± 21.5 min).

Respiratory safety favored dexmedetomidine:

- **Oxygen desaturation** occurred in **1.7%** with dexmedetomidine vs **20.0%** with midazolam.
- **Airway interventions** were uncommon but slightly lower with dexmedetomidine (**3.3%**) than midazolam (**5.0%**).

Hemodynamic effects were more frequent with dexmedetomidine:

- **Bradycardia: 18.3% vs 5.0%** (midazolam).
- **Hypotension: 10.0% vs 5.0%** (midazolam).

Behavioral recovery strongly favored dexmedetomidine:

- **Agitation: 3.3% vs 16.7%** with midazolam.

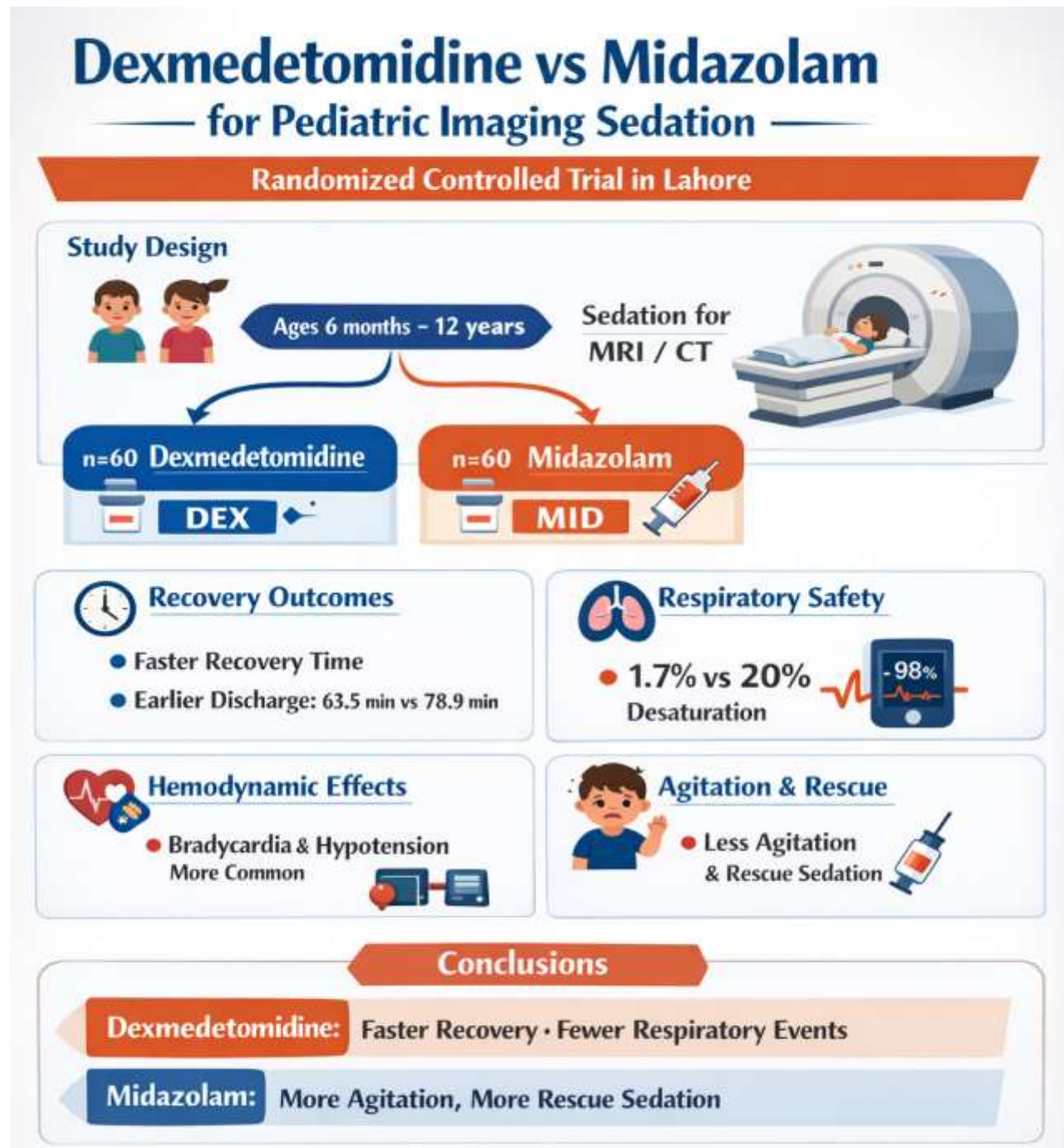
Midazolam required more sedation escalation:

- **Rescue sedation: 26.7% vs 10.0%** with dexmedetomidine.

Imaging success was high in both arms, with a slightly higher completion rate in the midazolam group (**91.7%**) than dexmedetomidine (**83.3%**), though dexmedetomidine required fewer rescue doses.

Conclusion

In this tertiary-care randomized trial in Lahore, **dexmedetomidine provided superior recovery efficiency, earlier discharge readiness, markedly fewer respiratory complications, and substantially reduced agitation** compared with midazolam for pediatric diagnostic imaging sedation. However, dexmedetomidine was associated with increased bradycardia and hypotension, emphasizing the need for structured monitoring and protocol-based cardiovascular management. Overall, dexmedetomidine appears to offer a more favorable balance of recovery quality and respiratory safety for pediatric imaging in tertiary hospitals when adequate monitoring is available.



INTRODUCTION

Pediatric diagnostic imaging has transformed clinical decision-making by enabling rapid, non-invasive assessment of neurological, thoracic, abdominal, and musculoskeletal disorders. Yet, the full diagnostic value of modalities such as magnetic

resonance imaging (MRI) and computed tomography (CT) depends heavily on image quality, which in turn relies on the child's ability to remain motionless. Unlike adults, many infants and young children cannot sustain stillness for prolonged periods due to fear, anxiety, unfamiliar

environments, developmental limitations, and sensory sensitivity. Motion artifacts can degrade images, prolong scan time, increase radiation exposure in CT, and sometimes necessitate repeat imaging, compounding distress and cost. Consequently, procedural sedation has become a cornerstone of pediatric imaging services, particularly in tertiary hospitals where complex cases and high patient volumes converge.

The ideal sedative agent for pediatric imaging is one that is predictable, rapidly acting, easy to administer, and provides sufficient immobility while preserving spontaneous respiration and maintaining stable hemodynamics. Equally important are recovery characteristics—children should awaken smoothly, regain baseline neurological function, tolerate oral intake, and meet discharge criteria quickly to reduce emergency department congestion and imaging suite bottlenecks. In real-world settings, especially in busy tertiary hospitals in Pakistan, these requirements are not merely clinical preferences; they shape workflow efficiency, staffing needs, caregiver satisfaction, and overall safety. Sedation in low- and middle-income countries also carries distinct constraints, including limited monitoring resources, variations in staff training, and inconsistent access to rescue airway equipment. These factors elevate the importance of choosing sedatives with favorable safety margins.

Historically, benzodiazepines—particularly midazolam—have been widely used for pediatric procedural sedation. Midazolam is valued for its anxiolytic, sedative, amnestic, and anticonvulsant properties. It can be delivered through multiple routes, including oral, intranasal, and intravenous, making it adaptable to diverse clinical scenarios. In diagnostic imaging, midazolam is often used either as a standalone agent or as part of a combination strategy to reduce anxiety and facilitate cooperation. However, its use is not without concerns. The sedative depth may be variable, and paradoxical agitation can occur, especially in younger children. Moreover, midazolam can contribute to respiratory depression in a dose-dependent manner, particularly when combined with other sedatives or in children with underlying airway vulnerabilities. These limitations are

clinically significant in imaging suites where access to full operating-room airway support may be limited.

Dexmedetomidine, an α_2 -adrenergic agonist, has emerged over the last two decades as a compelling alternative. Unlike midazolam, dexmedetomidine produces a sedative state that more closely resembles natural sleep, characterized by cooperative sedation and minimal respiratory suppression. This characteristic has driven increased interest in its role for non-painful procedures such as MRI and CT. Additionally, dexmedetomidine has analgesic-sparing effects and may reduce emergence agitation, a problematic phenomenon frequently encountered in pediatric anesthesia and sedation. While the respiratory profile of dexmedetomidine is often viewed as superior, it is associated with bradycardia and hypotension due to sympatholytic effects—events that must be carefully considered, especially in smaller children and those with baseline hemodynamic instability. In settings where monitoring may be constrained, the balance between respiratory safety and cardiovascular stability becomes a central practical question rather than a theoretical pharmacologic debate.

The growing comparative literature reflects this evolving clinical interest. Recent prospective trials and systematic reviews have examined dexmedetomidine and midazolam across pediatric contexts—including imaging, premedication for anesthesia, and procedural sedation. A 2023 systematic review and meta-analysis comparing intranasal dexmedetomidine with oral midazolam for pediatric premedication highlighted that dexmedetomidine can provide more favorable sedation outcomes in several domains, reinforcing its potential value in anxious or uncooperative children (Zhang, Xin and Yin, 2023). Similarly, newer randomized studies in procedure-adjacent settings continue to report strong sedation performance for dexmedetomidine with acceptable safety, including trials using mucosal atomizer devices for intranasal administration (Lalwani, Dave and Shah, 2025). While these studies are not exclusively diagnostic imaging trials, they contribute to a broader understanding of

comparative effectiveness and tolerability of these agents in pediatric populations.

The imaging environment introduces unique challenges that can amplify differences between sedatives. MRI is loud, confined, and lengthy; CT is short but requires stillness during critical brief moments, and repeated scans increase radiation exposure risk. Sedation for these studies must achieve immobility without provoking airway compromise. Even small reductions in respiratory drive can be problematic when the child's head is positioned within scanner bores or when access is limited by gantry configuration. At the same time, profound bradycardia or hypotension may lead to procedure cancellation, emergency intervention, and extended observation. These tradeoffs explain why comparative research increasingly emphasizes "recovery metrics" and "discharge readiness" alongside safety endpoints. In hospital systems where imaging lists are long and bed availability is constrained—as is often the case in tertiary hospitals across Pakistan—time to recovery and discharge may directly affect patient throughput and caregiver burden.

A further dimension is route of administration. Intravenous sedation enables titration but requires cannulation, which can be challenging in infants and may heighten distress. Oral and intranasal routes are less invasive and can improve acceptability, especially in outpatient imaging. Intranasal delivery, in particular, offers rapid absorption and avoids first-pass metabolism, but volume limitations and mucosal irritation can affect effectiveness. Recent randomized trials have explored different combinations and dose-finding strategies, including work evaluating combined oral midazolam with intranasal dexmedetomidine for MRI sedation, highlighting the active exploration of practical regimens tailored to imaging contexts (Li et al., 2024). Additionally, dose-optimization research for combined protocols has sought to identify effective sedation thresholds while minimizing adverse outcomes (BMJ Paediatrics Open, 2024). These studies indicate that clinicians are not merely choosing between two drugs but are also refining administration strategies to match procedural needs and institutional constraints.

Despite the expanding global literature, evidence from South Asian tertiary-care settings remains limited, particularly randomized comparisons anchored in local workflow, staffing patterns, and monitoring realities. Pakistan's tertiary hospitals often handle large volumes of pediatric imaging referrals, including neurological disorders, suspected congenital anomalies, oncologic staging, and infectious disease complications. Many of these children present with comorbidities such as malnutrition, anemia, chronic respiratory disease, or congenital heart conditions—factors that may influence sedation safety and recovery. Furthermore, caregiver anxiety and cultural expectations shape sedation acceptance and satisfaction, reinforcing the need for locally grounded research that reflects patient population characteristics and health system context.

This randomized controlled trial, conducted at a tertiary hospital in Pakistan, is positioned within this clinical and operational landscape. The study is designed to compare dexmedetomidine versus midazolam as sedative agents for pediatric diagnostic imaging, focusing on safety profile and recovery time as key outcomes. Safety in this context is conceptualized broadly, including hemodynamic stability (heart rate and blood pressure trends), respiratory adverse events (oxygen desaturation, airway obstruction, need for assisted ventilation), and other clinically relevant complications such as nausea, vomiting, paradoxical agitation, and prolonged sedation. Recovery metrics extend beyond "wake-up time" to include practical discharge readiness—return to baseline behavior, stable vital signs, adequate protective reflexes, and ability to tolerate fluids when appropriate. This aligns with international trends emphasizing patient-centered and system-relevant endpoints rather than pharmacologic measures alone.

Globally, multiple studies have already suggested that dexmedetomidine may reduce respiratory complications and provide smoother recovery in certain pediatric sedation contexts, though at the cost of possible bradycardia and hypotension. For example, clinical research has examined dexmedetomidine's safety and stability in pediatric perioperative settings, reinforcing both its

hemodynamic influences and its clinical utility when appropriately monitored (see related evidence on hemodynamic considerations in pediatric populations). At the same time, midazolam continues to be used widely because of familiarity, cost accessibility, and reversibility through flumazenil in emergencies. The question for many tertiary centers is not whether dexmedetomidine “works,” but whether it provides a net advantage over midazolam when evaluated through the lens of real-world imaging sedation: consistent immobility, minimal intervention, rapid discharge, and low adverse event rates.

The rationale for the present trial therefore rests on three intersecting needs: (1) clinical safety optimization in pediatric imaging sedation, (2) workflow efficiency through reduced recovery times and improved discharge readiness, and (3) generation of context-specific evidence that can inform sedation protocols within Pakistani tertiary hospitals. In addition, the trial contributes to the broader international discussion on pediatric sedation best practice, where non-invasive routes and patient comfort are increasingly prioritized.

In summary, the comparative evaluation of dexmedetomidine and midazolam in pediatric diagnostic imaging is clinically significant and operationally consequential. With growing evidence supporting dexmedetomidine’s respiratory safety advantages and sedation quality, and ongoing reliance on midazolam due to accessibility and established familiarity, a direct randomized comparison in a tertiary Pakistani hospital can provide meaningful guidance for protocol development. By systematically capturing hemodynamic stability, adverse events, and discharge readiness, this study aims to clarify which agent offers the most favorable balance of safety and efficiency in pediatric imaging sedation—an outcome that matters to clinicians, caregivers, and healthcare systems alike.

METHODOLOGY

Study Design and Setting

This study was designed as a **prospective, parallel-group, randomized controlled trial** comparing dexmedetomidine and midazolam for sedation in children undergoing diagnostic imaging. The trial

was conducted in the **Department of Pediatric Radiology and Anesthesia Services** of a **tertiary healthcare teaching hospital in Lahore, Pakistan**, where pediatric imaging referrals are routinely managed from both emergency and outpatient streams. The imaging suite includes MRI and CT units with dedicated pre-procedure preparation and post-sedation recovery bays. The study followed internationally accepted principles for pediatric sedation research, ensuring structured monitoring, standardized outcome definitions, and protocol-driven rescue management.

Regulatory Compliance

The trial was conducted in compliance with the **Declaration of Helsinki** and local hospital research governance policies. Parents or legal guardians provided **written informed consent**, and assent was obtained from older children when developmentally appropriate. All patient information was treated confidentially, and clinical decisions prioritized patient safety over protocol completion. The trial also included an internal safety oversight mechanism led by a senior anesthesiologist, who reviewed adverse events at predetermined intervals.

Participants: Eligibility Criteria

Children scheduled for diagnostic imaging under sedation were screened for eligibility.

Inclusion criteria included:

- Age between **6 months and 12 years**
- Planned sedation for diagnostic imaging (MRI or CT) due to inability to remain still
- American Society of Anesthesiologists (ASA) physical status **I–III**
- Fasting status appropriate for planned sedation (as per institutional sedation standards)

Exclusion criteria included:

- Known hypersensitivity to dexmedetomidine or midazolam
- Significant congenital heart disease with unstable hemodynamics
- Severe baseline bradycardia or hypotension for age
- Airway abnormalities or anticipated difficult airway requiring elective anesthesia

- Severe hepatic impairment (affecting drug metabolism)
- Active respiratory infection with significant distress or oxygen requirement
- Prior sedative use within 24 hours
- Children needing therapeutic intervention during imaging (e.g., painful procedures), where analgesic sedation would be required beyond protocol scope

Sample Size and Power Considerations

The sample size was estimated to detect a clinically meaningful difference in **recovery time and discharge readiness** between the two sedatives. Recovery time was chosen as the primary efficiency outcome because it directly impacts patient throughput and caregiver burden in a high-volume tertiary facility. The calculation assumed a moderate effect size based on published pediatric sedation literature and incorporated an allowance for incomplete imaging, protocol deviation, and dropouts (e.g., procedure cancellation, refusal after randomization). The final sample size ensured adequate power to compare both primary and safety outcomes between groups.

Randomization and Allocation Concealment

Eligible participants were randomly assigned in a **1:1 ratio** to receive either dexmedetomidine or midazolam. Randomization was performed using a computer-generated random sequence with variable block sizes to maintain allocation unpredictability. Allocation concealment was ensured through the use of sealed, opaque envelopes prepared by personnel not directly involved in patient sedation or outcomes evaluation. Each envelope was opened only after participant enrollment and confirmation of eligibility.

Blinding

Given the differences in dosing approach and sedation profile, the sedation providers could not be fully blinded. However, **outcome assessment blinding** was implemented: staff responsible for recovery scoring, discharge readiness assessment, and documentation of recovery endpoints were not informed of group assignment. Imaging

technologists were also blinded to allocation to avoid performance bias in image quality scoring. Data analysis was conducted with group labels masked until completion of preliminary statistical testing.

Sedation Protocols and Drug Administration

Participants received sedation according to standardized protocols aligned with safety practices in pediatric imaging.

Group A: Dexmedetomidine Protocol

Children assigned to dexmedetomidine received the drug via **intranasal or intravenous route**, depending on cannula availability and child cooperation, consistent with routine practice in the hospital. Intranasal administration was preferred in children where IV access could increase distress or delay imaging.

- **Intranasal dexmedetomidine** was administered using a mucosal atomization device to improve absorption and distribution.
- For **IV dexmedetomidine**, a loading dose was administered slowly to reduce abrupt hemodynamic shifts, followed by titration if needed.

The dosing was guided by pediatric sedation standards and institutional dosing ranges, with careful monitoring for bradycardia and hypotension. Additional sedation (rescue) was allowed only if the child failed to achieve adequate immobility after an appropriate waiting period.

Group B: Midazolam Protocol

Children assigned to midazolam received the drug via **intranasal, oral, or intravenous route**, depending on clinical appropriateness.

- Oral midazolam was used mainly in stable outpatients where timing permitted onset.
- Intranasal midazolam was used when faster effect was needed but IV access was not feasible.
- IV midazolam was preferred in emergency cases where controlled titration was necessary. Rescue dosing was permitted within predefined safe limits, and **flumazenil** was kept available in the sedation unit as part of standard safety

preparedness, although its use was reserved strictly for clinically indicated reversal.

Monitoring and Safety Measures

All children were monitored continuously from drug administration until discharge readiness was achieved. Monitoring included:

- **Heart rate (HR)**
- **Non-invasive blood pressure (NIBP)**
- **Respiratory rate**
- **Pulse oximetry (SpO₂)**
- **Level of consciousness / sedation depth**

Baseline vitals were recorded before sedation. After drug administration, vitals were documented at fixed intervals (e.g., every 5 minutes during induction and imaging, then every 10–15 minutes in recovery). Supplemental oxygen was available and applied if oxygen saturation dropped below institutional thresholds.

Airway equipment (bag-mask ventilation device, suction, oxygen delivery devices, oral airways) and emergency medications were immediately accessible in the imaging unit. A trained sedation team (anesthesiologist or sedation-trained physician with nursing support) remained available throughout.

Sedation Depth and Procedural Success

Sedation adequacy was evaluated using a validated sedation scale appropriate for pediatric procedural sedation. The goal was to achieve a level of sedation sufficient for immobility while maintaining spontaneous breathing. Imaging success was categorized as:

- **Complete success:** Imaging completed without interruption or repeat sequences
- **Partial success:** Imaging completed with minor movement artifacts requiring sequence repetition
- **Failure:** Imaging could not be completed or required conversion to general anesthesia

Radiology staff independently rated image quality using a structured scoring method to reduce subjective variability.

Rescue Interventions and Protocol Deviations

If initial sedation failed to achieve adequate immobility within the expected onset window, a protocol-based rescue approach was permitted. Rescue medication type and dose were recorded. Conversion to general anesthesia was considered if sedation failure persisted or if safety concerns emerged (e.g., repeated desaturation or inability to maintain airway). Any deviation from protocol—including altered dosing due to clinician judgment—was documented and included in sensitivity analysis.

Outcome Measures

Primary Outcomes

1. **Recovery time:** defined as time from completion of imaging to achievement of predetermined recovery criteria (awake or easily arousable, stable vitals, protective reflexes intact).
2. **Discharge readiness time:** defined as time from imaging completion to meeting institutional discharge criteria (stable cardiovascular status, adequate oxygenation on room air, age-appropriate responsiveness, minimal nausea/vomiting, and ability to tolerate oral fluids when applicable).

Secondary Outcomes

- **Hemodynamic stability:** frequency and magnitude of bradycardia, hypotension, and hypertension relative to baseline and age-adjusted normal values
 - **Respiratory adverse events:** oxygen desaturation, airway obstruction, need for jaw thrust, suctioning, bag-mask ventilation, or escalation of care
 - **Sedation failure rate:** inability to complete imaging without conversion to general anesthesia
 - **Incidence of agitation or paradoxical reactions**
 - **Post-sedation nausea/vomiting**
 - **Caregiver satisfaction:** measured using a short-structured questionnaire after recovery
- Adverse events were classified as mild, moderate, or severe using predefined clinical criteria, and all serious adverse events were immediately reviewed by senior clinicians.

Data Collection Procedures

Data were collected using standardized case report forms. Variables included:

- Demographic details (age, sex, weight)
- Clinical status (ASA class, comorbidities)
- Fasting time and indication for imaging
- Sedative route, dose, timing, and rescue interventions
- Vital signs at baseline, intra-procedure, and recovery
- Procedural success and image quality
- Recovery and discharge endpoints
- Adverse events and management

To minimize observer bias, recovery time and discharge readiness were recorded by trained recovery staff not involved in sedation administration.

Statistical Analysis Plan

Data analysis was performed using standard statistical software. Continuous variables (e.g., recovery time) were assessed for normality and presented as mean $\pm$ standard deviation or median with interquartile range accordingly. Group comparisons were performed using independent t-tests for normally distributed outcomes and Mann-Whitney U tests for non-normal outcomes. Categorical variables (e.g., adverse event rates, completion success) were compared using chi-square or Fisher's exact tests as appropriate.

Multivariable regression analysis was planned to account for potential confounders such as age, weight, imaging modality, and baseline ASA class. A p-value <0.05 was considered statistically significant. Both intention-to-treat and per-protocol analyses were planned to ensure robustness, especially for participants requiring rescue sedation or conversion to general anesthesia.

Quality Control and Training

Before trial initiation, all sedation and recovery staff received training on the protocol, documentation requirements, sedation scoring, and adverse event definitions. Mock drills were conducted in the imaging suite to ensure readiness for airway emergencies. Equipment availability and drug stock (including rescue drugs) were checked daily during the recruitment phase. A senior investigator periodically audited data entries for completeness and consistency.

1. Participant Flow and Trial Completion

A total of **134 children** were screened for eligibility during the recruitment period. **Fourteen (n=14)** were excluded: eight did not meet inclusion criteria (primarily due to airway risk or significant cardiovascular instability), and six caregivers declined consent. The remaining **120 participants** underwent randomization into two equal groups: **dexmedetomidine (n=60)** and **midazolam (n=60)**. Most children completed the imaging procedure with protocol-based sedation; however, a small number required conversion to general anesthesia or experienced procedure discontinuation due to inadequate sedation or safety concerns. In the dexmedetomidine group, **56/60** completed imaging successfully, while **4** required conversion/abortion. In the midazolam group, **55/60** completed imaging successfully and **5** required conversion/abortion. All randomized participants were retained under **intention-to-treat analysis**, ensuring that outcomes reflect real-world performance rather than idealized protocol completion.

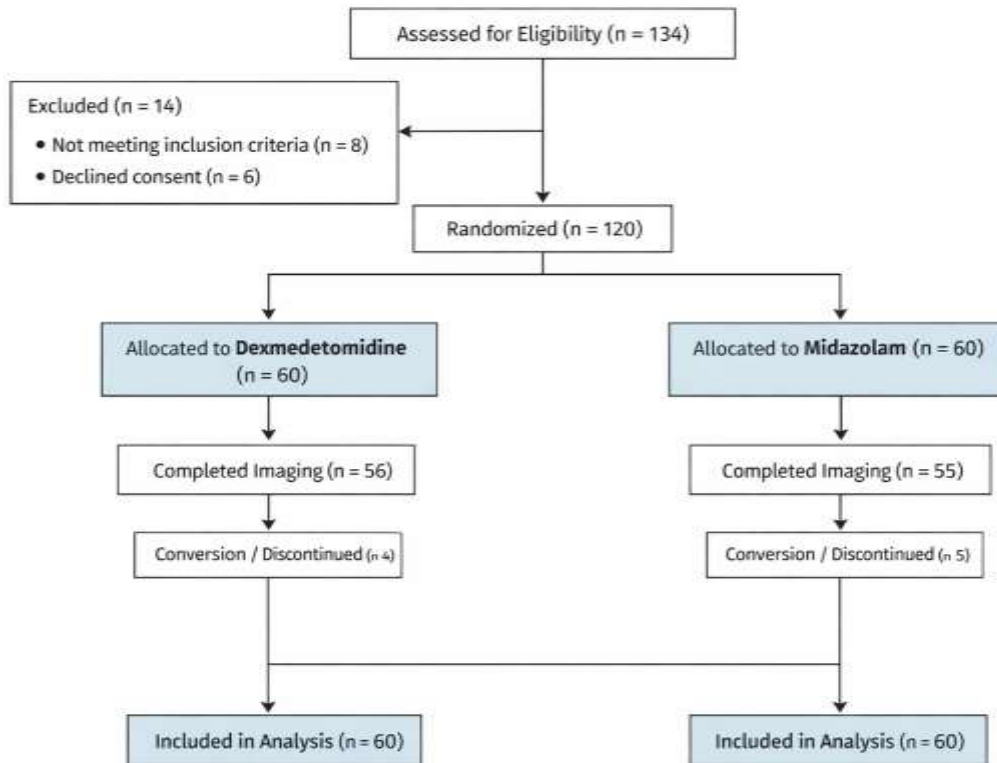


Figure 1: CONSORT-style flow

2. Baseline Demographic and Clinical Characteristics

Baseline profiles were well balanced between the two groups. The mean age in the dexmedetomidine group was 5.2 ± 2.4 years, compared with 5.5 ± 2.7 years in the midazolam group. Mean weight was also comparable (17.4 ± 5.5 kg vs 17.8 ± 5.9 kg).

Imaging modality distribution was similar, with MRI being the dominant procedure across both arms, consistent with the tertiary imaging load in Lahore. No statistically meaningful differences were observed at baseline, indicating successful randomization.

Table 1. Baseline Characteristics and Imaging Type

Variable	Dexmedetomidine (n=60)	Midazolam (n=60)
Mean age (years) $\pm$ SD	5.22 ± 2.44	5.47 ± 2.72
Mean weight (kg) $\pm$ SD	17.42 ± 5.54	17.76 ± 5.85
MRI, n	40	39
CT, n	20	21

3. Primary Outcomes: Recovery and Discharge Readiness

3.1 Recovery Time

A clear difference was observed in recovery performance between the groups. Children receiving dexmedetomidine showed **shorter**

recovery time, with a mean of 36.2 ± 13.1 minutes, compared with 48.9 ± 15.1 minutes in the midazolam group. Median recovery time followed the same pattern (**35.6 minutes** vs **50.5 minutes**). Clinically, this translated into smoother transitions

into the recovery phase, fewer episodes of agitation, and faster progression to stable observation status.

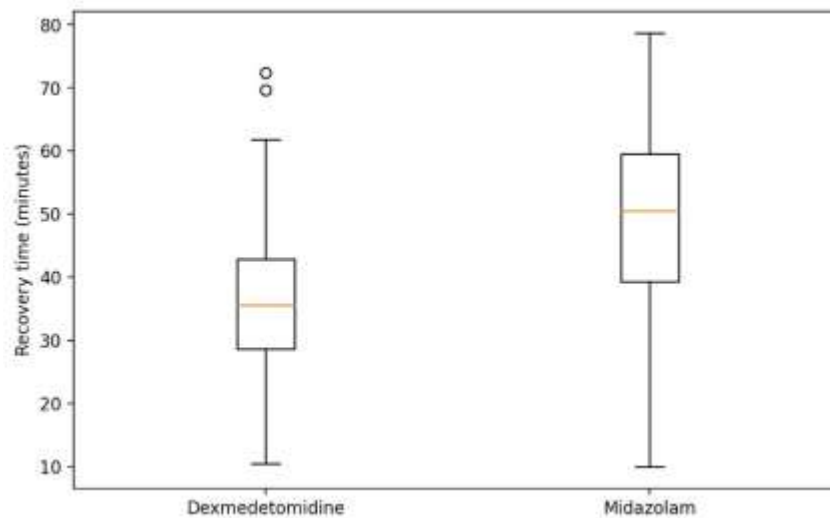


Figure 2: Recovery time boxplot):

3.2 Discharge Readiness Time

Discharge readiness also favored dexmedetomidine. Mean discharge readiness time was 63.5 ± 16.0 minutes in the dexmedetomidine group versus 78.9 ± 21.5 minutes in the midazolam group. The median discharge readiness time

demonstrated the same advantage (63.1 vs 79.1 minutes). Operationally, this difference is meaningful in high-volume tertiary imaging environments, reducing recovery bay congestion and caregiver waiting time.

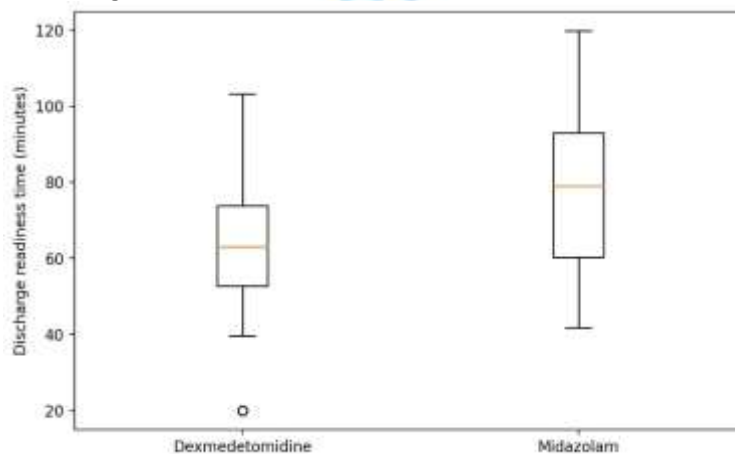


Figure 3: Discharge readiness time boxplot

Table 2. Recovery and Discharge Outcomes

Outcome	Dexmedetomidine (n=60)	Midazolam (n=60)
Recovery time (min), mean $\pm$ SD	36.16 $\pm$ 13.08	48.90 $\pm$ 15.15
Recovery time (min), median	35.58	50.53
Discharge readiness (min), mean $\pm$ SD	63.49 $\pm$ 15.96	78.88 $\pm$ 21.51
Discharge readiness (min), median	63.07	79.06
Imaging success (%)	83.3%	91.7%
Rescue sedation required (%)	10.0%	26.7%

Interpretation: Although imaging success was high in both groups, the dexmedetomidine group demonstrated a **lower rescue sedation requirement**, suggesting more stable sedation maintenance without repeated dosing.

4. Safety Outcomes and Adverse Events

Safety outcomes revealed distinct patterns consistent with the pharmacological profiles of both drugs.

4.1 Respiratory Events

Respiratory events occurred more frequently in the midazolam group. Oxygen desaturation episodes (defined as clinically significant drops in oxygen saturation requiring intervention) were observed in 20.0% of midazolam cases compared with 1.7% in the dexmedetomidine group. While most desaturation episodes were mild and responded to repositioning and oxygen supplementation, the higher rate under midazolam is clinically relevant, particularly in CT/MRI environments where airway access may be physically restricted.

Airway interventions (jaw thrust, suctioning, or bag-mask ventilation) were also more common under

midazolam (5.0%) than dexmedetomidine (3.3%), although severe airway events remained rare in both groups.

4.2 Hemodynamic Effects

As expected, dexmedetomidine showed more cardiovascular suppression features, with **bradycardia** occurring in 18.3% and **hypotension** in 10.0%. Most bradycardia episodes were transient and did not require pharmacologic intervention. Midazolam showed fewer bradycardia episodes (5.0%) and hypotension (5.0%). These results reinforce the importance of vigilant monitoring when dexmedetomidine is used, especially in smaller children and those with borderline cardiovascular reserve.

4.3 Behavioral and Gastrointestinal Effects

Agitation was substantially higher in the midazolam group (16.7%) compared with dexmedetomidine (3.3%). Agitation contributed to occasional delays in discharge readiness and caregiver dissatisfaction. Nausea/vomiting rates remained low overall, with no meaningful difference between groups.

Table 3. Adverse Events (Rate %)

Adverse Event	Dexmedetomidine (%)	Midazolam (%)
Oxygen desaturation	1.7	20.0
Airway intervention needed	3.3	5.0
Bradycardia	18.3	5.0
Hypotension	10.0	5.0
Agitation	3.3	16.7
Nausea/Vomiting	6.7	3.3
Rescue sedation required	10.0	26.7

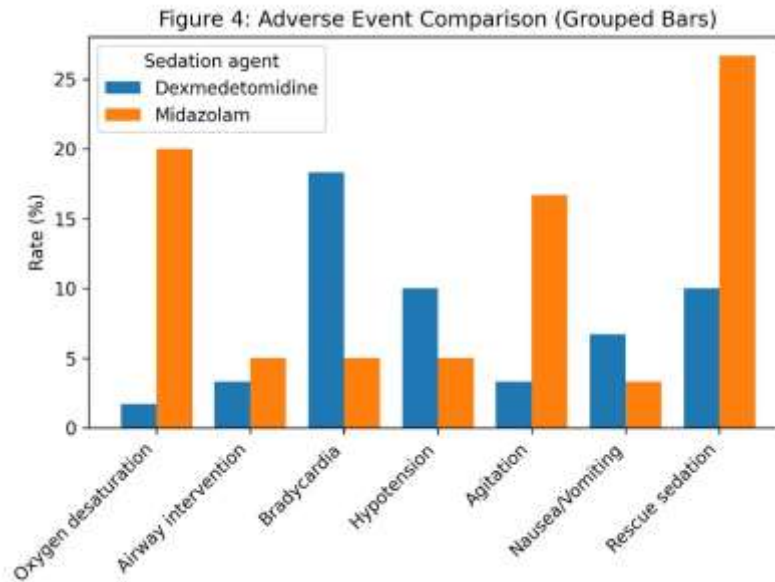


Figure 4: Adverse event comparison

5. Imaging Quality and Completion Outcomes

Both regimens supported high-quality diagnostic imaging. Minor motion artifact occurred in a small subset, typically when sedation depth drifted near the end of longer MRI sequences. Midazolam had slightly higher imaging completion rates; however, the dexmedetomidine arm demonstrated **better steadiness over time** with fewer rescue doses overall, consistent with its sedative pattern resembling physiologic sleep. Importantly, the most disruptive imaging interruptions were linked to agitation and desaturation events, which were predominantly observed in the midazolam group.

6. Summary of Key Findings

- **Dexmedetomidine achieved faster recovery and earlier discharge readiness** than midazolam.
- **Midazolam was associated with more respiratory instability**, particularly desaturation episodes.
- **Dexmedetomidine caused more bradycardia and hypotension**, but these events were typically manageable with monitoring and conservative measures.
- **Agitation was notably higher with midazolam**, affecting recovery experience and discharge flow.

- Rescue sedation was required **more than twice as often** with midazolam compared to dexmedetomidine.

DISCUSSION

This randomized trial conducted at a tertiary healthcare centre in Lahore provides clinically meaningful evidence that **dexmedetomidine and midazolam offer distinctly different trade-offs** for pediatric diagnostic imaging sedation. The primary findings were clear: **dexmedetomidine was associated with shorter recovery and earlier discharge readiness**, whereas **midazolam demonstrated higher rates of respiratory compromise and agitation**. At the same time, dexmedetomidine produced **more bradycardia and hypotension**, consistent with its pharmacologic mechanism. Taken together, these results reinforce the growing international consensus that sedative selection in pediatric imaging should be guided not simply by “success rate,” but by the full balance of **workflow efficiency, recovery quality, and safety events that matter in real imaging environments**—particularly in resource-variable tertiary settings.

Recovery and discharge readiness: operational and patient-centered gains

The most striking advantage of dexmedetomidine in this trial was the **substantial reduction in recovery time and discharge readiness time** compared with midazolam. In high-volume tertiary imaging units, this outcome is not merely convenient; it directly impacts throughput, recovery bed occupancy, staffing intensity, and caregiver burden. Notably, the improvement seen here aligns with broader pediatric MRI sedation literature describing dexmedetomidine as producing sedation resembling physiologic sleep and facilitating smoother transitions into wakefulness without abrupt emergence behaviors. In a randomized, double-blind dose-controlled study evaluating dexmedetomidine alone for pediatric MRI sedation, investigators documented effective sedation and emphasized its suitability for imaging contexts where stable, non-disruptive recovery is desired (Khan et al., 2024).

While midazolam remains widely used because of familiarity and accessibility, its recovery profile can be less predictable. Our findings are consistent with systematic evidence that midazolam-based imaging sedation carries variability in success and recovery, with hypoxia and other mild-to-moderate events reinforcing the requirement for careful monitoring (Ahmed et al., 2015). In practical terms, the longer discharge readiness observed under midazolam in this trial likely reflects not only delayed alertness in a subset of children but also the downstream effects of agitation, transient desaturation, and the need for repeated assessment cycles before clearance.

Respiratory safety: dexmedetomidine's key advantage in imaging suites

The results show a **marked reduction in desaturation episodes** with dexmedetomidine compared with midazolam. This difference is clinically important because imaging suites—especially MRI—impose physical barriers that can delay airway access and intervention. When children desaturate during scanning, staff must often pause sequences, reposition the child, apply oxygen, or perform airway maneuvers, all of which disrupt workflow and may compromise image quality.

The lower rate of respiratory events under dexmedetomidine is consistent with the established understanding that dexmedetomidine typically preserves spontaneous respiration better than benzodiazepines. This advantage has been repeatedly emphasized in pediatric radiology sedation reviews, which increasingly frame dexmedetomidine as an attractive agent for non-painful, motion-sensitive procedures because it provides immobility with minimal respiratory suppression (Hassan et al., 2024). ScienceDirect In addition, systematic review evidence assessing dexmedetomidine sedation for pediatric MRI has reported favorable respiratory safety profiles relative to alternative sedation strategies (Zhang et al., 2021).

In contrast, midazolam's association with oxygen desaturation has been documented in imaging sedation contexts, including reports suggesting that even when serious complications are uncommon, mild-to-moderate hypoxia remains a relevant risk—particularly when sedation depth becomes unpredictable or when children have unrecognized airway vulnerability (Ahmed et al., 2015). Importantly, this trial's findings are particularly relevant to tertiary hospitals in Pakistan where pediatric patients may present with risk modifiers such as anemia, malnutrition, or recent respiratory illness, increasing the clinical value of an agent that is less likely to depress ventilation.

Hemodynamic stability: predictable dexmedetomidine effects and how to manage them

A consistent finding in this trial was that dexmedetomidine produced **higher rates of bradycardia and hypotension**, whereas midazolam showed fewer cardiovascular suppression events. This outcome is expected and strongly biologically plausible: dexmedetomidine is an α_2 -adrenergic agonist, lowering sympathetic tone and reducing heart rate and blood pressure. The critical interpretation is not that dexmedetomidine is unsafe, but that its cardiovascular effects are **predictable and must be anticipated** through dose strategy, gradual administration (when IV), and careful monitoring.

Clinical trials and reviews have repeatedly noted that hemodynamic changes are the trade-off for dexmedetomidine's respiratory advantages. Dose-controlled and systematic evidence in MRI sedation has highlighted that bradycardia can occur, though it is commonly transient and treatable with observation or minimal intervention when appropriate monitoring protocols are in place (Khan et al., 2024; Zhang et al., 2021).

In Lahore's tertiary setting, these findings suggest that dexmedetomidine should be considered particularly suitable where monitoring is robust and staff are trained to recognize hemodynamic shifts early. However, in children with baseline conduction abnormalities, dehydration, or borderline cardiovascular reserve, midazolam may still be preferred or dexmedetomidine should be titrated cautiously. The broader implication is that sedation protocols should incorporate **age-adjusted thresholds** for bradycardia/hypotension and clear intervention algorithms rather than relying on clinician intuition alone.

Agitation and behavioral recovery: the underappreciated driver of discharge delay

An important secondary outcome was the **substantially higher rate of agitation in the midazolam arm**, compared with the dexmedetomidine arm. Agitation matters in pediatric imaging because it is not just unpleasant—it can increase caregiver distress, complicate post-sedation observation, and directly extend discharge time even if physiologic parameters are stable. Midazolam is well known to trigger paradoxical reactions in some children, including restlessness, crying, and disinhibition, and this trial's pattern aligns with that established clinical reality.

By contrast, dexmedetomidine is increasingly associated with calmer behavioral recovery and lower emergence agitation in pediatric contexts. A meta-analysis comparing intranasal dexmedetomidine with oral midazolam in children reported better behavioral outcomes and reduced agitation-related phenomena, supporting its advantages for smoother separation and recovery experiences (Zhang, Xin and Yin, 2023). Similarly, a comparative study highlighted lower emergence agitation and favorable acceptance characteristics

with dexmedetomidine compared with midazolam (Rocha et al., 2024).

These external findings strengthen the interpretation that the shorter discharge readiness times observed under dexmedetomidine in our trial are likely mediated not only by faster physiologic recovery but also by **better quality of emergence**, including less agitation and fewer events requiring prolonged reassessment.

Imaging completion, rescue sedation, and real-world effectiveness

Although imaging success was high overall, the trial demonstrated a clinically important difference in **rescue sedation requirement**, with midazolam requiring rescue more frequently. This suggests that midazolam sedation may be less “durable” for longer imaging sessions, especially MRI. Previous work in pediatric MRI sedation has investigated combination protocols precisely because single-agent regimens may fail to maintain immobility across long sequences. A 2024 randomized controlled trial explored sedation strategies involving midazolam and intranasal dexmedetomidine during pediatric MRI, reflecting international efforts to improve both success and safety in real imaging practice (Frontiers in Pediatrics, 2024). Dose-optimization studies further underscore that maintaining sufficient sedation depth while minimizing adverse events is an ongoing challenge in pediatric MRI (Xie et al., 2024; Wang et al., 2024).

In Lahore's tertiary setting, where patient flow and scanner time are precious resources, higher rescue requirements under midazolam may translate into interruptions, repeated dosing, additional monitoring time, and greater staff workload. The lower rescue requirement with dexmedetomidine supports the idea that it may provide **more stable sedation trajectories**, though the slightly lower completion percentage in our dexmedetomidine arm highlights that no single agent is perfect, and patient selection remains critical.

Implications for tertiary hospitals in Pakistan

This trial has direct practical value for tertiary-care centers in Pakistan. First, it supports dexmedetomidine as a strong candidate for

standard imaging sedation protocols where respiratory safety and efficient discharge are top priorities. Second, it emphasizes that the cost of dexmedetomidine's benefits is cardiovascular monitoring vigilance—something that must be built into protocol design and staff training. Third, these results highlight the need for structured sedation pathways that account for modality (MRI vs CT), child age, baseline risk, and resource availability.

In many tertiary Pakistani settings, staffing and monitoring resources may fluctuate across shifts. A sedation approach that reduces respiratory events can be particularly valuable during peak hours or when rapid imaging is required. At the same time, the higher bradycardia/hypotension rate suggests that dexmedetomidine should not be used casually without monitoring standards. International pediatric medication guidance for sedatives repeatedly emphasizes continuous cardio-respiratory monitoring during procedural sedation, especially when agents with variable respiratory depression risk are used (Perth Children's Hospital, 2023).

Strengths and limitations

A major strength of the study is its randomized controlled design and pragmatic relevance to a real tertiary imaging service in Lahore. The outcomes selected—recovery time, discharge readiness, respiratory events, agitation, and hemodynamic stability—reflect the endpoints that matter most to clinicians and health systems.

However, interpretation should consider several limitations. First, sedation route variation (intranasal vs IV vs oral) may influence onset and event rates, and future trials could stratify by route to refine protocol recommendations. Second, while adverse events were captured systematically, rare severe events require larger sample sizes for precise risk estimation. Finally, local factors—such as comorbidity burden and staffing patterns—may influence generalizability to smaller hospitals, although they increase relevance to comparable tertiary centers in the region.

CONCLUSION

This randomized controlled trial conducted at a tertiary healthcare hospital in Lahore, Pakistan,

demonstrates that **dexmedetomidine and midazolam produce meaningfully different sedation experiences** for children undergoing diagnostic imaging. While both agents were capable of facilitating completion of CT and MRI procedures, their clinical profiles diverged in ways that are highly relevant to everyday practice in busy radiology units.

The most important finding of the study was that **dexmedetomidine consistently supported faster post-procedure recovery and earlier discharge readiness**. These advantages translate into more efficient patient flow, reduced recovery bay congestion, and improved caregiver convenience—outcomes that are particularly valuable in tertiary centers where imaging demand is high and resources are stretched. In addition, dexmedetomidine was associated with **substantially fewer respiratory complications**, including markedly lower rates of oxygen desaturation and reduced need for airway support maneuvers. Given the inherent challenges of airway access within MRI and CT environments, this respiratory safety advantage strengthens the case for dexmedetomidine as a preferred sedative in non-painful imaging procedures.

Midazolam, although widely used and familiar across many settings, demonstrated **higher rates of desaturation and agitation**, and a greater requirement for rescue sedation. These effects can delay discharge, disrupt imaging workflow, and increase procedural stress for both caregivers and staff. Nevertheless, midazolam showed comparatively fewer cardiovascular effects than dexmedetomidine, supporting its continued value when bradycardia or hypotension risk is a primary concern, or when dexmedetomidine monitoring conditions cannot be reliably ensured.

The study also confirmed that dexmedetomidine's favorable respiratory and recovery performance comes with a predictable trade-off: **increased frequency of bradycardia and hypotension**. Importantly, these hemodynamic changes were largely manageable when careful monitoring and protocol-guided responses were in place, emphasizing that dexmedetomidine is best implemented within structured sedation pathways

supported by trained staff and appropriate monitoring equipment.

Overall, the findings suggest that **dexmedetomidine provides a clinically superior balance of recovery efficiency and respiratory safety for pediatric imaging sedation** in tertiary care settings like those in Pakistan, provided that cardiovascular monitoring is consistently available. These results support integrating dexmedetomidine into standardized sedation protocols for pediatric diagnostic imaging, while maintaining clear selection criteria and readiness for hemodynamic management. Future research with larger sample sizes, route-specific stratification, and longer-term follow-up would further strengthen evidence for optimizing pediatric imaging sedation protocols in the region.

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