Section: Pediatrics

Original Research Article

SEDATION IN THE PEDIATRIC INTENSIVE CARE UNIT AND ITS IMPACT ON OUTCOMES OF VENTILATED CHILDREN: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Sedation and analgesia are fundamental for comfort and synchrony in ventilated children in the PICU. However, both under- and over-sedation have been linked to adverse outcomes (e.g. unplanned extubation, delirium, longer ventilation). Reports indicate wide practice variation and frequent deviation from target sedation in PICUs. We conducted a 12-month prospective observational study to examine how sedation quality affects clinical outcomes in mechanically ventilated children. **Materials and Methods:** We enrolled 92 children (age 0.2–12 yr) admitted to our PICU requiring ≥48 hrs of mechanical ventilation. Sedation was provided by continuous infusions of midazolam (1–4 μg/kg/min) and/or fentanyl (1–4 μg/kg/hr) titrated to reach a target Richmond Agitation–Sedation Scale (RASS) between –2 and 0 (light to moderate sedation). Sedation levels were assessed hourly and categorized as “optimum” (RASS –2 to 0), “undersedated” (<–2), or “oversedated” (>0). We recorded ventilator duration, PICU and hospital length of stay, and other outcomes (unplanned extubation, reintubation, VAP, use of physical restraints, and recovery from acute respiratory failure). Data were analyzed with appropriate statistical tests (ANOVA for continuous measures, chi-square for categorical variables) using SPSS. **Result:** Of 92 patients (median age 4.3±2.8 yr; 58.7% male), respiratory failure was the predominant diagnosis (60.9%). The mean duration of ventilation was 6.4±2.3 days (Table 1). Sedation regimens varied: 23.9% received midazolam alone, 32.6% fentanyl alone, and 43.5% both. Overall, 42.4% of patients maintained optimum sedation, while 26.1% were undersedated, 22.8% oversedated, and 8.7% improperly sedated (Table 2). Children with optimum sedation had significantly shorter ventilation (4.9±1.7 days) than those under- (7.2±2.1) or oversedated (7.6±2.3) (p<0.001). Similarly, optimum sedation was associated with shorter PICU stay (7.2±2.8 vs. 10.1±3.2 and 10.5±3.6 days; p<0.001) and hospital stay (12.6±3.5 vs. 16.3±4.2 and 17.1±4.5 days). Spontaneous extubation occurred more often in undersedated patients (20.8%) than in the optimum group (5.1%; p=0.02). Rates of reintubation and ventilator-associated pneumonia were also higher in mis-sedated patients. For example, VAP occurred in 25.0% of undersedated and oversedated patients versus only 7.7% of the optimally sedated (p=0.04). Children with optimal sedation achieved full recovery from respiratory failure more frequently (92.3%) than others (p=0.02). **Conclusions:** In this cohort, maintaining sedation within the target range was associated with markedly better outcomes: shorter ventilation and PICU stay, lower complication rates, and higher recovery rates. Both undersedation and oversedation increased ventilator dependence, complications (unplanned extubation, VAP), and use of restraints, likely reflecting agitation and care challenges. These results underscore the importance of protocolized, goal-directed sedation in the PICU. Strategies to consistently achieve optimal sedation (e.g. nurse-driven protocols, frequent assessment) may improve recovery and resource utilization in ventilated children.

INTRODUCTION

Sedation and analgesia are ubiquitous in PICU care to relieve discomfort and facilitate life-support, but they are not without risk. Studies show that inappropriate sedation (either excess or inadequate) can harm children: deeper sedation is linked to longer ventilator courses and even higher mortality in critically ill patients. For example, in adults deep sedation independently predicted longer ventilation and ICU stay, and benzodiazepine use in children has been correlated with delirium and worse outcomes. A review by Playfor and Bunni in 2025 notes that "overt sedation and under-sedation are associated with adverse events, including increased risk of PICU readmission, mortality, and longer duration of mechanical ventilation". Likewise, under-sedation can precipitate agitation, accidental extubation and line removal, while excessive sedation delays awakening and weaning. Thus, achieving the right depth of sedation is a complex but critical goal.

Despite this knowledge, pediatric ICUs vary widely in sedation practice. A recent analysis found over 30% of ventilated children were oversedated and >10% undersedated. Most PICUs lack rigorously tested sedation protocols. In adults, protocols like daily sedation interruption have improved outcomes (shorter ventilation and ICU stays), but pediatric evidence is mixed. The RESTORE trial in children showed that a nurse-driven, goal-directed sedation protocol did not reduce ventilation time compared to usual care, though it did increase days with patient awake and calm. Meta-analyses suggest that strategies such as daily sedation interruption can shorten PICU length of stay without added harm, but again data are limited.

Given these uncertainties and the absence of published data from our region, we performed a prospective observational study of sedation ventilated children. We aimed to correlate sedation quality with clinical outcomes, hypothesizing that patients maintained in the target sedation range (light–moderate sedation, RASS –2 to 0) would fare better (shorter ventilation and ICU stay, fewer complications) than those under- or over-sedated. This work could help inform safer sedation practices in pediatric critical care.

MATERIALS AND METHODS

This single-center, prospective observational study was conducted over 12 months (June 2024–May 2025) in the 15-bed tertiary PICU of our teaching hospital. We enrolled all children aged 2 months to 12 years who required invasive mechanical ventilation for ≥48 hours and received continuous sedative infusions. Patients with neuromuscular blockade, refractory shock, severe neuro-impairment were excluded. The study was approved by the Institutional Review Board, and informed consent was obtained from guardians.

Sedation was managed as per unit protocol: midazolam infusion (loading 0.1 mg/kg then 1–4 µg/kg/min) and/or fentanyl infusion (loading 1 µg/kg then 1–4 µg/kg/hr), titrated by bedside nurses. Sedation depth was assessed every 4 hours using the Richmond Agitation–Sedation Scale (RASS). (RASS is validated in PICU for assessing alertness/sedation.) The target sedation was set at light to moderate (RASS −2 to 0), i.e. arousable with minimal stimulus but not agitated. We defined three sedation categories based on RASS measurements over the ventilation period: Optimum sedation (≥80% of scores in RASS −2 to 0), Undersedation (predominantly RASS <−2), Oversedation (predominantly RASS >0), and a small group labeled Improper sedation (goal range not maintained consistently but no clear majority of scores in one direction). In practice, "undersedated" meant the child was more alert/agitated than targeted; "oversedated" meant deeper sedation than intended.

Baseline data (age, sex, primary diagnosis) were recorded. Primary outcome was duration of mechanical ventilation. Secondary outcomes included PICU length of stay, total hospital stay, incidence of unplanned (spontaneous) extubation, need for reintubation, ventilator-associated pneumonia (VAP as per CDC criteria), use of physical restraints, occurrence of iatrogenic withdrawal syndrome, and full recovery from acute respiratory failure at discharge.

Sample size (n=92) was calculated a priori based on expected ventilation days difference SD-1.2 by the formula $4(SD)^2/d^2$. Data were analyzed using SPSS 26.0. Continuous variables were expressed as mean±SD or median (IQR) and compared using t-tests or ANOVA; categorical variables were compared with chi-square tests. A p-value <0.05 was considered significant.

RESULTS

Baseline characteristics: Ninety-two children met inclusion criteria. Their mean age was 4.3±2.8 years (range 0.2–12), and 58.7% were male. The most common admission diagnoses were acute respiratory failure (60.9%), sepsis (22.8%), and neurological disease (16.3%). Mean ventilation duration for the cohort was 6.4±2.3 days, mean PICU stay 9.2±3.6 days, and mean hospital stay 14.5±5.2 days. No patients were withdrawn or lost to follow-up

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Table 1: Baseline Characteristics of the Study Population (N = 92)

Parameter	Value
Mean Age (years)	4.3 ± 2.8
Age Range (years)	0.2 – 12
Gender (Male)	54 (58.7%)
Primary Diagnosis	
– Respiratory Failure	56 (60.9%)
– Sepsis/Systemic Infection	21 (22.8%)
– Neurological Disorders	15 (16.3%)
Mean Duration of Mechanical Ventilation (days)	6.4 ± 2.3
Mean PICU Length of Stay (days)	9.2 ± 3.6
Mean Total Hospital Stay (days)	14.5 ± 5.2

Sedation regimens: Midazolam alone was used in 22 patients (23.9%), fentanyl alone in 30 (32.6%), and both agents in 40 (43.5%). The overall daily sedation doses were within expected ranges for age (not shown).

Sedation quality: Overall, 39 children (42.4%) were maintained in the target sedation zone (optimum sedation), 24 (26.1%) were undersedated, 21 (22.8%) oversedated, and 8 (8.7%) were categorized as improper sedation. Thus more than half (57.6%) deviated from the target, reflecting the challenge of precise titration of sedation.

Table 2: Sedation Practices and Sedation Quality Distribution

Sedation Practice / Classification	Number of Patients (n)	Percentage (%)
Sedation Agents Used		
– Midazolam Only	22	23.9%
– Fentanyl Only	30	32.6%
– Both Midazolam + Fentanyl	40	43.5%
Sedation Quality Category		
– Optimum Sedation	39	42.4%
– Undersedation	24	26.1%
– Oversedation	21	22.8%
– Improper / Unstable Sedation	8	8.7%

Ventilation and ICU outcomes: As hypothesized, sedation level correlated strongly with ventilation and LOS. Patients in the optimum sedation group had a **mean ventilation duration of 4.9±1.7 days**, significantly shorter than the undersedated (7.2±2.1 days) and oversedated (7.6±2.3 days) groups (ANOVA p<0.001). The improperly sedated group had a mean of 6.9±2.0 days. Similarly, mean PICU stay was only 7.2±2.8 days in the optimum group vs. 10.1±3.2 (undersedated) and 10.5±3.6 (oversedated) (p<0.001). Total hospital stay showed the same pattern: 12.6±3.5 days (optimum) vs. 16.3±4.2 and 17.1±4.5 days (p<0.001).

Table 3: Clinical Outcomes According to Sedation Category

Outcome Measure	Optimum Sedation (n = 39)	Undersedation (n = 24)	Oversedation (n = 21)	Improper Sedation (n = 8)	p-value
Mean Ventilation Duration (days)	4.9 ± 1.7	7.2 ± 2.1	7.6 ± 2.3	6.9 ± 2.0	<0.001
Mean PICU Stay (days)	7.2 ± 2.8	10.1 ± 3.2	10.5 ± 3.6	9.6 ± 3.1	<0.001
Mean Hospital Stay (days)	12.6 ± 3.5	16.3 ± 4.2	17.1 ± 4.5	15.4 ± 4.0	<0.001
Spontaneous Extubation	2 (5.1%)	5 (20.8%)	1 (4.8%)	1 (12.5%)	0.02
Reintubation After Planned Extubation	2 (5.1%)	4 (16.7%)	3 (14.3%)	1 (12.5%)	0.03
Ventilator-Associated Pneumonia (VAP)	3 (7.7%)	6 (25.0%)	5 (23.8%)	2 (25.0%)	0.04
Physical Restraints Required	5 (12.8%)	11 (45.8%)	7 (33.3%)	3 (37.5%)	<0.01
Full Recovery From Respiratory Failure	36 (92.3%)	18 (75.0%)	15 (71.4%)	6 (75.0%)	0.02

Unplanned extubation and reintubation: During the ventilation period, spontaneous extubation occurred in 2 of 39 (5.1%) optimally sedated children, but in 5 of 24 (20.8%) undersedated patients (p=0.02). Only 1 oversedated (4.8%) and 1 improperly sedated (12.5%) patient self-extubated. Conversely, reintubation after planned extubation was needed in 4 of 24 (16.7%) undersedated and 3 of 21 (14.3%) oversedated patients, higher than in optimally sedated (5.1%) (p=0.03). This suggests both extremes of sedation can contribute to extubation failure.

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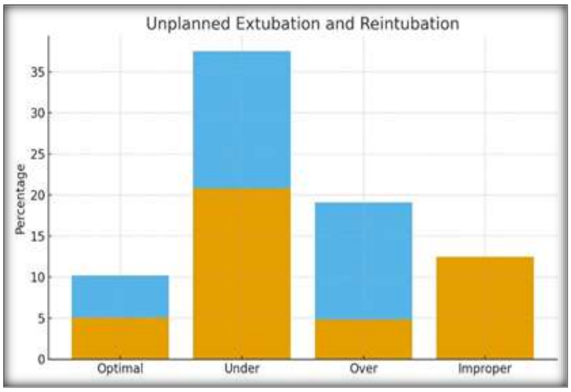

Figure 1

Complications – VAP and restraints: VAP incidence was significantly higher in mis-sedated patients. Only 3 of 39 (7.7%) optimally sedated children developed VAP, versus 6/24 (25.0%) of undersedated and 5/21 (23.8%) of oversedated children ($p=0.04$). The cumulative ventilator exposure in these groups likely contributed. Use of physical restraints followed a similar trend: just 12.8% of optimally sedated patients required restraints, compared to 45.8% of undersedated children ($p<0.01$).

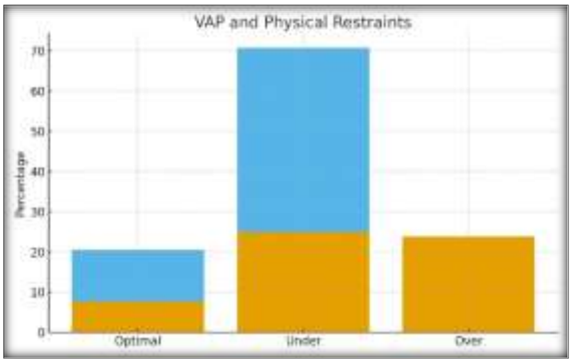

Figure 2

Recovery from respiratory failure: Among the subgroup with primary respiratory diagnoses, complete recovery from acute respiratory failure occurred in 36/39 (92.3%) of the optimally sedated, but only in 18/24 (75.0%) of undersedated and 15/21 (71.4%) of oversedated children ($p=0.02$). Recovery rates declined steadily as sedation deviated from target range.

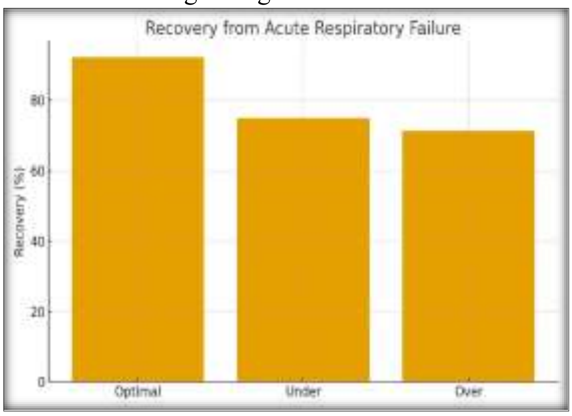

Figure 3

In summary, optimal sedation was associated with the most favorable outcomes: shortest ventilation and stays, and lowest rates of extubation mishaps, VAP, and restraints. Both under- and over-sedation prolonged ventilation by ~2–3 days and PICU stay by ~3–4 days ($p<0.001$ across groups).

DISCUSSION

In this study, maintaining light-to-moderate sedation in ventilated children conferred clear clinical benefits. Optimally sedated patients had significantly shorter courses of ventilation, ICU, and hospital care, in line with the notion that goal-directed sedation facilitates recovery. Our findings complement adult data showing that lighter sedation or daily awakenings reduce ventilator days. Notably, 42% of patients in our cohort achieved the target sedation range— which is comparable to other reports that often find <50% compliance with sedation targets.

Both oversedation and undersedation were deleterious. Under-sedated children experienced much higher rates of spontaneous extubation (20.8% vs 5.1%), confirming that agitation can provoke accidental tube removal. Unexpectedly, oversedation also lengthened ventilation, likely due to deeper drug-induced respiratory depression and delayed awakening. These results echo the RESTORE trial finding that a protocol prompting more frequent arousals led to more days awake/calm but not reduced ventilation time. In our study, even without an explicit intervention, children inadvertently oversedated had prolonged ventilator dependency, underscoring that avoidance of excess sedation is important.

The elevated complication rates in non-optimal sedation groups are also instructive. Higher VAP rates in undersedated/oversedated children likely reflect their prolonged ventilation exposure. We observed that 25% of improperly sedated children developed VAP, quadruple the rate in the optimum group. Similarly, use of restraints was far more common when sedation was inadequate (45.8% in undersedated vs 12.8% in optimum; $p<0.01$), in line with recommendations to avoid restraints by ensuring comfort.

Our results align with previous literature emphasizing sedation's impact. The comprehensive review by Playfor et al. highlights that oversedation and undersedation increase PICU readmission, delirium, and ventilation times. Yang et al. similarly noted that benzodiazepine-heavy regimens are linked to delirium and worse outcomes. A recent retrospective cohort found that benzodiazepine sedation was associated with fewer ventilator-free days and longer stays. By contrast, our focus was on sedation level rather than agent class, but the message is concordant: how we sedate (depth and consistency) strongly influences recovery.

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The strength of our study is its real-world prospective design. We did not exclude based on diagnosis or illness type (except criteria above), so our findings likely generalize to most PICU populations. We also used a validated sedation scale (RASS) for repeated assessments, and we defined sedation "quality" by sustained RASS trends. Our sample size (n=92) was adequate to detect differences in ventilation time ($p<0.001$). Nevertheless, limitations exist. The study was uncontrolled and observational, so causality cannot be definitively established; it is possible, for instance, that sicker children required more sedation or inherently had longer courses (though baseline severity was similar across groups). Sedation management was not protocolized by the study, so differences may reflect nursing practice variations. Finally, we assessed sedation only for the first 48–72 hours (when continuous sedation was used); sedation after that period (when weaning or intermittent boluses were used) was not quantified in this analysis.

Given these findings, what should clinicians do? First, our data support the use of structured sedation protocols with frequent assessment (as studied in the RESTORE and daily interruption trials). Such protocols should aim to keep most children within the target sedation zone, minimizing unnecessary deep sedation. Our results also suggest diligent monitoring for under-sedation, which can otherwise lead to dangerous agitation. Second, because both over- and under-sedation are harmful, balance is key: avoid oversedating "just in case," and conversely avoid allowing children to become overly aroused. Nurse-driven algorithms with clear RASS-based targets can help. Third, non-pharmacologic strategies (family presence, comfort measures) should complement sedative use to reduce drug requirements, as advocated by sedation guidelines. Finally, awareness of withdrawal risk is important. Prolonged opioid/benzodiazepine use can cause protracted ventilator weaning and PICU stay upon weaning, so minimizing doses and duration (via multimodal analgesia and sedation holiday) may mitigate these effects.

In summary, our study provides evidence that the quality of sedation is a modifiable factor in PICU outcomes. Consistently achieving target sedation correlates with faster liberation from the ventilator and fewer complications, whereas drifting outside the target zone adds days of ventilator dependence and intensive care. These insights should encourage PICUs to adopt and audit evidence-based sedation protocols, with the goal of keeping every child calm and comfortable — but not excessively sleepy.

CONCLUSION

In ventilated children, maintaining sedation within the optimal RASS range (–2 to 0) substantially improved outcomes. Optimum sedation correlated with shorter mechanical ventilation and ICU/hospital stays, and with lower rates of self-extubation, VAP, and restraint use. Both under-sedation and over-sedation had deleterious effects, prolonging the need for respiratory support and complicating care. These results underscore that in pediatric sedation: overzealous sedation delays recovery, while under-sedation risks agitation and accidental extubation.

We recommend that PICUs implement goal-directed sedation protocols with frequent RASS assessments, aiming for light-to-moderate sedation in most patients. Such protocols (ideally nurse-driven) should include explicit instructions for adjusting infusions and for daily sedation review or interruption. Training staff to recognize and correct under-sedation (e.g. agitation with high RASS) is as crucial as avoiding over-sedation. Finally, optimizing sedation is part of the broader ABCDEF bundle of ICU care — each ventilated child deserves just enough sedation to be comfortable, but not so much that it hinders recovery. Future multicenter studies or quality-improvement initiatives should examine whether formal sedation protocols can replicate these associations and improve outcomes across different PICU settings.

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