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A comparison of high dose versus low dose intranasal midazolam for sedation in the pediatric emergency department

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ABSTRACT

Objectives: In the pediatric emergency department (PED), minimal sedation is commonly used for procedures such as laceration repairs or radiological imaging, we sought to evaluate high-dose versus low-dose intranasal midazolam (INM) and correlation with the need for additional rescue sedation medications.
Methods: We conducted a single center, retrospective cohort analysis of pediatric patients admitted to the PED who received INM from August 1, 2022 to August 31, 2023. Patients were included if they were <18 years old, weighed ≤22 kg, and required INM for minimal sedation. The primary outcome was a composite measure of additional sedation medications administration following the initial dose of INM, defined as any additional dose given between 5 and 15 min, 15–45 min, or provider-documented failure after the initial dose of low-dose INM (0.2 mg/kg) or high-dose INM (0.5 mg/kg).
Results: During the study period, 336 patients received INM, with 161 patients meeting inclusion criteria. Among these patients, 25 patients received low-dose INM and 136 patients received high dose INM. Most patients received INM for a laceration repair. More patients required additional sedation medications to complete the procedure in the low-dose vs high-dose INM group (28.0% vs 7.4%, $p = 0.01$). There was no difference between groups on PED length of stay, time from arrival to initial INM, or time from initial INM to time of discharge.
Discussion: In this study, patients who received high dose INM for minimal sedation were less likely to need additional sedatives without an increase in adverse events or a longer PED length of stay.

1. Introduction

In the pediatric emergency department (PED), minimal sedation (anxiolysis) is commonly used for minor procedures (i.e., laceration repairs) or radiological imaging [2,6-11,17-21]. Sedation in pediatrics can help immobilize patients without the need for restraints, and relieve any anxiety or stress caused by the procedure [1,2]. Adequately sedating a pediatric patient has also been shown to reduce stress for the medical team and to decrease procedure time [2,3].

Midazolam, a γ-aminobutyric acid (GABA) receptor agonist, is commonly used in pediatrics for minimal sedation due to its sedative, anxiolytic, and amnestic effect [3]. By using a mucosal atomizer device (MAD), intranasal midazolam (INM) can be easily administered to a patient and can reach therapeutic levels of sedation [4]. Intranasal midazolam is able to adequately provide sedation due to the rich vascular plexus cavity which communicates with the subarachnoid space via the olfactory nerve [14,15]. Previous studies have demonstrated that there is improved cooperation when the INM is administered via a MAD versus drop instillation [16].

The onset of sedation for INM has been reported between four and 14 min, with a duration of sedation of 29 and 58 min, depending on dose [5-8]. INM is generally well tolerated with the most commonly reported adverse effects being irritation in the nose, a bitter taste in the mouth, and emesis [3].

Current literature has evaluated a wide range of dosing for INM, ranging from 0.2 to 0.5 mg/kg, with no clear guidance on the ideal dosing strategy [2,5-11]. This study aims to evaluate high-dose versus low-dose INM and correlation with the need for additional rescue sedation medications.

2. Materials and methods

We conducted a single center, retrospective cohort analysis of pediatric patients admitted to the PED following Institutional Review Board approval with a waiver of informed consent. We identified patients via documented administration of INM in the PED from August 1, 2022, to August 31, 2023. Patients were included in this study if they were < 18 years old, weighed ≤22 kg, were located in the PED, and

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were determined by the treating physician at initial assessment to be appropriate candidates for minimal sedation with INM… At our institution, minimal sedation is defined as, a drug-induced state in which the patient responds normally to verbal commands, may have impaired cognition and coordination, but maintains unaffected ventilatory and cardiovascular function, with only one medication administered via a single route.

We excluded patients if the INM was documented in the electronic medical record (EMR) as given for seizures or behavioral agitation not associated with anxiety secondary to a procedure, were wards of the state, were pregnant, or were in police custody. Patients who were admitted to the hospital were excluded so as not to skew PED length of stay analysis. Additionally, in accordance with our institutional definition of minimal sedation—we excluded patients who received any sedation medication (e.g., opioids or low-dose ketamine) within two hours prior to, or within five minutes after, INM administration to minimize confounding from concurrent or near-immediate co-administration, which could obscure the independent effect of INM on sedation outcomes. This short post-administration window was intended to exclude cases where additional medication was given before INM could exert its expected onset of action (typically 5–15 min). While the 15–45 min interval was designed to reflect the anticipated peak and maintenance phase of sedation. Before data collection, dosing cut-offs were set a priori to specifically target the lower and upper ends of the recommended INM range (0.2–0.5 mg/kg, max 10 mg/dose) used in the literature and our institutional practice. The low-dose group was defined as 0.2 mg/kg and the high-dose group as 0.5 mg/kg, with ±10% included to account for rounding in clinical practice (0.18–0.22 mg/kg and 0.45–0.55 mg/kg, respectively). Dosing cutoffs in this study were chosen to represent the upper and lower extremes of the dosing range, under the assumption that comparisons at these extremes would maximize the likelihood of detecting differences in outcomes. Patient's whose initial dose fell outside of these predefined groups were excluded from this study. During the study period there was no formal protocol at our institution dictating dosing for INM, therefore dosing selection was at the discretion of the treating physician. Categorization into either low-dose INM or high-dose INM was based on the first administered dose to reflect the initial clinical decision. The decision to give additional sedation medications was determined by the physician.

Data was extracted from the EMR (Cerner Millennium) using both electronic and manual methods. Demographic and clinical encounter data were primarily extracted electronically, while more detailed clinical variables (e.g., procedure or dose) were manually abstracted. Manual abstraction was conducted by the primary author using standardized data collection forms, with study data collected and managed in REDCap, hosted by the University of New Mexico [12]. Data collected includes patient demographics, PED length of stay, medications administered (including initial INM, additional sedation medications, local anesthetics, and any analgesics administered), and any documented side effects attributed to the INM. The indication for sedation was determined through review of the physician's primary documentation (discharge note), which summarized the care provided during the emergency department encounter. For patients that required a deeper level of sedation separate procedure notes were not reviewed. Baseline characteristics of patients are described by group. Categorical data are described as frequency and percentages, and continuous data are described as means and standard deviation. Statistical analysis was completed using the IBM® SPSS Statistics 19 software [13]. Categorical data was compared using Chi squared, Fishers Exact Test, and univariate logistic regression when appropriate. Continuous data was compared using an Independent *t*-test and Mann Whitney U. Statistical tests were interpreted using a two-sided alpha of *0.05* and were considered statistically significant if the $p < 0.05$.

The primary outcome was a composite measure of additional sedation medication administration following the initial dose of INM, defined as any additional dose given between 5 and 15 min, 15–45 min, or explicit physician-documented sedation failure. Patients who received an additional sedative medication between 5 and 45 min and had physician-documented sedation failure were included only once in the composite outcome. Patients who received an additional sedative medication after 45 min were only included in the primary composite outcome if they had explicit physician-documented sedation failure in the discharge note. The primary outcome was further evaluated based upon pre-defined subgroups including 1) the indication for the sedation and 2) the timing of additional doses of sedation medication (5–15 min and 15–45 min). Secondary outcomes included PED length of stay, time from PED presentation to initial INM dose, time from initial INM dose to PED discharge, and any documented adverse drug reactions attributed to INM.

3. Results

During the study period, 336 patients received INM in the PED, with 161 patients meeting inclusion criteria (Fig. 1). Among these patients, 25 patients received low-dose INM and 136 patients received high-dose INM. The median age was 34 months (IQR 31), mean weight 14.5 kg (range 5.3–22.0 kg), and 57.1% male. There was no statistical difference between baseline characteristics between groups (Table 1). As expected, the low-dose group received a statistically lower initial INM dose (2.8 ± 0.8 mg) compared to the high-dose group (7.2 ± 1.9 mg). There was no statistical difference between groups in regard to the indication for INM, with the majority of patients receiving INM for laceration repair (Table 1). There was no difference between the number of patients who received local anesthetics [14 (56%) vs 72 (52.2%), $p = 0.83$) or analgesics [5 (20%) vs 36 (26.5%), $p = 0.5$) Among patients who received analgesics, acetaminophen and ibuprofen were the most commonly used medications, with no patients receiving opioids prior to INM administration. Among patients who received an additional sedative medication between 5 and 45 min ($n = 10$), the median time to administration was not statistically different (26.2 ± 5.4 vs 23.3 ± 10.8, $p = 0.58$).

For the primary composite outcome (Table 2), patients in the low-dose INM group were more likely to require additional sedation medications compared to those in the high-dose INM group (7 [28.0%] vs 10 [7.4%], $p = 0.01$). Among patients who received an additional sedative ($n = 22$), 14 (63.6%) received midazolam, 7 (31.8%) received ketamine, and 1 (4.5%) received fentanyl. There was no statistically significant difference between groups with respect to the specific supplemental agent administered ($p = 0.325$).

There was no significant difference between groups in the administration of additional sedatives within 5 to 15 min of initial INM dosing (0 [0%] vs 2 [1.5%], $p = 1.00$). However, a significant difference was observed between 15 and 45 min (6 [24%] vs 2 [1.5%], $p < 0.001$). No statistically significant difference was observed between groups in physician-documented sedation failure (3 [12.0%] vs 6 [4.4%], $p = 0.15$).

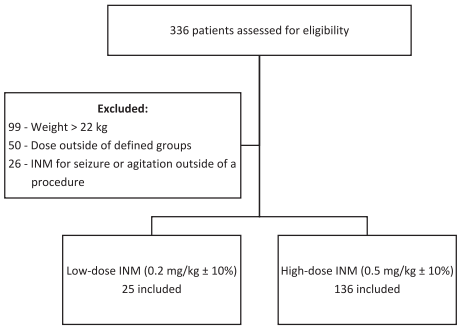

Fig. 1. Inclusion & Exclusion.
Intranasal midazolam (INM).

Table 1
Baseline Characteristics.

	Low-dose ($n = 25$)	High-dose ($n = 136$)	*P* value
Age, mo	33.2 ± 22.2	37.7 ± 20.1	0.43
Weight, kg	13.8 ± 4.3	14.6 ± 3.9	0.39
Male sex, n (%)	15 (60)	77 (56.6)	0.75
Race, n (%)			
White/Anglo	19 (76.0)	96 (70.6)	0.58
American Indian/Alaska native	3 (12)	16 (11.8)	1
Black/African American	0 (0)	0 (0)	1
Asian	1 (4)	2 (1.5)	0.4
Unavailable	2 (8)	22 (16.2)	0.38
Ethnicity, n (%)			
Hispanic/Latino	19 (76)	108 (79.4)	0.7
Initial INM dose, mg	2.8 ± 0.8	7.2 ± 1.9	<0.001
Initial INM dose, mg/kg	0.2 ± 0.01	0.5 ± 0.02	<0.001
Analgesics given in PED, n (%)	5 (20)	36 (26.5)	0.5
Local anesthetics given in PED, n (%)	14 (56)	72 (52.2)	0.83
Procedure, n (%)			
Imaging	4 (16)	26 (19.1)	0.71
Laceration repair	13 (52)	82 (60.3)	0.44
Other*	8 (32)	28 (20.3)	0.21
Time to repeat dose (≤45 mins)	26.2 ± 5.4	23.3 ± 10.8	0.58

Intranasal midazolam (INM), pediatric emergency department (PED).
* Other includes: bladder catheterization, IV-line placement, fracture/dislocation, foreign body removal, incision/drainage, nasogastric tube placement, visualization of the eye, and a bladder prolapse reduction.

When the primary composite outcome was evaluated by indication for sedation, patients who received low-dose INM for imaging were more likely to require additional sedation medications [2 (8%) vs 2 (1.5%), $p = 0.02$]. There was no statistically significant difference between groups in the proportion of patients who received INM for laceration repair [3 (12%) vs 6 (4.4%), $p = 0.10$] or all other indications [2 (8%) vs 2 (1.5%), $p = 0.21$].

There was no difference between the low-dose and high-dose INM groups, as shown in Table 2, on PED length of stay (4.9 ± 2.6 h vs 4.8 ± 2.4 h, $p = 0.91$), time from arrival to initial INM (1.7 ± 4.6 h vs 2.6 ± 1.7 h, $p = 0.08$), or time from initial INM to time of discharge (3.2 ± 5.0 h vs 2.2 ± 1.9 h, $p = 0.09$). Throughout the study period, only one side effect was documented that was attributed to INM, which occurred in the high-dose group. The reported side effect was dystonia and allergic reaction which resolved after intravenous diphenhydramine.

Table 2
Results.

	Low-dose ($n = 25$)	High-dose ($n = 136$)	*P* value
Primary composite outcome, n (%)	7 (28)	10 (7.4)	0.01
5–15 min	0 (0)	2 (1.5)	1
>15–45 min	6 (24)	2 (1.5)	<0.001
Provider-documented sedation failure	3 (12)	6 (4.4)	0.15
PED length of stay, hr	4.9 ± 2.6	4.8 ± 2.4	0.91
Time from arrival to initial INM, hr	3.1 ± 2.6	2.6 ± 1.7	0.08
Time from initial INM to discharge, hr	3.2 ± 5.0	2.2 ± 1.9	0.62
Reported adverse effects, n (%)	0 (0)	1 (0.7)*	1
Primary composite outcome by indication for sedation, n (%)			
Imaging	2 (8)	2 (1.5)	0.02
Laceration repair	3 (12)	6 (4.4)	0.1
Other**	2 (8)	2 (1.5)	0.21

Intranasal midazolam (INM), pediatric emergency department (PED).
* Reported adverse effect: dystonia and allergic reaction which resolved after intravenous diphenhydramine.
** Other includes: bladder catheterization, IV-line placement, fracture/dislocation, foreign body removal, incision/drainage, nasogastric tube placement, visualization of the eye, and a bladder prolapse reduction.

4. Discussion

In this single center, retrospective cohort analysis of pediatric patients admitted to the PED we compared low-dose INM with high-dose INM for minimal sedation with respect to the need for additional sedation to complete the designated procedure. High-dose INM was associated with a significantly lower need for additional sedation during the procedure compared with low-dose INM. No difference was observed in PED length of stay or adverse events; however, these findings should be interpreted with caution given the small sample size and the low number of reported adverse events.

In a pharmacokinetic study performed by Mellion et al. INM 0.4 mg/kg administered via a MAD had a median time to peak concentration of 10.1 min with a plasma concentration above 90% of max from 5 to 17 min [17]. Yealy et al. demonstrated that patients who received INM via drops had a recovery time of roughly 45 min [6]. In our study, time frames were chosen based on these previous pharmacokinetic studies in an attempt to differentiate differences between the doses. For our study, we did not include any patients who received a second sedation dose less than five minutes as they likely did not have a plasma concentration above 90%. Fifteen minutes was chosen as a cutoff for practicality and consistency to increase the reliability that the that patient would have a concentration above 90%. Finally, 45 min was chosen as the cutoff, as it is reasonable to expect that the effect of the INM would have worn off by then and a repeat dose might be needed for continued light sedation. Moreover, those who received a repeat dose prior to 45 min received that dose at a mean time of 27 min. It is possible that these patients either metabolized the midazolam quicker or just required a deeper level of sedation to complete the procedure despite the provider's initial determination that INM alone would be sufficient to complete the procedure.

There was no difference seen in PED length of stay between groups with both groups staying in the PED for a total of 5 h. Additionally, there was no difference in time from admission to initial INM dose or time from initial INM to discharge. Our mean time to discharge after INM for a laceration repair was 1.7 h which is similar to times reported by previous literature, which reported a discharge at one-hour post after receiving INM 0.4–0.5 mg/kg [2,6]. Our mean time to discharge after INM for imaging was slightly longer at 2.7 h, likely due to patients needing to wait for imaging results. Due to the retrospective nature of this trial, we were unable to assess time to recovery, which has been reported to be 42–47 min post INM [6].

In our cohort, only one adverse event was attributed to INM, with no observed episodes of hypoxia or nasal irritation. With INM, the most frequently observed side effect has been nasal irritation [18-20]. A large systematic review of procedural sedation reported a hypoxia rate of 12.6 per 1000 patients across all routes of midazolam administration, underscoring that hypoxemic events are uncommon but clinically relevant [21] Owing to the limited sample size, our study lacked sufficient statistical power to detect differences in adverse events between the low-dose and high-dose INM groups; however, the absence of hypoxemia in our cohort suggests a favorable safety profile. While both low-dose and high-dose INM have been reported to increase satisfaction when administered for minimal sedation, due to the retrospective nature of this study, we were unable to assess patient, family, or physician satisfaction with the administered INM dose [2,22].

Our study has several limitations that should be acknowledged. Due to the retrospective design, exact procedure start times were not consistently recorded in the medical record. This precluded precise measurement of the interval between INM administration and procedure initiation, which is a known factor influencing sedation effectiveness. To address this gap, we used available chart data as a proxy, including whether a second dose was administered within predefined time intervals (e.g., 5–15 min, 15–45 min) and/or explicit physician documentation of inadequate sedation. While this approach does not fully account for timing variability, it allowed us to incorporate relevant

temporal context into our analysis. Dosing information for medications administered after the initial INM was not collected. Accordingly, we are only able to report the specific supplemental agent administered (e.g., fentanyl) and the time frame in which it was given. For the patient who received fentanyl, we were unable to determine from the EMR whether it was administered for additional sedation during the procedure or for analgesia following completion of the procedure.

The utilization of low-dose INM, in this study, was lower than anticipated, which may reflect selection bias, with physicians preferentially administering the higher dose to certain children based on clinical judgment. Factors influencing this decision likely included patient age, level of anxiety or distress, anticipated procedural difficulty, and prior response to sedation. To address the potential impact of unequal group sizes, we performed comparisons using appropriate statistical methods that are robust to differences in sample size, including Fisher's Exact Test for categorical variables, as detailed in the Methods section. Importantly, there were no statistically significant differences between the high-dose and low-dose INM groups with respect to baseline demographic characteristics, including age, weight, or procedure type, which reduces the likelihood that observed outcomes were driven by confounding differences between groups rather than dosing strategy. Despite this limitation, when a post-hoc power analysis was performed for the primary outcome, we achieved 80.1% power, adding validity to our results.

An additional limitation of our study was the incomplete or limited documentation of side effects. As this was a retrospective study relying on physician documentation in the electronic medical record, it is possible that mild or transient side effects were not consistently recorded, particularly if physicians did not perceive them as clinically significant or relevant to the procedure outcome. As such, the true incidence of side effects may be underestimated in our analysis. Finally, INM failure was not defined a priori; as a result, repeat doses of sedatives were administered at the discretion of the treating physician.

5. Conclusion

In conclusion, high-dose INM administered via a MAD for minimal sedation was less likely to need additional sedatives and did not result in more adverse effects or a longer PED length of stay. These findings should be interpreted with caution given the small sample size and limited number of reported adverse events.

Ethics approval and informed consent

Given the nature of the study, exemption was granted by the institutional review board and informed consent was not required.

CRediT authorship contribution statement

Jarrett Bremmer: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Preeyaporn Sarangarm:** Writing – review & editing, Supervision, Methodology, Formal analysis, Data curation, Conceptualization. **Ellen Fernandez:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Tara Neubrand:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Declaration of competing interest

The authors declare no conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria. The authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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