Double-blind Randomized Controlled Trial of Intranasal Dexmedetomidine Versus Intranasal Midazolam as Anxiolysis Prior to Pediatric Laceration Repair in the Emergency Department

Desiree N. W. Neville, MD, Katharina R. Hayes, MD, Yaron Ivan, MD, Erin R. McDowell, MD, and Raymond D. Pitetti, MD, MPH

Abstract

Objective: The objective of this study was to compare anxiolysis with intranasal dexmedetomidine, an alpha-2 agonist, versus intranasal midazolam for pediatric laceration repairs.

Methods: We performed a double-blind, randomized controlled trial of 40 patients 1–5 years with lacerations requiring suture repair in an academic pediatric emergency department (ED). Patients were randomized to receive either intranasal dexmedetomidine or intranasal midazolam. Our primary outcome measure was the anxiety score at the time of patient positioning for the laceration repair. We chose this time point to isolate the anxiolysis from the medications prior to intervention. Patient encounters were videotaped and scored for anxiety at multiple time points using the modified Yale Preoperative Anxiety Scale. The scale is 23.3–100 with higher scores indicating higher anxiety. We also evaluated these scores as a secondary outcome by dichotomizing them into anxious versus not anxious with a previously validated score cutoff.

Results: Of the 40 patients enrolled, 20 in the dexmedetomidine group and 18 in the midazolam group completed the study and were included in the analysis. The median age was 3.3 years (range = 1.0–5.4 years). The median baseline anxiety score was 48.3. The anxiety score at position for procedure for patients receiving dexmedetomidine was 9.2 points lower than those receiving midazolam (median difference = 9.2, 95% confidence interval = 5 to 13.3; median score for dexmedetomidine = 23.3, median score for midazolam = 36.3). The proportion of patients who were classified as not anxious at the position for procedure was significantly higher in the dexmedetomidine group (70%) versus the midazolam group (11%). The number needed to treat with dexmedetomidine instead of midazolam to obtain the result of a not anxious patient at this time point was 1.7 patients. There were also significantly more patients who were classified as not anxious at the time of wound washout in the dexmedetomidine group compared to the midazolam group (35% vs. 6%). Dexmedetomidine and midazolam performed similarly with respect to all other measures including anxiety at other time points, parental perceived anxiety, parent and proceduralist satisfaction, procedural success, complications, and time in the ED. There were no serious adverse events seen in either group.

Conclusions: Intranasal dexmedetomidine is an alternative anxiolytic medication to intranasal midazolam for pediatric laceration repairs, performing similarly in our study, except that patients who received dexmedetomidine had less anxiety at the time of positioning for procedure.
A

nxiety of the young pediatric patient can add to the challenging nature of procedures performed in the emergency department (ED). Pharmacologic and nonpharmacologic means of distraction and anxiolysis are commonly used to optimize the patient and family experience as well as to allow for the successful procedure completion. Intranasal medication delivery has been described as safe and effective and provides high patient and provider satisfaction. Concentrated medications, those that require small volumes (0.2–0.3 mL per nostril), are preferred for intranasal delivery, as volumes over 1 mL per nostril are not reliably absorbed.

Midazolam is a GABA receptor agonist and has been shown to be safe and effective for use in children to provide anxiolysis and preanesthetic sedation. Studies evaluating midazolam have shown improvements with anxiety and crying, as well as need for restraint. The most common complaint with intranasal midazolam is that it is noxious and painful to the nasal mucosa. It also has a relatively low concentration (5 mg/mL) leading to relatively large volumes required for intranasal dosing.

Dexmedetomidine is an alpha-2 agonist that can be used to provide anxiolysis, analgesia, or sedation. Intranasal dexmedetomidine provides anxiolysis or sedation without clinically significant negative hemodynamic consequences in the pediatric patient; in particular, it does not cause respiratory depression. The studies describe decreases in heart rate and blood pressure, which is expected with an alpha-2 agonist, but within a range that does not require intervention.

Intranasal dexmedetomidine has been shown to provide adequate sedation at a dose of 2 µg/kg for children ages 1–8 years old. A study of dexmedetomidine in children described a mean onset of effect at 25–30 minutes after administration. Dexmedetomidine is odorless, tasteless, and not noxious to the nasal mucosa. It is significantly concentrated (100 µg/mL), so appropriate doses are given in small volumes. The studies of intranasal dexmedetomidine have shown that it has a high nasal mucosa bioavailability in addition to being well tolerated through the intranasal route.

Young patients have difficulty with laceration repairs despite the fact that the procedure may be painless with appropriate local anesthesia. A majority of the lacerations seen in the toddler age group are on the face, which makes accomplishing successful distraction difficult. Midazolam is commonly used for anxiolysis to facilitate laceration repairs in children in the ED setting. Intranasal dexmedetomidine has been reported to be better accepted by patients than intranasal midazolam. Several studies have demonstrated anxiolysis with dexmedetomidine and compared it to midazolam in the anesthesia, dental, and imaging literature. This is the first study of intranasal dexmedetomidine for procedural anxiolysis in either pediatric or adult emergency medicine literature. Considering the large number of procedures performed in EDs on children, this medication has potential to add to the anxiolytic repertoire and improve the pediatric procedural experience.

The objective of this study was to demonstrate superior anxiolysis with intranasal dexmedetomidine compared to intranasal midazolam for pediatric laceration repairs. Our primary outcome measure was the modified Yale Preoperative Anxiety Scale (mYPAS) score as a measure of anxiety at the time of patient positioning for the procedure.

METHODS
Study Design
We conducted a double-blind randomized controlled trial comparing the use of intranasal dexmedetomidine to that of intranasal midazolam for anxiolysis prior to pediatric laceration repair. The study was approved by the institutional review board at our institution and was registered as a clinical trial prior to initiation of the study (NCT02168439).

Study Setting and Population
The study was conducted in an academic pediatric ED with approximately 70,000 visits per year. Patients 1–5 years of age who presented to the pediatric ED with lacerations less than 5 cm that required suture repair with anxiolysis were eligible for enrollment. Patients were identified through communication between the treating physician and the researchers at the time they were recognized to be eligible for the study. Children were excluded if their laceration repair required intravenous sedation; if they had other injuries requiring attention; if they had an allergy or sensitivity to midazolam or dexmedetomidine; if they had abnormal vital signs for age, particularly bradycardia or hypotension; if they had cardiac disease or Moya-Moya; or if they had an illness with significant nasal congestion.

Patients were offered enrollment when a researcher was available and the researcher or provider identified the patient as eligible for enrollment. The family was approached for enrollment and underwent informed consent.

Study Protocol
At the time of enrollment, a study order was placed in the electronic medical record for the study drug “intranasal dexmedetomidine versus midazolam study.” The order had a field to enter the patient’s chronologic study identification number (1–40). The research pharmacist, who was not otherwise involved in the study, generated a randomization schedule prior to initiation of the study. The randomization schedule was then used by the pharmacy to randomize the patients to receive either 0.4 mg/kg midazolam or 2 µg/kg dexmedetomidine. The concentrations of the medications were 5 mg/mL for midazolam and 100 µg/mL for dexmedetomidine. The dosage tables accounted for 0.1 mL of dead space in the nasal atomizer used for delivery. The pharmacy utilized dosage tables, which gave the dose by weight that each patient should receive. The weight was obtained during the ED triage.

All treating providers, nurses, patients, patient families, ancillary staff, researchers, and data analysts were blinded to the medication received. Syringes sent from the pharmacy to the ED appeared the same and contained the same volume per syringe, regardless of medication. Patients randomized to midazolam received their
dose split between two syringes due to the large volume necessary and patients randomized to dexmedetomidine received one syringe of medication due to the small volume and one of normal saline. The midazolam volume was split unevenly between the two syringes to assure it mirrored the volumes of dexmedetomidine and saline. Each patient received the medication intranasally, one syringe per nostril, using nasal atomizers. A care provider, not involved in scoring of the patient’s anxiety, administered the medication. The increased tolerance of dexmedetomidine by the nasal mucosa was unknown by the ED providers at the time of this study. The patient’s parents were not told about the differing tolerability of the two intranasal compounds, and the patient’s acceptance of the medication was not discussed with the research team. The randomization schedule that determined which medication was dispensed was not released to the research staff until completion of the study. The time lapse between medication administration and procedure initiation was 30 minutes. Laceration repair was completed per the treating physician. Child life or a child life proxy was available for distraction.

Measurements
The mYPAS was scored from video recordings of the patient encounters by two independent researchers not present at the time of enrollment. They entered their raw scores into a database. A researcher present at the time of enrollment had the parents/guardians score the Visual Analog Scale for anxiety. The parent/guardian and proceduralist completed scores for satisfaction with anxiolysis. The researcher present at the encounter entered this information into the database, as well as demographic characteristics and clinical characteristics including laceration and laceration repair information.

Key Outcome Measures
The primary outcome measure was the patient’s anxiety at the time of positioning for the procedure. We designed and powered the study to evaluate the patients’ anxiolysis from the medication, specifically prior to varying provider and technical practices during the laceration repair. We chose to include other time points that may be clinically relevant as well, such as wound washout and first stitch placement.

The patient’s anxiety was measured with the previously validated mYPAS. The scale utilizes five categories: activity, vocalizations, emotional expressivity, state of apparent arousal, and use of parents, scoring of which are combined into a total anxiety score between 23.3 and 100. Higher numbers represent higher anxiety. The raw scores were used as our primary outcome and for the sample size determination.

Two researchers independently reviewed the encounter videos and scored them with the mYPAS. A correlation coefficient was calculated between the two reviewers’ scores. The two reviewers’ scores were averaged to obtain the score used in the analysis. If patients were noted to be completely asleep, they received the lowest score for anxiety (23.3).

Each patient interaction was videotaped at specific time points including:
- Baseline: during application of analgesia (lidocaine-epinephrine-tetracaine gel if possible) prior to receiving the anxiolytic medication.
- Position: at the time of positioning the patient for the laceration repair.
- Washout: at the time of wound washout.
- Stitch: at the time of first stitch placement.

The mYPAS scores at the other time points including baseline and during the repair were reported as secondary outcomes.

Studies that have used the mYPAS have evaluated the proportion of patients who were not anxious. Patients with scores less than or equal to 30 are classified as not anxious based on prior characterization of the scale. We also analyzed our data using this anxiety cutoff.

Other outcomes included patient anxiety scores as reported by parents/guardians, parent/guardian and provider satisfaction, complications, successful procedure completion, and need for sedation. Procedure failure was defined as inability to complete the procedure; we did not record maximal patient distress as a variable.

The parents/guardians completed the anxiety scores at three time points: baseline, position, and recovery. The parents/guardians reported their assessment of the patient’s anxiety using a Visual Analog Scale for anxiety by making a vertical line on the 10-cm horizontal Visual Analog Scale. The line had “Not anxious” at one end and “Anxious” at the other. A researcher measured distance in 0.5-mm increments to determine the Visual Analog Scale score and entered this information into the database. A score of 0 indicates no anxiety and 10 indicates the highest anxiety.

The proceduralist who repaired the laceration and the parents/guardians completed a paper copy of a Likert-type question for satisfaction with anxiolysis on a scale of 1–5. The scores were defined as very unsatisfied, unsatisfied, neutral, satisfied, and very satisfied for 1, 2, 3, 4, and 5, respectively.

Any complications reported to the research staff or providers were included. Any procedure failures defined as the inability to complete the repair or requiring more medications or conversions to intravenous ketamine sedation were also recorded. As the adverse reaction outcomes are uncommon, the sample size was not large enough to evaluate comparative safety.

The time spent in the ED was compared between the two groups. The time was measured from baseline assessment (the first time point) to the time of discharge from the ED.

Data Analysis
Sample size calculation was based on a previously published study, which showed improved mYPAS scores in patients receiving intranasal dexmedetomidine versus oral midazolam preoperatively. We chose this study to base our sample size calculation on because it was the only study comparing the two medications that provided enough data (means and standard deviations [SD]) needed to calculate our sample size. The mYPAS means ± SDs from the Ghali paper at the time of transfer to the operating room (their primary outcome time)
were $31.59 \pm 3.88$ for dexmedetomidine versus $44.35 \pm 4.51$ for midazolam. The sample size calculation was based on showing superiority of dexmedetomidine defined as a 20% reduction of the mYPAS scores of children receiving dexmedetomidine compared to the scores of the children receiving midazolam. A 20% reduction was felt to be a clinically significant reduction in anxiety. The 20% reduction was calculated as 20% of the midazolam score (8.87 points different mYPAS scores). A t-test was used for this calculation. The sample size calculation was done with PASS 12 (NCSS, LLC), Version 12.0.1.

A sample size of 32 patients (16 in each group) provided 80% power at a 0.05 level of significance to detect a 20% difference in the raw anxiety score at the time of positioning for procedure. We sought to enroll 20 children in each group for a total of 40 patients.

The software used in the data analysis was SPSS (IBM SPSS Statistics for Macintosh, Version 22.0). The initial analytic plan was to compare the means between our two treatment arms to show a 20% reduction in anxiety scores. Our data was nonparametric, so Mann-Whitney U and Hodges-Lehman were used to describe the differences between the two treatment arms. The two video reviewers’ mYPAS scores were compared using the Spearman’s correlation coefficient for nonnormally distributed data. The mYPAS scores were also categorized into a dichotomous variable of anxious versus not anxious. This dichotomous variable was analyzed using the Fisher’s exact test. The Visual Anxiety Scale scores and time in the ED were analyzed with a t-test and p-values and confidence intervals (CIs) were reported. The scores from the Likert-type question for satisfaction were analyzed with Mann-Whitney U.

RESULTS

Characteristics of Study Subjects

Patients were enrolled from July 1, 2014, through March 5, 2015. The participant flow diagram is shown in Figure 1. There were four study refusals, two due to not wanting to be videotaped, one family that did not feel medication was necessary, and one parent who requested the use of midazolam from prior experience. Of 40 enrolled patients, 38 underwent completion of the study and analysis. Twenty of the analyzed patients received dexmedetomidine and 18 received midazolam. The demographic and laceration repair characteristics of the patients in the two intervention arms are described in Table 1.

There was one patient whose data were not collected due to equipment malfunction and they had no results to include in the analysis. Another patient received over twice his or her appropriate dose of medication due to a weight recording error and was withdrawn from the study and analysis. Both of these withdrawals occurred around the time of enrollment, before any unblinding or further patient enrollments.

Main Results

The mYPAS scores for each time point with associated CIs in each group are summarized in Table 2. The anxiety score in the dexmedetomidine group was 9.2 points lower than that in the midazolam group (Table 2). We did not find any statistically significant difference in anxiety at any time point except position for procedure using the raw mYPAS scores (Table 2, Figure 2).

The agreement between video reviewers for the mYPAS scores was evaluated using Spearman’s rank correlation coefficient. The agreement was 0.74 at baseline, 0.86 at positioning for procedure, 0.88 at washout, and 0.92 at first stitch, with a mean of 0.85.

We also evaluated the proportion of patients in each intervention arm who met criteria for being not anxious (Table 3, Figure 3). Two patients (11%) were classified as not anxious in the midazolam group compared to 14 patients (70%) in the dexmedetomidine group. The odds of the patient being not anxious at the time of positioning for procedure was 19 times higher after receiving intranasal dexmedetomidine versus receiving intranasal...
midazolam (odds ratio [OR] = 19, 95% CI = 3 to 108). The number needed to treat with dexmedetomidine instead of midazolam to have a patient not anxious at the time of positioning for procedure is 1.7 patients.

There were significantly more patients who were not anxious at the time of washout in the dexmedetomidine group (35%) versus the midazolam group (6%; OR = 9, 95% CI = 1 to 84). The number of patients not anxious at the time of the first stitch was not statistically different between the two groups but trended toward more patients not anxious in the dexmedetomidine group (OR = 3, 95% CI = 1–12).

The parent/guardian reported what they perceived the patient’s anxiety to be at three time points using a continuous Visual Analog Scale for anxiety. There was no statistically significant difference in scores between the two groups at any time point: baseline (midazolam 3.5, dexmedetomidine 3.8), position (midazolam 1.6, dexmedetomidine 1.7), or recovery (midazolam 1.2, dexmedetomidine 0.7).

The parents/guardians and proceduralists scored their satisfaction with anxiolysis from the medication on a 1–5 scale (1 = very unsatisfied to 5 = very satisfied). The median scores given by the parents/guardians in both groups was 5 (p = 0.8). The median scores given by the proceduralists were 5 in the midazolam group and 4.5 in the dexmedetomidine group (p = 0.7).

There were two complications noted in the midazolam group: one patient with several episodes of emesis and one patient with several falls due to unsteadiness after the procedure. The study was not powered to evaluate complications between the two groups. There were no procedure failures or conversion to procedural sedation required in either group.

There was no difference between the groups with regard to time spent in the ED. The time (mean ± SD) from baseline assessment to discharge was 2 hours 36 minutes (±33 minutes) in the dexmedetomidine group and 2 hours 24 minutes (±29 minutes) in the midazolam group (p = 0.25).

**DISCUSSION**

Providing anxiolysis for procedures is common in pediatric EDs. Midazolam has historically been the most common pharmaceutical utilized for anxiolysis in this population. As our center began using intranasal dexmedetomidine for anxiolysis, there were anecdotal successes, which led some providers to feel that it provided superior anxiolysis as compared to midazolam. A review of the current literature supported the anecdotal cases with several studies showing that dexmedetomidine may be superior or comparable to midazolam in terms of anxiolysis.11,16–18

While there are no current studies in pediatric emergency medicine or emergency medicine regarding the use of intranasal dexmedetomidine preprocedurally, there are studies in the anesthesia and dental literature. A randomized double-blind study of 120 children undergoing adenotonsillectomy compared oral midazolam to intranasal dexmedetomidine preoperatively and found improved sedation, anxiolysis, and child-parent interactions.

### Table 1
Demographic, Laceration, and Repair Characteristics by Treatment Arm

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Midazolam (n = 18)</th>
<th>Dexmedetomidine (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yr), mean</td>
<td>3.15</td>
<td>3.44</td>
</tr>
<tr>
<td>Male sex</td>
<td>12 (67)</td>
<td>13 (65)</td>
</tr>
<tr>
<td>Weight (kg), mean</td>
<td>15.5</td>
<td>15.8</td>
</tr>
<tr>
<td>Laceration location</td>
<td>18 face (100)</td>
<td>19 face (95), 1 finger (5)</td>
</tr>
<tr>
<td>Laceration length (cm), mean</td>
<td>1.44/1.25</td>
<td>1.59/1.40</td>
</tr>
<tr>
<td>Number of stitches, mean</td>
<td>5.78</td>
<td>5.35</td>
</tr>
<tr>
<td>Deep sutures placed</td>
<td>6 (33)</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Proceduralist performing laceration repair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resident</td>
<td>6 (33)</td>
<td>9 (45)</td>
</tr>
<tr>
<td>Fellow</td>
<td>6 (33)</td>
<td>7 (35)</td>
</tr>
<tr>
<td>Attending</td>
<td>1 (6)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Plastics</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Advanced practice provider</td>
<td>2 (11)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Medical student</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Oral &amp; maxillofacial surgeon</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Analgesia used for laceration repairs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analgesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LET</td>
<td>15 (83)</td>
<td>16 (80)</td>
</tr>
<tr>
<td>LET &amp; injected lidocaine</td>
<td>3 (17)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Peripheral nerve block</td>
<td>0</td>
<td>1 (5)</td>
</tr>
<tr>
<td>LET &amp; block</td>
<td>0</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

Data are reported as n (%) unless otherwise reported. LET = lidocaine-epinephrine-tetracaine gel.

### Table 2
Anxiety Scores at Four Time Points in Each Treatment Arm

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Midazolam, Median (IQR)</th>
<th>Dexmedetomidine, Median (IQR)</th>
<th>Size of Effect, Difference (95% CI)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>47.1 (38–57)</td>
<td>48.8 (35–84)</td>
<td>-0.8 (-25.0 to 10.0)</td>
<td>0.815</td>
</tr>
<tr>
<td>Position</td>
<td>36.3 (32–41)</td>
<td>23.3 (23–35)</td>
<td>9.2 (6.0 to 13.3)</td>
<td>0.007</td>
</tr>
<tr>
<td>Washout</td>
<td>47.1 (34–71)</td>
<td>42.5 (23–96)</td>
<td>3.6 (-21.7 to 14.2)</td>
<td>0.671</td>
</tr>
<tr>
<td>Stitch</td>
<td>35.4 (30–62)</td>
<td>23.3 (23–93)</td>
<td>5 (-10.8 to 10.8)</td>
<td>0.208</td>
</tr>
</tbody>
</table>

IQR = interquartile range.
separation with dexmedetomidine compared to midazolam. They also noted that dexmedetomidine had better analgesic properties postoperatively. A study of 72 children age 3–6 years undergoing anesthesia for complete dental rehabilitation showed that dexmedetomidine provided increased sedation at the time of separation from parents and a higher proportion of patients with satisfactory mask acceptance compared with midazolam.

In our double-blind randomized controlled trial, the two medications performed similarly, except that we found superiority of dexmedetomidine over midazolam in terms of anxiety level at positioning for procedure. As a secondary outcome, we did evaluate the anxiety scores by dichotomizing them as previously studies have done. As expected, the precision of this finding was low due to the use of an exact cutoff point.

Figure 2. Anxiety scores by time point. mYPAS = modified Yale Preoperative Anxiety Scale.

Table 3
Patients Who Are Not Anxious by Time Point in Each Treatment Arm

<table>
<thead>
<tr>
<th></th>
<th>Midazolam</th>
<th></th>
<th>Dexmedetomidine</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Not Anxious</td>
<td></td>
<td>Not Anxious</td>
<td></td>
</tr>
<tr>
<td>mYPAS ≤ 30 (n = 18), n (%)</td>
<td>1 (6)</td>
<td></td>
<td>3 (15)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mYPAS ≤ 30 (n = 20), n (%)</td>
<td>14 (70)</td>
<td></td>
<td>7 (35)</td>
</tr>
<tr>
<td>Baseline</td>
<td>2 (11)</td>
<td></td>
<td>11 (55)</td>
<td></td>
</tr>
<tr>
<td>Position</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washout</td>
<td>1 (6)</td>
<td></td>
<td>5 (28)</td>
<td></td>
</tr>
<tr>
<td>Stitch</td>
<td>5 (28)</td>
<td></td>
<td>11 (55)</td>
<td></td>
</tr>
</tbody>
</table>

Anxiety scores dichotomized into anxious or not anxious based on a mYPAS score of less than or equal to 30 representing no anxiety. The percentage of patients who were not anxious at each time point is compared between the two treatment groups. mYPAS = modified Yale Preoperative Anxiety Scale; NNT = number needed to treat.
This study evaluated the use of intranasal dexmedetomidine in a specific population requiring laceration repair and is not generalizable to other procedures for which intranasal midazolam may be used, particularly if those procedures are painful.

The researcher present for video recording could have increased or decreased the patient’s anxiety. Patient anxiety could have been increased due to an extra observer present at times in the room or decreased due to the patient’s relative familiarity with the researcher by the time of the procedure. Involvement of parents/guardians in distracting or reassuring their child could have confounded the anxiolytic effect, but should have been accounted for by randomization.

In terms of internal validity, the videos had suboptimal views of the patient’s facial expressions at times, particularly during washout and stitch placement in some patients, which required some extrapolation of their body language and vocalizations to complete the anxiety score. This limitation should have been equivalent in both intervention arms. Reassuringly, there was a high agreement between the two video reviewers’ anxiety scores.

We did not necessarily power our study to compare intranasal dexmedetomidine versus intranasal midazolam at time points other than position for procedure given there was no previously published literature for these other time points. There were some patients in the dexmedetomidine arm who were asleep for the position, washout, and/or first-stitch time points. Our scale could not differentiate sleeping patients from other nonanxious patients. Finally, this was not a safety study and we cannot compare the relative safety of the two medications.

CONCLUSIONS

In summary, intranasal dexmedetomidine and intranasal midazolam performed similarly in terms of anxiolysis for laceration repair in our study. The patients who received intranasal dexmedetomidine had less anxiety at the time of positioning for procedure than those who received midazolam. Intranasal dexmedetomidine can be considered an alternative anxiolytic medication to intranasal midazolam for pediatric ED laceration repairs.

The authors acknowledge the research pharmacist, Michelle Ung-Barlas, PharmD, for her contribution to the study logistics, randomization, pharmacy training, and monitoring, and the Clinical and Translational Science Institute (CTSI) for their assistance calculating sample size and reviewing the statistical analyses.

LIMITATIONS

Limitations of our study include that it took place at one center, where the physicians may have a different threshold for utilizing anxiolysis or sedation for laceration repairs compared to other centers. Another limitation is the use of a convenience sample when the research team was available or contacted by the treating physician. Generalizability could be affected by participant selection by the time of day and preferences of the treating physician.

REFERENCES


The National Library of Medicine is offering a free online TOXNET class this fall

“TOXNET is a web-based system of databases covering hazardous chemicals, environmental health, toxic releases, chemical nomenclature, poisoning, risk assessment and regulations, and occupational safety and health. The independent modules cover TOXLINE, ChemIDPlus, TRI, TOXMAP, Hazardous Substances Data Bank, IRIS, Has-Map, LactMed, WISER, CHEMM, REMM, LiverTox and more. You’ll learn about the resources through videos, guided tutorials, and discovery exercises.”