RESEARCH ARTICLE

Safety and Efficacy of Buccal Dexmedetomidine for MRI Sedation in School-Aged Children

Juan P. Boriosi, MD,[a] Jens C. Eickhoff, PhD,[b] Gregory A. Hollman, MD[a]

ABSTRACT

OBJECTIVES: Intranasal, intramuscular, and intravenous (IV) dexmedetomidine routes have been used successfully for pediatric MRI studies. We designed this retrospective study to determine efficacy and safety of buccal dexmedetomidine for pediatric MRI sedation.

METHODS: Medical records were reviewed of outpatient children ages 5 to 18 years who received buccal dexmedetomidine with or without oral midazolam for MRI sedation at a freestanding children's hospital sedation program in 2015 and 2016.

RESULTS: A total of 220 outpatient encounters received buccal dexmedetomidine for MRI. Mean age of the cohort was 10.1 ± 2.6 years (range: 5–18.7). Buccal dexmedetomidine dose administered was a mean of 2.20 ± 0.38 μg/kg (range: 0.88–3.19). Of the 220 sedation encounters, 179 (81.4%) patients had satisfactory sedation with buccal dexmedetomidine with or without oral midazolam: 84 had buccal dexmedetomidine as the sole sedative, 95 had satisfactory sedation when buccal dexmedetomidine and oral midazolam (mean: 0.33 ± 0.07 mg/kg; range: 0.21–0.53) were given together, 1 (0.4%) had satisfactory sedation when intranasal fentanyl and midazolam were administered in addition to buccal dexmedetomidine, and 35 (15.9%) required IV sedatives to achieve satisfactory sedation. All patients completed their MRI successfully except 5 (2.2%): 2 encounters were sedation failures, 2 IV sedations developed severe upper airway obstruction, and 1 IV sedation experienced MRI contrast anaphylaxis.

CONCLUSIONS: In a selected population of pediatric patients, buccal dexmedetomidine with or without midazolam provides adequate sedation for most MRI studies with few adverse effects, but given a failure rate of almost 20%, modifications to buccal dexmedetomidine dosing should be investigated.

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MRI has become a critical diagnostic imaging tool in a host of pediatric diseases.[1,2] MRI is noninvasive, but sedation is frequently required in children to remain motionless and to achieve quality diagnostic images. For noncontrast MRI studies in children, the only need for an intravenous (IV) catheter would be to provide IV sedation. Consequently, the use of non-IV sedatives becomes an attractive and convenient alternative to IV sedation. Conventional oral agents such as chloral hydrate or benzodiazepines have been associated with sedation failure, respiratory depression, and paradoxical agitation.[3]

Dexmedetomidine is a highly selective $\alpha 2$ adrenoceptor agonist approved by the US Food and Drug Administration in 1999 for sedation in adults who are mechanically ventilated in the ICU and in 2008 for procedural sedation of adults who are nonintubated in areas outside the ICU. [4] To date, dexmedetomidine has not been approved by the Food and Drug Administration for use in children but has been used increasingly for sedation in children undergoing nonpainful procedures.[5] Dexmedetomidine has the advantage of causing minimal respiratory depression and limited hemodynamic effects compared to other sedatives.[6] Intranasal, intramuscular, and IV routes have been used successfully for pediatric MRI studies.[7–9] In 2015, our program started using buccal dexmedetomidine for MRI studies because of a preference of the buccal versus intranasal route of administration in school-aged children admitted to our program for sedation. Buccal dexmedetomidine as a primary sedation regimen for MRI examinations in children is not well described in the literature. We designed this retrospective study to determine the efficacy and safety of buccal dexmedetomidine with or without oral midazolam for pediatric MRI sedation.

METHODS

After institutional board review approval, the medical records of 220 outpatient encounters receiving sedation with buccal dexmedetomidine for 3 Tesla MRI procedures at a freestanding children's hospital pediatric sedation program from October 2015 to September 2017 were reviewed retrospectively. Subjects were identified from the pediatric sedation program database. All studies were performed in a 3 Tesla MRI scanner (General Electric Medical Systems, Milwaukee, WI) according to our radiology department protocols. Demographic characteristics, sedation-related adverse events (eg, oxygen desaturation, upper airway obstruction, laryngospasm, etc), interventions, and outcome data were collected from the database and patient's medical record. The pediatric sedation program is a pediatric critical care and pediatric hospital medicine-based program and an active member of the Pediatric Sedation Research Consortium (PSRC). Consequently, our program is used to observe data collection methodology and definitions of sedation-related adverse events employed by the PSRC.[10] Adverse events were defined as apnea, airway obstruction, desaturation, bradycardia, and inability to complete the procedure.

Sedation Procedure

Outpatients referred to the sedation clinic primarily (but not exclusively) for noncontrast MRIs were the targeted population for this study because the use of non-IV sedatives becomes an attractive and convenient alternative to IV sedation in this population. However, per our MRI process, all patients 9 to 12 years scheduled for an MRI received a pre–clinic visit phone call to assess whether sedation was needed. All patients who came to the clinic were assessed by a certified child life specialist and a sedation nurse for the need (and depth) of sedation for MRI. The assessment included having patients watch an MRI preparation video appropriate for their age. In addition, the wishes of the patient and parent regarding the need and level of sedation were considered in the management plan. The plan could be that no sedation was needed, moderate sedation was needed for an anxious child who could hold still for the duration of MRI, or deep sedation was needed for a patient who could not hold still for the duration of MRI. Standard fasting guidelines were followed by all children sedated in this study. Buccal dexmedetomidine was administered in accordance with protocols approved by our pharmacy. All children received the drug ~45 minutes before the procedure. We chose a buccal dexmedetomidine dose of 2 to 3 μg/kg on the basis of the study by Lami and Pereira[11] and our desire to provide adequate sedation for most MRI studies while minimizing adverse events and postprocedure recovery time. Per our pharmacy's protocol, there was no maximum dexmedetomidine dose and no dose adjustment in patients who were obese. Buccal dexmedetomidine was applied at the sublingual mucosa under the tongue, buccal mucosa on the inner cheek of the oral cavity, or in the buccal pouch between the cheek and gum by using the undiluted IV drug (200 μg/mL; Accord Healthcare, Inc, Durham, NC) in a 1-mL syringe. If after 40 minutes of receiving buccal dexmedetomidine the patient was anxious or upset and attempts to calm the patient before MRI arrival were unsuccessful, buccal dexmedetomidine sedation was considered inadequate, and midazolam (0.3–0.5 mg/kg) was administered orally (PO; maximum dose was 20 mg; no dose adjustment was considered for patients who were obese). If after 30 minutes of PO midazolam administration the patient was anxious or upset and attempts to calm the patient before MRI arrival failed, enteral sedation was considered a failure, and the patient received IV sedatives at the discretion of the sedation provider. In addition, a patient in the MRI scanner having too much movement, per the MRI technician, was considered inadequate sedation and received more sedatives, either PO or IV.

The response of the child to drug administration was assessed by using a modified (in reverse order) Children's Hospital of Wisconsin Sedation Scale to assess sedation levels (0 inadequate: anxious, agitated, or in pain; 1 minimal: spontaneously awake without stimulus; 2 drowsy: eyes open or closed, but easily arouses to consciousness with verbal stimulus; 3 moderate-deep: arouses to consciousness with moderate tactile or loud verbal stimulus; 4 deep: arouses slowly to consciousness with sustained painful

stimulus; 5 deeper: arouses, but not to consciousness, with painful stimulus; 6 anesthesia: unresponsive to painful stimulus).[12] Ideal sedation for MRI procedure was considered a sedation score of 2 or 3.

Vital signs, including continuous heart rate, respiratory effort, and pulse oximetry, were monitored noninvasively at baseline and documented every 5 minutes from the time of dexmedetomidine administration until discharge criteria were met in accordance with our hospital's pediatric sedation policy. During episodes of bradycardia, the sedation provider went into the MRI scanner to assess peripheral pulses and used pulse oximetry as another measure of pulsatile determination. Intraprocedural blood pressures were not routinely monitored in stable, well-oxygenated, and well-perfused patients. However, the blood pressure cuff stayed on the patient's arm during the MRI, and blood pressure could be easily checked if needed. Respiratory effort was monitored by using pulse oximetry. Nasal capnography was not used during enteral sedation to avoid patient stimulation and discomfort during the procedure. However, if the patient failed enteral sedation and needed IV sedatives, both capnography and oscillometric blood pressure were mandatory. Postprocedure discharge criteria included a return of vital signs to normal awake age values, tolerance of oral liquids, and normal gross motor function.

Sedation encounters were used for data analysis. Patients who had multiple encounters meeting the inclusion criteria were included in the study. Patients who successfully completed a sedated MRI without the need of IV sedatives in a sedation encounter were defined as successful. Patients who required IV sedatives in a sedation encounter to successfully complete a sedated MRI were defined as failed. Patients who received buccal dexmedetomidine for MRI in a sedation encounter but had additional procedures, excluding a blood draw or vaccination, were excluded from the study. We defined a priori the following outcome variables: time to sedation was defined as the time interval from buccal dexmedetomidine administration to the time ideal sedation conditions were met to proceed with the MRI; satisfactory sedation conditions included a relaxed, drowsy, or an asleep patient; time to procedure start was defined as the time interval from buccal dexmedetomidine administration to the time of MRI start; and procedure time end to discharge was defined as the time interval from the end of MRI to discharge of the patient from the sedation clinic.

TABLE 1 Demographic Characteristics ($N = 220$ Encounters)

Characteristic	Mean (SD), range, or n (%)
Age, y, mean (SD)	10.1 (2.6)
Range	5.0–18.7
Wt, kg, mean (SD)	39.7 (15.0)
Range	16.5–107.3
Male sex, *n* (%)	111 (51)
ASA level, *n* (%)	
I	64 (29)
II	156 (71)
III	0 (0)
IV	0 (0)
Sedatives, *n* (%)	
Buccal dexmedetomidine total	220 (100)
Buccal dexmedetomidine only	84 (38.1)
Buccal dexmedetomidine + oral midazolam	95 (43.1)
Buccal dexmedetomidine + intranasal sedatives	1 (0.4)
Buccal dexmedetomidine + oral midazolam + intranasal sedatives	2 (0.9)
Buccal dexmedetomidine + IV sedatives	38 (17.2)
Primary diagnosis categories, *n* (%)	
Neurologic	88 (40)
Orthopedic	55 (25)
Hematology and/or oncology	31 (14)
Metabolic and/or genetic	14 (6.3)
Infectious	2 (0.9)
Other	30 (13.6)
MRI type, *n* (%)	
Head	100 (45.4)
Cervical spine	2 (0.9)
Lumbar spine	14 (6.3)
Thoracic spine	2 (0.9)
Total spine	16 (7.2)
Quick spine	3 (1.3)
Pelvis	8 (3.6)
Extremity	34 (15.4)
Other	41 (18.6)

Statistical Analysis

Demographic characteristics included age, weight, sex, American Society of Anesthesiology (ASA) level, sedative type, primary diagnosis, and MRI type. MRI sedation times were measured in minutes and included time to sedation, time to MRI procedure start, MRI procedure time, and procedure time from end to discharge. Demographic characteristics were summarized in terms of means, SDs and ranges, or frequencies and percentiles. MRI

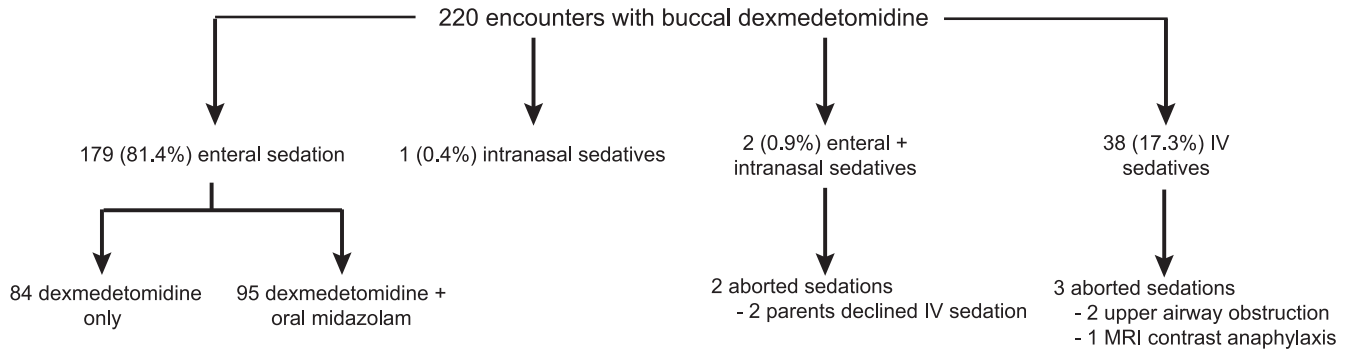

FIGURE 1 Flowchart of 220 sedation encounters with buccal dexmedetomidine.

sedation times were summarized by using means, SDs, and ranges. The frequencies and percentages of adverse events were summarized in tabular format. Statistical analyses were conducted by using SAS software version 9.4 (SAS Institute, Inc, Cary, NC).

RESULTS

A total of 220 outpatient encounters corresponding to 200 individual patients received buccal dexmedetomidine with or without other sedative medications for MRI sedation. A total of 220 sedation encounters were used for data analysis. No patient was excluded from the study because of incomplete data. However, the highest sedation score after administration of dexmedetomidine was not available for 1 patient.

The mean age of the cohort was 10.1 ± 2.6 years (Table 1). All sedation encounters were ASA classes I and II. The most common primary diagnosis was neurologic (40%), and the most common MRI type was head (45.4%). The monitoring provider in all encounters was a nurse practitioner with specific training in pediatric sedation as per our hospital's pediatric sedation policy.

Of the 220 sedation encounters, 179 (81.4%) had satisfactory enteral sedation with buccal dexmedetomidine with or without oral midazolam (Fig 1): 84 had buccal dexmedetomidine as the sole sedative; 95 had satisfactory sedation when buccal dexmedetomidine and oral midazolam were given together; 1 (0.4%) had satisfactory sedation when intranasal fentanyl and midazolam were administered in addition to buccal dexmedetomidine; and 35 encounters (15.9%) achieved satisfactory sedation with IV sedatives. All patients completed their MRI successfully except 5 (2.2%) aborted sedations: 2 were sedation failures in which patients received only enteral and intranasal sedatives because their parents declined IV sedation, 2 patients with IV sedation developed severe upper airway obstruction (1 after propofol, which improved with nasopharyngeal airway placement and suction, and 1 after IV midazolam, which improved with airway repositioning), and 1 patient with IV sedation experienced MRI contrast anaphylaxis.

The mean buccal dexmedetomidine dose administered was 2.20 ± 0.38 μg/kg (range: 0.88–3.19), and the mean oral midazolam dose administered was 0.33 ± 0.07 mg/kg (range: 0.21–0.53). Most patients who received buccal dexmedetomidine with or without oral midazolam for MRI sedation achieved a maximum pediatric sedation score of 2 or 3 (42.7% and 52.8%, respectively). In Table 2, we show sedation and procedure times for all 220 encounters.

TABLE 2 Sedation and Procedure Times (N = 220 Encounters)

	Mean (± SD)
Time to sedation, min	39.3 (± 12.7)
Range	10.0–90.0
Time to MRI procedure start, min	55.6 (± 16.1)
Range	13.0–130.0
MRI procedure time, min	58.1 (± 26.1)
Range	9.0–168.0
Procedure time end discharge, min	61.2 (± 30.4)
Range	15.0–170.0

Twelve of 220 (5.4%) sedation encounters experienced minor sedation-related adverse event (Table 3). Eight of 182 (4.3%) encounters who received only enteral sedatives had a minor sedation-related adverse event (2 oxygen desaturation requiring blow by O_2, 2 vomiting, 1 MRI contrast anaphylaxis, and 3 vasovagal episodes with 1 patient requiring a fluid bolus).

In 19 of 179 (10.6%) encounters in which patients received buccal dexmedetomidine with or without oral midazolam, the lowest heart rate was <20% below the age-specific normal range (Fig 2). In 3 of 179 (1.6%) encounters in which patients received buccal dexmedetomidine with or without oral midazolam, the lowest heart rate was ≥20% below the age-specific normal range.[13] The incidence of bradycardia was highest in the age range of 4 to 6 years (35%) compared to the rest of the cohort. No patient required pharmacologic treatment of bradycardia.

DISCUSSION

In our experience, school-aged children, when given a choice, prefer buccal over intranasal dexmedetomidine administration for MRI sedation. The bioavailability of dexmedetomidine in adults is 82%

TABLE 3 Adverse Events ($N = 220$ Encounters)

Events	*n* (%)
Total adverse events	12 (5.4)
Adverse events in enteral sedative encounters	8 (66.6)
Hypoxemia (Spo_2 <94% for >15 s)	2
Vomiting	2
Vasovagal episode	3
MRI contrast anaphylaxis	1
Adverse events in IV sedative encounters	4 (33.3)
Upper airway obstruction	3
MRI contrast anaphylaxis	1
Aborted sedations in 220 encounters	5 (2.2)
Aborted sedations in enteral sedative encounters	2
Parents declined IV sedation	2
Aborted sedation in IV sedative encounters	3
Upper airway obstruction	2
MRI contrast anaphylaxis	1

(73%–92%) and 16% (12%–20%) after buccal and oral administration, respectively.[14] The bioavailability of buccal dexmedetomidine in children is unknown but likely less than adults because the drug may be inadvertently swallowed and consequently subject to first-pass metabolism. Buccal dexmedetomidine has been effective as a preanesthetic in children at 3 to 4 μg/kg.[14] Lami and Pereira[11] reported using 2 to 3 μg/kg of buccal dexmedetomidine in 20 children as a single-drug computed tomography sedation regimen with 65% adequate sedation and no significant adverse events. In this retrospective study of school-aged children undergoing sedated outpatient MRI, we report satisfactory sedation in 81.4% of children after a buccal dexmedetomidine dose of 2 to 3 μg/kg with or without oral midazolam at 0.3 to 0.5 mg/kg.

The efficacy and safety of intranasal dexmedetomidine for MRI sedation in infants and toddlers has been well established. In a single-center study, intranasal dexmedetomidine at 4 μg/kg was shown to be highly effective (96.2%) as a single agent for MRI sedation in infants.[16] The PSRC reported an 88% success rate for MRI sedation in infants and toddlers using intranasal dexmedetomidine (median dose: 3; interquartile range: 2.5–3 μg/kg) in

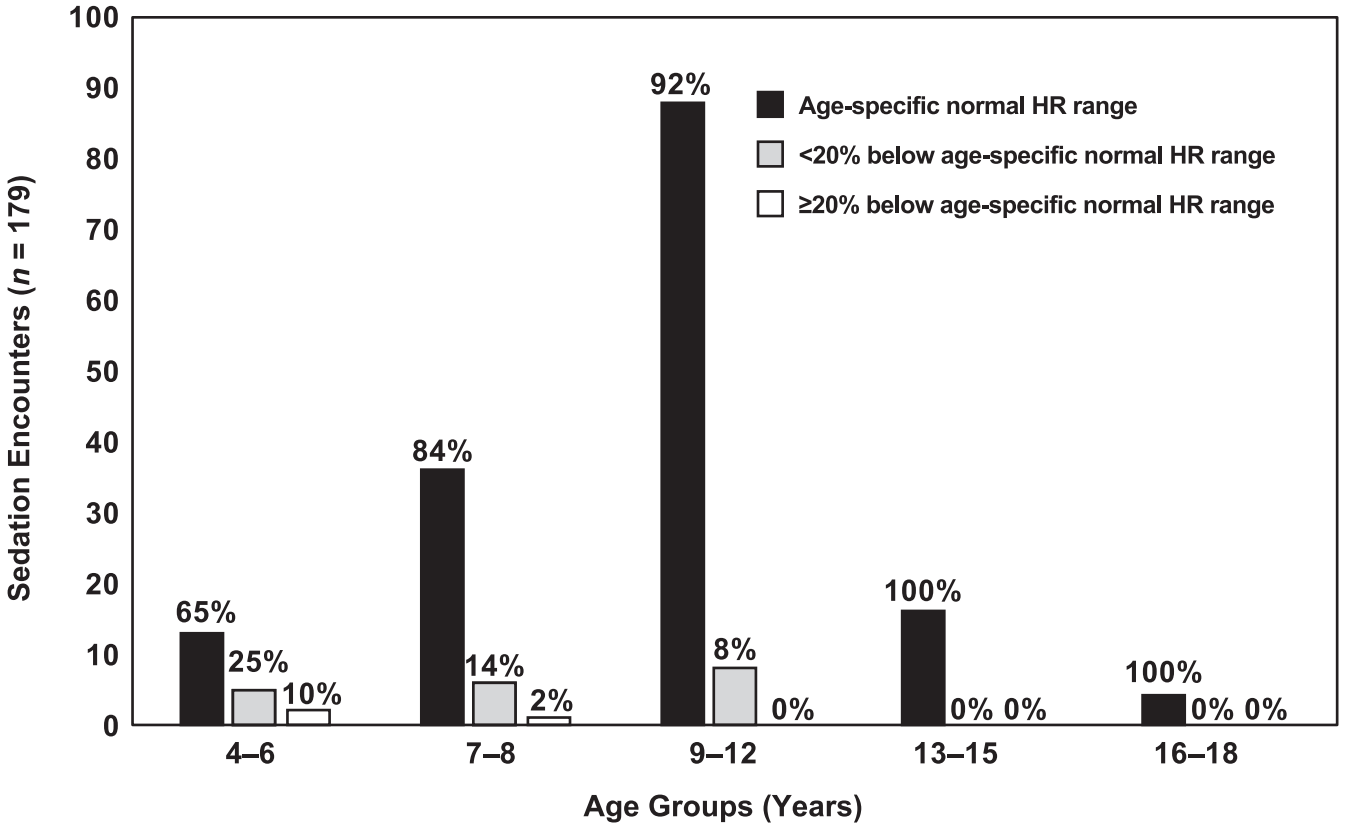

FIGURE 2 Heart rate (HR) ranges for 179 sedation encounters in which buccal dexmedetomidine was administered with or without oral midazolam for MRI sedation. Category age ranges are based on normal HR for age according to Fleming et al.[13]

combination with intranasal midazolam (median dose: 0.32 μg/kg; interquartile range: 0.29–0.39 mg/kg).[17] Authors of both studies reported no significant adverse events. Our lower MRI sedation success rate of 81.4% using buccal dexmedetomidine with or without oral midazolam in school-aged children may be due to the inability of some children to effectively sustain the drug adjacent to the buccal mucosa. Accordingly, Cimen et al[18] reported higher levels of sedation, parental separation acceptance, and mask acceptance scores with the intranasal administration of dexmedetomidine 1 μg/kg compared to buccal administration at the same dose as a preanesthetic in children.

The safety of dexmedetomidine in pediatric procedural sedation has been well established by the PSRC in a large retrospective study.[19] In our study, buccal dexmedetomidine was well tolerated with only a few minor adverse events. Seven (3.8%) of 182 encounters in which the patient received only enteral sedatives had a minor sedation-related adverse event (2 oxygen desaturation requiring blow by O_2, 2 vomiting, and 3 vasovagal episodes with 1 patient requiring a fluid bolus).

Dexmedetomidine hemodynamic effects are mild and unlikely to require pharmacologic intervention during pediatric procedural sedation.[19] In this study, we did not measure oscillometric blood pressure to avoid patient stimulation during MRI procedures. Moderate and severe bradycardia, defined as a heart rate <20% below age-specific normal and ≥20% below age-specific normal, respectively, were common in younger school-aged children. However, patients remained warm and well perfused and did not require pharmacologic intervention for bradycardia.

Our reported mean time to sedation of 39 minutes with buccal dexmedetomidine is comparable to the 30 to 31 minutes reported by Tug et al[20] who used 2 different doses of intranasal dexmedetomidine but more than twice the 12 to 13 minutes reported by Mason et al[9] who used different doses of IV dexmedetomidine for MRI sedation. Our reported mean discharge time of 61 minutes is shorter than the 92 to 94 minutes reported by Ahmed et al[21] who used IV dexmedetomidine for MRI sedation. Tug et al[20] reported a mean recovery duration of 46 to 56 minutes by using 2 different doses of intranasal dexmedetomidine for MRI sedation. However, recovery duration was defined as the time between the end of MRI and reaching an Aldrete score of 9, whereas in our study, MRI procedure end to discharge is defined as the actual time of leaving the sedation clinic to go home.

The most effective buccal dexmedetomidine dose for MRI sedation may be higher than the mean buccal dexmedetomidine dose of 2.20 ± 0.38 μg/kg administered in this study. In their study, Olgun and Ali[16] used 4 μg/kg of intranasal dexmedetomidine for MRI studies in infants and had an overall success rate of 96.2%. Potts et al[22] have shown decreased clearance of dexmedetomidine in neonates and infants compared with older children. In addition, uncooperative children may swallow some of the buccal dexmedetomidine, which limits the bioavailability of the drug. Consequently, children may require higher doses of buccal dexmedetomidine for effective MRI sedation. More studies are needed to determine the optimal dose of buccal dexmedetomidine for MRI sedation.

This study has several limitations. First, the age range (school-aged children) in this study precludes generalizing about the efficacy and safety of buccal dexmedetomidine in toddlers and infants. However, preschool-aged children are unlikely to cooperate with buccal administration, swallow more drug, and consequently have fewer sedative effects. Second, this is a single-center study making generalizability difficult. Third, we designed this retrospective study to determine efficacy and safety of buccal dexmedetomidine for pediatric MRI sedation. Although it would be valuable to characterize factors that predispose to success or failure of buccal dexmedetomidine with or without oral midazolam, the number of failed sedations is too small to say anything significant about it. Further study is needed in this area. Finally, this study is subject to the data collection limitations inherent to retrospective studies.

CONCLUSIONS

In a selected population of pediatric patients, buccal dexmedetomidine with or without oral midazolam provides adequate sedation for most MRI studies with few adverse effects, but given a failure rate of almost 20%, modifications to buccal dexmedetomidine dosing should be investigated. Further studies are required to identify optimal buccal dexmedetomidine dose and which patients are ideal for buccal dexmedetomidine sedation for MRI.

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