The Safety of Sedation for Overweight/Obese Children in the Dental Setting

by

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ABSTRACT

The Safety of Sedation for Overweight/Obese Children in the Dental Setting. Kang JA, Vann WF, Anderson JA, Lee JY, (University of North Carolina, Chapel Hill, NC)

Purpose: This study examined childhood overweight/obesity as a risk factor for adverse events during dental sedation procedures for children.

Methods: This was a cross-sectional, retrospective, IRB-approved study of pediatric dental sedation records which included 17 years of data (1991-2009). The outcome variables were desaturation, nausea/vomiting, prolonged sedation and true apnea. The explanatory variables were weight percentiles and BMI percentiles.

Results: 510 patient records met the inclusion criteria. 431 (86%) experienced no adverse events, 73 (14%) experienced one or more adverse events, and 6 had missing data. BMI data were available for 103 children. Patients who experienced one or more adverse events had higher weight and BMI percentiles. In summary, the normal weight children experienced 12% adverse events *versus* 18% for those overweight/obese.

Conclusions: Weight and BMI percentiles were higher in children who had one or more adverse events. These findings suggest that childhood overweight/obesity may be associated with adverse events during dental sedation procedures.

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General anesthesia (GA), obstructive sleep apnea (OSA), American Academy of Pediatrics (AAP), American Academy of Pediatric Dentistry (AAPD), Center for Disease Control and Prevention (CDC)

BACKGROUND AND SIGNIFICANCE

Childhood Obesity in Perspective

The Center for Disease Control and Prevention has categorized obesity as an epidemic with physical, psychological, and social consequences in adults and children.[1] The prevalence of obesity in adults in the United States (US) has more than doubled since 1980, a time-frame during which the prevalence of overweight in children has more than tripled.[2] Among U.S. children 6-11 years old, the prevalence of overweight over this time-frame has nearly quadrupled.[3] Currently, 32% of children and adolescents in the United States are overweight or obese.[4]

Flegal and colleagues reported an association between higher BMIs in children and higher levels of blood pressure, serum lipids, and other factors that are associated with increased cardiovascular risks in adults.[5] Children also have obesity-related medical risks including type II diabetes mellitus, asthma, and behavioral risks such as sedentary behaviors that promote energy imbalance.[6] Because overweight children often become obese adults, there is a need to better assess children for future adverse health outcomes resulting from being overweight/obese.[2]

Obesity as a Complication for Children Undergoing General Anesthesia (GA) and Sedation

In a prospective study, Tait and colleagues found an increased incidence of perioperative adverse respiratory events during GA for obese children *versus* those of normal weight.[7] Baker and Yagiela found that increased deposition of adipose tissue in the neck and pharynx cause

narrowing of the airway, increasing the severity of obstructive sleep apnea (OSA).[8] Obese children also have a higher incidence of difficult mask ventilation, laryngoscopy, aspiration, postoperative atelectasis, airway obstruction, bronchospasm, major oxygen desaturation, and overall critical respiratory events.[7]

Baker and Yagiela noted that excess weight added to the thoracic cage and abdomen can further restrict ventilation in obese patients, especially in the supine position. [8] This reduction in functional residual capacity and higher metabolic consumption of oxygen also may result in faster oxyhemoglobin desaturation *versus* patients of normal weight.[9] When taken together, this list of respiratory complications greatly increases the risk of adverse events for obese patients undergoing sedation or GA procedures.

A second risk factor for overweight/obese children relates to the impact of adiposity on many drugs. Casati and Putzu reported marked affects in the distribution, binding, and elimination of some anesthetics in obese patients because of an increased fat mass compared to lean body mass.[10] Greenblatt studied the effects of IV midazolam on obese *versus* non-obese adults, finding a three-fold increase in total volume of distribution and significantly prolonged elimination half-life in the obese, with the potential for respiratory depression when combined with opioids.[11] Opioids (e.g. meperidine) used commonly in pediatric dental sedation can increase the risk of respiratory depression, even in healthy children.

Lidocaine has shown a prolonged elimination half-life in obese patients, most likely related to the total volume of distribution.[11] Anatomic changes due to increased fat deposition can add to the challenge in the use of local anesthesia; further, obesity-related changes in respiratory and cardiovascular functions may influence the absorption and elimination of inhalation anesthetics.[11] In summary, the combination of respiratory compromise leading to and

increased risk of respiratory depression with opioid and sedative drugs in obese patients raises the question of safety during both GA and sedation procedures.

Adverse Events in Children Undergoing Sedation for Dental Procedures

Moderate sedation, formerly known as conscious sedation, is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands.[12] At this level of sedation no intervention is required to maintain a patent airway and spontaneous ventilation is adequate.[12] For older patients, moderate sedation implies an interactive state, while younger patients may display age appropriate behaviors (ie: crying).[12]

Baker and Yagiela emphasized that respiratory depression is a major complicating factor in obese children, with hypoxia as a major cause of serious adverse outcomes in sedation procedures.[8] These investigators also reported that obesity is a condition in which children may have chronic extrinsic restrictive lung disease and OSA, both of which can compromise the quality of sedation and increase morbidity. Other sedation adverse events may include respiratory complications, prolonged sedation, cardiac arrhythmias, brain injuries, and even death.[12]

It is common to use sedation to manage young, uncooperative children during invasive dental procedures; indeed, pharmacological sedation is used as an adjunct for behavioral management in as many as 20% of pediatric dental patients.[8,13] Leelataweedwud and Vann found that adverse events such as vomiting and nausea were not uncommon with the use of sedation medications.[14] In considering the escalating prevalence of overweight/obesity among children and the likelihood that many of these children are likely to need sedation for invasive dental care, an

examination of the safety of sedation for overweight/obese children is an important research question.

Sedation Guidelines for Pediatric Patients

The American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) published the most recent Pediatric Sedation Guidelines in 2006.[12] They emphasize that the most common serious complications of sedation involve compromise of the airway or depressed respirations resulting in airway obstruction, hypoventilation, hypoxemia, and apnea, underscoring that ***patient selection*** is a vital safety component during and after the sedation procedure. The Guidelines have elevated awareness among dentists and physicians and are recognized as the standard of care for pediatric sedation.[12] As related to airway obstruction, as per the Guidelines the child's health evaluation must include a history noting relevant diseases, physical abnormalities, and neurological impairment that may increase the potential for airway obstruction, such as a history of snoring or OSA. The Guidelines note that children with anatomic airway abnormalities or extreme tonsillar hypertrophy may require additional consideration, particularly for moderate and deep sedation procedures.[12]

Relative to overweight/obese children, the Guidelines are **silent**. The suggested pre-operative health evaluation requires documentation of age/weight but ***not*** height and there is no suggestion to obtain a Body Mass Index (BMI), so the extent of the child patient's overweight/obesity cannot be determined accurately; moreover, the Guidelines offer no recommendations or safety precautions related to weight.

SPECIFIC AIMS

The aims of this study were to (1) examine the association of weight and adverse events for children undergoing sedation in dental setting and (2) examine trends between BMI and adverse events for children undergoing sedation in a dental setting.

METHODS

This was a cross-sectional, retrospective, IRB-approved study of patient records of children who underwent sedation procedures in the University of North Carolina at Chapel Hill Department of Pediatric Dentistry's Sedation Clinic from 1992-2009. According to the child's age and gender, using standardized, time-honored weight percentile charts from the Center for Disease Control and Prevention (CDC),[15] each patient was assigned arbitrarily to one of two weight percentile categories: < 85th and >85th.

Unlike weight percentile, body mass index (BMI) is weight (in kilograms) divided by height squared (in meters). For children, the distribution of BMI changes with age, just as weight and height distribution change. Therefore, although absolute BMI is used to define body weight in adults, percentiles specific for age/gender are appropriate metrics to define underweight, healthy weight, overweight, and obesity in children.[6] The CDC defines four BMI categories for children; underweight = <5th percentile, healthy weight = 5-85th percentile, overweight = 85-95th percentile, and obese = >95th percentile.[16]

As a condition for undergoing sedation, all children received a clearance physical examination within six months prior to the sedation appointments. For a few children, height was recorded by their physician at the time of this examination. The recording of height became the *standard of practice* in this Clinic in 2006, so most of the BMI data were derived from the

2006-09 nested cohort of children but we also included those patients for whom the physicians had recorded height prior to 2006. In summary, when children's heights were available, we assigned the patients to one of two BMI categories: normal weight =<85th percentile or overweight/obese= greater than 85th percentile.[17]

For all children in the 1992-2009 cohort, we examined the relationship between the two weight percentile categories and the adverse events during the dental procedures. For those in the nested cohort, we also examined the correlation between the BMI percentile categories, total adverse events, and the four adverse events separately.

Sample

The inclusion criteria included healthy child patients (ASA I or II) who were age 24 months or older who underwent sedation using only one drug regimen: an oral elixir of chloral hydrate (50mg/kg), meperidine (1.5 mg/kg), hydroxyzine pamoate (25mg) and supplemental oxygen by a nasal cannula. If a child had multiple sedation procedures using this regimen, data from only the procedure was used for analysis. The sedation records included age in months, gender, and weight in pounds obtained on the day of the procedure.

For children for whom height was available, we relied upon weight in pounds and height in inches within 3-6 months of the sedation appointment. For all children we obtained sedation appointment data to include oxyhemoglobin saturation (SpO2) measured by a pulse oximeter, end-tidal carbon dioxide (ETCO2) measured by a capnograph, pulse and respiratory rates measured visually and audibly with precordial stethoscope and record documentation of adverse events.

We applied three exclusion criteria: 1) children with a diagnosis of asthma, 2) those who did not ingest the recommended dosage of sedation medications because they spit out some of their oral medications and 3) records that contained incomplete information.

Sample Size

Using adverse outcome data from a previous investigation[14], we completed a sample size calculation using 90% power with an alpha of 0.05. The power analysis revealed that we would be able to detect a difference with a sample of 360 cases. Because obtaining BMI data was a relatively recent routine in this Sedation Clinic, we recognized that we would be underpowered in the nested cohort; however, we calculated that we would have approximately 100 cases from which to observe trend data for BMI.

Variables

The major explanatory variables were weight percentile and BMI percentile. The former was measured on the day of the sedation appointment and the latter on the day of or within six months of the sedation appointment.

Dependent variables included adverse events and sedation outcomes. Four adverse events were identified and include the following: *oxyhemoglobin desaturation* measured as SpO2 below 95%[14,18], *vomiting* at any time during the sedation procedure, *prolonged sedation* measured by the child needing more than 30 minutes to recover postoperatively, and *true apnea* (defined as no visual signs of breathing, no audible breath sounds via precordial stethoscope, and capnograph reading of 0 for RR and ETCO2 for 25 seconds).

The control variables included age defined in months and gender.

Statistical Analysis

Data were entered in an Excel® file and analyzed using SAS 9.2 (Cary, North Carolina). Descriptive analyses included trends and correlations for gender, age, weight, and BMI when available. We relied upon Fisher's exact test and chi-square tests with the level of significance set an alpha of 0.05 for all tests.

RESULTS

From the 1992-2009 Cohort, 771 patients records met the inclusion criteria. Of these, some records were lost in the archival process, leaving 606 records for inspection. Of these, 96 did not meet the inclusion criteria, leaving 510 as our overall sample size. Of these 510 records, height data were available 103 who were included in the nested cohort to examine BMI trends.

Socio-Demographics

Socio-demographic information is presented in Table 1. Of the 510 patients, 259 were female. About 50% of the patients were White and 25% were African American or Latino. The mean age was 45 months, ranging from 24-115.

The mean weight percentile was 57^{th} for females and 55^{th} for males. Among races, the mean weight percentile was similar, ranging from 54-60. For age, the mean weight percentiles gradually decreased for older ages.

We calculated BMI percentiles for the 103 patients who had height recorded and for purposes of data analysis, we collapsed the overweight and obese groups into one category. The mean BMI percentile was 68 for females *versus* 57 for males. White patients had the highest BMI percentile (69) while Asian/other patients had the lowest (48). The mean BMI percentile ranged from 51-72 among the age groups, with the highest BMI percentile in the 30-35 month age range. No percentile differences were statistically significant.

Adverse Events

As illustrated in Table 1, males experienced more adverse events than females. The Latino population had a slightly higher percentage of adverse events. The oldest age group (42-120 months) experienced the greatest number of adverse events. None of these differences reached statistical significance.

Weight/BMI percentiles and adverse events are illustrated in Table 2. Of the 510 patients, 86% experienced no adverse events while 14% experienced one or more. Patients who experienced one or more adverse events had both higher mean weight and BMI percentiles, but differences were not statistically significant.

Oxyhemoglobin desaturations occurred in 50 patients. These patients had higher mean weight percentiles and BMI percentiles *versus* those with no desaturations, but differences were not significant. Nausea and vomiting occurred in 12 patients, a group with heavier mean weight and BMI percentiles that did not reach significance. Prolonged sedation was found in 11 patients, an outcome that showed no pattern of association with weight or BMI percentiles. Lastly, only 5 patients had true apneic episodes. These had higher but not significantly different weight percentiles and no available BMI data.

Another way to conceptualize the data is to contrast the adverse events for BMI-healthy *versus* BMI-overweight/obese children (Table 3). The former experienced 12% adverse events *versus* 18% for the overweight/obese group. The healthy group experienced 10% *versus* 11% oxyhemoglobin desaturations, 1% *versus* 7% nausea/vomiting and 11% *versus* 13% prolonged sedations. The BMI data were underpowered from the outset to detect statistically significant

differences, but the data point to a clear trend for more adverse outcomes in the BMI-overweight/obese children.

DISCUSSION

Obesity is a complicating factor for children undergoing sedation procedures. In dentistry, when indicated parents are often given an option for sedation. Studies have shown that adverse events can occur during dental sedation appointments.[14] Our hypothesis was that overweight/obese children may be at greater risk for respiratory complications and other adverse events. Our results indicate that children who experienced one or more adverse events had both higher mean weight and BMI percentiles, but differences were not statistically significant.

Socio-demographic Data

The demographic information included gender, age, and race. Females had higher weight and BMI percentiles than males. Weight percentiles generally decreased as patients aged and the highest BMI percentiles were found in the age group of 30-35 months. Latinos had slightly higher median weight percentiles and Whites had higher BMI percentiles.

Weight Percentiles

Due to the implications for patient safety and clinical practice, understanding the associations of childhood overweight/obesity with adverse events during sedation for dental procedures is an important research question. Relative to the weight percentile data, the study sample was sufficiently large to detect a significant difference but none was found. This was not totally unexpected because weight percentiles in children are not the best indicator of childhood

overweight/obesity;[1,16] rather, the CDC recommends the use of BMI percentiles to determine childhood overweight. However, it was timely to examine weight percentiles because obtaining a pre-sedation weight is the standard protocol in the dental setting as well as the current recommendation of the Pediatric Sedation Guidelines.[12] If a relationship with weight percentiles and adverse events had been discovered, such a finding would be valuable information for clinicians who practice sedation and for investigators who have access to retrospective sedation data. We should emphasize the value of this negative finding. That is, knowing the absence of the predictive value of weight percentile is an important finding because it tells us that weight percentiles cannot be used as a threshold for safety precautions.

In examining the data for weight percentiles and adverse events, it is noteworthy that while no statistical differences were found, the raw data seem to suggest a pattern of worse outcomes for heavier children. Overall, mean weight percentiles were higher in children who had one or more adverse events; moreover, children with higher weight percentiles were more likely to have an oxyhemoglobin desaturation event, nausea/vomiting, and true apnea.

BMI Data

We were aware during the study planning stages that the number of patients with BMI data would be limited and under-powered for a definitive examination of impact of BMI percentiles; however, we thought it would be timely to examine for trends. Mean BMI percentiles were higher among children who had one or more adverse events even though the mean BMI percentiles were well below the overweight/obese categories. Even so, children with higher BMI percentiles had more oxyhemoglobin desaturation events, nausea/vomiting, and prolonged sedations.

Data Quality Issues

For any study relying on record review for data, quality issues must be considered, especially where the records span 17 years. Four factors helped ensure data accuracy: 1) All sedation cases under review were obtained from the same Sedation Clinic at the same institution. All participants had been trained to emphasize careful attention to detail in the recording of sedation data. And, the same standardized time-based anesthesia monitoring record was utilized during the entire 17-year investigation time-frame; 2) This Clinic had a history of other clinical sedation studies that focused on comparing various sedation drug regimens for children as well as the safety and monitoring of children sedated for dental procedures .[14,18,19,20,21,22] In most instances, the definitions of adverse events and the success of sedation in those studies were the same as those in the present, adding validity to the reliance of the quality of records reviewed. This helped to ensure the precision of the data; 3) To enhance reliability, we relied on one trained record auditor (the PI) for whom we established test-retest reliability in the record auditing process; and 4) we limited this study to ***one*** drug regimen as a way of eliminating confounding due to the possible effects of multiple drug regimens.

Limitations and Strengths

The ideal study design for this research question would be a prospective clinical trial to examine the correlation of BMI percentiles with sedation adverse events using multiple drug regimens; however, considering the current standard of practice for obtaining height measurements for children in the dental arena, such a study is not likely to be available for years.

Although we have argued that the quality of our data is strong, the study was limited by the challenges inherent in collection of retrospective dental record data. Some cases had to be eliminated because they did not meet inclusion criteria for data record completeness. In short, in spite of reliance on standardized anesthesia records completed by faculty and/or residents with direct attending faculty supervision, some records were incomplete.

The major strength of this study was that it examined the relationship between weight percentiles and adverse events children undergoing sedation dental procedures. The study included 17 years of data from a standardized sedation protocol at the same institution. In a smaller subset of children, the study examined for trends in the association of BMI percentiles with adverse events. The study's findings were unique because this topic has received little research attention, yet it is a critical question for contemporary pediatric dental practice.

CONCLUSIONS

These findings, although preliminary in nature, reveal many trends indicating that childhood overweight/obesity may be a risk factor for adverse events during sedation for dental procedures. They should serve as a point of departure for future research aimed at addressing this research question in more depth. In the interim, we urge practitioners to obtain pre-sedation weight and height and calculate the patient's BMI prior to sedation; for children who are overweight/obese, practitioners may want to consider an alternate behavior management strategy.

Finally, these findings offer guidance for future Sedation Guidelines. At a minimum, consideration should be given to obtaining children's height as a conduit for calculating BMI percentiles prior to sedation.

Table 1. Distribution of socio-demographics and somatometric characteristics (weight percentile and BMI percentile) and frequency of adverse events among pediatric dental sedation patients.

Socio-demographics		%	Weight percentile n=510 Mean	BMI percentile n=103 Mean	Adverse events by category* %
Sex					P=0.07†
Female	259	50.8	56.7	67.7	12.0
Male	251	49.2	54.9	57.0	16.7
missing	0				
Race					P=0.2†
White	174	48.9	54.3	69.3	12.6
African American	80	22.5	57.0	60.5	17.5
Latino	85	23.9	57.7	61.6	20.0
Asian/Other	17	4.8	59.8	48.4	23.5
missing	154				
Age (months)					P=0.7†
24-29	52	10.2	63.9	50.6	9.6
30-35	80	15.7	57.5	71.8	13.8
36-41	84	16.5	52.2	63.9	13.1
42-120	293	57.6	54.9	60.9	15.7
missing	1				

*number of patients with one or more adverse events during a sedation procedure according to the specified category
† Fisher's exact test p-value

Table 2. Distribution of somatometric characteristics (weight percentile and BMI percentile) and adverse events and among pediatric dental sedation patients (n=510).

Outcome variables		n	%	Weight percentile Mean	BMI percentile Mean
Adverse event					
	One or more	73	14.5	60.8	70.4
	None	431	85.5	55.0	60.6
	missing	6			
Oxyhemoglobin desaturation					
	Yes	50	10.0	58.8	70.7
	No	450	90.0	55.8	61.1
	Missing	10			
Nausea/Vomiting					
	Yes	12	2.4	56.7	78.2
	No	493	97.6	55.9	61.4
	missing	5			
True apnea					
	Yes	5	1.0	69.9	
	No	487	99.0	55.8	61.5
	missing	18			
Prolonged sedation					
	Yes	11	2.2	56.2	70.4
	No	492	97.8	56.0	61.4
	missing	7			

Table 3. Distribution of somatometric charact ics (weight and BMI categories) and adverse events by percentage among pediatric dental

Soma-tometric categories		One or more Adverse Events	Positive Oxyhemo-globin Desaturation	Positive Nausea/ Vomiting	Positive True Apnea	Positive Prolonged Sedation
Wt. Percentile Category	<85%	14%	10%	2%	1%	2%
	>85%	17%	9%	3%	2%	3%
BMI Percentile Category	Normal Weight	12%	10%	1%	0%	1%
	Overweight/ Obese	18%	11%	7%	0%	4%

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