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A Practical Approach to Safe and Effective Dosage Selection for Sedation of the Challenging Pediatric Dental Patient: An Editorial

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Abstract

Despite an abundance of literature, substantive data does not yet appear to exist that identifies based on specific patient characteristics, both safe and effective agent and dosage selection criteria for management of challenging pediatric behaviors in the dental office. Considerable study remains largely clinical impression, most retrospective with but rare instances of prospective and controlled investigations since the 1960's.

This editorial addresses contemporary shortcomings of pediatric dosing and offers a pragmatic approach to agent and dosage selection on the basis of individual patient need, levels of anxiety and degree of resistance to be confronted, and the relative invasiveness of the planned procedure.

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Editorial

If asked most pediatric dentistry specialists would concede that the safe and effective use of pediatric sedation is more art than science. Some might argue that it falls short of predictability, and while seeking to avoid mishaps, are compelled to make use of minimal depths of sedation using low-end dosing of either single agents or combinations. Profound clinician instinct and experience, astute observational skills, and the unique ability to assess the origin and likely extent of patient resistance for a given visit comprise a few of the intangible nuances when selecting sedation dosing. 1 Despite an abundance of literature, objective data is lacking to clarify what to use and how much to achieve efficacious and predictable outcomes while maintaining mild to moderate levels of sedation.

The most fundamental of deficiencies is that no source to date attempts to assess patients' level of anxiety or resistance as they impact on dosage selection for pediatric sedation. A hypothesis that incorporates a methodology which includes this component and its impact on dosing efficacy seems needed to best provide insight into choosing and assessing the appropriateness of dosing schedules within both teaching programs and clinical practice. It should not be surprising therefore that differing levels of anxiety play a role in identifying whether to make use of low-end, mid-range, or high-end dosing of available regimens.

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Perhaps the foremost example of misuse of pediatric sedation agents is midazolam. This ultra-short and short-acting agent is the most frequently used agent taught and utilized in advanced training programs today. 2 When asked their range of dosing for midazolam 0.3 to a maximum of 0.5 mg/kg has been identified. Across 35 years this author and clinician's experience has found this dosage to be virtually if not universally unsuccessful in obtunding moderate to severe levels of apprehension in young children. For those presenting with mild levels of anxiety or incapacity to cooperate, control of behavior is at best brief or ultra-short and for the most part inadequate.

Many programs and institutions acknowledge removing other historically commonly used agents (chloral hydrate, meperidine for example) from their arsenals and rely on midazolam for all sedation visits in an effort to avoid mishap and over-dosage. Experience of training program directors and faculty in the art of sedation appears waning. The repeated occurrence of mishaps and impact of such events, regardless of etiology and/or practitioner failure to follow and comply with existing safety guidelines, appear to have contributed to greater need and deployment of physical restraint and/or the use of general anesthesia across the nation. 3,4 If known, this ratio may well be alarming particularly to those with enhanced sedation instincts and observational skills mentioned earlier.

The decision to restrain a child to perform invasive and needed treatment is not always a simple one. While less acceptable to clinicians experienced in securing positive and successful sedation outcomes, those lacking such training experience seem willing to accept more liberal use of physical restraint.

Based on child characteristics, personality variables, coping skills or their absence, practitioners and parents alike face challenging decisions. Where treatment needs are extensive and patient characteristics include ages below reason, the decision to make use of general anesthesia is both easy and appropriate. For those above three and four years of age with minimal or moderate treatment need, however, responsibility to exhaust conventional communication and behavioral management strategies falls on the proficient clinician. Pediatric specialty training programs have an obligation to equip their students with a broad range of management skills, well-versed in non-pharmacologic as well as pharmacological strategies. Preserving the psyche and self-esteem of the child, regardless of age or cooperative ability, is paramount in the goals of training pediatric specialists. "Do no harm" is the credo of every health care provider. How the implementation of physical restraints impacts on that outcome is not easy to discern, but the abandonment of conventional strategies prematurely, or the result of less than optimal training and exposure to non-mainstream behavior management approaches leaves an apparent void in how best to make use of safe and effective sedation for the child with less invasive or limited treatment needs where general anesthesia or restraint can be avoided. Practitioners differ in their skills and comfort levels; this editorial does not suggest or imply that all clinicians can make best use of all techniques; those not skilled in the art of sedation might prefer to refer to colleagues with such skills. Characteristic of those lacking successful experiences using sedative techniques during their training may on a frequent basis for lack of alternative in-office modalities, make use of a weak potency modality such as nitrous oxide. For moderate and heightened levels of anxiety this might be the last resort to general anesthesia. Disappointingly, a disregard for the potential merit of a well-chosen orally administered sedative agent or combination, may prematurely expose the patient to a general anesthetic.

Despite the unpleasantness of restraining a child to accomplish needed invasive treatment, or conversely, the financial gain (for all but the parent), of treatment provided under cost-prohibitive unconscious techniques (general anesthesia in offices, surgical centers or hospital operating rooms), it would be accurate to conclude that numerous children with limited treatment need may best prove candidates for well-chosen sedation techniques. Savings to health care in general through the use of safe and effective sedation, thereby avoiding costly general anesthesia, would seem sufficiently beneficial in today's health care. Alternately, routing the patient to the operating room under the supervision of the anesthesiologist, from the perspective of the dentist likely guarantee full deferment of risk from the dental team. Bottom line from an ethical perspective might be would the dentist recommend general anesthesia for their family member?

With respect to the basis for our shortcomings and lack of evidence based support for how to safely sedate children in the dental setting, there are numerous reasons. Designing well-controlled study is in and of itself difficult. Defining valid selection criteria which include reliable and consistent qualitative and quantitative patient anxiety assessment, adequate subject numbers, longitudinal evaluation, safety parameters intra-operatively as well as recovery all pose immense challenges. Time to complete multiple visit, physiologic and behavioral assessments is exhausting.

Diminished or vanishing funding sources further contribute to the dilemma. Fiscal rewards are unappealing to institutions where use of general anesthesia can be substituted; institutions with open O.R. time and non-utilization of operating room personnel and facilities might argue that general anesthesia represents a safer modality than less controlled in-office sedation. Turf battles between anesthesiology departments over who is best qualified to deliver and regulate safety within their institution is appropriate and understandable. One major and well respected institution following a catastrophic and preventable outcome in the Chicago area from an area clinician and another from its training program in pediatric dentistry mismanaging a simple sedation resulted in the elimination of non-anesthesiologist supervised sedation. 5 While these occurrences are not representative, they illustrate issues for training programs where qualifications to continue to perform safe sedation are problematic.

Arguments to the contrary include that when existing sedation guidelines are followed and responsible agents and dosing are used, there have been no reported adverse events and outcomes to date. The antithesis to the latter, however, includes non- compliance with safety guidelines inclusive of vigilant patient monitoring appropriate to the level of sedation sought and obtained. Problems associated with State regulation and documentation of practitioner compliance following such guidelines does not become apparent until which time that an adverse outcome comes to the attention of the courts and media. 5 Professional society monitoring of practitioner compliance does not appear to be a priority as of this date. No state or local data banks have been established to record incidents of adverse outcomes.

Alternately, a mandate recently established in the State of Illinois identifies several requirements for practitioners making use of sedation and general anesthesia to permit renewal of licensure for such. 6 These provisions include but are not limited to that each office must develop and implement emergency medical plans and protocol for its staff, arrange and conduct semi-annual hands-on emergency drills, that offices maintain an AED device at all times, that a minimum of 3 individuals are included in the support team for monitoring purposes with mandatory accredited training, that drugs selected for moderate sedation be limited to those not likely to induce general anesthesia, and lastly that practitioners maintain current ACLS or PALS as appropriate. These represent a distinct advancement if not an appropriate beginning to prevent mishaps and departure of standards of care.

A practical method upon which to base decisions related to agent and dosage for pediatric sedation.

That said, obligation exists to generate sound data that demonstrates safety and efficacy for the techniques we employ in managing challenging children in the dental office. In an effort to address deficiencies in existing research and the shortcomings described above, this author suggests the intentional if not mandatory inclusion of a selection criteria for assessment of various dosing of sedative agents or regimens that reflect variations in factors that in actuality impact on dosage selection. These include the degree of anxiety and resistance encountered, the duration of action anticipated, and the relative invasiveness of the planned procedure.

Based on these criteria, the practitioner has basis for determining whether to make use of low-end dosing, mid-range dosing, or high-end dosing. No studies have attempted to explore this approach; instead they seek to assess an agent(s) as to whether they successfully manage behaviors, necessitate limited or persistent application of restraint, or over-sedate the patient. The working hypothesis would assert that higher levels of anxiety and resistance and greater demands on the patient would necessitate which dosage to employ. Preliminary data from 35 years of over 3,500 sedations of varying levels of childhood apprehension is in progress. Retrospective records from these sedations where a sedation log has been maintained that includes pre-treatment patient physical assessment, qualitative and

descriptive evaluation of anxiety and resistance levels, qualitative evaluations of the effectiveness of sedation dosing employed is underway by this author. As data has accumulated, adjustments in dosing, based on levels of apprehension and patient responses to varying dosages appears to offer insight as to the validity of making use of these variables when selecting dosages for various conditions and durations of actions to improve efficacy while maintaining moderate or lighter levels of consciousness and safety.

A broad range of agents, inclusive of chloral hydrate combinations, hydroxyzine, diazepam, meperidine, lorazepam, midazolam combinations are explored. Future research might wish to explore the regimens cited prospectively incorporating the need to conduct comparisons using relevant criteria that influence dosage selection with focus on defining success by the absence of need for persistent patient restraint while minimizing need for unconscious techniques and prevention of adverse reactions.

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