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The Use of Intranasal Dexmedetomidine Compared to Oral Midazolam in the Pediatric Pre-operative Population for Separation Anxiety. An Educational Module

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Abstract

This quality improvement project aimed to identify anesthesia providers' knowledge of current and alternative methods to effectively treat perioperative anxiety in the pediatric population.

Background: Pediatric perioperative anxiety is a prominent complication that anesthesia providers face daily.

Methods: A literature review was conducted utilizing PubMed, Google Scholar, and the Cochrane database to research the PICO question. A project intervention was provided to both physician anesthesiologist as well as certified registered nurse anesthetists (CRNAs) that included a pre-intervention test, an interventional educational module, and a post-intervention survey. Statistical analysis was completed to assess the outcomes of the educational intervention.

Results: The majority of participants were able to identify clinical outcomes of high levels of preoperative anxiety, the most common pharmacological agent being utilized to sedate the pediatric population, and its negative side effects. Additionally, knowledge of DEX improved with all providers understanding not only its antianxiety benefits but also its analgesic properties.

Discussion: Following the educational intervention, anesthesia providers' knowledge on the benefits and use of DEX increased. Further research on improved methods of perioperative anxiety treatment is indicated. Limitations of the study included small sample size, time restrictions, and impersonal online platform.

Keywords: Pediatrics, Intranasal DEX, Intranasal Midazolam, Oral Midazolam, Agitation, Sedation, Anxiety

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I. Problem Identification

In the pediatric population, patient anxiety and agitation can result in adverse clinical, behavioral, and psychological complications. Preoperatively, children with high levels of anxiety can have complications that include increased length of induction, tachycardia, hypertension, tachypnea, and higher requirements for anesthetic medications.[1,2] Additionally, these patients can develop behavioral problems that include sleep disorders, eating problems, and separation anxiety from their parent(s).[3] Postoperatively, pediatric patients with high levels of anxiety have an increased risk of emergence delirium as well as chronic postsurgical pain. These maladaptive behaviors lead to longer hospital stays and poor recovery when compared to children with lower levels of anxiety.[1]

Preoperative anxiety and agitation can result from several factors. Determinants including previous hospitalizations, anxious parents, being an only child, and no premedication have been shown to be leading factors contributing to preoperative anxiety.[4] Additional causative factors of preoperative anxiety include age, gender, baseline anxiety, and type of surgery.[5] Within the pediatric population, parental anxiety is a contributing factor that directly correlates with patient anxiety. Parental anxiety can be attributed to factors such as previous hospitalizations, being the mother or father, occupation, fear of postoperative pain and situational factors.[5] All of these contributing factors should be addressed when caring for the pediatric population in order to decrease patient anxiety and agitation.

Background

Given the various negative side effects of perioperative anxiety and agitation, clinicians have prioritized methods to recognize and ease these conditions in children. Currently, multimodal approaches are being utilized to help alleviate unease and agitation in the pediatric population. These methodologies often include pharmacological, nonpharmacological, behavioral, and psychological approaches.[6] Nonpharmacological and behavioral methods include music therapy, parental presence, play intervention, child life specialist, handheld video games, and clowns during induction.[6] These methods are often well received and can be beneficial in reducing anxiety in both the patient as well as the parent.

While nonpharmacological and behavioral tactics have been shown to be successful, many pediatric patients need additional interventions to help alleviate their nerves. Pharmacological interventions vary and include midazolam, clonidine, ketamine alone or in combination with midazolam, fentanyl, melatonin, and DEX.[4] The most common pharmacological agent currently being utilized is midazolam. It can be given orally, intranasally, intravenously, and intramuscularly, and each method of administration has its own advantages and disadvantages. For example, intranasal administration is quick, easy, and noninvasive; however, this route of administration of midazolam can cause significant nasal irritation.[7,8] While effective in providing adequate sedation and reducing anxiety levels, midazolam has been shown to cause respiratory depression, can contribute to emergence delirium and cognitive impairment, and has no analgesic properties.[2,7] For these reasons, other agents are now being studied and utilized in order to provide more effective sedation while decreasing negative side effects.

Scope of the Problem

Preoperative anxiety is a common occurrence for anyone undergoing surgery and even more so in the pediatric population. Anxiety is a feeling of worry, nervousness, or unease about something with an uncertain outcome.[9] In the pediatric population, anxiety may manifest as trembling, being silent or crying, or being restless. The majority of this patient population does not have the bandwidth to communicate their fears or feelings with staff or with their parents. Pediatric patients often feel anxious due to the lack of knowledge and understanding of the process as well as the limited control of the environment. Adding to the stress of situation is the anticipation of being separated from their parent or caregiver. This preoperative anxiety is associated with both physical and psychological consequences.

Almost three fourths of all pediatric patients showcase preoperative anxiety, and just as many will shows sign of postoperative agitation.[5,10] Despite their high incidence, these topics remain understudied. Post-anesthesia agitation has been linked to increased levels of preoperative anxiety.[9] Despite the multimodal approaches that are currently being utilized, there continues to be a high incidence of anxiety in the pediatric population. New and alternative approaches to reduce perioperative anxiety need to be studied to facilitate enhanced recovery and decreased postoperative complications in the patient population.

Consequences of the Problem

Undergoing surgery can be a very stressful event for any individual and particularly so for the pediatric population. These patients may not always comprehend what is happening, are placed in a foreign environment, and are separated from their parents only to have masked strangers coming towards them from all angles. This preoperative anxiety can lead to

hemodynamic instability, increased postoperative pain, metabolic side effects, and emergence delerium.[11] Increased levels of anxiety and agitation can also lead to increased recovery times and increased incidence of postoperative surgical pain.[1,12] Effective multimodal approaches to mitigate anxiety in this patient population can be beneficial not only to the patient, but also to medical care givers and parents.

Knowledge Gaps

There are many approaches being utilized to help mitigate preoperative anxiety and agitation in the pediatric population. Each of these modalities have a variety of advantages and disadvantages. Additionally, the degree to which one approach works over another has not been consistently documented. Furthermore, there are a variety of pharmacological agents that are being utilized as anxiolytics. Each of these agents can be administered by various routes. There are a handful of medications that have been explored and are currently being used in the pediatric population. There remains no clear solution on which medication and which administration route can be administered fast, is effective, and will reduce preoperative anxiety with minimal side effects.

Proposal Solution

DEX is a selective alpha 2 receptor agonist that has a variety of properties, including sedation, antianxiety, hypnotics and pain relief.[3] The sedative properties of DEX are achieved from its effects on the locus ceruleus that result in a state of consciousness that closely mimics natural sleep.[13] This sleep-like resemblance allows for an easy arousal from sedation. There are numerous publications outlining the benefits and effective use of DEX; however, the

effectiveness of intranasal DEX compared to other agents have been not been readily documented.

Rationale and Objective

Currently, midazolam is the most utilized pharmacological agent to abate preoperative anxiety. Midazolam, while effective, also has a number of unwanted side effects including, cognitive impairment, respiratory depression, and postoperative behavioral changes.[7] DEX has been shown to be a useful and safe alternative. DEX most closely emulates sleep and does not have the depressive respiratory effects that can occur with benzodiazepines. For these reasons, further investigation into the intranasal effectiveness of DEX compared to midazolam in reducing preoperative anxiety in the pediatric population is warranted.

II. Literature Review

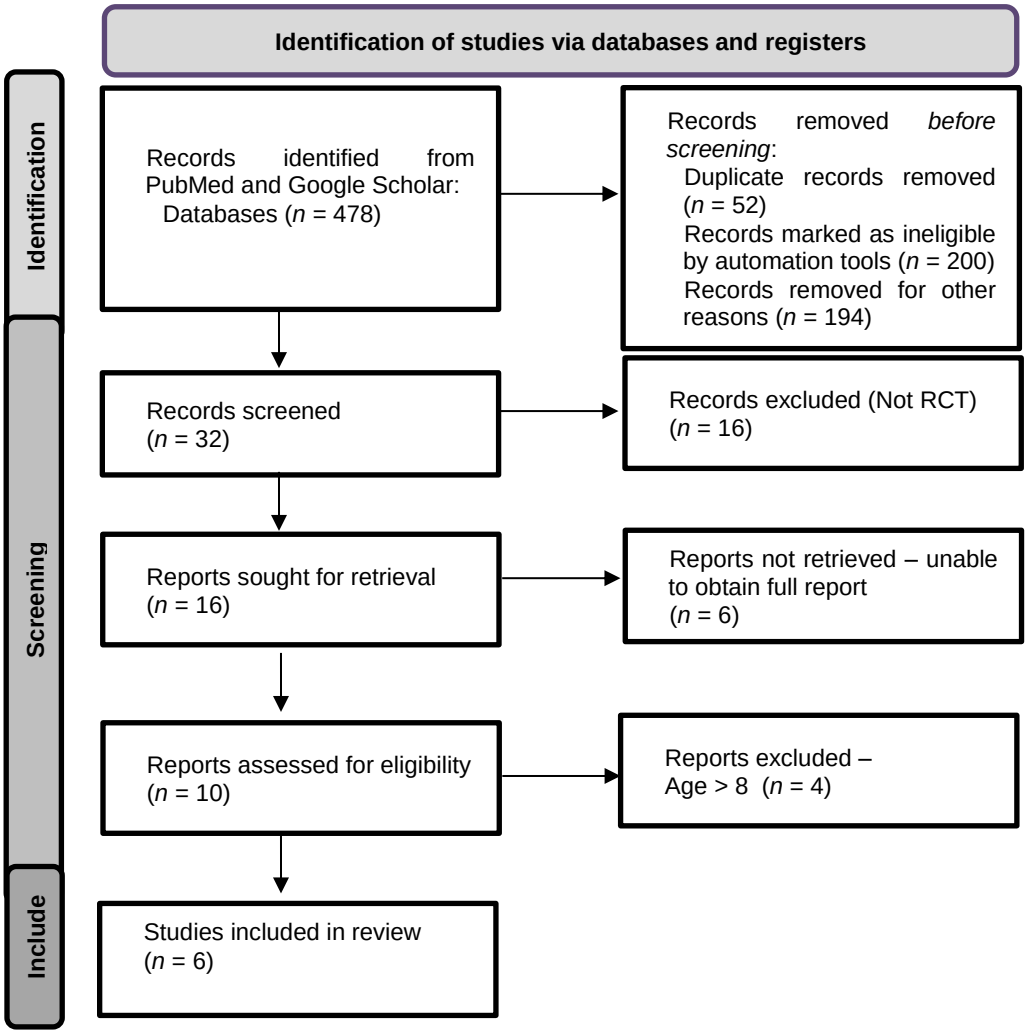
Eligibility Criteria

The studies evaluated for the literature review included those that would help to garner information on the knowledge gaps outlined above. Studies included in the search were those studies that were published within the last 7 years and those that were in English or translated into English and had full text availability. Exclusion criteria included those studies in which the patient population was exclusively over the age of 8. Additionally, the studies collected had to evaluate the effectiveness of intranasal DEX, intranasal or oral midazolam, or a comparison of both. The collected studies focused on both the effects and side effects of these medications and measured sedation levels and effects on preoperative anxiety.

Information Sources

The databases used to collect studies for the literature review included PubMed, Google Scholar, and the Cochrane database. The studies found on all databases were cross referenced to ensure that all available relevant studies were included in the review. Figure 1 below outlines the studies that were eliminated from the search and those that were included based on relevance.

Figure 1. Summary of Literature Search Process



Search Strategy

The keyword search terms included in the review were expanded to include: (Pediatric OR Child* OR Youth) AND (Intranasal DEX OR Intranasal Precedex) AND (Intranasal

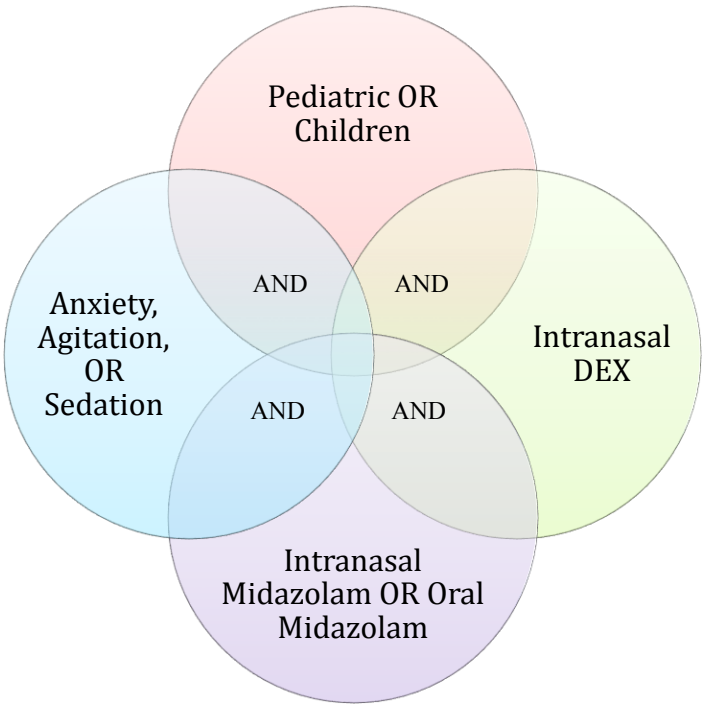
Midazolam OR Intranasal Versed OR Oral Midazolam) AND (Agitation OR Irritation OR Delirium) OR (Sedation OR Comfort OR Relaxation). The initial search produced a total of 478 articles. PubMed produced 219 results, and Google Scholar produced 259 articles. In order to ensure the most current studies were included, the search criterion included those studies published no more than 6 years ago. This generated 112 articles in PubMed and 134 articles in Google Scholar. The remaining articles were compared for duplicates and relevance and included only if they had full text. Titles were excluded if they did not include either intranasal DEX or midazolam along with pediatric and sedation or agitation. Additionally, articles were excluded if they had words such as adult, intramuscular, intravenous, teenagers, or any medication that was not DEX or Midazolam.

This yielded a total of 32 articles, and these remaining articles were analyzed by their abstracts. Of the 32 articles, 16 remained relevant to the study purpose and full texts were reviewed. Articles were resigned if there was not a direct study including intranasal DEX or midazolam. Additionally, articles that compared populations other than the younger pediatric population (aged 2-8) were eliminated. The final search resulted in 6 high quality articles that will be summarized.

Medical Subject Headings (MeSH)

Based on the PICO question, the search criterion included the following keywords: Pediatrics, Intranasal DEX, Intranasal Midazolam, Oral Midazolam, Anxiety, Agitation, and Sedation.

Figure 2. MeSH Terminology



Study Characteristics

Six studies were chosen for this literature review, and 2 main concepts were evaluated. The first concept was the use and effectiveness of intranasal DEX as an alternative premedication sedative to reduce anxiety in the pediatric population. The second concept was to assess post-anesthesia agitation and pain levels in children that received intranasal DEX versus intranasal or oral midazolam. The first study is a prospective observational study that analyzed the effectiveness and safety of the use of intranasal DEX in the preoperative period. Four of the articles were direct Level 1 clinical research studies that compared the effectiveness and use of intranasal DEX to intranasal or oral midazolam in the pediatric population. The studies included the pediatric population undergoing a variety of studies including, but not limited to strabismus studies, laceration repair, MRI studies, and cardiac catherization. The last study was a

systematic review to identify the effects of oral midazolam as a premedication in children.[14] As an exception, 1 study that was more than 6 years old was included in the study for its relevance to the concepts of the paper.

Results

Six studies ended up meeting the eligibility criteria for the literature review. Two systematic reviews were included 1- analyzing DEX and the other outlining the benefits and statistical data of midazolam. The other 4 studies were small scale randomized control studies that looked at the benefits, different application methods and different dosing of either DEX or midazolam. These studies included sample sizes ranging from 90 to 400 and included pediatric facilities from across the country.

Currently, there are many approaches being utilized to help mitigate preoperative anxiety in the pediatric population. Each of these modalities have a variety of advantages and disadvantages. The most common route in the pediatric population for administering premedication is oral; however, this route has low bioavailability.[14] Rectal administration can be painful, and children can expel the medication, leaving this option inappropriate for older children. Intramuscular approach is invasive, painful, and difficult to administer on young children. The most effective route of premedication for pediatric patients is transmucosal—this includes intranasal. This route is effective due to its high vascularization of mucosa and ability to circumvent first-pass metabolism.[14]

Additionally, there are a variety of pharmacological agents that are being utilized as anxiolytics. Each of these agents can be administered by various routes. There are a handful of medications that have been explored and are currently being used in the pediatric population. Currently, midazolam is the most utilized medication for premedication for the pediatric

population; however, it can cause significant respiratory depression in this age group. Intranasal DEX is beginning to be utilized more in this population with positive results. Intranasal DEX has a slower onset of action when compared to intranasal DEX;[8,11] however, it has superior sedative effects with parental separation and onset of induction and decreased levels of postoperative nausea and vomiting, pain and agitation. Additionally, the intranasal method of administration did not have the irritating effects that intranasal midazolam has been shown to have.[7,8] Lastly, although DEX has been shown to decreased levels of HR and BP in patients, these decreases have not been shown significantly enough to need rescue medication.[14]

Author(s)	Purpose	Methodology/ Research Design	Intervention(s)/ Measures	Sampling/Setting	Primary Results	Relevant Conclusions
Behrle et al., (2017)	To evaluate the use of intranasal DEX as a sedative in the pediatric population	Non-experimental Observation study, Level II	Patients were given 3 mcg/kg of intranasal DEX 40 mins prior to a scheduled procedure.	109 patients were included in the study and evaluated based on the 5-point University of Michigan Sedation Scale. Patients included in the study were those ranging in age from 6 months to 18 years, ASA levels of I or II, that were undergoing noninvasive procedures (ie., radiologic imaging, echocardiography, electrocephalography, and auditory brainstem response)	DEX is a safe sedative that offers sedation, anxiolytic and analgesic properties. DEX causes no respiratory depression and has only minor hemodynamic effects. These patients did have increased sleep times.	Intranasal DEX is a safe and effective medication to utilize prior to having to obtain intravenous catheters.
Li et al., (2016)	To compare the effectiveness of two different administration methods of intranasal DEX	Randomized Control Trial, Level 1	In the pediatric population, two different methods of administering intranasal DEX were compared. One group recieved 3 mcg per kg of DEX via and atmoizer and another group received 3 mcg per kg of DEX via drops from a syringe	279 children aged 0-3 were evaluated in the study. Children with a known allergy of DEX, renal or hepatic dysfunction, nasal discharge, and learning difficulties were excluded from the sample size. Blind registered nurses and anesthesia providers administered the medication and rated behavior, movement, and sedation scores.	There was no significant difference in onset of sedation, behavior and movement scores, or UMSS ratings between the two groups. There were no differences in vitals.	Intranasal DEX administered via atomizer and drops from a syringe are both effective routes of administration. Successful sedation levels can be achieved with both.
Lin et al,, (2016)	To evaluate the effects of premedication with intranasal DEX on inhalation induction and postoperative emergence in	Randomized Control Trial, Level 1	The study aims to test whether a single dose of intranasal DEX is effective in reducing preoperative anxiety and emergence agitation.	Patients were randomized into 1 of 3 groups. The first group, D1 (1 mcg/kg of intranasal DEX), D2 (2 mcg/kg of intranasal DEX), and Group C (intranasal saline). Each group had a total of 30 participants.	The participants in groups D1 and D2 has significantly lower mask induction scores and emergence delirium scores. The total time spent recovering in PACU was comparable among all three groups.	Intranasal DEX with either a 1 mcg/kg or 2 mcg/kg dose can reduce the resistance to mask induction and decrease the incidence of postoperative emergence agitation.

	the pediatric population			Exclusion factors included known adverse reactions to DEX, neurological illness, developmental delay, parental refusal, or moderate upper tract infection.	Lastly, clinically significant decreases in heart rate that required interventions were not observed in any of the 3 groups.	
Jun et al., (2017)	To identify the effects of intranasal DEX as a premedication in children	Systematic Literature Review Level 1	Literature review conducted using EMBASE, MEDLINE,Ovid MEDLINE Daily and Cochrane Controlled Trials Register, and Cochrane Database of Systematic Reviews. In addition, Web of Science, Google Scholar, and KoreaMed databases were utilized to retrieve relevant studies.	For the primary study, inclusion criteria were as follows: (a) Literature type: randomized-controlled trials in all published international journals without language restriction; (b) Subjects: children undergoing premedication treatment before surgery; (c) Interventions: studies evaluating the efficacy and safety of intranasal DEX premedication; (d) Outcomes: the primary outcomes were sedation at separation from patients, sedation at anesthesia.	Search of intranasal DEX resulted in 13 studies. Six of these studied compared intranasal DEX to intranasal midazolam. Comparison of the studies showed that intranasal DEX resulted in more sedation at parental separation, less need for rescue medications, decreased incidence of postoperative nausea and vomiting, and decrease nasal irritation when compared to other premedication regimes.	Intranasal DEX is a safe and effective alternative for premedication in children undergoing surgery.
Cote et al., (2002)	To compare 3 doses of a commercially prepared oral midazolam use in the pediatric population	Randomized Control Trial, Level 1	This study aims to look at what dose of oral midazolam would be most effective for use as a pre-sedative in the pediatric population.	A total of 405 patients from nine participating centers were enrolled in the study. The children were stratified by age into three groups: 6 months to less than 2 years, 2 to less than 6 years, and 6 to 16 years old. Within these groups, the children were divided further into three groups based on dosing – 0.25 mg/kg, 0.5 mg/kgm and 1 mg/kg. Exclusion criteria included seizure disorders,	In all groups and across all ages, sedation levels and onset as well as anxiety levels and onset times were recorded. Baseline anxiety levels were highest among the youngest age group; however, successful sedation and decreased anxiety was comparable among all groups and ages.	Doses as small as 0.25 kg/mg of oral midazolam can be effective in mitigating pre-procedure anxiety and as a sedative in the pediatric population.

				gastrointestinal disorders, and any medical condition that could compromise the safety of the patient.	Onset of sedation was longer in the group that received the smallest dose. Additionally, none of the patients demonstrated any significant drop in saturations before induction.	
Manso et al. (2019)	To determine the efficacy of oral midazolam for sedation in the pediatric population	Systematic Literature Review Level 1	The study was conducted to research the effectiveness of oral midazolam in the pediatric population. The systemic review was conducted using PubMed and Science Direct. Any study conducted from January 1998 to March 2016 that were written in English and contained the search terms "midazolam and sedation and child" were evaluated.	Only randomized studies that used midazolam as a sole medication were included in the review. Additionally, only the studies that were included had to include evaluation scales that measured sedation levels related to minimal or moderate sedation. Studies that were conducted as comparisons to other sedatives were not included. Observed vital signs and reported adverse effects were outlined.	A total of 25 articles were selected for the systematic review. In total, 1610 patients aged 4 months to 18 years were evaluated and given a dose ranging from 0.25 to 1.5 mg/kg of oral midazolam. In comparison, 138 of the participants were treated with placebo.	Overall, oral midazolam is an effective medication in providing satisfactory sedation levels in the pediatric population. Incidence of adverse effects, including paradoxical reactions and respiratory events were seen in with high doses.

Summary of Evidence

In the first study reviewed written by Behrle et al. (2017), the authors researched the use of intranasal DEX as a form of sedation in the pediatric population. Patients were recruited into the study based on age (6 months to 18 years), ASA levels (I or II), and procedure (non-invasive radiologic imaging, echocardiogram, electrocephalography, and auditory brainstem). Qualifying patients were administered 3 mcg/kg of intranasal DEX 40 mins prior to the start of the procedure. Registered nurses documented the patient's sedation level based a 5- point University of Michigan sedation scale, as well as vitals, observed interventions, and length of recovery. Observed interventions included airway events, cardiovascular events, gastrointestinal events, and patient tolerance.[13]

The 109 patients that were given intranasal DEX were compared to 690 subjects that underwent similar procedures but did not receive DEX and were given either midazolam or propofol instead. Overall, 92% of the patients that received intranasal DEX were successfully sedated. There were no clinically significant differences in adverse observed events or interventions in the group of patients that received DEX compared to the non-DEX group. It was noted that the group that received DEX did have longer sleep times.

While the effectiveness of DEX as a sedative has been documented, the optimal route of administration in the pediatric population has not been established. In a study completed by Li et al. (2016), the authors explore the difference in successfully administrating intranasal DEX via atomizer versus drops from a syringe. The study consisted of a total of 279 children aged 1-3. Children were randomly assigned to one of two groups, and each received a dose of 3 mcg per kg. Behavior and movement scores were collected as well as sedation scores based on the University of Michigan Sedation Score (UMSS). There were no statistically significant

differences in behavior, movement, or UMSS scores between the two groups. Additionally, sedation onset times were similar between the two groups, and there were no episodes of oxygen desaturation or respiratory depression.[3]

In a study conducted by Lin et al. (2016), the authors evaluate the effectiveness of intranasal DEX on pediatric patients undergoing cataract surgery. The study aims to prove that a single dose of intranasal DEX could not only reduce preoperative anxiety but also play a role in minimizing postoperative emergence agitation. The study included patients ranging from age 1 to 8 that were scheduled for cataract surgery. A total of 98 children were included in the study. All participants were classified as American Society of Anesthesiologist (ASA) levels of I or II. Exclusion criteria for the study included those that were allergic to DEX, had neurological or developmental delays, had a previous or current upper respiratory infection, or parental refusal. The children were grouped into 1 of 3 groups – Group D1 were given an intranasal DEX dose of 1 mcg/kg, Group D2 were given 2 mcg/kg and Group C were given normal saline.

After administration of medication or normal saline, patients were induced for the procedure using 8% sevoflurane via a facemask. Cooperation and successful sedation scores were based on a scale that measured whether the participants were: 1 = calm, cooperative, 2 = moderate fear of the mask, 3 = combative and crying.[15] After the procedure, patients were evaluated in the PACU every 5 minutes for postoperative agitation. Overall, the groups that received intranasal DEX were successfully sedated at the time of induction. Induction scores were highest among the group that received intranasal normal saline. Postoperative agitation scores were evaluated when using the Pediatric Anesthesia Emergence Delirium (PAED) and a score of 10 or higher was regarded as postoperative agitation. Treatment with intranasal DEX

(both doses) significantly decreased postoperative agitation scores when compared to the control group. Length of stay in the PACU was similar across all groups, and none of the groups showed significant reductions in vital signs. The study provided evidence that intranasal DEX cause be successfully and safely used as a pre-sedation as well as a modality to reduce postoperative agitation.

Included in this review is a meta-analysis completed by Jun et al. (2017) regarding prior studies conducted to evaluate the use of intranasal DEX in the pediatric patient population. The analysis included 13 studies and a total of 1168 participants. All of the studies included in the analysis compared intranasal DEX to an alternative sedative. Many of the articles compared intranasal midazolam, while a few compared oral midazolam, intranasal ketamine, intranasal clonidine, and intranasal saline. The analysis revealed that intranasal DEX used as a premedication in the pediatric population achieved excellent sedation levels at parental separation, no significant nasal irritation, decreased levels of postoperative nausea and vomiting, and postoperative alangsesia.[14]

In the pediatric population, the most commonly prescribed anesthetic medication is oral midazolam.[16] Historically, midazolam has been very successful as a sedative and anxiolytic. The authors of a study conducted by Cote et al. (2002) aimed to seek the efficacy, safety, and taste acceptability of three different doses of oral midazolam. The study was conducted across 9 children's hospitals around the nation and included a total of slightly over 400 patients. The patients included in the study were aged 6 months to 16 years. All patients were ASA levels I , II or III; however, exclusions were made if the participant had seizure disorders, gastrointestinal disorders, or any condition that would compromise the safety of the patient.

After administration of three different doses of 0.25 mg/kg, 0.5 mg/kg and 1.0 mg/kg, up to a maximum of 20 mg, patients were evaluated on several measures. Vitals were collected before administration and regularly there after until discharge. Sedation was assessed on a 5-point scale while anxiety, cooperation, and taste acceptability were assessed on a 4-point scale. Patients were broken into three age groups: 6 months to less than 2 years, 2 years to less than 6 years, and 6 years to 16 years. Each of these age groups were further divided into one of the three dosing groups.

Patients in the youngest group had the highest level of base line anxiety. The percentage of patients that were successfully sedated after ten minutes of administration of medication was similar across all groups with 91% of all patients reaching successful sedation between 10-20 minutes. [16] Again, the youngest group of participants had significantly more unsatisfactory sedation scores when compared to the other groups. This can possibly be attributed to the fact that this age group was more likely to grimace, express verbal disinterest, or reject the medication all together. The onset and level of anxiolysis was positively associated with the dose of medication. Cooperation at separation from parents was similar between all groups; however, the percentage of patients that showed cooperation with face masks was decreased. In addition to sedation and anxiety levels, adverse events were recorded at three different times. It was noted that the percentage of patients that received 1.0 mg/kg of midazolam had a higher incidence of adverse events. Overall, the data shows that oral midazolam can be successfully used to provide effective sedation and reduce anxiety in the pediatric population.

A systematic review of the effectiveness of oral midazolam was also included in this literature review. The review was conducted in 2018 by Manzo et al. and included published studies from January 1988 to March 2016. The studies included in the review were those that were randomized studies that assessed the effectiveness of oral midazolam as a sole medication and evaluated levels of sedation. A total of 25 articles and over 1600 participants were included in the review. Several studies included in the review also included information regarding comparative medications also used for sedation in this patient population. The participants of the study ranged in age from 4 months to 18 years old and the dosing range was between 0.25 mg/kg up to 1.5 mg/kg with the most common dose of 0.5 mg/kg being utilized. There is also data collected on 138 patients that were treated with a placebo. Evaluation of effectiveness, effectiveness in different context situations, comparisons of other sedatives and placebos, comparisons of doses, comparisons of different age ranges, and safety were among the points evaluated in the review.

Overall, oral midazolam is an effective medication that can provide satisfactory sedation levels in the pediatric population. Additionally, oral midazolam was shown to provide anxiolytic properties in this patient population. The oral form of the medication is comparable with its alternative competitors. Several different dosages were evaluated in a few studies and incidences of adverse effects, including paradoxical reactions and respiratory events, were mostly seen with increasing doses.

Conclusion

The pediatric population is a challenging subset of patients for anesthesia providers. They can have increased levels of anxiety not only from the procedure but also from parental separation, fear of the unknown, being placed in foreign locations, and being surrounded by strangers. Currently, midazolam is being utilized as a pre-medication to mitigate anxiety level in this patient population; however, it can cause nasal irritation and respiratory depression. DEX is an alternative that is being introduced as an alternative to midazolam. Studies have shown that DEX is a safe alternative that has increased success in preoperative sedation levels including separation anxiety and has been shown to result in decreased postoperative nausea, vomiting, pain, and agitation.

III. Purpose and PICO Clinical Questions

Primary DNP Project Goal

Current and common practice in many pediatric facilities includes the use of midazolam for moderate sedation. Midazolam has been shown to be effective in preventing stress and anxiety that comes from parental separation, fear, pain, and the presence of strangers in an unfamiliar environment.[17] This short acting benzodiazepam has been shown to offer not only sedative effects, but also been shown to offer anxiolytic and hypnotic properties.[17] As with all medications, midazolam comes with the possibility of adverse effects, including respiratory depression, nausea and vomiting, and paradoxical reactions. Ongoing research and development of new medications aim to provide the most effective sedation with minimal side effects. DEX is an alternative medication that is being considered as a sedative and to reduce anxiety among the pediatric population. The objective of researching alternative medications is to provide the most appropriate and effective anesthetic care while minimizing adverse effects to enhance patient satisfaction.

PICO Clinical Question

In the pediatric population (2-8 years old) (P), how does intranasal dexmedetomidine (I) compare to oral midazolam (C) in providing sedation and reducing separation anxiety (O)?

Population (P): Pediatric age ranging from 2-8 years

Intervention (I): Intranasal Dexmedetomidine

Comparison (C): Oral Midazolam

Outcomes (O): Agitation and sedation levels

IV. Conceptual Underpinning and Theoretical Framework

SMART Goals and Outcomes

Development of goals and intents were guided by the acronym SMART. These details include objectives that are specific, measurable, achievable, realistic, and timely and measure significance and quality.[18]

Specific

Anesthesia providers administering sedation to the pediatric population will have a clear understanding of the pros and cons of alternative medications. This will include dosing information as well as route of administration. The effectiveness and use of safe alternative sedation medication will be analyzed through the analysis of a questionnaire.

Measurable

The questionnaire measured knowledge pre and post an educational intervention. Results evaluated current practice regarding drugs, doses, and methods of administration with alternative medications and methods. All medical personnel, including but not limited to anesthesiologist, certified registered nurse anesthetist and student registered nurse anesthetist were involved in the educational intervention.

Achievable

Anesthesia providers were educated on the incidence of anxiety in the pediatric population. Additionally, providers learned about current practice being utilized and alternative medications that can help decrease preoperative anxiety in this patient population.

Realistic

Educational teaching was provided via an educational link to a PowerPoint presentation with video. For ease and convivence, access to educational modules as well as pre and post questionnaires will be provided in electronic form.

Time Based

The educational module as well as pre and post education questionnaire was available for a 3-week period. During this time, exposed health care personnel were asked to complete the educational module as well as the pre and post education questionnaire within a weeklong period. This will allow for evaluation on provider knowledge prior to and after the educational module.

Program Structure/SWOT Analysis

The development and implementation of the educational module requires a collaborative effort. In order to ensure that the educational program has the potential for sustainability, multidisciplinary teams and organizational cooperation is imperative.[18] Additionally, ascertaining opportunities for change, highlighting the value of the project, and identifying the significance of the project to the appropriate stakeholders will ensure success of its implementation. A strength, weakness, opportunity, and threat (SWOT) analysis assessment tool was utilized to anticipate any barriers that may be encountered during the development and implementation of the project.

As a patient undergoes surgery, they encounter a multidisciplinary group of individuals all of whom have an impact in their care. Everyone from the admitting nurse and primary physician to the anesthesia provider and PACU nurse are involved in ensuring that patient has the best outcome possible. The first step of the project was to identify the expert caregivers that

have an impact in developing and implementing positive change through education. Next, identification of individuals that advocated for the safe and effective administration of alternative sedation medications were targeted. These individuals were asked to complete a pre-education questionnaire to assess baseline knowledge of current and alternative forms of sedation in the pediatric population. Educational courses were then provided through a digital platform. Once completed, a post-education questionnaire was used to analyze and evaluate effectiveness of teachings.

Strengths

Anesthesia providers work diligently to provide effective anesthesia to their patients while ensuring their hemodynamic safety. In the pediatric population, mitigating anxiety is of utmost importance as uncontrolled anxiety can cause a variety of emotional, psychiatric and physical problems.[19] Administering adequate care for their patients while ensuring their safety is the primary goal for anesthesia providers. While current practices may be effective, they do not come without drawbacks. Developing and researching new and comparable ways to effectively sedate patients while decreasing adverse effects not only benefits the patients, but also allows for patient and provider satisfaction.

Anesthesiologists should consider how the pediatric population experiences perioperative care to improve practice and outcomes. In the pediatric population, pain and anxiety, along with thirst are among the most common complaints.[20] Therefore, the purpose of this project was to educate the multidisciplinary team of providers responsible for the care of the pediatric population on new and alternative forms of reducing anxiety. Developing a perioperative plan that ensured minimal anxiety while addressing the downfalls of current practice ensures best

practice. In the ever-changing field of health care, it is important to keep continued exposure to new and meaningful ways to care for patients.

Weaknesses

Implementation of evidenced-based ideas into practice takes a considerable amount of planning, discipline, collaboration, and time. Many barriers can prevent even the best of plans from being executed. Internal traits that could be harmful to a program attributes to the plan's weaknesses.[18] Additionally, several barriers contribute to the effective execution of an educational program or plan. Attributes such as culture, communication processes, external requirements, staff commitment, supportive components, and safety and legal issues can contribute to barriers to execution.[21] To mitigate the number of weaknesses that a project faces, it is important to identify barriers, be specific and selective in implementing interventions, and engaging end users.[22]

Several factors were identified as weaknesses for our organization. Among them were provider preference, ineffective communication, and lack of time. Anesthesia is an art that can be administered several different ways by several different providers. One provider may prefer to medicate all pediatric patients only with oral medications, while other may feel the intranasal route is best. The lack of consistency in provider preference will make it difficult to collaborate with all healthcare providers to implement a new medication and an alternate route of administration. Additionally, ineffective communication may result in inaccurate information being distributed among providers. Collaborative efforts must be taken to ensure that all end user individuals receive accurate and current information. Lastly, lack of time and resources to implement the educational program to an already time-crunched staff may be difficult.

Opportunities

Every year, the pediatric population undergoes millions of procedures involving anesthesia. In high-income countries, such as the United States, 1 in 7 children undergo at least on procedure requiring anesthesia by the age of 4.[23] One of the main goals for most medical facilities is to provide quality healthcare to the people they serve. The goals of perioperative anesthesia in the pediatric population consists of safe and effective care for both the patient and the parent. To achieve this, health care providers must stay abreast with new and developing research in their area of expertise. Anesthesia and its application have evolved tremendously since its beginning and continues to grow on a day-to-day basis.

Providing educational models to appropriate health care providers allows them to stay knowledgeable to current and new practice. As medications, methodologies, and models evolve, so must considerations for anesthesia providers. The educational model will allow providers to evaluate if using alternative medications, modes of administration or doses will provide better anesthesia for their patients. Providing the most effective sedation for the pediatric population allows for decreased length of induction, more stable vitals, and decreased requirements for anesthetic medications.[1,2]

Threats and Organizational Factors

In order for a planned project to be successful, it is important to evaluate the potential risks and barriers that may hinder its successful execution.[18] Threats that the education module may face include lack of time, ineffective communication, and downfalls of online teaching. During a typical day of a health care worker, time is limited, especially in the operating room environment. In most cases, there is little time for staff to commit to additional learning. Staff commitment influenced by the staff's attitude regarding the proposed intervention can impact the

implementation process.[21] Additionally, communication regarding the purpose of the project is essential as confusion or disregard of the intervention process can have a negative impact on the implementation.

To facilitate the ease of implementation of the education module, it can be offered online so that busy health care workers can complete it when the time is convenient. However, this method of implementation comes with its own set of threats. Factors that impact online learning include interaction and collaboration between learner and facilitator, learner motivation and technology interface.[24] In the online platform, collaboration with multiple administrative groups must occur to effectively implement the educational module.

Conceptual Underpinning and Theoretical Framework of the Project

Designing an intervention for individual-level change includes identifying barriers, selecting intervention components, using theory, and engaging end users.[22] For this educational module, self-efficacy will be utilized as the theoretical framework. Self-efficacy can be described as an individual's judgment of their capabilities to organize and execute courses of action. These beliefs provide the foundation for human motivation, well-being, and personal accomplishment.[25] Active learning allows in individual to play an active role in their educational and growth process.

V. Methodology

Setting and Participants

The study took place in a level one trauma center in Broward County, Florida that offers quality care to patients of all ages including the pediatric population. The development and implementation of the educational module will require a collaborative effort. In order to ensure that the educational program has the potential for sustainability, multidisciplinary teams and organizational cooperation are imperative.[18] Additionally, ascertaining opportunities for change, highlighting the value of the project, and identifying the significance of the project to the appropriate stakeholders ensured success of its implementation. The study participants are certified registered nurse anesthetists (CRNAs) and anesthesiologists working closely with the pediatric population. The aim of the study is to target CRNAs and anesthesiologists that work extensively in the pediatric sedation setting.

Description of Approach and Project Procedures

When a patient undergoes surgery, they encounter a multidisciplinary group of individuals all of whom have an impact in their care. Everyone from the primary physician to the anesthesia provider are involved in ensuring that patient has the best outcome possible. The first step of the project was to identify the expert caregivers that have an impact in developing and implementing positive change through education. Next, identification of individuals that will advocate for the safe and effective administration of alternative sedation and antianxiolytic medications were targeted. These CRNAs and anesthesiologists were asked to complete a pre-education questionnaire to assess baseline knowledge of current and alternative forms of sedation in the pediatric population. Educational courses were then provided through digital

platforms. Once completed, a post-education questionnaire was used to analyze and evaluate effectiveness of teachings.

Protection of Human Subjects

All healthcare personnel mentioned above that are involved in providing care to the pediatric population were asked to participate in the study. Participants were asked to join the study via email and had the ability to withdraw from the study at any time for any reason. Participants were asked to participate in a pre-educational survey used to collect data on current knowledge of practice as well as barriers to implementation of evidence-based practice. No personal or identifiable information was collected from participants. However, information regarding the participants' role in the care of the pediatric population was collected. Once obtained, all data was stored in a protected online database.

Data Collection

Participants of the study were asked to provide general demographic data including, but not limited to, age, gender, ethnicity, race, education level, and occupation. Additional information regarding their experience in the health care field including years of experience was collected. Participants of the study were asked to describe and evaluate the effectiveness of current practice methods.

Data Management and Analysis Plan

An electronic database was utilized to store and collect information regarding the study. Pre- and post-educational survey information was collected and analyzed to gather information regarding the knowledge and barriers to current and possible future practice. Means of the total scores pre- and post-educational interventions were compared.

VI. Results

Participants' Demographics

For this study, a total of 6 anesthesia providers from a large level one trauma center completed the survey. Informed consent was collected followed by the pretest survey, the educational PowerPoint module, and a posttest survey. Most participants were female (*n* = 5, 83.3%) with the remaining participant identifying as male (*n* = 1, 16,7%). The participants ranged in ethnicity from African American (*n* = 2, 33.3%) and Asian (*n* = 1, 16.7%) to Hispanic (*n* = 1, 16.7%) and Other (*n* = 2, 33.3%). All participants held advanced degrees with the majority of having completed a Doctoral in Nursing Practice (DNP) degree (*n* = 5, 83.3%) and the remaining participant holding a Master's in Science in Nursing (MSN) degree (*n* = 1, 16,7%). The participants were surveyed on number of years they have been practicing as anesthesia providers. Two thirds of the participants were new providers (less than a year, *n* = 2, 33.3%), while the remain were seasoned professionals having been in practice for more than 10 years (*n* = 4, 66.6%).

Table 1. Participants' Demographics

Participants (n = 6)	**Number**	**%**
Gender		
Male	1	16.7%
Female	5	83.3%
Ethnicity		
African American	2	33.3%
Asian	1	16.7%
Hispanic	1	16.7%
Other	2	33.3%
Level of Education		
Bachelors	0	0.0%
MSN	1	16.7%

DNP	5	83.3%
Years of Experience		
Less than 1 year	2	33.3%
1 – 5	0	0.0%
6 – 10	0	0.0%
More than 10 years	4	66.7%

Participant Knowledge of Pediatric Anxiety and Treatment

During the pretest, data was collected on the participants' baseline knowledge on the effects of pediatric anxiety as well as its current treatment. The results of these responses are in Table 2. In the pediatric population, high levels of preoperative anxiety can lead to several side effects including tachycardia and higher requirements for anesthetic management. Many participants recognized that increased need for anesthetic requirements prior to the educational module (n = 4, 66.7%); however, only 33.3% (n = 2) answered tachycardia as a side effect of anxiety. A number of participants also stated nausea (n = 2, 33.3%) and hypotension (n = 1, 16.7) as possible side effects. Post-educational knowledge showed a 17% increase in awareness of tachycardia as a side effect of anxiety. All participants recognized that midazolam (n = 6, 100%) is the most common pharmacological agent being utilized to treat peri-operative anxiety in the pediatric population. Although initially correct, one participant chose Ketamine as the agent of choice in the post-test survey. Participants were divided when identifying unwanted side effects of midazolam, with answers tallying as follows: Postoperative behavioral changes (n = 2, 33.3%), hypotension (n = 2, 33.3%), respiratory changes (n = 3, 50.0%), and polyuria (n = 1, 16.7%). Post-educational module teaching reveals an increase in knowledge for correct side effects including postoperative behavioral changes (n = 3, 50.0%), and respiratory changes (n = 5, 83.3%).

Table 2. Knowledge of Pediatric Anxiety and Treatment

*denotes correct answer	Pre-Test	Post-Test	% change
In the pediatric population, high levels of preoperative anxiety can lead to: (Select two)			
Nausea	33.3%	50.0%	17%
Hypotension	16.7%	0%	-17%
Higher requirements for anesthetic medications*	66.7%	50.0%	-17%
Tachycardia*	33.3%	50.0%	17%
The most common pharmacological agent being utilized in the pediatric population for the use of peri-operative anxiety is:			
Ketamine	0%	100%	100%
Midazolam*	100%	83.3%	-17%
Dexmedetomidine	0%	0%	0%
Clonidine	0%	0%	0%
Identify the unwanted side effects of midazolam. (Select two)			
Postoperative behavioral changes*	33.3%	50.0%	17%
Hypotension	33.3%	16.7%	-17%
Respiratory depression*	50.0%	83.3%	33%
Polyuria	16.7%	0%	-17%

Participant Knowledge of Dexmedetomidine

In addition to attaining a baseline guide of participants' knowledge of pediatric anxiety repercussions and its treatment, the survey also looked at participants' understanding and familiarity of DEX. DEX's clinical effects can be attributed to selective alpha 2 receptor agonism. Most participants were familiar with this mechanism of action (n = 4, 66.7%), however, a small majority chose N-Methyl-D-aspartate receptor antagonist (n = 2, 33.3%). Post-survey results indicate no additional teaching on this subject as overall percentages remained the

same. DEX has a number of beneficial properties that participants were aware of including its antianxielytic (*n* = 3, 50.0%) and pain relief (*n* = 4, 66.7%) properties. A small percentage of participants mistakenly chose antipyretic (*n* = 2, 33.3%) as a possible benefit of DEX; however, posttest survey results indicated appropriate elimination of knowledge gaps with no participants choosing this property. In addition, there was an 33% increase in knowledge of DEX's pain relief benefits. The peak effects of DEX are established within 15 mins, which only 33% of participants understood before the educational module. While there was an increase in awareness of DEX's duration of peak effects from 33% to 50%, half of the participants continued to believe that DEX's peak effect was less than 10 minutes (5 minutes – *n* = 2, 33%; 7-8 minutes – *n* = 1, 16.7%).

Table 3. Knowledge of Dexmedetomidine

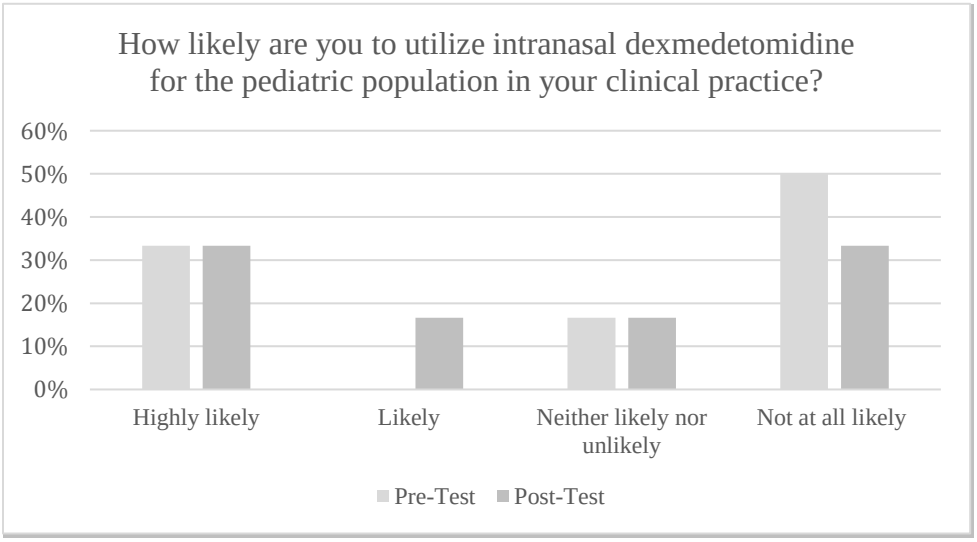
*denotes correct answer	Pre-Test	Post-Test	% change
Dexmedetomidine's clinical effect can be attributed to what mechanism of action?			
Potent μ-receptor agonist	0%	0%	0%
N-Methyl-D-aspartate receptor antagonist	33.3%	33.3%	0%
Selective alpha 2 receptor agonist*	66.7%	66.7%	0%
Inhibition of alpha 2 delta subunit of voltage gated calcium channels	0%	0%	0%
Select the beneficial properties of dexmedetomidine. (Select two)			
Antianxiety*	50%	50.0%	0%
Pain relief*	66.7%	100%	33%
Antipyretic	33.3%	0%	-33%
Antiemetic	0%	0%	0%
Select the peak effect of dexmedetomidine.			
5 minutes	50.0%	33.3%	-17%

7-8 minutes	16.7%	16.7%	0%
15 minutes*	33.3%	50.0%	17%
30 minutes	0%	0%	0%

Participant Likelihood of Use of Intranasal Dexmedetomidine in Future Practice

Prior to the educational module, participants were questioned on the likelihood of use of intranasal DEX for the pediatric population during their clinical practice. A total of 2 participants answered they were "highly likely," 1 participant answered "neither likely nor unlikely," and 3 participants answered "not at all likely" to use DEX. Survey results following the educational module showed a slight increase in likelihood of use. Half the participants were either "highly likely" or "likely" to use DEX in their practice. One participant continued to answer "neither likely nor unlikely" to use DEX, while 2 participants were "not at all likely" to use DEX in their practice.

Figure 3. Likelihood of Use of Intranasal Dexmedetomidine



VII. Discussion

Limitations

There were a few limitations to this study with the most relevant being the small sample size. The study took place at a large health care facility with initial surveys being sent to over 50 participants. A larger response rate would have been ideal, as it would have strengthened the results of the project. Another factor that was limited for this project was its time restrictions. The survey itself was available for a total of 3 weeks, which could have limited the number of participants that had the time to respond. Lastly, the survey was limited to an online format. Online platforms are unpersonal, often times not engaging, and are limited in two-way participation. These qualities could have possibly discouraged potential participants.

Future Implications of Advance Nursing Practice

In the health care arena, evidence-based practice is imperative to the growth and safety of the patient and can result in greater overall satisfaction for both the patient and the clinician.[26] The main agenda for this intervention was to inform and educate anesthesia providers on alternative sedation medications that can be utilized in the pediatric population. Adequate patient sedation with decreased side effects can lead to better outcomes for the patient, greater satisfaction for parents, and greater fulfillment for anesthesia providers.

Conclusions

The literature review outlined above showcased the many benefits of using intranasal DEX to help mitigate anxiety and reduce the prevalence of parental separation among the pediatric population. DEX is not only effective in providing adequate sedation levels but also comes with the added benefit of minimal respiratory and postoperative behavioral side effects over midazolam. Additionally, the Quality Improvement Project was designed to inform and

educate anesthesia providers on the medication profile of DEX. Anesthesia providers enhanced their knowledge of the potential harm of increased levels of anxiety, side effects of current medications being utilized to mitigate anxiety, and the uses and benefits of DEX. Following the education module, anesthesia providers were more likely to incorporate intranasal DEX into their clinical practice.

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Appendix

Appendix A. Letter of Support

March 1, 2022

Yasmine Campbell, DNP, CRNA, APRN
Clinical Assistant Professor,
Department of Nurse Anesthesiology
Florida International University

Dr. Campbell,

Thank you for inviting Broward Health to participate in the Doctor of Nursing Practice (DNP) project conducted by Shilpa Heald entitled "The Use of Intranasal Dexmedetomidine Compared to Oral Midazolam in the Pediatric Pre-operative Population for Separation Anxiety: An Educational Module" in the Nicole Wertheim College of Nursing and Health Sciences, Department of Nurse Anesthetist Practice at Florida International University. I have warranted her permission to conduct the project using our providers.

Evidence-based practice's primary aim is to yield the best outcomes for patients by selecting evidence-supported interventions. This project intends to evaluate if a structured education targeting providers will increase knowledge on the use of Dexmedetomidine in the pediatric population to decrease preoperative separation anxiety.

We understand that participation in the study is voluntary and carries no overt risk. All Anesthesiology providers are free to participate or withdraw from the study at any time. The educational intervention will be conveyed by a 15-minute virtual PowerPoint presentation, with a pretest and posttest questionnaire delivered by a URL link electronically via Qualtrics, an online survey product. Responses to pretest and posttest surveys are not linked to any participant. The collected information is reported as an aggregate, and there is no monetary compensation for participation. All collected material will be kept confidential, stored in a password-encrypted digital cloud, and only be accessible to the investigators of this study: Shilpa Heald and Dr. Campbell. We expect that Shilpa Heald will not interfere with normal hospital performance, behaving professionally and following standards of care.

Before implementing this educational project, the Florida International University Institutional Review Board will evaluate and approve the procedures to conduct this project. Once the Institutional Review Board's approval is achieved, this scholarly project's execution will occur over two weeks. We support the participation of our Anesthesiology providers in this project and look forward to working with you.

February 1, 2022

Edward Punzalan, DNP, CRNA, APRN — Date
Administrative Director of Nurse Anesthesia
Healthcare Performance Anesco

Appendix B. IRB Approval

FIU | FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To:	Dr. Yasmine Campbell
CC:	File
From:	Chris Grayson, MBA, CIM, CIP, Director, Research Integrity
Date:	March 25, 2022
Protocol Title:	The Use of Intranasal Dexmedetomidine Compared to Oral Midazolam in the Pediatric Pre-operative Population for Separation Anxiety. An Educational Module.

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #: IRB-22-0108 **IRB Exemption Date:** 03/25/22
TOPAZ Reference #: 111528

As a requirement of IRB Exemption you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

Appendix C. Invitation to Participants

FIU | FLORIDA INTERNATIONAL UNIVERSITY

Nicole Wertheim College of Nursing and Health Sciences
Department of Nurse Anesthetist Practice

The Use of Intranasal Dexmedetomidine Compared to Oral Midazolam in the Pediatric Pre-operative Population for Separation Anxiety. An Educational Module

Dear Participant:

My name is Shilpa Heald and I am a student from the Anesthesiology Nursing Program Department of Nurse Anesthetist Practice at Florida International University. I am writing to invite you to participate in my quality improvement project. The goal of this project is to improve health care provider knowledge on intranasal dexmedetomidine for pre-operative anxiety in the pediatric population. You are eligible to take part in this project because you are a member of the Anesthesia Department for Anesco at Broward General.

If you decide to participate in this project, you will be asked to complete and sign a consent form for participation. Next, you will complete a pre-test questionnaire, which is expected to take approximately 5 minutes. You will then be asked to view an approximately 15 minute long educational presentation online. After watching the video, you will be asked to complete the post-test questionnaire, which is expected to take approximately 5 minutes. No compensation will be provided.

Remember, this is completely voluntary. You can choose to be in the study or not. If you'd like to participate or have any questions about the study, please email or contact me at spate109@fiu.edu or 7347175481.

Thank you very much.

Sincerely,

Shilpa Heald, RN, BSN, CCRN

Appendix D. Informed Consent

FIU | FLORIDA INTERNATIONAL UNIVERSITY

CONSENT TO PARTICIPATE IN A QUALITY IMPROVEMENT PROJECT

The Use of Intranasal Dexmedetomidine Compared to Oral Midazolam in the Pediatric Preoperative Population for Separation Anxiety. An Educational Module

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** Educational module to improve knowledge in utilizing intranasal dexmedetomidine for preoperative anxiety in the pediatric population.
- **Procedures**: If you choose to participate, you will be asked to complete a pretest watch a voice PowerPoint and then a post test
- **Duration:** This will take about a total of 20 minutes total.
- **Risks**: The main risk or discomfort from this research is minimal. There will be minimal risks

  involved with this project, as would be expected in any type of educational intervention, which may have included mild emotional stress or mild physical discomfort from sitting on a chair for an extended period of time, for instance.

- **Benefits:** The main benefit to you from this research is increase the participants knowledge in utilizing intranasal dexmedetomidine for preoperative anxiety in the pediatric population.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Participation:** Taking part in this research project is voluntary. Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE PROJECT

You are being asked to be in a quality improvement project. The goal of this project is to improve health care provider knowledge on the use of intranasal dexmedetomidine for preoperative anxiety in the pediatric population. If you decide to be in this study, you will be one of approximately 10 people in this research study.

NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one of approximately 10 people in this research study under the purpose of the project.

DURATION OF THE PROJECT

Your participation will require about 20 minutes of your time. Page 1 of 2

PROCEDURES

If you agree to be in the project, we will ask you to do the following things:
1. Complete an online 10 question pre-test survey via Qualtrics, an Online survey product for which the URL link is provided
2. Review the educational PowerPoint Module lasting 10 minutes via Qualtrics, an Online survey product for which the URL link is provided.
3. Complete the online 10 question post-test survey via Qualtrics, an Online survey product for which the URL link is provided.

RISKS AND/OR DISCOMFORTS

The main risk or discomfort from this research is minimal. There will be minimal risks involved with this project, as would be expected in any type of educational intervention, which may have included mild emotional stress or mild physical discomfort from sitting on a chair for an extended period of time, for instance.

BENEFITS

The following benefits may be associated with your participation in this project: An increased understanding on the perioperative use of intranasal dexmedetomidine for pre- operative anxiety in the pediatric population.
The overall objective of the program is to increase the quality of healthcare delivery and improve healthcare outcomes for our patients.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this project. However, if you would like to receive the educational material given to the participants in this project, it will be provided to you at no cost.

CONFIDENTIALITY

The records of this project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report, we might publish, we will not include any information that will make it possible to identify you as a participant. Records will be stored securely, and only the project team will have access to the records.

PARTICIPATION: Taking part in this research project is voluntary.

COMPENSATION & COSTS

There is no cost or payment to you for receiving the health education and/or for participating in this project.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this project is voluntary. You are free to participate in the project or withdraw your consent at any time during the project. Your withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research project, you may contact Shilpa Heald at 734-717-5481 or spate109@fiu.edu and Yasmine Campbell at ycampbel@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights pertaining to being a subject in this project or about ethical issues with this project, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. By clicking on the “consent to participate” button below I am providing my informed consent.

Appendix E. Data Collection Instrument

Pretest and Posttest Questionnaire:

The Use of Intranasal Dexmedetomidine Compared to Oral Midazolam in the Pediatric Preoperative Population for Separation Anxiety. An Educational Module

INTRODUCTION

The primary aim of this QI project is to improve the knowledge of CRNAs pertaining to the utilization of intranasal dexmedetomidine for preoperative anxiety in the pediatric population.

Please answer the question below to the best of your ability. The questions include demographic information and knowledge of intranasal dexmedatomidine utilization in pediatric procedural patients. Questions are either in multiple choice or likert style format and are meant to measure the CRNAs knowledge of the effectiveness of intraoperative methadone reducing postoperative opioid consumption.

PERSONAL INFORMATION

1. **Gender:**
    a. Male
    b. Female
    c. Non-binary
    d. Prefer not to answer

2. **Ethnicity:**
    a. American Indian or Alaska Native
    b. Bla
    c. Black or African American
    d. Hispanic or Latino
    e. Native Hawaiian or Other Pacific Islander
    f. White
    g. Other

3. **Level of Education:**
    a. Certificate
    b. Bachelors
    c. Masters
    d. Doctoral (DNP, DNAP, EdD, PhD)

4. **Years of experience:**
    a. Less than 1 year
    b. 1 to 5
    c. 6 to 10
    d. More than 10 years

QUESSIONAIRE

5. **In the pediatric population, high levels of preoperative anxiety can lead to:**
    a. Nausea
    b. Hypotension
    c. Higher requirements for anesthetic medications
    d. Tachycardia

6. **The most common pharmacological agent being utilized in the pediatric population for the use of peri-operative anxiety is:**
    a. Ketamine
    b. Midazolam
    c. Dexmedetomidine
    d. Clonidine

7. **Identify the unwanted side effects of midazolam. (Select two)**
    a. Postoperative behavioral changes
    b. Hypotension
    c. Respiratory depression
    d. Polyuria

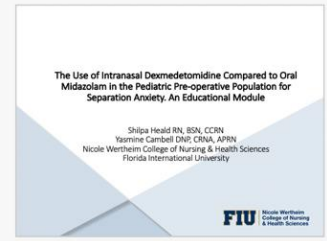
8. **Dexmedetomidine's clinical effect can be attributed to what mechanism of action?**
    a. Potent μ-receptor agonist
    b. N-Methyl-D-aspartate receptor antagonist
    c. Selective alpha 2 receptor agonist
    d. Inhibition of alpha 2 delta subunit of voltage gated calcium channels

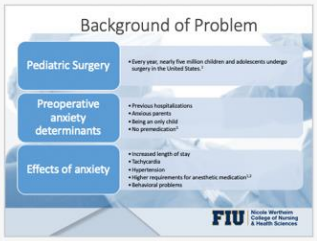
9. **Select the beneficial properties of dexmedetomidine. (Select two)**
    a. Antianxiety
    b. Pain relief
    c. Antipyretic
    d. Antiemetic

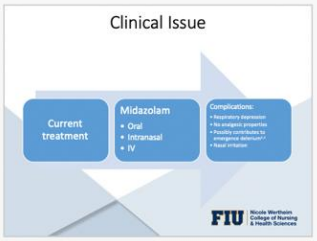
10. **Select the peak effect of dexmedetomidine.**
    a. 5 minutes
    b. 7-8 minutes
    c. 15 minutes
    d. 30 minutes

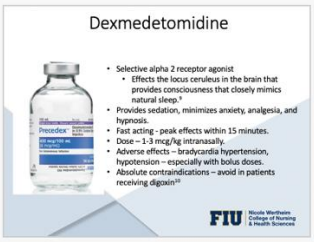
11. **How likely are you to utilize intranasal dexmedetomidine for the pediatric population in your clinical practice?**
    a. Highly likely
    b. Likely
    c. Somewhat likely
    d. Not at all likely

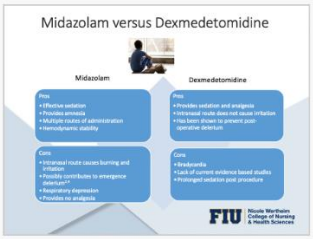
Appendix F. Educational Module

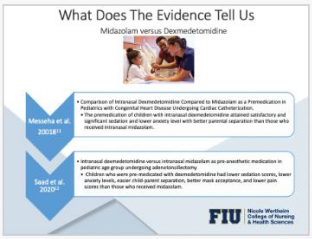


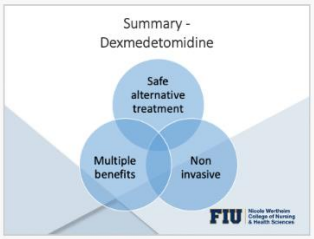












Appendix G. Poster

The Use of Intranasal Dexmedetomidine Compared to Oral Midazolam in the Pediatric Pre-operative Population for Separation Anxiety. An Educational Module

Shilpa Heald BSN, RN, CCRN, Yasmine Campbell DNP, CRNA, APRN
Florida International University Nicole Wertheim College of Nursing and Health Sciences

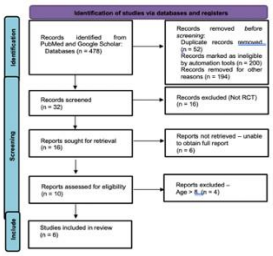
Background

Millions of children undergo surgery and surgical procedures requiring anesthesia every year. Currently, the most commonly used premedication in the pediatric population is midazolam. One of the most significant side effects of midazolam administration is respiratory depression that can lead to hypoxia. When administered intranasally, midazolam can cause significant nasal irritation. Dexmedetomidine (DEX) is an alternative sedative that is being utilized in the pediatric population. DEX has been shown to produce similar if not superior levels of pre-sedation in pediatric patients undergoing a variety of procedures without the respiratory side effects of midazolam. Intranasal DEX is a safe and effective alternative to oral midazolam for the pediatric population.

Purpose

Given the various negative side effects of perioperative anxiety and agitation, clinicians have prioritized methods to recognize and ease these conditions in children. The aim of this review is to compare Midazolam and Dexmedetomide as methods of sedation in the pediatric population.

Methodology



PICO

In the pediatric population (2-8 years old) (P), how does intranasal dexmedetomidine (I) compare to oral midazolam (C) in providing sedation and reducing separation anxiety (O)?

Literature Review

Author(s)	Conclusions
Behrle et al., (2017)	Intranasal DEX is a safe and effective medication to utilize prior to having to obtain intravenous catheters.
Li et al., (2016)	Intranasal DEX administered via atomizer and drops from a syringe are both effective routes of administration. Successful sedation levels can be achieved with both.
Lin et al,, (2016)	Intranasal DEX with either a 1 mcg/kg or 2 mcg/kg dose can reduce the resistance to mask induction and decrease the incidence of post-operative emergence agitation.
Jun et al., (2017)	Intranasal DEX is a safe and effective alternative for premedication in children undergoing surgery.
Cote et al., (2002)	Doses as small as 0.25 kg/mg of oral midazolam can be effective in mitigating pre-procedure anxiety and as a sedative in the pediatric population.
Manso et al., (2019)	Overall, oral midazolam is an effective medication in providing satisfactory sedation levels in the pediatric population. Incidence of adverse effects, including paradoxical reactions and respiratory events were seen in with high doses.

Results

- Intravenous dexmedetomidine is an effective alternative to oral midazolam to combat pre-operative anxiety in the pediatric population.
- Dexmedetomidine has increased success in pre-operative sedation levels including separation anxiety and has been shown to result in decreased post-operative nausea, vomiting, pain and agitation.

References

Available upon request. Email spate109@fiu.edu

Appendix H. Dissemination PowerPoint