Zagazig University Medical Journal
www.zumj.journals.ekb.eg
https://doi.org/10.21608/zumj.2025.348788.3767 Volume 31, Issue 3, March. 2025
Manuscript ID ZUMJ-2412-3767
DOI 10.21608/zumj.2025.348788.3767

ORIGINAL ARTICLE

Intranasal Dexmedetomidine versus Midazolam Using Mucosal Atomization Device for Sedative Premedication in Preschool Children Undergoing Magnetic Resonance Imaging

Enas Ezzat Abdelfattah Hessin[1], Zeinab, Ibrahim Ahmed Alhossary[1], Rania Ahmed Kamel[1], Nahla Mohammed Amin*[1]
[1]Department of Anesthesia, Intensive Care and Pain management, Faculty of Medicine, Zagazig University, Egypt

***Corresponding author:**
Nahla Mohammed Amin

Email:
nahlaamin3@gmail.com

Submit Date 03-01-2025
Revise Date 09-01-2025
Accept Date 13-01-2025

ABSTRACT

Background: While several studies assessed the effects of variant sedative premedication for pediatrics to decrease anxiety and fearing of parental separation, but the conclusions were various. We aimed to compare intranasal dexmedetomidine with midazolam using mucosal atomization device (MAD) for preschool children scheduled for magnetic resonance imaging (MRI) as a sedative premedication

Methods: This prospective randomized controlled double blind trial included 93 children who underwent MRI. They were randomly allocated into 3 groups (31 children in each one), Control group; intranasal 1ml 0.9% normal saline was given, Dexmedetomidine; group 2µg/kg dexmedetomidine was given intranasally and Midazolam group; 0.2 mg/kg midazolam was given intranasally using (MAD) in the three groups. After intra-nasal drug (IND) giving all patients were observed for 30 minutes before MRI and the sedation score 10,20,30 minutes following IND administration (primary outcome), , parental separation anxiety scale, acceptance of venous cannulation and adverse events were assessed.

Results: Regarding sedation score, there was significant difference among the studied groups (lower in dexmedetomidine group) with the difference is significant among each two individual groups 10, 20 and 30 minutes after IND administration (P=0.001). There were statistically significant difference among the studied groups regarding parental separation anxiety scale & acceptance of venous cannulation (better among dexmedetomidine group). The difference was significant between each two individual groups (P=0.001). No adverse events.

Conclusion: Intranasal dexmedetomidine compared to intranasal midazolam given via MAD for sedative premedication for preschool children undergoing MRI, has a better sedation score, an easier parental separation and venous cannulation.

Keywords: Intranasal; α2 agonist; **midazolam; sedative; premedication**; pediatrics

INTRODUCTION

Children need operation and imaging have anxiety, because of being separated from their parents and unusual place. If a child is taken by force from his parents, agitation raise postoperatively, and he may have psychic trauma for a long time. Therefore, sedative pre-medication is important for children before operation or imaging to alleviate the child's fear and irritability, which improves the child's separation from parents, and the imaging or operation can be completed easily. To reach this goal, several sedative

premedication in pediatrics, such as choral hydrate, midazolam, ketamine or dexmedetomidine can be used[1].

The magnetic resonance imaging (MRI) is an accurate diagnostic method, so its use is increased in patients of any age. However, pediatrics requiring MRI usually need sedation because the magnetic field produces a very high pitch sound. Anxiety and fear in pediatrics lead to raised hindrance in obtaining intravenous line, parental separation, and anesthetic induction. Sedative premedication allow overcoming such problems[٢].

Aerosol inhalation through the nasal route can be used for premedication in pediatrics. Aerosolized release of the drug has the advantage of decreasing drug lost in oropharynx, more patient acceptance, greater cerebrospinal fluid concentration, and superior sedation[1].

Dexmedetomidine, is a highly selective α2-adrenoceptor agonist characterized by (anxiolytic, sedative, sympatholytic, analgesic & opioid-sparing) properties [٣].

Intranasal administration in pediatrics does not require patient cooperation and facilitate giving an accurate dose. Mucosal Atomizer Device (MAD) can be utilized to enable aerosol delivery of Dexmedetomidine, that may decrease the burnt feeling and coughing which may happen throughout intranasal giving[٤].

Midazolam is a water-soluble benzodiazepine. It has fast onset of action and short half-life. It is a sedative used to relieve anxiety and it does not provide retrograde amnesia and is superior to long-acting benzodiazepines (e.g. lorazepam and diazepam). Midazolam can be administrated by any route and, intranasal route is the most tolerable and requires a short duration to achieve the maximum action [٥].

While several studies have assessed the effects of varient sedative premedication such as Dexmedetomidine and Midazolam, there isn´t yet a commonly reached drug of preference.

The objectives of this study was to compare intranasal dexmedetomidine and midazolam using MAD for sedative premedication in preschool children scheduled for MRI. The sedation score was the primary outcome. The secondary outcomes included smooth parental separation, easiness of IV cannulation and the incidence of side effects of intranasal dexmedetomidine and midazolam e.g. hemodynamic effects, respiratory depression, nausea and vomiting.

METHODS

Study design:

This prospective randomized controlled double blind clinical trial had been carried out at Anesthesia, Intensive Care and Pain management Department Faculty of Medicine Zagazig University Hospitals after approval of institutional review board (IRB#10885, 25-6-2023).

Duration of the study: from July to December 2023, in accordance with the code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria: Consent of the patient's parents or guardians of the first degree, age: 2-6 years old, scheduled for MRI scan for different diagnostic purposes, both sexes (males &females) belonging to American Society of Anesthesiologist (ASA) class I or II.

Exclusion criteria: History of allergy to any drug utilized in this study, history of psychological or neurological disorders or chronic intake of sedative or analgesics, congenital heart disease, respiratory tract infection, emergency MRI, nasal disease which may interfere with nasal handling of the drugs as severe septum deviation of nose, repeated nose bleeding, anticipated difficult airway, patient who had severe cardiac, respiratory, hepatic or renal dysfunction, or being administered beta blockers or digoxin.

Randomization:

All children were randomly assigned into three equal groups. Patients were randomized utilizing computer generated random table in a 1:1:1 ratio and allocated into Control group, Dexmedetomidine group and Midazolam group. Randomization assignments were put in sealed opaque envelopes. Prior to MRI those envelopes were given to investigator who not participating in the study or conduct of anesthesia. This investigator was responsible for the allocation and drug preparation. The child parents, the data collector, the existing anesthesiologist and the radiologist were all blinded to study group assignment.

Study procedure:

The following management were performed to all children included in the present study:

- All participating patient parents were interviewed prior to the procedure. The study design including procedure, drugs and possible adverse effects were discussed.
- All patients were assessed the day before the procedure by anesthesiologist; written informed

consent was acquired from parents, medical and surgical history was taken and clinical examination was done.

- Instruction was given for fasting before the procedure (6 h for solid meal, 8h for fatty meal and 2h for clear fluids)
- Routine laboratory investigations were performed on outpatient basis.
- Patient characteristics (gender, age, weight, height, BMI and ASA classification of children involved in the study) were recorded.
- On the determined day, the children entered the premedication place in the MRI scan unit.
- The patient had been covered with a blanket to avoid hypothermia, and devices for management of airway were prepared for any possible complications, if it happened.
- Basal reading of oxygen saturation SpO2, basal heart rate (HR), basal systolic blood pressure (SBP), basal diastolic blood pressure (DBP) and basal respiratory rate (RR) were recorded. Also the sedation degree was evaluated by Modified Observer's Assessment of Alertness/Sedation[(6)], (MOAA/S) Scale (a six points scale) **(Suppl.Table1)** [(6)]**.**
- The children were randomly assigned to three groups (31 cases in each group).
- All patients were given intranasal drugs 30 minutes before the procedure, and total volume was 1ml by adding 0.9 % normal saline.

Control Group (group C): patients were given intranasal 1ml 0.9% normal saline.

Dexmedetomidine Group (group D): patients were given intranasal dexmedetomidine (concentration, 100 µg/ml) at dose 2 µg/kg.

Midazolam Group (group M): patients were administered intranasal midazolam (concentration 5mg/ml) at dose 0.2 mg/kg.

The calculated dose of each drug was divided equally between nostrils via intranasal mucosal atomizer device ((MAD) [Nasal TM, Incorporated Teleflex, United states]. The patients were kept supine for 2 minutes to avoid spillage and to confirm drug absorption from the nose.

- After finishing intranasal drug giving all children were kept in the premedication room and observed for 30 minutes before MRI and the following data were recorded:

-The MOAA/S[(6)] score at ten, twenty and thirty minutes after intranasal drug giving.

-Time for onset of sedation (determined as the time from intranasal drug giving until an increase in the sedation degree in comparison to the baseline-1 (decrease in the MOAA/S score from6 to5)

- HR, SBP, DBP, SpO2 and RR (ten, twenty and thirty minutes following intranasal drug giving).

-Adequate sedation (was defined as achieving MOAA/S[(6)] Score of ≤4 that allow smooth parental separation then easy venous cannulation. **Children parental separation** was evaluated utilizing parental separation anxiety scale [(7)] **(Suppl.Table2)** [(7)]**.** (which is a 4point scale). **Accepting venous cannulation** was assessed utilizing 4 points scale [(8)] **(Suppl.Table3)** [(8)]**.** : Then the patients entered the MRI room where O2 mask was applied to all patients and propofol was given with bolus dose 0.5-1 mg/kg intravenously and repeated doses may be required until the child lay motionless to continue the imaging, (total IV propofol consumption during MRI was calculated and recorded). The duration of MRI Scan was recorded.

- After MRI imaging procedure children were admitted to recovery room where vital parameters were noted every 5 minutes for one hour in existence of parents and discharged from it after their modified Aldret score reached>9. In the recovery room. **Recovery quality** was evaluated utilizing the emergence agitation scale[(9)] (three-point scale): **(Suppl. Table 4)** [(9)]**.**

Recovery time (time from stoppage of propofol till modified Aldret score reached>9) was determined &recorded.

- Any side effects were recorded as: congestion of the nose or irritation, respiratory depression (SpO2 <95% or RR lower than16 breaths/min) treated by applying O2 mask, itching (treated by antihistaminic administration), shivering or hypothermia, nausea or vomiting (treated by antiemetic administration).

Sample size:

Assuming the mean sedation score was 3.7±0.8 vs 4.3±1.2 in dexmedetomidine vs midazolam group[(2)]**.** At 80% power and 95% confidence interval. The estimated sample size was 93 cases, 31 cases in any group**.**

Statistical analysis

Data were collected then analyzed utilizing IBM SPSS version25. Number and percentage was used for qualitative data, while the mean ± SD & median (range) were used for quantitative variables.Chi-square test (X2) was utilized for categorical data and one- way ANOVA was utilized for continuous

data. Kruskal-Wallis's test (K-W) was utilized to compare a variable between extra than two groups. *P*-value less than 0.05 was determined statistically significant.

RESULTS

In the present study 93 pediatric patients were included and randomly allocated into 3 equal groups (31 in every group), Control group, Dexmedetomidine group and Midazolam group **(Figure 1).**

Regarding patient's characteristics & clinical data of the studied groups, no statistical differences were found among the three groups (p >0.05). (Table1).

As regard sedation score, no statistically **significant** difference were found among the 3 studied groups at baseline reading. However, there were a statistically **significant** difference among the studied groups (lesser in dexmedetomidine group) with the difference is significant between each two individual groups, following 10, 20 and 30 minutes of intra-nasal drug giving. (Figure2) (p=0.001).

Regarding parent separation anxiety scale & acceptance of venous cannulation, a statistically **significant** difference among the studied groups were found (better among dexmedetomidine group) with the difference is significant among each two individual groups (P=0.001,Table 2).

Regarding heart rate (HR), there were no significant difference among the studied groups at baseline reading, after 10, 20 or 30 minutes of intra-nasal drug administration (figure3). (p=0.865, 0.321, 0.145, 0.052 respectively).

As regard the systolic and the diastolic blood pressure, no statistically significant difference were found among the studied groups; baseline reading, after10, 20 or 30 minutes following intranasal drug giving (p >0.05) (Table 3).

Regarding oxygen saturation, there were no detected statistically significant difference amongst the studied groups, baseline, after 10, 20 or 30 minutes (p >0.05) (Table 4).

As regard respiratory rate at baseline and after 10 minutes after intranasal drug giving, there were no detected statistically significant difference between the studied groups (p= 0.274, 0.128) respectively. However, a statistically **significant** difference were detected between the three studied groups after 20 minutes (lower in Dexmedetomidine group). This difference was significant among Midazolam group and Dexmedetomidine group. (P= 0.014*) Also a s **significant** difference amongst the studied groups was found after 30 minutes (lower in Dexmedetomidine group). The difference was significant among Dexmedetomidine group and the other two groups (P=0.04* and 0.013* respectively) (Table 4).

Regarding sedation onset, it was **significantly** rapid in dexmedetomidine group in contrast to midazolam group (P<0.001) **(Table 5).**

As regard recovery time, dexmedetomidine group had significantly shorter time than the other two groups(P=<0.001) and midazolam group had significantly shorter time than the control group (P=<0.001) **(Table 5).** Regarding total IV propofol consumption, there was a statistically **significant** difference among each two individual groups (P=<0.001**,Table 5). MRI scan duration was comparable between the three groups (P=0.522) (Table 5).

Regarding recovery score, a statistically **significant** difference among the studied groups was detected, as all patients within the control group were combative and disoriented. However 93.5% and 67.7% of patients within Dexmedetomidine and midazolam groups were calm (P=<0.001) (Figure 4)

As regard complication, we did not detect any adverse effects during the sedation procedure in the three studied groups.

Table 1: Modified Observer's Assessment of Alertness/Sedation Scale[6].

Grade	Assessment
6	appears alert and awake, responds readily to name spoken in normal tone.
5	asleep but responds readily to name spoken in normal tone
4	lethargic response to name spoken in normal tone
3	responds only after name is called loudly or repeatedly
2	responds only after mild prodding or shaking
1	does not respond to mild prodding or shaking

Table 2: Parental separation anxiety scale[7].

1.	Easy separation
2.	whimpers, but is easily reassured and not clinging
3.	cries and cannot be easily reassured, but not clinging to parents
4.	crying and clinging to parents

Table 3 Acceptance of venous cannulation[8].

Poor	uncooperative without success
Fair	Uncooperative with success
Good	minor resistance
Excellent	no reaction

Table 4: Emergence agitation scale [9].

1	Calm
2	Restless but calms in response to verbal instructions
3	Combative and disoriented

Table (5): Oxygen saturation and respiratory rate over time among the three studied groups

	Control group (N=31)	**Dexmedetomidine group(N=31)**	**Midazolam group(N=31)**	**F**	**p**
	Mean ± SD	**Mean ± SD**	**Mean ± SD**		
Oxygen Saturation -Baseline	99.84 ± 0.45	99.9 ± 0.4	99.61 ± 0.67	1.611	0.205
-After 10 minutes	99.71 ± 0.53	99.71 ± 0.64	99.58 ± 1.06	0.285	0.753
-After 20 minutes	99.65 ± 0.53	99.71 ± 0.4	109.58 ± 1.06	0.19	0.827
-After 30 minutes	99.83±0.45	99.87±0.42	99.58±1.11	1.42	0.245
Respiratory rate/ Minute - Baseline	19.68 ± 1.62	19.19 ± 2.33	19.97 ± 1.66	1.315	0.274
-After 10 minutes	19.61 ± 1.56	19.03 ± 2.15	19.97 ± 1.74	2.107	0.128
After 20 minutes	19.61 ± 1.59	18.65 ± 1.85	19.9 ± 1.74	4.498	0.014*
Tukey HSD	P_1 0.076	P_2 0.014*	P_3 0.787		
-After 30 minutes	19.68 ± 1.64	18.55 ± 1.93	19.87 ± 1.8	4.91	0.009*
Tukey HSD	P_1 0.04*	P_2 0.013*	P_3 0.906		

.

Data are presented as mean ± standard deviation (SD) and analyzed using F One way ANOVA test, p1 difference among control group & Dexmedetomidine group p2 difference among Midazolam group & Dexmedetomidine group p3 difference among control group & Midazolam group. *p<0.05 is statistically significant.

Table (6): Comparison among studied groups regarding sedation onset time, recovery time, total intravenous propofol consumption and MRI Scan duration

	Control group (N=31)	Dexmedetomidine group(N=31)	Midazolam group(N=31)	T	p
	Mean ± SD	Mean ± SD	Mean ± SD		
Sedation onset (minute)	-	7.0 ± 1.86	19.0 ± 2.88	-19.505	<0.001**
Recovery time (minute)	12.03 ± 2.77	4.03 ± 1.2	7.5 ± 2.3	F 96.259	<0.001**
Tukey HSD	P_1 <0.001**	P_2 <0.001**	P_3 <0.001**		
Total IV propofol(mg/kg)	3.67 ± 0.48	1.87 ± 0.5	3.03 ± 0.66	85.877	<0.001**
Tukey HSD	P_1<0.001**	P_2 <0.001**	P_3 <0.001**		
Scan duration (minutes)	17.13 ± 2.93	17.77 ± 2.92	17.97 ± 3.21	0.655	0.522

Data are presented as mean ± standard deviation (SD) and analyzed utilizing t independent sample t test, F one way ANOVA, MC Monte Carlo. p1 the difference among control group & Dexmedetomidine group p2 the difference among Midazolam group & Dexmedetomidine group p3 the difference among control group & Midazolam group **p≤0.001 is statistically highly significant.

DISCUSION:

Sedation for pediatrics needing radiological imaging processes has progressed more universally. The benefits of administering ideal procedural sedation include decreasing emotional discomfort of parents, decreasing fear of the patient and psychic trauma, and aid procedure's completion [(10)].

In the present study we found that, sedation onset was faster and sedation level was better in Dexmedetomidine group in comparison to midazolam group.

Also parental separation anxiety scale and venous cannulation acceptance were better among dexmedetomidine group.

As regard the onset of sedation and sedation score, a statistically significant difference was found among the two sedated groups, as dexmedetomidine group showed an earlier onset of sedation and better sedation score than midazolam group.

Abdelraheem et al. [(11)]. found the same findings according to the earlier sedation onset in dexmedetomidine group compared to midazolam one, in spite using higher dose of midazolam intranasally (0.3 mg/kg) than ours (0.2 mg/kg) but using the same our intranasal dose of dexmedetomidine (0.2 ug/kg) via the intranasal dripping method in 2-8 years old children scheduled for elective MRI.

On the other hand, **Medhat et al., [(12)]** showed that the **sedation onset** was significantly more rapid in midazolam group (using intranasal midazolam 0.2 mg/kg) than in dexmedetomidine group (using intranasal dexmedetomidine 1 µg/kg) which is a lower dexmedetomidine dose than used in the current study and also using a different method for intranasal administration (nebulization) in two to six years old patients underwent dental surgeries.

As regard **sedation score,** in agreement with us, **Gupta et al.,[(2)]** found that at the moment of venous cannulation the median score was 4 for midazolam group versus 3 for dexmedetomidine group. So sedation score was superior for dexmedetomidine group. Eighty percent of children in dexmedetomidine group fulfilled adequate sedation (MOAA/S score ≤4) in comparison to 53.3% of children in midazolam group (that was significant statistically).

On the other hand, **Thimmahanumaiah et al., [(13)]** found that midazolam group had more **sedation score** at five and ten minutes. The sedation level was assessed in children aged 2-10 years using modified Ramsay sedation scale. But their study used atomized midazolam intranasally (0.3mg/kg) in midazolam group and dexmedetomidine group received dexmedetomidine (1mcg/kg) intranasally utilizing syringe (graduated) and sprayed in nostrils,

that may give inaccurate results especially after the believed results of some researches that intranasal atomization caused superior dispersion of the drug through mucosa in contrast to nasal drops [14].

As regard **parental separation and venous cannulation**, dexmedetomidine group showed easier child parental separation and venous cannulation than midazolam group. **Mehta et al.,** [14] **Saad et al.,** [15] **and Xie et al.,** [16] agreed with these findings as all reported intranasal dexmedetomidine is more efficient than intranasal midazolam for smooth parental separation, successful mask acceptance and venous cannulation.

Unlikely, **Arora et al**[17]**.** reported that the two alpha-2-agonists, clonidine and dexmedetomidine didn't provide satisfied parental separation or mask induction in contrast to midazolam. But this study used oral administration for these premedicants.

Regarding vital signs (HR, SBP, DBP, and O2 saturation) we found no difference among groups, but respiratory rate showed no significant difference after 10 minutes readings but there was statistically **significant** difference at 20 and 30minutes readings among the studied groups with lowest respiratory rate in the dexmedetomidine group.

Panda et al., [18] were in agreement with our results, as they observed that, oxygen saturation did not have statistical difference among their groups. None of their patients had a difference in the features of nasal mucosa following intranasal dexmedetomidine or midazolam administration. None of their studied patients need oxygen or airway manipulation.

On the other hand, **Medhat et al.,** [12] showed that the RR was comparable at baseline reading in groups midazolam and dexmedetomidine and immediately after nebulization. RR decreased at 10, 20, and 30 min from the baseline. At 20 min midazolam group had a statistically significant decrease in RR in contrast to dexmedetomidine group.

We also found significant difference among the three groups regarding recovery time and recovery score. Dexmedetomidine group had the shortest **recovery time** and the best **recovery score**. The prolonged recovery time of controlled group, which was non-sedated at all, may be explained by the need of higher intravenous dose of propofol and that was logic in patient didn't receive any sedative as a premedication.

In agreement with us, **Vázquez-Reta et al.** [19]**.** found that recovery times was shorter with dexmedetomidine in contrast to midazolam in upper gastrointestinal endoscopy. They utilized (1μg/kg) loading dose infusion during twenty min, then (0.2 μg/kg/h) maintenance infusion of dexmedetomidine. Also, **Jannu et al.,** [20] found that 4 μg/kg dexmedetomidine administered orally had superior **recovery profile** in contrast to 0.75 mg/kg oral midazolam as sedative premedicant in pediatric anesthesia, when administered forty min before mask induction in pediatric aged one to seven years scheduled for elective, inferior abdominal operation underneath general anesthesia.

.

Sheta et al.,[21] demonstrated that the duration required to achieve modified Aldrete scale 9 were comparable among the midazolam and dexmedetomidine groups.

Unlikely, **Zeyneloğlu et al.,** [22] found that dexmedetomidine loading dose (1 μg/kg) after that (0.2 μg/ kg/h) was associated with significantly longer **recovery times** than a midazolam (0.05 mg/ kg) combined with fentanyl (1 μg/ kg) in shock wave lithotripsy. This may be explained by dissimilar dose and route of administration compared to our study.

In this study, Dexmedetomidine group had significantly less total IV propofol consumption when compared to the other groups. Our results were compatible with **Muniyappa et al.** [23]**.** who found that dexmedetomidine significantly reduced isoflurane use in surgical patients anesthetized by general anesthesia.

Also, **Menshawi & Fahim**[24]**.,** demonstrated that in pediatric cardiac catheterization, the dexmedetomidine-ketamine combination resulted in lower ketamine consumption and shorter recovery time compared to midazolam-ketamine. These findings suggest that dexmedetomidine is a superior choice to midazolam in various anesthetic settings, offering improved anesthesia consumption profiles and patient outcomes.

Regarding **complications** we did not find any side effects such as bradycardia, hypotension, hypertension. But regarding respiratory rate, we found **significant** difference among the studied groups following 20 and 30 minutes after intra-nasal drug giving. However, it was not clinically significant and did not need any medical management.

Gupta et al,. [2]**.** in agreement with us, found that none of the pediatrics in Midazolam group and

Dexmedetomidine group had untoward complications after premedication.

Unlikely, **Plambech and Afshari,.** [25] found that hypotension and bradycardia are the commonest complications observed with dexmedetomidine and respiration is affected to a little extent. However, these changes were not significant clinically and did not need any management.

The limitations of this study included our inclusion of children ASA I and II only and exclusion of children with comorbidities. Also lack of assessment of the used medication economics feasibility and long term behavioral changes of the studied children.

Conclusion

Intranasal dexmedetomidine when compared to intranasal midazolam administered via a MAD for sedative premedication for preschool children undergoing MRI, has a rapid sedation onset, better sedation score, an easier parental separation, easier venous cannulation, shorter recovery time, better recovery quality score and less total anesthesia consumption.

No Conflict of interest.

REFERENCES

1- Lin J., Wu, C., Zhao, D., Du, X., Zhang, W., & Fang, J. (2022). The sedative effects of inhaled nebulized dexmedetomidine on children: A systematic review and meta-analysis. Frontiers in Pediatrics, 10: 865107

2- Gupta A., Dalvi, N. P., & Tendolkar, B. A. (2017). Comparison between intranasal dexmedetomidine and intranasal midazolam as premedication for brain magnetic resonance imaging in pediatric patients: A prospective randomized double-blind trial. Journal of Anaesthesiology Clinical Pharmacology, 33(2), 236-40.

3 –Liu X., Li, Y., Kang, L., & Wang, Q. (2021). Recent advances in the clinical value and potential of dexmedetomidine. Journal of Inflammation Research, 7507-27

4-Lee Y., Kim, J., Kim, S., & Kim, J. (2016). Intranasal administration of dexmedetomidine (DEX) as a premedication for pediatric patients undergoing general anesthesia for dental treatment. Journal of dental anesthesia and pain medicine, 16(1), 25-29.

5-Khurmi N., Patel, P., Kraus, M., & Trentman, T. (2017). Pharmacologic considerations for pediatric sedation and anesthesia outside the operating room: a review for anesthesia and non-anesthesia providers. Pediatric Drugs, 19, 435-46.

6-Chernik D A., Gillings D, Laine H, Hendler J, Silver JM, Davidson A B, et al.(1990). Validity and reliability of the observer's: assessment of alertness/sedation scale: study with: intravenous midazolam. Journal of clinical psychopharmacology, 10(4), 244-51.

7-Wilton N C., Leig J, Rosen DR & Pandit UA. (1988). Pre-anesthetic sedation of preschool children using intranasal midazolam. Anesthesiology, 69:972-75.

8-McCormick ASM, Thomas VL, Berry D & Thomas PW. (2008). Plasma concentrations and sedation scores after nebulized and intranasal midazolam in healthy volunteers. Br J Aaesth, 100:631–36.

9-Bajwa S A., Costi D & Cyna AM. (2010). A comparison of emergence delirium scales following general anesthesia in children. Paediatr Anaesth, 20:704-11.

10- Wabelo O. N., Schmartz, D., Giancursio, M., De Pooter, F., Caruso, G., Fils, J. F, et al. (2023). Prospective, randomized, double-blind, double-dummy, active-controlled, phase 3 clinical trial comparing the safety and efficacy of intranasal dexmedetomidine to oral midazolam as premedication for propofol sedation in pediatric patients undergoing magnetic resonance imaging: the MIDEX MRI trial. *Trials*, *24*(1), 518.

11- Abdelraheem T. M., Hendawy, H. A., & Elkeblawy, A. M. (2023). Intranasal dexmedetomidine versus intranasal midazolam as sole sedative agents for pelviabdominal magnetic resonance imaging in pediatrics: A randomized double-blind trial. *Bali Journal of Anesthesiology*, *7*(2), 99-104.

12-Medhat M. M., & Abd Elnaby, S. M. (2022). Comparison of nebulized fentanyl, midazolam, and dexmedetomidine as a sedative premedication in outpatient pediatric dental surgeries: a randomized double-blind study. Research and Opinion in Anesthesia & Intensive Care, 9(1), 19-28.

13-Thimmahanumaiah B., Prabhu, P. J., & Datti, S. N. (2021). To Compare the Effects of Atomized Intranasal Midazolam with Intranasal Dexmedetomidine as Premedication in Children. Indian Journal of Anaesthesia and Analgesia Volume 8(1):15 – 19.

14-Mehta P., Sundaram, S. S., Furuta, G. T., Pan,

Z., Atkins, D., & Markowitz, S. (2017). Propofol use in pediatric patients with food allergy and eosinophilic esophagitis. Journal of pediatric gastroenterology and nutrition, 64(4), 546-49.

15- Saad B. B., Tharwat, A. I., Ghobrial, H. N., & Elfawal, S. M. (2020). Intranasal dexmedetomidine versus intranasal midazolam as pre-anesthetic medication in pediatric age group undergoing adenotonsillectomy. *Ain-Shams journal of anesthesiology*, *12*(1).

16- Xie Z., Shen, W., Lin, J., Xiao, L., Liao, M., & Gan, X. (2017). Sedation effects of intranasal dexmedetomidine delivered as sprays versus drops on pediatric response to venous cannulation. *The American Journal of Emergency Medicine*, *35*(8), 1126-30.

17-Arora S., Saini, K., & Bhardwaj, N. (2019). A comparative evaluation of midazolam, clonidine and dexmedetomidine as oral premedicants in children: A double blind randomized clinical trial. Anaesthesia, Pain & Intensive Care, 355-60.

18- Panda S., Pujara, J., Chauhan, A., Varma, A., Pandya, H., & Patel, S. (2021). Comparative study of intranasal dexmedetomidine v/s midazolam for sedation of pediatric patients during transthoracic echocardiography. *Annals of Cardiac Anaesthesia*, *24*(2), 224-29.

19- Vázquez-Reta J. A., Ferrer, J., Colunga-Sánchez, A., Pizarro-Chávez, S., Vázquez-Guerrero, A. L., & Vázquez-Guerrero, A. R. (2011). Midazolam versus dexmedetomidine for sedation for upper gastrointestinal endoscopy. *Revista de gastroenterologia de Mexico*, *76*(1), 13-18.

20-Jannu V., Mane, R. S., Dhorigol, M. G., & Sanikop, C. S. (2016). A comparison of oral midazolam and oral dexmedetomidine as premedication in pediatric anesthesia. Saudi Journal of Anaesthesia, 10(4), 390-94.

21-Sheta S. A., Al-Sarheed, M. A., & Abdelhalim, A. A. (2014). Intranasal dexmedetomidine vs midazolam for premedication in children undergoing complete dental rehabilitation: a double-blinded randomized controlled trial. Pediatric Anesthesia, 24(2), 181-89.

22- Zeyneloglu P., Pirat, A., Candan, S., Kuyumcu, S., Tekin, I., & Arslan, G. (2008). Dexmedetomidine causes prolonged recovery when compared with midazolam/fentanyl combination in outpatient shock wave lithotripsy. *European journal of anaesthesiology*, *25*(12), 961-67.

23- Muniyappa R. B., Rajappa, G. C., Govindswamy, S., & Thamanna, P. P. (2016). Effect of dexmedetomidine bolus dose on isoflurane consumption in surgical patients under general anesthesia. *Anesthesia Essays and Researches*, *10*(3), 649-54.

24- Menshawi M. A., & Fahim, H. M. (2019). Midazolam–ketamine versus dexmedetomidine–ketamine combinations for anesthesia of pediatric patients undergoing cardiac catheterization. Ain-Shams Journal of Anesthesiology, 11(1).

25- Plambech M. Z., & Afshari, A. (2014). Dexmedetomidine in the pediatric population: a review. Minerva Anestesiologica, 81(3), 320-32.

Citation

Abdelfattah, E., Elhossary, Z., Kamel, R., Amin, N. Intranasal Dexmedetomidine versus Midazolam Using Mucosal Atomization Device for Sedative Premedication in Preschool Children Undergoing Magnetic Resonance Imaging. *Zagazig University Medical Journal*, 2025; (1056-1066): -. doi: 10.21608/zumj.2025.348788.3767

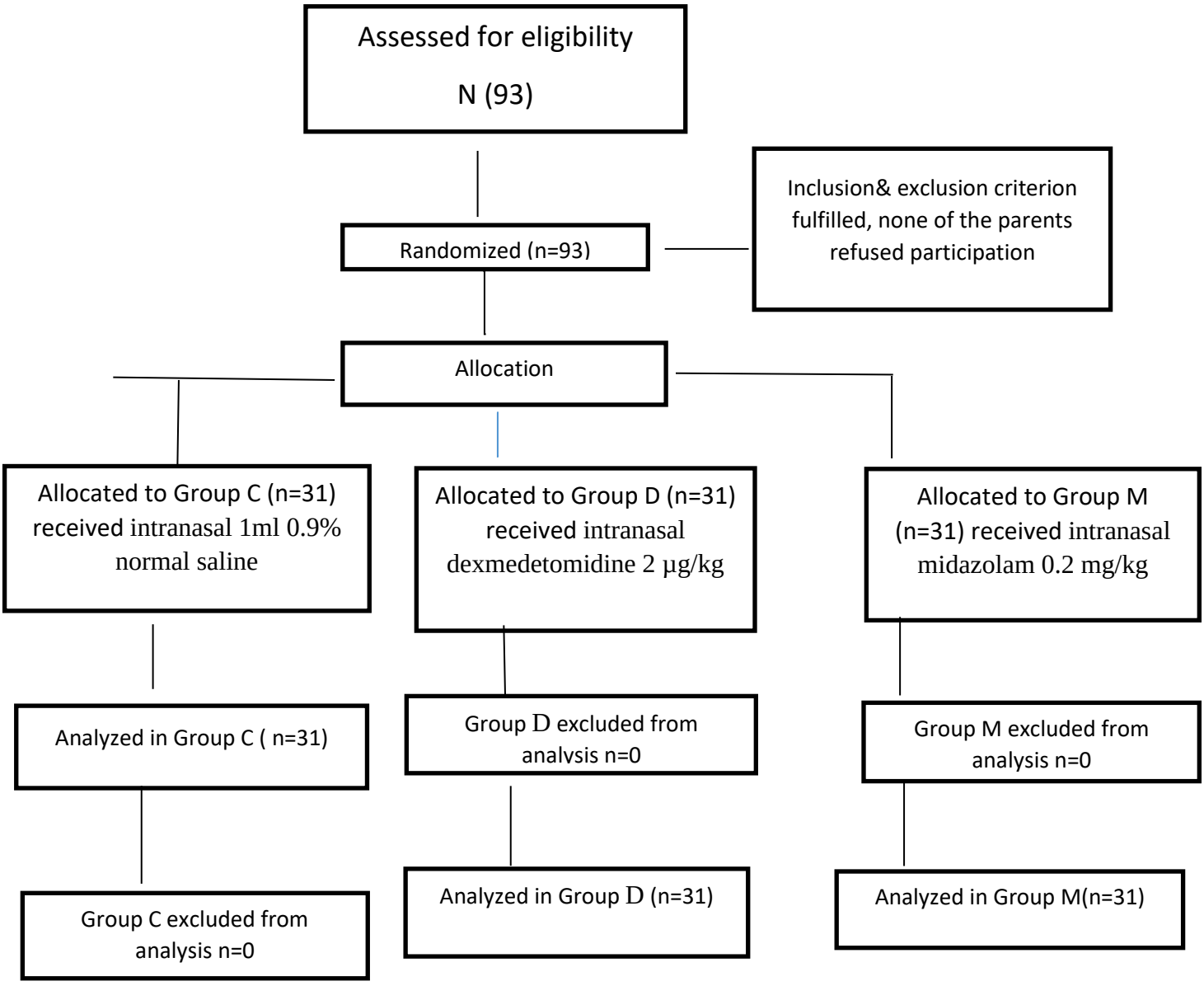

Figure 1: Patients flowchart diagram

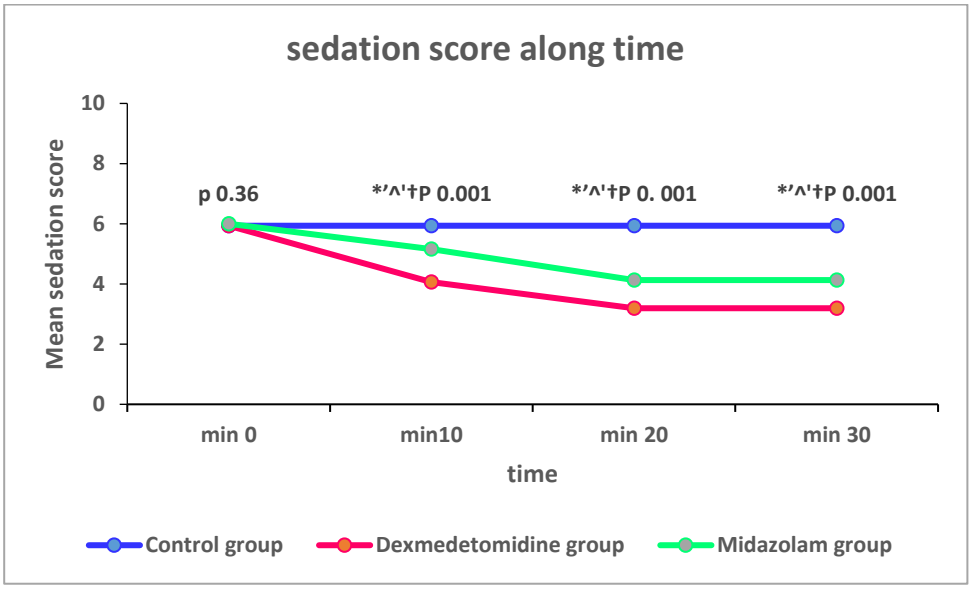

Figure (2): The mean sedation score over time compared among the studied groups (*significant control group &dexmedetomidine group), (^significant control group &Midazlam group), (†significant dexmedetomidine group & Midazlam group)