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Comparative study between intranasal dexmedetomidine and intranasal ketamine as a premedication for anxiolysis and sedation before pediatric general anesthesia

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Abstract

Background: This study compared dexmedetomidine versus ketamine as regard sedation and anxiolysis produced by giving them through intranasal route to pediatric patients undergoing adenotonsillectomy. This study was double-blinded randomized comparative prospective interventional clinical study done in Ain Shams University Hospital (El Demerdash Hospital) on 76 pediatric patients who underwent adenotonsillectomy, and they were randomly allocated equally into two main groups; group D received 2 μg/kg intranasal dexmedetomidine and group K received 5 μg/Kg intranasal ketamine 30 min before the operation, and the aim of this study was to compare the efficacy of intranasal dexmedetomidine versus intranasal ketamine for anxiolysis and sedation to alleviate stress, agitation, and anxiety in children before general anesthesia and for promoting good level of sedation for them.

Results: Results of this study as regards sedation level that was assessed by modified Ramsay sedation score showed that there was statistically significant difference between both groups at 10, 20, and 30 min from intranasal application of the drug (P value < 0.05), the median (IQR) of sedation score at 10, 20, and 30 min preoperative in group D was (2 (2 – 2)), (3 (3 – 4)), (4 (4 – 5)) compared to (2 (2 – 3)), (3 (2 – 3)), (4 (3 – 4)) in group K respectively which revealed that there was better and effective sedation in group D more than in group K, this difference was statistically significant but clinically insignificant as both drugs produced an acceptable level of sedation and decreased the level of anxiety in children.

Conclusion: Both drugs produce effective and favorable sedation level with superiority to dexmedetomidine in sedation scores and time of onset of sedation, and also there was little decrease in heart rate and mean arterial pressure which is favorable during such surgeries; also, there was accepted level of cannulation and parental separation scores, and the parents were highly satisfied with the procedure and were grateful for us due to alleviating stress and anxiety from them and from their children.

Keywords: Intranasal dexmedetomidine, Intranasal ketamine, Anxiolysis, Pediatric anesthesia

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Background

Premedication in children is helpful for both separating the child from their parent and reducing the child's stress and anxiety, thus facilitating smooth induction of anesthesia. Furthermore, the drugs given for this purpose should have little effect on hemodynamics and respiration so as to allow the child to recover quickly and to facilitate early discharge without side effects (Jun et al. 2017).

Anxiety of the pediatric patient can add to the challenging nature of procedures performed before induction of general anesthesia. Pharmacologic and non-pharmacologic means of distraction and anxiolysis are commonly used to optimize the patient and family experience as well as to allow for the successful procedure completion. Intranasal medication delivery has been described as safe and effective and provides high patient and provider satisfaction (Neville et al., 2016).

Many drugs can be taken by the intranasal route such as glucocorticoids, nasal decongestants, naloxone, midazolam, ketamine, and dexmedetomidine. The administration of intranasal dexmedetomidine or intranasal ketamine avoids the need for intravenous cannulation and is not associated with an unpleasant sensation in the nasopharynx. It requires little cooperation and is not associated with distressing side effects (Li et al., 2019).

Dexmedetomidine is a selective alpha 2 agonist similar to clonidine, but with higher affinity to the alpha 2 receptor. Dexmedetomidine produces dose-dependent sedation, anxiolysis, and analgesia without respiratory depression. Dexmedetomidine triggers and maintains natural sleeping status without eye movement by stimulating the locus coeruleus in the brain stem, so it increases the activity of inhibitory gamma aminobutyric acid (GABA) neurons in the ventrolateral preoptic nucleus (Liu et al., 2019).

Ketamine is proved to interact with many receptors, including the N-methyl-D-aspartate receptor (NMDA-R) producing a dissociative anesthesia. Ketamine is known to reduce central sensitization to pain, decrease overall opioid utilization, and produce effective sedation level (Reynolds et al., 2017).

Aim of the study

The aim of this study is to compare the efficacy of intranasal dexmedetomidine versus intranasal ketamine for anxiolysis to alleviate stress, agitation, and anxiety in children before general anesthesia and for promoting sedation for them.

Another aim from this study is to prove the adequacy and effectiveness of another safe, effective, easy, and rapid route of administration of drugs and to make the perioperative period non-stressful and uneventful for the pediatric population.

Methods

The study was double-blinded randomized comparative prospective interventional clinical study and was performed at Ain Shams University Hospitals from April 2019 to March 2020. After departmental ethical committee approval and an informed written consent had been taken from the guardians of the pediatric patients, 76 healthy pediatric patients aged between 3 and 6 years of age boys and girls, American Society of Anesthesiology (ASA) physical status I and II undergone elective adenotonsillectomy under general anesthesia. Patients were blindly randomized using their medical record number into two equal groups and subjected to a comparative study. In group D, 38 patients received 2 μg/kg of body weight dexmedetomidine by intranasal route (Lewis & Bailey, 2020); in group K, 38 patients received 5 mg/kg of body weight ketamine by intranasal route (Suvvari et al., 2020) 30 min before operation. The study was completed in duration of 1 year.

Exclusion criteria were refusal of participation in the study by guardians of the patients, Physical status: ASA III or above, children with history of allergy to dexmedetomidine and ketamine, presence of morbidity (cardiovascular, neurological, respiratory, hepatic, and/ or renal problems), children with any abnormal vital signs especially hypotension and/or bradycardia, children having an illness with significant nasal congestion or deviated nasal septum, mentally retarded children, operations with increased duration due to different causes lasting more than 30 min, operations with increased blood loss and operations started with difficult intubation and multiple manipulations of the airway, and finally, difficult cannulation (three trials of cannulation or more) excluded from the study.

In the OR, children were maintained by full monitoring with non-invasive blood pressure, pulse oximetry, ECG, and capnography. Induction of anesthesia with inhalational induction using sevoflurane and fentanyl 1 μg/kg was given, atracurium 0.5 mg/kg was given; then, intubation was done with a tube appropriate size to the child age, tube fixed to the middle of the chin; capnography was recording then anesthesia maintained with

Table 1 Modified Ramsay sedation scores (RSS) (Rasheed et al., 2019)

Level 1	Patient awake, anxious and agitated or restless, or both
Level 2	Patient awake, cooperative, oriented, and tranquil
Level 3	Patient awake, responds to commands only
Level 4	Patient asleep, brisk response to light glabellar tap or loud auditory stimulus
Level 5	Patient asleep, sluggish response to light glabellar tap or loud auditory stimulus
Level 6	Patient asleep, no response to light glabellar tap or loud auditory stimulus

Table 2 Groningen distress rating scale (GDRS) (Chau et al., 2019)

1	Calm
2	Mild distress
3	Serious distress, in control
4	Severe distress, out of control
5	Panic

sevoflurane 2% and oxygen 100% till the end of procedure, and they were on volume-controlled mechanical ventilation.

Measurements

a) Assessment of the vital signs mean blood pressure, heart rate, respiratory rate, and oxygen saturation preoperative baseline before application of the intranasal drug (0 min), 10 min preoperative after giving the intranasal drug, 20 min preoperative after giving the intranasal drug, at time of induction 30 min after giving the intranasal drug, intraoperative baseline before induction of anesthesia (0 min), 10 min intraoperative after induction of anesthesia, 20 min intraoperative after induction of anesthesia, 30 min intraoperative after induction of anesthesia and postoperative baseline in recovery (0 min), 10 min postoperative in the recovery, 20 min postoperative in the recovery, and 30 min postoperative in the recovery.
b) Assessment of the sedation level done by modified Ramsay sedation scores (MRSS) was (Table 1) as follows:

Modified Ramsay sedation scores (MRSS) recoded at different time intervals: preoperative baseline, 10 min, 20 min, at time of induction and postoperative 0 min, 10 min, 20 min, and 30 min.

c) Assessment of the response to intravenous cannulation done by the Groningen distress rating scale (GDRS) (Table 2) by an independent observer unaware of the premedication administered:
d) Assessment of the response of the child to parental separation using parental separation score (Table 3):
e) Assessment of parents' satisfaction score (Table 4) with as follows:

Table 3 Parental separation score (Mostafa & Morsy, 2013)

1	Patient unafraid, cooperative and asleep.
2	Slight fear or crying quite when reassurance.
3	Moderate fear, crying not quite with reassurance.
4	Crying need for restraint.

Table 4 Parent satisfaction score (Neville et al., 2016)

1	Very unsatisfied
2	Unsatisfied
3	Neutral
4	Satisfied
5	Very satisfied

f) All children observed postoperative till discharge criteria was met and monitored for presence of sedation, nausea/vomiting, and/or any other complications.
g) Vomiting was assessed by number of vomiting episodes.

Statistical package and analysis

Using PASS program, setting alpha error at 5% and power at 80% results from previous study (Gyanesh et al., 2014), showed that the parents satisfaction in dexmedetomidine was 97.3% compared to 92.4% in ketamine group, considering non inferiority study between the two drugs with 10% accepted difference between the two groups. The needed sample is 38 cases per group.

Sample size

Thirty eight patients in each group (total 76 patients)

Group D (intranasal dexmedetomidine): 38 patients will receive 2 μg/kg intranasal dexmedetomidine with concentration 100 μg/ml 30 min before the procedure.

Group K (intranasal ketamine): 38 patients will receive 5 mg/kg intranasal ketamine with concentration 50 mg/ml 30 min before the procedure.

The collected data will be revised, coded, and introduced to a PC using Statistical Package for Social Science (SPSS 15.0.1. for windows; SPSS Inc, Chicago, IL, 2001).

Data will be presented as mean and standard deviation (± SD) for quantitative prometric data. Suitable analysis will be done according to the type of data obtained.

$P < 0.05$ will be considered significant.

Table 5 Comparison between group D and group K as regards demographic data

		Group D No. = 38	Group K No. = 38	*P* value	Sig.
Gender	Female	13 (34.2%)	12 (31.6%)	0.807	NS
	Male	25 (65.8%)	26 (68.4%)		
Age (years)	Mean ± SD	4.45 ± 1.11	4.34 ± 1.12	0.682	NS
Weight (kg)	Mean ± SD	16.92 ± 2.38	16.71 ± 2.37	0.700	NS
ASA	I	35 (92.10%)	34 (89.50%)	0.692	NS
	II	3 (7.90%)	4 (10.50%)		

P value > 0.05, non-significant

Table 6 Comparison between group D and group K as regards heart rate (HR)

HR		Group D No. = 38	Group K No. = 38	*P* value	Sig.
Preoperative baseline before giving the intranasal drug (0 min)	Mean ± SD	105.34 ± 6.57	107.55 ± 5.39	0.113	NS
Preoperative 10 min after giving the intranasal drug	Mean ± SD	105.29 ± 6.02	108.45 ± 5.47	0.019	S
Preoperative 20 min after giving the intranasal drug	Mean ± SD	102.32 ± 6.10	105.76 ± 5.53	0.012	S
Preoperative 30 min after giving the intranasal drug	Mean ± SD	97.79 ± 3.54	104.92 ± 4.98	0.000	HS
Intraoperative before induction of GA (0 min)	Mean ± SD	97.79 ± 3.54	104.92 ± 4.98	0.000	HS
Intraoperative 10 min after induction of GA	Mean ± SD	97.66 ± 6.65	99.97 ± 5.83	0.111	NS
Intraoperative 20 min after induction of GA	Mean ± SD	96.58 ± 6.26	98.95 ± 5.54	0.085	NS
Intraoperative 30 min after induction of GA	Mean ± SD	98.24 ± 6.31	99.50 ± 5.27	0.347	NS
Postoperative in recovery (0 min)	Mean ± SD	99.66 ± 5.82	102.95 ± 5.38	0.013	S
Postoperative 10 min after recovery	Mean ± SD	98.32 ± 6.83	101.97 ± 5.23	0.011	S
Postoperative 20 min after recovery	Mean ± SD	97.16 ± 6.75	100.76 ± 5.72	0.014	S
Postoperative 30 min after recovery	Mean ± SD	96.18 ± 6.49	99.66 ± 5.80	0.016	S

P value > 0.05, non-significant; *P* value < 0.05, significant; *P* value < 0.01, highly significant

Results

Demographic data

Statistical analysis for the demographic data for two groups revealed that there was no statistically significant difference between the two groups (*P* value > 0.05) (Table 5)

Vital signs

Heart rate

When comparing heart rate changes after intranasal application of the drug, we observed that at the baseline before giving the drug there was no statistically significant difference (*P* value > 0.05) between the two groups. At 10 and 20 min after giving the drug, there was statistically significant difference between the two groups (*P* value < 0.05), and also at 30 min, the difference between two groups became statistically highly significant (*P* value < 0.01) as here we observed gradual decrease in heart rate in group D and little increase in heart rate or stationary heart rate in group K. Intraoperatively, the changes was statistically insignificant. Postoperatively, the difference was statistically significant (*P* value < 0.05) (Table 6).

Mean arterial pressure

On behave of mean arterial pressure (MAP) in our study, we observed that the results was statistically insignificant at baseline before giving the drug (*P* value > 0.05); at 10, 20, and 30 min, the results between two groups was statistically significant (*P* value < 0.05) with mean arterial pressure (MAP) lower in group D than that in group K.

Table 7 Comparison between group D and group K as regards mean arterial pressure (MAP)

MAP		Group D No. = 38	Group K No. = 38	*P* value	Sig.
Preoperative baseline before giving the intranasal drug (0 min)	Mean ± SD	68.00 ± 4.64	67.89 ± 4.25	0.918	NS
Preoperative 10 min after giving the intranasal drug	Mean ± SD	66.32 ± 4.70	68.63 ± 3.48	0.017	S
Preoperative 20 min after giving the intranasal drug	Mean ± SD	65.84 ± 4.62	68.24 ± 3.23	0.011	S
Preoperative 30 min after giving the intranasal drug	Mean ± SD	65.08 ± 4.29	67.18 ± 3.92	0.028	S
Intraoperative before induction of GA (0 min)	Mean ± SD	65.08 ± 4.29	67.18 ± 3.92	0.028	S
Intraoperative 10 min after induction of GA	Mean ± SD	63.58 ± 4.33	65.24 ± 3.90	0.085	NS
Intraoperative 20 min after induction of GA	Mean ± SD	62.89 ± 4.29	64.61 ± 3.72	0.067	NS
Intraoperative 30 min after induction of GA	Mean ± SD	63.68 ± 3.93	65.03 ± 3.68	0.128	NS
Postoperative in recovery (0 min)	Mean ± SD	64.50 ± 3.95	65.47 ± 3.78	0.276	NS
Postoperative 10 min after recovery	Mean ± SD	64.87 ± 4.01	65.68 ± 3.65	0.357	NS
Postoperative 20 min after recovery	Mean ± SD	65.63 ± 4.05	66.13 ± 3.84	0.582	NS
Postoperative 30 min after recovery	Mean ± SD	66.05 ± 4.18	66.32 ± 3.76	0.774	NS

P value > 0.05, non-significant; *P* value < 0.05, significant

Table 8 Comparison between group D and group K as regards respiratory rate (RR)

RR		Group D No. = 38	Group K No. = 38	*P* value	Sig.
Preoperative baseline before giving the intranasal drug (0 min)	Mean ± SD	22.16 ± 1.24	21.66 ± 1.58	0.130	NS
Preoperative 10 min after giving the intranasal drug	Mean ± SD	21.03 ± 1.62	21.71 ± 1.25	0.043	S
Preoperative 20 min after giving the intranasal drug	Mean ± SD	20.32 ± 1.51	21.13 ± 1.23	0.012	S
Preoperative 30 min after giving the intranasal drug	Mean ± SD	19.87 ± 1.38	20.55 ± 1.20	0.024	S
Intraoperative before induction of GA (0 min)	Mean ± SD	19.87 ± 1.38	20.55 ± 1.20	0.024	S
Intraoperative 10 min after induction of GA	Mean ± SD	20.63 ± 1.68	20.74 ± 1.64	0.783	NS
Intraoperative 20 min after induction of GA	Mean ± SD	20.63 ± 1.68	20.74 ± 1.64	0.783	NS
Intraoperative 30 min after induction of GA	Mean ± SD	20.63 ± 1.68	20.74 ± 1.64	0.783	NS
Postoperative in recovery (0 min)	Mean ± SD	20.55 ± 1.61	21.24 ± 1.82	0.087	NS
Postoperative 10 min after recovery	Mean ± SD	20.74 ± 1.52	20.89 ± 1.54	0.654	NS
Postoperative 20 min after recovery	Mean ± SD	20.26 ± 1.45	20.21 ± 1.38	0.871	NS
Postoperative 30 min after recovery	Mean ± SD	20.11 ± 1.67	20.03 ± 1.52	0.830	NS

P value > 0.05, non-significant; *P* value < 0.05, significant

The results revealed that the difference intraoperatively and postoperatively was statistically insignificant (*P* value > 0.05), with generally lower values of mean arterial pressure (MAP) in group D compared to group K (Table 7).

Respiratory rate (RR)

Results of study including respiratory rate revealed statistically insignificant results at baseline (*P* value > 0.05); at 10, 20, and 30 min from giving the drug, there was statistically significant difference (*P* value < 0.05).

The results showed little decrease in respiratory rate in both groups with more decrease in group D making the difference statistically significant and clinically insignificant.

The results also showed no statistically significant difference between both groups intraoperatively as respiratory rate was set by the anesthesiologist and patient on mechanical ventilation on fixed preset respiratory rate.

Also postoperatively, the results were statistically insignificant between both groups (Table 8).

Arterial oxygen saturation

Results of the study revealed that there was no statistically significant difference between both groups as regards oxygen saturation (*P* value > 0.05) through all the stages of evaluating the drug preoperative after intranasal application of drug, intraoperative, and postoperative in recovery.

Table 9 Comparison between group D and group K as regards arterial oxygen saturation

SO_2		Group D No. = 38	Group K No. = 38	*P* value	Sig.
Preoperative baseline before giving the intranasal drug (0 min)	Mean ± SD	99.26 ± 0.92	99.11 ± 0.92	0.458	NS
Preoperative 10 min after giving the intranasal drug	Mean ± SD	98.95 ± 0.93	98.89 ± 0.86	0.799	NS
Preoperative 20 min after giving the intranasal drug	Mean ± SD	98.24 ± 0.94	98.13 ± 0.93	0.626	NS
Preoperative 30 min after giving the intranasal drug	Mean ± SD	97.68 ± 1.19	97.84 ± 0.82	0.503	NS
Intraoperative before induction of GA (0 min)	Mean ± SD	97.68 ± 1.19	97.84 ± 0.82	0.503	NS
Intraoperative 10 min after induction of GA	Mean ± SD	99.16 ± 0.82	99.21 ± 0.62	0.754	NS
Intraoperative 20 min after induction of GA	Mean ± SD	99.29 ± 0.61	99.26 ± 0.55	0.845	NS
Intraoperative 30 min after induction of GA	Mean ± SD	98.97 ± 0.75	98.82 ± 0.80	0.379	NS
Postoperative in recovery (0 min)	Mean ± SD	98.37 ± 0.82	98.00 ± 0.90	0.066	NS
Postoperative 10 min after recovery	Mean ± SD	97.74 ± 0.89	97.95 ± 0.96	0.324	NS
Postoperative 20 min after recovery	Mean ± SD	97.61 ± 1.05	97.74 ± 1.03	0.584	NS
Postoperative 30 min after recovery	Mean ± SD	97.79 ± 0.99	98.05 ± 0.90	0.229	NS

P value > 0.05, non-significant

Table 10 Comparison between group D and group K as regards modified Ramsay sedation score

Sedation score		Group D No. = 38	Group K No. = 38	Test value	*P* value	Sig.
Preoperative baseline before giving the intranasal drug (0 min)	Median (IQR)	1 (1–2)	1 (1–2)	− 0.480	0.631	NS
Preoperative 10 min after giving the intranasal drug	Median (IQR)	2 (2–2)	2 (2–3)	− 2.071	0.038	S
Preoperative 20 min after giving the intranasal drug	Median (IQR)	3 (3–4)	3 (2–3)	− 2.383	0.017	S
Preoperative 30 min after giving the intranasal drug	Median (IQR)	4 (4–5)	4 (3–4)	− 2.520	0.012	S
Postoperative in recovery (0 minute)	Median (IQR)	4 (4–4)	4 (4–5)	− 1.509	0.131	NS
Postoperative 10 min after recovery	Median (IQR)	3 (3–4)	3 (3–4)	− 0.127	0.899	NS
Postoperative 20 min after recovery	Median (IQR)	3 (2–3)	3 (2–3)	− 0.472	0.637	NS
Postoperative 30 min after recovery	Median (IQR)	2 (2–2)	2 (2–2)	− 0.013	0.990	NS

P value > 0.05, non-significant; *P* value < 0.05, significant

The least saturation recorded in group D was 95% and 96% in group K which there was no needed intervention in both groups (Table 9).

Modified Ramsay sedation score

Results of this study as regards sedation level that was assessed by modified Ramsay sedation score showed that there was statistically significant difference between both groups at 10, 20, and 30 min from intranasal application of the drug (*P* value < 0.05); the results revealed that there was better and effective sedation in group D more than in group K; this difference was statistically significant but clinically insignificant as both drugs produced an acceptable level of sedation and decreased the level of anxiety in children.

By observing the results regarding the sedation scores, we also observed that the time to reach better sedation level in patients was shorter with dexmedetomidine when compared to ketamine, and this denotes that the onset time of sedation and anxiolysis in patients premedicated with dexmedetomidine was rapid than patients premedicated with ketamine.

Postoperatively in the recovery room, the difference between both drugs was statistically insignificant (*P* value > 0.05), and also, the effect may be masked by the effect of residual inhalational anesthetics and narcotics given intraoperatively (Table 10).

Cannulation score, parental separation score, parental satisfaction score, and vomiting:

Results of this study as regards cannulation score which was assessed by Groningen distress rating scale showed that there was no statistically significant difference between both groups (*P* value > 0.05) with median (IQR) score in group D (1 (1 – 2)) versus (1 (1 – 2)) in group K. As regards parental separation score was statistically insignificant with Median (IQR) score in group D (1 (1 – 1)) versus (1 (1 – 2)) in group K. As regards parental satisfaction the results also was statistically insignificant with Median (IQR) score (5 (4 – 5)) in group D versus (4.5 (4 – 5)) in group K. Two patients only (5.3%) in group D experienced vomiting in recovery area compared to 4 patients (10.5%) in group K (Table 11).

Induction of anesthesia was standardized for all patients starting with inhalational induction using sevoflurane, after that fentanyl 1 μg/kg and atracurium 0.5 mg/kg were given so as not to make an effect on different groups and different patients, and all patients were completely relaxed and were on volume-controlled ventilation so most of results after induction of anesthesia was statistically non-significant.

Discussion

Results of this study revealed statistically significant increase in sedation score in children premedicated with

Table 11 Comparison between group D and group K as regards cannulation score, parental separation score, parental satisfaction score, and vomiting

		Group D No. = 38	Group K No. = 38	Test value	*P* value	Sig.
Cannulation score	Median (IQR)	1 (1–2)	1 (1–2)	− 0.243	0.808	NS
Parental separation score	Median (IQR)	1 (1–1)	1 (1–2)	− 1.736	0.083	NS
Parental satisfaction score	Median (IQR)	5 (4–5)	4.5 (4–5)	− 1.228	0.219	NS
Vomiting	No	36 (94.7%)	34 (89.5%)	0.724	0.395	NS
	Yes	2 (5.3%)	4 (10.5%)			

P value > 0.05, non-significant

dexmedetomidine more than children premedicated with ketamine at 10, 20, and 30 min from giving the drug (P value < 0.05), but this difference is clinically insignificant as the two drugs produce effective sedation and anxiolysis.

Similar results were observed in another study done by Suvvari et al.; they compared intranasal dexmedetomidine 2.5 μg/kg with intranasal ketamine 5 mg/kg for sedation in children undergoing radiotherapy showed that that there was an increase in mean sedation score when using dexmedetomidine in comparison to ketamine (Suvari et al., 2020).

In study published by Natarajan et al., they compared intranasal dexmedetomidine in two groups given the drug at dose of 1 μg/kg and 1.5 μg/kg for the other group and midazolam 0.2 mg/kg and ketamine 5 mg/kg for assessment of their sedative, and analgesic properties revealed that the sedation was highest in dexmedetomidine groups 90.5% and 95.2% respectively and 76.2% for the ketamine group (Natarajan et al., 2014).

Qiao et al. also assessed the time of onset of sedation which revealed that there was rapid onset of sedation with dexmedetomidine more than ketamine which was in agreement with results of this study (Qiao et al., 2017).

As dexmedetomidine and ketamine produced effective sedation and anxiolysis in pediatrics before operations, this had a significant effect on response of children to cannulation, parental separation, and parental satisfaction making this situation passes smooth, painless, and uneventful; according to this study, both drugs dexmedetomidine and ketamine showed no fear and anxiety and aggression to intravenous cannulation, and good behavioral response, and children were calm during separation from parents while taking them to OR, and also, parents were highly satisfied by this clinical outcome; the results of this study were clinically apparent but statistically insignificant between both groups (P value > 0.05).

Similar results were observed by study done by Gyanesh et al.; they compared intranasal dexmedetomidine 1 μg/kg versus intranasal ketamine 5 mg/kg as premedication for procedural sedation in children undergoing MRI; the results of this study showed that both ketamine and dexmedetomidine were equally effective in this context, and there was no significant difference between both groups (P value > 0.05) (Gyanesh et al., 2014).

Gyanesh et al. assessed the parent's satisfaction with the drug. Higher numbers of parents were satisfied with the use of ketamine (92.4%) and dexmedetomidine (97.3%), and this difference was statistically insignificant (p = 0.212) and this was in agreement with results of this study (Gyanesh et al., 2014).

Conclusion

This study revealed that both drugs produce effective and favorable sedation level with superiority to dexmedetomidine in sedation scores and time of onset of sedation, and also, there was little decrease in heart rate and MAP which is favorable during such surgeries; also, there was accepted level of cannulation and parental separation scores denoting that there was smooth insertion of cannula and smooth and easy separation from guardians or caregivers; finally, the parents were highly satisfied with the procedure and were grateful for us due to alleviating stress and anxiety from them and from their children.

Abbreviations

GABA: Gamma aminobutyric acid; NMDA-R: N-methyl-D-aspartate receptor; ASA: American Society of Anesthesiology; MRSS: Modified Ramsay sedation score; GDRS: Groningen Distress Rating Scale; Sig: Significance; SD: Standard deviation; HR: Heart rate; S: Significant; NS: Non-significant; HS: Highly significant; MAP: Mean arterial pressure; RR: Respiratory rate; SO_2: Oxygen saturation

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Authors' contributions

AE designed the study, revised literature, performed the analysis, followed the patients, measured vital data, modified Ramsay sedation score, cannulation score, parental separation score, and parent satisfaction score and wrote the manuscript. GF designed the study, performed the analysis, wrote and critically revised the manuscript. EH revised the literature, performed the analysis, and critically reviewed the manuscript. MS and RM revised the literature, followed the patients, collected the data, performed the analysis, and critically reviewed the manuscript. All authors approved the final version of the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Approval of research ethical committee of Faculty of Medicine, Ain-Shams University was obtained (code number: FMASU M D 12/2018), and informed written consent was obtained from patients' legal guardian(s) after description of the procedure and its potential complications.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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