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The effect of intranasal dexmedetomidine premedication in children undergoing adenotonsillectomy suffering from recent mild upper respiratory tract infection

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Abstract
Background: Pediatric patients are susceptible to significant levels of stress and anxiety during the phase of perioperative. The use of sedative premedication has the potential to mitigate the levels of anxiety and emotional distress experienced by individuals. The use of dexmedetomidine and midazolam as preoperative sedatives for pediatric patients has been more prevalent in recent years. However, the impact of these sedatives on postoperative respiratory adverse events (PRAEs) remains uncertain.
Objectives and Aims: The objective of this research is to assess the effectiveness of intranasal dexmedetomidine as a premedication for general anesthesia in pediatric patients who are having adenotonsillectomy and have respiratory comorbidities.
Methods and Subjects: The present research was conducted at Tanta University Hospitals, specifically in the Department of Anesthesiology. It used a prospective double-blind randomized controlled trial (RCT) and focused on pediatric patients who were scheduled to undergo adenotonsillectomy and had a recent mild infection of upper respiratory tract.
Results: A statistically important variance was observed among the groups under study in terms of Total PRAEs. Additionally, a comparison among the two group's revealed differences in heart rate (HR), excluding the baseline HR, as well as at fifteen minutes post sedation, thirty minutes post sedation, at induction, fifteen minutes intraoperatively, and thirty minutes intraoperatively in terms of mean arterial blood pressure (MAP) measured in millimeters of mercury (mmHg).
Conclusion: The results of this research indicate that intranasal administration of dexmedetomidine might effectively induce sedation before to surgery and perhaps mitigate the risk of PRAEs.

Keywords: Intranasal, dexmedetomidine, premedication, adenotonsillectomy, URTI

Introduction

The presence of respiratory comorbidities is correlated with a higher occurrence of peri-operative respiratory adverse events (PRAE). Adenotonsillectomy is often associated with the occurrence of upper and lower respiratory infections, with asthma, in pediatric patients. Children diagnosed with respiratory diseases have a three-fold elevation in the prevalence of PRAEs in comparison to their healthy relatives [1].

There is an established correlation among a recent occurrence of upper respiratory tract infection (URTI) and an airway inflammation in children. The duration of the underlying physiopathological abnormalities might range from four to six weeks. During this period, there has been a correlation established between anesthesia and a heightened occurrence of postoperative respiratory adverse events (PRAE) and the administration of general in pediatric patients [2].

Pediatric patients often experience PRAE, which contribute significantly to anesthesia-related morbidity and mortality [3]. The existence of PRAEs has been shown to have a significant impact on hospitalization duration, resulting in an extension of patients' stay. Moreover, the occurrence of PRAEs has been associated with a notable rise in hospital expenses, with costs potentially escalating by up to thirty percent. Additionally, the presence of PRAEs has been linked to increased expenditures in out-patient settings [4].

Dexmedetomidine (DEX), a highly selective α2 adrenergic agonist, offers sedation without

inducing depression of respiratory. The use of this medicine as a preoperative intervention has been observed to, decline the necessary dosage of anesthetic agents, induce a more profound state of anesthesia and effectively mitigate preoperative anxiety [5, 6].

The optimal premedication for pediatric patients should include features that facilitate easy acceptance, consistent onset and have a prompt, and exhibit minimum adverse effects. Various methods may be used for drug administration, including oral, intramuscular (IM), transdermal, intravenous (IV), intranasal, rectal and nebulized approaches [7].

Healthcare professionals often use IV drug administration to induce sedation in pediatric patients. Nevertheless, the process of IV cannulation may elicit discomfort and often requires the use of constraints, potentially leading to enduring psychosocial consequences in pediatric patients, including a reluctance to engage with healthcare professionals. The use of intranasal premedication is a potential option for the delivery of medication to children, since it eliminates the need for vein puncture. Due to its favorable vascularization and drug permeability, the administration of drugs by intranasal delivery at this particular site leads to quick absorption into the systemic circulation, hence prompt sedation and facilitating effective [8].

The objective of this research was to assess the effectiveness of intranasal dexmedetomidine as a preoperative drug for general anesthesia in pediatric patients with respiratory comorbidities who are having adenotonsillectomy.

Methods and Patients

The present investigation was conducted at Tanta University Hospitals, specifically in the Department of Anesthesiology. It focused on pediatric patients who were scheduled to have adenotonsillectomy and had a recent history of mild URTI. The research design used a prospective double-blind randomized controlled approach.

Following the endorsement of the institutional ethics committee of the Faculty of Medicine at Tanta University, with the assigned permission number 6/12/22, and subsequent registration on clinical trials.gov under the registration code NCT05639777.

Parents of all patients were provided with a written informed permission, whereby they were told about the aim of the research. Additionally, a secret code number was assigned to each participant to maintain the confidentiality of the collected data and safeguard their privacy.

The use of research findings was exclusively limited to research efforts. The procedures obtained approval from both the Institutional and Regional ethics committees.

Any unanticipated refers to that emerged throughout the research process were promptly communicated to the ethics committee and the participants. Appropriate steps were mitigate these risks and implemented to address.

Inclusion criteria

This research aimed to evaluate the eligibility of children aged three to ten years, with recent mild URTI, ASA Physical Status II, who were scheduled to have adenotonsillectomy.

On the day of operation, individuals were observed to exhibit zero or more of the following symptoms: A limited number of brief instances of sneezing. Infrequently experienced the need to clean the nose. A minimal amount of respiration occurring via the nasal passages. A limited number of brief instances of coughing. The object exhibited a warm temperature upon contact, without any visible symptoms of flushing. Expressing dissatisfaction with the sensation of lacking additional garments, coldness or coverings. Dysphagia-associated discomfort of a mild kind The individual's vocal quality is characterized by a mild huskiness or hoarseness.

Exclusion criteria

Parental noncompliance with participation. There is observable evidence of a moderate to severe URTI upon the patient's arrival on the day of operation. A lower respiratory tract infection is a kind of infection that affects the structures below the vocal cords and airways, including the trachea, lungs and bronchi. Congenital heart disorders refer to a group of structural abnormalities in the heart that are present at birth. The patient has a documented hypersensitivity to a particular anesthetic drug, as well as the presence of renal or liver illness.

Assessment of Preoperative

The study of history and laboratory investigations, including the analysis of complete blood picture, clotting time and bleeding time, are essential components in the field of and diagnosis and medical research.

Randomization

The participants in this research were randomly allocated to two groups, with thirty-five people in each group. The first group, referred to as the DEX Group, received intranasal dexmedetomidine at a dosage of 1.5 mcg/kg. The second group, referred to as the C Group, served as the control group. The intervention included administering a two ml amount of intranasal normal saline.

In the OR

The children had routine monitoring, which included the use of electrocardiography (ECG), pulse oximetry, noninvasive arterial blood pressure (ABP) measurement, and capnography.

The following measurements were recorded

At the commencement of the trial, demographic information including weight, age and gender was gathered. The anaesthesiologist documented any PRAEs and their respective timing (induction, maintenance, or emergence) on a data sheet, along with the Ramsay sedation scale.

Statistical Analysis

The data were inputted into the computer and afterwards analyzed using IBM SPSS software package version 20.0. The source of this information is IBM Corp, located in Armonk, NY. The qualitative data were represented using numerical percentages and values. The Shapiro-Wilk test was used to assess the normality of the distribution. The quantitative data were characterized by several statistical measures, including the range (comprising the maximum and lowest values), the average, the standard deviation (SD), the median, and the interquartile range (IQR). The statistical significance of the acquired findings was evaluated using a significance threshold of five%.

The used tests were

The statistical tests used in this research include the chi-square test, Monte Carlo correction or Fisher's exact test, Student's t-test, Mann-Whitney test, Friedman test, and ANOVA with repeated measurements.

Results

There was no statistically important difference observed among the examined groups in terms of demographic data. Table one presents the data.

A statistically importan difference was seen among the control group and the DEX group in relation to Total PRAEs, with a p-value of less than 0.05. Table two presents the relevant data.

A statistically significant reduction in HR was observed at several time points in the DEX group compared to the control group. These time points included fifteen minutes before and thirty min after sedation, at the time of induction, as well as fifteen minutes, thirty minutes, forty five minutes, sixty minutes, and thirty minutes following the surgical procedure (p value < 0.05). Table three presents the relevant data.

The investigation observed a statistically significant reduction in the average values of MAP at several time points in the DEX group compared to the control group. These time points included 15 minutes and 30 minutes after sedation, at the time of induction, and 15 minutes and 30 minutes throughout the intraoperative period. The p-value obtained was less than 0.05, indicating statistical significance. There were no further statistically significant differences seen between the two groups under investigation in mean arterial pressure (MAP) for the remaining time frame, as shown by a p-value greater than 0.05. Table four presents the relevant data. There was statistically important difference in the mean values of O_2 saturation at all time intervals in the two studied groups with (P value > 0.05). [Table five]

DEX Group: 4 (11.4%) patients developed marked changes in HR (bradycardia developed in two patients at induction of anesthesia and tachycardia developed in two patients at induction of anesthesia and fifteen min intraoperative) and C group: seven (20.0%) patients developed marked changes in HR (tachycardia developed in seven patients, six patients at induction of anesthesia and one patient fifteen min intraoperative) and two (5.7%) patients developed desaturation at induction of anesthesia and at emergence)

Comparison among the two groups revealed statistically insignificant variance (p. value > 0.05). [Table six]

Discussion

The occurrence of PRAEs is a prevalent complication seen in pediatric anesthesia. A significant percentage of children who have tonsillectomies encounter PRAEs, with an incidence rate reaching as high as fifty percent. There are other independent risk factors that have been identified, including age 6 years and younger, URTI, lung illness, obesity, passive smoking and obsructive sleep apnea (OSA). These features are often observed in pediatric patients following adenoidectomy and tonsillectomy procedures. [9].

The primary finding of the research indicated a reduced occurrence of PRAE in the DEX)\ group, particularly during the recovery phase, among children who had adenotonsillectomy and had a recent moderate URTI.

In our research as regard to demographic data. There was no statistically important variance among the studied groups as regard gender, weight and age like most researches as in Shen *et al*., [10], Sharma *et al*., [11]

The present research showed that as regard to PRAEs, at induction there was no statistically imporant variance among the two groups, during maintenance no event occurred in both groups while at emergence PRAEs were developed less in DEX group compared to control group.

The positive impact of DEX in avoiding PRAE could be attributed to a number of factors. First, DEX might have lowered airway reflexes by increasing the level of anaesthesia [12]. Second, DEX's direct influence on airway smooth muscles might have played a role. Accordingly, it has been shown that DEX lessens isolated tracheal ring contraction caused by exogenous acetylcholine as well as contraction caused by C fibre. Last but not least, DEX may have controlled the inflammatory response [13].

The present research showed that according to Ramsay sedation scale; after fifteen minutes, after thirty minutes and Postoperative, DEX group was better than control group as there was important variance between DEX group and control group.

One possible explanation is that DEX interacts with α2 adrenergic receptors located in the locus coeruleus, a nucleus in the pons that serves as the main source of norepinephrine in the brain. This interaction leads to a sedative effect that resembles natural sleep, while causing minimal respiratory depression and allowing for easy awakening. Consequently, the patient's orientation and cooperation remain unaffected [14].

In the present research examining the relationship between parental separation and mask acceptability, a statistically important difference was observed between the group administered with the control and DEX group.

The observed phenomenon may be attributed to the enhanced sedation observed in the group administered with DEX. DEX exerts its effects by acting on α2 adrenergic receptors located in the locus coeruleus, leading to sedation that closely resembles natural sleep and allows for easy awakening. While, in research conducted by Wang *et al*., [15] compared intranasal dexmedetomidine and oral midazolam in pediatric dental patients undergoing general anesthesia. intranasal dexmedetomidine and oral midazolam provided adequate sedation, but no important differences were reported in terms of mask acceptance and parental separation anxiety (p> 0.05).

Our results showed that regarding the vital signs; there was statistically significant decrease in heart rate HR 15- and 30-min post sedation, at induction, 15, 30, 45 and 60 min intraoperative and 30 min post-operative in DEX group compared to control group. There was statistically significant decrease in the mean values of MAP 15- and 30-min post sedation and at induction in DEX group compared to control group. There was no other statistically significant difference between the two studied groups in MAP at the remaining time interval with. There was statistically insignificant difference in the mean values of O_2 saturation at all-time intervals in the two groups with. According to any event occurred in hemodynamic parameters during procedure: comparison among the two groups revealed statistically insignificant difference (p. value > 0.05).

The explanation could be that DEX is a highly selective α_2 agonist that causes a decrease in serum norepinephrine concentration that leads to a dose dependent decrease in HR

and MBP, another reason may be that preoperative stress increases HR and MBP that decrease after sedation.

Our results were supported by study of Sharma *et al*., [11] as they reported that significant difference between HR and MBP was also found at all the readings, namely, post intubation, preincision, and every 5 min' readings till the end of 30-min postincision ($P < 0.05$).

In the study of Diwan *et al*., [16] in both groups, HR was found to be statistically significant until thirty min of drug administration. In both groups, systolic BP (SBP) and diastolic BP (DBP) were comparable and found to be statistically insignificant.

Limitations of the study

In this experimental research, the researchers were unaware of the specific treatments being administered, however it is worth noting that experienced anesthesiologists have the ability to discern among the various sedatives by only monitoring patient behavior, particularly during the induction phase. The possibility exists that investigator bias may have been introduced, whereby those responsible for diagnosing the result were cognizant of both the group allocation and/or the research premise. Nevertheless, it is crucial to acknowledge that the anesthesiologists included in this research were unaware of the study premise, so mitigating the potential for bias.

Table 1: Comparison between the 2 studied groups according to demographic data

Demographic data	DEX Group (n = thirty five)		C Group (n = thirty five)		Test of sig.	p
	No.	%	No.	%		
Sex						
Male	19	54.3	21	60.0	χ^2= 0.233	0.629
Female	16	45.7	14	40.0		
Age (years)						
Min. - Max.	3.0-9.0		3.0-10.0			
Mean ± SD.	5.44 ± 1.74		5.33 ± 1.98		t=0.234	0.816
Median (IQR)	5.50 (4.0-6.50)		5.0 (3.75-6.20)			
Weight (kg)	(n = thirty five)		(n = thirty four)			
Min. – Max.	14.0-27.0		13.0-28.0			
Mean ± SD.	19.26 ± 3.91		18.41 ± 4.27		t=0.857	0.394
Median (IQR)	18.0 (16.0 – 22.0)		17.50 (15.0-20.0)			

IQR, SD

χ^2: Chi square test t: Student t-test

p: p value for comparing between DEX and C Groups DEX Group, C Group

Table 2: Comparison between the 2 studied groups as regard PRAEs

PRAEs	DEX Group (n = thirty five)		C Group (n = thirty five)		χ^2	p
	No.	%	No.	%		
Induction						
Negative	34	97.1	31	88.6	2.176	MCp= 0.421
Laryngeospasm	1	2.9	2	5.7		
Bronchospasm	0	0.0	2	5.7		
Maintenance	0	0.0	0	0.0	-	-
Emergence						
Negative	33	94.3	25	71.4		
Stridor	1	2.9	5	14.3	6.601*	MCp= 0.049*
Laryngeospasm	0	0.0	3	8.6		
Severe cough	1	2.9	2	5.7		
Total PRAEs	3	8.6	14	40.0	9.401*	0.002*

χ^2: Chi square test MC: Monte Carlo test FE: Fisher exact test

p: p value for comparing between DEX and C Groups

*: Statistically significant at $p \leq 0.05$ DEX Group: C Group:

Table 1: Comparison among the two studied groups as regard HR:

HR (bpm)	DEX Group (n = thirty five)	C Group (n = thirty five)	t	P
Basal				
Mean ± SD	104.43 ± 7.12	105.49 ± 7.27	0.615	0.541
Median (Min-Max)	104.0 (94.0-120.0)	104.0 (95.0 – 120.0)		
15 min post sedation				
Mean ± SD	100.23 ± 7.87	106.06 ± 8.54	2.968*	0.004*
Median (Min-Max)	100.0 (85.0-115.0)	106.0 (94.0-130.0)		
30 min post sedation				
Mean ± SD	94.71 ± 8.54	110.57 ± 9.74	7.240*	<0.001*
Median (Min-Max)	93.0 (82.0-125.0)	110.0 (95.0-130.0)		
At induction				
Mean ± SD	96.20 ± 13.75	126.40 ± 15.06	8.763*	<0.001*
Median (Min – Max)	94.0 (60.0-140.0)	125.0 (100.0-170.0)		
15 min intra operative				
Mean ± SD	107.20 ± 10.40	126.14 ± 10.11	7.727*	<0.001*

Median (Min-Max)	105.0 (90.0-130.0)	125.0 (100.0-150.0)		
30 min intra operative				
Mean ± SD	98.11 ± 9.42	121.17 ± 7.59	11.273*	<0.001*
Median (Min-Max)	98.0 (80.0-122.0)	120.0 (105.0-137.0)		
45 min intra operative				
Mean ± SD	99.11 ± 10.10	117.43 ± 8.79	8.092*	<0.001*
Median (Min-Max)	96.0 (83.0-125.0)	118.0 (95.0-133.0)		
60 min intra operative				
Mean ± SD	97.0 ± 9.74	123.13 ± 5.89	6.492*	<0.001*
Median (Min-Max)	92.50 (88.0-110.0)	124.0 (116.0-130.0)		
30 min postoperative				
Mean ± SD	95.34 ± 6.92	111.60 ± 11.11	7.347*	<0.001*
Median (Min-Max)	95.0 (85.0-115.0)	110.0 (90.0-130.0)		

t: Student t-test
p: p value for comparing between the two studied groups
*: Statistically significant at $p \leq 0.05$ IQR: Inter quartile range SD: Standard deviation

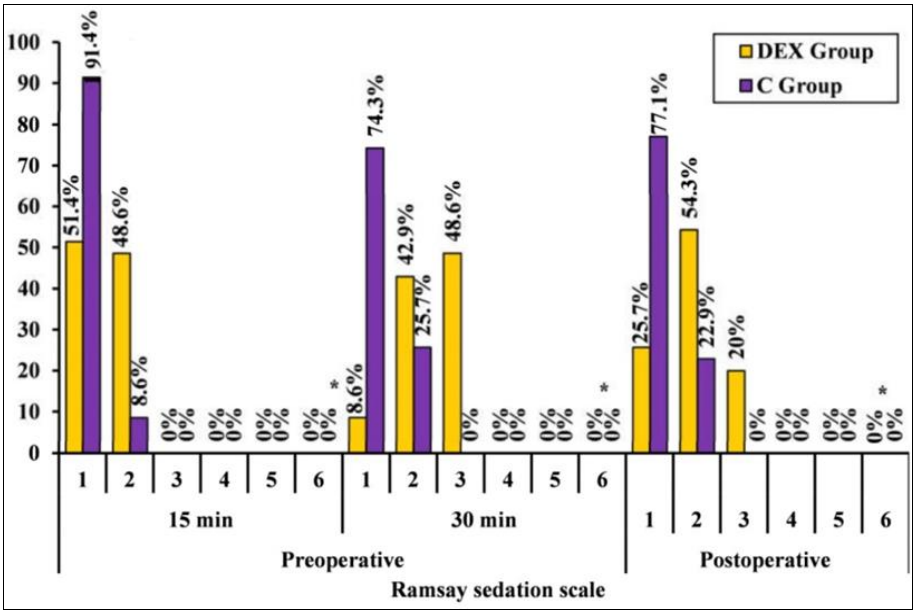

Fig 1: Comparison among the two studied groups according to Ramsay sedation scale (Data presented as percentage)

Table 4: Comparison among the two studied groups as regard MAP (mmHg)

MBP	DEX Group (n = thirty five)	C Group (n = thirty five)	t	p
Basal				
Mean ± SD	70.14 ± 3.11	70.60 ± 3.47	0.150	0.881
Median (Min-Max)	70.0 (65.0-75.0)	71.0 (60.0-77.0)		
15 min post sedation				
Mean ± SD	71.26 ± 2.81	72.54 ± 2.38	2.065	0.043*
Median (Min-Max)	71.0 (65.0-78.0)	73.0 (68.0-80.0)		
30 min post sedation				
Mean ± SD	70.60 ± 2.75	72.83 ± 2.35	3.651*	0.001*
Median (Min – Max)	70.0 (64.0-75.0)	73.0 (69.0-77.0)		
At induction				
Mean ± SD	72.37 ± 3.77	75.49 ± 2.74	3.952*	<0.001*
Median (Min-Max)	73.0 (66.0-78.0)	76.0 (70.0-80.0)		
15 min intra operative				
Mean ± SD	75.66 ± 3.37	77.83 ± 2.92	2.883*	0.005*
Median (Min-Max)	75.0 (67.0-81.0)	78.0 (70.0-82.0)		
30 min intra operative				
Mean ± SD	72.80 ± 2.31	74.49 ± 1.98	3.280*	0.002*
Median (Min-Max)	72.0 (69.0-78.0)	74.0 (72.0-80.0)		
45 min intra operative				
Mean ± SD	72.46 ± 1.88	72.91 ± 2.19	0.938	0.352
Median (Min-Max)	72.0 (69.0-77.0)	72.0 (70.0-79.0)		
60 min intra operative				
Mean ± SD	73.25 ± 2.66	73.25 ± 2.96	0.000	1.000
Median (Min-Max)	74.0 (69.0-77.0)	72.50 (70.0-78.0)		
30 min postoperative				

Mean ± SD	72.86 ± 4.16	73.31 ± 4.84	0.424	0.673
Median (Min – Max)	72.0 (63.0-80.0)	73.0 (63.0-81.0)		

t: Student t-test p: p
*: Statistically significant at $p \leq 0.05$ IQ, SD:

Table 5: Comparison among the two studied groups as regard O_2 saturation

O_2 saturation	**DEX Group** (n = **thirty five**)	**C Group** (n = **thirty five**)	**T**	**p**
Basal				
Mean ± SD	98.31 ± 0.68	97.97 ± 0.79	1.957	0.054
Median (Min-Max)	98.0 (97.0-99.0)	98.0 (97.0-99.0)		
15 min post sedation				
Mean ± SD	98.34 ± 0.64	98.09 ± 0.66	1.658	0.102
Median (Min-Max)	98.0 (97.0-99.0)	98.0 (97.0-99.0)		
30 min post sedation				
Mean ± SD	98.46 ± 0.61	98.20 ± 0.63	1.730	0.088
Median (Min-Max)	99.0 (97.0-99.0)	98.0 (97.0-99.0)		
At induction				
Mean ± SD	98.69 ± 0.47	98.46 ± 0.61	1.753	0.084
Median (Min-Max)	99.0 (98.0-99.0)	98.0 (97.0-100.0)		
15 min intra operative				
Mean ± SD	99.63 ± 0.49	99.57 ± 0.50	0.482	0.632
Median (Min-Max)	100.0 (99.0-100.0)	100.0 (99.0-100.0)		
30 min intra operative				
Mean ± SD	99.63 ± 0.49	99.57 ± 0.50	0.482	0.632
Median (Min-Max)	100.0 (99.0-100.0)	100.0 (99.0-100.0)		
45 min intra operative				
Mean ± SD	99.63 ± 0.49	99.60 ± 0.50	0.242	0.809
Median (Min-Max)	100.0 (99.0-100.0)	100.0 (99.0-100.0)		
60 min intra operative	(n = 8)	(n = 8)		
Mean ± SD	99.75 ± 0.46	99.63 ± 0.52	0.509	0.619
Median (Min-Max)	100.0 (99.0-100.0)	100.0 (99.0-100.0)		
30 min postoperative				
Mean ± SD	98.34 ± 0.76	98.09 ± 0.89	1.299	0.198
Median (Min-Max)	98.0 (96.0-100.0)	98.0 (96.0-100.0)		

S.D, T, P; P p:

Table 6: Shows comparison among the two studied groups as regard to any event occurred in hemodynamic parameters during procedure:

Any event	**DEX Group (n = thirty five)**		**C Group (n = thirty five)**		**χ^2**	**p**
	No.	**%**	**No.**	**%**		
HR	4	11.4	7	20.0	0.971	0.324
MAP	0	0.0	0	0.0	–	–
SPO_2%	0	0.0	2	5.7	2.059	FEp= 0.493

χ^2: Chi square test, FE: Fisher Exact p: p
DEX Group: C Group
DEX group;

Conclusion

The results of this research indicate that intranasal administration of dexmedetomidine might effectively induce sedation before to surgery and perhaps mitigate the risk of PRAEs

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Conflict of Interest: Nil

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