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Effect of preoperative application of midazolam oral solution on agitation during awakening after tonsillectomy in children

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Abstract: *To observe the effect of preoperative application of midazolam oral solution on postoperative agitation during postoperative awakening in children undergoing tonsillectomy proposed to be performed under general anaesthesia. Sixty children who underwent elective tonsil surgery in our hospital from March to July 2023 were selected for the study and were divided into control group and study group using random number table method, 30 cases/group. In the experimental group, midazolam 0.5 mg/kg was administered orally 30 min before surgery, and the same dose of saline was administered orally in the control group. The heart rate and mean arterial pressure of the children in both groups were observed and recorded before the oral administration of the drug (T0), 15 min after the oral administration of the drug (T1), 30 min after the administration of the drug (T2), and after the end of the operation (T3), and the time of awakening, the time of extubation, and the Ricker sedation-agitation scale (SAS). Comparison of HR and MAP levels at the moment of T0 and T1 between the two groups was not statistically significant ($P > 0.05$); HR and MAP levels at the moment of T2 and T3 in the experimental group were significantly lower than those in the control group, and the difference was statistically significant ($P < 0.05$); comparison of the time of awakening and extubation time between the two groups was not statistically significant ($P > 0.05$); the SAS scores of the experimental group and the number of cases in which SAS scores ≤ 5 were significantly lower, and the difference was statistically significant ($P < 0.05$). The SAS score and the number of cases with SAS score ≤ 5 in the experimental group were significantly reduced, and the difference was statistically significant ($P < 0.05$). Preoperative oral midazolam 0.5 mg/kg is safe and effective in sedation during paediatric tonsillectomy and reduces agitation scores during awakening from general anaesthesia without affecting awakening time or extubation time.*

Keywords: *Midazolam oral solution; agitation during awakening*

1. Introduction

Recurrent tonsillitis and tonsillar hypertrophy not only lead to pain and itching in the throat, but also affect breathing and sleep in severe cases, and such diseases mostly occur in paediatric patients[1]. Therefore, paediatric tonsillectomy is one of the common surgeries in paediatrics, mainly for children with ineffective medication, and currently the commonly used surgical methods are plasma and laser treatment[2]. Considering the children's general condition, surgical methods and operation time, general anaesthesia is routinely chosen to ensure safety, and the most common adverse reaction after general anaesthesia is agitation during the awakening period[3]. Due to the rich distribution of peripheral nerves in the pharynx, children inevitably feel pain during postoperative awakening, which may lead to coughing, choking, restlessness, and in severe cases, traumatic haemorrhage, regurgitation and aspiration, and even respiratory depression[4]. Therefore, reducing postoperative agitation in children under general anaesthesia is important to ensure their comfort and safety during the awakening period.

Midazolam injection is one of the common induction drugs for anaesthesia and has sedative, hypnotic and anticonvulsant properties[5]. However, midazolam injection is an intravenous preparation with a bitter taste, which is difficult for children to swallow, while midazolam oral solution made by adding adjuvant to it has a slightly sweet taste that is more acceptable to children and has a clear sedative effect[6]. Therefore, the aim of this study was to investigate whether the preoperative application of midazolam oral solution could improve the agitation of children undergoing

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tonsillectomy during the awakening period of general anaesthesia, and improve the comfort and safety of children.

2. Methods

Sixty children who underwent elective tonsillectomy under general anaesthesia in our hospital from March to July 2023 were selected for the study, and were divided into the control group and experimental group using the random number table method, 30 cases/group. Inclusion criteria:

① all children were clearly diagnosed with tonsillar hypertrophy and met the indications for surgery;

② age 3-7 years old;

③ ASA grade I-II;

④ children could walk into the operating room accompanied by nurses and anaesthesiologists.

Exclusion criteria:

1) allergic to the drugs used in this study;

2) emotional fluctuation or the condition needs to be changed to other treatments;

3) accompanied by serious psychological diseases or perceptual dysfunction;

4) personal reasons for dropping out of the study. The general information of the two groups, such as age, gender, body mass index, ASA classification, surgical method, operation time and anaesthesia time, were comparable without statistical significance (P＞0.05;Table 1). The children's families were informed and signed an informed consent form.

Table 1: Comparison of general condition of children in two group

Variables	Experimental group(n=30)	Control group(n=30)	t/χ2-Vaule	P-Vaule
Age (years), mean (SD)	4.83(1.12)	4.80(1.27)	0.108	0.914
Gender, (%) male female	 16(53.3) 14(46.7)	 14(46.7) 16(53.3)	0.267	0.606
BMI (Kg/m2), mean (SD)	17.28(1.71)	17.29(2.00)	-0.026	0.980
Operation time (minutes), Mean (SD)	52.97(5.28)	54.53(5.05)	-1.175	0.245
Anaesthesia time (min), mean (SD)	77.60(4.83)	78.80(5.85)	-0.867	0.390
ASA,(%) I II	 24(80.0) 6(20.0)	 23(76.7) 7(23.3)	0.098	0.754

Note: Data are expressed as mean (SD) or numbers (%). Abbreviations: SD, standard deviation.

All children to be treated with elective paediatric tonsillectomy followed the standard guidelines for abstinence from drinking and fasting, discontinued the use of anti-anxiety drugs or sedatives 12 h before the operation, and were admitted to the operating theatre by the anaesthesia nurses and monitored for non-invasive blood pressure, pulse, oxygen saturation and electrocardiograms, after the establishment of a good venous access in the otorhinolaryngology ward. In the experimental group, children were given midazolam oral solution 0.5mg/kg with a maximum dose not exceeding 15mg by the anaesthesiologist; in the control group, the same dose of saline was given. 30min later, children in both groups adopted a uniform mode of anaesthesia induction, and according to the patient's body weight, sufentanil (0.5μg/kg), propofol (2-4mg/kg), cisatracurium (0.1mg/kg) were administered Tracheal intubation and connection of ventilator was performed afterwards. Anaesthesia was maintained in both groups by respiratory inhalation of sevoflurane at a concentration of 2%-3% and intravenous pumping of remifentanil 0.1-0.3ug/(kg-min) during surgery. At the end of the operation, sevoflurane and remifentanil were stopped, and the endotracheal tube was removed when the child reached the indication for extubation, and the child was sent to the recovery room for further observation.

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3. Presentation of observations

Heart rate and mean arterial pressure were compared between the two groups of children before oral medication (T0), 15 min after oral medication (T1), 30 min after oral medication (T2), and at the end of the procedure (T3), as well as time to awakening, time to extubation, and SAS scores of the two groups.SAS score of 7 indicated dangerous agitation; 6 was very agitated; 5 indicated restlessness; 4 indicated quiet co-operation; 3 indicated sedation; 2 was very sedated; and 1 implied inability to be aroused; and the criteria for assessing agitation was a SAS score of ≥5 [7].

4. Statistics

SPSS26.0 statistical software was used for analysis, and differences were considered statistically significant at $P < 0.05$. Normally distributed measurements were expressed as $x \pm s$, and independent samples t-test was used for between-group comparisons; count data were statistically described as percentages (%), and chi-square test was used for between-group comparisons.

5. Results

Comparison of heart rate and mean arterial pressure at various time intervals between the two groups of children. When comparing the heart rate and mean arterial pressure at the moment of T0 and T1 between the two groups, the difference was not statistically significant ($P > 0.05$); compared with the control group, the heart rate and mean arterial pressure of the experimental group were significantly lower than those of the control group at the moments of T2 and T3, and the difference was significant ($P < 0.05$). See Tables 2 and 3.

Table 2: Comparison of MAP at various time intervals between two groups of children

Groups	n	MAP levels (mmHg) at each time point, mean (SD)			
		T0	T1	T2	T3
Experimental group	30	74.70(2.78)	69.57(2.90)	64.60(2.87)	61.50(2.56)
Control group	30	75.03(3.00)	69.97(3.29)	67.97(3.41)	65.10(3.55)
t-Vaule	-	-0.448	-0.500	-4.137	-4.511
P-Vaule	-	0.656	0.619	< 0.001	< 0.001

Note: Data are presented as mean (SD). Abbreviation: SD, standard deviation.

Table 3: Comparison of HR between the two groups of children at various time intervals

Groups	n	HR levels at each time point (times),mean (SD)			
		T0	T1	T2	T3
Experimental group	30	109.50(4.08)	106.53(3.34)	98.13(3.38)	97.50(3.63)
Control group	30	110.27(4.15)	107.17(3.46)	105.10(2.78)	104.97(3.52)
t-Vaule	-	-0.721	-1.063	-8.713	-8.093
P-Vaule	-	0.474	0.292	< 0.001	< 0.001

Note: Data are presented as mean (SD). Abbreviation: SD, standard deviation.

Comparison of postoperative awakening time and extubation time between the two groups of children showed no statistically significant difference ($P > 0.05$). See Table 4.

Table 4: Comparison of postoperative awakening time and extubation time between the two groups of children

Variables	Experimental group(n=35)	Control group(n=35)	t-Vaule	P-Vaule
Awakening time, (min)	12.67(2.26)	12.27(2.25)	0.171	0.864
Extraction time, (min)	18.27(2.07)	17.93(2.03)	0.630	0.531

Note: Data are expressed in per cent.

Comparison of agitation during awakening in two groups of children. Compared with the control group, the number of cases in which children in the experimental group had SAS scores and SAS scores ≧ 5 during the postoperative awakening period was significantly reduced, and the difference was significant ($P < 0.05$). See Table 5.

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Table 5: Comparison of SAS score and the number of cases with SAS score ≥5 between the two groups of children

Groups	n	SAS score [points, mean (SD)]	SAS score ≥5 [cases (%)
Experimental group	30	3.53(0.73)	3(10.0)
Control group	30	4.07(0.83)	10(33.3)
t/χ2-Vaule	-	-2.646	4.812
P-Vaule	-	0.010	0.028

Note: Data are expressed as mean (SD) or numbers (%). Abbreviations: SD, standard deviation.

6. Discussion

Globally, tonsillar diseases are among the most common clinical paediatric diseases, with approximately 42-70% of children presenting to ENT departments each year, and the current common treatment is surgical resection under general anaesthesia[8]. Paediatric general anaesthesia is very easy to wake up agitation, which may be related to the low age and general anaesthesia drugs, often manifested as limbs and trunk movement, irritable, uncooperative, do not follow the instructions of medical staff, etc., and in severe cases, even may appear orientation dysfunction and paranoid behavior, which undoubtedly aggravate the burden of doctors and nursing work[9]. And due to tonsillectomy its special surgical site, blood vessels and peripheral nerves are abundant, the pain during the awakening period leads to coughing and choking, which stimulates the pharynx and triggers a series of adverse events such as traumatic haemorrhage, respiratory depression and so on[10]. Therefore, in order to improve the perioperative comfort and safety of children, the intervention of agitation during awakening is of great practical significance.

In this study, school-age children who were to undergo tonsillectomy were selected for the intervention with 0.5 mg/kg midazolam oral solution applied 30 min before induction of anaesthesia. The results of the study showed that the heart rate and mean arterial pressure of the experimental group were lower than those of the control group at T2 and T3, and the SAS score and the number of cases with SAS score ≥5 were significantly lower and less than those of the control group in the experimental group. This suggests that the preoperative application of midazolam oral solution achieved a good sedation effect during paediatric tonsillectomy, and at the same time reduced the children's agitation score during the awakening period.

In conclusion, the use of 0.5mg/kg midazolam orally 30min before tonsillectomy can significantly reduce the agitation score during the awakening period, the sedation effect is accurate, safe and reliable, and does not affect the postoperative awakening time of the child and the time of extubation, nursing satisfaction is high, it is worthy of clinical promotion.

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