

## **A randomized double-blind controlled study on non-invasive ventilation in the treatment of children obstructive sleep with apnea syndrome (OSAS).**

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### **Abstract**

**Objective:** This research aimed to explore the curative effect of noninvasive ventilation in the treatment of children Obstructive Sleep Apnea Syndrome (OSAS).

**Methods:** From Nov 2015-2016, 70 children OSAS patients in Binzhou People's Hospital were selected as the study subjects and were randomly divided into surgery group (n=35) and ventilation group (n=35). Patients in the surgery group were treated with routine operation while ventilation group were received non-invasive ventilation followed by the routine operation. The curative effects in the two groups were analyzed with statistical comparison method.

**Results:** Total effective rate of the ventilation group was significantly higher than that of the surgery group, partial pressure of carbon dioxide of the ventilation group was lower than that of the surgery group and the longest time of apnea, apnea hypopnea index as well as Epworth Sleepiness Score (ESS) of the ventilation group was obviously lower than that of the surgery group ( $P < 0.05$ ), while abortion and ectopic pregnancy rate of the intervention group was strikingly lower than that of the control group significantly.

**Conclusion:** Non-invasive ventilation has good effects in the treatment of children Obstructive Sleep Apnea Hypopnea Syndrome (OSAS).

**Keywords:** Children obstructive sleep apnea syndrome (OSAS), Non-invasive ventilation, Effects.

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### **Introduction**

Sleep Apnea Hypopnea Syndrome (SAHS) is currently a common sleep-related breathing disorder with unclear disease cause with the symptoms like apnea during sleep, hypercapnia, low ventilation and sleep interruption [1]. SAHS is divided into three types, central type, obstructive type and mixed type in clinical treatment. OSAS is the most common sleep-disordered breathing disease among children [2]. Surgical treatment is current commonly used in the clinical treatment of OSAS, but the treatment effect remains to be promoted. In this study, 35 children OSAS patients were treated with noninvasive ventilation followed by the routine operation and the effects of the treatment with the routine care groups were compared. The retrospective analysis of specific treatment process is as follows.

### **Material and Methods**

#### **General data**

From Nov 2015-2016, a total of 70 children OSAS patients in our hospital were selected as the study subjects. Enrolment

condition: children diagnosed as OSAS sufferers by implementation of comprehensive diagnosis like imaging examination, lung examination and laboratory examination based on relevant diagnosis criteria established by Chinese medical association; Parents of the patients voluntarily agree the participation of their children in the treatment research. Exclusion condition: child patients with serious illness of important organs such as heart, lung, spleen and kidney; children with other respiratory system diseases; children with surgical contraindication; children with disturbance of consciousness or difficulties in cooperating with the study. All patients were divided into surgery group (n=35) and ventilation group (n=35) by means of random number table. Among the surgery group there were 21 males and 14 females at the age of 4 to 13 with the average of 8.6 (s=3.7) and a disease course of 1-15 months, 6.6 months on average (s=4.7) while among the ventilation group there were 20 males and 15 females at the age of 4 to 13 with the average of 8.7 (s=3.6) and a disease course of 1-15 months, 6.6 months on average (s=4.7). The comparison of general data in two groups is of statistical significance by way of independent sample test,  $P > 0.05$ .

## Methods

The children participants were given more time of rest in the process of treatment free and cut down on excitant food [3]. Patients in the surgery group were all treated with appropriate routine operation according to their diseases realities. Children with palatal pharyngeal obstruction received hard palate truncation treatment, children with nasal congestion received nasal cavity expansion treatment and patients with tongue base obstruction received low temperature ion tongue base reduction treatment [4,5]. In the process of surgical treatment, the patient's sleep state should be closely monitored and targeted first aid should be taken in a timely manner if any abnormal signs appear.

Patients in the ventilation group received noninvasive ventilation followed by the routine operation which contains the same surgical procedures as the processes in the surgery group. Besides children in the ventilation group were treated with continuous non-invasive positive airway pressure through oral-nasal masks through the application of single level breathing machine-Kaidi Thai Floton-CPAP. The sleeping state of the patients during the treatment was monitored by way of polysomnogram. Children with treatment using multiple guide children sleep figure monitoring, ventilation pressure was adjusted according to responses and actual sleep status of the patients with an initial minimum pressure of 4-5 cm H<sub>2</sub>O and the pressure might be increased in process of treatment [6,7]. Blood oxygen saturation of the patients remained >90% during treatment [8]. The treatment was continuously given no less than 5 h each day with a continue treatment for 2 weeks.

## Observation index

**Treatment effects in two groups:** Significant effect: Symptoms such as snoring, suffocation, mouth breathing and disturbed sleep basically disappeared and the rate of children with apnea decreased more than 80%.

**Effective:** Symptoms such as snoring, suffocation, mouth breathing and disturbed sleep were mitigated and the rate of children with apnea decreased more than 50%.

**Invalid:** Symptoms such as snoring, suffocation, mouth breathing and disturbed sleep remained unchanged overall or went worse and the rate of children with apnea decreased less

than 50% or remained unchanged [9]. Total effective rate=significant effect rate+effective rate.

Vital energy and blood (oxygen partial pressure, CO<sub>2</sub> partial pressure) status before and after treatment; Status of patients with sleep apnea after treatment: the longest time of apnea before and after treatment, apnea hypopnea index, Epworth Sleepiness Score (ESS) with a total score of 0-24, the result of more than 6 scores signified drowsy.

## Statistical analysis

Data of vital energy and blood and sleep with apnea were described as mean ± SD. T test and  $\chi^2$  test were applied with statistical significance of P<0.05. Statistical software: SPSS 19.0 and Microsoft office excel.

## Results

### Analysis of curative effect in two groups

The total effective rate of the ventilation group was significantly higher than that of the surgery group of statistical significance (P<0.05, Table 1).

### Analysis of vital energy and blood status in two groups

There was no statistical difference in oxygen partial pressure and CO<sub>2</sub> partial pressure between the two groups (P>0.05), oxygen partial pressure of ventilation group was significantly higher than that of the surgery group while CO<sub>2</sub> partial pressure strikingly lower of statistical significance (P<0.05, Table 2).

### Analysis of sleep with apnea status in two groups

Before treatment, there was no statistical difference in the longest time of apnea, apnea hypopnea index, Epworth Sleepiness Score (ESS) between the two groups (P>0.05). After treatment, the longest time of apnea, sleep with apnea, hypopnea index and ESS results of the ventilation group were obviously lower than those of the surgery group of statistical significance (P<0.05, Table 3).

**Table 1.** Comparison of curative effect in two groups (n (%)).

Group	Case	Significant effect	Effective	Invalid	Total effective rate
Surgery group	35	15 (42.9)	13 (37.1)	7 (20.0)	28 (80.0)
Ventilation group	35	24 (68.6)	10 (28.6)	1 (2.8)	34 (97.2)
$\chi^2$	-	-	-	-	5.081
P	-	-	-	-	0.031

*A randomized double-blind controlled study on non-invasive ventilation in the treatment of children obstructive sleep with apnea syndrome (OSAS)*

**Table 2.** Comparison of vital energy and blood status in two groups.

Group	O <sub>2</sub> partial pressure		CO <sub>2</sub> partial pressure	
	Before treatment	After treatment	Before treatment	After treatment
Surgery group	61.3 ± 10.3	76.3 ± 9.7	52.3 ± 3.6	44.3 ± 2.7
Ventilation group	61.4 ± 10.2	85.3 ± 8.4	52.2 ± 3.7	38.1 ± 2.6
t	0.041	4.148	0.115	9.786
P	0.325	0.047	0.511	0.039

**Table 3.** Comparison of sleep apnea status in two groups.

Group	The longest time of apnea (s)		Hypopnea index (times/h)		ESS score	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Surgery group	49.6 ± 10.3	35.9 ± 8.9	38.6 ± 6.3	29.1 ± 6.7	15.1 ± 4.3	8.6 ± 6.3
Ventilation group	49.8 ± 10.6	20.1 ± 7.4	38.5 ± 6.7	22.3 ± 9.4	15.2 ± 4.1	4.2 ± 3.3
t	0.08	8.076	0.064	3.485	0.1	3.66
P	0.592	0.021	0.441	0.047	0.325	0.022

## Discussion

Children Obstructive Sleep Apnea Syndrome (OSAS) is currently a common sleep-related breathing disorder with such symptoms as snoring, suffocation, mouth breathing, sleep interruption and hyperhidrosis, prone to cause inattention, hyperactivity, recurrent respiratory tract infections, cognitive impairment, and nerve behaviour change. In addition, it may lead to a series of pathophysiological changes like enlargement of heart, high blood pressure and pulmonary, posing a serious threat to children in mental state, growth and development as well as life safety and quality, or even death [10-12]. Developing the treatment of children patients, improving their breathing and sleep status become the focus of clinical research.

The more common clinical treatment of OSAS in children currently is surgery, which can eliminate airway obstruction in children and improve their respiratory obstruction, clinical symptoms [13]. But surgery therapy could cause moderately larger trauma and requires higher tolerance level of the patients. What's worse, operation fails to improve airway nerve or ease muscle tension, which could cause a high possibility of repeated congestion and higher recurrence rate. And for child patients with obesity or developmental abnormalities, surgical treatment fails to have good curative effects [14-16]. Continuous non-invasive positive airway pressure through oral-nasal masks is a method commonly used in noninvasive ventilation, with the advantages of lower tolerance requirements and non-invasion. Besides, in the process of this kind of treatment, ventilation pressure can be adjusted in a timely manner according to polysomnogram which effectively improve ventilation effect, thus enabling to keep organic oxygen delivery status, promote balance restoration within the body and improve qi and blood condition. Also, noninvasive

ventilation can enhance patient's respiratory recovery and reduce the occurrence of apnea. In addition, the implementation of noninvasive ventilation can facilitate airway tension recovery and effectively reduce the obstruction state, thus further enhancing treatment efficacy [17-20].

Above all, non-invasive ventilation has good effects in the treatment of children obstructive sleep apnea hypopnea syndrome and it has high application value with its function of promoting vital energy and blood condition as well as sleep-disordered breathing.

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