

Efficacy of Automated Continuous Positive Airway Pressure in Children With Sleep-Related Breathing Disorders in an Attended Setting

Luciana Palombini, MD; Rafael Pelayo, MD; and Christian Guilleminault, MD

ABSTRACT. *Introduction.* The purpose of this study was to evaluate the safety and efficacy of automated continuous positive airway pressure (Auto-CPAP) in children.

Sleep-related breathing disorders (SRBDs) include the clinical spectrum of symptomatic chronic snoring, upper airway resistance syndrome, and obstructive sleep apnea. This spectrum occurs in adults and children. Less data are available for children despite recognition of the condition's prevalence. CPAP has been an established treatment for adults and children. Treatment with Auto-CPAP has been available for adults but has not been reported previously in children.

Methods. A group of 14 children (8 months to 12 years old) was evaluated prospectively with baseline polysomnographic study and CPAP titration performed with Auto-CPAP under sleep technologist supervision.

Results. The results demonstrated that Auto-CPAP is sensitive and effective for children with obstructive sleep apnea in an attended setting. There was 1 subject who did not seem to tolerate Auto-CPAP, but when she was switched to conventional CPAP, she did not tolerate that either. In this subject, the mask never fit well. She was excluded from the analysis. All other patients had a decrease in the number of abnormal breathing events during sleep. The respiratory disturbance index decreased from a mean of 12.6 (SD: 12.4) to 2.6 (SD: 2.7) events per hour. The lowest oxygen saturation improved from a mean of 86% (SD: 10.8) to 93.6% (SD: 3.9).

Conclusions. We conclude that Auto-CPAP is safe and effective in an attended environment. Auto-CPAP did not eliminate all the abnormal respiratory events. In subjects 1 and 14, the final respiratory index improved but remained >5 events per hour (5.9 and 7.7, respectively). We suspect that this was because of problems with the masks leaking, which illustrates the importance of follow-up and possible need for retitration in some patients. Proper mask fit is essential for successful treatment. Additional work is needed to evaluate its utility in the home setting. This study was designed to evaluate Auto-CPAP titration in an attended environment. It did not indicate information about the effectiveness in an unattended or home setting. We demonstrate that Auto-CPAP is able to detect abnormal breathing events during sleep in children and may provide the necessary pressure to correct these events. Auto-CPAP can be used safely for pressure titration in an attended setting. Auto-CPAP devices from different manufactures are commercially available for adults. These different devices may have

different algorithms and sensitivities to detect abnormal breathing episodes. This study was performed with only 1 specific model of Auto-CPAP. Our results should not be extrapolated to other Auto-CPAP devices without empirical confirmation of the devices' ability to detect and correct events in children. Auto-CPAP can be an alternative treatment for SRBDs in the pediatric population. These results allow for speculation of possible applications for Auto-CPAP in children. A potential advantage of Auto-CPAP includes permitting the initiation of treatment while awaiting a standard CPAP titration. The variable pressure response of Auto-CPAP allows for treatment under different situations such as upper airway infections, different sleeping positions, and changes in weight. As the child grows, the amount of positive pressure needed to maintain airway patency may change. Auto-CPAP may be able to adjust to these changing pressure requirements. Auto-CPAP does not eliminate the need for periodic office visits and evaluations of the clinical course. *Pediatrics* 2004;113:e412-e417. URL: <http://www.pediatrics.org/cgi/content/full/113/5/e412>; *sleep, breathing, obstructive sleep apnea, child, treatment, oxygen saturation, snoring, CPAP.*

ABBREVIATIONS. SRBD, sleep-related breathing disorder; CPAP, continuous positive airway pressure; Auto-CPAP, automated CPAP; SaO₂, arterial oxygen saturation; RDI, respiratory disturbance index.

In children, sleep-related breathing disorders (SRBDs) are estimated to occur in ~2% to 6% of the population.¹

Consequences of SRBDs in children include cardiovascular complications.²⁻⁵ In addition to the cardiovascular consequences, behavioral changes have been associated with SRBDs and may include irritability, aggressiveness, hyperactivity, and disciplinary problems. Several studies have demonstrated a high incidence of impaired school performance, hyperactivity, decreased intellectual performance, and emotional problems associated with SRBDs in children.⁶⁻⁹ SRBD symptoms were associated with attention-deficit/hyperactivity disorder in a cross-sectional study involving 866 children.¹⁰

Treatment options for children with SRBDs typically are surgery and continuous positive airway pressure (CPAP). Oral appliances are available for adults but are not routinely used in children. Surgery (adenotonsillectomy) is the most common form of treatment in children. The cure rate with surgery is unknown, but improvement of the condition has been reported at 85% by Suen et al.¹¹ In the presence of craniofacial or neurologic problems, the effectiveness of surgery may be lower.¹²

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CPAP is usually recommended when adenotonsillectomy is unsuccessful or contraindicated rather than as primary treatment. CPAP can be used also as a bridge until surgery is available. CPAP also may be useful between surgeries in cases such as cranial facial anomalies requiring multiple surgical interventions. For the children with specific surgical contraindications, minimal adenotonsillar tissue, or persistent SRBD after adenotonsillectomy, CPAP is the main treatment option. Successful use of CPAP in children has been reported.¹⁰ Fixed-pressure CPAP is safe, effective, and well tolerated by children and adolescents with obstructive sleep apnea.^{11,12} One of the barriers to CPAP therapy is the requirement of an initial, attended pressure titration performed in a sleep laboratory during polysomnography. The pressure found to be effective during the sleep study then is prescribed for CPAP use in the child's home.

The need for an attended polysomnogram to determine the optimal CPAP pressure limits the availability of CPAP for children. Sleep disorders clinics with pediatric expertise are less available than those for adults. Optimal use of CPAP in children during an acute hospitalization may be hampered by the inaccessibility of the pediatric sleep center personnel and equipment.

Automated CPAP (Auto-CPAP) is an automated positive airway pressure treatment that has been effective in adults.¹³ Auto-CPAP provides variable pressure delivery based on the patient airflow. Instead of providing a constant pressure, such as in CPAP, the device adjusts the pressure during sleep by monitoring the patient's airflow. Average Auto-CPAP pressures tend to be lower than conventional CPAP, because it is a proactive form of treatment. It increases pressure in response to subtle airflow limitation episodes, which precede conventional apneas and hypopneas.¹³ The application of variable pressure according to a patient's airflow during sleep may improve comfort and possibly increase treatment compliance. Current Auto-CPAP devices retain in memory information regarding the pressure and airflow events during several nights. This information can be downloaded and analyzed to further adjust the treatment and monitor compliance.

If Auto-CPAP is safe and effective in children, it possibly might improve access to therapy by allowing faster application of positive airway therapy while awaiting a traditional pressure titration in the laboratory. The information retained in memory may also allow for adjustments to the pressure settings when a titration study is not readily available. This is the first report of the effectiveness of Auto-CPAP in children. In this initial study, the Auto-CPAP device was used only in an attended setting. Children were not prescribed Auto-CPAP for use in the home; instead, they were prescribed conventional CPAP after the attended sleep study.

MATERIALS AND METHODS

Study Design

The study was designed as a prospective study. The objective was to ascertain the safety and effectiveness of Auto-CPAP in an attended environment.

Subjects

All successive pediatric patients meeting the inclusion/exclusion criteria were approached to participate. The inclusion criteria were all children with an age range of 6 months to 18 years. The study was open to boys and girls of all ethnic backgrounds. The child must have been documented with sleep-disordered breathing confirmed by polysomnography at the Stanford Sleep Disorders Clinic. The child had to be able to tolerate the use of CPAP and have parents or guardians willing to use CPAP in the home. The exclusion criteria were children with bullous emphysema, acute otitis media, or history of claustrophobia.

A sleep center physician explained the study to the parents, who then were asked to sign an informed consent form for their children to undergo the research protocol. The informed consent was approved by Stanford University's Investigational Review Board.

Patients were referred to the sleep clinic from the community for chronic snoring and evaluation for SRBD. A total of 14 children (10 boys and 4 girls) with SRBDs was prospectively recruited and evaluated at the Stanford Sleep Disorders Center. The diagnosis of SRBD was made after an initial baseline polysomnography and clinical evaluation. After the diagnostic evaluation, patients were referred for CPAP titration.

Polysomnographic Studies

A standard overnight diagnostic polysomnographic evaluation was performed at the Stanford Sleep Disorders Clinic. The following equipment was used and parameters measured: electroencephalogram, right and left electrooculogram, submental and tibial electromyogram, nasal airflow (recorded with nasal cannula pressure), respiratory effort (with thoracic and abdominal piezo bands), arterial oxygen saturation (Sao₂), and neck microphone. Sleep center staff attended all studies. Parents were required to remain for the entire time of the sleep study. Sleep technologists experienced with children performed the polysomnograms.

CPAP-Titration Studies

The polysomnograms performed with Auto-CPAP measured the same parameters as the baseline sleep study. The airflow information was derived from mask pressure with the use of a pressure transducer. The Auto-CPAP device used was the ResMed AutoSet-T model (ResMed, San Diego, CA). The range of pressure of the Auto-CPAP was set from 4 to 15 cm H₂O.

One investigator (Dr Palombini) was designated to assist the sleep study and intervene if continuous respiratory events persist during CPAP titration in automatic mode. If persistent apneas, hypopneas, or oxygen desaturations (Sao₂ < 90%) were present in automatic mode, the child would be switched to manual titration with conventional-pressure CPAP.

Some of the masks used in the study were commercially available, but a smaller size was made available by the Auto-CPAP manufacturer (ResMed). This small mask is not commercially available in the United States but is sold in other countries. The possibility of using this mask was included in the informed consent.

Scoring Criteria: Sleep Parameters

Sleep studies were scored following Rechtschaffen and Kales criteria for sleep staging.¹⁴ Arousals were scored according to American Academy of Sleep Medicine criteria for short arousals.¹⁵ Accredited polysomnographic technologists scored all the studies.

SRBD was defined as having a minimum respiratory disturbance index (RDI) of 1.0 with symptoms consistent with the disorder. Respiratory events were scored following American Thoracic Society criteria consensus for children.¹⁶ An apnea was defined as a cessation of respiration of any duration and was subdivided into central, mixed, and obstructive. Hypopneas were defined as a decrease of airflow of $\geq 50\%$ for 10 seconds associated with arousal or oxygen desaturation. A respiratory-event-related arousal was defined as a sequence of at least 2 flow-limited breaths (with flattening between 20% and 50%) leading to an arousal or oxygen desaturation. RDI was defined as the number of apneas, hypopneas, and respiratory-event-related arousals per hour of total sleep.

Pressure and respiratory information derived from AutoScan 3.0 software was reviewed and analyzed (ResMed). The following

parameters were obtained from the software: 95% centile pressure (pressure exceeded only in 5% of the night), leak amount, and hours of usage.

RESULTS

Characteristics and baseline sleep study information of the patients are presented in Table 1. The total population studied consisted of 14 subjects. The most common clinical complaints of the patients were snoring, restless sleep, witnessed apneas, nose congestion, oral breathing during sleep, drooling, and nasal congestion (71%). Of 14 patients, 6 (42%) reported feeling unrefreshed when waking up in the morning, and 5 complained of daytime sleepiness (35%).

Statistical Analysis

Baseline results were compared with titration night results by using Wilcoxon's paired signed test (SPSS 7.5 statistics software, Chicago, IL).

Treatment Night With Auto-CPAP

The results of sleep study performed with Auto-CPAP are presented in Table 2. Data are summarized with means and SD in Fig. 1 and Table 3. On the treatment night, there was a significant improvement in RDI and oxygen saturation compared with baseline studies, with a decrease in RDI and increase in oxygen saturation nadir (Figs. 2 and 3).

All the subjects had an improvement in the RDI on Auto-CPAP. Of the total group of 14 subjects, 8 showed a decrease of the RDI to <1 event per hour with AutoSet T. The remaining 6 subjects with improvement had an RDI of >1 event per hour. The latter group had a significant amount of mask leak that was detected by the technologist and confirmed by the software.

The mean lowest oxygen saturation improved from 86% to 93.6% (Table 3). The mean sleep efficiency of the baseline study was 84.8% and remained at a similar level on the treatment night (mean: 86%) (Table 3).

None of the subjects required a change from Auto-CPAP to fixed-pressure CPAP because of persistence of abnormal breathing vents. There was 1 subject who did not seem to tolerate Auto-CPAP, but when

TABLE 1. Subjects Demographics and Anthropometric Data

Subjects	Age	Gender	Body Mass Index, kg/m ²
1	8 y	Male	26.1
2	8 y	Male	15.2
3	6 y	Female	16.7
4	11 y	Male	15.8
5	5 y	Male	26.5
6	7.2 y	Male	16.8
7	8 mo	Female	19.4
8	4 y	Male	15.4
9	8 y	Female	28.4
10	12 y	Male	21.6
11	6 y	Male	17.2
12	6 y	Male	15.0
13	12 y	Male	32.0
14	12 y	Male	16.8

The mean age was 7.6 y (SD: 3.3) and the mean body mass index was 20.2 kg/m² (SD: 5.7).

TABLE 2. Polysomnographic Studies Values

Subjects	RDI, events/h		Lowest Sao ₂ , %	
	Baseline	Treatment	Baseline	Treatment
1	8.2	5.9	85	91
2	27.1	3.7	95	96
3	7.7	0	74	87
4	8.9	0.4	95	92
5	1.4	1.2	92	97
6	3.8	0	95	92
7	7.9	0	92	94
8	40.67	3.4	93	92.7
9	11	0.3	89.5	98
10	2.3	0	88	96
11	4.5	0.6	94	94.6
12	5.8	3.6	78	95.9
13	35	4.9	84	95.9
14	9	7.7	87.7	96.6

The mean RDI was 12.6 (SD: 12.4) and 2.6 (SD: 2.7) for baseline and on the treatment night, respectively. The mean lowest Sao₂ was 86 (SD: 10.8) and 93.6 (SD: 3.9) for baseline and on the treatment night, respectively.

she was switched to conventional CPAP, she did not tolerate that either. This subject's results were excluded from the data analysis. All other subjects tolerated the Auto-CPAP throughout the night. Overall, subjects accepted the Auto-CPAP well and slept with the device for at least 7 hours (mean: 8:35 hours).

The mean 95th centile pressure was 9.7 cm H₂O, and the mean maximal pressure was 11 cm H₂O. Mean hours of usage was 8:35 hours.

Auto-CPAP software (AutoScan) analysis results for RDI were significantly higher (mean: 10.43; SD: 5.5) compared with manually scored values on the polysomnogram in most of the patients (mean: 2.6; SD: 2.7).

The most frequent problem encountered during the night was related to the fit of an appropriated sized mask. Several mask types had to be tried after a period of initial observation during the sleep study. After changing the mask, the problem was resolved.

DISCUSSION

Previously published reports of Auto-CPAP treatment for SRBDs have only studied adults. In adults, Auto-CPAP has been found to be effective in specific clinical settings.¹⁷ There are no previous studies evaluating the use of Auto-CPAP in children.^{18,19}

SRBDs have a high prevalence in children and can result in significant problems if not addressed properly. Although adenotonsillectomy is the most common treatment, it does not always resolve the problem completely. CPAP treatment is an alternative treatment to surgery in situations for which additional surgery is not indicated or available. CPAP may offer a temporary solution until other treatment options are available.

The results show that the Auto-CPAP overall was well tolerated. The mean sleep efficiency on the baseline study was 84.8% and remained at a similar level on the treatment night (mean: 86%). If the device was not tolerated, the sleep efficiency would have been expected to decrease, especially considering the first-night effect of CPAP initiation. As mentioned above,

RDI BASELINE AND TREATMENT

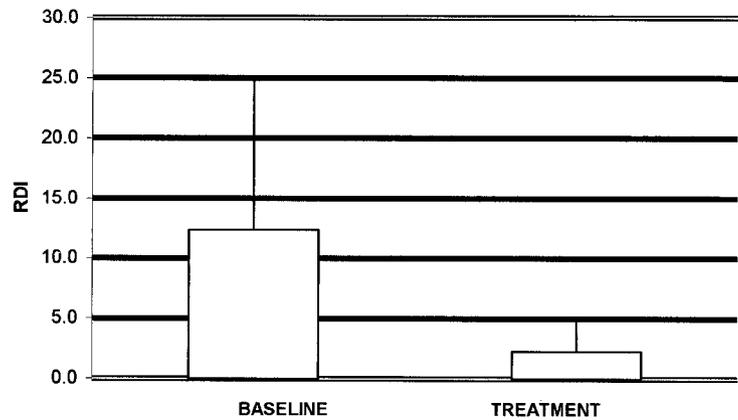


Fig. 1. Mean and SD values of AHI at baseline and after the titration night for all subjects.

TABLE 3. Polysomnographic Results

	Baseline, Mean (SD)	AutoSet T (Manually Reviewed)
RDI baseline, events/h	12.4 (12.4)	2.3 (2.6)*
Lowest O ₂ saturation, %	86 (10.8)	93.6 (3.9)*
Sleep efficiency, %	84.8 (7.2)	86.8 (7)
Sleep latency, min	10.4 (13)	6.7 (7.5)

* $P < .05$.

the 1 child that was excluded because of difficulty tolerating the AutoSet also was unable to tolerate conventional CPAP. This intolerance was felt by the technologist staff to be caused by the mask fit.

Auto-CPAP did not eliminate all the abnormal respiratory events. In subjects 1 and 14 the final RDI improved but remained >5 events per hour (5.9 and 7.7, respectively). We suspect that this was because of problems with the masks leaking, which illustrates the importance of follow-up and possible need for retitration in some patients.

Auto-CPAP can be an alternative treatment for SRBDs in the pediatric population. These results allow for speculation of possible applications for Auto-CPAP in children. An advantage of Auto-CPAP includes permitting the initiation of treatment while awaiting a standard CPAP titration. The variable pressure response of Auto-CPAP allows for treatment under different situations such as upper airway infections, different sleeping positions, and changes in weight. As the child grows, the amount of positive pressure needed to maintain airway patency may change. Auto-CPAP may be able to adjust to these changing pressure requirements. Auto-CPAP does not eliminate the need for periodic office visits and evaluations of the clinical course.

Our results demonstrate that Auto-CPAP is safe, well tolerated, and effective in giving the appropriate pressure for children with SRBDs in an attended setting. Special attention should be given to appropriate mask fitting, because Auto-CPAP will increase the pressure unnecessarily in the presence of a significant mask leak. The mask fit must be adjusted to prevent leak problems with Auto-CPAP to ensure appropriate treatment. Currently, there are few op-

tions for child-sized masks, and better development of equipment for this age group is necessary.

An analysis of RDI performed by the proprietary AutoScan software for the Auto-CPAP model used was different from the manually scored polysomnography values. There are probably 2 reasons for this discrepancy. The software performs the calculations based on specific masks of the same brand of the CPAP machine. Most of the patients (80%) in this study had to use masks of other brands for an adequate mask fitting, and we had to use masks from different sources. The results of the software analysis probably were unreliable because of the use of different mask types. The software also seems to score brief postarousal central events that inflate the post-treatment RDI. These brief postarousal events are not typically scored as abnormal when the studies are scored manually. Based on our results, use of the Auto-CPAP device's software to score abnormal respiratory events in children should not be relied on without reviewing the data manually.

This study was designed to evaluate Auto-CPAP titration in an attended environment. It did not indicate information about the effectiveness in an unattended setting. We demonstrate that Auto-CPAP is able to detect abnormal breathing events during sleep in children and may provide the necessary pressure to correct those events. Auto-CPAP can be used safely for pressure titration in an attended setting.

Auto-CPAP devices from different manufacturers are commercially available for adults. These different devices may have different algorithms and sensitivities to detect abnormal breathing episodes. For example, some devices use vibration and some use airflow to determine the pressure. This study was performed by using only 1 specific model of Auto-CPAP. Our results should not be extrapolated to other Auto-CPAP devices without empirical confirmation of the devices' ability to detect and correct events in children.

More studies are necessary to evaluate the use of Auto-CPAP in an unattended or home setting. If the use of Auto-CPAP is found to be safe and effective in an unattended setting also, then Auto-CPAP would allow faster application of positive airway pressure.

RDI

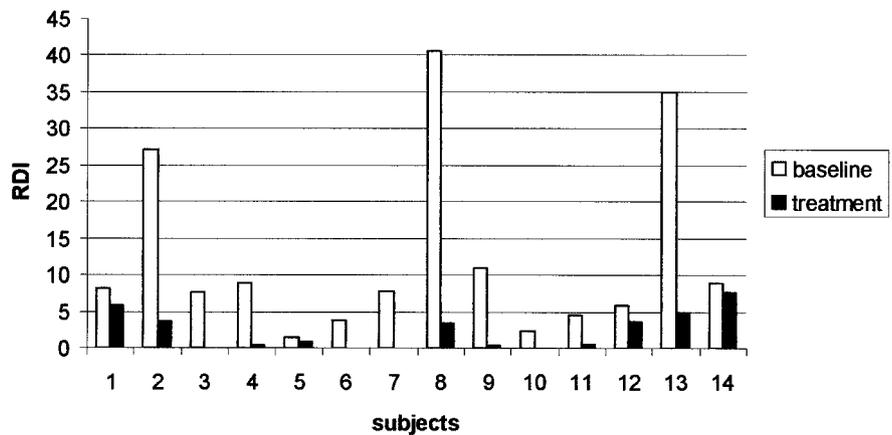


Fig. 2. Individual patient values of RDI at baseline and on the Auto-CPAP-titration night.

Oxygen saturation

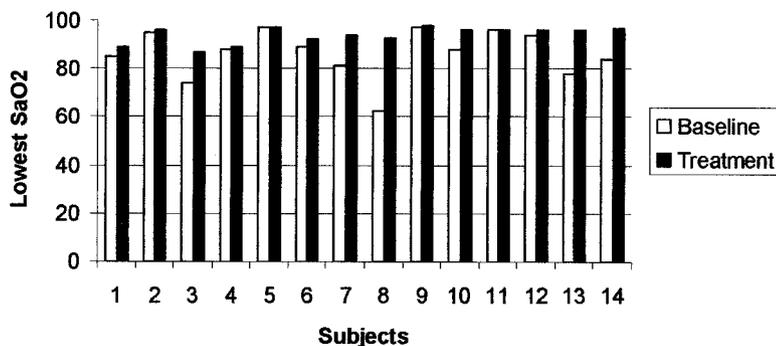


Fig. 3. Individual values of the lowest oxygen saturation at baseline and after titration with AutoSet T.

There probably will remain a need for an attended sleep study to evaluate the effectiveness of treatment in the individual patient after the Auto-CPAP is initiated. The Auto-CPAP would serve as a bridge until the attended study was available. Additionally, the clinical experience with Auto-CPAP and the retained memory of the pressure range and mean used may facilitate individually tailoring the attended CPAP titration.

Problems with mask fitting are well known in the adult setting. These problems seem to be greater in children. Masks that are appropriate for different-sized patients need to be developed and validated with the Auto-CPAP device and any associated software applications. Monitoring of facial development and growth is important when using these masks. Mask-fitting problems are compounded in children for several reasons. First, as the child grows, the mask size may need to be changed, and there are relatively few sizes available for children. Second, the child may not understand the importance of treatment and may not be cooperative with the mask fitting. If the child's ability to communicate is limited, then finding a comfortable mask is more difficult. Also, adult patients are able to make minor adjustments to their mask during the course of the night when the mask shifts position because of movement or brief arousals. If the child has difficulty doing this or requires assistance to adjust the mask

during the night, it can be problematic. Finally, a possibility of pressure on the maxilla from the mask influencing facial development requires periodic evaluation. Because of these reasons, even if Auto-CPAP is found to be safe and effective for home use children, it still will need to be monitored by experienced clinicians with regular follow-up visits.

Auto-CPAP has the potential to allow greater access to treatment for children with sleep-disordered breathing while at the same time allowing them to sleep in their own homes, which would be welcomed by both the children and their parents.

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