



## Comparison of diagnostic reliability of out-of-center sleep tests for obstructive sleep apnea between adults and children



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### ARTICLE INFO

#### Article history:

Received 22 September 2016

Received in revised form

8 January 2017

Accepted 10 January 2017

Available online 12 January 2017

#### Keywords:

Obstructive sleep apnea

Out-of-center sleep test

Pulse oximetry

Polysomnography

Children

Adenotonsillectomy

### ABSTRACT

**Objectives:** Sleep studies for diagnosing obstructive sleep apnea (OSA) in children are laborious, expensive, inconvenient, and often not readily available. Out-of-center sleep test (OCST) devices have been studied for diagnosing OSA in adults, but few OCST studies have been done in children. The purpose of this study was to clarify the diagnostic reliability of OCST devices for children.

**Methods:** OCSTs using pulse oximetry and in-laboratory polysomnography (PSG) were performed separately in 686 adults and 119 children. For each apnea–hypopnea index (AHI) measured with PSG, accuracy, sensitivity, specificity, positive/negative likelihood ratio (PLR/NLR), and positive/negative predictive value (PPV/NPV) were calculated for several cutoff values of 3% oxygen desaturation index (ODI) measured with OCST and analyzed.

**Results:** For definitive diagnosis in adults, the specificity, PLR, and PPV with a cutoff value of OCST-ODI 20/h were 98.3%, 29.26, and 97.4%, respectively, to detect PSG-AHI  $\geq 20$ /h. Corresponding values with a cutoff value of OCST-ODI 15/h were 99%, 46.19, and 99.6% to detect an AHI  $\geq 5$ /h. For exclusive diagnosis (screening) in adults, sensitivity, NLR, and NPV with a cutoff value of OCST-ODI 5/h were 96.4%, 0.068, and 91.9% to detect PSG-AHI  $< 20$ /h and 84.1%, 0.21, and 45.9% to detect PSG-AHI  $< 5$ /h. For definitive diagnosis in children, the corresponding values with a cutoff value of OCST-ODI 25/h were 98.6%, 16.0, and 90.9% to detect PSG-AHI  $\geq 10$ /h and 98.1%, 8.281, and 90.9% for PSG-AHI  $\geq 5$ /h. For exclusive diagnosis in children, with a cutoff of OCST-ODI 10/h, the corresponding values were 62.2%, 0.446, and 78.2% to detect PSG-AHI  $< 10$ /h, 45.3%, 0.674, and 55.1% for PSG-AHI  $< 5$ /h, and 34.0%, 0.908, and 10.3% for PSG-AHI  $< 1$ /h. Statistical data of preschool children tended to be worse than those of school age children.

**Conclusions:** In adults, OCST is reliable for the definitive diagnosis of AHI  $\geq 20$ /h or  $\geq 5$ /h and the exclusive diagnosis of AHI  $< 20$ /h. However, in children, OCST should not be used alone for the definitive diagnosis or exclusive diagnosis.

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### 1. Introduction

Pediatric obstructive sleep apnea (OSA) can result in significant neurocognitive, cardiovascular, and craniofacial consequences. In a recent population study, the prevalence of OSA with apnea–hypopnea index (AHI)  $\geq 1$ /h was 3.5% in elementary school children aged 6–8 years and 12.8% in preschool children [1,2]. In-laboratory polysomnography (PSG) is the gold standard for diagnosing OSA in children. However, it is labor-intensive and requires

specialized expertise. Sleep laboratory resources are limited and are not readily available in every district, resulting in long wait times. To address this clinical issue with limited health care resources, out-of-center sleep test (OCST) devices have become an alternative diagnostic tool in clinical practice for children with suspected OSA. Type 4 pulse oximetry devices are potentially more convenient than type 3 devices for OCST examination. According to the clinical guideline of the American Academy of Sleep Medicine (AASM), OCST may be indicated to monitor the response to non-continuous positive airway pressure (CPAP) treatments for OSA, including oral appliances, upper airway surgery, and weight loss for adult patients [3]. OCST may be used to monitor the efficacy of therapies other than CPAP when the diagnosis of OSA has already been made, either through OCST or in-laboratory PSG [3]. After the

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publication of this clinical guideline, OCST became a recognized diagnostic tool for adult patients with OSA in the International Classification of Sleep Disorders 3rd edition (ICSD-3) and the recent AASM scoring manual [4,5].

There have been many previous investigations to evaluate the capability of OCST devices for adults, but few studies have been performed in children. This study sought to clarify the diagnostic reliability of OCST devices for children by comparing the results with the diagnostic gold standard PSG and with the results of OCST and PSG in adults.

## 2. Methods

Type 4 pulse oximetry OCST and type 1 in-laboratory PSG were performed separately in 686 adults (540 men, 146 women; mean age  $47.9 \pm 14.0$  [range, 12–88] years; body mass index (BMI)  $25.7 \pm 5.7$  [14.2–51.8]  $\text{kg}/\text{m}^2$ ; AHI  $31.9 \pm 28.2$  [0–147.5/h]; prior probability of OSA, 84.8%) and 119 children (77 boys, 42 girls; age  $7.0 \pm 2.6$  [4–12] years; AHI  $12.8 \pm 17.6$  [0–94.6/h]; prior probability of OSA, 90.6%). Type 4 pulse oximetry preceded the PSG study in all subjects. Subjects with clinical symptoms such as snoring or excessive daytime sleepiness (EDS), or anthropometric findings such as obesity or enlarged tonsils, were referred (or self-referred) to our outpatient clinic. The Ethics Committee of Teikyo University approved this study, and informed consent was obtained from all subjects (approval number 15–194).

For OCST examination, patients were instructed on the use of home pulse oximetry (PMP-200GplusX, Philips Respironics, Pittsburgh, PA) through one-on-one instruction with a sleep technologist. A pulse oximeter was attached to the subject's finger using a flexible probe. The data obtained were fed into a personal computer, and the signals were digitalized and recorded using the package software. The graphic display shows oxygen saturation (50–100%) against time with 10 data points per minute, each point representing the lowest saturation in a 6-s interval. Baseline saturation was defined as the mean saturation in the previous minute. The algorithm sequentially scans each recorded oxygen saturation value, and if the lowest oxygen saturation value is  $\geq 3\%$  lower than the baseline oxygen saturation, the program assigns an event marker as a 3% desaturation event. We set 3% desaturation as the index criteria of ODI for OCST according to the home sleep apnea testing rules of the AASM scoring manual [5]. Records were manually reviewed for all patients by sleep specialists. The 3% oxygen desaturation index (ODI) was calculated by dividing the total number of 3% oxygen desaturation events by the total monitoring time. Monitoring time was defined as total recording time minus periods of artifact and time the patient was awake [5]. In most cases, type 4 pulse oximetry was performed for two nights. For patients with multiple measurements by OCST, the higher ODI was included in the analyses.

For the subsequent PSG study, type 1 in-laboratory overnight PSG (Alice 6, Philips Respironics, Pittsburgh, PA) was conducted as described in our previous report and in accordance with the AASM scoring manual Ver. 2.3 [5,6].

### 2.1. Statistical analysis

Accuracy, sensitivity, specificity, positive/negative likelihood ratio (PLR/NLR), and positive/negative predictive value (PPV/NPV) were analyzed at each cutoff value of OCST-ODI for PSG-AHI 20/h and 5/h for adults and for PSG-AHI 10/h, 5/h, and 1/h for children. All statistical analysis was performed using BellCurve for Excel (SSRI Co., Ltd., Tokyo, Japan).

## 3. Results

No subjects were diagnosed as having central sleep apnea (CSA) as assessed by PSG in both adults and children. The areas under the curve (AUCs) for PSG-AHI 20/h and 5/h for adults were 0.90 and 0.88, respectively (Fig. 1). The AUCs of PSG-AHI 10/h, 5/h, and 1/h for children were 0.80, 0.67, and 0.60, respectively (Fig. 2; data for AHI 1/h are not shown).

### 3.1. Definitive diagnostic capability of OCST-ODI for PSG-AHI $\geq 20$ /h or $\geq 5$ /h in adults

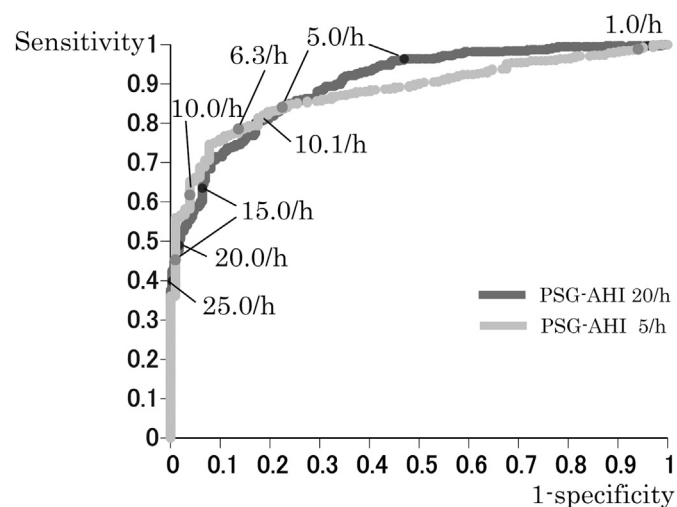
The specificity, PLR, and PPV with an OCST-ODI cutoff of 20/h were 98.3%, 29.26, and 97.4%, respectively, to detect PSG-AHI  $\geq 20$ /h for adult patients with suspected OSA (Fig. 1 & Table 1). Corresponding values with an OCST-ODI cutoff of 15/h were 99%, 46.19, and 99.6% to detect PSG-AHI  $\geq 5$ /h (Fig. 1 & Table 2).

### 3.2. Exclusive diagnostic capability of OCST-ODI for PSG-AHI $< 20$ /h or $< 5$ /h in adults

The sensitivity, NLR, and NPV with an OCST-ODI cutoff of 5/h were 96.4%, 0.068, and 91.9% to detect PSG-AHI  $< 20$ /h and 84.1%, 0.21, and 45.9% to detect PSG-AHI  $< 5$ /h for adults (Fig. 1, Tables 1 and 2). These results suggest that 8.1% and 54.1% of adults who tested negative by OCST had PSG-AHI  $\geq 20$ /h and  $\geq 5$ /h, respectively. Thus, the OCST can be used with care for exclusive diagnosis (for screening) of AHI  $< 20$ /h. However, the OCST should not be used to exclude OSA in adult patients with AHI  $\geq 5$ /h.

### 3.3. Definitive diagnostic capability of OCST-ODI for PSG-AHI $\geq 10$ /h or $\geq 5$ /h in children

The specificity, PLR, and PPV with an OCST-ODI cutoff of 25/h were 98.6%, 16.0, and 90.9%, respectively, to detect PSG-AHI  $\geq 10$ /h and 98.1%, 8.281, and 90.9% to detect PSG-AHI  $\geq 5$ /h in children with suspected OSA (Fig. 2, Tables 3 and 4). These results mean that 9.1%



**Fig. 1.** Receiver operating characteristic (ROC) curves of PSG-AHI 20/h and 5/h for adults. The higher the cutoff value, the higher specificity becomes, meaning that this cutoff would be more suitable for definitive diagnosis. Conversely, the lower the cutoff value, the higher sensitivity becomes, meaning that this would be more suitable for exclusive diagnosis. ODI 10.1/h and 6.3/h were the cutoff points at the highest accuracy for PSG-AHI 20/h and 5/h, respectively. The areas under the curve (AUCs) for PSG-AHI 20/h and 5/h for adults were 0.90 and 0.88, respectively. Dark gray: PSG-AHI 20/h; light gray: PSG-AHI 5/h.

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