Evaluation of a New Device for Home Cardiorespiratory Recording in Children

Patrick J. P. Poels, MD; Anne G. M. Schilder, MD, PhD; Sandra van den Berg, RN; Arno W. Hoes, MD, PhD; Koen F. M. Joosten, MD, PhD

Objective: To evaluate the feasibility of using a new home cardiorespiratory recording device (HCRD) in children.

Design: Cross-sectional study.

Patients: Consecutive children scheduled for adenotonsillectomy to treat habitual snoring and/or apneas at otorhinolaryngology clinics in 2 academic and 7 general hospitals.

Intervention: Single-night unattended home cardiorespiratory recording prior to adenotonsillectomy using the HCRD.

Main Outcome Measures: Number of technically acceptable recordings and successful recordings with artifact-free signals (respiration, saturation, and nasal flow) present for sufficient duration to allow scoring of the polysomnogram and to make a diagnosis.

Results: Of 53 eligible children, 24 participated in the study. The main reason for nonparticipation was refusal of caregivers (n=16). Mean (SD) age of participants was 4.2 (1.6) years; median Brouillette obstructive sleep apnea score was 2.54. Technically acceptable recordings were obtained in 18 children (75%). Only 7 recordings (29%) were classified as successful. The poorest signal quality was obtained from the nasal cannula.

Conclusion: Based on strict scoring criteria in this study, the results of single-night unattended recordings at home with the HCRD fell short of expectations.

come of the cardiorespiratory recording. Exclusion criteria were previous tonsil surgery, fever on the day of recording, neurologic or craniofacial abnormalities, and inability of caregivers to understand the Dutch language. All eligible patients were invited by a telephone call from 1 of us (P.J.P.P.) to participate. When interest was confirmed, the investigator arranged a home visit to explain the recording procedure. All caregivers gave written informed consent.

RECORDING DEVICE

The HCRD (Embletta PDS; Flaga hf Medical Devices, Reykjavik, Iceland) was used to record respiratory movement, nasal airflow (pressure transducer), heart rate (pulse), oxygen saturation, and body position (internal sensor) according to international guidelines.12 The recorded signals from the sensors were displayed in Somnologica version 3.0 (Flaga hf Medical Devices) as traces: thorax, nasal flow, pulse, oxygen saturation by pulse oximeter (SpO2), and gravity trace. We assessed the quality only of the thorax, nasal flow, and SpO2 traces because pulse signal and oxygen saturation were derived from the same sensor.

Caregivers were instructed how to place and remove all sensors, to start the HCRD by connecting the sensor adapter to the device at the usual bedtime, and to continue recording for about 14 hours. The day after the recording, the investigator revisited the caregivers and asked about problems with the device and the sensors. All children were scheduled for adenoidectomy regardless of the sleep study results, and no further cardiorespiratory recordings were planned.

POLYSOMNOGRAPHY

The minimum duration for overnight recordings on sleep apnea evaluation in adults is 360 minutes,13,14 but for children no such criteria are set.13,14 We chose a minimum duration of 390 minutes recorded total sleep time (TST) as the criterion for a technically acceptable recording. The TST was defined as the period between the beginning and the end of sleep as determined by the regularity of the breathing pattern and measured by respiratory movement and body position.

Within the TST, the duration of time with artifacts (ie, non-interpretable signal for at least 2 minutes) was determined per trace separately. Then the duration of artifact-free signal present simultaneously in the 3 examined traces was determined. Successful recordings were those with 390 minutes of artifact-free signal present in 3 traces simultaneously within the TST. Only for successful recordings were the apnea-hypopnea index (AHI) and oxygen desaturation index (ODI) calculated manually. The AHI was calculated as the number of apneas (obstructive, central, and mixed) and hypopneas per hour of artifact-free TST. The ODI was calculated as the number of desaturations per hour of artifact-free TST.

Apnea was defined as a reduction in the airflow signal to below 10% of the reference amplitude for at least 10 seconds. Hypopnea was defined as a reduction in airflow signal to below 50% of the reference amplitude for at least 10 seconds. Oxygen desaturation was defined as either a 4% or greater decline in oxygen saturation or any saturation below 90% for at least 10 seconds. According to Guilleminault et al,13 mild OSAS is defined as an AHI ranging from 1 to 5, moderate OSAS as an AHI ranging from 6 to 25, and severe OSAS as an AHI of more than 25.

STATISTICAL ANALYSIS

Recordings were evaluated separately by 2 of us (P.J.P.P. and S.v.d.B.) who are experienced in assessing cardiorespiratory recordings. Interobserver agreement was tested in a random sample of 8 recordings evaluated by both investigators for duration and location of artifacts. For normally distributed data, results were expressed as the mean (SD). For data that was not normally distributed, results were expressed as median and interquartile ranges. The interobserver variability was assessed using the Cohen k value.15 The study protocol was approved by the institutional medical ethical review board of the University Medical Center Utrecht.

RESULTS

Of 53 eligible children, 24 (45%) participated in the study. Reasons for nonparticipation were refusal of caregivers (n = 16), adenotonsillectomy no longer indicated after a treatment with antibiotics (n = 3), and logistic reasons (n = 10) (eg, surgery scheduled before recording could be planned). Most of the participants had moderate to severe adenotonsillar hypertrophy (Table).

The HCRD was installed in 24 homes. The recording results proved to be technically acceptable in 18 (75%) of these 24 cases. Six of the recordings failed: in 2 cases, technical problems caused the failure; in 2 cases, the children did not tolerate the sensors; and in 2 cases, the caregivers switched off the recording prematurely. The mean (SD) age of these 6 children was 3.7 (1.4) years. Among the 18 technically acceptable recordings, 7 were successful by our definition of 390 minutes of artifact-free signal present in 3 traces simultaneously. The mean (SD) age of these 18 children was 4.3 (1.6) years. For these 7 recordings, the AHI and ODI of the 1 child with severe OSAS were 26.5 and 11.3, respectively; for the 1 child with moderate OSAS, 20.3 and 13.3, respectively; and for the 5 children diagnosed as having mild OSAS, from 0 to 2.8 and from 1.1 to 3.7, respectively.

Most artifacts were found in the nasal flow trace. For the 18 technically acceptable recordings, the median cumulative duration (interquartile range) with artifacts in the traces was 12.5 minutes (0-22.3 minutes) in the thorax trace, 14.0 minutes (0-406 minutes) in the SpO2 trace, and 218 minutes (62.3-459.8 minutes) in the nasal flow trace. In 8 of the 18 recordings, the duration of time with artifacts in the nasal flow traces was between 50% and 100% of the recorded TST.
Fourteen (58%) of 24 caregivers reported that the nasal cannula caused irritation. The oximetry sensor caused difficulties in 7 recordings. In 3 cases, the connection between the sensor and the sensor adapter was lost. In 3 recording procedures the respiratory sensor shifted from the chest to the abdomen.

Interest in home-based PSG is growing because hospital-based PSG is costly and time-consuming. To replace hospital-based PSG, however, the home-based monitoring device should be reliable and well tolerated by the children. In the present study with the Embletta PDS HCRD, despite careful instructions, only 7 of the 24 recordings were successful. All of these children had some degree of OSAS.

Only 45% of the caregivers agreed to participate in our study. Jacob et al reported a similar participation rate of 53%. The participants in our study were older and had higher obstructive sleep apnea scores than the non-participants. As a result of our selection criteria, a high proportion of positive tests (OSAS present) could be expected among the participants, but this does not necessarily influence the feasibility of home recordings. It is likely that similar selection would play a similar role in everyday practice.

In contrast to the use of the sensors of this HCRD in adults, children did not tolerate these sensors well, or they were attached inadequately despite careful oral and written instructions to the caregivers. Like Goodwin et al, we found the nasal cannula to cause the most discomfort and produce the most artifacts. Apparently, the attachment procedure as a whole at home is demanding for the children and the caregivers. We believe that the tolerance of the sensors could be improved if the children would sleep with the nasal cannula for a few days before the actual recording to grow accustomed to it being in place.

Contrary to reports on the effective use of portable systems for diagnosing adult OSAS, detailed reports on HCRDs for childhood OSAS are scarce, and definitions of successful recordings and duration of artifact-free signal vary greatly. We chose a rather strict level of 390 minutes with artifact-free signal in 3 traces simultaneously because (1) we could not interpret artifacts because we had no video recording, electroencephalogram, or electromyogram, and (2) the software we used did not discriminate between the parts of the recording to be rejected and those to be analyzed. This latter ability would have been desirable because the plethora of artifacts ruled out automatic analyses.

Jacob et al reported an 83% success rate but did not provide a definition of a successful study; all successful recordings were classified as interpretable. Goodwin et al reported an initially technically successful recording rate of 91%. In their study, a minimum of 240 minutes of artifact-free signal was considered sufficient compared with 390 minutes in our study. Naturally, if we would have used less strict criteria, our percentage of successful recordings would also have been higher than the current 29%, but this would make our study less sensitive.

Another explanation for the difference between the present results and those of Goodwin et al is that Goodwin et al used older children (aged 5-12 years). However, in accordance with Goodwin et al, we also found that the results of technically acceptable recordings were better among older children: the mean (SD) age of the participants with a successful recording was 5.4 (1.3) years vs 3.6 (1.3) years for unsuccessful recordings.

Probably the most important explanation for better results in the studies of Jacob et al and Goodwin et al is that the equipment in those earlier studies was set up by a qualified technician. This has been shown to improve the success rate. We chose to instruct the caregivers to set up the equipment to reflect daily practice, but apparently this resulted in more technical problems. A controlled study with a larger sample size should be performed to compare the use of the HCRD with help of caregivers vs technicians.

Important in this context is a discussion about the costs of home-based PSG vs hospital-based PSG. In the Netherlands, this comparison was undertaken recently in a project sponsored by the government (SENTER [Agency of the Dutch Ministry of Economic Affairs], the Netherlands, 2001). The costs of home-based PSGs were found to be 150 Euro less per measurement than those of hospital-based PSGs, and, even more important, bed availability in the pediatric intensive care ward improved.

Based on the literature and our present finding that the oximeter sensor gave the best results, nocturnal pulse oximetry could be very useful as a first screening modality in children. Pulse oximetry is easy to apply, reliable, and inexpensive.

In conclusion, HCRD use to evaluate OSAS in children scheduled for adenotonsillectomy is not very effective. Under the conditions of our study, which were designed to reflect everyday real-life conditions, the device is of only limited use.

Submitted for publication October 3, 2002; final revision received April 4, 2003; accepted April 25, 2003.

Flaga hf Medical Devices (Reykjavik, Iceland) provided the Embletta PDS HCRD system and technical support for its use in this study.

Parts of this article were presented at the Eighth International Congress of Pediatric Otorhinolaryngology (ESPO 2002); September 13, 2002; Oxford, England.

We thank the ORL surgeons of the participating hospitals for referring their patients. We also thank Peter N. A. Zutthoff, MSc, for statistical help.

Corresponding author and reprints: Anne G. M. Schilder, MD, PhD, Department of Otorhinolaryngology, Wilhelmina Children’s Hospital, University Medical Center Utrecht, KE 04.139.1, PO Box 85090, 3508 AB Utrecht, the Netherlands (e-mail: A.Schilder@wkz.azu.nl).
REFERENCES

1. Teculescu DB, Cailier I, Perrin P, Rebstock E, Rauch A. Snoring in French pre-
2. Ali NJ, Pitson DJ, Stradling JR. Snoring, sleep disturbance, and behaviour in 4-5
3. Suen JS, Arnold JE, Brooks LJ. Adenotonsillectomy for treatment of obstruct-
530.
4. Stradling JR, Thomas G, Warley ARH, Williams P. Freeland A. Effect of adeno-
tonsillectomy on nocturnal hypoxaemia, sleep disturbance, and symptoms in snor-
5. Peppard PE, Young T, Patla M, Skatrud J. Prospective study of the association
1378-1384.
6. Marcus CL, Greene MG, Carroll JL. Blood pressure in children with obstructive
7. Ramakrishna S, Ingle VS, Patel S et al. Reversible cardio-pulmonary changes due
8. Guilleminault C, Pelayo R, Clerk A, Leger D, Bocian RC. Home nasal continuous
positive airway pressure in infants with sleep disorder breathing. J Pediatr. 
9. Siegel S. Nonparametric Statistics for the Behavioral Sciences. 2nd ed. Sin-
10. Jacob SV, Morielli A, Mograss MA, Ducharme FM, Schloss MD, Brouillette RT.
Home testing for pediatric obstructive sleep apnea syndrome secondary to ad-
11. Van Someren V, Burmester M, Alusi G, Lane R. Are sleep studies worth doing?
Arch Dis Child. 2000;83:76-81.
12. Golpe R, Jiménez A, Carpizo R. Home sleep studies in the assessment of sleep
13. Saeed M, Keens TG, Stabile MW, Bolokowicz J, Davidson Ward SL. Should chil-
dren with suspected obstructive sleep apnea syndrome and normal nap studies
have overnight sleep studies? Chest. 2000;118:360-365.
14. ASDA Standards of Practice Committee, Practice parameters for the use of por-
table recording in the assessment of obstructive sleep apnea. Sleep. 1994;17:
372-377.
15. American Thoracic Society. Standards and indications for cardiopulmonary sleep
17. Marcus CL, Greene MG, Caroll JL. Blood pressure in children with obstructive
18. Marcus CL, Greene MG, Caroll JL. Blood pressure in children with obstructive
19. Marcus CL, Greene MG, Caroll JL. Blood pressure in children with obstructive
20. Marcus CL, Greene MG, Caroll JL. Blood pressure in children with obstructive