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Original Article

Monitoring noninvasive ventilation in neuromuscular patients: feasibility of unattended home polysomnography and reliability of sleep diaries

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ABSTRACT

Background: In-hospital polysomnography (PSG) often is performed to monitor neuromuscular patients under noninvasive ventilation (NIV), but success of home PSG has not been established for that purpose. Reliability of sleep diaries in neuromuscular patients is unknown. The aims of our study were to evaluate feasibility, quality, and acceptability of unattended home PSG, as well as the reliability of sleep diaries in neuromuscular patients on long-term NIV.
Methods: Fifty-two neuromuscular patients underwent unattended home or hospital PSG during NIV. Patients were questioned about their sleep during the PSG and their attitudes towards the procedure.
Results: One home and one hospital PSG were scored as failure or low quality due to prolonged signal loss or sleep duration of <3 h. Objective and subjective sleep duration and efficiency often showed large differences. Subjective awakenings reflected objective awakenings lasting for >4 min in 86.5% patients. Preference for home PSG was expressed by 82% subjects.
Conclusions: In neuromuscular patients under NIV unattended home PSG is feasible and preferred, with a low failure rate. The degree of reliability of different parameters of subjective sleep assessment should be considered when used as a complement of nocturnal cardiorespiratory recordings.

1. Introduction

Sleep-disordered breathing (SDB) is observed in patients with neuromuscular disorders at various times after diagnosis [1]. It precedes diurnal respiratory failure, which is an unfavorable prognostic marker. Characteristics and severity of SDB differ among patients, partially depending on the type of the neuromuscular disorder and the time after diagnosis. In Duchenne patients in particular a bimodal presentation of SDB has been described, with obstructive sleep apnea (OSA) in the first decade of life and hypoventilation in the second [2]. Nocturnal noninvasive ventilation (NIV) may abolish SDB and prevent or delay diurnal respiratory failure; in cases in when SDB is already present, NIV can alleviate or revert the condition. In addition, NIV alleviates dyspnea and improves performance in daily activities and health-related quality of life [3]. Nocturnal monitoring in neuromuscular patients is essential for identifying when NIV should be initiated and it should be performed routinely, as clinical features increase the suspicion of SDB [4,5]. Further, it is useful to confirm the appropriateness of ventilator setting, both when NIV is started and after its initiation to periodically control its efficacy and modify the setting if necessary. Recent studies have clearly demonstrated that abnormal sleep respiratory events may occur during NIV, even in stable neuromuscular patients on long-term ventilation. These events, mainly caused by air leaks or incorrect ventilator setting, can affect alveolar ventilation and sleep quality [6,7].

When considering nocturnal monitoring in neuromuscular patients, polysomnography (PSG) with continuous carbon dioxide (CO_2) monitoring is considered the best option, not only for diagnostic purposes but also for periodic controls during NIV application, as it allows the evaluation of respiratory disorders, gas exchange, sleep quality, and sleep architecture [8,9]. However, it has not yet been clearly established where this therapy should be performed, with laboratories, hospitals, and home environment being considered as potential settings. From a technical point of view, the laboratory environment is preferable, as a sleep technician is available to supervise patients; moreover, unattended recordings may be associated with unnoticed sensor failure and more often may need to be repeated [10]. However, being studied

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in a sleep laboratory can be challenging for certain patients with advanced neuromuscular disease and special medical needs who are more easily accommodated in specialized neuromuscular centers within hospitals. These centers provide specialized services, facilitating the mobilization of patients and making their stay more comfortable and safe. In such environments unattended PSG may be easily performed, but the procedure may require one night of hospitalization. Home PSG offers a more comfortable environment than hospitalization and enables sleep quality and NIV effects to be similar to those usually experienced by the patient [11]. However, one drawback of home PSG is that somewhat complex equipment must be brought into patients' homes and patients or their relatives may need to cooperate through manually starting and stopping the recording or calibrating the capnograph [12]. These matters raise questions if home PSG may be technically similar or worse than hospital PSG and if its advantages really overcome the disadvantages. To our knowledge, no previous study has assessed feasibility, accuracy, and acceptability of unattended PSG during NIV conducted in different settings among neuromuscular patients.

In addition to cost reduction, labor intensity, and time, another advantage may be found in the use of a home cardiorespiratory monitoring supplemented with detailed information on subjective sleep parameters [13]. In fact, neuromuscular patients also may report sleep concerns during NIV [14]. However, it is unknown if these subjective concerns reflect the objective sleep measures; if they do, this finding may suggest that objective sleep disturbances are possibly caused by inadequate ventilation, thus representing an inexpensive useful complement to cardiorespiratory monitoring. To address these questions, we performed a semirandomized parallel-group study in a relatively large sample of neuromuscular patients. Our first aim was to evaluate the feasibility, failure rate, acceptability, and possible preference of unattended home PSG compared to hospital PSG. As a secondary aim, we evaluated the reliability of subjective sleep parameters in the same patients.

2. Methods

From April 2011 to December 2011, 52 consecutive neuromuscular patients in a stable condition on long-term ventilation, defined as absence of respiratory exacerbations during the previous 2 months, who had been using NIV for more than 3 months, were assigned to two different groups according to their residential area. Group 1 included 26 patients who lived in Palermo, Italy, who were submitted to home PSG; group 2 included 26 patients who lived outside Palermo, Italy, who were studied using hospital PSG. Before inclusion, patients gave written consent to participate in our study. The protocol was approved by the ethics committee. Patients with severe concomitant diseases, mental retardation, or failing (or unable) to give their consent were excluded.

Standard unattended PSG was performed both at home and in the hospital. During the hospital recording, nurses controlled the patients at least twice per night and reapplied the mask, sensors, or electrodes that were displaced. Patients recorded at home were asked to call the technician to solve possible unexpected problems. Three unipolar electroencephalograms (EEGs) (one frontal, one central, and one occipital), right and left electrooculograms, and an electromyogram of the chin muscle for conventional sleep staging were recorded (SomnoLab 2 AASM, Weinmann, Hamburg, Germany). The same device and methodology were used in both settings and the same technician was engaged in the setup of both recordings. Parallel to the PSG recording, partial pressure transcutaneous CO_2 ($PtcCO_2$) was recorded with a SenTec Digital Monitor (software version SMB SW-V04.03). The V-SignTM Sensor was applied to the earlobe with a dedicated Ear Clip (SenTec AG, Therwil, Switzerland). The $PtcCO_2$ device was calibrated before and at the end of each recording to perform automatic drift correction, when necessary, and to improve interpretation of the $PtcCO_2$ values.

Sleep and arousals were scored according to American Academy of Sleep Medicine 2007 criteria [15]. Total sleep time (TST), sleep efficiency (SE) (defined as TST/total recording time $*$ 100), percentage of each sleep stage, and wake after sleep onset (WASO) were calculated. Arousals lasting >15 s were classified as awakenings. Two awakening indices (Aw/I) were calculated: one for all awakenings events lasting $\geqslant$15 s (total Aw/I) and one for events lasting $\geqslant$4 min (4Aw/I). Abnormal respiratory events were classified according to Gonzalez-Bermejo et al. [9]. Asynchronies were evaluated as previously described [16]. Asynchrony index was calculated as sum of all events per hour of sleep time. The following oxygen saturation (SaO_2) parameters were calculated: mean SaO_2, lowest SaO_2, time spent with SaO_2 <90% (T<90), and oxygen desaturation index (ODI) (number of oxygen desaturations $\geqslant$4%/hour). From the $PtcCO_2$ recordings, mean and peak $PtcCO_2$ were automatically calculated after manual elimination of artifacts.

All patients used the same ventilator (IdeaUltra ResMed) with an optional double-limb configuration incorporating an expiratory spirometer and with an appropriate nasal or oronasal mask. The ventilator was equipped with a built-in software (Easy diag Version 1.1.1, SAIME-RESMED, Savigny le Temple, France) for the recording and the measurement of several ventilation parameters, including mean nocturnal minute ventilation and leaks that were automatically calculated as percent differences between inspiratory and expiratory tidal volumes (Vti-Vte/Vti$*$100).

In the morning following the recording, night arterial blood gas values were routinely measured. Then patients were asked to answer a five-item questionnaire about their sleep during the previous night, including time they spent in bed with lights off (time in bed), time taken to fall asleep (sleep-onset latency [SOL]), amount of time spent awake during the night (WASO), total sleep duration (TST), and the number of perceived awakenings. Subjective SE was calculated as subjective TST/time in bed$*$100.

Patients also were asked how they would rate the quality of their sleep the previous night on a scale between 0 (very bad) and 10 (very good). Finally, they were asked how they rated acceptability of the procedure they had undergone (home or hospital PSG) using a visual analog scale from 0 to10 (0 = very bad and 10 = very good), as well as where they would have preferred to perform PSG if they could choose.

2.1. Data quality evaluation

Data were initially reviewed for technical quality and for evidence of abnormalities in breathing, heart rate, and SaO_2 that could require timely participant notification according to criteria for medical alerts (SaO_2 <88% for more than 5 min, $PtcCO_2$ >50 mmHg, heart rate <30 or >150 for more than 2 min). During preliminary review, each study was given an aggregate quality grade based on the overall interpretability and duration of artifact-free signals. Following preliminary review and automatic analysis by the device software, each study was assigned to a trained specialist for manual scoring of sleep and breathing. The quality of the recording was graded according to the criteria by Redline et al. [17], but definitions of fair or good studies were slightly modified to better adapt to requirements for interpretation of studies during NIV application (Table 1). Failure rate of recordings was evaluated as the sum of percentages of poor and unsatisfactory recordings and recordings with a TST of <3 h [18].

2.2. Statistical methods

Because our study was a pilot study, sample size considerations were not based on a predefined clinically significant difference