

Validation of a Telemonitoring System for Sleep Apnea Treatment

Valentina Isetta
University of Barcelona-CIBERES,
Faculty of Medicine
Unit of Biophysics and Bioengineering
Barcelona, Spain
valentina.isetta@ub.edu

Josep M. Montserrat
Sleep Lab, Pneumology Department,
Hospital Clinic-IDIBAPS-CIBERES,
Barcelona, Spain
jmmontserrat@clinic.ub.es

Geraldine Thiebaut
Air Liquide,
Paris, France
geraldine.thiebaut@airliquide.com

Claude Weber
Air Liquide,
Paris, France
claudeweber@airliquide.com

Daniel Navajas
University of Barcelona-IBEC-CIBERES,
Faculty of Medicine,
Unit of Biophysics and Bioengineering
Barcelona, Spain
dnavajas@ub.edu

Ramon Farré
University of Barcelona-IDIBAPS-CIBERES,
Faculty of Medicine,
Unit of Biophysics and Bioengineering
Barcelona, Spain
rfarre@ub.edu

Abstract—Patient's compliance is crucial for the effectiveness of continuous positive airway pressure (CPAP) treatment of obstructive sleep apnea (OSA), but many patients withdraw it due to its side effects. Air Liquide developed NOWAPI, a novel telemedicine system, which provides the CPAP treatment remote monitoring of the patient at home and is designed to be compatible with all CPAP devices under clinical use. The aim of this study was to validate NOWAPI in a bench test simulating OSA patients. First, the influence of NOWAPI sensor unit geometry to the CPAP treatment was assessed. Then, NOWAPI's performance in correctly detecting the treatment duration and the residual events was tested. Recorded data were wirelessly sent to a secure server by NOWAPI, then downloaded and analyzed. NOWAPI sensor unit connection to the setting did not influence the CPAP treatment. The difference between the treatment duration estimated by the device and actual values was never higher than 3 min over the 4-hour test. The difference between the apnea-hypopnea index (AHI) estimated by NOWAPI and the actual values was not significantly different from the one between the AHI estimated by the CPAP machines and the actual values ($p=0.171$). NOWAPI showed an excellent performance in this bench test and could be a valuable tool for telemonitoring the treatment of OSA.

Keywords: telemedicine; eHealth; home monitoring; sleep apnea; CPAP.

I. INTRODUCTION

Obstructive sleep apnea (OSA) is a very prevalent disease mainly associated with daytime sleepiness and deterioration of quality of life and is suffered by 2% to 4% of middle-aged adults [1]. OSA entails repetitive partial or total occlusion of the upper airway, which results in significant levels of sleep disturbance and snoring. However, the seriousness of untreated OSA is stressed by its significant consequences, including depression, ischemic heart disease, stroke, hypertension and significantly increased risk of motor vehicle crashes [2;3].

The treatment of choice for OSA is continuous positive airway pressure (CPAP) applied through a nasal mask during sleep. This constant pressure is transmitted to the pharyngeal area, thereby avoiding upper airway obstruction [4]. Despite the documented clinical efficacy of CPAP, up to 50% of patients suspend or underuse CPAP treatment, mainly due to its discomforting side effects, such as pressure intolerance, claustrophobic reaction to the mask, mask displacement, and machine noise [5;6]. Many of these problems could be easily solved by a closer follow-up, especially during the first weeks, but busy sleep centers have difficulties in giving such support.

If patients do not use CPAP for the recommended minimum of 4 hours per night, clinical outcomes are compromised [7], demonstrating that adherence optimization is a critical aspect of patient management.

Several studies confirmed that treatment compliance could be significantly improved by comprehensive support programmes and timely interventions by health professionals [8]. In recent times, it has been recognized that telemedicine could have a valuable role in improving CPAP therapy adherence [9]. In fact, telemedicine has been used in various studies to promote and reinforce CPAP treatment. In most of them a cognitive behavioural intervention was applied to OSA patients at home, by telephone [6], the Internet [10] and videoconference [11]. Despite mixed results were achieved in terms of significant improvement of CPAP compliance, the potential of telemedicine to be integrated into the care of OSA patients was confirmed.

Two recent randomized studies [12;13] combined elements of psychoeducational interventions together with technological innovation. Usual care was compared to a wireless telemonitoring of CPAP compliance and efficacy data, which physicians were able to daily monitor through a secure web browser and thus contact the patient if needed. Both studies resulted in higher CPAP adherence and improved OSA outcomes and demonstrated that continuous monitoring of patient's compliance could be useful to early detect underuse and to properly address possible problems.

Some existing CPAP and APAP (Automatic Positive Airway Pressure) devices monitor patient's compliance by using different algorithms, but only few of them offer continuous remote monitoring. Air Liquide developed NOWAPI, a telemonitoring system designed to be compatible with all commercially available CPAP/APAP devices. The aim of this study was to validate this new monitoring system in a bench test.

II. METHODS

A. System Description

NOWAPI system has been designed to remotely monitor the CPAP or APAP treatment of patients with sleep apnea at home. The system overview is depicted in Fig. 1. NOWAPI comprises a small sensor unit (15x4x7 cm) powered by a rechargeable battery, which contains a pressure and flow sensing module, a specifically developed detection software for the analysis of the measured signals and detection the breathing events, a GPRS communication module, which enables data transmission to a server, and a clinical interface,

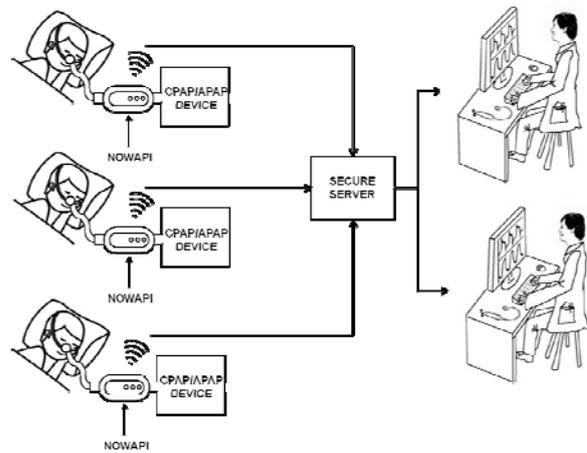


Figure 1. NOWAPI system data flow.

which enables the physician to visualize and properly evaluate the data downloaded from the server. The NOWAPI sensors unit is connected between the CPAP/APAP device outlet and the patient's tubing. During the patient's CPAP/APAP treatment, the system detects the pressure and flow signals which characterize the patient's breathing and estimates the treatment use rate and some important parameters to assess the effectiveness of the therapy, such as the number of apneas, hypopneas, flow limitations, snoring periods, and average breathing flow and nasal pressure. The system stores all data in 2 different files, a detailed file with a sampling rate of 25 Hz and a synthetic file where data are recorded as mean values over 15-minute consecutive periods. The latter file is sent by the GPRS module integrated into the device to a secure server then available to be downloaded and analyzed.

Furthermore, a led in the sensors unit turns red if the treatment duration is less than the minimum standard of 4 hours/night, giving an immediate useful feedback to the patient about his/her treatment compliance.

B. Patterns of disturbed breathing

NOWAPI was tested with 2 different sets of simulated breathing patterns. In the first phase, a series of 20 waveforms consisting of the successive repetition of apneic or hypopneic events or persistent flow limitation [14;15] was used.

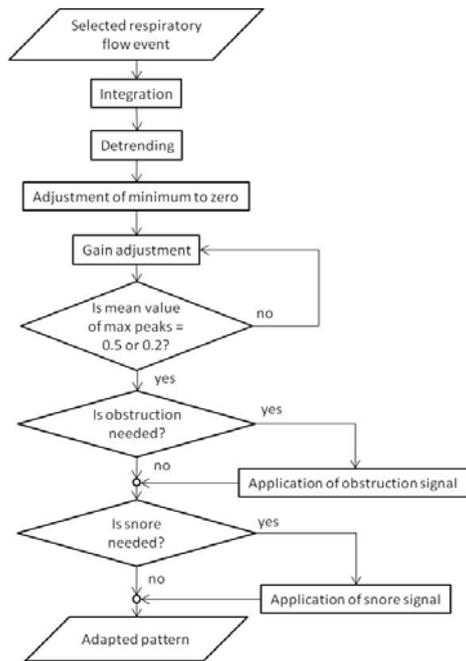


Figure 2. Block diagram of the algorithm implemented to obtain the breathing patterns simulating patients with OSA.

In the second phase, the system performance was tested in 30 different test scenarios especially developed for this study, simulating 30 sleep periods of OSA patients under CPAP treatment, lasting 4 hours each. These simulated breathings consisted of realistic airflow patterns built from a library of actual events (e.g. normal breathing, apneas, hypopneas, flow limitations) selected from real OSA patients' polysomnographic recordings. The selected events were exported by using the polygraph software with a sampling frequency of 64 Hz. Then, each event was properly elaborated by an algorithm implemented for this study. The block diagram describing the algorithm, developed by using Matlab computing tool, is shown in Fig. 2. First, the flow

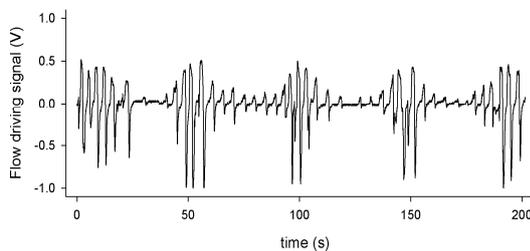


Figure 3. Fragment of a pattern of disturbed breathing which simulated an OSA patient's sleep periods of treatment.

event was integrated to obtain the volume signal. Then, the signal was detrended and adjusted in order to have the minimum signal point at zero. Then, to reproduce the typical tidal volumes for normal breathing (0.5 l approx) and hypopnea (0.2 l approx), the signal gain was iteratively adjusted until the mean value of the signal peaks was 0.5 in the case of normal breathing and 0.2 in the case of hypopnea. Subsequently, the obstruction signal controlling the test bench valve was added to obstructive events. Moreover, a snore signal was added where requested. Then, the processed events were assembled to obtain the 30 4-hour simulated breathing patterns (Fig. 3).

C. Measurement Setup and Protocol

NOWAPI sensors unit was plugged between the CPAP/APAP device (or its humidifier) outlet and a model simulating an OSA patient [14;15], as shown in Fig. 4. This computer-driven model comprises a flow generator and an obstruction valve which allows the simulation of obstructive events. Other two valves (the leak and the exhalation valves) allow the simulation of leaks and mouth breathing and a loudspeaker simulates snoring. The test bench is equipped with two sensors, which record pressure and flow signals. A calibrated leak (EP on Fig. 4) simulates the mask leak.

This validation study comprised two phases in which the same test setting (Fig. 4) was employed.

1) First Test Phase

The aim of the first test phase was to verify that the NOWAPI sensors unit connected between a CPAP/APAP machine and the conventional tubing connected to the patient did not modify the normal performance of the CPAP/APAP machine. Two commercially available CPAP/APAP devices (S9 AutoSet, Resmed and Remstar Auto, Resprionics) were subjected to a set of 20 breathing patterns described elsewhere [14;15] with 2 alternative settings: with or without their Comfort Mode (CPR) activated and with or without NOWAPI sensors unit connected to the test setting. The responses obtained in the 4 different experimental conditions were compared and evaluated.

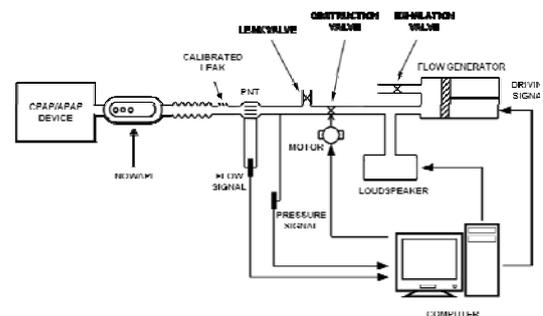


Figure 4. Scheme of the test setting.

2) Second Test Phase

In the second test phase, NOWAPI was subjected to the 30 patterns especially implemented for this study, which simulated 30 sleep periods of OSA patients under CPAP treatment. The aim of this phase was the assessment of NOWAPI’s performance in correctly detecting the treatment duration and the residual disturbed-breathing events.

In order to assess the effect of water condensation into the tubing on the measurements, usually caused by patient’s breathing, three of the tests were performed with the APAP device humidifier turned on. To guarantee realistic water condensation, humidifier was set to maximum level and the APAP device tubing was immersed in ice.

The simulated patients were treated with 3 different currently available devices for APAP treatment: S9 Autoset (Resmed), Remstar Auto (Respironics) and Goodknight 420E (Sefam). Each APAP device was connected to the monitoring device with its own tubing. A Whisper Swivel valve (Respironics) was used as exhalation port for all devices.

Each 4-hour test was preceded and followed by a 30-minute period during which the NOWAPI device was functioning but not subjected to either APAP device pressure or patient simulator’s breathing. This was to ensure test two epochs in which no treatment time and no events should have been detected.

The synthetic files for each of the 30 tests, containing the data recorded as mean values over 15–minute consecutive periods, were sent via GPRS to the Air Liquide secure server and then downloaded for analysis. In this study, treatment duration and respiratory events, measured as apnea-hypopnea index (AHI), detected by NOWAPI were considered for analysis and compared to the ones detected by the CPAP/APAP devices and to the actual simulated patterns generated by the bench.

III. RESULTS

The results of first test phase are summarized in Table I. The absolute differences between the two test settings with and without the NOWAPI sensor unit in the circuit of the following parameters were calculated: the time taken by the CPAP/APAP machine to reach the pressure of 10 cmH₂O (T₁₀) and the maximum pressure applied by the machine (P_{max}). The minor differences founded between the two test conditions are imputable to the intrinsic variability.

TABLE I. RESULTS OF THE FIRST TEST PHASE

CPAP/APAP machine	Absolute difference with NOWAPI/without NOWAPI (mean±SD)	
	T ₁₀ (min)	P _{max} (cmH ₂ O)
S9 Autoset with CPR ^a	0.40±0.43	0.50±0.77
S9 Autoset without CPR	0.19±0.29	0.11±0.14
Remstar Auto with CPR	1.23±0.98	0.78±1.54
Remstar Auto without CPR	1.50±1.75	1.26±1.41

a. CPR = Comfort Mode.

In the second test phase, all data sent to the server via GPRS were successfully received and analyzed. The percentage difference between the treatment duration estimated by NOWAPI and actual values was never higher than 1.25% (3 min) and never lower than -0.42% (-1 min).

The difference in absolute values between the AHI estimated by NOWAPI and the actual values, 0.9±1.6 events/hour (mean±SD), was not significantly different from the difference in absolute value between the AHI estimated by the CPAP/APAP machines and the actual values, 0.9±1.0 events/hour (p=0.171, the normality condition was achieved). This good agreement was confirmed by Bland-Altman analysis of AHI values estimated by NOWAPI in

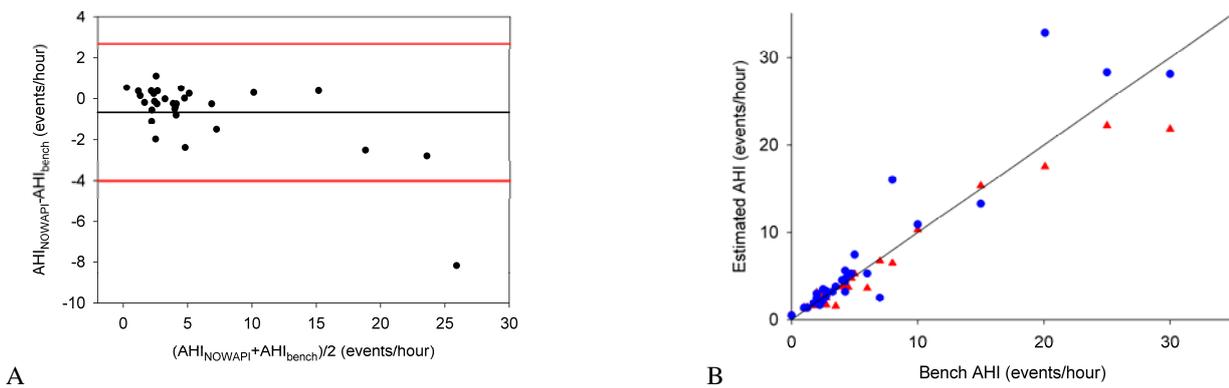


Figure 5. (A) Bland-Altman analysis of AHI values estimated by NOWAPI in each test versus the actual ones; (B) AHI values estimated by NOWAPI (red triangles) and the PAP machines (blue circles) versus the bench ones for each test.

each test versus the actual ones (Fig. 5A). Also, AHI values estimated by NOWAPI showed a very good correlation with the actual values ($R^2=0.97$), slightly better than the ones estimated by PAP machines ($R^2=0.88$) (Fig. 5B).

IV. DISCUSSION

NOWAPI is a novel telemedicine system which provides remote monitoring of CPAP/APAP treatment of OSA patients at home. It detects critical parameters to evaluate the patient's adherence (treatment duration), and the effectiveness of the treatment (residual respiratory events) and sends them via GPRS to a secure server. In this way the data can be easily downloaded and revised by the physician or the health professional providing CPAP, who can perform a closer patient's monitoring and timely intervene to improve his/her treatment compliance.

Few systems in the market provide this kind of remote treatment monitoring, which is usually integrated in the CPAP/APAP devices and implemented with a different algorithm for each manufacturer. Since NOWAPI is a stand-alone system, it can be compatible with all the commercially available CPAP/APAP devices currently in clinical use. This fact would make it easy to remotely monitoring any patient, regardless of the specific CPAP device he/she uses.

In this study, NOWAPI system was evaluated in a bench. In a first test phase, two different CPAP/APAP machines were subjected to a previously validated set of disturbed breathing patterns [14;15] with or without NOWAPI device connected between the CPAP/APAP and the bench. The results of this phase demonstrated that the geometry of NOWAPI does not influence the CPAP treatment.

In the second test phase, NOWAPI was subjected to 30 different breathing patterns especially built for this study by assembling real respiratory flow signals recorded during polysomnography in OSA patients. The telemedicine system successfully sent the recorded data to the central server and showed an excellent performance in estimating the CPAP treatment duration and in detecting residual respiratory events.

A bench test is a useful tool to validate new systems such as NOWAPI, because it allows the comparison of different devices response when they are subjected to exactly the same patterns of disturbed breathing, which is not possible in patients, due to the biological variability in their disturbed breathing patterns [13]. Actually, bench tests and clinical studies are both useful and should be considered complementary when evaluating a specific system [14]. Subjecting NOWAPI to reference breathing patterns at the bench was a first step for evaluating the performance of the hardware/software implemented in the system.

V. CONCLUSION AND FUTURE WORK

NOWAPI showed good compatibility with the CPAP machines and an excellent performance in estimating the duration of the CPAP treatment and in detecting residual respiratory events in simulated OSAS patients. The results of this study demonstrated that NOWAPI system could be a

valuable tool for telemonitoring the treatment of obstructive sleep apnea.

The results of the study will be verified in a clinical trial on patients in the clinical routine.

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REFERENCES

- [1] T. Young, P. E. Peppard and D. J. Gottlieb, "Epidemiology of obstructive sleep apnea: a population health perspective." *Am J Respir Crit Care Med* 2002; 165(9):1217-1239.
- [2] N. M. Al Lawati, S. R. Patel and N. T. Ayas, "Epidemiology, risk factors, and consequences of obstructive sleep apnea and short sleep duration." *Prog Cardiovasc Dis* 2009; 51(4): pp.285-293.
- [3] J. Duran, S. Esnaola, R. Rubi and A. Izutueta, "Obstructive sleep apnea-hypopnea and related clinical features in a population-based sample of subjects aged 30 to 70 yr." *Am J Respir Crit Care Med* 2001; 163(3 Pt 1): pp.685-689.
- [4] C. A. Kushida, M. R. Littner, M. Hirshkowitz, T. I. Morgenthaler, C. A. Alessi, D. Bailey, B. Boehlecke, T. M. Brown, J. Coleman Jr., L. Friedman, S. Kapen, V. K. Kapur, M. Kramer, T. Lee-Chiong, J. Owens, J. P. Pancer, T. J. Swick and M. S. Wise, "Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders." *Sleep* 2006; 29(3): pp.375-380.
- [5] I. Rolfe, L. G. Olson and N. A. Saunders, "Long-term acceptance of continuous positive airway pressure in obstructive sleep apnea." *Am Rev Respir Dis* 1991; 144(5): pp.1130-1133.
- [6] D. Sparrow, M. Aloia, D. A. Demolles and D. J. Gottlieb, "A telemedicine intervention to improve adherence to continuous positive airway pressure: a randomised controlled trial." *Thorax* 2010; 65(12): pp.1061-1066.
- [7] L. S. Doherty, J. L. Kiely, V. Swan and W. T. McNicholas, "Long-term effects of nasal continuous positive airway pressure therapy on cardiovascular outcomes in sleep apnea syndrome." *Chest* 2005; 127(6): pp.2076-2084.
- [8] R. Zozula and R. Rosen, "Compliance with continuous positive airway pressure therapy: assessing and improving treatment outcomes." *Curr Opin Pulm Med* 2001; 7(6): pp.391-398.
- [9] M. Kwiatkowska and N. Ayas, "Can telemedicine improve CPAP adherence?" *Thorax* 2010; 65(12): pp.1035-1036.
- [10] Y. Taylor, A. Eliasson, T. Andrada, D. Kristo and R. Howard, "The role of telemedicine in CPAP compliance for patients with obstructive sleep apnea syndrome." *Sleep Breath* 2006; 10(3): pp.132-138.
- [11] C. E. Smith, E. R. Dauz, F. Clements, F. N. Puno, D. Cook, G. Doolittle and W. Leeds, "Telehealth services to improve nonadherence: A placebo-controlled study." *Telemed J E Health* 2006; 12(3): pp.289-296.
- [12] C. J. Stepnowsky, J. J. Palau, M. R. Marler and A. L. Gifford, "Pilot randomized trial of the effect of wireless telemonitoring on compliance and treatment efficacy in obstructive sleep apnea." *J Med Internet Res* 2007; 9(2):e14.

- [13] N. Fox, A.J. Hirsch-Allen, E. Goodfellow, J. Wenner, J. Fleetham, C.F. Ryan, M. Kwiatkowska, N.T. Ayas, "The impact of a telemedicine monitoring system on positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial." *Sleep* 2012; 35(4): pp.477-481.
- [14] R. Farre, J. M. Montserrat, J. Rigau, X. Trepal, P. Pinto and D. Navajas, "Response of automatic continuous positive airway pressure devices to different sleep breathing patterns: a bench study." *Am J Respir Crit Care Med* 2002; 166(4): pp.469-473.
- [15] J. Rigau, J. M. Montserrat, H. Wohrle, D. Plattner, M. Schwaibold, D. Navajas and R. Farre. "Bench model to simulate upper airway obstruction for analyzing automatic continuous positive airway pressure devices." *Chest* 2006; 130(2): pp.350-361.