A New Device for Sleep Apnea Treatment Telemonitoring: a Bench Study

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***Abstract*—Patient's compliance is crucial for the effectiveness of continuous positive airway pressure (CPAP) treatment of obstructive sleep apnea (OSA). Unfortunately, up to 50% of patients withdraw CPAP because of treatment side effects. Monitoring a patient's CPAP compliance at home would be useful to early detect underuse and to properly address problems. Air Liquide developed NOWAPI, a novel telemedicine system, which provides a remote monitoring of the CPAP treatment and is designed to be compatible with all CPAP devices under clinical use. The aim of this study was to validate this novel telemonitoring system in a bench test. NOWAPI detects important CPAP treatment efficiency parameters, such as the usage time and residual events, and sends them to a secure server, from which can be downloaded for analysis by the healthcare staff. In this study, NOWAPI was tested when using CPAP devices applied to a model simulating OSA patients. In a first test phase, to assess the influence of NOWAPI sensor unit geometry to the CPAP treatment, the responses of 2 different CPAP machines to a series of 10 disturbed breathing patterns with NOWAPI connected or not to the setting was compared. Then, the telemedicine system performance was tested in 30 simulated patients' sleep periods of CPAP treatment, lasting 4 hours each. They consisted of disturbed breathing patterns built from selected events of real OSA patients' polysomnographic recordings. The recorded data of each test were telemetrically sent to a server by the NOWAPI GPRS module, then downloaded and analyzed. The simulated patients were treated with 3 different currently available CPAP devices. NOWAPI sensor unit connection to the setting did not influence the CPAP treatment in the two CPAP devices analyzed. The difference between the treatment duration estimated by the device and actual values was never higher than 3 minutes over the 4-hour test. The absolute difference between the apnea-hypopnea index estimated by NOWAPI and the actual values, 0.9±1.6 events/hour (mean±SD), was not significantly different from the absolute difference between the AHI estimated by the CPAP machines and the actual values, 0.9±1.0 events/hour (p=0.171). NOWAPI showed an excellent performance in estimating the duration of the CPAP treatment and in detecting residual respiratory events in simulated OSAS patients. NOWAPI system could be a valuable tool for telemonitoring the treatment of obstructive sleep apnea.**

Keywords-component; telemedicine; eHealth; home monitoring; sleep apnea; CPAP.

I. INTRODUCTION

The original version of this paper has been presented at eTELEMED 2013 conference, in Nice, France [1]. This extended version includes more detailed data across all paper sections.

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 [2]. 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 [3][4]. In addition, OSA is strongly related to obesity even though it is also increasingly identified in non-

obese subjects with a particular craniofacial structure. The incidence of OSAS is likely to grow in parallel with the spread of obesity now occurring in many countries.

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 [5]. 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 [6][7]. 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 [8], 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 [9]. In recent times, it has been recognized that telemedicine could have a valuable role in improving CPAP therapy adherence [10]. 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, the Internet and videoconference. Namely, a randomized clinical trial showed that the use of a telephone-linked communication system, which provided feedback and counselling to OSAS patients at home, improved CPAP adherence, patients' functional status and reduced depressive symptoms [7]. Another study employed an Internet-based informational support service for problems due to CPAP use [11]. Despite the organizational limitations and poor differences between intervention and control group follow-up, they obtained good patients' acceptance of this monitoring strategy. It is also noteworthy that telehealth interventions, such as long-distance visit via videoconference (or "televisits"), have been found to improve CPAP adherence in a small group of nonadherent patients versus a placebo-controlled group [12]. The cost of the interventions, including the telehealth monitor, home installation and telephone charges, was lower than the same number of face-to-face visits. However, larger studies are needed to generalize any conclusion.

Although these previous studies achieved mixed results in terms of significant improvement of CPAP compliance, the potential of telemedicine as part of an integrated care for OSA patients was confirmed.

Two recent randomized studies [13][14] combined elements of psycho-educational 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 hypothesis of this study was that this new telemedicine system for CPAP therapy remote monitoring could provide valuable and useful data about treatment compliance and efficacy for the follow-up OSAS patients.

The specific aims of this study were: a) to assess whether the connection of NOWAPI sensor unit to different CPAP/APAP machines influenced their normal functioning and responses to the disturbed breathing patterns generated by a simulated OSAS patient in a bench; b) to evaluate the NOWAPI's performance in accurately detecting the CPAP/APAP treatment duration and the residual disturbed-breathing events 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), shown in Fig. 2, 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, which enables the physician to visualize and properly evaluate the data downloaded from the server. The NOWAPI sensors unit is connected between the

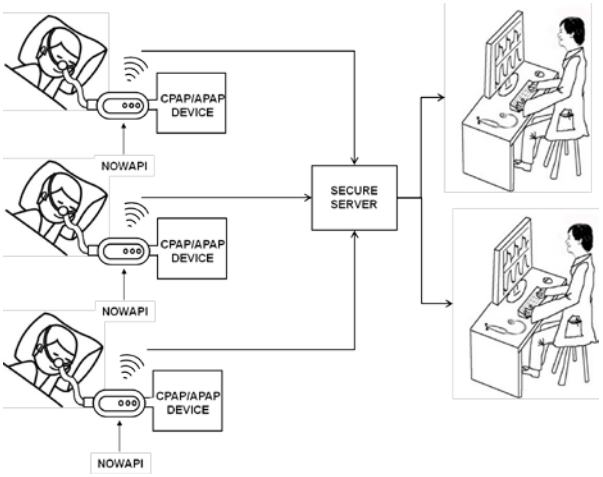

Figure 1. NOWAPI system data flow.

Figure 2. NOWAPI sensor unit.

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.

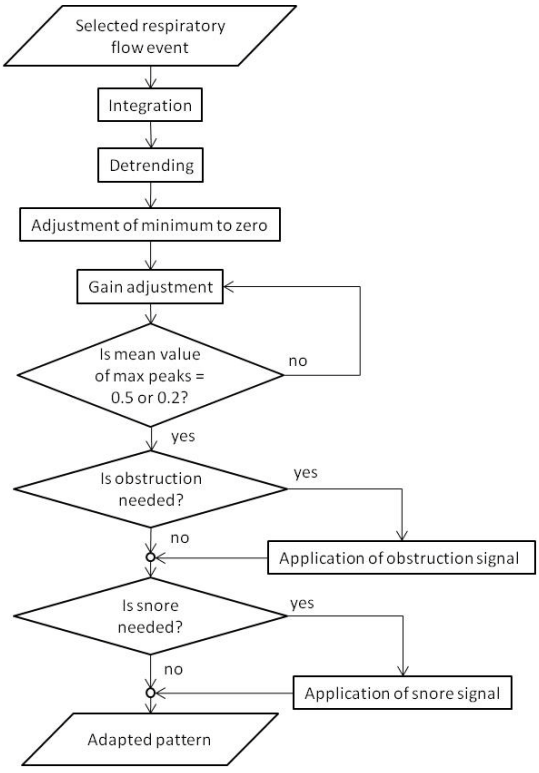

Figure 3. Block diagram of the algorithm implemented to obtain the breathing patterns simulating patients with OSA.

B. *Patterns of disturbed breathing*

NOWAPI was tested with 2 different sets of simulated breathing patterns. In the first phase, a series of 10 waveforms consisting of the successive repetition of apneic or hypopneic events or persistent flow limitation with or without snoring [15][16] was used. For each flow pattern, the waveform generator (see Section C) produced a specific pattern of airway obstruction with the proper magnitude and duration for simultaneously mimicking the obstructive events and the flow shapes observed in OSA patients. The flow and obstructive events were combined for generating 10 different breathing patterns. The description of these disturbed breathing patterns is summarized in Table I. Test 1 simulated a breathing pattern with repetitive apneas with obstruction that correspond to the total airway occlusion. Test 2 simulated a breathing pattern known as central apnea, in which patients stop breathing due to brain's respiratory control centers imbalance, but no airway obstruction is present. Tests 3 and 4 reproduced two different severity levels of partial airway obstruction, called hypopnea. Test 5 simulated a mild hypopnea with the addition of snoring vibrations synchronized with the inspirations.

TABLE I. DISTURBED BREATHING PATTERNS USED FOR THE COMPATIBILITY TEST PHASE.

Test #	Test Description
1	Apnea with Obstruction
2	Apnea without Obstruction
3	Severe Hypopnea
4	Mild Hypopnea
5	Mild Hypopnea with Snoring
6	Prolonged Flow Limitation with Obstruction
7	Prolonged Flow Limitation with Obstruction and Snoring
8	Mouth Expiration
9	Apnea with Obstruction and Leaks
10	Simulated OSA patient

Tests 6 and 7 reproduced the breathing events known as flow limitation that occurs when flow ceases to increase with increasing expiratory effort. In the case of Test 7 snoring signal was superimposed to the flow limitation pattern. Test 8 mimicked the occurrence of patient's expiration through the mouth. In Test 9 a signal mimicking the mask leaks was added to the repetitive obstructive apnea pattern. Test 10

simulated a breathing condition representative of a complete OSA patient breathing pattern that depended on the CPAP applied. Specifically, the generator reproduced apneas if CPAP was less than 5 cmH_2O, severe hypopneas when applied CPAP was between 5 and 7 cmH_2O, moderate hypopneas if CPAP was between 7 and 10 cmH_2O, prolonged flow limitation when CPAP was between 10 and 12 cmH_2O, and normal breathing for CPAP greater than 12 cmH_2O.

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. In Table II the 30 breathing patterns generated for this study are described in

TABLE II. NUMBER OF SIMULATED EVENTS ASSIGNED FOR EACH TEST AND EXPERIMENTAL CONDITIONS.

Test number	Average AHI[a]	Number of obstructive apneas	Number of central apneas	Number of hypopneas with snoring	Number of hypopneas without snoring	Number of flow limited events with snoring	Number of flow limited events without snoring	Number of prolonged flow limitations without snoring	Number of prolonged flow limitations with snoring	CPAP machine	With/without comfort mode	With/Without humidifier
1	0	0	0	0	0	2	2			S9 Autoset	without	without
2	1	1	0	2	1	9	73			Goodknight 420E	without	with
3	1,25	1	0	4	0				1	Goodknight 420E	without	without
4	1,75	0	0	4	3			1		Goodknight 420E	without	without
5	2	0	0	2	6	35	15			S9 Autoset	without	with
6	2	0	0	3	5	20	90			S9 Autoset	without	without
7	2,25	0	1	7	1					S9 Autoset	without	without
8	2,5	1	2	7	0				1	S9 Autoset	without	without
9	2,5	3	0	6	1			1		Remstar Auto PR1	without	without
10	2,5	6	0	2	2			1		Remstar Auto PR1	without	with
11	2,75	2	0	6	3				1	Remstar Auto PR1	without	without
12	2,75	2	0	9	0	0	17			S9 Autoset	without	without
13	3,25	1	2	0	10			1		S9 Autoset	without	without
14	3,5	0	0	8	6	2	1			Remstar Auto PR1	without	without
15	4	6	1	7	2					Goodknight 420E	without	without
16	4,25	0	1	14	2					Remstar Auto PR1	without	without
17	4,25	2	3	7	5					Remstar Auto PR1	without	without
18	4,5	5	2	9	2					Goodknight 420E	without	without
19	4,75	18	1	0	0					S9 Autoset	without	without
20	4,75	4	3	9	3					S9 Autoset	without	without
21	4,75	2	0	0	17	38	17			Remstar Auto PR1	without	without
22	5	17	1	2	0	6	89			Goodknight 420E	without	without
23	6	1	1	5	17	14	1			Remstar Auto PR1	without	without
24	7	0	0	18	10					S9 Autoset	without	without
25	8,75	4	5	13	13	0	4			Goodknight 420E	without	without
26	10,8	12	6	25	0					Remstar Auto PR1	without	without
27	15	15	21	10	14	7	11			S9 Autoset	without	without
28	20,3	37	2	32	10					Goodknight 420E	without	without
29	25,3	9	8	48	36					Remstar Auto PR1	without	without
30	30	31	31	29	29	38	17			S9 Autoset	without	without

a. AHI = Apnea-hypopnea Index, which is the number of disturbed breathing events per hour.

detail.

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. 3. First, the flow 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

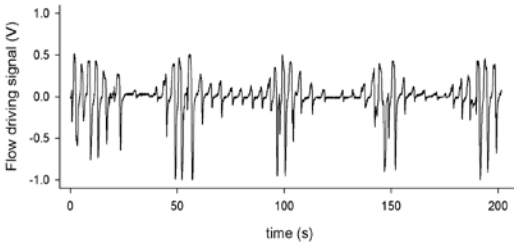

Figure 4. Fragment of a pattern of disturbed breathing which simulated an OSA patient's sleep periods of treatment.

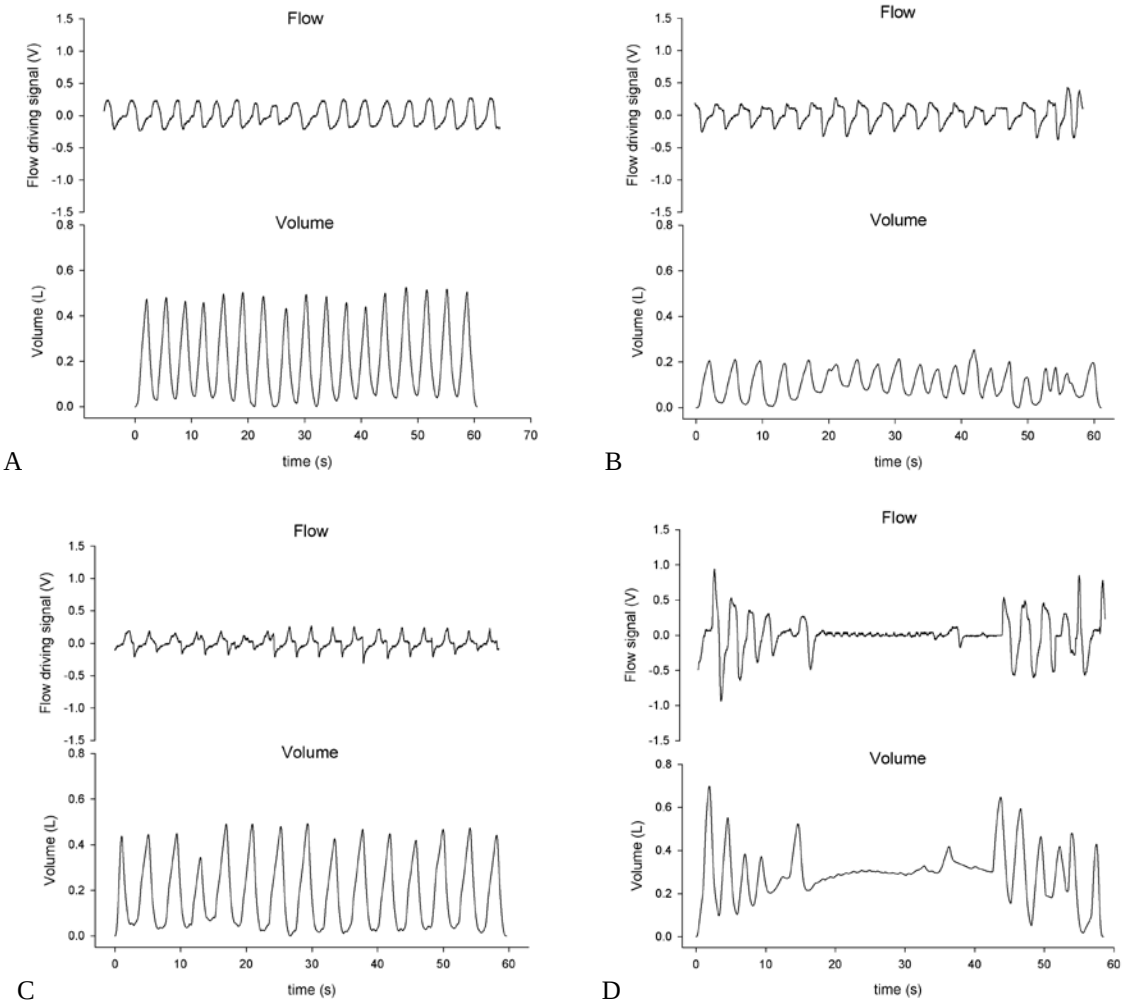

Figure 5. Breathing patterns obtained by using the algorithm developed in this study: (A) Normal breathing, (B) Hypopnea, (C) Flow limitation, (D) Apnea.

events were assembled to obtain the 30 4-hour simulated breathing patterns (Fig. 4). In Fig. 5 some representative breathing patterns obtained by using the algorithm developed in this study are depicted.

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 [15][16], as shown in Fig. 6. 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. 6) simulates the mask leak.

This validation study comprised two phases in which the same test setting (Fig. 6) was employed.

1) First Test Phase

The aim of the first test phase was to verify that the NOWAPI sensor 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, Respironics) were subjected to a set of 10 breathing patterns described elsewhere [15][16] 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.

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 PR1 (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.

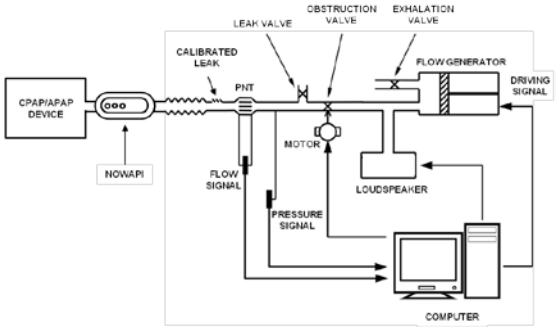

Figure 6. Scheme of the test setting.

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

To assess whether the connection of NOWAPI sensor unit to the CPAP/APAP machines influenced their responses to the disturbed breathing patterns generated by the OSAS patient simulated by the bench, the absolute differences between the test setting with and test setting without NOWAPI in the circuit of the following parameters were calculated: the time taken by the CPAP/APAP machine to reach the pressure of 10 cmH_2O (T_{10}) and the maximum pressure applied by the machine (P_{max}). These values were calculated for CPAP/APAP machines S9 Autoset (Resmed) and Remstar Auto (Respironics) with and without CPR. Table III summarizes the results, which corresponded to the 4 experimental conditions.

TABLE III. RESULTS OF THE FIRST TEST PHASE

CPAP/APAP machine	Absolute difference with NOWAPI/without NOWAPI (mean±SD)	
	T_{10} (min)	P_{max} (cmH_2O)
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 PR1 with CPR	1.23±0.98	0.78±1.54
Remstar Auto PR1 without CPR	1.50±1.75	1.26±1.41

a. CPR = Comfort Mode.

In order to assess the intrinsic variability of the CPAP/APAP machines' response to the same breathing pattern, we performed 3 rounds of the same 10 disturbed breathing patterns in both machines without the NOWAPI sensor unit in the circuit. The absolute differences between test rounds of T_{10} and P_{max} are comparable with the ones found previously (Table IV and V), hence they can be imputable to the intrinsic variability of the CPAP/APAP devices' response.

In the second test phase, all data sent to the server via GPRS were successfully received and analyzed. Detailed results of the CPAP treatment duration analysis are summarized in Table VI. 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).

Detailed results of the residual event detection analysis are summarized in Table VII. 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 each test versus the actual ones (Fig. 7A). 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. 7B).

TABLE IV. ANALYSIS OF CPAP/APAP MACHINES' INTRINSIC VARIABILITY ON T_{10} (MIN)

CPAP/APAP machine	Absolute difference with NOWAPI/without NOWAPI (mean±SD)		
	R1 – R2[a]	***R1 – R3***[b]	***R2 – R3***[c]
S9 Autoset	0.77±1.34	0.62±0.79	0.87±1.12
Remstar Auto	4.47±7.11	5.1±6.54	2.6±4.30

a. Round 1 – Round 2; b. Round 1 – Round 3; c. Round 2 – Round 3.

TABLE V. ANALYSIS OF CPAP/APAP MACHINES' INTRINSIC VARIABILITY ON P_{MAX} (CMH_2O)

CPAP/APAP machine	Absolute difference with NOWAPI/without NOWAPI (mean±SD)		
	R1 – R2[a]	***R1 – R3***[b]	***R2 – R3***[c]
S9 Autoset	0.36±0.47	0.32±0.40	0.87±1.12
Remstar Auto	0.87±0.41	0.69±0.54	0.80±0.56

a. Round 1 – Round 2; b. Round 1 – Round 3; c. Round 2 – Round 3.

TABLE VI. DETAILED RESULTS OF THE CPAP TREATMENT DURATION ANALYSIS.

Test number	CPAP	Actual treatment duration (hours)	Estimated treatment duration (hours)	Error on the treatment duration estimation (%)
1	S9 Autoset	4.000	4.017	0.417
2	Goodknight 420E	4.000	3.983	-0.420
3	Goodknight 420E	4.000	4.017	0.417
4	Goodknight 420E	4.000	4.000	0.000
5	S9 Autoset	4.000	4.000	0.000
6	S9 Autoset	4.000	4.017	0.417
7	S9 Autoset	4.000	4.000	0.000
8	S9 Autoset	4.000	4.017	0.417
9	Remstar Auto PR1	4.000	4.017	0.417
10	Remstar Auto PR1	4.033	4.033	0.000
11	Remstar Auto PR1	4.000	4.017	0.417
12	S9 Autoset	4.000	4.000	0.000
13	S9 Autoset	4.000	4.017	0.417
14	Remstar Auto PR1	4.000	4.000	0.000
15	Goodknight 420E	4.000	4.017	0.417
16	Remstar Auto PR1	4.000	4.050	1.250
17	Remstar Auto PR1	4.000	4.017	0.417
18	Goodknight 420E	4.000	4.017	0.417
19	S9 Autoset	4.000	4.017	0.417
20	S9 Autoset	4.000	4.033	0.833
21	Remstar Auto PR1	4.000	4.000	0.000
22	Goodknight 420E	4.000	4.017	0.417
23	Remstar Auto PR1	4.000	4.017	0.417
24	S9 Autoset	4.000	4.017	0.417
25	Goodknight 420E	4.000	4.017	0.417
26	Remstar Auto PR1	4.000	4.000	0.000
27	S9 Autoset	4.000	4.017	0.417
28	Goodknight 420E	3.983	3.983	0.000
29	Remstar Auto PR1	4.000	4.000	0.000
30	S9 Autoset	4.000	4.017	0.417
			Mean	*0.292*
			Max	*1.250*
			Min	*-0.420*
			Standard Dev	*0.312*

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 [15][16] 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 delivered by the devices considered in this study.

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

TABLE VII. DETAILED RESULTS OF THE RESIDUAL EVENT DETECTION ANALYSIS.

Test number	CPAP	Actual AHI	CPAP estimated AHI	Absolute difference AHI CPAP-Actual	NOWAPI estimated AHI	Absolute difference AHI NOWAPI-Actual
1	S9 Autoset	0.00	0.50	0.50	0.53	0.53
2	Goodknight 420E	1.00	1.33	0.33	1.36	0.36
3	Goodknight 420E	1.25	1.33	0.08	1.39	0.14
4	Goodknight 420E	1.75	1.87	0.12	1.56	0.18
5	S9 Autoset	2.00	2.50	0.50	3.11	1.11
6	S9 Autoset	2.00	3.00	1.00	2.37	0.37
7	S9 Autoset	2.25	1.66	0.59	2.49	0.24
8	S9 Autoset	2.50	2.20	0.30	2.37	0.13
9	Remstar Auto PR1	2.50	3.50	1.00	1.95	0.55
10	Remstar Auto PR1	2.48	2.20	0.28	2.84	0.37
11	Remstar Auto PR1	2.75	3.30	0.55	1.67	1.08
12	S9 Autoset	2.75	2.70	0.05	2.50	0.25
13	S9 Autoset	3.25	3.20	0.05	3.24	0.01
14	Remstar Auto PR1	3.50	3.80	0.30	1.52	1.97
15	Goodknight 420E	4.00	4.53	0.53	3.77	0.23
16	Remstar Auto PR1	4.25	4.40	0.15	4.00	0.25
17	Remstar Auto PR1	4.25	3.20	1.05	3.86	0.39
18	Goodknight 420E	4.25	5.63	1.38	3.77	0.48
19	S9 Autoset	4.25	4.70	0.45	4.75	0.50
20	S9 Autoset	4.50	5.20	0.70	3.72	0.78
21	Remstar Auto PR1	4.75	5.30	0.55	4.77	0.02
22	Goodknight 420E	5.00	7.50	2.50	5.25	0.25
23	Remstar Auto PR1	6.00	5.30	0.70	3.62	2.38
24	S9 Autoset	7.00	2.50	4.50	6.75	0.25
25	Goodknight 420E	8.00	16.07	8.07	6.50	1.50
26	Remstar Auto PR1	10.00	10.90	0.90	10.29	0.29
27	S9 Autoset	15.00	13.30	1.70	15.38	0.38
28	Goodknight 420E	20.08	32.82	12.74	17.57	2.51
29	Remstar Auto PR1	25.00	28.30	3.30	22.21	2.79
30	S9 Autoset	30.00	28.10	1.90	21.82	8.18
			Average	*0.93*		*0.87*
			Standard Dev	*1.04*		*1.59*

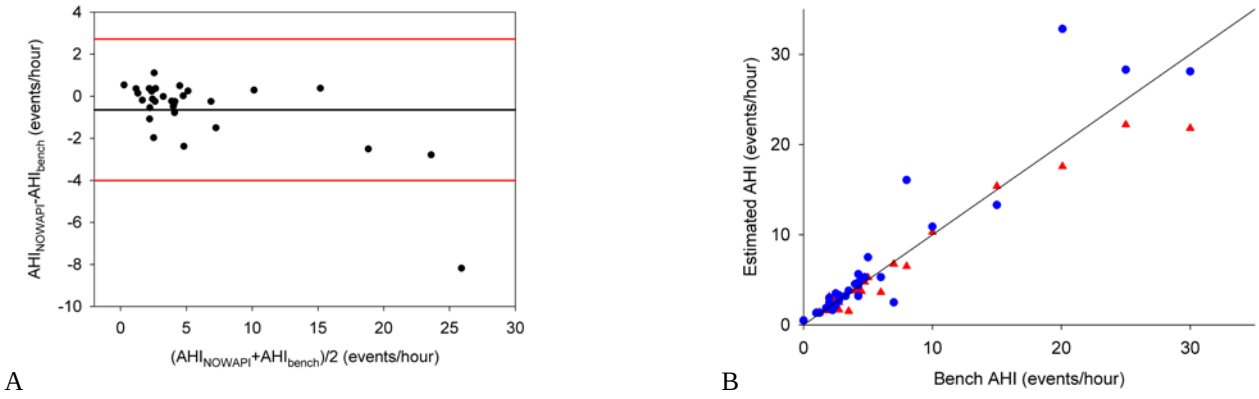

Figure 7. (A) Bland-Altman analysis of AHI values estimated by NOWAPI in each test versus the actual ones; (B) AHI values estimated by NOWAPI (red triangles) and the PAP machines (blue circles) versus the bench ones for each test.

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.

This validation study was performed on a reduced number of NOWAPI devices. For this reason the conclusions of the study are limited to the tested devices. In addition, since this study was performed on a bench test and not in real patients, it could be argued that the results could lead to limited conclusions. Indeed, 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. The results of the study should subsequently be confirmed on patients in the clinical routine.

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 [15]. Actually, bench tests and clinical studies are both useful and should be considered complementary when evaluating a specific system [16]. 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.

The encouraging results of this kind of study highlight the potential of Information and Communication Technology applications in the management of patients affected by respiratory diseases and, more generally, by chronic conditions.

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 with real OSA patients, in which beside the assessment of NOWAPI system performance in a real setting, also other critical aspects will be analyzed, such us usability, implementation viability and cost-effectiveness.

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