

Comparison of CPAP Titration at Home or the Sleep Laboratory in the Sleep Apnea Hypopnea Syndrome

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Study Objectives: Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea hypopnea syndrome (OSAHS) is conventionally started after in-laboratory overnight titration. This use of sleep laboratory space is both costly and limits access for diagnostic studies. This study aimed to evaluate whether automated CPAP titration in the home produced patient outcomes equal to those following laboratory-based automated CPAP titration. The main outcomes were Epworth Sleepiness Scale score, objective daytime sleepiness (Oxford SLEep Resistance test or OSLEer test), and CPAP use; we also performed quality-of-life questionnaires: Functional Outcomes of Sleep Questionnaire and SF-36[®].

Design: Prospective, randomized, single-blind, parallel-group, controlled trial

Setting: Regional sleep center and patients' homes.

Patients: Two hundred CPAP-naïve patients with OSAHS requiring CPAP treatment.

Interventions: One hundred patients were randomly assigned to a standard 1-night in-hospital CPAP titration and 100 to 3 nights' home CPAP

titration and then issued with fixed pressure CPAP. Data were analyzed on an intention-to-treat basis.

Measurements and Results: The patient groups did not differ at baseline. The CPAP pressures defined at titration (mean \pm SEM: 10.6 \pm 0.2, 10.4 \pm 0.2 cm H₂O, $p = .19$), number of mask leaks, and initial acceptance rates were similar in the sleep-laboratory and home-titrated groups. At 3-month follow-up, there was no significant difference in CPAP use (mean \pm SEM: 4.39 \pm 0.25, 4.38 \pm 0.25 h/night; $p > .9$), Epworth Sleepiness Scale score (9.5 \pm 0.5, 8.5 \pm 0.5, $p = .14$), OSLEer, Functional Outcomes of Sleep Questionnaire, or SF-36[®] between the sleep-laboratory and home-titrated groups.

Conclusions: Home-based automated CPAP titration is as effective as automatic in-laboratory titrations in initiating treatment for OSAHS.

Keywords: Obstructive sleep apnea hypopnea syndrome, CPAP titration, automated CPAP, home titration

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INTRODUCTION

THE OBSTRUCTIVE SLEEP APNEA-HYPOPNEA SYNDROME (OSAHS) AFFECTS 0.3% TO 4% OF THE ADULT POPULATION^{1,2} AND IS ASSOCIATED WITH sleepiness, impaired work performance, and hypertension.³ Continuous positive airway pressure (CPAP), which provides a pneumatic splint to maintain upper airway patency, is the treatment of choice for OSAHS.^{4,5}

Determining the correct pressure required to overcome the upper airway obstruction conventionally requires an overnight stay in a sleep laboratory. However, the recent availability of effective and portable automated CPAP machines has raised the potential of determining the optimal CPAP pressure in the patients' homes, with some studies indicating home titration is as effective⁶⁻⁹ and others not as good as¹⁰ sleep-lab titration. There are many health-economic benefits to be gained were home CPAP titration as effective as in-hospital titration, such as the reduction in service

provision costs by reducing admission to costly sleep laboratory beds, the reduction in waiting list times, and potentially accelerating the provision of CPAP and thus reducing patients' morbidity and mortality. However, there is the risk of inadequate support on the home-titration night leading to poor CPAP acceptance and poor CPAP use, resulting in poorer clinical outcomes.

The aim of this study was to determine, in a large series of consecutive unselected CPAP-naïve patients, whether automated CPAP titration performed unattended at home is as effective as in-hospital automated CPAP titration.

METHODS

Design

In a randomized, single-blind, parallel-group study, patients who had standard single-night laboratory-based CPAP titration were compared with those who had a 3-night "home" titration. The study was transparent to those coordinating the trial but blinded to the researchers gathering and analyzing all outcomes.

Patients

Consecutive new OSAHS cases recommended for CPAP treatment who lived within 100 miles of Edinburgh Royal Infirmary were recruited. Patients were diagnosed with OSAHS on the basis of an Epworth Sleepiness Scale (ESS) score of 11 or higher or disabling sleepiness when driving or working plus an apnea-hypopnea index of 15 or more per hour of sleep on inpatient polysomnography (Compumedics, Melbourne, Australia) or the number of apneas plus hypopneas being 25 or more per hour of time in bed on a limited sleep study (Hypno PTT, Tyco Healthcare,

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Elancourt, France) carried out in the patients' home. Apneas and hypopneas were defined according to our standard definitions.¹¹

Exclusion criteria included any serious learning, cardiorespiratory, or other sleep disorder. All patients provided written informed consent, and the trial was approved by the local ethics committee.

PROCEDURES

Recruitment and Randomization

Eligible patients were invited to participate, and acceptors were randomly assigned to either home or hospital titration using a pre-determined, balanced-block schedule with block sizes of 10.

All acceptors attended pretitration education conducted by the same sleep nurse in all cases with in-house educational video, amplified by personal experience, provision of explanatory literature, and mask fitting from a range of more than 20 masks—both nasal and full-face masks—from Res Med, Respirationics, and Fisher & Paykel. Thereafter the subjects spent at least 30 minutes lying with a CPAP mask and machine attached during the daytime on average 1 week before their CPAP titration. For home titrations, the nurse also gave them instruction on and issued an automated CPAP unit.

Auto-Adjusted Titration

All titrations were performed using the automated CPAP unit (Spirit; Res Med, San Diego, Calif) and an individually fitted mask. The patients randomly assigned to hospital titration had a single-night study attended by 2 trained sleep nurses. The patient was continuously monitored overnight by the CPAP device and also by added video, sound, oxygen saturation, and position monitoring, and the patients also could summon the nurse either verbally or using a call button. The sleep nurses intervened if there were recurrent desaturations, snoring, or mask displacement or on request from the patient. The home patients had the automated CPAP titration for 3 nights. Home-titration patients had telephone access to the sleep center on their first titration night and received calls after the first 2 titration nights from clinical staff, returning to the sleep center with their automated unit for downloading on day 3.

Fixed-Pressure Determination

After titration, all patients were issued a CPAP unit (ResMed Sullivan 6) set at the fixed pressure determined from the titration study. Fixed pressure was selected using a protocol, involving inspection of the automatic pressure profile by the same nurse. The titrations were acceptable if (1) satisfactory CPAP recording period was at least 6 hours in total over the 1 or 3 titration nights and (2) the median mask leak was 0.4 L per second or less. The nurse then determined the 95th percentile titration pressure from the technically satisfactory periods with leak less than 0.8 L per second.

Follow-Up

All patients were encouraged to use a 24-hour helpline manned by a trained sleep nurse who managed any subsequent CPAP problems during the 3-month follow-up period. All patient contacts were recorded, and action taken was documented.

Three-Month Assessment

The assessment at 3 months was carried out by a researcher totally blind to the patients' titration condition and who had not been involved in recruitment, titration, or any other aspect of the study. This researcher downloaded objective CPAP use and, conducted two 20-minute OSLEs (Oxford SLEep Resistance test) (12:00 noon and 2:00 PM).¹² A 20-minute OSLE was used because we wished to determine whether patients were seriously sleepy, which can be done in less than 20 minutes, and, also, the briefer the duration allowed the study day to be 40 minutes shorter, which was important to ensure high uptake from the patients. The same researcher obtained an ESS score; results of 2 health-status questionnaires—1 general, the Short Form 36 (SF-36®),¹³ and 1 sleep specific, the Functional Outcomes of Sleep Questionnaire (FOSQ)¹⁴; and a CPAP side-effects questionnaire.^{12,15} The same blinded observer performed all the data entry, which was locked at the end of the study prior to disclosure of treatment type.

Cost Analysis

Resource use of health services associated with home and hospital titration was recorded prospectively during the study. Costs to the patients, in terms of travel costs and out-of-pocket expenses, were excluded. We excluded resource use that was common to both home and hospital titration, including the initial clinic visit and basic CPAP education. All other resource use was measured, including nurse time for explaining the automated CPAP machine for home titration, all subsequent patient contacts, and all additional consumable and equipment requirements. Unit costs were applied to each unit of resource use, using the costs from our sleep center.

Data Analysis

The primary outcome was average nightly CPAP use over 3 months. The secondary objective outcomes were ESS score and objective sleepiness from the OSLE test¹² at 3 months and also titration results (mask leak, CPAP pressure data). Analysis was on an intention-to-treat basis with SPSS, (Version 11; SPSS Chicago, IL). Independent t tests were used for parametric and Mann Whitney tests for nonparametric data, and mean \pm SEM are reported, unless otherwise indicated.

RESULTS

Four (2%) of the 204 initially evaluated subjects were excluded prior to randomization for "refusal to participate in the study protocol" "psychophysical disability with no independent transport" "coexistent severe chronic disease", and "alcohol addiction". Of the 200 patients recruited and randomized, 2 (1% both in the hospital limb) refused CPAP [1 mask claustrophobic and 1 did not attend titration]. Of the 198 patients recruited and initially accepting CPAP, 5 (2.5%) returned CPAP within the 3-month follow-up period; there was no significant difference in number of CPAP returnees between hospital(n=3)and home(n=2)groups (Figure 1). The severity of OSAHS was similar in the 2 groups at baseline (Table 1).

The CPAP-titration pressures resulting from the 2 different methods were similar (hospital 10.6 ± 0.2 , home 10.4 ± 0.2 cm H₂O; $p = .19$). At 3 months' follow-up, there was no significant

Table 1— Characteristics of Patients Prior to CPAP

	Hospital (n = 100)	Home (n = 100)	p Value
Age, y	50 ± 1	50 ± 1	.64
ESS Score	15 ± 0.3	15 ± 0.3	.75
BMI, kg/m ²	34.5 ± 1.0	34.6 ± 0.8	.97
AHI ^a	37 ± 3	38 ± 4	
	n = 60	n = 51	.54
A+H ^b	56 ± 4	50 ± 3	.32
	n = 40	n = 49	

Data are presented as mean ± SEM unless otherwise indicated. CPAP refers to continuous positive airway pressure; ESS, Epworth Sleepiness Scale; BMI, body mass index; AHI, apnea-hypopnea index.

^aFor patients having polysomnography.

^bApneas and hypopneas per hour in bed for those with limited study.

difference between the 2 groups in the primary outcome variable, CPAP use (Table 2). The ESS scores improved to a similar extent after CPAP treatment in both groups and there was also no difference in the objective sleepiness, as measured by the OSLER test, after CPAP treatment between the groups (Table 2). The health-status questionnaires SF-36[®] and FOSQ showed no statistical difference at 3 months' follow-up between the 2 groups (Table 2). During the first 3 months of fixed CPAP therapy, the overall additional costs of CPAP treatment were marginally higher in the hospital-titrated group (Table 3 and 4).

In the patients who had 3 consecutive nights of CPAP titration at home, there was no significant difference between the CPAP pressures on the 3 nights (night 1, 10.3 ± 0.2; night 2, 10.7 ± 0.2; night 3, 10.5 ± 0.2 cm H₂O; p > .3).

DISCUSSION

This randomized controlled study demonstrates that home-based automated CPAP titration produces similar outcomes to those of a conventional automatic sleep-laboratory CPAP titration in the treatment of the OSAHS. The acceptance rates were high and similar in both groups, there were no failures of home CPAP titration, and the optimal CPAP pressures determined by home titration and hospital titration were similar and resembled those found in other studies.¹⁶⁻¹⁸ The CPAP use was similar in both groups at 3 months. This early CPAP use is strongly predictive of long-term use.¹⁹ The subjective and objective outcomes at 3

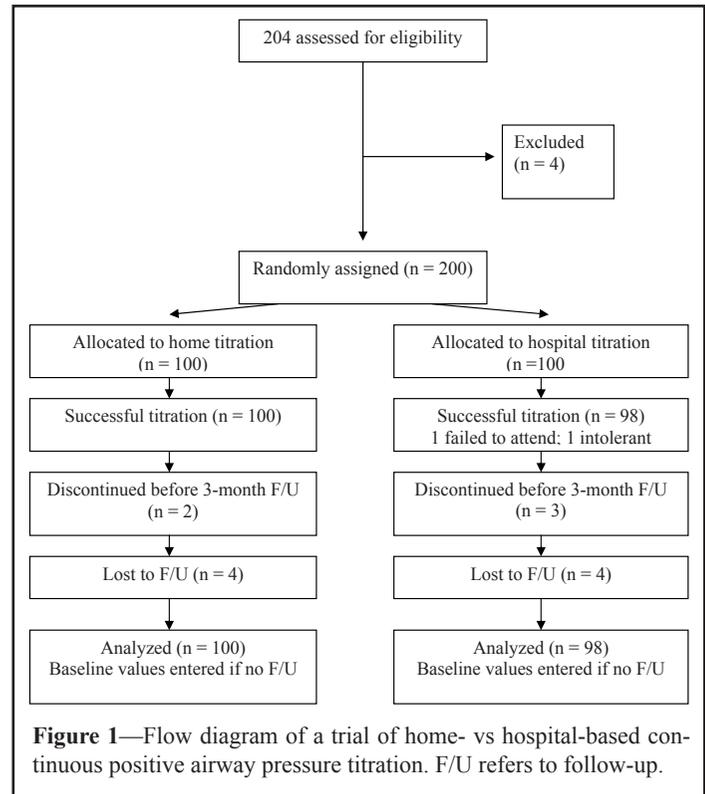


Figure 1—Flow diagram of a trial of home- vs hospital-based continuous positive airway pressure titration. F/U refers to follow-up.

months were similar in the home- and hospital-titration groups, with no significantly different outcomes between the groups.

This study confirms and extends the findings of a recently published concurrent study.¹⁶ Our study differed from that of Masa et al,¹⁷ which was published when our study was underway, by differences in design and greater study power. We decreased potential confounders by using the same automatic CPAP device for both the home and hospital limbs, whereas Masa used manual laboratory titration against automatic home titration. Because automatic CPAP titration is the standard approach in many centers with American Academy of Sleep Medicine accreditation,²⁰ our approach results in a significant extension of Masa and colleagues' results. In addition, we used a 3-night home CPAP titration rather than a single night because the additional costs were minimal and potential benefits significant. The other difference between the 2 studies is that Masa et al¹⁷ had a third limb (prediction formula), which resulted in a 3-way comparison. Because they had a number of subjects per limb similar to the design of our study, this resulted in our study having significantly greater statis-

Table 2— Outcomes at 3 Months Post-CPAP Titration

	Hospital	Home	Difference	95% CI of Difference	p Value
CPAP Use, h/day	4.39 ± 0.25	4.38 ± 0.25	0.009 ± 0.35	-0.69,+0.71	.98
ESS score	9.5 ± 0.5	8.5 ± 0.5	0.98 ± 0.72	-0.45,+2.41	.18
OSLER	20.0 (17.6-20.0)	20.0 (14.3-20.0)	NA	NA	.37
Health transformation (from FOSQ)	13.4 ± 0.3	13.8 ± 0.2	0.39 ± 0.36	-1.11,+0.32	.28
SF 36					
Physical	38.0 ± 1.5	40.5 ± 1.5	2.5 ± 2.1	-6.71,+1.67	.24
Mental	48.4 ± 1.2	49.4 ± 1.1	1.0 ± 1.6	-4.22,+2.18	.53
Side effects of CPAP (Total)	9.5 ± 0.7	9.6 ± 0.8	0.08 ± 1.0	-2.22,+2.06	.94

Data are presented as mean ± SEM, except OSLER, which is the median and interquartile range in parentheses. CPAP refers to continuous positive airway pressure; ESS, Epworth Sleepiness Scale; OSLER, Oxford SLEep Resistance test; FOSQ, Functional Outcomes of Sleep Questionnaire; SF-36, Short-Form 36.

Table 3— Variable Cost Elements Over 3 Months After Randomization

	Hospital Titration (n = 98)	Home Titration (n = 100)
Nights in sleep lab	98	0
Nights of variable CPAP machine	98	300
CPAP titration download and review	98	300
Issue of CPAP machine	0	100
Additional phone contacts	6	23
Additional visits to sleep lab	6	13
Humidifiers provided	1	9
Mask changes	14	17
Chin straps	2	3

Data are presented as numbers. CPAP refers to continuous positive airway pressure.

Table 4— Costs per Patient

	Hospital	Home	Cost Per Item
Night in sleep lab	104.1	0	104.1
Nights of variable CPAP machine	2	6	2
CPAP titration download and review	9	27	9
Explanation of CPAP machines	0	4	4
Phone calls in protocol	0	3	
Additional daytime phone contacts	0.2	0.6	
Additional visits to sleep lab	0.2	0.4	
Humidifiers provided	3	25	281
Mask changes	23.3	27.7	163
Chin straps	0.4	0.6	22
Total cost US\$	142.2	91.3	

Costs are variable costs (excluding routine clinic visits, patient's costs, and capital costs of sleep laboratory), in 2005 US\$, based on actual costs to Edinburgh Sleep Centre. Nurse time is based on \$9/h. CPAP refers to continuous positive airway pressure.

tical power for the simple comparison of home versus laboratory titration. We also had a lower withdrawal rate (3.5% vs 12.5%), perhaps reflecting either the high motivation in a single-site as opposed to a multisite trial or a different patient population. The results of the 2 studies combined clearly indicate that home titration is as effective as automatic in-laboratory titration for CPAP in OSAHS.

Adopting this method of unattended home CPAP titration could minimize the cost and delay in establishing CPAP titration and therapy without sacrificing clinical outcomes. The primary end points, CPAP compliance and ESS score, are, of course, influenced by more than the mode of titration adopted. Intensive CPAP education and support can have a positive effect on the patient's response to treatment and, thus, long-term compliance.²¹ The accessibility, frequency, and quality of ongoing support provided by the sleep nurse specialist may have resulted in improved patient compliance in both limbs of this study.

Limitations of this study include study power, study dropouts, and study design. The study had 80% power to detect a 1-hour difference in CPAP use at the 5% level. Given that the resulting CPAP-use s were identical to the nearest minute per night, it is extremely unlikely that a bigger study would have shown significant differences in use. Four patients dropped out prior to randomization, and, of those randomized, 5 returned their CPAP machines. All 200 patients who were randomly assigned to treatment were asked to return for a 3-month review but 4 of the home-titrated and 4 of the hospital-titrated patients did not. Their data were included in the analysis of outcomes at 3 months by assuming no CPAP use. We deliberately chose to compare a 1-night sleep-lab titration—the standard titration in Edinburgh—with a 3-night home-based titration because having patients return the next morning from up to 100 miles away would have given them up to 400 miles driving in 24 hours, which was undesirable. Further, having gotten them an intelligent CPAP machine at home, we were keen to optimize the CPAP-titration data obtained because letting them have the machine for 3 days rather than 1 incurred only the cost of the loan of the machine—less than \$2. We have not done a direct comparison of home titration with a split-night titration, the routine procedure in many centers. However, although split-night studies may be as good as whole-night lab-based titrations, there is no evidence that they are better than whole-night studies,²²⁻²⁴ so it is likely that home titrations are at least as good as split-night titrations. Several studies have suggested that CPAP pressure can

be set from formulae²⁵ or by pressure adjustment by the patient and bed partner.¹⁶ Both deserve more investigation, but, with this lifelong therapy, it is good practice to document that patients respond to CPAP, and the use of an intelligent CPAP device at home provides the required data.

We also used the OSLEER test differently, as compared with the originally described use.¹² We used 2 rather than 4 tests per day to decrease the time requirement on the subjects, most of whom were in work, from 2 whole days to 2 half days. We chose to perform the morning sleep tests because reliability has been found to be better for these earlier rather than later naps.^{26,27} Our use of 20- rather than 40-minute test durations allowed each day of tests to be 40 minutes shorter for the subjects. This design builds on the original observation of Bennett that a 20-minute mean-latency cutpoint is 100% accurate in differentiating sleepy from normal individuals, and our approach has also been used by others.²⁸

Other limitations of the study include the fact that the results cannot be extrapolated to other automatic CPAP units nor to manual titration (although Masa's study¹⁷ addressed that issue), that the costs may vary markedly between different locations and health systems, and differing diagnostic studies used. Our standard protocol is to use home tests as diagnostic if the home-test result is obviously positive,²⁹ and we applied this to patient selection for this study. This was an entry criterion prior to randomization and not an outcome measure, so it will not have affected the results of the study. Furthermore, as expected from a randomized study, the baseline data indicate a similar severity of OSAHS in the study groups.

This study provides evidence that automatic home-based CPAP titration delivers quality of care equal to that of sleep laboratory titrations and at lower cost per patient, thus potentially speeding up throughput and protecting sleep-laboratory space for patients with complex problems.

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