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Identifying poor compliance with CPAP in obstructive sleep apnoea: A simple prediction equation using data after a two week trial

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Summary
Introduction: It is important to identify those patients with OSA who are likely to benefit from long term CPAP, not only for symptomatic relief, but also potentially to reduce vascular morbidity and mortality, but are unlikely to adhere to treatment. We have validated a model which we developed previously for predicting long term compliance with CPAP using data after a 2 week trial.
Methods: The model was applied retrospectively to patients undergoing a trial of CPAP. Predicted outcomes were compared with the actual outcomes.
Results: Prediction equation was applied to 448 patients [77% males, Age 53 ± 11 years, ESS 14 ± 4, AHI 37 ± 24]. Of 407 patients included in the study 333 were issued a CPAP and 74 declined long term CPAP. At one year, 81% patients were using CPAP at least 2 h and 70% > 4 h. A score >50% from the equation was associated with a high probability of CPAP usage at one year. 295 patients had a probability score of >50% and of them 84% were using CPAP satisfactorily at 1 year. The sensitivity in identifying compliers was 91%. Of the 112 patients with a score ≤50%, 38 opted to accept CPAP and 60% of them were still using it at 1 year.
Conclusions: This simple equation has now been validated to be highly sensitive in identifying long term compliers and it also identifies those with worse compliance. This group could be targeted for a more intensive follow up regime with the aim of improving their compliance.

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Introduction

Obstructive Sleep Apnoea Syndrome (OSAS) is common and has a prevalence of 2—4% in the general adult population.[1] It is under diagnosed and under treated.[2—4] Daytime intellectual and physical function are affected and the incidence of systemic hypertension, diabetes, cardiovascular, and cerebrovascular disease increased.[5—12] Patients with OSAS have been shown to be at increased risk of traffic accidents.[13] Continuous positive airway pressure (CPAP) is recommended as first-line therapy for most patients with symptomatic OSAS and has been shown to improve sleep quality, reduce daytime sleepiness, and enhance quality of life.[14] Long term treatment with CPAP might reduce vascular morbidities and hence it is important to identify patients who might have problems with compliance in the long term.[15—17]

Instituting CPAP treatment usually includes a short trial of CPAP lasting between 2 and 4 weeks. During this period pressure is titrated and problems, particularly with the mask are addressed. Patients then make a decision about whether they wish to continue it. However long term compliance with CPAP is variable and studies quote non-compliance rates as high as 50% by 1 year.[18] Organizing CPAP trials and issuing machines is an expensive and time intensive process. Various attempts have been made to predict and identify factors which predict short and long term compliance, based on clinical and polysomnographic data.[18] However the available data is diverse and conflicting, with no clear predictive factors emerging.[19—22]

Similarly we have previously shown that it is not possible, from baseline data to predict which patients offered CPAP will opt to continue it long-term after a two-week trial. However we found that using data available at the end of a two-week trial we could predict those patients who would continue to use it satisfactorily at one year.[23] Other studies have also shown that short term compliance with CPAP can predict long term compliance.[21,24] In our study a logistic regression model indicated that nightly mean CPAP use during the loan period and a simple satisfaction score accurately defined continuing CPAP and "satisfactory" CPAP use at one year. For patients with low CPAP usage and no symptomatic improvement during the trial period the addition of baseline AHI and difference of Epworth score between baseline and the end of the loan to the regression equation improved the predictive value of the model but only slightly. The models were much less reliable at identifying patients who would not use CPAP, as some patients with a low probability of using CPAP were actually using it "satisfactorily" at one year. We now attempt to assess the impact of these models in a different patient population and explore the possibility of any practical utility.

Methods

The study was conducted in the Department of Respiratory Medicine at St. James's University Hospital, Leeds, UK. Diagnosis of OSAS is based upon the clinical history and examination and confirmed by either an overnight respiratory variable sleep study (Embletta®) or pulse oximetry. Usual demographic information, Epworth Sleepiness Score (ESS), Apnoea Hypopnoea Index (AHI), Oxygen Desaturation Index (ODI) or 4% dip rate for oxygen saturations were recorded.

The decision to offer patients a trial of CPAP depends on a balance between the severity of the sleep disordered breathing, the patient's symptoms and their impact upon quality-of-life. Broadly speaking patients with significant sleep disordered breathing (AHI or ODI greater than or equal to 30 events per hour) are offered the trial of CPAP whether or not they perceived that they had significant symptoms, whereas patients with AHI or ODI less than 30 events per hour were offered a trial of CPAP if they had symptoms which had an impact on quality-of-life and daytime function. Other factors such as occupation, miles driven per year, marital disharmony, potential for benefit from other interventions (eg. alcohol avoidance, weight reduction, relief of nasal obstruction), patient's preference and expectation also influence the decision. CPAP was usually offered as the first choice treatment.

Patients who accepted the offer of a CPAP trial were loaned a smart CPAP (ResMed® Autoset Spirit S7 or S8) device for a two-week home trial in a one to one appointment of 45 min with a specialist nurse. They were fitted with an appropriate mask and head gear and explained the rationale, benefits and possible side effects of CPAP in detail. They were provided with information leaflets and troubleshooting tips. They are encouraged to contact the team in case of any problems. At the end of the two weeks they were reviewed by the nurse specialist in a 30 min appointment. They completed an Epworth score and a five point satisfaction score ("much better" to "much worse") of how they felt during the two week period. The mean overnight use and the AHI while on CPAP were downloaded from the machine. The AHI estimated by Auto-titrating CPAP has been shown to correlate with AHI from polysomnography.[25,26] At this consultation patients were asked whether they wished to continue CPAP long-term. Occasionally patients were offered an extension of the two-week period or a second trial either because they had developed a problem which compromised their ability to use CPAP (for instance upper respiratory tract infection) or if they had severe symptomatic disease, had struggled with CPAP initially and were willing to have another try. During the second trial patients were offered any of the following: a different mask, a humidifier or with the machine set with a lower maximum allowable pressure, as deemed appropriate.

For those accepting CPAP a machine (fixed pressure CPAP machine with setting based on pressures recorded by auto-titrating machine) was issued and the patient followed up either in person or by telephone at 2 months. Patients were also encouraged to contact the nurse specialists in case of any problems. Those with low machine use and/or poor symptom control had further inputs which included change of mask type, addition of a humidifier, adjustment of CPAP pressure or further education. Patients with residual sleepiness, despite adequate CPAP use, noted at any consultation had a CPAP machine download and/or check sleep study performed while using CPAP and any issues identified corrected.

Patients on CPAP were then reviewed in a yearly CPAP users' clinic at which point the assessment included

completion of an Epworth score and an estimate of the mean nightly use of the machine, calculated by dividing the total recorded hours of use by the number of days since the last reading.

Equations and analysis

The first equation derived from the regression analysis included average hourly use during the trial and patients' response to how they feel after the trial. The second equation included the above with in addition diagnostic and treatment ESS and diagnostic AHI. Both the equations have been converted to a simple Excel® based tool for ease of use. In these models a probability score of 50% was suggested as the cut off value, above which it was predicted that a patient will use CPAP satisfactorily at one year. Patients using the CPAP machine for more than 2 h per night on average were considered to have "satisfactory" levels of use. This 2 h cut off is derived from the original study.[23] The analysis was rerun using cut offs of 3 and 4 h. The actual equations are shown in Table 1. The Excel® based tool and instructions are provided as an online supplement, and a simple summary table with various combination of average overnight usage and patients' responses is provided in Fig. 1.

All the patients who had undergone a trial of CPAP in 2007 were identified from the sleep services database using only a numerical identifier and thereby all data was completely anonymised. The equations were applied to come up with a predicted probability score. A score above 50% should predict satisfactory use at one year and this was compared with the actual outcomes to calculate the sensitivity, specificity and predictive values of the models. The equations had not been used to inform the decision as to whether CPAP should be issued or not.

Logistic regression was carried out in an attempt to predict satisfactory use at 1 year with baseline demographic and polysomnographic information as was performed in the original study.[23] The outcome variables were "using CPAP satisfactorily" and "not using CPAP satisfactorily" at one year. The independent variables were age, sex, BMI, diagnostic AHI and ESS. This was to validate the original findings in a different population.

Overnight usage at the time of trial and at one year was correlated using Pearson's coefficient.

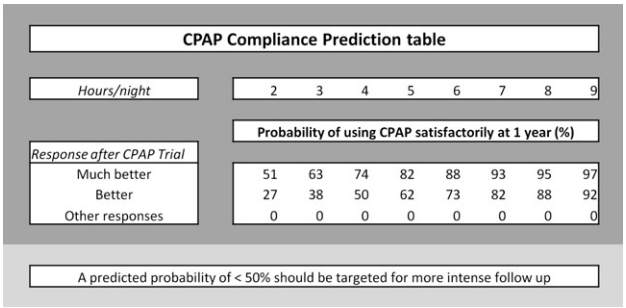

Figure 1 CPAP compliance prediction table derived from the prediction equation.

Statistical analysis was carried out using GraphPad Prism® 5 and SPSS® 17 software. As anonymised data were used for this study, formal ethical approval was deemed unnecessary by the local NHS Research Ethics Committee.

Results

In 2007 a total of 502 patients with various severities of OSA were referred for a trial of CPAP. There was sufficient information on 448 patients [346 (77%) males, Age 53 ± 11 years, BMI 35 ± 8 kg/m,[2] ESS 14 ± 4, AHI 37 ± 24, ODI 43 ± 26] to apply the first equation. A further 41 patients were excluded from the analysis due to various factors including moving to a different area, incomplete 1 year data, planned temporary CPAP for peri-operative use only. Of the 407 patients 333 (82%) were issued with a CPAP machine and 74 (18%) declined long term CPAP.

A regression analysis was performed utilizing the baseline information, prior to the commencement of the CPAP trial, in an attempt to predict who would decline CPAP option after the 2 week trial and also to predict 1 year compliance. The analysis showed that it is not possible to predict either of them, confirming the findings from the original study.

At one year, 270 (81%) patients were using CPAP for at least 2 h while 256 (76%) were using it for at least 3 h and 236 (70%) had a usage of more than 4 h per night. One hundred and eighty eight (56%) and 53% patients had a usage of more than 5 and 6 h respectively. The patients using CPAP at least for 2 h at 1 year were more likely to be

Table 1 The regression equations.

Equation (1)	Equation (2)
Probability of using satisfactorily at 1 year = X/(1 + X) Where X = EXP (−0.9655 + H * 0.4984 + R) H = Average overnight usage in hours during the 2 week trial period R = Response to the question "How do you feel after CPAP trial?" Much Worse = −9.2373, Worse = −10.1182, Same = −11.9076, Better = −1.0157, Much better = 0	Probability of using satisfactorily at 1 year = Y/(1 + Y) Where Y = EXP(−1.1987 + 0.7555 *H + 0.0304 * DA + R + DE + TE) H = Average overnight usage in hours during the 2 week trial period R = Response to the question "How do you feel after CPAP trial?" Much Worse = −8.637, Worse = −8.8342, Same = −11.18, Better = −1.2612, Much better = 0. DA = Diagnostic AHI (or ODI in case of oxymetry) DE = Diagnostic ESS. ESS "0–6" = −5.3914, "7–12" = −4.9789, "13–18 " = −5.5893, " 19–24" = 0 TE = Treatment ESS. ESS "0–6" = 2.743, "7–12" = 3.7408, "13–18 " = −0.6703, "19–24" = 0

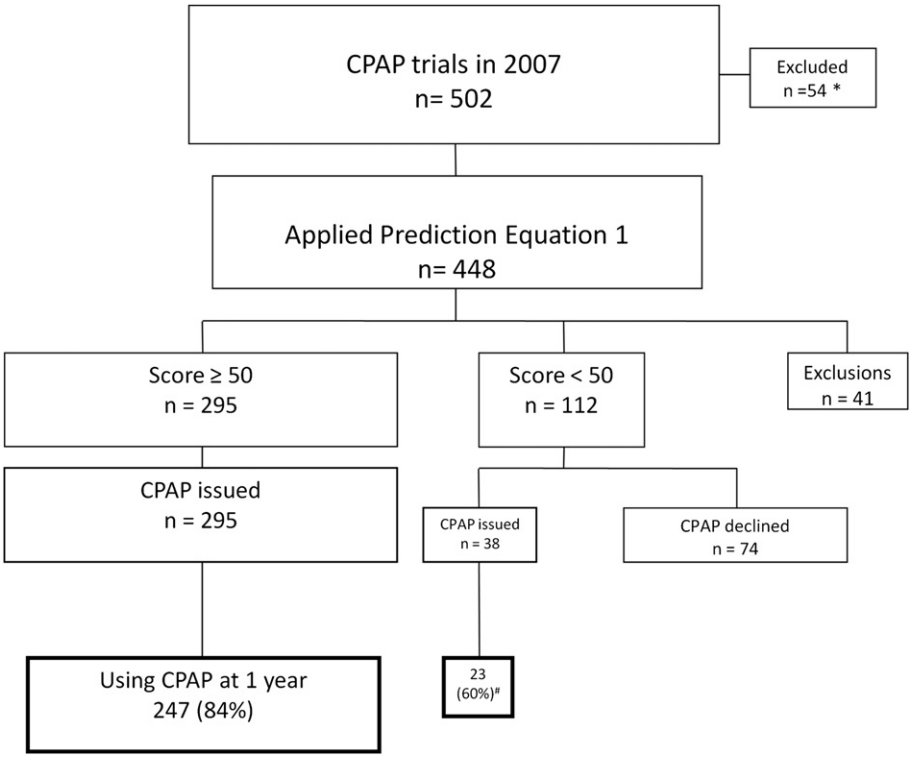

Figure 2 Outcomes at 1 year using the first equation (patient numbers are proportional to the area of text boxes, * = Excluded due to insufficient information, # = Using CPAP satisfactorily at 1 year).

males ($p = 0.004$, OR = 2.3), had higher diagnostic ODI/4% dip rate (46 ± 26 vs 36 ± 25, $p = 0.01$), showed a greater drop in ESS (change 8 ± 6 vs 6 ± 6, $p = 0.005$) and higher overnight usage during the trial period (5.9 ± 1.4 vs 4.9 ± 1.5, $p < 0.001$). There was a strong correlation between overnight CPAP usage during the trial period and at one year (Pearson's $r = 0.55$, $p < 0.001$).

Fig. 2 shows the outcomes of the CPAP trials in 2007 and how the patients scored on prediction equation (1) (applied retrospectively).

All 295 patients with a score of ≥50%, had been issued with CPAP. 247 (84%) patients, (baseline ESS 15 ± 4, AHI 40 ± 26, ODI 44 ± 26) were using CPAP "satisfactorily" at 1 year. The average CPAP usage at 1 year for patients with scores of ≥50% and below 50% were 5.4 ± 2.5 and 4 ± 2.1 h respectively.

Of the 112 patients with a score below 50%, 74 had declined CPAP. 38 patients had accepted CPAP treatment & 23 (60%) patients (ESS 15 ± 5, AHI 40 ± 21, ODI 45 ± 23) were still using CPAP "satisfactorily" at 1 year. This difference in CPAP compliance at 1 year between patients with scores below and above 50 was highly significant (Chi square $p < 0.001$).

The sensitivity & specificity of the first equation were 91% & 24% respectively. The Positive Predictive Value was 84% with a Negative Predictive Value of 39%. The sensitivity of this equation in identifying compliers in the original study was 94%.

The second equation, despite utilizing more information was not superior to the first equation. If the definition of satisfactory usage was changed to 3 or 4 h, the negative predictive value ie. the likelihood of predicting who will not be using CPAP above a certain threshold goes up. However the sensitivity and specificity remains similar. (Table 2).

Discussion

It is important not only to know which patients are likely to be compliant with CPAP treatment in the long term but also who are likely to have problems. Predicting short and long term compliance with CPAP from the initial demographic, clinical and polysomnographic data is difficult.[20] In our original study there was no significant difference

Table 2 Sensitivities, specificities, positive predictive values (PPV) and negative predictive values (NPV) for equations (1) and (2) using different definition for satisfactory usage.

	Average overnight use		
	2 h	3 h	4 h
Equation (1)			
Sensitivity	91	92	95
Specificity	24	25	27
PPV	84	80	76
NPV	39	52	71
Equation (2)			
Sensitivity	79	80	82
Specificity	32	34	35
PPV	84	80	76
NPV	25	33	45

between the groups who accepted CPAP after initial trial period and who declined or between the groups of satisfactory users and non users at one year in terms of age. Collen et al found only the use of a sedative/hypnotic during CPAP titration ($p < 0.0005$) and higher age ($p = 0.02$) were associated with better short term compliance.[18] Poulet et al could accurately predict in 85% patients who would be compliant in the short term using psychological variables.[27] Other studies have shown conflicting evidence regarding impact of age and gender on long term compliance.[19,28] A high AHI has been shown to correlate positively with long term compliance.[22,29,30] In our study the diagnostic ODI was significantly higher in the compliant group but only in univariate analysis. In a more recent study by Kohler et al, ODI was found to be the only predictor of long term compliance after multivariate analysis.[31] However this study did not include any patient satisfaction score like ours which could potentially have been better in predicting compliance. Our second equation which included AHI was not any superior to the first equation in predicting compliance in the validation cohort. High ESS did not correlate with short or long term compliance, similar to our previous study and other published data.[18,22,31]

We have previously shown that data obtained after a 2 week trial can predict compliance at one year.[23] A small number of patients might choose not to use CPAP long term because of symptomatic improvement due to other causes like losing weight, tonsillectomy etc. This group will not be identified by these models but is unlikely to influence the model due to very small numbers. We have now validated this equation in a different population which has not been done before for any prediction models. A score above 50 in the first equation predicted with a high level of confidence, which patients would be using the CPAP at 1 year. The majority of the patients who scored below 50 declined to have CPAP. However if they opted to accept CPAP treatment, 60% continued to use "satisfactorily" at 1 year. But this is significantly lower than the group with score above 50 (84%, $p = 0.0004$). These data, and those from other studies, confirm that it is reasonable to offer all patients with a high ODI/AHI a trial of CPAP regardless of their symptom burden. Our practice of offering CPAP to anybody with AHI/ODI > 30 is supported by recent data from Kohler et al where the adherence rate at 10 years was 79% for patients with ODI $>30-60$.[31] We now know that long term compliance is vital not only for symptomatic improvement but also for effects on cardiovascular morbidities like hypertension, diabetes, stroke, etc.[17,32,33] However currently we do not have enough evidence to offer CPAP to patients with less severe OSAS who do not have excessive day time somnolence.

Various interventions have been shown to improve long term compliance. It is important to identify the issues that might affect compliance and address them as far as practicable. Common issues include difficulty with masks, nasal or pharyngeal problems and lack of subjective improvement.[28] Weekly phone calls during the first month of CPAP usage or use of a short educational video during the initial titration improved the compliance compared to standard written information.[34,35] Extra early support improved re-attendance rates at 1, 6 and 12 months.[36] A compliance rate of $>85\%$ at 6 months was achieved by an intensive follow up and "troubleshooting" regime.[37] There are other newer methods being tried to improve compliance which include use of Eszopiclone during initial trial, Cognitive-Behaviourally informed and Motivational interventions and telemonitoring.[38–41]

All these interventions are simple but labour intensive. It is not feasible to provide intensive follow up regimes for all patients. Our validated prediction equation can identify patients who are less likely to persist with CPAP long term and might therefore benefit more from these regimes and help to prioritize resources accordingly. The simple Excel® based tool makes it easy to use on a day to day basis.

Eighteen percent (74/407) of our patients declined to continue CPAP after the initial two week trial; other studies report that around 30% of patients have either declined longer term CPAP or are not using it at 1 month.[27,42] Overall 81% of our patients who were issued with a CPAP were using it for at least 2 h/night and 70% for 4 h at one year. Our mean overnight use over the first year was 6.0 ($\pm$ 1.8) hours. This is comparable to the recent data published for long term compliance by Kohler et al and other previous studies.[29,31,43] Therefore our population of patients using CPAP is likely to be similar to those in other studies and our results generalisable. It is worth noting that compliance and adherence rate of CPAP treatment in general is higher or comparable to other therapies in respiratory medicine. Adherence to inhaler therapy in COPD varies between 40 and 60% in the general population. Percentage of patients using the inhalers properly is even lower.[44,45] Even in the research setting adherence to inhalers is reported as 79%.[46] Measuring compliance for CPAP is easier, and therefore more likely to be accurate, than medical therapies with the ability to download data from the machines.

In summary, it is important to identify patients who are likely to benefit from long term CPAP but are less likely to adhere to treatment. Potential benefits of long term adherence are not only reduced symptoms and improved quality of life, but also potentially reduced cardiovascular morbidity and mortality. This simple tool which has now been validated can identify this subset of patients who might benefit from more intensive follow up, particularly if they have severe OSA or many symptoms. The simplicity of the tool makes it an attractive practical option in busy clinics.

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Conflicts of interest statement

There are no competing interests to declare.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.rmed.2012.10.008.

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