Comparison of ResMed AutoSet (version 3.03) with polysomnography in the diagnosis of the sleep apnoea/hypopnoea syndrome

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Comparison of ResMed AutoSet (version 3.03) with polysomnography in the diagnosis of the sleep apnoea/hypopnoea syndrome. M. Gugger. ©ERS Journals Ltd 1997.

ABSTRACT: In patients with the sleep apnoea/hypopnoea syndrome (SAHS), accurate and timely diagnostic evaluation and initiation of effective treatment is important. Therefore, an increasing number of limited sleep studies are now performed nowadays diagnosing the SAHS in typical patients. It was the aim of the present study to evaluate the diagnostic accuracy of one such system, the updated ResMed Sullivan AutoSet, against polysomnography.

Sixty seven patients underwent full overnight polysomnography and simultaneous data acquisition with the AutoSet. Up to now, the AutoSet was designed for apnoea detection only. The new AutoSet, with software version 3.03, detects apnoeas if ventilation drops to <25%, and apnoeas+hypopnoeas if ventilation drops to <50%, compared with the recent average (100 s), using two independent detectors. A two page report with graphically displayed information on oximetry, snoring and breathing parameters, and an apnoea+hypopnoea index (AHI) and an apnoea index (AI) are provided at the end of each study night.

There was a correlation between the AHI assessed by the AutoSet (AHI-AutoSet) and by polysomnography (AHI-PSG; r=0.95). The mean difference between the AHI-AutoSet minus the AHI-PSG was 4.2 (sp 7.2) respiratory events·h⁻¹ (p<0.001). The AutoSet identified patients with an AHI-PSG >20 events·h⁻¹ (a level of respiratory disturbance that would warrant consideration for treatment in most centres for sleep disorders), with a sensitivity of 97% and a specificity of 77%. The AutoSet was superior to oximetry alone.

As event counting was similar between the two methods, the AHI-AutoSet may provide a reasonable indicator of the respiratory disturbance at night, especially when taking the patients graphic study report into consideration. In conjunction with full clinical information on the patients under investigation, the AutoSet might become a useful device in diagnosing the sleep apnoea/hypopnoea syndrome. Eur Respir J 1997; 10: 587–591.

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Patients with sleep-disordered breathing represent by far the largest patient group needing overnight investigations in sleep medicine. A large number of people with breathing abnormalities during sleep have been identified in recent years [1, 2]. The obstructive sleep apnoea/ hypopnoea syndrome (SAHS) contributes to the morbidity and mortality of patients who are afflicted with this condition [3–5]. Accurate and undelayed assessment is important, since with nasal continuous positive airway pressure (nCPAP) effective treatment for this condition is available [6-8]. Therefore, an increasing number of limited sleep studies are now being performed. Polysomnography is time and labour intensive, and doubts are sometimes raised as to whether polysomnography can still be regarded as the "gold standard" method for diagnosing SAHS and for reviewing sleep studies in patients with nCPAP treatment [9, 10]. However, unless these important issues are resolved, new devices have to be validated against polysomnography. Despite the many reports on limited sleep studies, there is still no generally accepted simplified method for the management of the typical patient with the SAHS [7, 11, 12].

The AutoSet seems to offer a cheaper approach to the management of patients with a typical case history and clinical findings [11, 13, 14]. Up to now, the AutoSet was designed to detect only apnoeas, whereas the new software is supposed to detect both apnoeas and apnoeas+hypopnoeas. It was the aim of the present study to validate the updated software version 3.03 of the AutoSet in detecting respiratory events by comparison with the results of simultaneous polysomnography. A proposal for the practical use of the AutoSet in a clinical setting is given.

Method

Sixty seven consecutive patients (9 females and 58 males) of mean (SE) age 51 (1) yrs, mean (SE) body mass index (BMI) 31 (0.9) kg·m⁻², and mean (SE) Epworth

sleepiness score 10 (0.7) were assessed in our sleep laboratory. Their main final diagnosis was: obstructive SAHS (48); simple snoring (10); hypersomnia with mood disorder (2); insomnia (1); postpolio syndrome (1); thalamic stroke (1); and periodic limb movement disorder (4).

Polysomnography and simultaneous monitoring by the AutoSet (Sullivan AutoSet; ResMed Ltd, Sydney, Australia) were performed, using the AutoSet-software version 3.03 and a 486 PC. An oximeter (Biox 3700; Ohmeda, Essex, UK) and standard nasal prongs are the only sensors needed for the AutoSet. The nasal cannulae are connected to a pressure transducer in the AutoSet device. Nasal airflow is assessed semiquantitatively (arbitrary units, range 0–20), measuring pressure in the anterior nares [11, 15]. The pressure versus nasal flow relationship is then linearized in software. The manufacturers claim that, although the magnitude of the signal will depend on the fit between the cannulae and the nostrils, relative changes are measured with an accuracy of $\pm 10\%$ in the range 0–150% control. The threshold for the apnoea count is a reduction in the ventilation to $\leq 25\%$, and for the apnoea+hypopnoea count to $\leq 50\%$, compared with the recent average (time constant 100 s). The apnoea index assessed by the AutoSet (AI-AutoSet) and the apnoea/hypopnoea index assessed by the Auto-Set (AHI-AutoSet) are detected independently and are calculated per hour of recording. AutoSet does not specifically report the hypopnoea index, but it can be calculated as the difference between the apnoea+hypopnoea index (AHI) and the apnoea index (AI).

Two electroencephalograms, two electro-oculograms, electromyograms (submental, left and right tibial), oronasal flow (thermistors), thoracoabdominal movements (respiratory inductive plethysmography, Respitrace), electrocardiography, and position were recorded for standard overnight polysomnography. The oximeter was connected both to the polygraph (Nihon Kohden, Tokyo, Japan) and the AutoSet, and the nasal prongs to the AutoSet. All recordings were made simultaneously. Online display of the AutoSet flow curve and data and an infra-red videosystem with zoom facilities and a microphone allowed continuous supervision by the sleep technician.

Standard criteria were used for the analysis of the polysomnography data [16], i.e. apnoea was defined as a cessation of oronasal flow for ≥ 10 s, hypopnoeas as a reduction of oronasal airflow by >50% for ≥10 s, without a desaturation criterion and using a baseline of 120 s. After each recording night, polysomnography scoring was performed before generating the AutoSet report. The AutoSet report shows oxygen saturation (every 2 s), 8 s moving average nasal minute ventilation in arbitrary units (every 2 s), time and duration of apnoeas, and AI and AHI. Also shown are indices of snoring and airflow limitation, which are not relevant to the present study. The software offers no editing facilities, and data have to be accepted as they are, but raw airflow, snore, and oximetry data are stored at 50 Hz, and may be replayed off-line.

Data analysis

The number of apnoeas+hypopnoeas per hour of sleep from polysomnography was compared with the number of apnoeas+hypopnoeas per hour of AutoSet-recording, using Wilcoxon rank test, Bland and Altman [17] plots and correlation analysis. Results are reported as mean (SE). Polysomnography results and oximetry recordings were categorized as indicative of sleep apnoea/hypopnoea warranting treatment, when more than 20 apnoeas+hypopnoeas or more than 20 4% dips per hour of sleep were found. A p-value less than 0.05 was taken as the level of significance.

Results

Only one patient experienced problems and refused the nasal prongs after 2.3 h of recording (total sleep time (TST) 5.6 h; AHI assessed by polysomnography (AHI-PSG) 29.5 events·h-1; AHI-AutoSet 46.6 events·h-1). All recordings performed were included in the study. The mean (SE) total recording time was 6.9 (0.1) h for polysomnography and 6.8 (0.1) h for the AutoSet. The TST during polysomnography was 5.9 (0.1) h. On polysomnography, the patients had a mean (SE) of 26.2 (2.9) apnoeas+hypopnoeas·h-1 of sleep (a total of 10,390 apnoeas+hypopnoeas for all 67 subjects together). The mean number of apnoeas+hypopnoeas assessed with the AutoSet was 30.4 (2.7) events·h-1 of recording (a total of 13,780 events).

The difference in the number of respiratory events, scored by the two techniques, was statistically significant (p<0.001). Figure 1 shows the correlation between the AHI-PSG and the AHI-AutoSet (r=0.95; p<0.001). Figure 2 shows a Bland and Altman [17] plot (mean AHI difference 4.2 events·h⁻¹) and the limits of agreement for the AHI were (±2 sd: from +18.7 to -10.3 events·h⁻¹). There was also a significant correlation between the AI derived from polysomnography (AI-PSG) and the AI-AutoSet (r=0.95; p<0.001). The difference between the AI-PSG (16.1 events·h⁻¹ of sleep; a total of 6,440 apnoeas in all 67 patients together) and the AI-AutoSet (18.6 events·h⁻¹ of recording; a total of 8535 apnoeas) was significant (p<0.005) (the mean difference was 2.5 apnoeas·h⁻¹, and

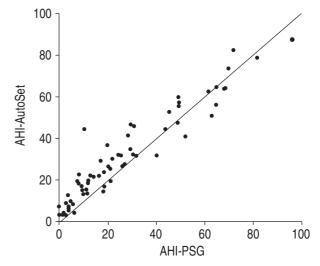


Fig. 1. – Correlation between the apnoea+hypopnoea index (AHI) assessed with the AutoSet (AHI-AutoSet) and the AHI assessed by polysomnography (AHI-PSG). The line of identity is shown.

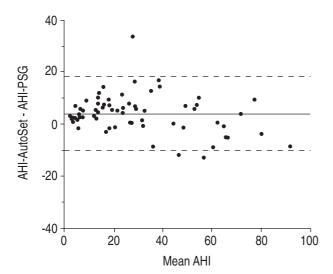


Fig. 2. – Difference between the apnoea+hypopnoea index (AHI) assessed with the AutoSet (AHI-AutoSet) and by polysomnography (AHI-PSG) plotted against the mean apnoea+hypopnoea index (Bland and Altman [17] plot). The solid line represents the mean difference, the dashed lines represent the limits of agreement (±2 sd).

the limits of agreement for the AI were ± 2 sp: from +15.6 to -10.6 apnoeas·h⁻¹).

The sensitivity and specificity of the AutoSet in detecting patients with an AHI >20 events·h-¹ during standard polysomnography was 97% and 77%, respectively, and of oximetry (>20 4% $\rm O_2$ dips) 66% and 94%, respectively.

Discussion

The main finding of this study is the good correlation between the AHI assessed with the ResMed Auto-Set software version 3.03 and the AHI derived from simultaneous standard polysomnography (fig. 1). As with the previous software, which was designed for apnoea detection only, the AutoSet still tended to overscore respiratory events (fig. 2). The difference between the two methods was statistically significant (p<0.001) in this study, which included more subjects than the previous two studies together [13, 14]. The sensitivity and specificity of the method were calculated for an AHI-PSG

>20 events·h-1, a level of respiratory disturbance that would warrant consideration for treatment in most centres for sleep disorders [18, 19]. The AutoSet is not designed to replace full diagnostic evaluation in all patients with sleep-disordered breathing, but to provide adequate, although in some cases possibly provisional, information for the typical patient with the SAHS at less cost and labour within a reasonable time. As in the previous studies, the AutoSet was superior to oximetry alone in the patients studied [13, 14]. It appears that with this device a reasonable number of patients with suspected SAHS can be diagnosed in a first step, as suggested in table 1, where factors other than the AHI are considered (see below).

However, although the current results appear acceptable, there are several aspects and limitations which have to be considered carefully. As with the previous software version, we are still left with the problem of an unexplained obvious outlier, a trend for overscoring of respiratory events, and especially, a wide scatter of the data [13, 14]. These problems are presumably related to each other.

Our results were obtained under ideal conditions in a sleep laboratory with a sleep technician. Although handling of the AutoSet is easy, false positive or negative results may be obtained due to problems, such as nasal prong dislodgement or blockage by secretions, especially during unattended studies, or if the patient is predominantly mouth-breathing. As the Autoset derives all its data from one signal, it is particularly important to examine the raw data to assess the adequacy of the flow signal. From information on snoring, oximetry, the inspiratory flattening index and nasal ventilation, provided in the AutoSet-report at the end of the study, the suspicion of a false positive or negative result can usually be raised by a sleep expert and a repeat study or full polysomnography ordered, whenever the results are ambiguous [13].

Despite careful consideration of the complete data set provided in the report in conjunction with the polysomnography data, no obvious reason for the discrepancy of the AHI obtained by the two methods was found in the outlier of the current study, who was a patient suffering form periodic limb movement disorder. Looking at the outliers in the two recently published studies with software version 2 and the current study together leaves

Table 1. - Suggested diagnostic or therapeutic options for the practical use of the AutoSet

AHI-AutoSet events·h-1	Classification	CPAP treatment		Further investigation
0–10	Normal	Don't treat		No further investigation# or polysomnography ^{‡\$}
10-20	Mild	Might treat*	or	Polysomnography#\$
20–40 40+	Moderate Severe	Probably treat* Always treat	or	Polysomnography#\$

^{*:} depending on: 1) symptoms (especially sleepiness); 2) the degree of desaturation/hypoxaemia, snoring and sleep disturbance; 3) motivation and compliance; 4) concomitant cardiovascular, cerebrovascular or pulmonary diseases/risk factors; and 5) age. #: in simple snorers with no features of sleep apnoea; †: in patients highly likely to have sleep apnoea; *s: in equivocal cases. AHI-AutoSet: apnoea/hypopnoea index assessed by AutoSet; CPAP: continuous positive airway pressure. Patients who may have other disease than sleep apnoea should have polysomnography, not an AutoSet study. Patients who only had an AutoSet study and who do not respond to CPAP as expected should have polysomnography.

us with a total of three true outliers (three false positive results) out of 125 patients investigated [13, 14]. In these three patients, the AHI-AutoSet was misleading and considerably overestimated the severity of the breathing disorder during sleep, despite the fact that the investigation was taking place in a sleep laboratory and despite detailed inspection of all available raw data.

Although the problem of occasional outliers cannot be solved by putting the patients AHI results into categories [18, 20], as suggested in table 1, this approach still has several advantages. Except for the one obvious outlier in the current study, there was only one more patient classified two categories too high. The AHI of all other 65 patients was never more than one category out and, in fact, 16 patients were classified one category too high, two patients one category too low, and 47 (70%) in the correct category. Thus, categorizing patients AHIs but including clinical and additional laboratory features, reduces the importance of the apparent data scatter. Therefore, a major advantage of categorizing the data is that it helps to demonstrate that the AHI is only one parameter out of many others both of full polysomnography and AutoSet-data reports. Although this is well-known to sleep specialists, this point is becoming increasingly important, as limited sleep studies are being performed by an increasing number of doctors with no training in sleep and who are not fully familiar with the whole spectrum of sleep medicine and with polysomnography. Furthermore the situation may be complicated by any other sleep disorder, as was the case in our outlier patient with periodic limb movement disorder.

It is necessary to integrate the laboratory diagnosis into the clinical setting of the patient. Therefore, using a system to categorize the procedures (table 1) stresses the point that the diagnosis of SAHS needs both the laboratory assessment, appreciating the AHI in the context of the additional data provided in the report, together with some key features of the clinical syndrome [20]. All these aspects together must be taken into account in making the final decision. Of course, the schematic presentation in table 1 is not supposed to be taken as a rigid dogma, but rather as a practical guideline to assist in making individual clinical decisions in any single patient after an AutoSet study. The relatively high requirements for a nCPAP trial after an AutoSet study is proposed to avoid uncritical overuse in equivocal cases, or in patients with a low degree of sleep-disordered breathing, and to encourage proper baseline investigations in all such patients, who are often difficult to treat because of mild symptoms and in whom follow-up is

Why are these points so important in a simple validation study? Because it is necessary to understand what a new system is being validated against, and whether a gold standard method actually exists. In the current study, only one aspect, the AHI was truly validated, and the AHI-AutoSet was validated against polysomnography, a method which may not be regarded as the gold standard for sleep apnoea for ever. This background makes it easier to accept some inaccuracies of the measurements and of categories, as there is currently no definite scientific answer to questions, such as "What should we measure", "How should we measure" and, especially, "How

accurately do we need to measure" [9, 10]. These questions bring us back to the third problem of AutoSet, namely overscoring respiratory events. Apart from the technical aspects leading to incorrect results discussed above, there are other issues that may be even more important. One of the reasons for overscoring may be that the so-called gold standard method, polysomnography, rather than the new device, is not accurate enough, as thermistors and thermocouples are known to be highly nonlinear flow-sensors, and definitions of hypopnoea vary from centre to centre.

If we accept and remember the limitations discussed, the AutoSet may be used in a sensible way in patients with suspected SAHS. Nevertheless, achievements like the AutoSet should not allow us to slow down the further development of professional sleep disorders centres offering the full multidisciplinary diagnostic and therapeutic spectrum of sleep medicine, as it might be hazardous to focus exclusively on only one segment of the broad spectrum of sleep medicine, and to rely on a single assessment technique at a time where many important questions remain without a scientific answer.

Despite the fact that event counting was similar between the two methods and in the light of the above arguments, we should keep in mind that outliers occur and that there may be a considerable difference between the AHI assessed by the two methods in individual patients. Comparing the results obtained with the software version 3.03, which is supposed to detect apnoeas plus hypopnoeas, with those obtained with the previous software shows that only minor improvement has been achieved

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