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Evaluation of ApneaGraph in the diagnosis of sleep-related breathing disorders

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Abstract ApneaGraph relies on measuring pressure and airflow simultaneously at different levels in the pharynx identifying the segment of airway obstruction and providing baseline respiratory parameters. This study aims to evaluate ApneaGraph and correlate results with both sleep nasendoscopy and polysomnography. This was a prospective study of 49 patients with snoring and/or obstructive sleep apnoea. Thirty of the these patients underwent a PSG and an ApneaGraph study simultaneously in the Sleep Lab. Nineteen patients attended the day surgery unit and had a sleep nasendoscopy with a 10-min ApneaGraph analysis. Polysomnography was used to validate the ApneaGraph system. There are no significant differences (independent *t* test, $P > 0.15$) between ApneaGraph compared to Polysomnography based on the apnoea–hypopnoea index, total number of apnoeic events, average oxygen saturations and maximum desaturation. This suggests that the ApneaGraph can be used to assess OSA. Statistically, there is poor correlation between the two groups (Spearman's ρ 0.29). In the cases of discordance, ApneaGraph places greater emphasis on a lower pharyngeal contribution. This unique study analyses the ApneaGraph system in the diagnosis of obstructive sleep apnoea and snoring. It demonstrates the benefits of this new system and highlights certain limitations in localizing the site and level of pharyngeal obstruction in patients with sleep disorders.

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Introduction

Sleep-related breathing disorders (SRBD) affect 1–4% of the population [1] causing daytime somnolence, impaired work performance, increased road traffic incidents, hypertension and ischaemic heart disease [2, 3]. It is classically diagnosed by the in-laboratory overnight polysomnography (PSG) sleep study [4]. However, the limited number of sleep centres and beds often results in long-waiting lists for diagnosis and treatment of SRBD. There is evidence that untreated sleep apnoea is both deleterious to the patient and expensive to the healthcare budget [5, 6].

The AG200 ApneaGraph system (MRA, Medical, UK) is a relatively newer technology designed for the evaluation of SRBD. It stores and analysis the cardio-respiratory pattern of a patient with simultaneous recording of two different sites in the upper airway using a micro-pressure and temperature transducer catheter. By measuring pressure and airflow (via temperature) simultaneously in the pharynx, it is possible to identify the segment of obstruction during sleep in patients with upper airway obstructions (apnoea, hypopnoea and snoring). Previous work has shown that the use of continuous airway pressure and flow monitoring is repeatable [7] and reproducible between ambulatory and hospital settings [8].

Potentially, the ApneaGraph system could replace home sleep studies and sleep nasendoscopy (SNE), as it can provide an equivalent level of information, implying a significant cost-saving. It is also more portable with less connections compared to some other devices. However, the quality of information gathered from ApneaGraph (AG) and probe-related problems have not been evaluated.

This study aims to evaluate the ApneaGraph system as compared to full polysomnography and the current practise of sleep nasendoscopy.

Methods

Patients awaiting an overnight sleep study based in the sleep lab or a sleep nasendoscopy on the elective waiting list were enrolled in to the study. Two groups were defined: the first was a comparison of the studied device (ApneaGraph) with full PSG (Sleep acquisition computer, Oxford Instruments, UK) in a dedicated sleep lab over a 6-h period and the second included a synchronous recording of ApneaGraph with sleep nasendoscopy over a 10-min period.

The AG system does not require thoracic or abdominal pressure transducer bands, making it easier to apply to the patient. A pulse oximetry probe is attached to the finger and a fine-bore catheter inserted into the nose and placed in the upper oesophagus, similar to a naso-gastric tube (see Fig. 1). There are four transducers (two pressure and two temperature) with one marker probe positioned at the lower border of the soft-palate (see Fig. 2), this ensures that all transducers are correctly aligned. The device can be pre-programmed to start at a set time and record for a maximum of 6 h. Data can then be downloaded and analyzed using dedicated software (Apnea Analysis version 6.61, MRA).

All patients were recruited from the sleep clinic at the Royal National Throat, Nose and Ear Hospital, London. Inclusion criteria included a history of snoring or possible OSA with patients having provided informed consent to participate in the study. The exclusion criteria included patients with: body mass index (BMI) >33 kg/m^2, requiring CPAP, ishaemic heart disease or previous treatment for SRBD.

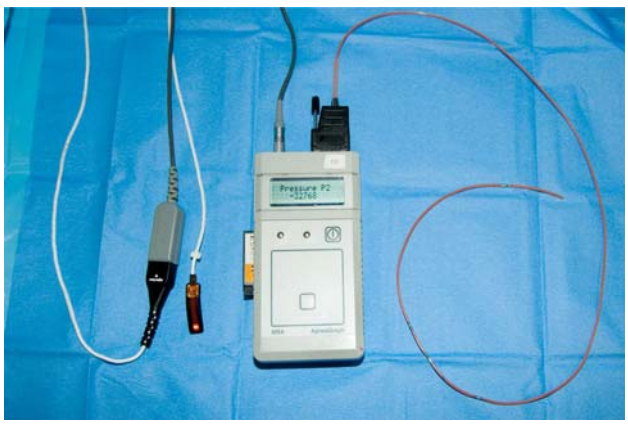

Fig. 1 The ApneaGraph device with its components: a pulse oximetry probe and the fine-bore nasal catheter with four transducers

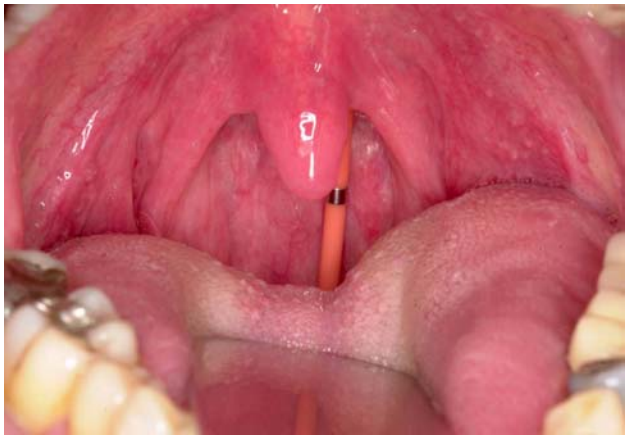

Fig. 2 Silver marker in the oropharynx denoting correct position of ApneaGraph probe

Patients attending for overnight PSG were managed in the usual way by a dedicated nurse and had the AG system attached, in addition to the standard equipment. Independent printed reports were provided for PSG and the AG analyses. For patients attending for SNE, the AG catheter was placed with the patient awake and the marker probe checked for position. These patients would then undergo SNE in the usual way. The surgeon would grade the levels of pharyngeal obstruction and record them on a proforma. The data from AG were not analyzed at the same time and sent to an independent assessor blinded to the results of SNE to reduce bias.

Ethical approval for this study was provided by the local research and ethics committee.

Data were analyzed using SPSS software (SPSS version 13, Chicago, IL). Age, BMI, Epworth sleepiness scores and respiratory parameters (AHI, apnoeic and hypopnoeic events, average oxygen saturation, maximum desaturation) were treated as continuous variables with parametric analysis (normal distribution verified using the Kolmogorov–Smirnov test). All other data was considered ordinal and Spearman's ρ employed for correlation analysis.

Results:

Forty-nine patients (36 males and 13 females) participated in the study with the following parameters (mean ± standard deviation): age 47.6 ± 11.7 years, BMI 31.1 (±5.8) kg/m^2, Epworth sleepiness score 10.5 ± 5.8.

Thirty patients underwent an overnight PSG with a 4–6 h AG study and 19 patients underwent a simultaneous ApneaGraph and sleep nasendoscopy. Ten patients experienced catheter displacement but seven patients had obtained 4 h of recording and so their data were included in

the study. In addition to the 49 cases, 13 patients were unable to tolerate the naso-oesophageal probe due to discomfort and no AG recording was possible. Therefore, the total number of patients unable to provide an AG recording (due to discomfort or displacement) was 26% (16/62).

AG versus PSG

PSG was used to validate the ApneaGraph system and the mean values are shown in Table 1. There are no significant differences (independent t test, $P > 0.15$) between AG compared to PSG based on the apnoea–hypopnoea index, total number of apnoeic events, average oxygen saturations and maximum desaturation. Hypopnoeic events did demonstrate a significant difference (67.4 versus 18.9 events, $P < 0.0001$).

Both SNE and AG provide information on the levels of pharyngeal obstruction and can be grouped into predominantly upper or predominantly lower pharyngeal obstruction. However, we prefer to refine this further by looking at percentage contribution of upper and lower pharyngeal segments to the overall pharyngeal obstruction [for example, 80% palatal obstruction (upper) and 20% tongue base obstruction (lower)]. SNE percentage scores are based on the senior author (BK) assessment. This same approach can be applied to AG as it produces percentage obstruction generated from the recorded data. These results are summarized in Table 2 and illustrated by Fig. 3, in which upper pharyngeal obstruction is represented by bars above the dotted line and implies a predominantly velopharyngeal component to the SRBD.

Using Spearman's rank, there is poor correlation between SNE and AG based on the upper and lower percentage pharyngeal contribution to overall obstruction ($\rho = 0.29$). We also looked at agreement between the two methods. In order to do this pragmatically, the findings were translated into predominantly upper or predominantly lower pharyngeal obstruction as shown in Table 3. Two cases showed an equal upper and lower contribution (i.e. mixed) on AG recording precluding them from further analysis. On this basis, when AG predicts an upper pharyngeal obstruction SNE agrees in all (7/7) the cases. Conversely, when AG predicts a predominantly lower obstruction SNE agrees in only 40% (4/10) of the cases. This suggests that

Table 1 Parameters compared using AG and PSG (standard deviations in brackets)

	AHI	Apnoea events	Hypopnoea events	Average O_2 saturation (%)	Maximum desaturation (%)
PSG	18.3 (16.4)	59.3 (76.7)	67.4 (49.4)	95 (2.0)	82 (8.0)
AG	17.3 (16.7)	52.5 (46.9)	18.9 (27.9)	94 (2.0)	79 (10.0)

AHI, apnoea–hypopnoea index; O_2, oxygen

Table 2 Details of site of obstruction by percentage contribution of upper and lower pharyngeal components

Case number	AG		SNE	
	Upper (%)	Lower (%)	Upper (%)	Lower (%)
1	80	20	30	70
2	80	20	20	80
3	70	30	70	30
4	100	0	50	50
5	100	0	70	30
7	80	20	20	80
8	100	0	10	90
9	65	35	20	80
10	60	40	40	60
11	100	0	80	20
12	40	60	20	80
13	60	40	95	5
14	80	20	90	10
15	20	80	40	60
16	75	25	50	50
17	40	60	40	60
18	75	25	90	10
19	10	90	20	80

Table 3 Details of the site of obstruction based on AG and SNE

Case number	AG main site	SNE main site
1	U	L
2	U	L
3	U	U
4	U	M
5	U	U
6	U	U
7	U	L
8	U	L
9	U	L
10	U	L
11	U	U
12	L	L
13	U	U
14	U	U
15	L	L
16	U	M
17	L	L
18	U	U
19	L	L

U, predominantly upper; L, predominantly lower obstruction; M, mixed

upper airway obstruction has better agreement between the two methods Fig. 3.

Discussion

There is no statistically significant difference between the in-lab recording of ApneaGraph and polysomnography on the basis of apnoea/hypopnoea index, apnoeic events, oxygen saturations and maximum desaturation.

Hypopnoeic events did differ significantly and may be explained by the different technologies. Obstructive hypopnoea is defined as a decrease in airflow to less than 50% baseline amplitude for a minimum of two respiratory cycles or an abnormal respiratory event lasting >10 s with a smaller reduction in airflow amplitude, but with an associated arousal or desaturation. Methods for the measurement of hypopnoea are related to the ability of a particular method to detect the presence of a hypopnoea. Criteria for measuring hypopnoeas have varied widely [9] AG utilises oesophageal pressure, which is considered to be a reliable way of assessing flow changes. This contrasts with PSG, in which, reduction in airflow is detected by the nasal cannula and corroborated with changes in respiratory rate and heart rate.

Previous work has shown that pressure recordings provide comprehensive diagnostic information in SRBD [10]. The AG device, in the diagnosis of OSA, compares favourably with polysomnography. Importantly, the addition of AG to patients having PSG does not significantly affect respiratory parameters [11].

In ascertaining the level of the pharyngeal obstruction, we found that AG and SNE had significant discordance suggesting different interpretations are provided. Neither is an agreed standard for the evaluation of upper pharyngeal collapse and not unsurprisingly there is poor correlation between the two different technologies. This does not mean that either technology is inappropriate for assessment. In fact, we believe, that both methods used in conjunction may have a role to play. The authors feel that the absence of direct dynamic visualization, as provided by SNE, limits information gathered on sites of obstruction especially in the lower pharyngeal tract.

If AG predicts an upper site of obstruction there is a high chance that SNE findings would agree. In contrast, of the lower cases of obstruction predicted by AG, less than half were confirmed by SNE. This finding raises the possibility of using AG as a screening tool. If we perform AG instead of the current home-based sleep study we should get reliable information on their AHI parameter and some idea of the site of obstruction. Our results suggest that upper obstruction is better correlated between AG and SNE but discrepancies arise when AG makes a diagnosis of lower obstruction. So, If AG reports an upper problem we could go on and offer a management plan for upper pharyngeal collapse (for example, a mandibular advancement device or palatal surgery). If AG reports a lower problem then these patients need to undergo SNE to further evaluate their lower pharyngeal airway and then formulate appropriate treatment options. This could help streamline services and may save in costs in the long term.

Flowchart demonstrating role of AG in evaluation of SRBD:

All patients have home AG

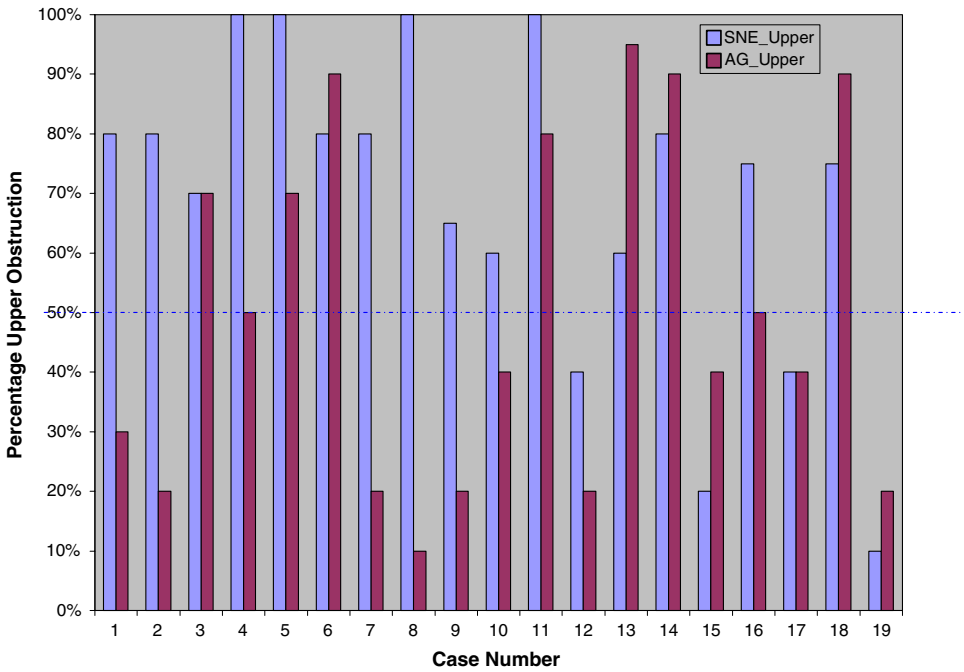

Fig. 3 Bar chart showing the percentage upper obstruction based on SNE and AG recordings. *Bars* above the *dotted line* suggest predominant upper pharyngeal obstruction

- mainly upper obstruction→palatal obstruction→splint or palatal surgery
- mainly lower obstruction→proceed to SNE→formulate treatment plan

The ApneaGraph system is applicable in the sleep state as well as the sedation state (i.e. as in sleep nasendoscopy). However, even in our limited analysis, the acquisition of data in these two different states is performed over different time periods making any comparison inappropriate.

There is no test/investigation that is the gold standard, to determine the degree and site of pharyngeal obstruction in the evaluation of SRBD. Therefore, we have no way of knowing which test (AG or SNE) is more accurate. Both modalities have their advantages and disadvantages; SNE is minimally invasive and provides a dynamic visualization of pharyngeal collapse but is operator dependent and requires sedation; AG does not need sedation and combines the sleep study with data on site of obstruction in one investigation but is poorly tolerated by some patients and relies on accurate placement and limited respiratory movement artefact. During the SNE part of our study, we noted that the AG catheter moved with respiration and often required repositioning endoscopically due to probe displacement. Further, the microtransducers are all at fixed distances but morphological variations in pharyngeal dimensions may prevent appropriate placement of the transducers. We note, from the literature, that over the last 10 years three different systems have been described varying the number of transducers and the distances between them. In restricted oropharyngeal views it was difficult to know which transducer was being visualized and which direction the catheter need to be adjusted in order to see the marker. We felt that using different colour transducers would be extremely helpful in obtaining accurate positioning and are aware that this technique was employed in an early study [12].

The high number of patients unable to tolerate the AG catheter differs from the impression gleaned from the previous studies. Generally, patients felt that the insertion of the probe caused discomfort and some found it an eye-watering experience. Initially, catheter displacement was attributed to problems with the fixation of the probe to the nose. However, the actual tape used remained attached to the nose and it was the distal probe which had become displaced. One possibility which may explain the discomfort levels is that the transducers add stiffness to the catheter making it less tolerable then an ordinary fine-bore nasogastric tube.

In our practise, we do not feel that AG can replace SNE but it is, nevertheless, a welcome addition to our armamentarium in the evaluation of SRDB. In cases where both AG and SNE were to agree in their findings then this may lend greater support in the subsequent management. If disagreement occurs between the two tests then we would favour the findings of SNE; as we feel dynamic, three-dimensional, real time evaluation of the anatomical sites of upper airway collapse remains invaluable. Further, SNE allows detailed assessment of the lower aerodigestive tract including the tongue base, epiglottis and larynx which is not available with AG.

The findings of the study are interesting and certainly commend that AG be further evaluated. It is reliable as a home sleep study providing an accurate measure of apnoeic/hypopnoeic events and pulse oximetry. Secondly, it provides an insight into the level of obstruction but needs further evaluation before it can be relied upon in the decision-making process for SRDB. The sophisticated use of both AG and SNE in the evaluation of multi-segmental obstruction may allow us to provide a better tailored solution for the patient eventually leading to a more successful outcome. For example, if SNE predicts a predominant upper level of obstruction but AG differs, then this may suggest that the patient needs to have both upper and lower segments addressed to improve symptoms. Clearly, to clarify this intriguing concept further studies are needed.

Conclusion

Our results and experience reaffirm the need for polysomnography and sleep nasendoscopy in the multidimensional evaluation of upper airway obstruction in SRBD. The ApneaGraph is a different technology which is potentially exciting but poorly tolerated by some and requires further evaluation to ascertain the reliability of data regarding upper and lower pharyngeal obstruction.

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