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Feasibility study of Flextube reflectometry for localisation of upper airway obstruction in obstructive sleep apnea*

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SUMMARY

One hundred and twenty-three patients with snoring problems and/or obstructive Sleep Apnea Syndrome (OSAS) were offered Rhinosleep Flextube- reflectometry during sleep registration to assess the upper airway. The main point of interest was patient acceptance of the procedure. 36 patients with OSAS received Rhino Flextube reflectometry. Of these, 19 (53%) completed a whole night registration with the Rhinosleep tube and 17 (47%) did not. This low success rate is multifactorial and will be discussed in detail in the text. The development of Rhinosleep is a challenge, as it improves the topical diagnostic work-up of OSAS patients. At present however various practical problems have to be solved to make it a viable alternative to sleep endoscopy.

Key words: obstructive sleep apnea, diagnosis, acoustic reflection, obstruction

INTRODUCTION

The diagnostic work-up of obstructive sleep apnea syndrome (OSAS) and socially unacceptable snoring (SUS) are currently of great interest. To differentiate between these two forms of snoring sleep registration is mandatory and is regarded as the golden standard (Ferber et al., 1994; Douglas et al., 1992; Hessel et al., 2002a). Many forms of topical diagnostic have been described, such as the Mueller manoeuvre, lateral cephalometry, CT/MRI scanning, somnofluoroscopy, pharyngeal pressure measurements during sleep and sleep endoscopy (Schwab, 1998). We believe that sleep endoscopy is the best form of routine diagnosis presently available to the general ENT specialist and we reported recently on our experiences with it (Camilleri et al., 1995; Quinn et al., 1995; Croft and Pringle, 1995; Hessel et al., 2002b). The advantages are obvious: it is a dynamic diagnostic procedure during sleep, with direct visual information, with almost always accurate information about the level(s) of obstruction, and it often shows snoring and apneas. All three levels of obstruction (nose-nasopharynx, retropalatal level and retrolingual level) can be analysed.

However, the procedure has disadvantages. The endoscopy is only performed for a short period of time, often only one sleeping position is studied, during only one sleep phase, and sedation is not always successful; it costs the patient almost a complete day in order to get awake to regain normal daytime functions. Intravenous sedation with midazolam is not without risk, in particular in patients in poor health and is in case of a high apnea-hypopnea index (AHI) contra indicated. Some doubt whether artificial induction of sleep reflects natural sleep.

A recent new development is the Rhinosleep, Flextube reflectometry for assessment of the upper airway in OSAS patients (Faber et al., 2001a; Faber et al., 2001b; Miyazaki et al., 2001). If feasible this form of diagnostic work-up could possibly replace sleep endoscopy and other diagnostic tools with many obvious advantages. In this feasibility study, we present our first experiences with it.

MATERIALS AND METHODS

Between January 2001 and January 2002, 170 patients were seen with SUS and OSAS. All patients were scheduled for sleep registration and sleep endoscopy. Preceding the sleep registration it was unknown if the patient was an OSAS patient. The majority of these patients were regarded as suitable for Rhinosleep; exclusion criteria were previous retropalatal and retrolingual surgery. The OSAS patients were retrospectively selected for Rhinosleep analyses. An AHI of more than 15 apnoeas per hour established OSAS (Hessel et al., 2002a). The patients were informed about the study objectives and gave written informed consent to participate. The study was approved by the local

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Medical Ethical Committee. We stressed that the insertion of the tube could be a little uncomfortable, that having the tube in situ could be uncomfortable as well, but the procedure could be terminated at will. We explained that one of the parameters under study was acceptance and our advice would be given on the results of sleep registration and sleep endoscopy. We also stressed that it was an additional experimental investigation. Since the tube is meant to detect the level of obstruction during sleep in OSAS patients, we focused only on this group.

THE ACOUSTIC REFLECTION SYSTEM

Rhinosleep Flextube reflectometry

Rhinosleep Flextube reflectometry is a device developed to detect the level(s) of obstruction in patients who have OSAS. It is not meant to detect level(s) of obstruction in SUS patients.

Mini probe

The acoustic device consisted of a portable computer and a Miniprobe; a small and light metal rod (10 cm and 70 g), containing a microphone/telephone and attached to a flexible tube (Rhino Flextube) as shown in Figure 1.

Measuring device

The computer contained a 24-bit digital signal processor (DSP) and an analogue to digital (A/D) and digital to analogue (D/A) converter. The digital Signal Processor supply, a continuous white band noise signal characterised by a bandwidth from 125 to 20 000 HZ, to the miniprobe.

Rhino Flextube

The proximal part of the Flextube, placed in the nose, was relatively thick walled (0,7 mm, shore 64A, PVC). The distal part of the Flextube (55 cm), which was placed in the pharynx and oesophagus, was thin walled (wall thickness 0,2 mm). It is made of soft PVC (shore 38A). 'Shore' specifies a method for determination of the indentation hardness of plastics and ebonite by means of durometers of two types: type A is used for softer materials and type D is used for harder materials. The diameter of the Flextube was 4,4 mm. The Flextube was closed at the distal end.

Software/ Sleep registration

The software performed a statistical comparison of the generated noise and the measured noise providing information concerning the internal diameter of the Flextube, the number and the duration when narrowing of the upper airway occurred (Figure 1).

Intubation Rhino Flextube

When the soft palate, the tongue, or other structures of the pharynx narrow the Flextube, its cross-sectional area decreases. This results in a reflection of the sound from the narrowed level. Flextube narrowing, which result in a cross-section area reduction of 16 % or more for at least 10 sec, should be scored as an obstructed event.

The distance from the nostril to the nose was determined by endoscopy in each patient. Preceding the endoscopy the nose and nasopharynx were sprayed with a local anaesthetic and decongestive (xylomethazoline 0,1% and tetracaine 1%). The Flextube was advanced slowly while the patients swallowed some water. The Flextube was fixed to the nose and cheek with the aid of adhesive tape and the 0 point of Flextube was placed exactly at the posterior border of the nasal septum. The tube is for logistic reasons already inserted in the afternoon, while registration only starts at 11.00 P.M. In many patients the tube eight hours in situ, before registration started. Ideally, the tube should be inserted just before the sleep period and only in OSAS patients.

Sleep registration

Polysomnography was performed on an digital recorder (Embla, Flaga Medical devices, Reykjavik, Iceland) and consisted of electroencephalogram (Fp2/C4, C4/O2), electrooculogram (right and left), electrocardiogram, surface electromyography of right anterior tibial muscle, mentalis muscle, and right diaphragm, arterial oxygen saturation and heart rate by pulse oximeter (numerical depicted), thoracoabdominal excursions (piezoelectric transducers), oronasal airflow by thermocouple sensors (Pro-Tech, Woodinville, WA, USA), snoring registration by small microphone attached to the neck, and a body position sensor (Pro-Tech, Woodinville, WA, USA). Electrodes and sensors were placed and the equipment was calibrated late in the afternoon. The battery-powered system was switched on and off automatically at 7.00 p.m. and 7.00 a.m., respectively. All signals were recorded with DDD (digital sampling, digital filtering, digital storage) recording technology, permitting a sample efficiency of 90% and a sample rate up to 200 Hz. Storage was done on a PCMCIA flash-card. The

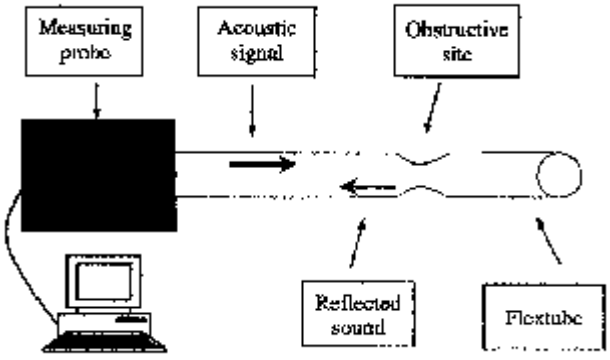

Figure 1. The Flextube reflectometry system. A continuous white band noise was generated in the probe and sent into the Flextube. When the Flextube was narrowed the noise was reflected. A microphone in the probe recorded the reflected sound. The distance to the Flextube narrowing and the duration and degree of the narrowing were calculated by the measuring system and graphically illustrated by the software.

following day, the data were down-loaded, analyzed by a dedicated sleep software (Somnologica 2.0.2, Flaga Medical Devices, Reykjavik, Iceland) and manually reviewed by an experienced sleep investigator for final analysis, using 30-second epochs for sleep staging, and 2-minute epoch for apnea detection. A sleep apnea, respectively hypopnea, was detected when a four second(s) interval of the oronasal airflow signal dropped below 22%, respectively 70%, of the reference. The reference was the median value of the amplitude during the last 5 minutes before the event. All apnea/hypopnea events shorter than 10 seconds and longer than 120 seconds were ignored.

Sleep endoscopy

For dynamic sleep research with midazolam, patients only qualify with ASA (American Society of Anaesthesiologists) classification I (the patient is healthy) and II (an illness or abnormality with minor systemic effects, for example: hypertension). In dynamic sleep nasendoscopy anatomy of the nose, nasopharynx, oropharynx, hypopharynx and larynx were studied by means of flexible endoscopy. The level of obstruction and soft tissue collapse were noted.

Preceding the dynamic sleep endoscopy the nose and nasopharynx were sprayed with a local anaesthetic and decongestive (xylomethazoline 0,1% and tetracaine 1%). The investigation took place in supine position and if necessary on the left or right side. We used midazolam starting with 0.07 mg/kg bodyweight to a maximum of 0.1 mg/kg.

RESULTS

Between January 2001 and January 2002, 170 patients visited our department for snoring problems. Hundred and twenty-three patients were suitable for standard diagnostic work-up with sleependoscopy and sleepregistration. Rhinosleep reflectometry was offered with the purpose to analyse only OSAS patients by Rhinosleep. Forty-seven patients were not suitable candidates for reasons such as expected lack of motivation and/or co-operation because of language problems, and exclusion criteria as previous retropalatal en retrolingual surgery.

Of the remaining 123 patients, there were 63 participants and 60 patients who refused the investigation. In the group of participants, 36 turned out to be OSAS patients, in whom 19 (53%) had a successful registration. Of the 17 (47%) failures, there were 11 patients who regurgitate tube during or before registration, 4 patients experienced severe discomfort in the nose leading to removal of the tube, in 2 patients artefacts and/or logistics problem during the night prevented successful analysis. Our findings were compared with the Miyazaki et al. (2001) and the Faber et al. (2001) study (Table 1). We also made a comparison of the advantages and disadvantages of the Rhinosleep Flextube-reflectometry and sleep endoscopy (Table 2 and 3).

Table 1. Comparison of studies.

	Japanese study by Miyazaki *et al*	Danish study by Faber *et al*	Present study
Patient numbers	16	21	36
Successful participation	13 (81%)	21 (100%)	19 (53%)
Total failures	3 (19%)	0	17 (47%)
due to removal	0	0	4 (24%)
hardware problems/ logistics	3 (19%)	0	2 (12%)
regurgitating	[3 (19%) re-inserted]	0	11 (64%)

Table 2. Rhinosleep.

Advantages	***Disadvantages***
• In one setting diagnosis of severity of OSAS and localisation of obstruction	• No visual information
• Registration of all sleep phases	• In case of multi-level obstruction, only the most dominant obstruction is scored.
• Information about varying obstruction levels possible	• Nasal passage is theoretically slightly influenced
• A poor health is no contraindication	• Patient experience insertion of the tube sometimes troublesome
• A high AH-index is no contraindication	• Patient experience the tube in situ troublesome
	• Patient sometimes regurgitate the tube out
	• Logistic problems in terms of time between insertion and registration

Table 3. Sleep endoscopy.

Advantages	***Disadvantages***
• Dynamic investigation	• Only analysis during a short period of time
• Direct visual information	• (Often) only endoscopy in one position
• Usually good information about the level of obstruction	• Only one sleep phase
• Often obvious about snoring and apneas	• Length of time and inconvenience for patient considerable
• Best available reflection in clinical practice of the situation during sleep	• Side effects and risks of sedation with Midazolam
• All three levels of obstruction (nose, retro-palatal, retro-lingual) are analysed	• A poor health is a contraindication
	• A high AH-index is a contraindication
	• Artificial induction of sleep might not be a good reflection of natural sleep
	• Sedation is not always successful

DISCUSSION

In this study we present our preliminary experiences with Rhinosleep Flextube reflectometry for assessment of the upper airway in cases of OSAS. The advantages of Rhinosleep are that diagnostic work-up can be performed in only one night of registration, (instead of one night and one day), a complete night can be analysed (instead of only the relative short period of sleep endoscopy), all stages of sleep are being analysed, changes in the level of upper airway obstruction changes during the night and during different sleeping phases will be recorded, while poor health and/or higher AH-indexes are no exclusion criteria for this investigation. SUS patients were felt to be not suitable for Flextube reflectometry, because the system detects an area reduction from the tube of 16% or more for at least 10 seconds. Although SUS patients can have a limited number of apnoeas during sleep registration, simple snoring causes usually an area reduction from the Rhinoflex tube below 16%, lasting less than 10 seconds.

The present study was meant as feasibility study, while in a separate study the results of Rhinosleep are being compared with the - in our view - "golden standard" in terms of topical diagnostic work-up, of sleep endoscopy. In another study, the results are compared with the outcome of sleep registration (Embla).

The main problem is that in only 19 of 36 (47%) of the total group of OSAS patients, insertion of the tube was successful and the tube remained in situ during the whole night. This low percentage can be explained by various reasons. The low threshold in the way the investigation was explained to the patient, has undoubtedly kept some candidates away. Patients were informed that the Flextube registration was for experimental use only, and that the topical diagnosis of level(s) of obstruction itself was based on the sleep endoscopy findings. The consistency of the tube as used so far might have played a role as well. A tube of softer consistency is presently being developed. The tube was in all cases already 8 Hs in situ, before registration started. Finally some patients had nasal discomfort with the tube in situ, because of nasal narrowing. Compared to the 21 patients described by Faber et al. (2001b) and the 16 patients by Miyazaki et al. (2001), our percentage of successful insertion and complete registration is considerably lower. This is almost certain due to a combination of differences in patients (in our case SUS and mild OSAS, in the Faber et al. (2001b) studies severe OSAS and motivated volunteers). In addition we informed patients that the sleep endoscopy would inform us about obstruction level(s) and that Flextube acceptance was meant as important endpoint of this feasibility study. The threshold to take the tube out was low, patients were not pressed to keep it in when they experienced discomfort by it. We are presently working on solutions on these practical problems in order to increase the success percentage of insertion and remain of the tube during the complete registration.

There might be distinct disadvantages of the Rhinosleep as well. There is no direct visual information, which means that in case of obstruction on retropalatal level, the site of obstruction remains unclear (uvula, tonsil, palate or circular) while in cases of retrolingual obstruction, exact localisation may be the laterel pharyngeal wall, base of the tongue or epiglottis can not be established. Total obstruction of the airways will not in any case give a reduction of the Rhino Flextube´s cross-sectional area greater than 25 per cent. The reason for this is the relationship between soft tissues and the stiffness of the Rhino flex tube. The nasal passage is slightly decreased with the tube in situ, and this could influence the outcome as well. An overview of the advantages and disadvantages of Rhinosleep and sleep endoscopy is given in Table 2 and Table 3.

Presently we are comparing the results of Rhinosleep and of sleep endoscopy on one hand, and with the findings of the Embla recording on the other hand. Only after meticulous comparing the results of Rhinosleep with the golden standards, can we assess its exact contribution.

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