

# Flextube reflectometry for level diagnosis in patients with obstructive sleep apnoea and snoring\*

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## SUMMARY

*The aim of this study was to use sound reflections in a flexible tube (flextube reflectometry) for identifying the predominant obstructive level of the upper airway in a series of patients referred to a sleep clinic. We also wished to study the relationship between the number of flextube narrowings per hour recording and the RDI (respiratory disturbance index = apnoeas and hypopneas per hour recording) by ResMed AutoSet (AS), which is a device based on nasal pressure variations.*

*We performed sleep studies on 54 patients referred for snoring or OSA; 1) at home with AS; 2) in hospital using flextube reflectometry and AS simultaneously.*

*The predominant obstructive level of the upper airway was retropalatal in 15 of the patients and retrolingual in 25 of the patients determined by flextube reflectometry. In 14 there was no predominant level of narrowing.*

*We found a statistically significant correlation between the number of flextube narrowings per hour recording and the RDIs by the AS*

*(Spearman's correlation coefficient  $r = 0.62$ ,  $p < 0.001$ ,  $n = 54$ ).*

*Flextube reflectometry may provide useful information regarding the level of obstructive predominance during obstructive events. The method also determines the frequency of respiratory disturbances and records snoring sound.*

**Key words:** obstructive sleep apnoea, acoustics, diagnosis, upper airway, endoscopy

## INTRODUCTION

Recurrent episodes of narrowing or collapse of the upper airway during sleep are characteristic in obstructive sleep apnoea (OSA) resulting in asphyxia and interruptions of the normal sleep pattern. The result is daytime sleepiness and OSA may be associated with a higher risk of road traffic accidents, cardiac arrhythmias, ischaemic heart disease, cardiac failure, systemic or pulmonary hypertension and stroke (Wright et al., 1997).

In a recent Cochrane Library Document it was suggested that further research should be undertaken to identify and standardise techniques to identify the obstructive sites in the upper airway of patients with OSA. This would allow specific selection of treatment according to the anatomical site of upper airway obstruction (Bridgman and Dunn, 2000). A number of studies have suggested that surgery following identification of the specific area of obstruction is more likely to be successful than surgery carried out without knowledge of the obstructive site (Sher et al., 1985; Petri et al., 1994; Sher et al., 1996).

The aim of the present study was to use a new acoustic reflection method for determination of the severity of OSA and for localisation of the predominant level of pharyngeal narrowings during sleep. The method is based on sound reflections in a flexible tube inserted into the nose, pharynx and oesophagus during sleep.

The study was designed to compare the number of narrowings per hour by flextube reflectometry with the RDIs (respiratory disturbance index = apnoeas and hypopneas per hour recording) obtained by AutoSet, ResMed (AS) which is a validated sleep recording system for determination of the severity of OSA. We additionally wished to evaluate the agreement between nocturnal flextube reflectometry and fiberoptic endoscopy performed during wakefulness in the determination of the narrowest part of the pharynx. We finally wanted to evaluate the influence on the number of respiratory disturbances per hour recording by the use of a flextube.

## MATERIALS AND METHODS

### Patients

Sixty two consecutive patients (55 males and 7 females) referred to the Department of Otorhinolaryngology, Aarhus University Hospital, for OSA and/or snoring, accepted to participate in the study. Two patients were excluded from the study because they could not accept insertion of the flextube. One patient was excluded due to technical problems with the microphone of the flextube device and 2 were excluded due to technical problems with the oximeter of the flextube device. One patient was excluded due to kinking of the flextube. Two patients were excluded due to inadequate nasal ventilation signals of the AS. Table 1 shows the characteristics of the 54 patients (48 males and 6 females) included in the study.

The patients were informed about the study objectives and gave written informed consent to participate. The study was performed in accordance with the Declaration of Helsinki and was approved by the local Ethics Committee.

Table 1. Characteristics of the patients (N = 54) included in the study.

| Patient characteristics                       | Mean (SD)   |
|-----------------------------------------------|-------------|
| Age (years)                                   | 47.4 (12.0) |
| BMI (kgm <sup>-2</sup> )                      | 28.1 (4.1)  |
| Neck circumference (cm)*                      | 42.8 (3.5)  |
| Epworth Sleepiness Scale                      | 11.2 (5.0)  |
| Total MCA (cm <sup>2</sup> )                  |             |
| before decongestion                           | 1.03 (0.28) |
| Total MCA (cm <sup>2</sup> )                  |             |
| after decongestion                            | 1.23 (0.29) |
| Relative decongestion effect on total MCA (%) | 23.4 (25.3) |

Total MCA = minimum cross-sectional area of the nasal cavity (sum of right and left sides), \* measured at the cricoid level.

### Study design

The participants were investigated; 1) one night at home by the AS system and; 2) one night in hospital using AS and flextube reflectometry simultaneously.

The longest period with good quality data from both recording systems (1 to 6 hours) was analysed. We analysed periods where snoring or repetitive breathing pauses indicated sleep. The observer who analysed the sleep recordings was unaware of the identity of the patients. We compared the number of flextube narrowings per hour recording with the RDIs determined by the AS.

We determined the agreement between endoscopic assessments during wakefulness by 2 experienced observers (LG and CEF) and the results of nocturnal flextube reflectometry studies regarding the level of obstructive predominance

(retropalatal, retrolingual or equal). We also studied the inter-observer agreement in endoscopic assessment performed by the 2 observers.

We assessed the effect on RDI caused by the presence of the flextube. This was done by comparing RDIs measured by the AS during - baseline - home recordings with RDIs from recordings where the flextube was inserted (studies performed in hospital and the RDIs determined by AS).

We finally searched for a relationship between the relative level distribution and BMI and between the relative level distribution and RDI.

## MATERIAL AND METHODS

### Acoustic reflectometry

The acoustic reflectometry system (SRE2100, RhinoSleep version 3.0.3.53, RhinoMetrics, Lyngby, Denmark) has been described previously (Faber et al., 2001a; Faber et al., 2001b). It consisted of a portable computer and a miniprobe, a small and light metal rod (10 cm and 70 g), attached to a flexible PVC tube (RhinoFlex Tube) with a diameter of 5.2 mm. The flextube was closed at the distal end.

The probe generated a noise signal and a microphone measured the reflected sound. When the soft palate, the tongue, or other structures of the pharynx narrowed the flextube, its cross sectional area decreased. This was followed by a reflection of the sound from the narrowed site (Figure 1). The flextube was fixed to the nose and cheek using a plaster and the zero point

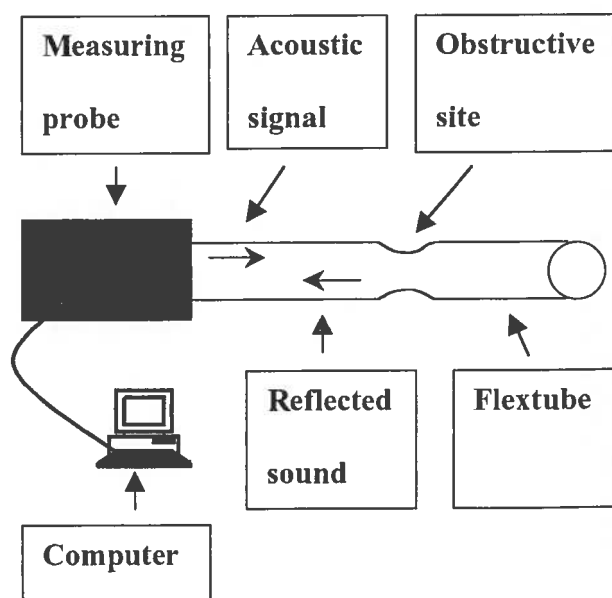


Figure 1. The flextube reflectometry system. A continuous white band noise was generated in the probe and sent into the flextube. The flextube was inserted into the nose, pharynx and oesophagus. When the flextube was narrowed during obstructions the noise was reflected. A microphone in the probe recorded the reflected sound. The distance to the obstructive site and the duration of obstructions was calculated by the measuring system and graphically illustrated by the software

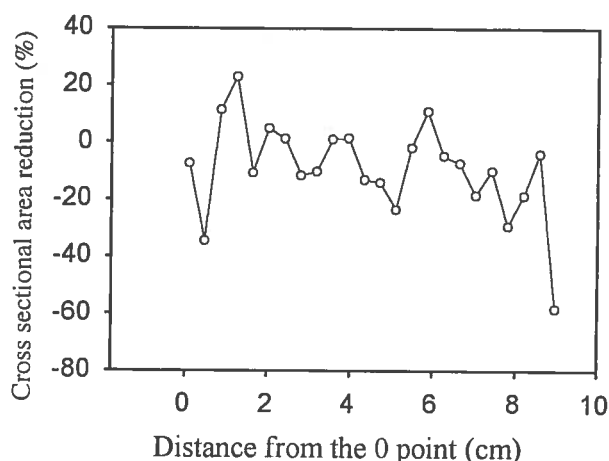


Figure 2. The level distribution of flextube narrowings during obstructive events determined in an OSA patient. The mean cross-sectional area reduction of the flextube during obstructive events from the 0 point of the flextube to 9 cm below is shown. This person had a maximum of the mean flextube area reduction at the retropalatal level of 22.6% located 1.3 cm from the 0 point. He had a maximum of the mean flextube area reduction at the retrolingual level of 10.5% located 5.9 cm from the 0 point. Consequently the maximum narrowing at the retropalatal level was 68.3% of the sum of the maximum narrowing at the retropalatal and retrolingual levels during events ( $22.6/(22.6+10.5)$ ).

of the flextube was placed exactly at the posterior border of the nasal septum. The flextube was advanced slowly while the patients drank some water.

Data was collected simultaneously by the flextube system and the AS. During the hospital investigations the patients were monitored with an infrared camera to be able to confirm sleep. The internal diameter of the flextube and the number and duration of the flextube narrowings were calculated by the software. The narrowings were divided into 2 groups depending on their localisation: retropalatal narrowing (from the posterior border of the septum to 4.7 cm below) and retrolingual narrowing (from 4.7 to 9 cm below the posterior border of the septum). The distances were measured from the posterior border of the nasal septum to the lower border of the soft palate (retropalatal level) and from the lower border of the soft palate to the esophageal inlet (retrolingual level). These distances were determined for a previous study by fiberoptic measurements on 100 adult patients consecutively referred to our sleep centre for snoring and sleep apnoea (Faber et al., 2001a). The mean cross-sectional area reductions during obstructive events of the retropalatal and retrolingual parts of the flextube were found by the software. The retropalatal narrowing as percentage of the total narrowing (retropalatal and retrolingual) during obstructive events provided the pharyngeal level distribution (Figure 2).

#### *Detection of apnoeas and hypopnoeas by the AS system*

The AS device relies on nasal pressure fluctuations in the anterior nares measured by nasal prongs and also includes pulse oximetry and thoracoabdominal movements (AutoSet, version

3.03, ResMed Ltd., North Ryde, Australia).

The AS has been validated by comparisons with full polysomnography (Fleury et al., 1996; Mayer et al., 1998; Rees et al., 1998). The data from the AS recorder were transferred after the studies via a cable to a computer for analysis by dedicated software. The recordings were hand-scored visually on a high-resolution screen by the same observer. Hypopnoeas were defined as a reduction below 70% of baseline pressure fluctuations for at least 10 seconds. Apnoeas were scored if there was a cessation of air pressure fluctuations for at least 10 seconds.

#### *Fiberoptic endoscopy*

Fiberoptic examinations were performed during wakefulness with the patient in a supine position. Surface analgesia was achieved by spraying the nasal and pharyngeal mucous membranes with Xylocaine spray. A slim fiberoptic endoscope (Olympus ENF type P2) with an outer diameter of the insertion tube of 3.6 mm was applied. The observers assessed whether the narrowest part of the pharynx was retropalatal or retrolingual or the narrowing was equal. These assessments were performed during quiet natural respiration.

#### *Statistical analysis*

Means and standard deviations (SD) were used for descriptive purposes. To compare means we used paired *t*-tests. The correlation between the number of flextube narrowings per hour and the RDIs determined by the AS was determined using the Spearman's rank test. To study the agreement between endoscopy and flextube reflectometry for determination of the predominant obstructive level we used Cohen's Kappa statistic. Cohen's Kappa statistic was also used to study the inter-observer agreement in the endoscopic assessments performed by the 2 experienced observers. Statistical analyses were carried out using SPSS for Windows, version 9.0.0. Significance was accepted at  $p < 0.05$ .

## RESULTS

The flextube reflectometry procedures were accompanied by only minimal discomfort in most patients. Two patients were, however, excluded from the study because they could not accept insertion of the flextube. There were no complications, including bleeding or mucosal tears. The patients did not have to abstain from drinking or eating while the flextubes were inserted.

#### *Distribution of upper airway narrowing*

The mean (SD) percentage of retropalatal flextube narrowing of the total narrowing (retropalatal and retrolingual) during obstructive events for all 54 patients was 41.9% (33.5%). The distribution of patients in different intervals of retropalatal flextube narrowing is illustrated in Figure 3.

The predominant obstructive level of the upper airway during obstructive events was defined as "retropalatal" when the

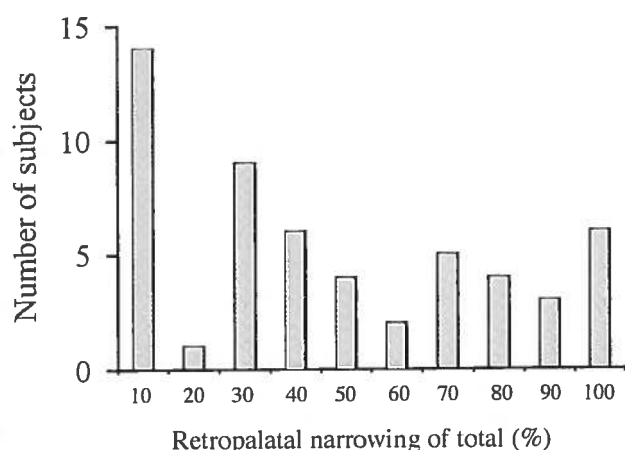


Figure 3. The distribution of patients in different intervals of retropalatal flextube narrowing of total narrowing (retropalatal and retrolingual). The level distribution during obstructive events was automatically calculated by the dedicated software as described in Figure 2.

retropalatal narrowing of total narrowing was 66.7% or more. "Retrolingual" predominance was defined as less than 33.3% retropalatal of total narrowing. "No predominant obstructive level" was defined as a percentage of retropalatal of total narrowing between 33.3% and 66.7%.

Using these definitions 15 of the 54 patients had predominantly "retropalatal" narrowing and 25 had predominantly "retrolingual" narrowing. In 14 patients we found "no predominant obstructive level".

Table 2. Endoscopic assessment of the narrowest part of the pharynx (retrolingual or retropalatal or equal) during wakefulness versus level of obstructive predominance determined by nocturnal flextube reflectometry (N = 54).

| Endoscopy    | Flextube reflectometry |              |       | Total |
|--------------|------------------------|--------------|-------|-------|
|              | Retropalatal           | Retrolingual | Equal |       |
| Retropalatal | 3                      | 15           | 4     | 22    |
| Retrolingual | 4                      | 7            | 5     | 16    |
| Equal        | 8                      | 3            | 5     | 16    |
| Total        | 15                     | 25           | 14    | 54    |

- "Retropalatal" flextube narrowing = more than 66.7% of the flextube narrowing was located in the retropalatal area.
- "Retrolingual" flextube narrowing = less than 33.3% of the flextube narrowing was located in the retropalatal area.
- "Equal" flextube narrowing = between 33.3% and 66.7% of the flextube narrowing was located in the retropalatal area.
- LG performed 40 endoscopic assessments and 14 were performed by CEF. The observers assessed whether the narrowest part of the pharynx was at the retropalatal level or the retrolingual level or the narrowing at both levels was equal.

#### The relationship between obstructive level distribution, BMI and RDI

The percentage of retrolingual flextube narrowing was not related to the BMI (Spearman's correlation coefficient  $r = -0.07$ ,  $p = 0.61$ ). The percentage of retropalatal flextube narrowing was not related to the RDI measured by AS at home without a flextube inserted either (Spearman's correlation coefficient  $r = 0.008$ ,  $p = 0.96$ ).

There was a significant correlation between the RDIs measured by AS at home without a flextube inserted and the BMIs of the subjects (Spearman's correlation coefficient  $r = 0.45$ ,  $p = 0.001$ ).

#### The relationship between fiberoptic endoscopy and flextube reflectometry

The level of maximum narrowing determined by endoscopy and the predominant level of flextube narrowing was similar in 15 out of 54 patients and unlike in the other 39 patients. This agreement was no better than chance (value of kappa = -0.07). Table 2 provides details concerning the agreement between endoscopy and flextube reflectometry.

#### Inter-observer agreement in the assessment of fiberoptic endoscopies

Two observers (LG and CEF) used endoscopy to assess the level of maximum narrowing in 40 patients. The remaining 14 patients were only examined by one observer (CEF). The observers agreed in the assessment of 16 of 40 patients and disagreed in 24 patients. This agreement was no better than chance (value of kappa = 0.09). Table 3 provides details concerning the agreement between the 2 observers.

Table 3. Inter-observer agreement between endoscopic assessments of the narrowest part of the pharynx (retrolingual or retropalatal or equal) during wakefulness (N = 40).

| Observer LG  | Observer CEF |              |       | Total |
|--------------|--------------|--------------|-------|-------|
|              | Retropalatal | Retrolingual | Equal |       |
| Retropalatal | 9            | 3            | 2     | 14    |
| Retrolingual | 9            | 2            | 2     | 13    |
| Equal        | 5            | 3            | 5     | 13    |
| Total        | 23           | 8            | 9     | 40    |

Two observers independently performed endoscopies on 40 patients during wakefulness (LG and CEF). The observers assessed whether the narrowest part of the pharynx was at the retropalatal level or the retrolingual level or the narrowing at both levels was equal.

#### Sleep study results

The mean (SD) RDI determined by AS with and without the flextube inserted and the mean (SD) number of flextube narrowings per hour recording are shown in Table 4.

Table 4. Results of nocturnal measurements (N = 54).

|                                            | Mean (SD)   |
|--------------------------------------------|-------------|
| RDI at home by AutoSet (1)                 | 44.1 (21.5) |
| RDI by AutoSet with flextube inserted (2)  | 45.5 (22.0) |
| Flextube narrowings per hour recording (2) | 40.7 (24.3) |

The first study was performed at home using the AutoSet device without a flextube inserted (1). The second study was performed in hospital using AutoSet and the flextube device simultaneously (2). RDI = respiratory disturbance index (apnoeas and hypopnoeas per hour recording).

#### *Relationship between flextube reflectometry and AS*

The mean difference (SD) between the number of flextube narrowings per hour recording and the RDIs by AS when both devices were used simultaneously was 4.9 (20.7), which was not statistically significantly different from 0 ( $p = 0.09$ ,  $t$ -test). The correlation was statistically significant (Spearman's correlation coefficient  $r = 0.62$ ,  $p < 0.001$ ,  $n = 54$ , Figure 4).

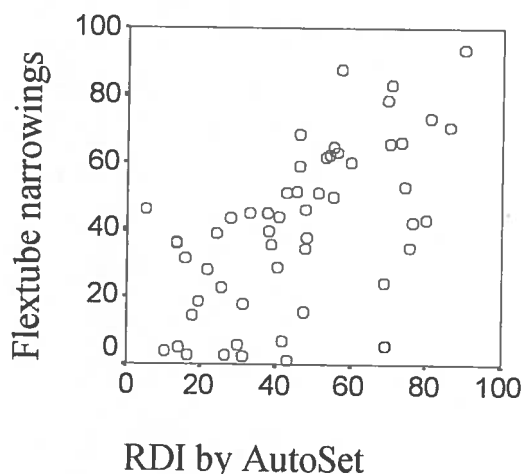


Figure 4. The relationship between the number of flextube narrowings per hour nocturnal recording and the RDIs per hour nocturnal recording determined by AutoSet (AS). The patients were investigated in hospital by AS and flextube reflectometry simultaneously,  $N = 54$ .

#### *Effect of flextube insertion on RDI*

The mean difference (SD) between the RDIs determined by AS with and without a flextube inserted was 1.4 per hour recording (16.3), which was not statistically significantly different from 0 ( $p = 0.52$ ,  $t$ -test). The correlation was statistically significant (Spearman's correlation coefficient  $r = 0.71$ ,  $p < 0.001$ ,  $n = 54$ , Figure 5).

#### DISCUSSION

In the present study we found a statistically significant correlation between the frequency of respiratory disturbances deter-

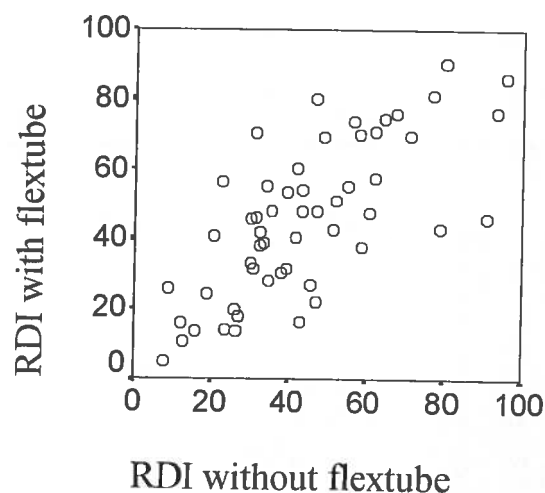


Figure 5. The relationship between the RDIs per hour nocturnal recording determined by AutoSet (AS) in hospital with a flextube inserted and the RDIs per hour nocturnal recording determined by AS at home without a flextube inserted.  $N = 54$ , measurements were performed on two different nights.

mined by the flextube device and the AS system which is a validated tool for identifying patients with OSA (Fleury et al., 1996; Rees et al., 1998). Mayer et al. (1998) found a significant correlation between RDIs determined by AS and polysomnography ( $r = 0.87$  for total sleep time,  $p < 0.0001$ ) in their study of 95 patients with suspected OSA. In a previous study we found a statistically significant correlation between the number of flextube narrowings per hour of sleep and the number of obstructive apnoeas and hypopnoeas per hour of sleep determined by Polysomnography (Spearman's correlation coefficient  $r = 0.79$ ,  $p < 0.001$ ,  $n = 21$ ) (Faber et al., 2001a). We therefore anticipated a significant relationship between the number of flextube narrowings per hour of nocturnal recording and the RDIs per hour of nocturnal recording found by AS, which was indeed found. The scoring of events by AS and the flextube device is based on different principles and therefore discrepancies were expected.

It is a limitation of our study that we analysed only periods where snoring or repetitive breathing pauses indicated sleep. The diagnostic devices used in the study do not record neurophysiologic data necessary to characterise sleep stage (electroencephalography, electrooculography and electromyography).

In the present study we found predominantly retropalatal narrowing in 15 patients and retrolingual predominance in 25 of the patients determined by flextube reflectometry. In 14 there was no predominant level of narrowing.

Upper airway pressures at several levels have previously been applied to study the level distribution of pharyngeal narrowings during sleep. Rollheim et al. (1997) studied 24 patients

with OSA using pressure catheters and found that 13 patients had predominantly retrolingual obstructions and 11 had predominantly retropalatal obstructions. Woodson et al. (1992) also used multi-transducer pressure catheters in 12 OSA patients and found that the initial site of obstruction was retropalatal in 9 patients and retrolingual in 3 patients.

Fiberoptic endoscopy during sleep - nocturnal nasendoscopy - has also been applied to study the level distribution of nocturnal pharyngeal narrowings. Using this technique retropalatal collapse was found in 18 patients and multi-segment collapse in 31 patients and simple palatal snoring in 7 patients (Croft and Pringle, 1991). These different studies using various techniques suggest that OSA patients have varying patterns of narrowing or collapse of the pharynx. The level of obstructive predominance may depend on the specific population or the methods used. The pressure catheter method allows information only regarding the most proximal obstruction during obstructive events. The flextube device in contrast provides information regarding the whole length of the flextube during all obstructive events. This may reduce the risk of bias when the predominant obstructive level is determined.

In a previous study we compared the obstructive level distribution using MRI with the level distribution found using flextube reflectometry. The mean difference between the percentage of retropalatal flextube narrowing and the percentage of retropalatal obstructions found by MRI on 2 different nights was not statistically significantly different from 0 ( $p = 0.24$ ,  $t$ -test,  $n = 7$ ) (Faber et al., 2001a). In future studies the flextube method could also be compared with sleep endoscopy. A gold standard for the determination of the predominant obstructive level during obstructive events fails to be identified so further development of methods and validation of existing techniques is required (Bridgman and Dunn, 2000).

There seemed to be a shift towards lower levels of obstruction with increasing obesity in a recent study (Rollheim et al., 1997). We did, however, not find a significant correlation between BMI and the percentage of retrolingual narrowing of the total flextube narrowing during obstructive events in the present study. Further studies are consequently necessary to investigate the relationship between obesity and the level distribution during obstructive events.

We found a discrepancy between endoscopy during wakefulness and nocturnal flextube reflectometry for the determination of the narrowest part of the upper airway. Similar levels were found in only 15 out of 54 patients. The inter-observer agreement was not better than chance in our study. This is in accordance with the findings of Skatvedt (1993) who made use of fiberoptic endoscopy with the Muller manoeuvre during wakefulness and nocturnal pressure measurements to determine the primary level of obstruction of the upper airway in 20 snorers and/or patients with OSA. Similar results by both

methods were obtained in only 5 of the 20 patients in Skatvedts study. A discrepancy between the obstructive level distribution found during wakefulness and during sleep was expected because the muscular tone and respiratory drive may be different in the two situations.

Very large tonsils or abundant adenoid tissue could result in constant narrowing or kinking of the flextube resulting in misleading results. We therefore visually inspected the oropharynx and found that the tonsils were located laterally to the posterior palatine arch in 30 of the patients. The tonsils were located laterally to the halfway between the posterior palatine arch and the uvula in 12 persons and slightly medially to the halfway between the posterior palatine arch and the uvula in 2 persons. There was not contact between the tonsils in any of the patients. The adenoid tissue was not so abundant in any of the patients that it obstructed the choana or Eustachian tube orifices. No significant flextube narrowing during quiet respiration at the level of the tonsils or the nasopharynx was observed in any of the patients.

The number of flextube narrowings per hour recording and the level distribution of flextube narrowings were determined by the dedicated software. We assessed the flextube software independently of manual analysis because we have previously studied the flextube system by hand scoring of recordings. The RDIs by the AS device were determined by visual scoring of airflow tracings. The cause for this is that previous studies have demonstrated that visual scoring of recordings from screening devices for OSA gives better agreement with polysomnography - the gold standard of diagnostic sleep studies - than automatic scoring (Koziej et al., 1994; Carrasco et al., 1996).

There is some nuisance associated with the insertion of a flextube. Two patients had to be excluded from the study because they could not accept the flextube. The insertion of a flextube may also affect the patients sleep stage distribution and consequently influence the frequency of apnoeas and hypopnoeas. Also the level of obstructive predominance may be influenced by the presence of a flextube. On the other hand we did not observe a statistically significant difference between the RDIs determined by AS at home without a flextube inserted and the RDIs determined by AS in hospital with a flextube inserted.

In a prior study we performed polysomnography with and without a flextube inserted and we observed a minor but statistically significant decrease in the total sleep time and percentage REM sleep and an increase in percentage stage 1 non-REM sleep during nights when the flextube was inserted. The number of obstructive apnoeas per hour of sleep and the RDIs were also influenced by insertion of the flextube, but the clinical significance of these minor changes was doubtful (Faber et al., 2001a).

In conclusion the present study suggests that nocturnal flex-tube reflectometry studies can provide valuable information regarding the level distribution of upper airway obstructions before and after treatment. Thus the method may provide new insights into the patho-physiology of the upper airway during sleep and provide guidance to the treatment most likely to be successful in a specific patient. The flextube investigations were associated with only minimal discomfort in most patients and did not influence the RDIs compared to home recordings without flextubes inserted.

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