

European position paper on drug-induced sedation endoscopy (DISE)

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Abstract

Background Although drug-induced sedation endoscopy (DISE) represents the most widespread diagnostic tool for upper airway endoscopic evaluation of snoring and obstructive sleep apnea hypopnea syndrome (OSAHS), many controversies exist about how to perform the sedation, the

indications for DISE, and how to report DISE findings. The present position paper reports on a consensus as proposed by a group of European experts in the field of DISE after discussion during a recent dedicated meeting.

Methods The authors have evaluated all the available evidence reported in the literature and have compared experience

Site plan In the summer of 2013, a group of European experts in the field of sleep endoscopy met in Italy, with the intention of composing a consensus document on drug-induced sedation endoscopy (DISE). The present paper is a reflection of the meeting.

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among various departments in leading European centers in order to provide a standardization of the DISE procedure and an in-depth insight in the main aspects of this technique.

Results A proposal of the DISE procedure standardization has been achieved with a general agreement concerning the terminology, indications, contraindications, required preliminary examinations, setting, technical equipment required, staffing, local anesthesia and nasal decongestion, patient positioning, basis and special diagnostic maneuvers, and the applied sedation drugs and observation windows. Otherwise, no consensus has been reached on a scoring and classification system.

Conclusions Although consensus has been reached on several aspects of the DISE procedure, some topics remain open to future research, such as a better analysis of the importance of positional aspects during DISE and a further comparison of the differences in degree, level and pattern of upper airway collapse observed during DISE versus during natural sleep and awake endoscopy. Finally, a universally accepted scoring and classification system is lacking.

Keywords Obstructive sleep apnea hypopnea syndrome · Prediction · Sleep endoscopy · Sleep-disordered breathing · Upper airway collapse · Therapy

Introduction

Obstructive sleep apnea hypopnea syndrome (OSAHS) is the most common sleep-disordered breathing (SDB) disease, with a prevalence of 2–4 % of adult population and an increasing rate of morbidity and mortality as well as rising healthcare costs [1]. The gold standard treatment of OSAHS is continuous positive airway pressure (CPAP) [2], but its effectiveness is often limited by low acceptance, poor tolerance, and sub-optimal compliance [3–5].

Alternative non-CPAP treatments consist of surgery and/or oral appliance therapy (OAT). In the case that non-CPAP therapy is considered, meticulous assessment of the level(s) of upper airway (UA) collapse is of paramount importance. The higher compliance observed with OAT might translate into a similar effectiveness for OAT as compared to CPAP [6, 7].

Surgical treatment has the advantage of 100 % adherence, so effectiveness will be critically dependent on efficacy [5, 8]. Nevertheless, surgery is often not recommended as a first-line treatment due to its low success rates in unselected patients [9, 10] and the overall success rate for uvulopalato-pharyngoplasty (UPPP), which is the most common surgical procedure performed in OSAHS patients, of only about 40 % [9]. However, careful observation of the level(s), degree, and patterns of obstruction of the UA would intuitively lead to better selection of surgical techniques and subsequent better treatment outcomes. When

addressing the pathophysiology of OSAHS, one has to consider the anatomical and functional characteristics of the upper airway, sleep-wake, and ventilatory control instability and arousal threshold, which encompass the complexity of sites and patterns of pharyngeal collapse, that occur during the respiratory events. UA evaluation in awake OSAHS patients has limited usefulness, because the sites and patterns of UA collapse during sleep can be significantly different to those observed in awake patients primarily due to differences in muscle tone [11].

In 1978, Borowiecki introduced sleep endoscopy during natural physiological sleep in order to better understand the complex mechanism leading to UA obstruction during sleep apneas [12]. Sleep endoscopy during spontaneous sleep is not routinely feasible, requiring dedicated human resources and a long period of time to carry out the procedure. Subsequently, Croft and Pringle reported on assessment of the UA in OSAHS patients under sedation [13], which allows the patient to tolerate the endoscope and the evaluation to be carried out during the day routine and, since the first publication in 1991, drug-induced sedation endoscopy (DISE) has increased in popularity and has been utilized worldwide (Fig. 1).

Evidence is emerging that certain DISE findings are related to treatment outcome, and that DISE is a valuable selection tool in treatment advice [14–17].

Although DISE represents the most widespread diagnostic tool for UA endoscopic evaluation of OSAHS patients, many controversies exist about how to perform the sedation, in which patients DISE should be performed, and how to report the DISE findings. Moreover, the literature raises various issues regarding its validity and reliability and poses questions regarding if the sleep architecture during DISE is reproducible and comparable to that in natural sleep [18–42]. In this position paper, the authors have evaluated all the available evidence reported in the literature and have compared experience among various departments in leading European centers in order to provide a standardization of

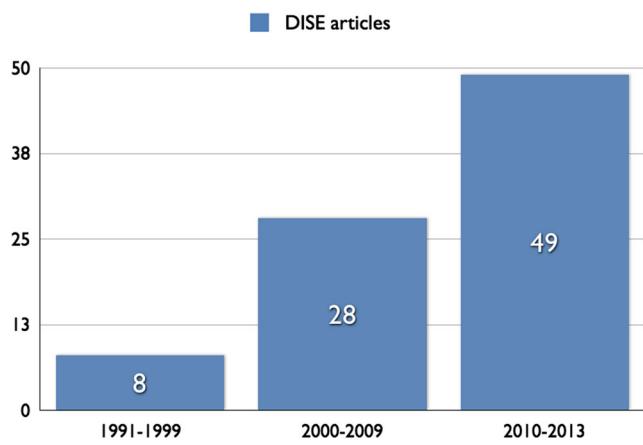


Fig. 1 Number of articles about DISE published until November 2013 (articles in Chinese have been excluded)

the procedure and an in-depth insight into the main aspects of this technique.

Terminology

This procedure was first introduced as sleep nasendoscopy, abbreviated SNE [13]. Various other names that have been used are sleep endoscopy [18, 43], video sleep nasendoscopy [44], drug-induced sleep endoscopy [45, 46], and fiber-optic sleep endoscopy [27]. We propose the term DISE, which better describes the use of sedation during the study, and it is the name and abbreviation that will be used in this paper.

Indications

As DISE gives additional information about UA site(s) and pattern(s) of obstruction, it should be performed in selected patients in whom this additional information about the dynamics of the UA is considered useful. Therefore, DISE should be performed in patients affected by socially disturbing snoring and OSAHS, in whom non-CPAP therapy is considered [47]. Furthermore, DISE may be performed in patients who have failed CPAP therapy or who encounter difficulties in tolerating CPAP, as reasons for failure or difficulty in tolerating CPAP could be potentially highlighted. In addition, DISE could provide further information in patients in whom previous surgery has failed and may allow the clinician to recommend either OAT or further surgical intervention addressing the relevant anatomical segment that may be causing residual symptoms [48, 49].

On the other hand, the information about UA collapse observed during DISE might lead to suggesting CPAP treatment in patients with mild OSAHS. Besides, a recent study suggests DISE for CPAP pressure titration [50].

Contraindications

The safety of DISE is of paramount importance. DISE should be performed in patients with acceptable anaesthetic risk profile. Absolute contraindications are ASA 4, pregnancy, and patients with an allergy to Propofol or to other DISE drugs. Relative contraindications may include morbid obesity.

Required preliminary examinations

The Working Group recommends obtaining the following preliminary examinations before performing DISE: types 1, 2, or 3 sleep studies according to American Academy of Sleep Medicine (AASM) [51, 52], clinical and endoscopic awake

UA examination, and clinical presedation assessment according to the local departmental guidelines.

Where to perform DISE

DISE can be performed in any safe clinical setting such as the operating theatre or endoscopy room or a similar clinical room set up with standard anaesthetic equipment (basic monitoring and resuscitation kits in case of emergency), and where relevant ambience such as silence and darkness is available. DISE can usually be performed as a day-case while, in rare cases, overnight stay may be necessary depending on the patient's general condition and if surgical therapy has been concurrently performed.

Technical equipment required

The following *essential* setting is required: standard anaesthesiological monitoring [oxygen saturation (SatO_2), electrocardiogram (ECG), blood pressure (BP)] and flexible endoscope (as small as possible).

Other *useful* facilities are an infusion pump or, more preferably, target-controlled infusion (TCI) as the drug delivery system and EEG-derived indices. The latter are available to assess the depth of sedation and anaesthesia, e.g. bispectral (BIS) index or cerebral state index (CSI) [20, 53–57]. If BIS is available, it can be used while BIS levels between 50 and 70 correlate most closely with the appropriate level of sedation for the DISE procedure. However, further research is needed on the validation of using EEG-derived indices during DISE, as well as polygraphic real-time monitoring.

Desirable facilities include documentation (video, audio).

Staffing

The following essential setting is required (Adult Sedation Guidelines, NHS, 2010) [58]:

The clinicians who perform the endoscopic procedure.

An individual whose sole responsibility is to monitor the patient and observe their response to the medication and the procedure. This could be an anaesthetist or an appropriately clinically trained individual.

A third person has to be available in case of emergency.

Local anesthesia, nasal decongestion, other medications

In the literature, nasal decongestion, nasal local anesthesia, and antisecretory drugs are described as preparatory measures and may be used as an option [6, 31, 33, 36–38]. These

preparatory measures can potentially interact with UA and breathing control and therefore have to be used with caution. UA suction may be necessary during DISE if hypersalivation occurs. This could be the case in 5–10 % of patients, and suction would assist in obtaining a better UA assessment during the exam. We do not suggest an atropine infusion, because it could result in a significant change of sleep physiology. Furthermore, local anesthesia prior to inserting the endoscope is not recommended due to the possibility of having an influence on the tone of the pharyngeal muscles of the UA.

Theoretically the use of atropine-like drugs could be useful in patients who have excessive secretions that may interfere with the view attained. However, the Working Group felt that due to the lack of knowledge on the impact of these drugs on sleep physiology and the changes it may create on the cardiovascular system this would be inappropriate. Similarly, the Working Group agreed that although the use of local anesthesia or decongestants may increase the ease of scope insertion and possibly reduce the incidence of nasal irritation, these drugs could interfere with the nasal resistance and therefore the airflow. Thus, the dynamics of the upper airway would be made somewhat different to what actually occurs during natural physiological sleep.

Patient positioning

The procedure is commenced in the standard supine primary position, with or without pillow(s) according to the patient's usual sleep habit. However, if the patient's sleep study or clinical history is suggestive of a nonsupine snoring or OSAHS position, then the DISE could be started in nonsupine position, followed by assessment in supine position thereafter. This should be discussed with the anaesthetic colleague prior to commencing the assessment. The background is that, traditionally, DISE is performed in the "worst" sleeping position, namely the supine position. However, with the implementation of new forms of positional therapy in patients with positional OSAHS, it would be more logical to perform DISE in the lateral position as well. Safiruddin et al. recently showed that a change of body position (rotation from supine to lateral) during DISE leads to improvement of upper airway collapse in patients with positional OSAHS. This improvement was noted regardless of the direction (left or right) [59].

Basic and special diagnostic maneuver

The basic diagnostic tool is the trans-nasal fiberoptic endoscopic UA assessment. Trans-oral fiberoptic endoscopy could give additional information in selected patients if the mouth is open. In particular, the degree of tongue retraction and

position could be evaluated both from the oral cavity as well as from the nasopharynx.

It should be borne in mind that there may be a possibility that an oral appliance (OA) may be a useful treatment modality and so during DISE, it is recommended to mimic both the mandibular advancement and the vertical mouth opening in a standard and reproducible fashion, closely related to the OA characteristics, which might be constructed for the patient [60, 61]. There is evidence that a hyperprotrusion/maximal protrusion of the mandible has no predictive value towards the OA therapy outcome [61]. Therefore, performing a maximal mandibular protrusion maneuver is not advisable. If the patient's OA is available during the DISE procedure, the Working Group recommends starting the sedation process with the OA in situ and after the assessment of the UA with the OA, to remove it and reassess in order to avoid arousals. This would inform the clinician on the efficacy of the OA and would also allow determining if further advancement of the OA is necessary or not. It should be taken into account that during DISE, an increase in vertical opening will increase the collapsibility of the UA at the level of the tongue base in a large majority of patients [62].

Drugs

Both Propofol and Midazolam are suitable as sedative agents, alone or in combination, with advantages and disadvantages as demonstrated in Table 1. Poor responders both of Propofol and Midazolam could be possible. There are evidences that show that the UA findings using Propofol or Midazolam do not differ [23]. There are three possible ways in which Propofol could be administered; the preferred option would be to use TCI but if this is not available, then either a standard pump system or manual bolus technique could be utilized [63]. Irrespective of the delivery system used, great care should be taken to avoid an overdose of the sedative agent and to limit excessive muscle relaxation, resulting in overrating of the upper airway collapse as a consequence.

Suggestions for drug dosage (Table 2):

1. Propofol:

- TCI (brain concentration)

Basic mode (variations are possible according to team experience)—starting dose, 1.5–3.0 µg/ml, if required, increasing rate 0.2–0.5. \times number of increasing rate delivered according to multiparametric observations (vibration collapse and respiratory drive and SatO₂), up to freeze at the observation window.

- Pump (blood concentration)—delivering dose, 50–100 ml/60 min, up to freeze at the observation window.

Table 1 Sedative agents list suitable for DISE

	Advantages	Disadvantages
Propofol	quick safe manageable less muscle relaxation more closely mimics natural sleep easier control of titration	Technique dependent (pump or TCI)
Midazolam	longer and more stable examination window antidote available	More difficult to handle in case of overdosing Longer hospital stay
Combined	Quicker and more stable mimicking of natural sleep Midazolam antidote available	Technique dependent (pump or TCI)

- Bolus technique (variations are possible according to team experience)

Proposal 1 loading dose, 30–50 mg; increasing rate of 10 mg every 2 min.

Proposal 2 loading dose, 1 mg/kg; increasing rate of 20 mg every 2 min.

2. Midazolam

- Bolus technique (variations are possible according to team experience)—loading dose, 0.03 mg/kg, observe for 2–5 min, increasing rate of 0.03 mg/kg only if patient is awake, then wait 5 min, if patient is not completely asleep further increasing rate if needed of 0.015 mg/kg

Pump—no shared experiences and evidences in literature

3. Combined (variations are possible according to team experience)

- Midazolam—single bolus, starting dose of 0.05 mg/kg
- Propofol—2 min later start TCI, loading dose of 1.5–3.0 µg/ml, if required, increasing rate 0.2–0.5, \times number of increasing rate delivered according to multiparametric observations (vibration collapse and respiratory drive and SatO₂), up to freeze at the observation window.

Observation window

The Working Group suggests observing at least two or more cycles both for each segment of UA and during the

maneuvers. We define cycle as a complete and stable sequence of snoring–obstructing hypo/apnea–oxygen desaturation–breathing with good observation of levels, starting from nasopharynx to hypopharynx and larynx. Depending on the sedative agents used, it may be prudent to start the assessment of the procedure after the first cycle of snoring and obstruction has been completed. This is particularly the case if the combination of Midazolam and Propofol is used to avoid a possible exaggerated early response. More cycles may be required if the bolus technique is used. If BIS is available, it is thought that the correct depth of sedation level occurs between BIS values of 50 and 70 [18, 20].

List and definitions of the target events

- Pharyngeal and/or laryngeal vibration (snoring), without obstruction, with partial obstruction
- Pharyngeal and/or laryngeal obstruction—partial, complete, anteroposterior, circumferential, lateral wall collapse, laryngeal stridor, involvement of ary-epiglottic folds, and epiglottic trapdoor phenomenon (Figs. 2, 3, 4, 5, 6, and 7).

Scoring and classification systems

The Working Group reached consensus on the fact that a scoring and classification system should include the following features: level (and/or structure), degree (severity), and configuration (pattern, direction) of obstruction (Table 3).

Table 2 Drugs dosage schedule

	Drug dosage		
	MIDAZOLAM	PROPOFOL	
Propofol alone		TCI (brain concentration): Starting dose: 1.5 – 3.0 µg/ml If required, increase with rate of 0.2 – 0.5 µg/mL	
		PUMP (blood concentration): Delivering dose: 50 – 100 ml/hour	
		BOLUS TECHNIQUE (blood concentration): Starting dose: 30 – 50 mg or 1 mg/kg If required, increase with rate of 10 - 20 mg	
Midazolam alone	BOLUS TECHNIQUE (blood concentration): Starting dose: 0.03 mg/kg Observe 2 – 5 min If required, increase with rate of 0.015- 0.03 mg/kg		
Midazolam and propofol	SINGLE SHOT BEFORE ADMINISTRATION OF PROPOFOL: Single starting dose: 0.05 mg/kg or 1.5 mg	TCI (brain concentration): Starting dose: 1.5 – 3.0 µg/mL If required, increase with rate of 0.2 – 0.5 µg/mL	

Levels vs. structures

There was agreement on the fact that assessment of the nose, nasopharynx, and glottis does not have the highest priority during DISE. In the first place, the role of the nose and nasopharynx is not as important as previously thought. Secondly, the situation in the nose and nasopharynx does not differ during awake and sleep states. The same arguments hold true for the larynx; the larynx only very rarely plays a role in OSAHS, while assessment in awake situation is feasible. The results of the examination do not differ during awake and sleep states (e.g., a mobile

larynx in the awake state does not change in an immobile larynx during sleep).

There was discussion however on the levels/structures in between the nose/nasopharynx and glottis. Regarding the number of levels, some presently used systems identify four levels of obstruction, others distinguish five (Table 3). Some systems use *levels*, others prefer *structures*, others, for pragmatic reasons, use a hybrid system, including both levels and structures. Unfortunately, consensus on four or five levels/structures and on levels vs. structures has not been obtained. Some see oropharyngeal wall and tonsil as one level, others try to



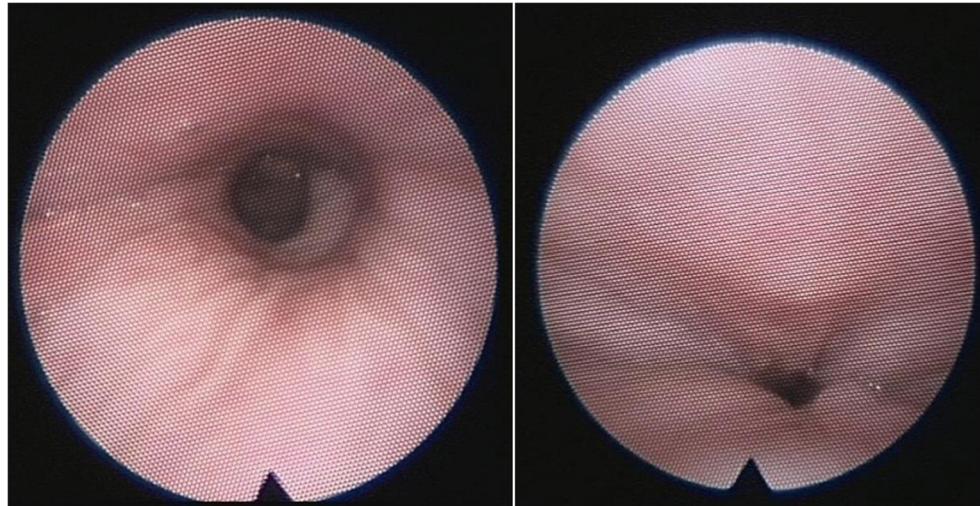
Fig. 2 Complete anteroposterior collapse in the velum region

distinguish between oropharynx and tonsils. A controversial phenomenon is “lateral wall collapse”.

Severity

The VOTE system has only 3 degrees of severity—none, partial, and complete obstruction. Other systems use a semi-quantitative system with 0–25, 25–50, 50–75, and 75–100 % of obstruction. The simplicity of the VOTE system is a deliberate compromise to (over)comprehensiveness. Of all possible ideal features of such a system, during development of the VOTE system, good inter-rater agreement was considered of higher importance than including all possible and rare forms of obstruction thinkable in a semiquantitative fashion, at the expense of reliability, reproducibility and inter-rater agreement. Other prefer the semiquantitative way; and again, consensus has not been obtained.

Fig. 3 Circumferential collapse in the velum region



Configuration

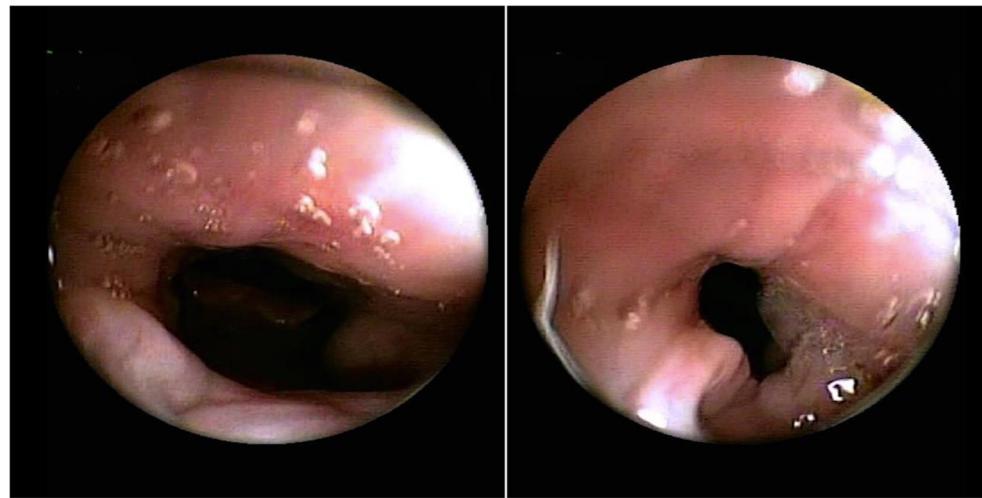
There was agreement on the three forms of obstruction—anteroposterior, lateral, and concentric.

During the discussion, the following list of information was considered: severity of event, open airway segment, sound generation (snoring or stridor without impression of increased upper airway resistance), partial obstruction/collapse (airway lumen cross-sectional area reduced with impression of increased upper airway resistance), complete obstruction/collapse (no airway lumen can be seen), site of event, palate (cranial of upper tonsillar pole), tonsil region (upper to lower tonsillar pole), tongue base (lower tonsillar pole to base of vallecula), larynx (supraglottis and glottis), and pattern of event (anteroposterior, lateral, and circumferential).

Recommended report format

UA evaluation is considered to be vital in order to attain site-specific treatment and thus better surgical and nonsurgical treatment outcomes [68]. Numerous techniques to evaluate and assess the upper airway exist and include imaging, acoustic analysis, pressure manometry, and DISE. Numerous disadvantages have been outlined such as radiation with some imaging techniques, cost issues, and lack of standardization with acoustic analysis software. Similarly with DISE, doubts have been raised about various aspects but most of these have been addressed by various studies. Issues of inter-rater variation, test-retest reliability, and depth of sedation are a few examples [69]. The ideal evaluation of UA should include a three-dimensional assessment and representation during sleep

Fig. 4 Lateral wall collapse in the velum and lateral pharyngeal walls



as well as in the awake state. We believe that DISE provides a three-dimensional visualization of what actually happens during sleep, albeit during sedation. We strongly advocate the use of DISE and this European Position Paper provides a collective view on various aspects of the technique used by various European centers regularly dealing with management of patients with sleep related breathing disorders. To date, we believe that DISE provides the most useful information of upper airway collapse during sleep compared to other evaluation techniques available.

Future research agenda

Some areas for future research can be defined:

To come to one universally accepted scoring and classification system. Consensus should be reached on levels vs.

Structures and number (four of five) of levels/structures, severity (none/partial/complete vs. semiquantitative assessment), and configuration of obstruction.

To assess in more detail whether certain DISE findings are related to treatment outcome and treatment advices.

To assess the role of DISE for titration of titratable OSAHS therapies such as upper airway stimulation therapy or OA therapy.

To better understand the impact of the use of the sedative drugs and their influence on UA collapse levels and patterns, as well as their influence on sleep patterns and stages.

To improve the options for the measurement of the depth of sedation during DISE; different EEG-derived indices available should be evaluated and compared.

To analyze the importance of positional aspects during DISE and differences concerning DISE findings among

Fig. 5 Epiglottic trapdoor phenomenon

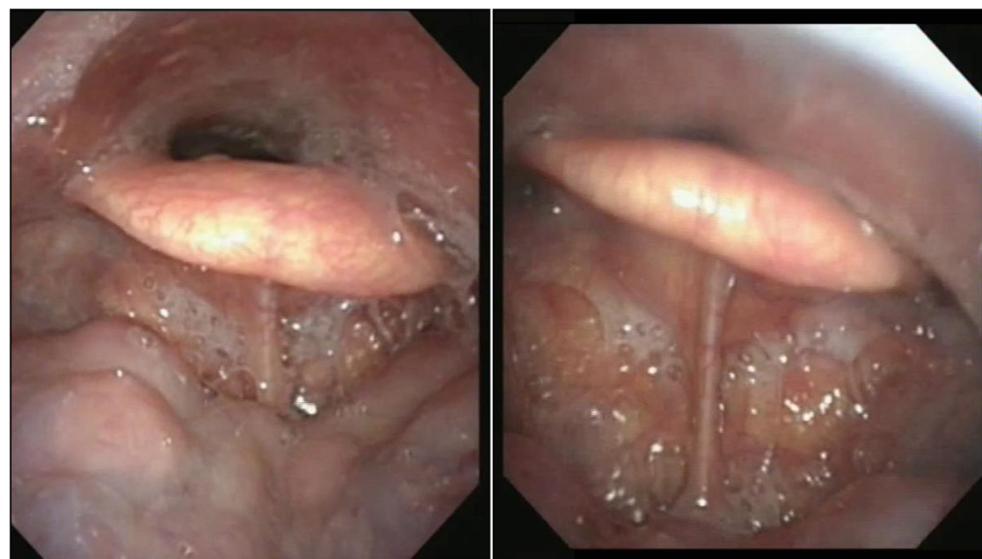
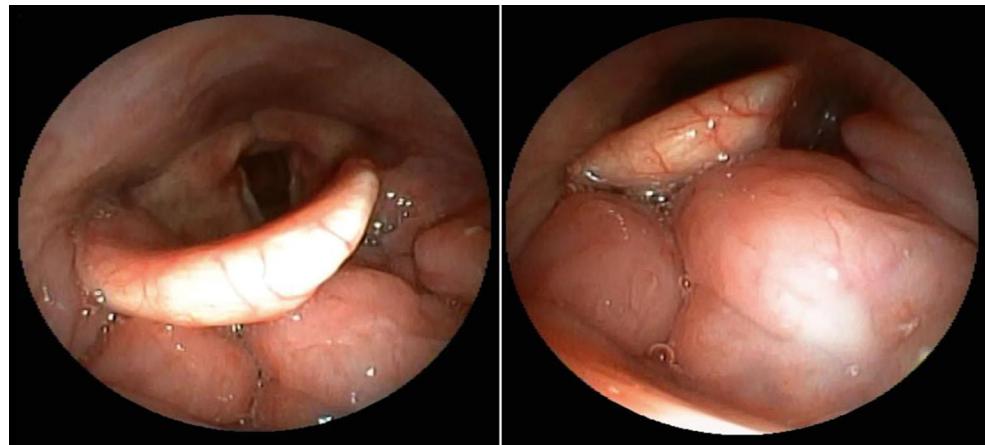


Fig. 6 Tongue base collapse due to lingual tonsil hypertrophy



supine-dependent OSAHS patients as compared to non-supine dependent OSAHS patients.

To further compare the differences in degree, level, and pattern of UA collapse observed during DISE versus during natural sleep and awake endoscopy.

To further explore the potential of DISE for the optimization of OSAHS treatment.

To devise a thorough method of calculating the cost-effectiveness of DISE in clinical practice.

To assess and study the characteristics of central apnea during DISE taking into account that esophageal pressure measurement is regarded as the gold standard measurement of respiratory effort.

To standardize the methods for application of a reproducible mandibular advancement during DISE in order to mimic OA wear in an appropriate fashion.

To increase the reproducibility of the mouth closing during DISE taking into account the importance of vertical opening in relation to UA resistance.

Conclusion

At this first European Position Consensus Meeting on DISE, consensus was reached on indications, required preliminary examinations, where to perform DISE, technical equipment required, staffing, local anesthesia, nasal decongestion, other medications, patient positioning, basics and special diagnostic maneuvers, drugs and observation windows. It is disappointing that so far no consensus has been reached on a scoring and classification system. There are several DISE scoring systems, varying from perhaps too simple, to perhaps too complex or comprehensive. The goal remains to come to one universally accepted classification system in order to enable comparison of the different series, and to base subsequent treatment advice on the same globally accepted system. A common DISE language is mandatory, and attempts to come to a generally accepted system have to be pursued.

Fig. 7 Tongue base collapse due to muscle relaxation

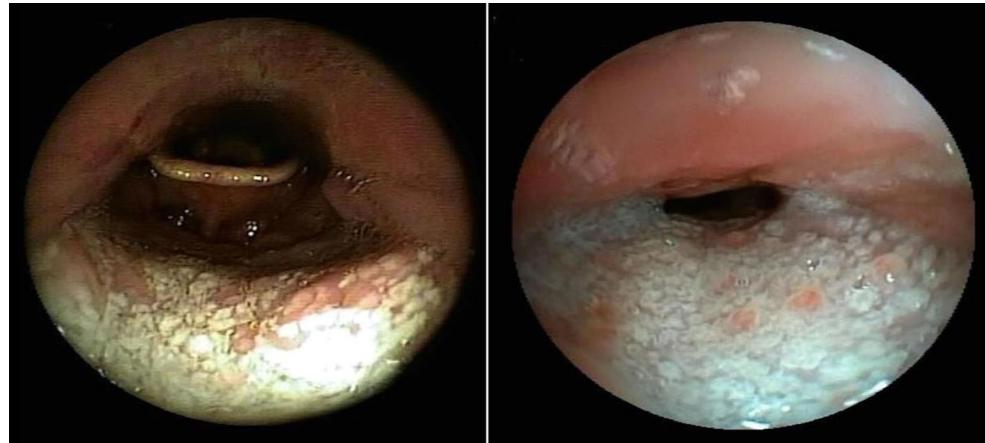


Table 3 Classifications systems for DISE published until November 2013

Author, year	Classification				
Pringle, 1993 [64]	Grade 1: simple palatal snoring Grade 2: single level palatal obstruction Grade 3: multi-segmental involvement: intermittent oropharyngeal collapse Grade 4: Sustained multi-segmental collapse Grade 5: Tongue base collapse				
Camilleri, 1995 [65]	Grade 1: Palatal snoring Grade 2: Mixed snoring Grade 3: Non-palatal (tongue base) snoring				
Kezirian, 2011 [66]	Zone	Grade	Configuration		
			AP	Lateral	Circular
	Velum				
	O r o l a t e r a l pharyngeal walls				
	Tongue Base				
Vicini, 2012 [67]	Zone	G r a d e 0-25%: 1 25-50%: 2 50-75%: 3 75-100% 4	Configuration		
			AP	Lateral	Circular
	Nose				
	Oropharynx				
	Hypopharynx				
Bachar, 2012 [70]	Zone	No collapse		Partial collapse	Complete collapse
	N o s e + nasopharynx	0		1	2
	Palate (tonsils included)	0		1	2
	Tongue base	0		1	2
	Larynx	0		1	2
Gillespie, 2013 [14]	Hypopharynx	0		1	2
	DISE Index	0	1	2	3 4

Table 3 (continued)

Author, year	Classification					
	Palate AP	No collapse	Partial collapse	Complete collapse	NA	NA
O P W Hypopharynx	O P W Hypopharynx	No collapse	Partial collapse	Complete collapse	NA	NA
	Tonsils	No collapse	Partial collapse	Complete collapse	NA	NA
	Tongue Base	No collapse	Partial collapse with lingual tonsil present	Partial collapse without lingual tonsil	Complete collapse with lingual tonsil present	Complete collapse without lingual tonsil present
	Epiglottis	No collapse	Partial collapse	Complete collapse	NA	NA
	Koo, 2013 [71]	Level	Degree of obstruction	Configuration		
				AP	Lateral	contributing structure
				Retropalatal	0/1/2	Palate +/- LPW +/- Tonsils +/-
				Retrolingual	0/1/2	Tongue Base +/- LPW +/- Epiglottis

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Conflict of interest Andrea De Vito, Marina Carrasco, Agnoletti Vanni, Marcello Bosi, Alberto Braghiroli, Aldo Campanini, Ottavio Piccin, Bhik Kotecha, and Giovanni Sorrenti declare no conflict of interest. Nico de Vries shares in NightBalance, and has otherwise not received any payment or services for this work. de Vries is a member of the Medical Advisory Board of Night Balance, consultant for Philips Healthcare and Olympus, researcher for Inspire Medical Systems, and is a member of the Medical Advisory Board ReVent. Evert Hamans is a consultant for Philips Healthcare. Winfried Hohenhorst is an investigator for Inspire Medical Systems. Joachim Maurer received grant support and

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