

# Standard procedures for adults in accredited sleep medicine centres in Europe

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**SUMMARY** The present paper describes standardized procedures within clinical sleep medicine. As such, it is a continuation of the previously published European guidelines for the accreditation of sleep medicine centres and European guidelines for the certification of professionals in sleep medicine, aimed at creating standards of practice in European sleep medicine. It is also part of a broader action plan of the European Sleep Research Society, including the process of accreditation of sleep medicine centres and certification of sleep medicine experts, as well as publishing the *Catalogue of Knowledge and Skills* for sleep medicine experts (physicians, non-medical health care providers, nurses and technologists), which will be a basis for the development of relevant educational curricula. In the current paper, the standard operational procedures sleep medicine centres regarding the diagnostic and therapeutic management of patients evaluated at sleep medicine centres, accredited according to the European Guidelines, are based primarily on prevailing evidence-based medicine principles. In addition, parts of the standard operational procedures are based on a formalized consensus procedure applied by a group of Sleep Medicine Experts from the European National Sleep Societies. The final recommendations for standard operational procedures are categorized either as 'standard practice', 'procedure that could be useful', 'procedure that is not useful' or 'procedure with insufficient information available'. Standard operational procedures described here include both subjective and objective testing, as well as recommendations for follow-up visits and for ensuring patients' safety in sleep medicine. The overall goal of the actual standard operational procedures is to further develop excellence in the practice and quality assurance of sleep medicine in Europe.

**KEYWORDS** sleep medicine centres, standard procedure, sleep medicine

## INTRODUCTION

This paper is a continuation of the previous guidelines for the accreditation of sleep medicine centres (SMCs) (Pevernagie

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*et al.*, 2006) and the certification of professionals in sleep medicine (Pevernagie *et al.*, 2009). It is intended to further develop excellence in the practice of sleep medicine in Europe. The paper has been reviewed and approved by the Assembly of National Sleep Societies (ANSS), a forum within the European Sleep Research Society (ESRS), representing the presidents of the European National Sleep Societies and the Board of the ESRS.

The paper describes standard operational procedures (SOPs) regarding the diagnosis (using subjective and objective testing) and therapeutic management of patients who are evaluated at SMCs, accredited according to the European Guidelines (Pevernagie *et al.*, 2006). Recommendations are based on prevailing evidence-based medicine (EBM) principles.

This paper is part of a broader action plan of the ESRS including the process of accreditation of sleep medicine centres and certification of sleep medicine experts, as well as creating standards of practice in European sleep medicine. A subsequent step will be the development of an inventory that lists all relevant aspects of knowledge and skills pertaining to the practice of sleep professionals, including physicians, non-medical health care providers, nurses and technologists. In order to delineate the competence area in this field, the ESRS will produce a *Catalogue of Knowledge and Skills* for sleep medicine experts. This manual will be a basis and guide in the development of relevant educational curricula. The current standard procedures fit into the policy of the ESRS to define the landmarks of state-of-the-art sleep medicine practice in Europe.

The aim of this paper is to be used as an instrument of standardization and quality assurance of current operational procedures, both in terms of proper patient management as well as with regard to adequate resource and time allocation. This standardization may help the various European countries to calculate the operational costs of SMC procedures in relation to other procedures in medicine and in relation to the gross domestic product (GDP).

It is envisaged that this document will be reviewed, and where necessary revised, 4 years after publication.

## COST-EFFECTIVENESS IN SLEEP MEDICINE

Sleep disorders are recognized increasingly as a health care burden. Sleep disorders such as insomnia, sleep-related breathing disorders and sleep-related movement disorders are prevalent. In addition, sleep disorders are associated with other chronic diseases (and occasionally can be even the first manifestation of, e.g. Parkinson's disease and depression), contributing to increased morbidity, mortality, decreased quality of life and may also lead to severe social and professional impairments (Ohayon, 2007). Finally, in recent years many studies have shown that excessive sleepiness is associated with an increased risk of working and motor vehicle accidents (Philip and Åkerstedt, 2006; Rodenstein, 2009; Sassani *et al.*, 2004).

Recent studies suggest that the direct and indirect costs of undiagnosed and untreated sleep disorders have major negative implications for national health care systems (Hillman *et al.*, 2006). Also, it is recommended that the treatment of most common chronic diseases such as arterial hypertension, diabetes mellitus, metabolic syndrome, chronic pain (Vitiello *et al.*, 2009) or the management of most acute cardiac or cerebral disease (e.g. stroke) should include the assessment of sleep (Bassetti and Hermann, 2011; Bayon

*et al.*, 2007; Brown *et al.*, 2005; Grigg-Damberger, 2006). This is specifically important for a modern and cost-effective national health care system when health care-related expenses constitute a steadily growing proportion of the national budgets (Bodenheimer, 2005; Stuckler *et al.*, 2010). Indeed, there is strong evidence for the positive effects of proper sleep disorders management for the national budgets (Banno *et al.*, 2009; Jennum *et al.*, 2009; Léger and Bayon, 2010; McDaid *et al.*, 2009; Ndegwa *et al.*, 2009; National Institute for Health and Clinical Excellence (NICE), 2008; Sassani *et al.*, 2004; Weatherly *et al.*, 2009). This implies that adequate medical procedures are used to diagnose the patients with the above-mentioned chronic or acute diseases. Similarly, appropriate treatment of the patients diagnosed with sleep disorders is a significant cost-effective measure for the national budget.

## STANDARD PROCEDURES FOR ADULTS IN ACCREDITED SLEEP MEDICINE CENTRES

### EBM levels and recommendations

The level of evidence and the grades of recommendations are described differently in various documents that are used worldwide, e.g. health technology assessment (HTA) reports, guidelines, practice parameters, Cochrane Database Systematic Reviews and Recommendations. Most of them are based on the Oxford Centre of Evidence-Based Medicine (2009) 'levels of evidence' published by Sackett (1993).

Based on existing guidelines, the American Academy of Sleep Medicine (AASM) established three 'levels of recommendation' for patient-care strategies, decrementally named 'standard', 'guideline' and 'option' (adapted from Eddy, 1992), with the purpose of including varying degrees of clinical certainty ('high', 'moderate' and 'uncertain') into AASM practice parameters.

In the current paper, which deals with the procedures of clinical practice in accredited SMCs in Europe, we propose the qualifications 'standard practice' (+), 'procedure that could be useful' ( $\pm$ ), 'procedure that is not useful' (-) and 'procedure on which there is no information available' (?). All the recommendations used in this paper are based on the best EBM levels from the most recently published Guidelines, HTA reports, Practice Parameters, Cochrane Database Systematic Reviews, meta-analyses and publications since 2005.

In the case of a lack of data or inconclusive data in the existing literature, and after a formalized Delphi-round, a consensus conference, held at the ESRS 2010 Congress in Lisbon, Portugal, decided which recommendation had to be stated ('Consensus'). This was achieved if at least 85% of the participants of the consensus group, who are all Presidents of the National Sleep Societies in Europe who are members of the ANSS of the ESRS, voted for the consensus. Otherwise, the need for further research was stated. The approval of this paper was 100% in the final consensus conference.

## DIAGNOSTIC PROCEDURES

### General evaluation

#### *General medical history, sleep history and physical examination*

All sleep disorders must be diagnosed through a careful, detailed general medical history, which includes a specific sleep history concerning sleep patterns and waking processes (Table 1). A physical examination is necessary to detect essential comorbidities (Mayer *et al.*, 2009) (+).

#### *Sleep logs and interviews*

Sleep logs and structured interviews have substantial diagnostic value and should therefore be used in cases of specific sleep disorders and complaints of symptoms of insomnia, hypersomnias and circadian rhythm disorders (Mayer *et al.*, 2009; Morgenthaler *et al.*, 2007c) (+).

#### *Specific questionnaires*

In all categories of sleep disorders, specific questionnaires should be available in the accredited SMC and should be used appropriately (+) (see examples of questionnaires in Table 2).

The questionnaires should be validated in each national language (e.g. Vignatelli *et al.*, 2003 for the Epworth Sleepiness Scale in Italian; Valko *et al.*, 2008 for the Fatigue Severity Scale in German).

#### *Workload of the professionals.*

The admissions procedure consists of taking the general and sleep-specific history of the patient, analysis and assessment of the specific sleep questionnaires and the physical examination. The time a trained medical doctor needs to complete this is, on average, 1 h (Consensus).

### Objective testing

#### *Actigraphy*

Actigraphy is a valid way to assess sleep–wake patterns in patients suspected of certain sleep disorders, but the method cannot fully be a substitute for polygraphy or polysomnography. Actigraphy is used commonly in patients suspected of advanced sleep phase syndrome (ASPS), delayed sleep phase syndrome (DSPS) or shiftwork sleep disorder. It can also be indicated in circadian rhythm disorders, including jet lag and non-24-h sleep–wake syndrome, including that associated with blindness (Morgenthaler *et al.*, 2007a) (+). However, because actigraphic rest–activity patterns cannot provide a reliable unconfounded marker of circadian timing, circadian rhythm assessment (e.g. melatonin, core body temperature, cortisol) is useful for diagnosis. Currently the timing of the melatonin rhythm (e.g. time of melatonin onset) is considered the most reliable marker of circadian phase (Consensus).

In patients with insomnia (including those with depression), excessive daytime sleepiness/hypersomnia (including those with behaviourally induced sleep insufficiency syndrome) or sleep-related movement disorders, actigraphy can be of additive diagnostic value (Consensus).

#### *Workload of the professionals.*

The time needed for the technical management is 15 min; the time needed for the medical consultation is 30 min (Consensus).

#### *Limited-channel (one to three) monitoring*

Devices for the monitoring of one to three parameters, e.g. O<sub>2</sub>-saturation (SaO<sub>2</sub>), heart rate, electrocardiogram (ECG), respiration, flow or snoring, are not useful for the final diagnosis of any sleep disorder. This procedure may be helpful in cases of suspected sleep-related breathing disorders in certain patient groups with a high pre-test probability (Mulgrew *et al.*, 2007), but in the majority of cases it is not suited for the diagnosis of sleep-related breathing disorders (Collop *et al.*, 2007; Kushida *et al.*, 2005; Mayer *et al.*, 2009; McNicholas, 2008; Ndegwa *et al.*, 2009) (–).

#### *Workload of the professionals.*

The time needed for the technical management is 20 min; the time needed for the medical consultation is 20 min (Consensus).

#### *Polygraphy (portable monitoring)*

Polygraphy (PG or portable monitoring) has four to eight channels of physiological data, but EEG is not recorded. The minimum set of channels comprises O<sub>2</sub>-saturation, airflow, breathing effort, heart rate and body position. It is particularly useful for the diagnosis of obstructive sleep apnoea without significant comorbid condition (Collop *et al.*, 2007; Kushida *et al.*, 2005; Mayer *et al.*, 2009; Ndegwa *et al.*, 2009). It is not useful for the diagnosis of other sleep disorders. It has to be performed by trained and certified medical sleep specialists. Manual scoring is mandatory. Equivocal test results require the subsequent performance of full polysomnography as a standard practice. The final outcome is a report, as described in the European Guidelines for Accreditation of SMCs (Pevernagie *et al.*, 2006) (+).

#### *Workload of the professionals.*

The workload comprises admitting the patient by the medical specialist, as specified above (1 h). Preparation of the equipment, patient hook-up (0.5 h) and scoring of the record (0.5 h) are performed by the technician. The medical doctor (MD) subsequently reviews the scoring, creates the report and gives feedback to the patient (0.5 h). These procedures requires a total time for the licensed MD of 1.5 h, and for the trained technician of 1 h. Attended PG requires continuous monitoring by trained technical and nursing staff for the duration of recording, i.e. 8 h (Consensus).

**Table 1** Grade of recommendations for subjective and objective diagnostic procedures in different sleep disorders

		<i>Diagnostic procedures in sleep medicine</i>																
		<i>Subjective testing</i>				<i>Objective testing</i>												
		<i>General/specific history + Physical examination</i>		<i>Logs, interviews, sleep diary</i>		<i>Specific questionnaire</i>		<i>Actigraphy</i>		<i>Respiration</i>		<i>Polysomnography</i>		<i>Videometry</i>		<i>Optional parameters (CO<sub>2</sub>, oesoph.-pressure, BP, PAT, temp.)</i>		
		<i>1-channel- monitoring (SaO<sub>2</sub>, ECG, respiration)</i>		<i>1-3 channel- monitoring (SaO<sub>2</sub>, ECG, snoring, respiration)</i>		<i>Portable monitoring 4-6 channels— cardioresp. polygraphy</i>												
Insomnia	+	+	+	+	±	-	-	-	-	±	±	±	±	±	±	±	±	±
Sleep-related breathing disorders	+	?	+	+	-	-	-	-	-	±	±	±	±	±	±	±	±	±
Hypersomnias	+	+	+	+	±	-	-	-	-	±	±	±	±	±	±	±	±	±
Circadian rhythm disorders	+	+	+	+	±	?	?	?	?	±	±	±	±	±	±	±	±	±
Parasomnia	+	?	+	+	±	?	?	?	?	±	±	±	±	±	±	±	±	±
Sleep-related movement disorders	+	?	+	+	±	?	?	?	?	±	±	±	±	±	±	±	±	±

ICSD-2 = International Classification of Sleep Disorders, 2nd edn, 2005. + = standard practice; ± = could be useful; - = not useful; ? = no information available; ECG: electrocardiography.

**Table 2** List of frequently used assessment instruments for different sleep disorders

<i>Subjective testing</i>			
<i>Name</i>	<i>Acronym</i>	<i>Testing for</i>	<i>Literature</i>
Structured interview for sleep disorders DSM-IV/ICSD	SLEEP-EVAL	Insomnia	Ohayon <i>et al.</i> , 1997
Berlin questionnaire risk for the diagnosis of sleep apnoea syndrome	Berlin-Q	Sleep-related breathing disorders	Netzer <i>et al.</i> , 1999
Pittsburgh sleep quality index	PSQI	Sleep disorders/insomnia	Buysse <i>et al.</i> , 1989
Landecker Inventar zur Erfassung von Schlafstörungen [Landeck inventory for detection of sleep disorders]	LISST	SBRD/narcolepsy/insomnia	Weeß <i>et al.</i> , 2008
Epworth sleepiness scale	ESS	Hypersomnia, daytime sleepiness	Johns, 1991
Karolinska sleepiness scale	KSS	Daytime sleepiness, hypersomnia	Åkerstedt and Gillberg, 1990
Stanford sleepiness scale	SSS	Daytime sleepiness	Hoddes <i>et al.</i> , 1973
Morningness/eveningness questionnaires	MEQ	Circadian rhythm disorders	Horne and Östberg, 1976
Münchener Parasomnie-Screening (Munich parasomnia screening)	MUPS	Parasomnias	Fulda <i>et al.</i> , 2008
RLS screening questionnaire	RLSSQ	Restless legs syndrome	Stiasny-Kolster <i>et al.</i> , 2009
Johns Hopkins RLS Severity Scale	JHRLSS	Restless legs syndrome	Allen and Earley, 2001
REM sleep behaviour disorder screening questionnaire	RBDSQ	RBD screening	Stiasny-Kolster <i>et al.</i> , 2007
Sleep apnoea quality of life index	SAQLI	Quality of life in sleep apnoea syndrome	Flemons and Reimer, 1998
Short form 36	SF-36	Health-related quality of life	Ware and Sherbourne, 1992; McHorney <i>et al.</i> , 1993
STOP and STOP-Bang questionnaire	STOP	Sleep apnoea syndrome	Chung <i>et al.</i> , 2008
Athens insomnia scale	AIS	Insomnia	Soldatos <i>et al.</i> , 2000
Frontal lobe epilepsy and Parasomnia scale	FLEP scale	Epilepsy–parasomnias	Derry <i>et al.</i> , 2006
Fatigue severity scale	FSS	Fatigue	Hjollund <i>et al.</i> , 2007
Insomnia severity index	ISI	Insomnia	Bastien <i>et al.</i> , 2001

ICSD: International Classification of Sleep Disorders.

### *Polysomnography*

Polysomnography (PSG) as specified in the European Guidelines (Pevernagie *et al.*, 2006) is used as the reference method in the diagnostic procedures of sleep medicine (Kushida *et al.*, 2005). The minimum montage for EEG recordings depends on the scoring rules adopted by the SMC (Iber *et al.*, 2007; Rechtschaffen and Kales, 1968). For the diagnosis of motor/complex parasomnias and nocturnal epilepsy, more EEG and EMG recordings are needed.

Relevant indications for this diagnostic procedure are published in the ICSD-2 (American Academy of Sleep Medicine, 2005). The final outcome is a report as described in the European Guidelines for Accreditation of SMCs (Pevernagie *et al.*, 2006) (+).

A comprehensive manual for the scoring of sleep and sleep-related events has been published by the AASM (Iber *et al.*, 2007). The scoring method to use, however, is still a matter of discussion in different countries of Europe, therefore the reference for the scoring procedure used should be included in the PSG report (Consensus).

### *Workload of the professionals.*

The workload comprises admitting the patient by the medical specialist, as specified above (1 h). Preparation of the equipment, patient hook-up, disconnecting (1.5 h) and scoring the record (1.5 h) is performed by the technician. The MD subsequently reviews the scoring, creates the report and gives

feedback to the patient (1 h). These procedures require a total time for the licensed MD of 2 h, and for the trained technician of 3.0 h. Attended PSG requires continuous monitoring by trained technical and nursing staff for the duration of recording, i.e. 8 h (Consensus).

### *Video-polysomnography*

The polysomnography report may also include analysis results from simultaneous video recording. Videographic recordings are particularly important for the recognition/diagnosis of parasomnias and nocturnal epilepsy (Aldrich and Jahnke, 1991; Derry *et al.*, 2009; Tinuper *et al.*, 2007) (Consensus).

### *Multiple sleep latency test (MSLT)/maintenance of wakefulness test (MWT)*

In clinical practice the MSLT can be used to provide an objective evaluation of reported daytime sleepiness in different clinical conditions. It is indicated if narcolepsy is suspected (standard practice) and may be useful in the evaluation of patients with suspected idiopathic hypersomnia and other central nervous system (CNS) hypersomnias (including excessive daytime somnolence, EDS) secondary to Parkinson's disease, head trauma and stroke (+). MSLT usually requires full PSG recording the night before assessment (Littner *et al.*, 2005).

The MWT can be used in order to evaluate the capability to stay awake when the inability to remain awake may constitute a public or personal safety issue; it may also be used to assess the response to treatment (Littner *et al.*, 2005) (+).

Regarding nocturnal PSG, MSLT and MWT reports should specify the adopted scoring procedure. The final outcome is a report as described in the European Guidelines for Accreditation of SMCs (Pevernagie *et al.*, 2006) (+).

#### *Workload of the professionals.*

As the hook-up has been performed during the preceding PSG, the additional workload for the technician is 30 min to check technical issues. Scoring of the record (0.5 h) is performed by the technician. The MD subsequently reviews the scoring, creates the report and gives feedback to the patient of the results from the PSG and the MSLT/MWT (1 h). These procedures require a total time for the licensed MD of 1 h, and for the trained technician of 1 h. Attended MSLT requires monitoring by trained technical and nursing staff for a duration of 8 h (Consensus).

## TREATMENT PROCEDURES

### Treatment with PAP devices

In standard practice it is recommended to treat patients with obstructive sleep apnoea syndrome (OSAS) with nasal continuous positive airway pressure (n-CPAP) (Epstein *et al.*, 2009; Gay *et al.*, 2006; Kushida *et al.*, 2006a,b; Mayer *et al.*, 2009; McDaid *et al.*, 2009; Ndegwa *et al.*, 2009; National Institute for Health and Clinical Excellence (NICE), 2008) (+).

An effective CPAP level is reached at the point where no residual obstructive respiratory events are observed. The best procedure to establish the effective CPAP level is currently unknown. Several methods for the assessment of the effective CPAP level exist and are used currently in SMCs in Europe. These include manual CPAP titration, application of auto-adjustable-CPAP (APAP) and prediction formulae (Consensus).

Individual mask-fitting and education in using the CPAP device is always necessary (Epstein *et al.*, 2009; Mayer *et al.*, 2009; Smith *et al.*, 2009) (+).

Besides fixed CPAP devices, APAP and so-called expiratory pressure relief devices can be used (Littner *et al.*, 2002; Mayer *et al.*, 2009). There is currently not sufficient evidenced advantage in terms of clinical benefit and compliance (Bakker and Marshall, 2011), but low compliers may improve their adherence when moving to pressure relief devices (Pepin *et al.*, 2009) (+).

APAP devices are not useful in defining an apnoea-hypopnoea index for diagnosing obstructive sleep apnoea, but may be used to determine the number of residual events under CPAP (Morgenthaler *et al.*, 2008) (-).

It is standard that patients with congestive heart failure, significant lung disease such as chronic obstructive pulmonary disease (COPD), patients expected to have nocturnal arterial oxyhaemoglobin desaturation due to conditions other than

OSAS (e.g. obesity hypoventilation syndrome), patients who do not snore (either naturally or as a result of palate surgery) or patients who have central sleep apnoea syndromes are not currently candidates for APAP titration or treatment (Morgenthaler *et al.*, 2008) (+).

If the patient is uncomfortable or intolerant of high pressures on CPAP the patient may be treated with bilevel-PAP (Kushida *et al.*, 2008). A very important point is to reinforce education and mask-fitting before any change of device (Consensus).

In cases of daytime hypoxaemia ( $\text{PaO}_2 < 55$  mmHg in a stable state of disease), supplemental  $\text{O}_2$  should be added (Kushida *et al.*, 2008) (+).

In cases of central sleep apnoea or Cheyne–Stokes respiration in congestive heart failure or positive pressure ventilation-induced central apnoea (complex apnoea which makes less than 2% of OSA patients if a sufficient period of follow-up is used), adaptive servoventilation can be considered (Allam *et al.*, 2007; Kushida *et al.*, 2006a, 2008) (+).

#### *Workload of the professionals.*

Workload of the professionals for polysomnography or polygraphy is described above. Depending on the ventilation procedure chosen, different amounts of workload are necessary. For educating the patient in the use of the pressure device and mask-fitting the workload for the technicians is 0.5–1 h. Overnight pressure titration and monitoring requires a workload for technicians of 8 h. In the case of ambulatory APAP titration information on the pressure device and mask adaptation the workload for the technician is 1 h.

The evaluation by the MD amounts to 0.5 h independent of the procedure (Consensus).

#### *Non-invasive ventilation*

In patients with symptoms (e.g. dyspnoea, reduced performance, oedema, headache, daytime sleepiness) of thoraco-skeletal, neuromuscular diseases or obesity hypoventilation syndrome with chronic hypercapnia, non-invasive ventilation (NIV) is recommended (Berry *et al.*, 2010; Chouri-Pontarollo *et al.*, 2007; Mayer *et al.*, 2009; Piper *et al.*, 2008; Ward *et al.*, 2005; Young *et al.*, 2008) (+).

Need for therapy is given in patients with hypercapnia in the wake state ( $\text{PaCO}_2 \geq 50$  mmHg,  $>45$  mmHg in neuromuscular or thoraco-skeletal diseases, respectively) or in the sleep state ( $\text{Pa CO}_2 > 55$  mmHg or  $\geq 10$  mmHg in comparison to wake state), respectively, in polygraphically measured hypoventilation (desaturations  $< 85\%$ ,  $\geq 5$  min) (Mayer *et al.*, 2009) (+).

#### *Workload of the professionals.*

The amount of workload for the initiation of non-invasive ventilation may vary considerably. This depends on patient factors such as disease severity, age, comorbidities and the

mode of ventilation chosen. In general terms, for information on the pressure device and the mask-fitting the workload for the technician is 2–3 h. Daytime training sessions may amount to 8–16 h. The overnight pressure titration and monitoring involves a workload for technicians amounting to at least 8 h (for 1 night). The adaptation procedure may often require several nights. Ambulatory titration procedures are usually not used for this patient category.

The evaluation by the MD and interaction with the patient may also vary substantially; between 2 and 4 h is considered to be realistic (Consensus).

#### *Treatment using oral devices*

Mandibular advancement devices (MAD) are indicated for use in some patients with mild or moderate OSA (Elshaug *et al.*, 2008; Ferguson *et al.*, 2006; Lim *et al.*, 2006; Mayer *et al.*, 2009) (+).

Before application of oral devices the diagnostic procedure for sleep apnoea syndrome has to be performed as mentioned above. Fitting the patient with MAD has to be performed by a qualified dental professional (Kushida *et al.*, 2006b) (+).

To ensure that the treatment is efficacious, the patient should be subsequently monitored. Once optimal fit is obtained, a PSG or PG should be performed (Epstein *et al.*, 2009) (±).

#### *Surgical treatment*

Surgical treatment may be considered in patients with mild OSA when obstructing anatomy can be identified and a high likelihood exists that corrective surgery will be clinically effective. Furthermore, surgery can be considered if other treatment such as PAP ventilation or oral devices are not accepted or tolerated by the patient or provide an unacceptable improvement of clinical symptoms (+), especially in cases of mild OSA and normal to mild obese patients (Epstein *et al.*, 2009) (Consensus).

Maxillary and mandibular advancement can improve PSG parameters comparable to CPAP in the majority of patients with maxillomandibular pathology (Epstein *et al.*, 2009; Holty and Guilleminault, 2010; Mayer *et al.*, 2009; Vicini *et al.*, 2010) (Consensus).

Tracheostomy can eliminate OSA as an effective single intervention. This procedure, however, should be considered only when other options do not exist, have failed, are refused or when this procedure is required by urgent clinical intervention in an emergency clinical condition (Aurora *et al.*, 2010). It does not treat central hypoventilation syndromes appropriately (Epstein *et al.*, 2009) (+).

Laser-assisted uvulopalatoplasty is not recommended for the treatment of obstructive sleep apnoea (Franklin *et al.*, 2009; Littner *et al.*, 2001) (Consensus).

Radiofrequency-assisted uvulopalatoplasty (RAUP) is not recommended for the treatment of obstructive sleep apnoea (Franklin *et al.*, 2009).

#### *Workload of the professionals.*

Follow-up assessments after MAD or after surgical treatment are performed with cardiorespiratory polygraphy or polysomnography, which are outlined in the diagnostic chapter above. The workload of professionals is comparable for these procedures (Consensus).

#### *Cognitive-behavioural therapy (CBT)*

Cognitive-behavioural therapy can be recommended as short- or long-term treatment of insomnia (Morgenthaler *et al.*, 2006a) (+).

Components of CBT are stimulus control therapy, relaxation treatment (e.g. progressive muscular relaxation), biofeedback, paradoxical intention therapy, cognitive therapy techniques, sleep restriction and combinations of these (Espie, 2009; Morgenthaler *et al.*, 2006a,b) (+).

CBT is as effective as prescription medication for short-term treatment of chronic insomnia. Moreover, there are indications that the beneficial effects of CBT, in contrast to those produced by medication, may last well beyond the termination of active treatment (Morgenthaler *et al.*, 2006a,b; Riemann and Perlis, 2009; Wilson *et al.*, 2010) (+).

CBT can be used to improve CPAP treatment compliance in adults with obstructive sleep apnoea syndrome (Richards *et al.*, 2007; Smith *et al.*, 2009).

#### *Workload of the professionals.*

Administration of CBT for insomnia patients can be performed in different models. Time estimates cannot be stated in the scope of this paper (Consensus).

#### *Pharmacological treatment (PCT)*

Short-term hypnotic treatment in chronic insomnia should be supplemented with behavioural and cognitive therapies when possible (Schutte-Rodin *et al.*, 2008) (Consensus).

Benzodiazepine receptor agonists (BzRAs) can only be recommended for short-term treatment for 3–4 weeks (Mayer *et al.*, 2009) (+). Intermittent treatment with BzRAs can be recommended as an alternative to permanent treatment (Hajak *et al.*, 2003; Mayer *et al.*, 2009) (Consensus).

Sedating antidepressants are recommended for short-term treatment of insomnia, especially when used in conjunction with treating comorbid depression/anxiety (Schutte-Rodin *et al.*, 2008) (+). The sedating antidepressants trazodone, amitriptyline and doxepin can be recommended for reduction of nightly wake periods (Schutte-Rodin *et al.*, 2008) (+).

Timed melatonin administration is indicated in certain circadian rhythm sleep disorders (Arendt *et al.*, 2008; Morgenthaler *et al.*, 2007a,b) (+). Melatonin is considered the treatment of choice for non-24-h sleep-wake disorder suffered mainly by totally blind people (Skene and Arendt, 2007) (+). Appropriately timed, light is also indicated for circadian rhythm sleep disorders, such as DSPS and shiftwork

sleep disorder (+). In addition, melatonin has been used successfully to treat rapid eye movement (REM) sleep behaviour disorder (Aurora *et al.*, 2010) (+), as well as chronic insomnia in the elderly (Wade *et al.*, 2007).

Herbal and nutritional substances (e.g. valerian and melatonin) as well as over-the-counter (OTC) 'sleep aids' are not recommended for the therapy of chronic insomnia due to the lack of efficacy and safety data (Schutte-Rodin *et al.*, 2008) (Consensus).

Pharmacotherapy for OSA is effective only in patients with hypothyroidism or acromegaly (Epstein *et al.*, 2009; Veasey *et al.*, 2006) (+).

L-Dopa and non-ergot-dopamine agonists are recommended for the treatment of restless legs syndrome (RLS) (Trenkwalder *et al.*, 2008a,b) (+).

In the case of augmentation, the therapy needs to be changed (e.g. L-dopa to dopamine agonist) ( $\pm$ ). In such a case, increasing the dose is contraindicated (Garcia-Borreguero *et al.*, 2007a,b) ( $\pm$ ).

Modafinil is the first-line drug for the treatment of EDS in adult patients with narcolepsy (Billiard *et al.*, 2006; Morgenthaler *et al.*, 2007c), after controlling for potential cardiac, psychiatric and cutaneous side effects (EMA, 2010) (+).

Methylphenidate and sodium oxybate are another treatment option for EDS in narcolepsy (Billiard *et al.*, 2006). Sodium oxybate is the first-line treatment of cataplexy and in the treatment of a combination of symptoms such as cataplexy, daytime sleepiness and disturbed night sleep (Mayer *et al.*, 2009; Morgenthaler *et al.*, 2007c) (+). Second-line treatments are antidepressants, either tricyclics or newer antidepressants (Billiard *et al.*, 2006).

Modafinil was also proved recently to be effective in EDS/fatigue after traumatic brain injury (Kaiser *et al.*, 2010) (+). In other CNS hypersomnias (e.g. due to stroke or Parkinson's disease) the efficacy of modafinil and methylphenidate remains controversial.

Clomipramine and sodium oxybate are effective and approved drugs in the treatment of cataplexy and facultative symptoms (hypnagogic hallucinations) (Billiard *et al.*, 2006) (Consensus).

#### *Workload of the professionals.*

Pharmacotherapy will be administered during the consultation with the MD. Follow-up schemes may vary depending on diagnosis, disease severity and comorbidities. In general, the assessment visit lasts about 1 h and follow-up visits take 30 min (Consensus).

Objective measurements of sleep or sleep-wake patterns require the same workload as described above for the diagnostic work-up (actigraphy, limited channel recording, polygraphy, polysomnography).

Specific amounts of workload may be necessary for application and evaluation of disease-specific questionnaires (e.g. Epworth Sleepiness Scale, restless legs symptom scales, fatigue and depression scales) (Consensus).

## PATIENTS SAFETY IN SLEEP MEDICINE

### General considerations

The diagnosis of sleep disorders should be established prior to any treatment procedure and the severity determined by clinical investigation and subjective and objective testing (Consensus).

In addition to sleep evaluation, the eligibility for the type of treatment should be evaluated. This can depend on gender, age, body weight and identification of anatomical variations, and includes the assessment of any medical, psychological or social comorbidity that may affect the outcome of treatment (Epstein *et al.*, 2009) (+).

A patient with sleep disorders who is considered to fulfil the indication for a specific treatment should be counselled on the different treatment options, likelihood of success, goals of treatment, risks and benefits of the procedure, possible side effects, complications and alternative treatments (Epstein *et al.*, 2009) (+).

### Follow-up procedures

It is recommended that short- or long-term treatment with CBT and PCT is evaluated in appropriate follow-up visits (National Institutes of Health (NIH), 2005).

Following any kind of surgery for sleep-disordered breathing it is recommended that the efficacy of treatment with PSG or PG is evaluated (Consensus).

Following treatment with oral devices for sleep disordered breathing it is recommended that the efficacy of treatment with PSG or PG is evaluated (Consensus).

### Follow-up procedures in patients with PAP treatment

In patients undergoing PAP therapy it is standard practice to evaluate the efficacy of the pressure after the start of treatment using PSG or PG.

Follow-up of PAP treatment is mandatory for good compliance. The first follow-up after initiation of PAP treatment should be within a time-frame of 3 months. The need for long-term follow-up may vary between patient populations depending on severity, comorbidities and residual symptomatology (e.g. decrease or increase of body weight more than 10%, return of symptoms such as daytime sleepiness). During stable conditions it is recommended that the efficacy of the treatment is checked once a year (Consensus).

Control of long-term PAP treatment can normally be performed by assessment of symptomatology, extraction of CPAP log data and/or polygraphy. In the case of inadequate treatment, a pressure adaptation by retitration may be necessary using the methods described above (attended or unattended polysomnography/polygraphy) (Mayer *et al.*, 2009) (+).

The maintenance of a PAP ventilation device can ideally be performed once a year, e.g. by the provider. The device should



be replaced when it becomes dysfunctional. This is often the case after 5 years, or an average usage of 15 000–20 000 h (Consensus).

The mask should be replaced when function is inappropriate. Typical problems include mask leakage, skin erosion due to the mask or discomfort for the patient. In general, masks may be replaced at least once a year to avoid these side effects of PAP therapy. Regular medical follow-up and patient contact may be organized in association with mask replacement and device control (Consensus).

### Follow-up in medically treated patients

Follow-up in medically treated patients with insomnia, parasomnia, narcolepsy, restless legs or chronic insomnia may vary substantially depending on a number of factors, such as specific drug requirements, patient populations, occupation and/or disease severity. A comprehensive recommendation cannot be given within the scope of this paper. However, general follow-up principles include a short-term follow-up scheme after treatment initiation and regular follow-up schemes over 1 to several years in clinically stable patients in order to assess efficacy, side effects and the need for treatment continuation (Consensus).

In patients under treatment for EDS (CPAP, drugs, sleep hygiene/extension) vigilance tests (and in particular MWT) may be helpful to assess treatment response and improved driving ability (Consensus).

### Evaluation of driving and working performance

There is increasing evidence concerning driving and working accidents due to EDS and fatigue (Garbarino *et al.*, 2001). Standards for evaluation of driving/working performance are currently being developed so that all aspects of vigilance, cognition and appropriate behaviour are taken into account. There is still limited evidence about the best use of MWT, real drive testing on the road, neuropsychological tests and different types of driving simulators.

### Special considerations

Pressure for alternative approaches to current recommended in-laboratory management of patients with OSA will continue to increase, given the cost of PSG and the limited number of laboratory facilities relative to patient need. There is growing evidence that PSG and limited channel monitoring should be compared in terms of outcomes, rather than a simple head-to-head clinical comparison (Consensus).

Sleep medicine is a very young interdisciplinary area in clinical medicine, but there already exist many original papers, as well as national and international guidelines. However, it is the international consensus that there is further need for more clinical studies and basic research to optimize good clinical practice and health care for in- and outpatients (Kuna *et al.*, 2011).

## CONCLUSION

Although health care systems and resource allocations for health care vary considerably between European countries, it is aimed to create standardized diagnostic and treatment procedures for sleep disorders in European countries. It is intended that, irrespective of citizenship, patients will receive proper sleep medicine care. In particular, procedures with a high evidence level or those with a worldwide consensus of expert groups should be covered by the health systems of the different European countries. This should be conducted according to the workload of the professionals, the costs of therapeutic devices and the costs related to behavioural or pharmacological therapy (Consensus).

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