

Respiratory polygraphy in sleep apnoea diagnosis

Report of the Swiss respiratory polygraphy registry and systematic review of the literature

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Summary

Background: Sleep related breathing disorders (SBD) are common and associated with morbidity and mortality. Since polysomnography, the conventional diagnostic gold standard is costly and not generally available, ambulatory respiratory polygraphic sleep studies (RP) are used. To evaluate whether RP reimbursement by health insurance companies was justified, the Swiss Federal Office of Public Health (FOPH) requested registration of RP during 36 months and a literature review on RP. The results are reported here.

Methods: RP reimbursed from July 2002 to December 2005 by Swiss health insurance companies were analysed. A review of the literature from 2003 comparing RP with PSG was updated. The outcome of interest was the apnoea/hypopnoea index.

Results: Datasets on 11,485 RP were evaluated, 8179 were performed to evaluate suspected obstructive sleep apnoea syndrome (OSAS). In patients with snoring, witnessed apnoea and hypersomnia (n = 4180), 80.2% of RP confirmed OSAS, 3.5% of RP were inconclusive prompting polysomnography. Six studies published between 2003

and 2005 were pooled with a former review of 12 studies. With a mean pre-test probability of 64% for OSAS, the post-test probability after a negative result ranged from 8% (negative likelihood ratio of 0.05) to 23% (negative likelihood ratio of 0.20). The post-test probability after a positive result was within a range of 98% (positive likelihood ratio of 23.8) to 90% (positive likelihood ratio of 5.7).

Conclusions: In selected patients with clinically suspected OSAS RP allows accurate and simple diagnosis of OSAS. According to the practice in Switzerland as reflected by the registry additional PSG are rarely required, suggesting relevant cost savings by RP. Granting reimbursement for RP as introduced in the meantime by the FOPH seems justified.

Key words: obstructive sleep apnoea syndrome; diagnosis; apnoea-hypopnoea index; respiratory polygraphy; polysomnography; systematic review; simplified sleep studies; portable monitoring

Introduction

The obstructive sleep apnoea syndrome (OSAS) is the best recognized and most prevalent breathing disturbance in sleep [1], affecting 2–26% of the general population depending on sex, age, and criteria for syndrome definition [2, 3].

OSAS causes major suffering from excessive sleepiness and other symptoms, impaired quality of life and it is associated with a high risk for road traffic accidents and cardiovascular disease. The most effective treatment is nocturnal application

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Abbreviations

CPAP Continuous positive airway pressure

FOPH Federal Office of Public Health

OSAS Obstructive sleep apnoea syndrome

PSG Polysomnography; RP: Respiratory polygraphy

SBD Sleep related breathing disorders

SGP Swiss Respiratory Society

SGSSC Swiss Society of Sleep Research, Sleep Medicine and Chronobiology

of nasal continuous positive airway pressure (CPAP) [4, 5].

Although the diagnosis of OSAS is suspected on clinical grounds based on a typical history and findings such as obesity and a large neck circumference, confirmation of the diagnosis requires the documentation of the sleep related breathing disturbances. According to current standards this is performed by polysomnography (PSG), an overnight study in a quiet room using techniques to assess sleep and wakefulness, (i.e., electroencephalography, electro-oculography, and electromyography) whilst simultaneously monitoring cardio-respiratory function (i.e. airflow, chest wall motion, pulse oximetry, the ECG) and audio-visual recordings. PSG is supervised by a technician, and analysis requires tedious manual scoring. Since PSG is technically demanding, labour and cost intensive and not readily available, simplified portable techniques limited to the recording of cardio-respiratory variables (respiratory polygraphy; RP) have become increasingly popular. This can be conveniently applied in ambulatory patients at their home. Whether RP is equivalent or even superior to polysomnography in the diagnosis of sleep disordered breathing as it reflects the patient's condition in their usual environment rather than in an artificial laboratory environment has been debated. There has also been controversy in regard to the costs of RP vs. PSG [6]. No outcome oriented scientific evidence for PSG as the diagnostic "gold standard" for sleep disordered breathing has been published. Thus, it has not been shown, that symptom relief, daytime vigilance, quality of life, risk for accidents or cardiovascular

disease is better in patients with OSAS or other forms of sleep related breathing disorders (SBD) if the diagnosis is based on PSG compared to limited cardio-respiratory sleep studies [7–9].

In contrast to PSG, RP performed outside certified sleep laboratories was not covered by the mandatory health insurance in Switzerland. Nevertheless, RP has been widely used for several years in the diagnosis of OSAS by pulmonary physicians in private practice. Since the concept of simplified ambulatory evaluation of patients with sleep disordered breathing is sound and implies potential cost savings, the Swiss Respiratory Society requested that the Swiss authorities declare RP remunerable by health insurances. Following a decision of the Swiss Federal Office of Public Health (FOPH), RP performed by a licensed pulmonary physician outside a certified sleep laboratory in patients with a high clinical pre-test probability of OSAS was provisionally granted compensation by health insurances from July 1st, 2002, with the provision that an evaluation registry of all RPs remunerated by health insurance companies from this date onwards until December 31st, 2005 be set up. The purpose of the registry was to monitor the use of RP in Switzerland, to characterize the cohort studied and to evaluate the diagnostic yield of RP. An additional aim was to compare the direct costs of RP with the costs of PSG had the latter be performed instead of RP. Furthermore, the authorities requested a systematic review of the literature on diagnostic performance of RP. This paper reports the analysis of the Swiss registry and the results of the systematic literature review.

Methods

Swiss RP registry

All pulmonary physicians intending to request reimbursement from mandatory health insurance companies for unattended RP performed outside sleep laboratories were required to report these examinations together with complementary information to the registry from July 1st, 2002 until June 30th 2005. Adherence to the Swiss Guidelines for requirements to conduct RP was requested from all participants [10]. All participants were certified by the executive board of the Swiss Respiratory Society. The variables of interest were jointly defined by the FOPH and the authors representing the Swiss Respiratory Society (SGP) and the Swiss Society of Sleep Research, Sleep Medicine and Chronobiology (SGSSC). They included patient characteristics, the setting, the indication, the result and consequences of RP.

A software application that allowed decentralized data entry and transmission by internet to the central database was distributed to participating physicians.

Patient characteristics included the following mandatory entries: age, gender, body mass index, presence of cardiovascular disease (hypertension, ischaemic heart disease, stroke), previous PSG. The setting of RP was specified as: ambulatory home study, in hospital study and in hospital study while hospitalised for other reasons. Selectable in-

dications for RP were: high clinical suspicion of OSAS based on hypersomnia, snoring, observed apnoeas, snoring and hypersomnia, CPAP titration study and follow-up study under therapy. Patients with a history mainly pointing to insomnia or complex sleep disorders were not candidates for RP but were referred for another primary diagnostic approach (fig. 1).

Selectable results of RP were: OSAS confirmed, sleep associated hypoventilation confirmed, sleep associated breathing disorder excluded, non-conclusive study prompting further evaluation with full polysomnography.

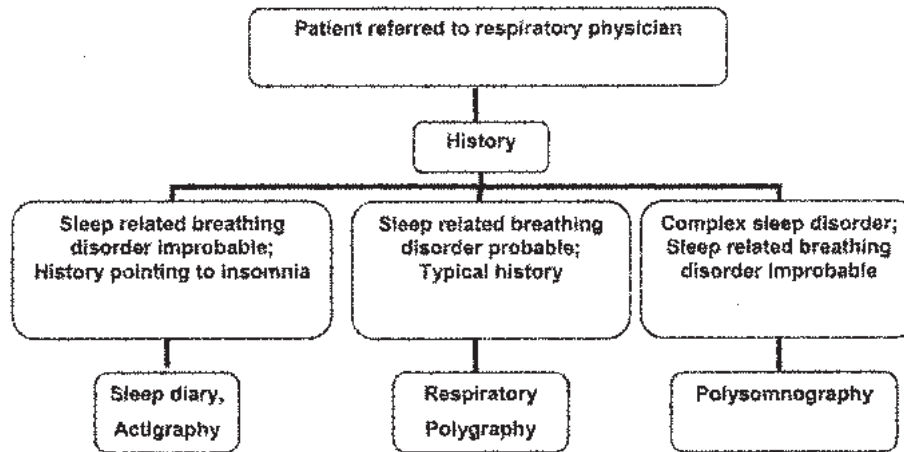
Selectable consequences of RP were: Start of CPAP-therapy, start of other treatment (to be specified), therapy adjusted or confirmation of adequate therapy, treatment stopped, confirmation that treatment was not necessary, further evaluation with PSG, further evaluation with sleep diary or actigraphy and other treatment.

Eighty-nine licensed pulmonary physicians working in private practice or hospital contributed to the registry.

Systematic Review

We conducted a Medline search on systematic reviews of the performance of RP in the diagnosis of OSAS in adults using the search query: [sleep apnea diagnosis]

Figure 1
Diagnostic
procedure.



AND systematic [sb] NOT childhood NOT pediatric]. The terms “portable diagnostic system (PDS)”, “portable monitoring device (PMD)”, “modified portable sleep apnea testing” or “Type 3 monitors” are more commonly used than “respiratory polygraphy” or “cardio-respiratory monitoring”. Therefore, these various terms describing RP were included in the query [10]. RP incorporates a minimum of four channels, including signals of airflow (at least two channels of respiratory movement, or respiratory movement and airflow, measured with thermistors or pressure-curves as surrogates of airflow), heart rate or ECG and oxygen saturation. Some RP devices also register snoring sounds, body position and leg movements. RP may be performed attended or unattended in a hospital room or as an outpatient study in the patient’s home. In the Swiss registry, portable unattended overnight studies were recorded. Thus, these RP corresponded to unattended type 3 cardio-respiratory recordings [11].

The search yielded 123 citations. The following four systematic reviews met the topic of portable monitoring devices: [6, 11–13].

From these four systematic reviews, we identified [11] as the most recent and comprehensive. In this review, 12 studies were included. We performed an updated literature search for original research articles from 2003, the end of the search period in the systematic review [11],

until May 2005 with the following search string: [Database: Ovid MEDLINE(R) <1996 to May Week 2 2005 >Search Strategy: 1) exp sleep apnea syndromes/ (6367); 2) polysomnograph\$.af. (5322); 3) polygraph\$.af. (666): 4) 2 or 3 (5779); 5) 1 and 4 (2722); 6) exp “sensitivity and specificity”/ (139 147); 7) exp reproducibility of results/ (82 694); 8) 6 or 7 (196 440); 9) 5 and 8 (288); 10) limit 9 to yr = 2001–2005 (167); 11) limit 10 to (case reports or comment or editorial) (8); 12) 10 not 11 (159)]. Explanations of concepts and online calculators may be retrieved from the following web-sites: <http://www.medcalc.com/bayes.html>; http://www.cebm.net/likelihood_ratios.asp; http://www.poems.msu.edu/EBM/Diagnosis/likelihood_ratios_2.htm

Evidence level and quality of the studies were rated according to Flemons et al. [11].

Estimation of costs

Estimations were performed to illustrate the direct costs for RP in comparison to PSG. According to the Swiss health care regulations, a RP is compensated with 494.53 tax points (TP), PSG with 1740.14 TP. Direct costs in monetary units were calculated assuming an equivalent of 0.90 Swiss francs per TP. Initial evaluation (history, physical examination) were assumed to be identical for RP and full PSG and are therefore not included in the calculation.

Results

Swiss respiratory polygraphy registry

Analysis of indications and diagnostic yield

The registry included 11,485 datasets, 76% were performed in men. Mean (SD) age was 53.8 (13.3) years, 86% of patients were >40 years old. Mean (SD) body mass index (BMI) was 30.9 (6.2); 49% of patients were obese (BMI >30 kg/m²). Indications for RP are shown in figure 2. In 67.9% of all studies, OSAS was confirmed and in 4.0% alveolar hypoventilation was diagnosed; in 18.8% OSAS was ruled out. The remaining 9.3% were control or titration studies. Confirmation or exclusion of sleep disordered breathing was possible in 96.0% of the diagnostic studies (n = 8865). Depending on the symptoms suggesting OSAS (snoring, hypersomnolence, witnessed apnoeas and a combination of these), the yield of RP was differ-

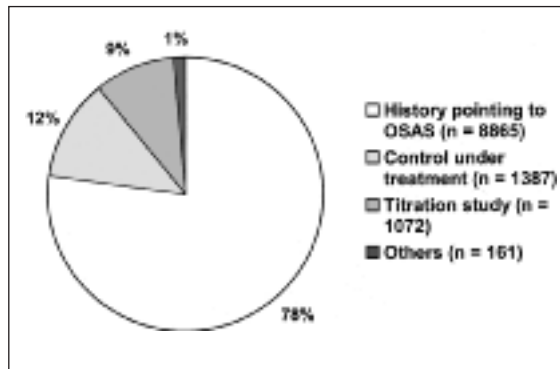
ent (fig. 3). For example, with a history of snoring, witnessed apnoeas and hypersomnia, the proportion of studies confirming OSAS was 80.2%. Therapeutic consequences included initiation of CPAP or bi-level therapy (42.1%), adjustment or confirmation of treatment pressures (29.6%), exclusion of an indication for treatment (14.8%) and treatment other than CPAP (10.0%). Only 3.5% of all studies were not conclusive thus prompting an additional polysomnography. Most studies were done at the patient’s home (71%), 21% were done in outpatients but at an institution, the remaining were done in hospitalised patients.

Systematic review

Six original investigations published between 2003 and 2005 were identified. A summary of these six studies can be found in table 1. The list of the

Figure 2

Indications for respiratory polygraphy in the Swiss Registry.



12 earlier original investigations has been published [11]. The diagnostic accuracy was defined as the ability of RP to modify the probability that a patient had an apnoea/hypopnoea index >15/h by PSG. Meta-analyses were not undertaken because the devices, patients included and definitions of sleep parameters were too heterogeneous. The following likelihood ratios and ranges apply to all 18 studies identified by the systematic review: Negative likelihood ratios ranged from 0.03 to 0.43. The range for the best studies (evidence level I) was from 0.05 to 0.20. Thus, based on a pre-test prob-

ability of 64%, similar to that found in the patients in our database (see Swiss Registry, i.e., 67.9%), the post-test probability after a negative test result would range from 8% (negative likelihood ratio of 0.05) to 23% (negative likelihood ratio of 0.20).

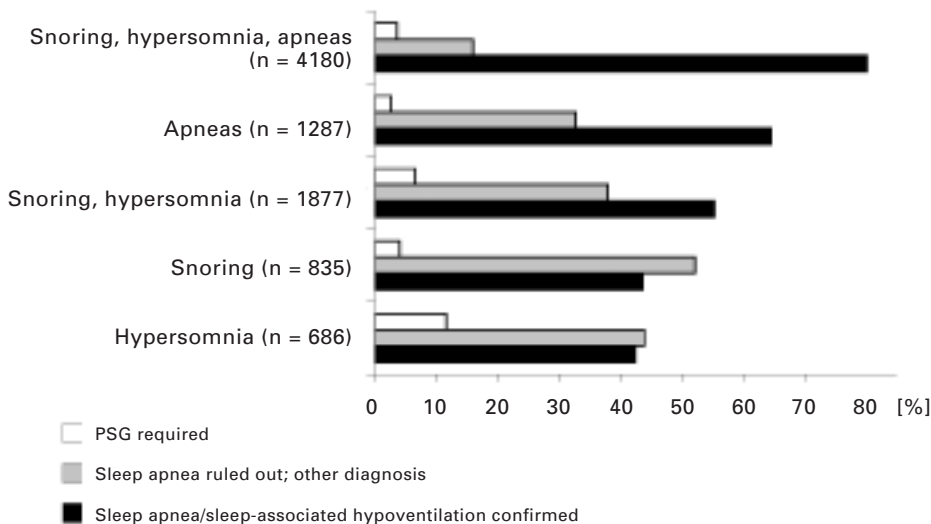
The positive likelihood ratios ranged from 1.8 to 23.8 for all studies and from 5.7 to 23.8 for the evidence level I studies. Based on a pre-test probability of 64%, the post-test probability after a positive test result would range from 98% (positive likelihood ratio of 23.8) to 90% (positive likelihood ratio of 5.7).

Estimation of direct costs

Assuming 5000 RP per year in Switzerland (494.53 tax points) the costs would be: $5000 \times 494.53 \times 0.9 = 2,225,385$ SFr. The same number of PSG (1740.14 tax points) would cost: $5000 \times 1740.14 \times 0.9 = 7,830,630$ SFr. Thus, even taking into account the 3.5% of inconclusive RP leading to additional PSG, the use of RP in patients with a high clinical suspicion of OSAS would allow annual savings of 5,331,173 SFr.

Figure 3

Percentage of confirmation and exclusion of obstructive sleep apnoea syndrome (OSAS), and need for additional polysomnography (PSG) according to presenting symptoms (n = 8865).



Discussion

Our analysis of the Swiss registry for unattended respiratory polygraphy illustrates the current clinical practice of sleep apnoea diagnosis by Swiss pulmonary physicians in private practice. The data suggest that guidelines discouraging the use of unattended sleep studies to confirm or exclude OSAS were often not followed. Apparently, long standing positive clinical experience with RP outweighed the endorsement by scientific evidence and authorities. The analysis further indicates that a vast majority of patients in whom there was a high clinical suspicion of OSAS might be appropriately evaluated at their homes by an unattended respiratory sleep study.

The systematic literature review reveals a fair diagnostic accuracy of RP in predicting respiratory

events measured by PSG. However, studies that compare the clinical outcome of RP and PSG in terms of improvement in quality of life, symptoms and successful treatment of diagnostic strategies [14] are scant.

Polysomnography has been regarded as the gold standard for the diagnosis of OSAS despite several shortcomings. It cannot accurately predict which patients will benefit from CPAP therapy [15] and has not been proven to be more accurate and cost-effective than RP in randomized trials [7]. Moreover, access to polysomnography is restricted due to its cost and limited availability [16]. Since untreated OSAS is deleterious to patients and expensive to the healthcare budget [17, 18], limited in-laboratory and even home-based sleep study de-

Table 1

Literature Review on Studies Evaluating Diagnostic Performance of Respiratory Polygraphy.

Study location	Home			Sleep laboratory				
	II	II	I	II	II	II	I	I
Evidence level	II	II	I	II	II	II	I	I
Quality rating	D	A	B	A	D	C	C	C
First author	Reichert	Dingli	Quintana-Gallego	Dingli	Reichert	Calleja	Marrone	Golpe
Reference	(25)	(26)	(27)	(26)	(25)	(28)	(29)	(30)
Device	NovaSom QSG	Embletta	Apnoescreen II	Embletta	NovaSom QSG	MERLIN	POLY-MESAM	Apnoe-screen II
Flow	Thermistor	Nasal Cannula	Thermistor	Nasal Cannula	Thermistor	Thermistor	Nasal Cannula	Thermistor
Effort	Impedance TH	Impedance TH	Impedance TH/AB	Impedance TH	Impedance TH	Impedance TH/AB	Impedance TH/AB	None
Score	M/A	M	M	M/A	M/A	M/A	M/A	M/A
DI included in AHI-definition	2%	yes	≥4%	≥2%	≥2%	≥3%	≥4%	≥4%
Number of patients	51	50	75	50	51	86	50	55
Prevalence	45.5	74	68	74	45.5	81	84	51
Negative likelihood ratio	0.05	0.08	0.20	‡	0.05	0.11	0.05	0.06
Sensitivity	95	92	79.3	‡	95	90	95	95
False negative	9	9	21	‡	5	9	5	5
Positive likelihood ratio	5.2	§	18.8	‡	11.4	6.8	§	5.68
Specificity	91	93	79.3	‡	95	91	95.2	94.7
False Positive %	20	0	2	‡	8	3	0	14

Abbreviations: AB: Abdominal effort, AHI: Apnoea-Hypopnoea-Index, DI: Desaturation Index, M/A: Manual/Automated analysis, TH: Thoracic effort, † Total is 0 because Sensitivity = 100%; ‡ cannot be calculated from raw data; § Total is infinite because Specificity = 100%.

vices have emerged. We have recently shown, that in OSAS patients diagnosed by RP, treatment effect size was comparable to earlier studies with OSAS diagnosed by polysomnography [19].

Our systematic review of unsupervised in- and outpatient RP added six reports to a former review with 12 studies comparing RP with PSG, always taking PSG as the gold-standard in respect to detection of respiratory disturbance. However, the superiority of polysomnography over RP in identification of those patients who benefit from CPAP treatment has not been proven [20, 21]. In a recent trial, PSG and pulse oximetry performed equally in this respect [21]. Patients suspected of having OSAS were randomised to undergo either PSG or ambulatory nocturnal pulse oximetry as a diagnostic test. Subjective sleepiness and quality of life after four weeks of treatment with CPAP were not different between groups. In another trial, a positive response to a two week trial of empiric auto CPAP therapy was superior to polysomnography in identifying snorers with excessive sleepiness who suffered from OSAS and successfully used CPAP for >4 months [22].

As recommended by the Swiss task force [10], it has become common practice to evaluate cases with high pre-test probability for OSAS by RP. A positive result is adequate to confirm the diagnosis and to initiate CPAP therapy without further testing by polysomnography. Conversely, patients in whom CPAP therapy was unsuccessful and those

with a less than high clinical suspicion for OSAS at initial presentation should be evaluated by polysomnography [23, 24]. Following these guidelines, the physicians participating in the Swiss registry achieved a positive result with RP confirming OSAS in nearly 68% of 11,485 studies. Based on these favourable results in this large cohort, further adherence to the proposed algorithm is recommended. In our cohort, 71% of RPs were performed in outpatients.

The limitations of RP and PSG should always be considered. The methods do not allow a diagnosis of nocturnal hypoventilation if CO₂ is not measured and they do not distinguish between low oxygen saturation related to ventilation/perfusion mismatch or hypoventilation. The simplicity of RP and computerized scoring have added to the wide distribution of devices. However, relying on inbuilt scoring software alone is strongly discouraged.

As the register was not designed as a controlled study, results of RP were not verified against the gold standard. The 3.5% “inconclusive studies” that prompted an additional PSG consisted mainly of equivocal results of RP or treatment failures. The low rate of inconclusive studies may be explained by the selection of patients with a high clinical suspicion of obstructive sleep apnoea and by the fact that they were evaluated by pneumologists experienced in diagnosing sleep related breathing disorders.

The direct costs of RP have been compared to the direct costs for PSG had this been done instead, suggesting relevant cost savings, even including inconclusive RP studies. Our results suggest cost savings of more than five million Swiss Francs per year. This assumption is limited by the lack of a cost-utility analysis for both methods.

In conclusion, RP and PSG are complementary diagnostic tools, depending on patient population and suspected diagnosis. RP is capable of obviating a great proportion of the more expensive and less widely available PSG. Thus, in well selected patients, RP has the potential for relevant cost savings in Switzerland in patients with suspected OSAS. Based on the results of the registry and of the literature review, RP has recently been granted reimbursement status by the social health insurance authorities for evaluation of suspected OSAS.

K.E.B., M.G. and M.H. designed the questionnaire for the registry. K.E.B. and his collaborators developed the software for the electronic data input. M.H. was respon-

sible for the registry and the data analysis and statistics. R.T., K.E.B. and I.L. performed the systematic review and prepared the manuscript. R.T. wrote the application for "Funding for new medical technologies and procedures" to the FOPH, with contributions from K.E.B., M.G. and I.L.

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