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Detection of OSAHS using home-monitoring with Somnolter®: a follow-up study.

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ABSTRACT

Context: Obstructive sleep apnea hypopnea syndrome (OSAHS) is highly prevalent but often asymptomatic and undiagnosed. It is associated with negative health consequences. An efficient screening strategy for detecting OSAHS in primary care is therefore needed. The aim of this study was to identify patients with undiagnosed OSAHS in general practice's (GP) and to investigate the accuracy of the used screening strategy.

Methods: During five months questionnaires with 3 screenings questions were handed out in 2 Flemish GP's to patients aged 45 to 75. In combination with their Epworth Sleepiness Scale score and BMI, patients were classified as high or low risk for OSAHS. All 45 high risk and 19 low risk patients were investigated by home-monitoring.

Results: In the high risk group the number of patients with mild, moderate and severe OSAHS was respectively 14, 19 and 8. In the control group respectively 9, 7 and 0. The number of patients with severe OSAHS was significantly higher in the high risk group. The used screening strategy has an sensitivity of 70% and specificity of 38% for detecting at least moderate OSAHS.

Conclusion: Using a combined strategy (3 screening questions and ESS), the authors identified 57 patients with undiagnosed OSAHS. These data support the hypothesis that OSAHS is highly prevalent but often undiagnosed The used screening strategy is considered useful and relatively sensitive to detect patients with at least moderate OSAHS. Nevertheless, further optimization is needed in order to use it as an efficient screening tool with an optimal sensitivity and specificity.

BACKGROUND

Obstructive sleep apnea hypopnea syndrome (OSAHS) is a syndrome originally described by Guilleminault et al. in 1976 sleep (1). It is the pathological phenomenon when people stop breathing and start gasping during sleep. This can result in clinical symptoms, e.g. daytime fatigue, excessive sleepiness, impaired concentration, depression, ...

According to the Wisconsin Sleep Cohort study, a longitudinal study started in 1988, OSAHS is highly prevalent with an estimated prevalence of 4% in middle aged men and 2% in middle aged women (2). In more recent literature however, epidemiologic studies with asymptomatic patients show increased apnea-hypopnea indices (AHI) in up to 26% of patients, suggesting that OSAHS indeed is highly prevalent but remarkably under-diagnosed. OSAHS is often associated with negative consequences such as traffic accidents, cardiovascular disease, stroke and type 2 diabetes mellitus (3–8).

From all suggested risk factors for OSAHS the most important seem to be excess body weight and arterial hypertension (9,10). On the other hand nocturnal gasping and choking seem to be the most useful in identifying patients with a high risk of having OSAHS (positive likelihood ratio (LR+) of 3,3) according to Myers et al. (9). Snoring however is useful to exclude OSAHS (negative likelihood ratio 0.6). Except for nocturnal gasping and choking, all other risk factors have a relatively low LR+ meaning that they have limited value in increasing the pre-test probability of having OSAHS. Therefore better diagnostic strategies are needed in primary health care so only patients with a high pre-test probability of OSAHS could be referred for in-hospital PSG.

In the past many questionnaires were established to increase this pre-test probability of OSAHS. The Epworth Sleepiness Scale (ESS) is probably the most known and used worldwide to quantify excessive daytime sleepiness (11,12). The Berlin Questionnaire classifies patients as high- or low-risk for OSAHS with a high degree of specificity for the diagnosis of moderate to severe OSAHS but a rather low sensitivity (13). Other questionnaires such as the STOP questionnaire and the STOP-Bang questionnaire attempt to identify high risk patients for OSAHS in surgical patients.

In this follow-up study, a case-finding strategy from the author's previous study was implemented on a larger scale expecting to find a high number of patients with undiagnosed OSAHS as patients are often asymptomatic (14). The authors further aim to investigate the accuracy of their previously developed strategy in screening for OSAHS

METHODS

Sampling

In this observational study, Dutch screening questionnaires were handed out systematically by the secretary in two Flemish general practitioner (GP) practices to all patients aged 45 to 75 years during five consecutive months. These screening questions enclosed : 1) '*Do you snore or did someone ever tell you that you snore?',* 2) '*Do you often feel immensely tired at daytime?*' and 3) '*Do you often experience difficulties to concentrate at daytime?*' Patients were also asked to fill in their name, date of birth, sex, weight and height. In case two or more screening questions were answered positively, the patient was contacted (either by telephone or during a follow up consultation) and asked to fill in the Epworth Sleepiness Scale (ESS).

Inclusion and exclusion criteria for the high risk group

To be included in the group with high risk for OSAHS patients had to be at least 45 years old and should not be older than 75 years. Secondly patients had to answer 'yes' to at least 2 out of the 3 screening questions. The third criterion was an ESS score $\geq$ 10 score as this is considered as an indication of excessive daytime sleepiness due to an underlying sleep-related breathing disorder (11,12). Finally patients had to have a BMI of ≥ 25. The only exclusion criteria for the high risk group were a previous diagnosis of OSAHS or the inability to fill in the Dutch questionnaires because of either lack of intelligence or language skills.

Inclusion and exclusion criteria for the control group

To be included in the control group (i.e. group of patients with a low risk of having OSAHS who would be investigated with Somnolter®), patients had to be aged 45 to 75 years and had to have a BMI of ≥ 25 in order to prevent selection bias. Thirdly, patients should not have answered 'yes' to more than one screening question. All patients who met the inclusion criteria were divided into 3 groups (1: age 45-54; 2: age 55-64; 3: age 65 -75). In each group a certain number of male and female patients were selected randomly to form a control group of 19 patients that matches the high risk group for age and sex. The exclusion criteria for the control group were the same as for the high risk group.

Home monitoring

Patients who met all predetermined inclusion criteria were offered to participate in the second part of this study. In this second part a device called Somnolter® was attached to the patient by one of the authors during a home visit not long before the patient went to bed. Patients were allowed to take their regular medication. The next morning, the device was detached by the patient himself and brought back to the GP's practice.

Somnolter® device

Somnolter® is a recently developed ambulant sleep recorder to detect apneas and hypopneas during overnight home-monitoring (Additional files, 1). The device records the same parameters as an in-hospital polysomnography (PSG): pulse-oximetry, body position, heart rate, nasal air flow and chest and abdominal movements. PSG is the current gold standard for the diagnosis of OSAHS. The Somnolter® device however additionally records mandibular movements (the Jaw Activity signal or Jawac signal) representing the respiratory effort during sleep, which is an important parameter in the diagnosis of sleep-disordered

breathing (SDB) (15). This signal also allows to accurately assess the total sleeping time in a home setting. This in contrast to a PSG in a hospital setting, where camera recording is done to distinguish whether the patient is awake or asleep.

Interpretation procedure

The interpretation of results was based on automatic analysis of the Somnolter® and manual revision of the research team. AASM criteria were used to distinguish between mild, moderate and severe OSAHS. Patients with a diagnosis of at least moderate OSAHS were suggested to see a specialist for further investigation and treatment. Statistical analyses were performed by the authors themselves using Excel formulas and the statistical programs SPSS and MedCalc.

Approval

This study was approved by the Medical Ethics Committee of the Catholic University Hospital Leuven (ML10464) (Additional files, 2). All patients gave informed consent to the investigations. No physical or emotional harm was done to participating patients and all data were processed and analyzed anonymously. There was no financial reward for those participating in this study.

RESULTS

A flow chart with the selection of patients for the high risk group is shown in figure 1. A total of 980 patients filled in the questionnaire. Thirty patients were lost during further follow up and 7 patients met the pre-set exclusion criteria; the screening population therefore counted 943 patients.

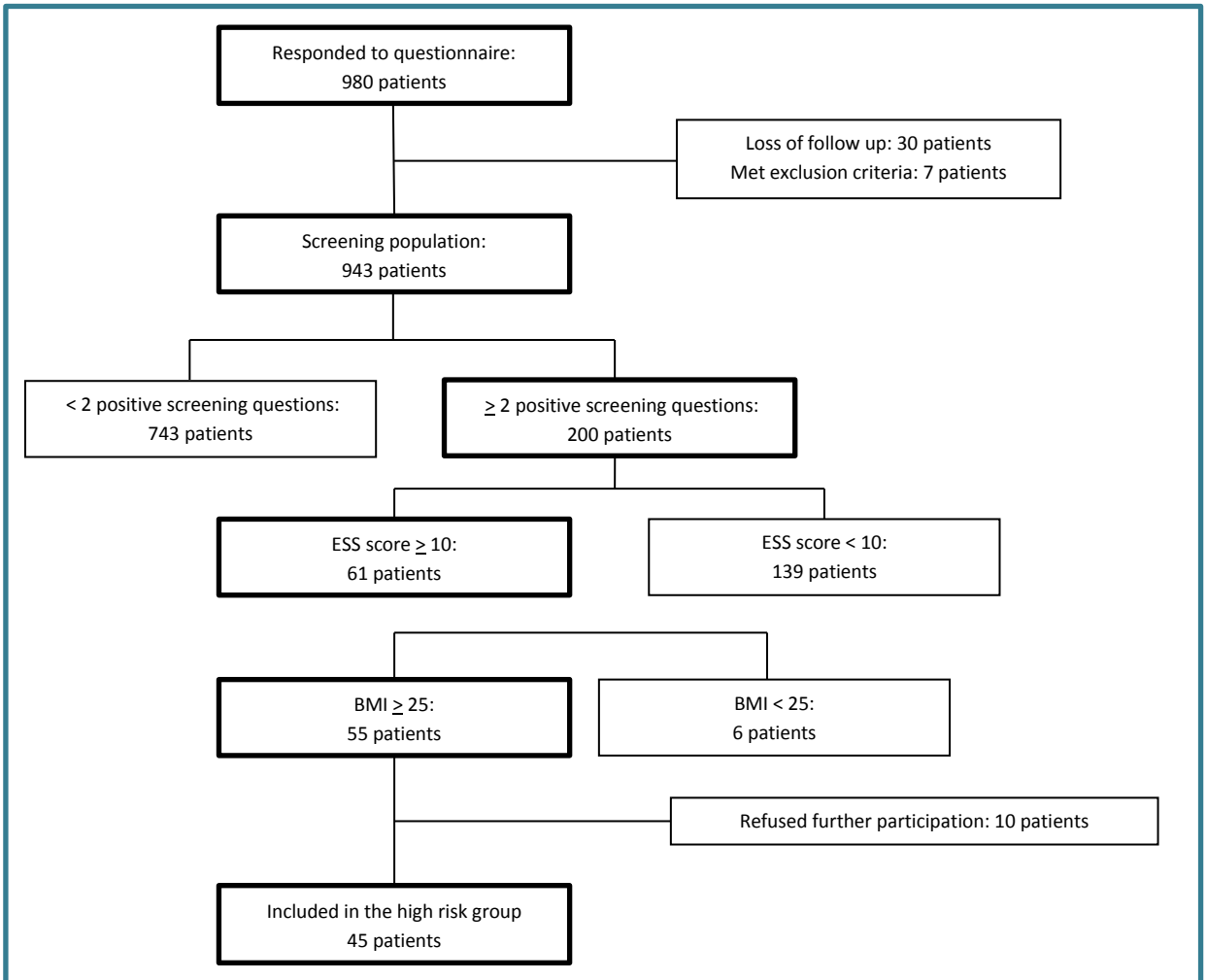

Figure 1. Flow chart of patient selection and inclusion in the high risk group.

The final group counted 45 patients. From the 943 patients in the screening population, 743 patients answered positively on < 2 screening questions. From those 743 patients, patients with a BMI of < 25 were excluded. From the 449 remaining patients, 19 patients were selected as described above to form the control group.

Patient characteristics from both high risk group and control group are summarized in table 1 . The high risk group counted 23 women and 22 men; the control group respectively 9 and 10. The mean age of the high risk group was 57 years with a minimum and maximum of respectively 45 and 75 years, compared to an average age of 57.5 years in the control group with a minimum and maximum of 46 and 73 years respectively.

There was no significant difference in BMI (using the Wilcoxon rank sum test; p>0.01) between both groups, nor in the proportion of patients smoking, with arterial hypertension, other cardiovascular diseases, chronic obstructive pulmonary disease (COPD) or type 2 diabetes mellitus (using the Chi-Square test; p >0.01).

The average and standard deviation of the most important parameters from the Somnolter® reports are summarized in table 2. Using a T-test for two independent samples, a statistical significant difference was found (p <0.001) between the means of the ESS in the control and high risk group. Table 3 shows the proportion of patients with at least mild, moderate or severe OSAHS in both groups and the absolute number of patients with mild, moderate or severe OSAHS. With a one-tailed right sided Chi-Square test a statistical significant difference ($p < 0.05$) was found between the number of patients with severe OSAHS (AHI $\geq$ 30) in both groups. Comparing the mean AHI between the control group and the high risk group with a Mann-Whitney test, a statistical significant difference was found between both groups ($p < 0.05$).

Receiver Operating Characteristics (ROC) curve analysis was independently performed for two variables: ESS score and the number of positively answered screening questions. Analysis was performed for the diagnosis of at least mild, moderate and severe OSAHS separately. Data are shown in table 4.

Sensitivity and specificity for the diagnosis of mild, moderate and severe OSAHS in this group, based on the ESS alone, are summarized in table 5. The same calculations were made for the diagnosis based on the number of positive screening questions alone.

Values for the specificity, sensitivity, positive predictive value (PPV), negative predictive value (NPV) and the odds ratio (OR) for the combined screening strategy used in this study are summarized in table 6. Patients have a positive test when they have at least 2 positive questions out of the 3 screenings questions and an ESS score $\geq$ 10. Calculations were made for diagnosing at least mild, moderate and severe OSAHS. Data were also calculated for a test positive when the patient answers all 3 questions positively and an ESS score $\geq$ 10. Table 7 compares these findings with recent literature.

Table 1. Patients characteristics

	High risk group (n=45)	**Control group** (n=19)	**P-value (two-tailed)**
Average BMI	30.9 kg/m²	27.9 kg/m²	P = 0.002
Arterial hypertension	60.0%	47.3%	P = 0.352
Cardiovascular disease	15.6%	21.1%	P = 0.719
Smoker	11,1%	31.6%	P = 0.070
COPD	6.7%	5.3%	P = 1,000
Type 2 diabetes mellitus	20,0%	10.5%	P = 0.483
Sleep medication	37.8%	42.1%	P = 0,746

BMI: Body Mass Index, COPD: chronic obstructive pulmonary disease

Table 2. Somnolter® recordings

	Average high risk group (SD)	Average control group (SD)
ESS	12,7 (1,9)	4,4 (2,4)
TST	18:10:53 (2:10:06)	8:21:21 (2:36:21)
AHI	20,5 (12,8)	14,2 (7,2)
OA/hr	4,8 (1,5)	1,5 (2,4)
Hyp/hr	13,9 8,4)	11 (4,9)
CA/hr	0,9 (2,0)	1,2 (2,3)
RDI	31,9 (14,9)	20,5 (11,1)
RAI	25,5 (12,8)	17,0 (8,3)
Arl	34,8 (14,9)	27,0 (9,8)
CT RE	2:49:22 (1:48:24)	0:29:12 (0:51:00)
RERA I	11,8 (0,1)	7,3 (6,2)
SaO_2 CT90	0:57:31 (1:22:13)	0:29:12 (0:51:00)
Min sat (%)	82,7 (5,9)	84,0 (4,0)

abbreviations: see end of article

Table 3. Proportion of patients with mild, moderate and severe OSAHS

	High risk (n=45)	%	Control (n=19)	%
AHI < 5	3	6,7	2	10,5
AHI ≥ 5	42	93,3	17	89,5
AHI ≥ 15	27	60	9	47,4
AHI ≥ 30	8	17,8	0	0
mild OSAHS	14	31,1	9	47,4
moderate OSAHS	19	42,2	7	36,8
severe OSAHS	8	17,8	0	0
central apnea	1	2,2	1	5,3

Table 4. Data from ROC analysis

	AHI ≥ 5		**AHI ≥ 15**		**AHI ≥ 30**	
	ESS score	**pos Q**	**ESS score**	**pos Q**	**ESS score**	**pos Q**
best cut-off value	> 4	> 0	> 10	> 2	> 8	>2
Sensitivity (95% CI)	0,83 (0,71-0,92)	1 (0,94-1,00)	0,69 (0,52-0,84)	0,47 (0,30 - 0,64)	1 (0,64-1,00)	0,87 (0,43-1,00)
Specificity (95%CI)	0,4 (0,05-0,85)	0 (0,00-0,52)	0,53 (0,34-0,72)	0,75 (0,55-0,89)	0,32 (0,20-0,46)	0,7 (0,56-0,81)

ROC: Receiver operator characteristics; CI: confidence interval

Table 5. Sensitivity and specificity with 95% confidence interval for ESS and screening questions separately

	AHI ≥ 5		AHI ≥ 15		AHI ≥ 30	
	ESS score	**≥ 2 pos Q**	**ESS score**	**≥ 2 pos Q**	**ESS score**	**≥ 2 pos Q**
sensitivity	0,74 (0,62-0,84)	0,71 (0,58-0,81)	0,78 (0,62-0,88)	0,75 (0,59-0,86)	1,00 (0,67-1,00)	1,00 (0,67-1,00)
specificity	0,40 (0,12-0,77)	0,40 (0,12-0,77)	0,32 (0,18-0,51)	0,36 (0,21-0,54)	0,30 (0,20-0,43)	0,34 (0,23-0,47)

ESS: Epworth Sleepiness Scale, CI: confidence interval

Table 6. Sensitivity, specificity, PPV, NPV and Odds ratio for the combined screening strategy (with ESS ≥ 10 and pos. Q ≥ 2 or = 3)

	AHI ≥ 5		AHI > 15		AHI > 30	
	≥ 2 pos Q	**3 pos Q**	**≥ 2 pos Q**	**3 pos Q**	**≥ 2 pos Q**	**3 pos Q**
sensitivity (95% CI)	0,71 (0,58-0,81)	0,39 (0,27-0,51)	0,75 (0,58-0,86)	0,47 (0,32-0,63)	1,00 (0,67-1,00)	0,88 (0,53-0,98)
specificity (95% CI)	0,4 (0,11-0,76)	0,8 (0,37-0,96)	0,38 (0,23-0,56)	0,75 (0,57-0,87)	0,34 (0,23-0,47)	0,70 (0,57-0,80)
PPV	0,93	1,95	0,6	0,71	0,18	0,29
NPV	0,11	0,1	0,55	0,53	0	0,98
Odds Ratio (95% CI)	1,65 (0,25-10,74)	2,56 (0,26-24,3)	1,83 0,63-5,31)	2,68 (0,91-7,88)	-	16,06 (1,83-140,00)

Q: questions, CI: confidence interval, PPV: positive predictive value, NPV: negative predictive value

Table 7. Comparison of the sensitivity and specificity for ESS, screening questions, combined strategy and BQ

	AHI ≥ 5		AHI ≥ 15		AHI ≥ 30	
	sensitivity (95% CI)	**specificity (95%CI)**	**sensitivity (95% CI)**	**specificity (95%CI)**	**sensitivity (95% CI)**	**specificity (95%CI)**
≥ 2 pos. Q in this study	0,71 (0,58-0,81)	0,40 (0,12-0,77)	0,75 (0,59-0,86)	0,36 (0,21-0,54)	1,00 (0,67-1,00)	0,34 (0,23-0,47)
ESS ≥ 10 in this study	0,74 (0,62-0,84)	0,40 (0,12-0,77)	0,78 (0,62-0,88)	0,32 (0,18-0,51)	1,00 (0,67-1,00)	0,30 (0,20-0,43)
BQ - Chung et al.(13,16)	0,69 (0,60-0,77)	0,77 (0,59-0,90)	0,49 (0,67-0,87)	0,50 (0,41-0,6)0)	0,87 (0,073-0,96)	(0,46 (0,38-0,55)
BQ - Netzer et al.(13,17)	0,86 (0,75-0,93)	0,95 (0,84-0,99)	0,54 (0,41-0,66)	0,97 (0,83-1,00)	0,17 (0,09-0,28)	0,97 (0,83-1,00)
Combined strategy in this study	0,71 (0,58-0,81)	0,4 (0,11-0,76)	0,75 (0,58-0,86)	0,38 (0,23-0,56)	1,00 (0,67-1,00)	0,34 (0,23-0,47)

ESS: Epworth Sleepiness Scale, CI: confidence interval, BQ: Berlin questionnaire, Q: screening questions

DISCUSSION

After screening 980, 64 patients were tested with Somnolter®. Forty five of them had a high risk of having OSAHS after screening. Of those 45 patients 93,3% had at least a mild form of OSAHS compared to 89,5% in the control group. Twenty five patients had mild OSAHS (control group = 9; high risk group = 14), 26 patients had moderate OSAHS (control group = 7; high risk group = 19) and 8 patients had severe OSAHS (control group = 0; high risk group = 8). The number of patients with severe OSAHS was significantly higher in the high risk group, as was the mean AHI. Although these findings might suggest an efficient screening, the significantly higher BMI of the high risk group ($\alpha = 0.05$) could contribute as well as a high BMI is a known risk factor for OSAHS. With $\alpha = 0{,}001$ however, there was no significant difference seen and patient and control group match for BMI.
The high proportion of patients with OSAHS in the control group supports the previous mentioned hypothesis that OSAHS is highly prevalent and that patients are often asymptomatic. The high number of patients with moderate and severe OSAHS, who will benefit the most from therapeutic intervention, confirms the need for active screening in primary health care.

ROC analysis confirms that for the diagnosis of moderate and severe OSAHS an ESS score of $\geq$ 10 is the cut-off value with the best sensitivity and specificity. Comparing results of the ROC analyses for the diagnosis of moderate and severe OSAHS based on the number of positively answered screening questions, the authors conclude that a cut-off value of 3 seems to have the best sensitivity and specificity.

For the used screening strategy (combination of screening questions and ESS score) sensitivity and specificity, for diagnosing at least moderate OSAHS, were respectively 75% and 38%. These percentages are relatively close to the sensitivity and specificity Chung et al. found offering the Berlin questionnaire to surgical patients (13,16). Compared to the findings of Netzer et al. however, the author's used strategy might seem more sensitive but less specific than the Berlin Questionnaire (13,17). The 95% confidence intervals of this study however are relatively broad signifying greater imprecision. This might be the result of the rather small sample size of this study.

As mild OSAHS is often asymptomatic and has few therapeutic consequences; the authors suggest a more rigorous screening strategy than the one they used. When a positive test consists of 3 positively answered screening questions and an ESS score $\geq$ 10; a sensitivity of 88% and the specificity of 70% suggest a good benefit-cost ratio and thus an efficient screening tool in primary health care. The corresponding high OR of 16 presumes that health care practitioners could refer these patients directly for in hospital-PSG. Here as well, the broad 95% CI must be taken into account. The sensitivity and specificity at a cut off value of $\geq$ 2 positive screening questions (and ESS score $\geq$ 10) are remarkably lower but there is still a high prevalence of patients with moderate to severe OSAHS among them. As the capacity of sleep laboratories nowadays is often exceeded, it might be interesting to test those patients first with a home-monitoring device before sending them for an in-hospital PSG. This way the pre-test probability of having OSAHS increases.

LIMITATIONS

The authors are well aware of the limitations of their study. Sampling bias might be assumed as only those patients between 45 and 75 years old who visited their GP during the course of the study were offered a questionnaire. There might also be information bias because Somnolter® is less specific than in-hospital PSG. The presence of attrition bias is also plausible as 10 patients who met the inclusion criteria for the high risk group refused further participation. The authors also acknowledge that there are no patients with $\geq$ 2 positively answered screenings questions and ESSS < 10 investigated with Somnolter®. They assume however that the prevalence of moderate to severe OSAHS in this group is rather low as literature states that only a score of $\geq$ 10 is indicative of excessive day time sleepiness due to SBD. They are aware though that a normal ESS score does not exclude he presence of significant SBD and patients with OSAHS might have been missed.

CONCLUSION

Using a combined strategy (3 screening questions and ESS), the authors identified 57 patients with undiagnosed OSAHS, 41 in the high risk group and 16 in the control group. These data support the hypothesis that OSAHS is highly prevalent but often undiagnosed. As OSAHS has many negative consequences, active screening in primary health care is absolutely necessary. Home-monitoring might play an important role in this screening in the future. The used screening strategy is considered useful and relatively sensitive to detect patients with at least moderate OSAHS. Nevertheless, to be used as an efficient screening tool with an optimal sensitivity and specificity, this screening strategy needs further optimization.

COMPETING INTERESTS

The authors declare that they have no competing interests. This study was only financially supported by KULeuven. No other companies were involved financially.

ACKNOWLEDGEMENTS

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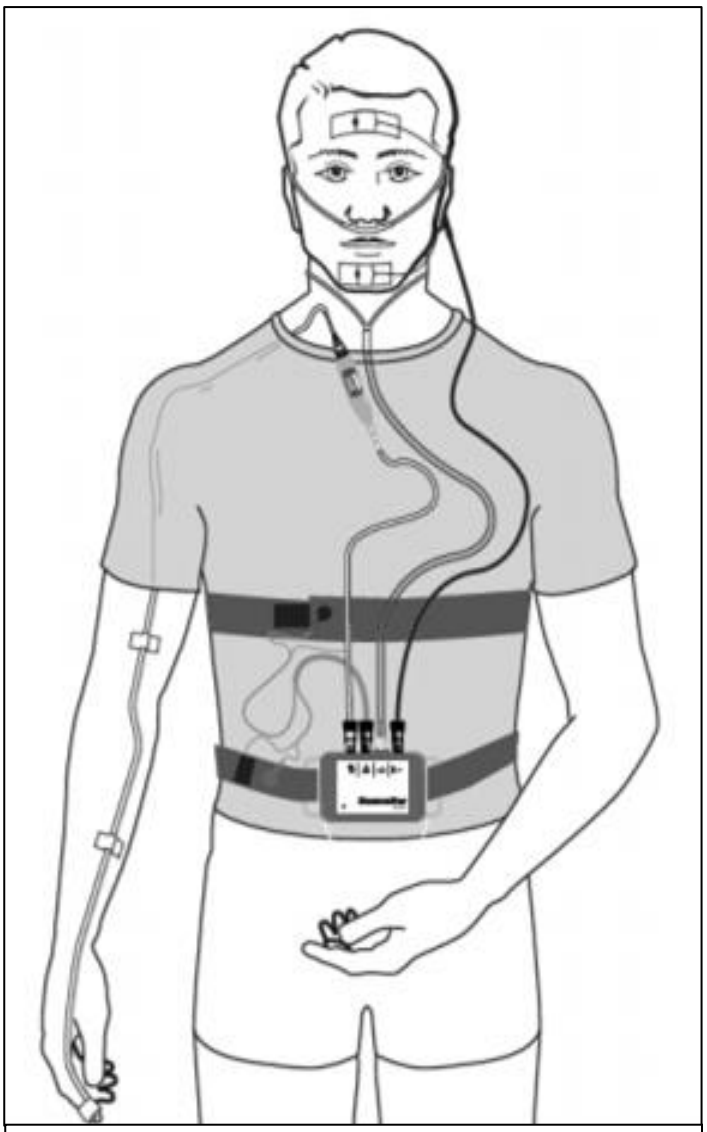
ABBREVIATIONS

TST: total sleeping time; AHI: apnea-hypopnea index; OA/hr: obstructive apneas per hour of sleep; Hyp/hr: hypopneas per hour of sleep; CA/hr: central apneas per hour of sleep; RDI: respiratory disturbance index; RAI: respiratory arousel index ArI: arousel index; CT RE: cumulative time in respiratory effort; RERA I: respiratory related arousal index; SaO_2 CT 90: cumulative time with a O_2 saturation below 90%; min sat: minimum saturation

ADDITIONAL FILES

1. Somnolter® Device



Somnolter® Device. Somnolter® records the midsagittal jaw movements, arterial oxygen saturation, body position, nasal airflow and thoracic and abdominal movements. Adapted from: http://www.nomics.be.uploads/pdf/Somnolter_Leaflet_EN-615.pdf.

2. Dutch Protocol approved by the Medical Ethics Committee of the Catholic University Hospital Leuven (ML10464)

In 2013 werd in de Somnolter© pilootstudie een case-finding strategie getest om ongediagnosticeerde gevallen van slaapapneu in de huisartsenpraktijk te ontdekken. De case-finding strategie bleek efficiënt in het selecteren van patiënten met een hoog risico op slaapapneu. 365 patiënten beantwoordden een vragenlijst. Op basis van deze vragenlijst en klinisch onderzoek vertoonden 32 patiënten een verhoogd risico op slaapapneu. 18 van deze 32 patiënten werden getest aan de hand van het toestel Somnolter© (evenwaardig aan de gouden standaard, nl. polysomnografie, in het diagnosticeren van slaapapneu) (15). 14 van deze 18 patiënten werden gediagnosticeerd met slaapapneu.

Volgens de huidige literatuur varieert de prevalentie van slaapapneu van 2% tot 26% en blijft 70-80% van de gevallen ongediagnosticeerd (18–20). Slaapapneu is evenwel een aandoening die het risico op andere gezondheidsproblemen vergroot. Zo is slaapapneu geassocieerd met een verhoogd risico op hypertensie, cardiovasculaire aandoeningen, verkeersongevallen e.a. … .

Het is dus belangrijk om de diagnose van slaapapneu tijdig te stellen zodat de patiënt behandeld kan worden en het risico op bijkomende gezondheidsrisico's geminimaliseerd wordt. Gebaseerd op de prevalentiecijfers en het grote aantal vermeende ongediagnosticeerde gevallen van slaapapneu in de algemene bevolking stellen de onderzoekers de hypothese dat er ook in de huisartsenpraktijk een groot aantal patiënten zijn met ongediagnosticeerd slaapapneu.

In de 'Somnolter© Vervolgstudie 2014-2015' zal de case-finding strategie uit de Somnolter© Pilootstudie geoptimaliseerd worden op basis van de meest recente literatuurgegevens en zal getracht worden om in 2 Vlaamse huisartsenpraktijken een groot aantal Nederlandstalige patiënten te selecteren en te onderzoeken aan de hand van de Somnolter© om een zo groot mogelijk aantal van deze ongediagnosticeerde gevallen van slaapapneu op te sporen.

De onderzoekers hopen zo de aandacht van Vlaamse huisartsen te trekken op het feit dat er zich onder hun patiënten mogelijks een aanzienlijk aantal ongediagnosticeerde gevallen van slaapapneu bevindt en dat in de toekomst systematische screening naar slaapapneu nuttig kan zijn.

Tijdens de 'Somnolter© Vervolgstudie 2014-2015' zullen in 2 Vlaamse huisartsenpraktijken, na volledig ingelicht te zijn, Nederlandstalige patiënten systematisch bevraagd en onderzocht worden. Indien zij op 2 of meer van de 3 screeningsvragen positief antwoorden én een BMI hebben van ≥ 27 kg/m², wordt hen gevraagd een gevalideerde vragenlijst voor slaapapneu, de Epworth Sleepiness Scale, in te vullen. Indien zij op deze vragenlijst een score van ≥ 10 behalen, vertonen zij een verhoogd risico op slaapapneu. Dit verhoogd risico zal hen medegedeeld worden en er zal hen voorgesteld worden om aan de rest van de studie deel te nemen, namelijk een volledig klinisch onderzoek, noteren van medische voorgeschiedenis en chronische medicatie en thuismeting met het toestel Somnolter©.

Indien de patiënt bereid is om aan de rest van de studie deel te nemen, zal hiervoor een datum afgesproken worden. Op deze datum zal één van de onderzoekers bij de patiënt thuis langs gaan voor het klinisch onderzoek, noteren van medische voorgeschiedenis, chronische medicatie (waarna deze vergeleken worden met deze uit het EMD) en aanhangen van het Somnolter©-toestel. Het Somnolter©-toestel kan de volgende ochtend door de patiënt zelf losgekoppeld worden en in onderling overleg door de onderzoeker opgehaald worden of door de patiënt afgegeven worden in de huisartsenpraktijk.

3. References

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