Peer reviewed article

Sleep and wakefulness disturbances in Swiss pharmacy customers

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Summary

Background and objective: Sleep disturbances are prevalent but often overlooked or underestimated. We suspected that sleep disorders might be particularly common among pharmacy customers, and that they could benefit from counselling. Therefore, we described the prevalence and severity of symptoms associated with sleep and wakefulness disorders among Swiss pharmacy customers, and estimated the need for counselling and treatment.

Methods: In 804 Swiss pharmacies (49% of all community pharmacies) clients were invited to complete the Stanford Sleep Disorders Questionnaire (SDQ), and the Epworth Sleepiness Scale (EPW). The SDQ was designed to classify symptoms of sleep and wakefulness into the four most prevalent disorders: sleep apnoea syndrome (SAS), insomnia in psychiatric disorders (PSY), periodic leg movement disorders/restless legs (RLS) and narcolepsy (NAR). Data were entered into an internet-linked database for analysis by an expert system as a basis for immediate counselling by the pharmacist.

Results: Of 4901 participants, 3238 (66.1%) were female, and 1663 (33.9%) were male. The mean age (SD) of females and males was 52.4 (18.05), and 55.1 (17.10) years, respectively. The

percentages of female and male individuals above cut-off of SDQ subscales were 11.4% and 19.8% for sleep apnoea, 40.9% and 38.7% for psychiatric sleep disorders, 59.3% and 46.8% for restless legs, and 10.4% and 9.4% for narcolepsy respectively. The prevalence of an Epworth Sleepiness Scale score >11 was 16.5% in females, and 23.9% in males. Reliability assessed by Cronbach's alpha was 0.65 to 0.78 for SDQ subscales, and for the Epworth score.

Conclusions: Symptoms of sleep and wakefulness disorders among Swiss pharmacy customers were highly prevalent. The SDQ and the Epworth Sleepiness Scale score had a satisfactory reliability to be useful for identification of pharmacy customers who might benefit from information and counselling while visiting pharmacies. The internet-based system proved to be a helpful tool for the pharmacist when counselling his customers in terms of diagnostic classification and severity of symptoms associated with the sleeping and waking state.

Key words: sleep disorders; sleepiness; sleep apnoea; insomnia; narcolepsy; restless legs

Introduction

Disordered sleep is very common in the general population and in primary care, and is considered an economic burden and a cause for high health costs [1]. Both patients and health professionals tend to underestimate the importance of sleep disorders during consultation, and do not talk about sleep problems spontaneously and routinely [2, 3]. On either side there is a lack of awareness of possible sleep disorders, and as a consequence, affected patients often do not receive adequate treatment.

To promote health-education in the field of sleep and sleep disorders, the Swiss Pharmacists Association in cooperation with the Pharmaceutical Care Research Group of the University of Basel, and the Swiss Society of Sleep Medicine, Sleep Research and Chronobiology initiated a campaign (Self Care campaign) to reach a large number of subjects with information on sleep and its various disorders. From earlier studies [4] it is known that pharmacy customers in Switzerland tend to have medical problems and often seek for

This study was funded by the Swiss Association of Pharmacists and the Health Care Consulting Group, Zug, Switzerland. help in a pharmacy before consulting a physician. We reasoned that pharmacy customers might also have a particularly high prevalence of sleep disorders and investigated them in terms of demographics, sleep-related symptoms and daytime sleepiness

The main purpose of the study was to obtain information on prevalence of sleep-related symptoms and daytime sleepiness in a population also relevant for the general practitioner. In addition, we calculated the reliability of the questionnaires.

Our hypothesis was that sleep related symptoms and sleepiness during the day are common and potentially relevant for individuals and community, and that the need for counselling, information on medical investigation and treatment could be obtained with the questionnaires used.

Methods

Subjects

Subjects were recruited among customers of the 804 Swiss pharmacies (49% of the 1657 community pharmacies in Switzerland) participating in the "Self Care" campaign. Over the 4-weeks period (Oct. 15th to Nov. 15th 2003) of the campaign, all customers understanding and speaking the local language were invited to fill out a questionnaire evaluation independently of their medical and/or psychological problems i.e. their reason for the pharmacy visit. Information on the campaign was distributed in newspapers, radio and television before and during the ongoing activities. Information was also posted in the windows and inside the pharmacies. A record of patients who refused to take part in the investigation was not kept for organisational reasons.

Questionnaire

The questionnaire comprised three parts. First, demographic data including sex, age, body-mass-index, neck circumference, state of employment and shift-work, were collected. Shift work included changing work schedules including night and day shifts. Second, daytime sleepiness was assessed by the Epworth Sleepiness Scale (EPW) consisting of 8 items, each describing an everyday situation for which the subject had to estimate the likelihood of falling asleep on a four-level scale ranging from 0, "would never fall asleep" to 3, "would fall asleep with high probability" [5, 6]. The sum of the answers to the 8 items with a range of 0 to 24 represents the Epworth score. The Epworth score has been validated in several Australian populations of patients and normal subjects, and in Switzerland in 174 patients with various sleep disorders and in 159 healthy subjects [5, 6]. Third, the Stanford Sleep Disorders Questionnaire (SDQ) was offered to fill out [7]. It has been developed and validated in a cohort of 519 subjects, 435 of those were clinic sleep disorders patients and 84 healthy controls [7]. Of the patients, 141 were diagnosed with sleep apnoea, 39 with narcolepsy, 47 with psychiatric sleep disorders, and 66 with periodic limb movement disorder, respectively. The SDQ has 45 items related to symptoms of the four most prevalent sleep disorders (see table 3). Each item is self-rated on a scale from 1, "strongly disagree" to 5, "strongly agree". The sum of scores of 4 different sets of items allows to assess the presence of symptom clusters suggestive of obstructive sleep apnoea (SAS, 12 items), psychiatric sleep disorders (PSY, 9 items), restless legs / periodic limb movement (RLS, 9 items) and narcolepsy (NAR, 15 items) A German version

of the SDQ and EPW has been validated in Swiss patients visiting a sleep disorders centre [6, 8]. For the purpose of this study two native speaking sleep-specialists translated the German version of SDQ and EPW into Italian and French. A validation was not conducted.

Data collection

The 68 items questionnaire had to be filled in online in the pharmacy. The customers could also complete a paper copy of the questionnaire and the pharmacist entered the data into the internet-based computerised database [9]. If required, they discussed certain items with the pharmacist. A central server provided storage and immediate on-line analysis of the data. It included tests for plausibility, completeness, and duplicates, computation of individual sum scores for SDQ and EPW, and corresponding percentiles in relation to reference populations without sleep disorders [6, 7]. These results enabled the pharmacist to supply participants with a feedback and served as a basis for counselling in regard to sleep hygiene or referral to a physician if appropriate.

Statistical analysis

Descriptive statistics are shown in terms of medians and interquartile ranges (IQR), counts and percentages. The frequencies (prevalences) of SDQ scores above the 90th percentile observed in a healthy reference population in the original paper of the SDQ and the frequencies of cases with scores above cut-off values for the 4 symptom clusters were also computed. Douglass defined cut-off values for each of the four SDQ scales (SAS: f = 32, m = 36; PSY: f = 21, m = 19; RLS: f and m = 21; NAR: f = 31, m = 30) by calculating sensitivity and specificity using the receiver operator characteristics technique [7]. For the Epworth score, the prevalence of cases with a score >11 considered as reflecting excessive sleepiness was determined [5, 6]. This cut-off of >11 points corresponds to the 95% percentile found in healthy subjects [5, 6]. To evaluate the dimensions of the SDQ, a factor analysis was carried out (principal component analysis, varimax rotation). To estimate the reliability of scales, Cronbach's alpha [10] was computed for SDQ subscales and EPW. Spearman correlations were used to determine the relationship among scales. In order to prevent distortion of reliability analysis, for this step only complete questionnaires were included, i.e. for SDQ N = 3491 and for EPW N = 4729. Chi-squared tests for proportions were applied to compare the prevalence between females and males.

Table 1 Prevalence of sleep disorder symptoms and daytime sleepi ness in 4901 questionnaire respondents (3238 females, 1663 males). Data are medians, interquartile ranges (IQR), and prevalence. *P < 0.001 males vs females Raw score cut-off values sleep disorders questionnaire (7): SAS (sleep apnoea syndrome) females = 32, males = 36; PSY (psychiatric sleep disorders) females = 21, males = 19; RLS (restless legs and periodic limb movement disorder) females and males = 21; NAR (narcolepsy) females = 31, males = 30; cut-off value EPW (Epworth Sleepiness Scale score) (6): females and males

Raw Scores		Percentage of respondents with elevated scores					
		Above cut-off		Above 90th percentile of reference			
Females Median (IQR)	Males Median (IQR)	Females	Males	Females	Males	Total	
23 (19–27)	28 (23–34)	11	20	33	39*	35	
19 (15–23)	17 (13–21)	41	39	4	2*	3	
22 (18–25)	20 (17–24)	59	47	25	16*	22	
21 (18–25)	20 (17–24)	10	9	9	2*	7	
6 (3–9)	7 (4–10)	17	24	28	39*	32	
	Females Median (IQR) 23 (19–27) 19 (15–23) 22 (18–25) 21 (18–25)	Females Median (IQR) 23 (19–27) 28 (23–34) 19 (15–23) 17 (13–21) 22 (18–25) 20 (17–24) 21 (18–25) 20 (17–24)	Above cut-of Above cut	Above cut-off Females Males Median (IQR) Females Median (IQR)	Above cut-off Above 90th p Females Median (IQR) Males Median (IQR) Females Males Females 23 (19-27) 28 (23-34) 11 20 33 19 (15-23) 17 (13-21) 41 39 4 22 (18-25) 20 (17-24) 59 47 25 21 (18-25) 20 (17-24) 10 9 9	Above out-off Above 90th percentile of response to the females Above 90th percentile of response to th	

Results

Demographics

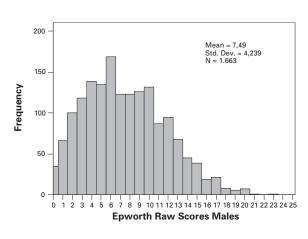
Of 4915 questionnaires submitted to the central database, 14 were incomplete or contained non-plausible data. Thus, 4901 questionnaires were available for analysis. Corresponding participants included 3238 (66.1%) females with a mean $(\pm SD)$ age of 52.4 (± 18.1) years, a body mass index of 23.8 (±4.3 kg/m²), and a neck circumference of 34.6 (±3.1 cm). The mean age of the 1663 participating males was 55.1 (±17.1) years, body mass index was 25.7 (±3.9 kg/m²), and neck circumference was 40.6 (±2.9 cm). Seventy-six percent of the participants were German speaking, 16% French speaking, and 8% Italian speaking. Fifty-six percent had a professional employment, 33% were retired, 7% were shift workers, including 1% working night shifts, and 4% attended school.

Table 2

Cronbach's alpha of scales, Spearmans correlation coefficients for sum scores of symptom clusters in 4901 questionnaire respondents (3238 females, 1663 males). * P <0.01. SAS: sleep apnoea syndrome; PSY: psychiatric sleep disorders; RLS: restless legs and periodic limb movement disorder; NAR: narcolepsy; EPW: Epworth Sleepiness Scale.

	Cronbach's alpha	RLS	PSY	NAR	EPW
SAS	0.74	0.28*	0.09*	0.17*	0.19*
RLS	0.65		0.52*	0.36*	0.00
PSY	0.74			0.48*	0.01
NAR	0.78				0.41*
EPW	0.77				

Figure 1
Histogram of
Epworth score distributions among male
and female pharmacy
customers.



Frequencies and distribution of symptoms

Table 1 indicates that a considerable proportion of participants (between 11.4% and 59.3%) had elevated scores in various domains of the SDQ and in the EPW, indicating sleep disorders, and excessive daytime sleepiness. The distribution of EPW scores is further illustrated in figure 1. Gender differences were found in all subscales of the SDQ and the EPW (p <0.01).

Reliability and internal consistency of symptom scales

Table 2 shows Cronbach's alpha-values for SDQ scales and EPW.

Correlations between symptom clusters

To describe the relationship between scores of symptom clusters (SAS, RLS, PSY, NAR, EPW) Spearman correlations were computed (table 2). According to the fact that evaluation of sleepiness is included in the SDQ items contributing to sleep apnoea and narcolepsy scores, but not in items of PSY and RLS scores, there was a correlation between SAS and EPW (r = 0.19, p < 0.01), and, to an even stronger extent, between NAR and EPW (r = 0.41, p < 0.01). The most pronounced correlations were found between PSY and RLS (r = 0.52, p < 0.01), and between PSY and NAR (r = 0.48, p < 0.001). Furthermore NAR and RLS (r = 0.36, p <0.001) correlated fairly strong with each other. Conversely, no significant correlations were found between EPW and RLS and between EPW and

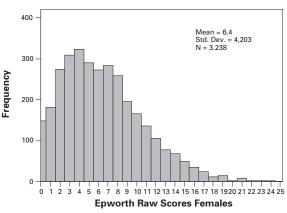


Table 3

Factor analysis, coefficients ≥.4 are bold.
The questions are labelled as in Douglass et al. 1994, and ordered according to factor analysis.
Factor loadings below 2 are not shown. N = 3491

Items	Factor 1	Factor 2	Factor 3	Factor 4	Description
NAR_Q058	.59				Trouble on job due to sleepiness
NAR_Q055	.57				Sleepy during the day
NAR_Q039	.56				Paralysed after a nap
NAR_Q040	.53	_			Hallucinations upon awakening
NAR_Q011	.52				Feel paralysed as falling asleep
NAR_Q060	.52				Hallucinations after napping
NAR_Q067	.50				Muscular weakness if strong emotion
NAR_Q042	.49				Slept for several days
NAR_Q062	.47				Paralysed upon morning awakening
NAR_Q057	.44				Bad grades due to sleepiness
NAR_Q059	.43				Too sleepy to drive
PSY_Q038	.42				A lot of nightmares
NAR_Q066	.40				Weak knees when laughing
NAR_Q063	.39				Failure to remember driving
NAR_Q056	.35				Accidental sleep
PSY_Q089	.33				Considered / attempted suicide
NAR_Q156	.33	_			Work accidents due to sleep
PSY_Q101	.21	_			Family: psychiatric hospitalisation
RLS_Q045		.76			Insomnia
PSY_Q003		.71			Trouble getting to sleep
RLS_Q004		.63			Wake up often during night
RLS_Q001		.58			Length of longest wake period at night
PSY_Q006		.57			Racing thoughts at bedtime
PSY_Q043		.55			Unable to sleep for days
PSY_Q007	<u> </u>	.54			
		.54			Sad / depressed at bedtime
PSY_Q033					Sadness / depression disturbs sleep
RLS_Q080		.37			Loss of sexual desire / interest
RLS_Q024		.36			Palpitations at night
RLS_Q155		.36			Night urination (number of times)
PSY_Q084		.29			Unhappy with loving relationships
SAS_Q025		.28			Sweat at night
SAS_Q021			.76		Snore that bothers others
SAS_Q141			.73		Snoring / breathing worse if on back
SAS_Q163			.67		Current weight
SAS_Q176			.64		Body Mass Index
SAS_Q142			.61		Snoring / breathing worse with alcohol
SAS_Q022			.59		Stop breathing in sleep
SAS_Q071			.41		High blood pressure (history)
SAS_Q173			.40		Age
SAS_Q023			.35		Awake unable to breathe
SAS_Q139			.33		Nose blocks up while trying to sleep
RLS_Q108				.61	Smoking two hours before bedtime
SAS_Q170				.50	Number of years as a smoker
RLS_Q031				47	Restless-legs disturb sleep
RLS_Q012				43	Restless-legs as falling asleep

PSY, confirming the clinical observation that excessive sleepiness is not a predominant feature of insomnia and restless legs syndrome.

Factor analysis

The factor analysis of the SDQ revealed 12 factors with an eigenvalue >1, but the scree plot

clearly indicated to extract only 4 factors. These 4 factors explain 32.8% of variance: factor 1: 10.5%, factor 2: 10.0%, factor 3: 8.0%, and factor 4: 4.3%. In the rotated component matrix (table 3) coefficients >0.2 are listed.

Discussion

We described the frequency of sleep related symptoms and daytime sleepiness in a relatively large sample of Swiss pharmacy customers by means of the Sleep Disorders Questionnaire (SDQ) and the Epworth Sleepiness Scale (EPW). The high scores in SDQ subscales of a considerable proportion of participants suggested that sleep and wakefulness disorders, and excessive daytime sleepiness were prevalent in the studied population. Therefore, information was provided and counselling on sleep hygiene or referral to a physician was recommended to pharmacy customers based on SDQ scores i.e. the severity of *symptoms*. The aim was to enhance the awareness of sleep and wakefulness disturbances and of treatment opportunities in affected customers [11].

While the population under investigation might be comparable to some extent to the one encountered in general practice it likely included patients with acute and chronic somatic and/or mental conditions that may have influenced the prevalence of sleep-related-symptoms. Because the information on sleep disorders was obtained by questionnaires without any further diagnostic work-up, the results of our study reflected the symptoms perceived by the pharmacy customers rather then the prevalence of any specific sleep disorder. Furthermore our population cannot be characterised more specifically and represented a highly selective and heterogeneous sample.

Earlier epidemiological data for Switzerland and other countries showed a high prevalence of sleep disorders. Symptoms indicating insomnia were found in 19% of a middle-aged Swiss working population [12], whereas the prevalence of insomnia in Swiss primary care was 44% [13]. Ohayon et al. [14] stressed the fact that the prevalence of insomnia depended on the population investigated and the criteria used. He reported a frequency of insomnia of 30-48% in a general population sample, but only 6% could be diagnosed with chronic insomnia according to the Diagnostic and Statistic Manual of the American Psychiatric Association, 4th edition (DSM-IV). According to the PSY subscale of SDQ, 40.9% of females and 38.7% of males showed relevant symptoms of psychiatric sleep disorder, which included insomnia as a symptom.

In a sample of 602 middle-aged employees 2% of women and 4% of men met the diagnostic criteria for obstructive sleep apnoea syndrome (OSAS) [15]. Schmitt et al. [12] reported a prevalence of 6% (n = 668) with symptoms suggestive of OSAS. Corresponding prevalence rates in our population of pharmacy customers were 11.4% in females and 19.8% in males. Since no sleep studies were performed among the pharmacy customers to confirm the diagnosis of OSAS we cannot exclude that the symptoms of some of these subjects were related to other conditions.

The prevalence of the restless legs syndrome (RLS) was estimated at 2.5 to 15% in the general population, increasing with age and with a female preponderance [16]. The RLS subscale in the current investigation scored very high with restless legs symptoms in 59.3% of females and 46.8% in males, whereas in the above mentioned Swiss population [12] only 6% had symptoms suggestive for RLS.

Among 12504 participants of a Finish study, the prevalence of narcolepsy was 0.026% [17]. Schmitt et al. [12] reported symptoms typical for narcolepsy in 0.5% of questionnaire respondents. In contrast, we found elevated subscale scores for narcolepsy in 10.4% of females and 9.4% of males suggesting that the cut-off value might be too low resulting in a low specificity. Alternatively, either the prevalence of narcolepsy among the pharmacy customers was higher than in other populations, or hypersomnia due to sleep deprivation, mental disorders, and other conditions, might have played a role.

Daytime sleepiness as measured by the Epworth Sleepiness Scale [5] was found to be above 11 in 13% by Schmitt et al. [12]. In the study by Bloch et al. [6], Epworth scores correlated with the apnoea-hypopnoea index in patients with the obstructive sleep apnoea syndrome. In addition, the score was elevated in patients with psychiatric disorders and narcolepsy. In our sample, the Epworth scores of 16.5% of females and 23.9% of males were above 11 points, indicating that the prevalence of excessive sleepiness was high.

As expected, correlations among the Epworth score and the sum scores of SDQ, SAS and NAR subscales were statistically significant. No correlation was found between EPW and PSY, or EPW and RLS, reflecting that daytime sleepiness is a symptom of SAS and NAR, whereas neither PSY nor RLS were frequently associated with sleepiness. The correlation of sum scores of PSY and RLS, and PSY and NAR was high as already reported by Douglass et al. [7] suggesting some overlap in the symptoms of underlying disorders. In particular, the high correlation between PSY and RLS scores (r = 0.52, P <0.001) clearly illustrated that some of the PSY symptoms were also present in subjects with symptoms of RLS and vice versa.

Internal consistency of SDQ subscales (Cronbach's alpha values of 0.65 to 0.78, table 2) and of the EPW scale (Cronbach's alpha of 0.77) was comparable with earlier data [6–8]. This confirmed the reliability of both tests and demonstrated that the SDQ as well as the EPW assessed symptoms reliably, independent of the population under investigation. Factor analysis revealed that questions in the SAS and NAR subscales identified one distinct factor, ie one cluster of symptoms encountered frequently together. In contrast, the values of the coefficients of several questions of the

PSY and RLS subscales varied widely (table 3), again supporting the suspicion that PSY and RLS symptoms show an overlap in our population.

In conclusion, this study demonstrated a high prevalence of daytime sleepiness and symptoms associated with sleep and wakefulness disorders among pharmacy customers. Providing information and counselling on these disorders in pharmacies may allow affected customers to identify the nature and relevance of their symptoms, and to seek medical help. Correspondence:
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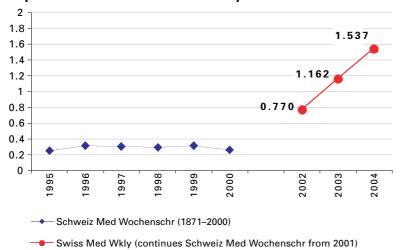
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