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MULTIFUNCTIONAL MONITORING: IS IT POSSIBLE TO SIMULTANEOUSLY EVALUATE BLOOD PRESSURE AND SLEEP-DISORDERED BREATHING?

<i>Objective</i>	Carry out a comparative assessment of respiratory performance, based on multifunctional monitoring (MFM) and the recommended practice for complete polysomnography (PSG), and evaluate the effect of the blood pressure (BP) measurements in MFM on the quality of sleep.
<i>Materials and Methods</i>	At the first stage, 22 healthy volunteers (control group) underwent concomitant PSG and MFM, and 14 patients with suspected sleep-disordered breathing (SDB) underwent only PSG. At the second stage, concomitant PSG and MFM were performed in patients with confirmed SDB.
<i>Results</i>	In the control group, MFM detected a lower level of SpO ₂ , a lower desaturation index (DI), and a higher apnea index (AI) than in the PSG group. However, the apnea-hypopnea index (AHI) was comparable in both groups. During concomitant PSG-MFM, the measurements of BP increased the number of micro-arousals only in the SDB group.
<i>Conclusion</i>	Results of the assessment of respiratory performance in MFM are comparable in both groups. The detected features of MFM indicators in the evaluation of the chest movements using rheopneumography, criteria different from that generally used for desaturation and hypoxemia, can lead to underestimation of desaturation and DI and underestimation of AI in the control group. The measurements of BP during sleep induced micro-arousals in the SDB group.
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The relation between sleep-disordered breathing (SDB) and cardiovascular diseases (CVD) is now doubtless. The significant increase in the risk of CVD and complications, particularly arterial hypertension (AH), stroke, and diabetes mellitus (DM), has been shown in obstructive sleep apnoea (OSA). OSA is a recognized risk factor for the development of AH, a reason for secondary hypertension and resistance to antihypertensive treatment [1]. The main risk factor for SDB is obesity, which, given the continuously increasing prevalence, is considered a reason for the increased incidence of SDB by 14–55% depending on a population in the recent 20 years. The epidemiological studies showed that the prevalence of SDB in the United States is from 10% (apnea/hypopnea index – AHI >15 episodes per hour of sleep) to 26% (AHI >5 episodes per hour of sleep) [2]. In the HypnoLaus study, the prevalence of moderate to severe SDB was 52.7% in females and 74.7% in males

in the European cohort >40 years old [3]. The main complaint of patients with SDB is snoring, which affects more than 50% of Russians [4].

According to the criteria established by the American Academy of Sleep Medicine (AASM), all devices for the diagnosis of sleep disorders are categorized into four different types depending on the number of parameters registered. The standard complete polysomnography (PSG) belongs to Type 1 and Type 2 and is a “gold standard” of SDB diagnosis [5]. However, health facilities do not widely use this examination due to its labor-consuming nature. Portable devices of Type 3 and Type 4 can be used for screening. Such devices are compact, have no electroencephalogram (EEG) recording channels, and thus are easier to use.

The AASM clinical guidelines recommend home sleep testing for the assessment of SDB in patients with a high pre-test probability of sleep apnea and the lack

of severe comorbidities that could affect the findings. This examination is not also recommended to be used with comorbid sleep disorders [6]. Multifunctional monitors «Kardiotekhnika-07-AD-3/12R» belong to the same type. They provide 24-hour registration of 12-lead electrocardiogram (ECG) (optional), rheopneumogram, spirogram, snoring, pulse oximetry, and patient's motor activity. The simultaneous registration of all these channels allows evaluating SDBs frequently accompanying cardiovascular pathologies and their relation with blood pressure (BP) and irregular heart rhythms. It has been demonstrated that concomitant monitoring of SDB and ECG is useful to detect the relation of irregular heart rhythms and cardiac conduction disorders with episodes of apnea/hypopnea [7]. Monitors for diagnostic screening of SDB and ECG Holter monitoring with rheopneumography have been widely used in the Russian healthcare facilities since 2003.

At the same time, BP assessment is not listed as a registered parameter in the AASM classification [5]. Several studies and clinical experience show that a process of BP measurement with a cuff is not always well tolerated by patients and can deteriorate the quality of sleep [8].

The objective of the study was to carry out a comparative assessment of respiratory performance, based on MFM and the recommended practice for complete PSG, and evaluate the effect of the measurements of blood pressure (BP) in MFM on the quality of sleep.

Materials and Methods

The study was performed in 2 phases in the sleep laboratory of Almazov National Medical Research Centre of the Ministry of Health of the Russian Federation (see Figure 1). A local ethical committee approved the study. In the first phase, healthy volunteers (control group) underwent concomitant multifunctional monitoring with the evening and night measurements of BP (from 8 pm until waking up) and PSG. In the second phase, the study was carried out in the group of patients complaining of SDB, who underwent PSG at baseline to confirm SDB. Subsequently, these patients underwent concomitant PSG and multifunctional monitoring in a single night.

The volunteers were selected subject to general clinical examination and questioning (using questionnaires drawn up in the sleep laboratory, based on standard questionnaires). After the concomitant PSG and MFM examination, volunteers with AHI >5/h (PSG) were excluded from the study. The control group consisted of 22 subjects (11 males and 11 females), the median age was 36 years (ranging from 17 to 56 years), mean body mass index (BMI) was 24.5 kg/m². The SDB group consisted

of 14 subjects (11 males and 3 females), the median age was 58 years (ranging from 37 to 75 years), mean BMI – 31.3 kg/m².

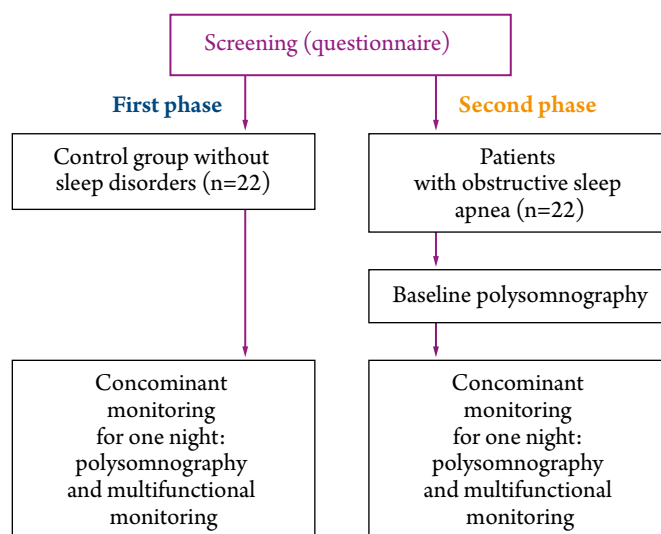
Monitoring of blood pressure, ECG and respiration carried out using the «Kardiotekhnika-07-AD-3/12R». The standard 12-lead ECG was registered, BP was measured using an oscillometric method and by listening to Korotkoff sounds, breathing disorders were assessed by registering arterial oxygen saturation, nasal airflow, and rheopneumography. BP was measured every 15 minutes at daytime and every half hour at night (from 11 pm to 7 am). Then MFM findings were uploaded and analyzed using the in the KTRResult 3 program. The data were synchronized with PSG. The time of falling asleep and waking up was registered according to PSG.

The complete PSG was carried out using the Embla N7000 polysomnographic system with video recording and without night-time monitoring. It included the registration of EEG (6 leads: F3, F4, C3, C4, O1, O2), electrooculography (2 lead: LOC and ROC), electromyography of chewing muscles, body position, pneumatography (sensors attached to chest and abdomen), nasal airflow, SpO₂, ECG (1 lead), electromyography of lower extremities.

EEG was used to estimate the percentage of micro-, macro-, and sub-arousals associated with BP measurement (cuff inflation when BP is measured). The PSG findings were analyzed according to the AASM 2012 criteria [9]. Micro-arousal (or EEG-activation) was registered when the EEG wave changed, and the rhythm frequency increased, ranging from 3 to 15 seconds.

Macro-arousal was registered when the duration of this phenomenon exceeded 15 seconds, i.e., the current stage of sleep transits to the stage of wakefulness. Sub-arousal was registered when the current stage of sleep shifted to a more

Figure 1. Phases of the study



superficial sleep stage. Macro- and micro-arousals were considered to be associated with the measurement of BP if the time between these events was less than 30 seconds from the beginning of cuff inflation (there are no distinct time criteria in the literature). The findings of PSG and MFM were used to evaluate respiratory performance: the number of snoring episodes, the mean level of SpO₂, desaturation index (DI), number of apnea and hypopnea episodes and severity of OSA by AHI (number of apnea and hypopnea episodes per hour of sleep). As MFM cannot determine whether a subject is asleep, the duration of sleep, used to calculate AHI, was determined in MFM as time spent in bed registered in the patient diary, i.e., time from going to sleep to waking up. Assessment of the sleep duration during PSG allows excluding sleep latency and awakenings after the beginning of sleep from the time spent in bed.

Statistical analysis of data was performed using IBM SPSS Statistics v. 21. Due to the non-normal distribution of parameters, non-parametric statistical methods were used. Data of quantitative variables are presented as median (range); data of the ordinal and nominal values are presented as shares.

The variables were compared using the non-parametric statistical methods for related groups: Wilcoxon signed-rank test for the quantitative variables and McNemar test for the qualitative variables. Differences were considered to be statistically significant with $p < 0.05$ (two-tailed test).

Results

In the control group, PSG showed the AHI was less than 5 episodes per hour. Mean AHI was 1.2 per hour, and mean SpO₂ was 96.4%. The cyclic structure of sleep was not disrupted. The mean duration of sleep stages in all patients of this group was within normal values (see Table 1) except for the increase in wakefulness time after falling asleep.

According to MFM, the duration of sleep, including awakenings after falling asleep, was predictably 70 minutes more than according to the PSG findings in the control group ($p = 0.001$). PFM showed that the period of sleep was also longer in patients with SDB by 104 minutes at the first examination ($p = 0.001$) and by 130 minutes at the repeat examination ($p = 0.02$; see Table 2).

In the group with a high pre-test probability of SDB (see Table 2), AHI was 15 episodes per hour and more in all patients (moderate to severe OSA). Besides AHI, PSG abnormalities characteristic of SDB were observed: increase in the duration of the 1st stage of sleep, time of wakefulness after falling asleep, increase in the number of lower limb movements, decrease in mean SpO₂. At the same time, when comparing the baseline PSG

Table 1. Sleep parameters according to PSG in the control group

Parameter	Value
Total duration of sleep, min	463 (260.3–581)
Effectiveness of sleep, %	88.3 (55.7–97)
Sleep latency, min	18.7 (2.5–92)
REM sleep latency, min	113 (11–320)
Stage 1 of NREM sleep, %	3.8 (2–12)
Stage 2 of NREM sleep, %	51 (35–64)
Stage 3 of NREM sleep, %	22 (11–42)
REM sleep, %	24 (4–33)
Lower limb movement index, episodes per hour of sleep	7.6 (3–26)
Periodic lower limb movement index, episodes per hour of sleep	1.3 (0–13)
Index of micro-arousals, episodes per hour of sleep	4.7 (0–36)
Time of wakefulness after falling asleep	76 (0–272)

The data are presented as median, minimal and maximal values, Me (range). PSG, polysomnography, NREM, nonrapid eye movement sleep, REM, rapid eye movement sleep.

Table 2. Sleep parameters according to PSG patients with SDB

Parameter	PSG with concomitant MFM	Baseline PSG	P
Total duration of sleep, min	356.5 (163–596)	442 (176–565)	0.169
Effectiveness of sleep, %	63.9 (53–94.2)	76 (53–95)	0.169
Sleep latency, min	11.2 (4.3–46)	15 (3–46)	0.799
REM sleep latency, min	105 (45–292.5)	83 (38–329)	0.721
Stage 1 of NREM sleep, %	12 (6–47)	9.3 (5–31)	0.050
Stage 2 of NREM sleep, %	49 (16–63)	47 (17–60)	0.721
Stage 3 of NREM sleep, %	18.8 (0–194)	18 (0.8–48)	0.959
REM sleep, %	17 (10–37)	22 (10–30)	0.415
Time of wakefulness after falling asleep, min	130 (12–285)	104 (17–270)	0.445
LLM index, episodes per hour of sleep	34 (5.6–67)	23 (5–63)	0.386
PLLM index, episodes per hour of sleep	1.5 (0–33)	0.3 (0–35)	0.345
Index of micro-arousals, episodes per hour of sleep	13.5 (7–79)	13 (7–62)	0.646
Mean SpO ₂ , %	93 (82–95)	93 (77–96)	0.185
AHI, episodes per hour of sleep	43.8 (12–97.2)	34 (18–94)	0.799
DI, episodes per hour of sleep	41.6 (16–101.4)	32 (10–94)	1.0

The data are presented as median, minimal and maximal values, Me (range). PSG, polysomnography, SDB, sleep-disordered breathing, MFM, multifunctional monitoring, AHI, apnea/hypopnea index, DI, desaturation index, NREM, nonrapid eye movement sleep, REM, rapid eye movement sleep, LLM, lower limb movements, PLLM, periodic lower limb movements.

Table 3. Respiratory performance according to MFM and PSG

Parameter	Control			SDB		
	MFM	PSG	p	MFM	PSG	p
Total duration of sleep, min	539	463	<0.001	486	356.5	<0.018
AHI, episodes per hour of sleep	3 (0–19)	1.2 (0–18.8)	0.430	38 (10–81)	43.8 (12–97)	0.086
Number of apnea episodes	9 (0–206)	1 (1–78)	0.010	305 (39–603)	156 (3–497)	0.160
Number of hypopnea episodes	2 (0–49)	5 (0–46)	0.720	21.5 (2–117)	83.5 (0–401)	0.085
DI, episodes per hour of sleep	0 (0–12)	2.4 (0–17.2)	0.023	26 (8–59)	37.8 (16–101)	0.120
Mean SpO ₂ , %	94.3 (92.7–97)	96.4 (93–98)	0.001	92.3 (88–96)	92.9 (82–95)	0.670
Number of snoring episodes, n	7 (0–221)	6 (0–253)	0.90	95 (4–265)	100 (0–379)	0.630

The data are presented as median, minimal and maximal values, Me (range). PSG, polysomnography, SDB, sleep-disordered breathing, MFM, multifunctional monitoring, AHI, apnea /hypopnea index, DI, desaturation index.

and PSG with concomitant MFM in this group, there were no significant differences in most sleep parameters. The exception was the duration of the 1st stage of sleep, which was by 22.5% more in PSG with concomitant MFM ($p=0.05$). It was probably because the measurements of BP during the initiation of sleep prevented the onset of the deeper stages of sleep.

When comparing the respiratory indicators detected by MFM-PSG, it was found that the mean SpO₂ is much lower, as measured by PFM, only in the control group ($p<0.05$; see Table 3). Nevertheless, AHI, the primary indicator of SDB severity, was comparable when both methods were used. However, when apnea (AI) and hypopnea (HI) indices were calculated separately, it turned out that AI was higher with MFM as compared with the reference method, i.e., PSG (27.4 vs. 10.7 per hour of sleep; $p<0.001$). A separate evaluation of the number of episodes of apnea and hypopnea showed that MFM overestimates the number of apnea episodes in both groups, however statistically significant differences are observed only in the control group ($p=0.01$). Although PSG showed four times fewer episodes of hypopnea in patients with OSA due to a substantial dispersion of values, the differences were statistically insignificant. Thus, MFM can give false-positive results. At the same time, the differences in DI and snoring indicators were statistically insignificant. In the SDB group, AHI and DI, as assessed by MFM, were slightly lower as compared with the PSG findings.

The assessment of all types of arousals showed that the measurement of BP caused an increase in the number of micro-arousals only in the SDB group ($p<0.001$; see Table 4).

Discussion

Our study showed that screening of patients for the diagnosis of SDB is reasonable to detect episodes of apnea

Table 4. Comparative evaluation of awakenings, micro- and sub-arousals according to PSG with BP measurement in the groups of volunteers and patients with SDB

Parameter	Control group	SDB group	p
Macro-arousals, n	5.5 (1–13)	10 (6–15)	0.470
Micro-arousals, n	3 (0–12)	8 (1–36)	<0.001
Sub-arousals, n	5 (2–12)	8.5 (1–15)	0.53

The data are presented as median, minimal and maximal values, Me (range). PSG, polysomnography, SDB, sleep-disordered breathing, BP, blood pressure.

and hypopnea in patients with a high pre-test probability of SDB.

The assessment of SDB in MFM is not always comparable with the PSG findings. Thus, the mean SpO₂ in MFM was lower than in PSG. The PSG system has a flexible finger sensor Nonin 8000J, which is rigidly fixed on a finger, and in MFM, a soft type sensor Nonin 8000SM is used, which can move during the procedure. According to the manufacturer of the MFM system, the testing of pulse oximeter sensors used in MFM revealed no differences from the sensor used in the PSG system. The manufacturers of Nonin 8000SM sensors used during MFM state that their accuracy is ± 2 units at 80–100% saturation and ± 3 units at 70–100% saturation [10]. These parameters question the accuracy of detecting episodes of hypopnea since a 3% change in the saturation is a criterion of diagnosis of hypopnea [9].

Another feature of MFM is the assessment of the chest movements by rheopneumography, which is recorded between the active (+) electrode of the 3rd lead and the “earth” electrode, which are placed on the left and right midclavicular lines at the 5th intercostal space. Rheopneumogram is registered from the electrocardiograph electrodes, which does not require placing

any additional sensors, but movements of the abdominal wall are omitted.

The accuracy of the pulse oximeter in assessing oxygen saturation and of the rheopneumography in the evaluation of the chest movement amplitude as compared with PSG can influence the classification of SDB. Unfortunately, we have not found such information on the manufacturer's website and in the available literature. In the publication of 2009, authors found that the sensitivity of a method of detecting apnea in the SDB patients was 0.91 and 0.71 by rheopneumogram and pulse oximetry, respectively, as compared with the cardiorespiratory monitoring with the assessment of SDB by rheopneumography, pulse oximetry and nasal airflow in summary [7]. Rheopneumography is not included in the standard assessment of thoracoabdominal movements described in the SDB assessment guidelines and required further study to evaluate its accuracy.

MFM showed a higher rate of detection of sleep apnea in the control group. The default setting of SDB assessment program «KTRResult 3» uses 3.5% as a criterion for the evaluation of desaturation for apnea and hypopnea unlike AASM recommended diagnostic standards [9]: 3% desaturation in sleep apnea, and 70% decrease in the amplitude of nasal airflow and 3% desaturation or 50% decrease in the amplitude of nasal airflow and 4% desaturation for hypopnea. Standardization of estimation of the desaturation parameters would improve the comparability of findings.

When analyzing the SDB screening data, the accuracy of the assessment of sleep periods should be kept in mind. Due to the software deficiency in data processing of the assessment of respiratory performance in MFM, which omits awakenings after falling asleep and sleep latency, time in bed is considered equivalent to the duration of sleep, which is used to calculate AHI. Insomnia, which frequently accompanies SDB, is a limitation for screening examinations and an indication for PSG. Thus, the duration of wakefulness after falling asleep in both groups of our study was above normal ($N < 40$ min) [11]. The baseline sleep efficiency in patients with SDB was reduced to 76%. It means that patients did not sleep for almost a quarter of the time in bed. Reduced sleep efficiency due to frequent awakenings in sleep apnea increases the differences between the respiratory indicators used in screening examinations.

The sleep assessment during concomitant PSG and MFM showed changes in sleep phases, e.g., an increase in the duration of the first stage of sleep and the number of micro-arousals related to the measurement of BP, and the tendency to the decrease in the duration of sleep and its quality. The foreign authors showed the influence

of BP measurements on sleep and the increase in the number of macro- and micro-arousals. Despite frequent patient complaints on difficulty falling asleep and night awakenings due to the cuff inflation when BP is measured, we have found in the available literature only two studies in which sleep was assessed in 24-hour BP monitoring (ABPM) according to PSG. The study by M.C.S Lenz and D. Martinez was aimed at assessing the influence of the sleep-wakefulness classification based on PSG on a 24-hour BP profile and did not include the first phase, i.e., PSG without ABPM. The findings showed that patients with SDB had higher BP during the night awakenings, which lead to a false positive classification of the 24-hour BP profile, 66% of patients had a non-dipper profile in the standard assessment of sleep, and 33% of patients when sleep was assessed by PSG [8]. Another study carried out in a group of patients with clinically proven depression [12] with near absent deep sleep also found a significant increase in the number of awakenings. Differences in the assessment of the relation of awakenings with the measurement of BP during sleep may be associated with a lack of a generally accepted time-based criterion, i.e., during what time after the beginning of BP measurement awakenings can be considered as associated with the measurement of BP. We used the criterion of 30 seconds after the measurement, and Lederbogen et al. used a 90-second interval after the measurement of BP [12].

Limitations of the study. Several other factors can also influence the probability of awakenings during the cuff inflation, such as the subject's stage of sleep, rate and duration of the cuff inflation at different levels of BP, which we did not estimate in our study. Moreover, the technical characteristics of the monitors and subjective perception of a BP measurement process by patients within 24 hours can be relevant.

Conclusion

The assessment of the respiratory performance in multifunctional monitoring can be used for the diagnosis of moderate to severe obstructive sleep apnea. The identified features of multifunctional monitoring (lower levels of blood oxygen saturation, the assessment of the chest movements in rheopneumography and non-generally accepted criteria of desaturation) can result in the underestimation of desaturation index and the overestimation of the number of apnea episodes in the control group.

The measurement of blood pressure during sleep is associated only with micro-arousals in patients with sleep-disordered breathing and does not influence sleep in those who have no sleep disorders. It allows adequately estimate the parameters of blood pressure during sleep

in patients with a high probability of sleep-disordered breathing. Taking into account the detected features of the assessment of respiratory performance in the group with no sleep disorders, we consider it reasonable to estimate the accuracy of detecting sleep-disordered breathing in the patients with mild obstructive sleep apnea, and the development and implementation of the mechanism of detecting awakening episodes after falling asleep (e.g., actigraphy and other methods) for a more accurate estimation of the duration of sleep and the measurement of blood pressure during sleep.

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Conflict of Interests.

Tikhonenko V.M. is the head of the company manufacturing the equipment used in the study.

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