

BioSomnia – a new mobile screening device to detect sleep and its quality

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Introduction: In out-patient sleep medicine, portable systems to detect and to evaluate sleep-disorders and their therapeutic outcome are needed. For several disorders like Sleep Related Breathing Disorders (SRBD) or Periodic Limb Movements Disorders (PLMD), there exist ambulatory screening devices so far, but they comprise the disadvantage of ignoring sleep itself by not recording the EEG. BioSomnia is a portable one-channel-EEG system which is able to describe sleep by neural network analysis and to calculate the most important sleep-parameters, such as Sleep Latency (SL), Sleep Period Time (SPT), Total Sleep Time (TST), Sleep Efficiency (SE), Slow Wave Sleep (SWS), Intermittent Time Awake/ Wakefulness After Sleep Onset (ITA), Episodes of Wake (WE) and the number of Micro-Arousals (MA), similar to the Quisi device [3, 4, 6]. Moreover it is able to create a hypnogram on the basis of EEG frequency analysis.

The aim of the study is to determine the predictive value of BioSomnia in comparison to Rechtschaffen & Kales criteria.

BioSomnia Device



Methods: Sleep parameters of BioSomnia were compared to visually scored polysomnographic results of experienced sleep experts in the sleep lab of the Pfalz-Klinikum in Klingenmünster /Germany. Polysomnographic results are based on a visual classification of sleep stages according to Rechtschaffen & Kales [5]. All polysomnographic recordings were made with 24 channel Mepal-Systems or 18 channel Somnolab-Systems. To enable comparable timings for all sleep parameters, BioSomnia was started exactly at the moment of "lights off" and was stopped with "lights on" in the morning. A quasi-experimental design was applied. Statistical analysis are based on 75 simultaneous sleep recordings comprising 36 patients suffering from Obstructive Sleep Apnea Syndrome (OSAS) (35 male, 1 female; average age 55.91 years, range 35 – 77 years, SD: 10.43) from the sleep lab of Pfalz-Klinikum Klingenmünster.

Because of instability or wrong handling of the BioSomnia device, 8 out of 75 registrations were artificial and subsequently excluded from further analysis. Three more recordings delivered incomplete results, so that in these cases only parameter SL could be performed.

Statistical analysis is based on the complete sample of recordings (Gc). To control the effects of different amounts of sleep fragmentation, severely dependent subgroups of OSAS were performed on the basis of Respiratory Disturbance Index (RDI). Polysomnographic recordings with a RDI lower than 10 constitute Group 1 (G1), with a RDI from 10th to 20th Group 2 (G2), with a RDI from 20th to 40th Group 3 (G3) and with a RDI beyond 40th Group 4 (G4).

Due to the number of patients in each subgroup we decided not to implement an analysis of variance and therefore performed paired T-tests and adjusted the level of significance to .0125, corresponding to Bonferroni [2]. To provide a more valid comparison of the two methods, differences about the average values according to Bland & Altman [1] for clinically relevant sleep parameters (SL, TST, SE and AI) were additionally calculated for the complete sample of registrations (Gc).

In addition, logistic regression for clinically relevant sleep parameters was performed in order to give a quotation about specificity and sensitivity of BioSomnia. The dependent variable was calculated by dichotomising the sample with respect to the RDI: Subjects with a RDI < 10th were considered as healthy sleepers (n = 31), subjects with an RDI > 10th were considered as poor sleepers (n = 32).

Visual comparison of hypnograms:

As the BioSomnia sleep hypnograms display the second by second analysis of the EEG during the study period and hypnograms by Rechtschaffen & Kales display 30 sec epochs, statistical comparisons of the two hypnograms were not possible. Thus, the quality of congruence of the hypnograms was checked by the evaluating sleep experts. Each hypnogram has been classified as "high" or "low level of concordance" (Fig. 2.a-b).

Results: For the whole sample (Gc) of recordings no statistically significant differences could be found for the major sleep parameters: SL (t = 0.768; p = .445; df = 66), SPT (t = -0.896; p = .373; df = 63), ITA (t = 1.782; p = .080; df = 63) and MA (t = -1.957; p = .055; df = 63). For BioSomnia Parameters SE (t = -4.157; p < .001) and TST (t = -2.274; p = .026) statistically significantly elevated results were obtained and they are lower for WE (t = 2.276; p = .026) and SWS (t = 4.841; p < .001) in comparison to the polysomnographic results (Tab. 1.a).

The average deviation in parameter TST is 11.17 minutes and in parameter SE 4.13%. Detailed information for each parameter is shown in figures 1.a) - h) as well as in table 1.a). With respect to the influences of sleep fragmentation, analysis of subgroups was performed. In G1 (RDI < 10h) a significant difference is shown only for SWS (t = 3.755; p = .001; df = 31). In G2 and G3 no significant differences were found between Biosomnia and visual scoring of polysomnographic registrations. However, in G4 (RDI > 40), in which sleep fragmentation peaks, we found a significantly reduced amount of micro-arousals (MA: t = -4.892; p = .003; df = 7) in BioSomnia calculations.

Table 1. a): Sleep related parameters – whole sample (Gc)

Sleep Parameter	BioSomnia	PSG	P-Value	n	
Alpha = 0.025					
SL (min)	21.01	15.9	20.21	16.38	449
SPT (min)	322.89	324.4	4.028	40.37	133
TST (min)	337.88	342.9	4.269	8.34	<.001
SWS (min)	75.67	84.1	64.21	37.76	699
SE (%)	73.62	84.1	69.87	37.76	<.001
MA (Total No.)	45.34	30.64	38.19	28.70	<.001
MA (Total No.)	128.84	88.2	149.58	99.83	992
AI (No/h)	24.33	10.92	27.08	20.26	214

Table 1. b): Sleep related parameters G1 (RDI < 10h)

Sleep Parameter	BioSomnia	PSG	P-Value	n	
Alpha = 0.025					
SL (min)	22.57	17.36	28.36	10.47	852
SPT (min)	307.88	313.39	388.42	40.74	359
TST (min)	337.88	342.9	348.14	46.07	211
SWS (min)	74.98	81.23	4.45	9.74	<.001
ITA (min)	50.73	41.56	51.84	28.78	120
SE (%)	77.70	11.03	81.50	8.22	<.01
SWS (%)	18.13	14.59	1.23	2.75	<.001
WE (Total No.)	33.63	18.02	26.41	9.91	107
MA (Total No.)	101.35	33.13	98.38	38.03	684
AI (No/h)	18.02	6.41	17.41	7.24	420

Table 1. c): Sleep related parameters G2 (RDI 10 – 20h)

Sleep Parameter	BioSomnia	PSG	P-Value	n	
Alpha = 0.025					
SL (min)	22.57	17.36	28.36	10.47	359
SPT (min)	307.88	313.39	388.42	40.74	130
TST (min)	337.88	342.9	376.84	60.03	114
SWS (min)	75.79	80.91	4.45	5.24	253
ITA (min)	62.39	37.06	82.21	37.00	972
SE (%)	77.54	12.92	76.39	11.85	078
SWS (%)	7.82	12.34	1.45	1.88	064
WE (Total No.)	49.14	13.89	38.39	12.62	052
MA (Total No.)	123.07	48.02	134.19	53.29	714
AI (No/h)	39.38	13.98	26.70	10.62	375

Table 1. d): Sleep related parameters G3 (RDI 20 – 40h)

Sleep Parameter	BioSomnia	PSG	P-Value	n	
Alpha = 0.025					
SL (min)	26.55	18.88	22.09	16.12	204
SPT (min)	300.00	307.0	400.00	22.00	001
TST (min)	300.00	307.0	345.05	22.00	001
SWS (min)	30.75	28.59	4.59	8.91	043
ITA (min)	71.56	42.57	54.80	28.14	113
SE (%)	73.03	11.50	81.40	8.88	041
SWS (%)	7.21	8.50	1.05	2.44	113
WE (Total No.)	16.30	42.42	33.60	13.30	108
MA (Total No.)	148.54	80.24	183.82	80.47	402
AI (No/h)	27.72	8.98	28.85	12.83	111

Table 1. e): Sleep related parameters G4 (RDI > 40h)

Sleep Parameter	BioSomnia	PSG	P-Value	n	
Alpha = 0.025					
SL (min)	16.05	12.43	10.71	36.33	456
SPT (min)	306.43	27.52	388.71	36.33	456
TST (min)	296.29	87.61	388.71	77.87	818
SWS (min)	9.07	20.37	1.26	2.12	389
ITA (min)	64.29	82.20	101.07	33.49	521
SE (%)	62.10	17.02	71.33	14.34	340
SWS (%)	2.70	5.98	6.43	6.82	461
WE (Total No.)	72.86	38.11	34.57	68.87	341
MA (Total No.)	162.00	58.14	348.07	131.00	360
AI (No/h)	34.30	8.89	73.03	22.59	302

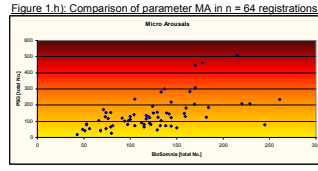
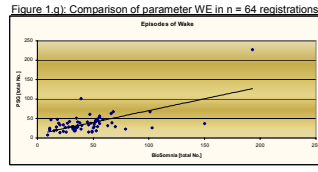
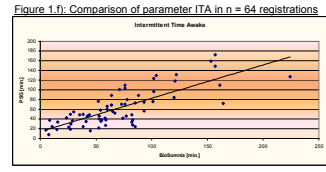
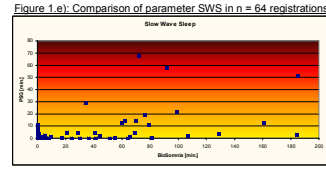
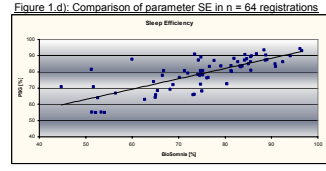
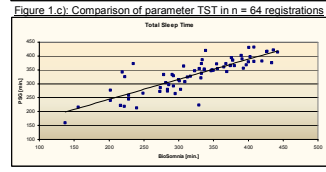
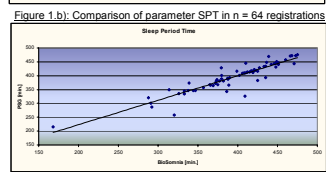
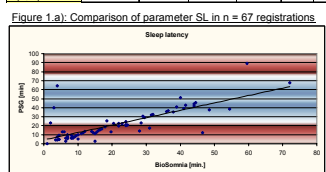


Table 2): Results of logistic regression analysis

Specificity (74.19%) and sensitivity (71.87%) of BioSomnia

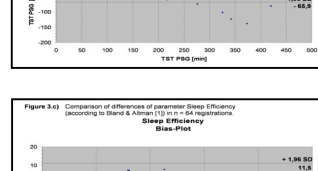
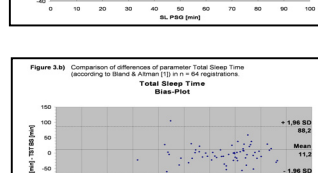
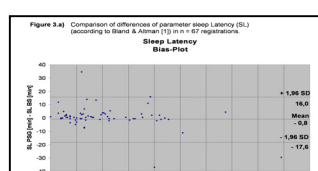
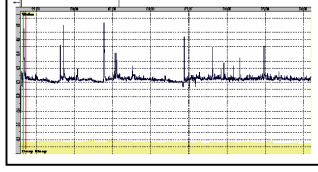
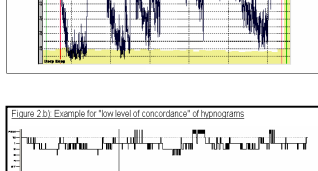
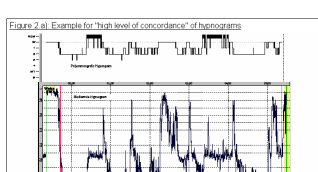
Dependent Variable: DIAGN

Classification Table

Actual \ Predicted	Healthy	Not healthy	Prevalence
Healthy	21	7	28 (28.57%)
Not healthy	10	12	22 (22.22%)
Total	31	19	50 (50.00%)

Classification Statistics

Classification	Count	Percentage
Healthy	21	74.19%
Not healthy	19	71.87%



This may be due to classification criteria as BioSomnia identifies arousals only as those that result in an awake episode. See detailed results in tables 1.b) to e). In conformance with T-test-results the bias-plot according to Bland & Altman [1] (Fig. 3.a) displays no clinical relevant difference for parameter SL. According to statistically significant differences in the respective T-tests, for TST and SE a higher variability of scores is shown (Fig. 3.b-c). These are still in the range of two standard deviations. The variability of Micro-Arousals (AI) increases with higher values, but is still in the range of two standard deviations. Furthermore the distribution of AI underlines a systematic (linear) underestimation of AI by BioSomnia with higher AI scores (Fig. 3.d). Logistic regression results for the 4 clinically relevant sleep parameters of BioSomnia reveals only a statistically significant contribution of variable AI (p < .001). For this reason, parameters SL, TST and SE were excluded from further calculation. Detailed results of the recalculation of logistic regression for variable AI are shown in table 2.

23 out of 31 cases are correctly scored as "healthy" or normal sleepers. This complies to a specificity of 74.19 %. 23 out of 32 cases were correctly scored as "not healthy" and describe a sensitivity of 71.87 %. The Youden-Index is 0.46. In summary out of 63 subjects BioSomnia delivers 9 false negative and in 8 cases false positive results.

Concerning the hypnograms we found a high level of concordance in 41 out of 56 cases (73.21 %). In about 26.79 % only a low level of concordance is estimated by sleep experts. No systematic reason for the prediction of high or low level of concordance has been determined.

Discussion: We found significant differences in the parameters SWS, WE, TST and SE, whereas for mean absolute differences in TST with 11.17 min, for Wake episodes (WE) with 7.15 min and for SE with 4.13 % no clinical relevance can be recognized. This fact is underlined by the respective bias-plots according to Bland and Altman (Figure 3.a-d). The variability of differences is relatively small, within the range of two standard deviations and, with the exception of figure 3.d, no systematic effect is demonstrated. The differences in SWS are expected due to the second by second analysis with the BioSomnia algorithms. The statistically significant difference in detecting the correct amount of SWS is also shown in Group 1. Recordings with higher sleep fragmentation, such as in Groups G2 to G4, reveal no significant differences between the two methods of analysis because of the absence of SWS in these groups.

The detailed analysis of subgroups with different levels of sleep fragmentation reveals difficulties in correct identification of Micro-Arousals (MA) in recordings with high sleep fragmentation (fig. 3.d).

In most cases the BioSomnia sleep hypnograms are in good agreement with hypnograms based on visual classification according to Rechtschaffen & Kales. The current version of BioSomnia does not distinguish between REM- and NonREM sleep. However, a detailed determination of sleep disorders and the assessment of the cyclicity of normal and pathological sleep requires the classification of REM sleep.

Also some problems in the handling of the BioSomnia device should be mentioned. In the authors' opinion it is not helpful that patients have to mark events like "lights off/ lights on", to get correct results. This function reduced the stability of the system and resulted in lost data. Therefore a modification of the device to allow programming of the time of study, for example, might be advisable. Furthermore BioSomnia needs a continuous phase of 90 seconds of sleep to be able to detect 'sleep onset'. In one case of extreme high level of sleep-fragmentation 'sleep onset' could not be found at any point of the registration.

Conclusions: In summary, BioSomnia differentiates between sleep and wakefulness in many cases and seems to be a supporting tool for outpatient sleep medicine. Sure enough BioSomnia is not able to replace polysomnographic recordings in sleep laboratories because a lack of several sleep parameters referring to e.g. nocturnal breathing or leg movements. In most cases sleep disruptions can be determined in the case of light to moderate sleep fragmentation. High levels of sleep fragmentation seem to be underestimated. The estimation of Quality of Sleep in the form of amount of SWS is limited and is not possible in the case of REM sleep. Due to the lack of REM sleep detection, the classification of REM sleep cannot be determined.

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