Objective Assessment of Sleep using a 2-Channel Portable, Self-Applicable Device

Georg Gruber[1], Silvia Parapatics[1], Erna Loretz[1], Manuel Kemethofer[1], Markus Simeoni[2], Lorenz Rainer[2], Georg Dorffner[1,3]

[1:] The Siesta Group, Vienna, Austria; [2:] Medical University of Vienna, Vienna, Austria; [3:] Medical University of Vienna, Section for Artificial Intelligence and Decision Support, Vienna, Austria

OBJECTIVES AND AIMS

Objective assessment of human sleep in clinical trials requires the recording of multiple biological signals

Currently, this method, known as polysomnography (PSG), is carried out at highly specialized sleep centers requiring skilled personnel and full equipment, and thus limits the number of measurements to only a few nights in a protocol. Portable solutions still rely on the availability of a full montage according to the published standards, preventing the easy self-applicability and thus limiting the potential scope of those instruments. Recently, we presented a new method of sleep staging based on a reduced setting using two EOG channels only (Gruber et al. 2016). We could demonstrate that the algorithm effectively identified the three main states wakefulness, NREM sleep and REM sleep from the two EOG channels.

The aim of this paper is the application of the 2-EOG based algorithm in data acquired with a 2-channel, self-applicable recording device, and to compare the results to simultaneously recorded standard PSG.

DESIGN

20 healthy subjects (aged 18 – 32 years) participated in the experiment. Standard PSG was recorded using the EEG channels F4, C4, and O2 referenced versus the contralateral mastoid (A1), submental EMG, and 2 EOG electrodes placed at the standard positions. The reduced montage included 2 EOG electrodes placed one cm above LOC and below ROC respectively, referenced versus A2 and signals were recorded using an Actiwave miniature recorder (Camntech, Cambridge UK).

All 40 recordings were analyzed either using a validated computer assisted scoring system (Anderer et al. 2010) for the standard PSGs and a modified version adapted for the reduced 2-channel montage, respectively.

The calculated target variables included the sleep efficiency index (EFF), wake after sleep onset (WASO), latencies to sleep onset persistent sleep (LCONT), and REM as well as the percentages of sleep stages N1, N2, N3, and R.

RESULTS

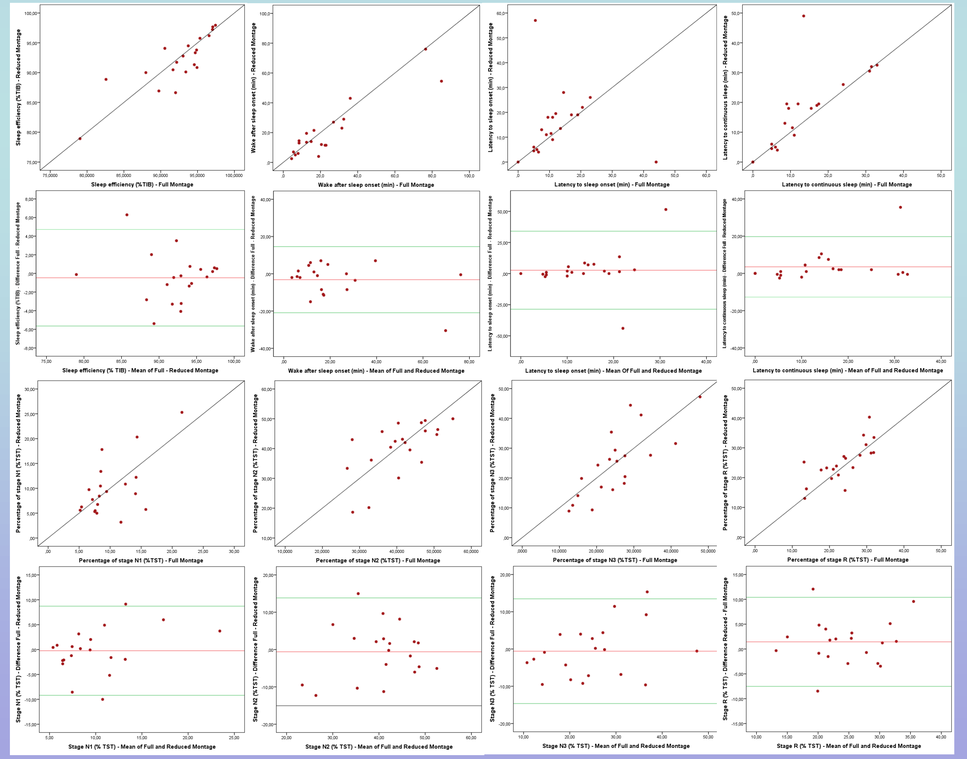
Data loss as a result of absent backup channels was minimal in the 2-channel recorder. The number of epochs not scoreable was 1.3 % in the portable device (0 % in the standard recording).

In general, the average differences between the target variables between reduced and standard montage were marginal in absolute terms: EFF: -0.47 % (SD=2.6), WASO: -3.2 minutes (SD= 9.1), LCONT: +3.5 minutes (SD=8.3), N1%: -0.2 % (SD=4.6), N2%: -0.6% (SD=7.4), N3%: -0.5% (SD=7.2), and R%: +1.4 (SD=4.6), see Table. As expected, no significant differences were found in a paired samples t-test in any variable. In order to evaluate the effect-size, Cohen's d was calculated, indicating predominantly small or very small effect sizes. (Bland-Altman plots showed no evidence of a systematic bias (see Figure).

CONCLUSION

The results provide further indication that, with appropriate computer-supported sleep scoring, data obtained by means of a 2-channel portable device lead to sleep measurements comparable to a full PSG. Yet, a final proof of equivalence needs to be demonstrated in a non-inferiority design.

Sleep Parameter	Full Montage (Mean)	Reduced Montage (Mean)	Mean Difference (Reduced - Full)	SD Difference (Reduced - Full)	p-value (one sample t-test)	Effect Size (Cohen's d)
Sleep efficiency (%TIB)	92.42	91.95	-0.47	2.64	.438	-.18
Wake after sleep onset (min)	23.58	20.40	-3.18	9.05	.133	-.35
Latency to sleep onset (min)	12.50	15.20	2.70	16.00	.460	.17
Latency to continuous sleep (min)	13.30	16.83	3.53	8.28	.072	.43
Stage R latency (min)	81.95	76.20	-5.75	21.27	.241	-.27
Percentage of stage N1 (%TST)	10.13	9.89	-0.24	4.57	.814	-.05
Percentage of stage N2 (%TST)	40.80	40.19	-0.61	7.37	.717	-.08
Percentage of stage N3 (%TST)	25.34	24.75	-0.59	7.17	.719	-.08
Percentage of stage R (%TST)	23.73	25.17	1.44	4.58	.177	.31



Reference: Gruber G, Parapatics S, Loretz E, Schmittner S, Dorffner G. Validity of sleep staging based on a reduced montage using 2 EOG channels. Journal of Sleep Research. 2016 25 (Suppl. 1):344.

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