

Proving the equivalence of simplified home sleep testing to polysomnography

Submitter Georg Dorffner

Affiliation Medical University of Vienna

SUBMISSION DETAILS

What is the Methodological Question Being Addressed? Can it be statistically proven whether a reduced, self-applicable electrophysical montage for measuring sleep in a subject's home delivers endpoint variables equivalent to the gold standard?

Introduction The Covid-19 pandemic has changed the landscape of clinical trials considerably. Alternative procedures minimizing contacts between patients and staff are urgently needed. When it comes to measuring sleep in a CNS drug trial, such a strive amounts to replacing the gold standard – polysomnography (PSG) – with an instrument applicable in a subject's home without assistance. Such solutions for home sleep testing (HST) have been introduced before, but for none of them it could be convincingly shown whether the main endpoints needed for measuring a drug's influence on sleep are close enough to those delivered by the gold standard. In this work we introduce a conclusive way of testing this question, by employing the well-known equivalence test to prove the equivalence of HST endpoints to those of PSG.

Methods We performed a retrospective analysis on data from 20 healthy subjects using a self-applicable reduced montage of electrodes. The montage used two electrodes besides the eyes in standard electrooculography positions and one at the mastoid behind the right ear. Subjects self-applied them for five consecutive night measurements. During the first night, a standard portable PSG with a full electrophysiological montage patched by trained staff was applied in parallel. Data from this first night was used in the equivalence test.

The equivalence test requires a tolerance interval defining which discrepancy between methods is still considered negligible. Here the well-known inter-rater variability among expert scorers can be exploited. In another previous study around 100 PSG recordings had been scored by 4 randomly assigned experts. The average difference of the main variables was reported for each pair of experts. The largest of these can be considered as still tolerable. The test is then based on calculating the 90% confidence interval for the average discrepancy between reduced montage and full PSG. If this confidence interval lies completely within the tolerance interval a statistical proof of equivalence is deduced.

Results Most of the important sleep variables could be proven to be equivalent. Tolerance intervals were defined for the following variables: sleep efficiency: [-4.1 4.1] % points, percentage of N1 sleep: [-5.6 5.6] %, N2 sleep: [-7.5 7.5] %, N3 sleep [-7.7 7.7] %, REM sleep [-2 2] %. With one exception, 90% confidence intervals for the mean deviation between the reduced HST and the full PSG were fully within those tolerance intervals: efficiency: [-0.55 1.49], N1: [-1.52 2.01], N2: [-2.24 3.45], N3: [-2.19 3.36]. Only for REM sleep the confidence interval went outside the

tolerance: [-3.21 0.33].

Conclusion The results from the equivalence tests show that for most common endpoint variables for sleep architecture the measurement by a self-applicable HST can be considered as statistically equivalent to those of a full PSG. In addition to considering this as a proof for the feasibility of HST for CNS-active drug trials we also propose this procedure as a general methodology when comparing two measurement alternatives.

Co-Authors

* Presenting Author

First Name	Last Name	Affiliation
Georg *	Dorffner *	Medical University of Vienna
Manuel	Kemethofer	The Siesta Group
Georg	Gruber	The Siesta Group
Silvia	Parapatics	The Siesta Group
Erna	Loretz	The Siesta Group

Keywords

Keywords
Sleep
polysomnography
home sleep testing
Covid-19 pandemic
Equivalence testing

Guidelines I have read and understand the Poster Guidelines

Disclosures if applicable The original study was partly funded by the Vienna Center for Innovation and Technology (ZIT). Georg Dorffner, Manuel Kemethofer, Silvia Parapatics, Erna Loretz and Georg Gruber are employees and shareholders of The Siesta Group, a service provider for measuring electrophysiological signals including sleep in clinical trials.

Related tables <blank>