Towards proving the validity of computer-supported sleep scoring for pediatric trials

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What is the Methodological Question Being Addressed? Is it possible to prove statistical equivalence of computer supported sleep scoring in a pediatric population, as compared to visual expert scoring?

Introduction In previous work (Dorffner et al., 2021, ICSTM 2021 fall conference) we have shown that existing algorithms for scoring sleep based on polysomnographic recordings can be adapted to the characteristics of infant and child recordings, especially that of the electroencephalogram (EEG) which is known to change during maturation. Here, we took this observation a step further and ventured to derive a validated version of the adapted algorithm that would be fit to be used in pediatric clinical trials involving sleep as an endpoint.

Methods Based on a dataset from a children's sleep laboratory (reported in Dorffner et al., 2021), we focused on the two age groups, 5-9 and 9-14 years. In the previous study, it was found that for both age groups, a 50% EEG amplitude scaling factor and a cut-off frequency between alpha and theta bands of 5Hz (as opposed to 7Hz for adults), represent optimal scoring parameters applied to the fully validated sleep scoring tool, known as Somnolyzer. Here, Somnolyzer, with those adaptations, was applied to a randomly selected validation data set, that was not part of parameter adaptation. For each of those recordings, two independent expert scorings were available. Their average difference in any of the main sleep endpoints considered – percentage in each sleep stage (N1P, N2P, N3P, and RP) – was seen as a tolerable deviation in a statistical equivalence test. For such a test, the 90%-confidence interval of differences between the adapted Somnolyzer and the primary expert scoring would need to be fully within the tolerance to be considered statistically equivalent.

Results For both age groups, most of the endpoint variables could be proven statistically equivalent when compared to visual expert scoring. For age group 9-14, the 90%-confidence intervals of N1P [3.31 4.88], N2P [7.39 10.22], and N3P [7.05 10.55] were entirely below the tolerance intervals of 4.89, 11.22, and 11.50, respectively. Only RP [4.15 7.03] did not reach equivalence as compared to the tolerance of 5.81. For age group 5-9, equivalence was proven for N2P ([5.79 9.09], as compared to 11.99), and N3P ([6.49 10.67] as compared to 12.67). RP ([2.56 4.41] as compared to 4.36) was slightly outside the significant equivalence, while N1P ([3.55 5.45] as compared to 3.4) clearly missed equivalence.

Conclusion With only a few exceptions (N1P for age group 5-9 and RP for age group 9-14) the main sleep endpoint variables passed the statistical equivalence test, as compared to the average deviation of two human experts. Since only two such expert scorings were available, a more truthful estimate of the acceptable tolerance interval could reveal that even those exceptions are within acceptable limits. In conclusion, the study has largely proven that adapted sleep scoring algorithms can be considered validated to children as young as 5 years old.

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Disclosures Georg Dorffner, Georg Gruber and Michael Lagler are employees, Dorffner and Gruber also shareholders, of The Siesta Group, a service provider for measuring electrophysiological signals including sleep in clinical trials.

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