Investigating the proper adaptation of sleep scoring algorithms for pediatric trials

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SUBMISSION DETAILS

What is the Methodological Question Being Addressed? Can adapting algorithms for computer-supported sleep scoring lead to improved automated scoring in infant and child data?

Introduction Computer-supported scoring, i.e. scoring by an algorithm followed by visual expert review, is gaining importance in clinical trials when it comes to objectively measuring a drug's effect on nocturnal sleep, mainly due to the high reliability of such methods as compared to pure visual scoring. While validated systems exist for approved use in adults, the validity of the underlying algorithms for infants or children still needs to be proven. Sleep scoring, by standards of the American Academy for Sleep Medicine, is based on identifying features in electrophysiological recordings (EEG, EOG, EMG) and assigning sleep stages to 30s epochs. With the exception of neonates, the qualitative criteria for such features and their classification into stages are the same for pediatric and adult subjects. However, the quantitative basis of the EEG changes considerably during neural development requiring adaptations in any algorithm.

Methods Based on a data set of around 150 anonymized recordings from a children's sleep laboratory, manually scored by two independent experts, covering a range from 1 to 12 years of age, we investigated the applicability of previously developed sleep scoring algorithms to such data. Our hypothesis was that the main quantitative characteristics of infant electrophysiology is reflected by two values: (a) the average amplitude of the EEG, which is generally higher in younger children, and (b) the cutoff frequency between the alpha and the theta bands, which is known to be lower in children. While these effects can be expected to be of continuous nature, for better statistical comparison we considered several discrete values for (a) and (b) and divided the age range into three age groups known from literature to reflect major phases in brain and sleep development.
Therefore, we applied our standard sleep scoring algorithm in 9 different settings, by varying (a) the average amplitude (original, scaled by a factor of 75% or 50%) and (b) the cutoff between alpha and theta (7Hz, as for adults, 6Hz, or 5Hz). We validated the results by calculating a set of standard sleep endpoints (sleep efficiency, percentage of time in each sleep stage) and comparing the values of these endpoints to those derived by a visual expert scorer, in terms of bias (average deviation between the two scoring methods) and consistency (correlation coefficient). Subsequently, we selected the one setting, out of the nine different ones applied, that overall resulted in the smallest bias and the largest correlation, with emphasis on the most important distinctions wake vs. sleep, REM (rapid eye movement sleep) vs. non-REM as well as light vs. deep sleep. The band cutoff value was expected to largely influence the former two distinctions, whereas the amplitude scaling factor was expected to affect the latter.

Results Results demonstrated that, indeed, varying the two main parameters led to much improvement in automated scoring as compared to the visual baseline. The bias for major sleep

variables could be reduced by 50% or more, leading in some cases to statistical equivalence. For all three age groups considered the optimal configuration turned out to be a 50% amplitude scaling and a 5Hz cutoff value for alpha/theta. With respect to the most important sleep stages, the results for bias and correlation reached a range (as quantified by 90% confidence intervals) comparable to that of the interrater agreement in the data set.

Conclusion These results constitute an important step toward full validation of computer-supported scoring of infant and child data achieving a significant reduction in expert review time. This points toward the availability of efficient and reliable sleep scoring for pediatric CNS trials.

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Keywords

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Guidelines I have read and understand the Poster Guidelines

Disclosures if applicable Georg Dorffner, Georg Gruber, Marco Hirner and Peter Anderer are employees and (except for Marco Hirner) shareholders of The Siesta Group, a service provider for measuring electrophysiological signals including sleep in clinical trials.

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