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Validation of a New Index, qCON, for Assessment of the Level of Consciousness During Sedation

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Background

EEG derived indices are continuous and objective but they have been optimized for general anesthesia mostly at deep levels of drug concentration as compared to the concentrations used in sedation-analgesia. A relevant limitation for the use of EEG or AEP derived indicators of depth of hypnosis in sedation is the presence of significant electrical activity of the muscles, especially around the frontal area that contaminates EEG and artefacta the calculation of hypnotic indexes. The objective of this work was to compare a recently introduced index of hypnosis, the qCON (Quantium Medical, Spain) with the clinical sedation Ramsay scale and the Bispectral index (BIS) (Covidien, USA), in patients undergoing Ultrasonographic Endoscopy (USE) under sedation and analgesia with propofol and remifentanil.

Methods

After IRB approval and written informed consent, 119 patients, undergoing USE under sedation with a combination of propofol and remifentanil, were included in this study. Propofol and remifentanil were infused using a TCI system (Base Primea, Fresenius Vial, France). The TCI system administered propofol and remifentanil according to the predictions of pharmacokinetic-pharmacodynamic models [1,2]. In both cases the TCI was targeting the effect site. BIS of the EEG was continuously measured with an A2000 monitor and the degree of sedation was monitored by the attending anesthesiologist, using the Ramsay Sedation Score (RSS) at random times. The qCON index was calculated offline from the raw EEG using technology from Quantium Medical S. L., based on ANFIS models that include EEG and EMG frequency ranges. qCON and BIS indices were compared using Pk statistic, Pearson's correlation coefficient (r^2) and Bland-Altman plot (average difference [confidence interval]). The prediction ability of both indicators, to predict changes in RSS, was calculated using the Pk statistic.

Results

The Pk statistic and Pearson's correlation coefficient were Pk=0.89 and r^2=0.73, respectively, when qCON was compared with BIS. The average difference [confidence interval] from the analysis of qCON and BIS with Bland-Altman plot was 2.91 [-12.10; 17.92]. The ability to predict the changes in RSS, estimated by means of the Pk values, were: Pk=0.75 for qCON and Pk=0.76 for BIS.

Conclusion

The qCON index showed a high correlation and agreement with BIS index, being the ability to predict the changes in the sedation Ramsay scale similar in qCON and BIS indices. In this order, qCON index was able to satisfactorily assess the level of sedation during administration of propofol and remifentanil in patients undergoing USE. Ref: (1) Schnider TW Anesthesiology 1998, (2) Minto CF Anesthesiology 1997.