

**Validation of the patient state index for monitoring sedation state in critically ill patients: a prospective observational study**

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**Purpose:** The Patient State Index (PSI) is a newly introduced electroencephalogram-based tool for objective and continuous monitoring of sedation levels of patients under general anesthesia. This study investigated the potential correlation between the PSI and the Richmond Agitation–Sedation Scale (RASS) score in intensive care unit (ICU) patients and established the utility of the PSI in assessing sedation levels.

**Methods:** In this prospective observational study, PSI values were continuously monitored via SedLine® (Masimo, Irvine, CA, USA); the RASS score was recorded every 2 h for patients on mechanical ventilation. Physicians and nurses were blinded to the PSI values. Overall, 382 PSI and RASS score sets were recorded for 50 patients.

**Results:** The PSI score correlated positively with RASS scores, and Spearman's rank correlation coefficient between the PSI and RASS was 0.79 (95% confidence interval [CI]: 0.75–0.83). The PSI showed statistically significant difference among the RASS scores (Kruskal–Wallis chi-square test: 242, df = 6,  $P < 2.2 \times 10^{-16}$ ). The PSI threshold for distinguishing light (RASS score  $\geq -2$ ) sedation from deep sedation (RASS score  $\leq -3$ ) was 54 (95% CI: 50–65; area under the curve, 0.92 [95% CI: 0.89–0.95]; sensitivity, 0.91 [95% CI: 0.86–0.95]; specificity, 0.81 [95% CI: 0.77–0.86]).

**Conclusions:** The PSI correlated positively with RASS scores, which represented a widely used tool for assessing sedation levels, and the values were significantly different among RASS scores. Additionally, the PSI had a high sensitivity and specificity for distinguishing light from deep sedation. The PSI could be useful for assessing sedation levels in ICU patients. University Hospital Medical Information Network (UMIN000035199, December 10, 2018).