

ventilator fitting period or developing ventilator-related pneumonia (VAP) [4]. On the contrary, under a shallow sedation depth, a report shows that the case of accidental extubation in ventilators increases, followed by restlessness or agitation [5]. Therefore, establishing an objective "sedation scale," a common standard among medical professionals in evaluating the sedation depth, should be mandatory. The use of the sedation scale is currently recommended in practice on patients under intensive care management, particularly during mechanical ventilation management [6]. Given this situation, the use of the Richmond Agitation Sedation Scale (hereinafter referred to as "RASS") has been recently recommended, mainly for adult patients, as an appropriate sedation scale [3, 7, 8].

However, on the other hand, no recommendation has been made to use a specific sedation scale in the field of Pediatrics [9]. The cognitive and language abilities of pediatric patients are underdeveloped, in which the process of informed consent is often problematic. To make matters worse, those infants may suffer significant stress, not only from medical treatment or surroundings of a unique ICU environment but also from being separated from their family. Therefore, the management of pediatric patients in ICU is often challenging, which requires deeper sedation depth and a higher level of pain relief than those of adult patients [8]. However, the number of sedation scales assessed for their reliability and validity in pediatric patient management in mechanical ventilation is quite limited [10]; although the state behavioral scale (SBS) has been reported as a candidate for sedation scale of pediatric patients, no recommended sedation scale has been established in the treatment of pediatric patients as in its adult counterpart. Consequently, a simple and reliable scale in determining appropriate sedation depth according to each patient's growth development stages is required. We have introduced RASS since 2014 in our hospital, and our physicians and nurses have assessed the optimal sedative level for each patient.

Methods

The study was conducted in pediatric patients admitted to PICU of A Pediatric hospital from January to May 2014 and are under mechanical ventilation management with sedative dosage. Patients administering the muscle relaxant, patients under mechanical ventilation management by high-frequency oscillatory ventilation, and airway pressure release ventilation

was excluded. We adopted RASS for the sedative scale since its validity and reliability have been verified.

As for the method for measuring the sedative depth, I assigned two medical professionals as raters, namely, the nurse assigned to the patient and the physician of PICU. These two raters measured the sedation depth simultaneously or independently using RASS. I performed the assessment based on the assessment criteria of RASS as follows.

1. Observe patient (0-+4 judgment): Observe patient for 30 seconds only by visual diagnosis to determine score 0 to +4.
2. Give the patient the call stimulation (-1 to -3 judgment): Call the patient's name out loud or instruct him/her to open eyes. Repeat if the patient cannot make eye contact for more than 10 seconds. Determine score -1 to -3 only by the reaction to the call stimulation.
3. Gives body stimulation to the patient (-4 to -5 judgment): If the patient poses no response to the call stimulation, shake his/her shoulder or rub the breastbone. Based on the reaction to body stimulation, determine score -4 or -5.

Assessment results were filled out on the designated form and kept in the envelope placed in PICU.

As for data analysis, after creating a bubble chart, I calculated Spearman's rank correlation coefficient and verified the concordance rate. Then, I verified each score's concordance rate.

There are no conflicts of interest in this study. This study was conducted following the Ministry of Health, Labour and Welfare's "Ethics Guidelines for Medical Research involving Human subjects" with the proper ethical considerations. I also obtained approval from the Research Ethics Committee at each relevant institution before commencing my study.

Results

The relationship of scores of the RASS evaluated by a bedside nurse and physician

I conducted a total of 445 assessment on 133 patients. Backgrounds of the subjects are; the median age in the month was 14 months, the median of mechanical ventilation days was six days, and the median days admitted to PICU was 10 days (Table 1).

Table 1: Patient's demographics and outcomes (n=133)

Age, median months (IQR)	14 (5-51)
Pediatric Index of Mortality 2, median % (IQR)	4 (1.3-4)
Before entering the PICU, Pediatric Cerebral Performance Category, median (IQR)	1 (1-3)
PICU stay, median days (IQR)	10 (5-24)
Duration of mechanical Ventilation, median day (IQR)	6 (3-21)

Mismatch scores the RASS evaluated by a bedside nurse and physician

As for the administration of the analgesic sedative agent, based on the continuous administration of midazolam and opioids as a first-line drug, dexmedetomidine, ketamine, or phenobarbital was dosed as a second-line drug or an adjuvant. Adjustment of the drug dose was adequately performed under the instruction of an intensive care physician stationed there. RASS score results of physician and nurse showed a

high correlation, with the correlation coefficient of $\rho = 0.914$ (Figure 1). In patients' discordance, the nurse assessed as RASS=-2 to 1, indicating that the nurse tended to assess the patients with the sedation level shallower than the physician (94%: 16/17) (Table 2). Concordance rate for each RASS score was low in RASS=+1 (54%: 7/13), RASS=-2 (80%: 21/26), and RASS=-3 (80%: 47/59) (Table 3).

Concordance rate for each RASS score was low in RASS= + 1(54%, 7/13), RASS=-2 (80%, 21/26), and RASS=-3 (80%, 47/59)

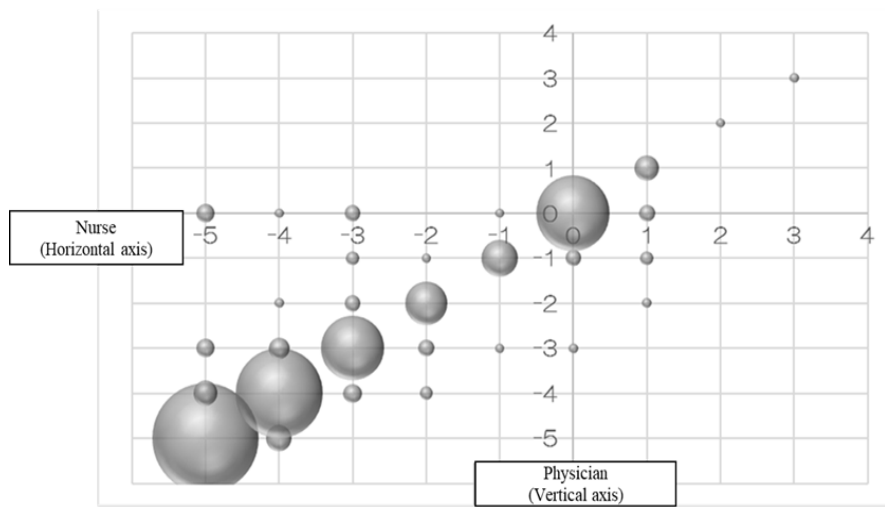


Figure 1: The relationship of scores of the RASS evaluated by a bedside nurse and physician^{abc}

- a. Spearman's rank correlation coefficient
- b. The correlation coefficient of $\rho = 0.914$
- c. 445 assessments

		Nurse (Horizontal axis)								
		-5	-4	-3	-2	-1	0	1	2	3
Physician (Vertical axis)	3									1
	2								1	
	1							7		
	0	4	1	3		1	65	3		
	-1					15	3	2		
	-2				21			1		
	-3	4	5	47	3	1	1			
-4	7	92	4							
-5	138	7								

Table 2: Mismatch scores the RASS evaluated by a bedside nurse and physician^{ab}

- a. 445 assessments
- b. The nurse assessed as RASS=-2 to 1, indicating that the nurse tended to assess the patients with the sedation level shallower than the physician (94%, 16/17)

Table 3: RASS level evaluated by nurses^{ab}

RASS	The Inter-rater agreement rate (%)	Match number/Total
3	100	1/1
2	100	1/1
1	54	7/13
0	94	65/69
-1	88	15/17
-2	80	21/26
-3	80	47/59
-4	86	92/106
-5	90	138/153

a. 445 assessments

b. Concordance rate for each RASS score was low in RASS=+1(54%, 7/13), RASS=-2 (80%, 21/26), and RASS=-3 (80%, 47/59)

Discussion

RASS enabled us to assess pediatric patients in PICU in a relatively short time. Rater's concordance rate demonstrated a high correlation with the correlation coefficient of $\rho = 0.914$, showing high concordance. On the contrary, the concordance rate was low in scores +1, -2, and -3. In the assessment of consciousness level by eye contact and gaze, it is difficult to assess correctly in infants, and therefore it is likely that it depends mostly on the experiences and skills of physicians and nurses. We judge that the infant shows interest if we observe its eyes being open, pursued, or fixed on something, whereas the duration of pursuit or vision fixation of infants is relatively short in most cases [11]. Depending on the patient and the rater's positional relationship, the pursuit and vision fixation cognition can be challenging. For that reason, the assessment itself was considered to be complicated. Similarly, it is difficult for infants to be calm even when the consciousness is clear, and then even in the same patient's condition, it is considered to be different assessments of "calm (0)" or "restless (+1)" depending on the rater.

The physician was inclined to assess the sedation deeper than the nurse for the raters' discordance. Caring nurses are always sensitive to the patient's condition at the bedside, so the condition of a "calm" patient that the nurse thinks may suppose a less body movement state than the physician thinks "calm" patient is. Nurses often encounter situations where patients do not feel at ease and are working to prevent accidental extubation. Furthermore, when introducing RASS, we conducted a questionnaire survey on the optimal sedative level to physicians and nurses in advance. Among them, the result that nurses usually feel "sedation is shallow" accounts for a majority. Further, when the pediatric patient did not feel at ease, the nurse took about 10 minutes to play with him/her. From this situation, the condition of a "calm" patient that the nurse thinks may suppose a less body movement state of

the patient than the physician thinks "calm" patient is, which affects the likelihood to assess the sedation depth shallower. Therefore, it is considered that physicians are inclined to assess the sedation depth deeper than nurses.

An appropriate use of sedatives contributes to improving outcomes in adults, such as prevention of VAP, reduction in the period of artificial respiration management, and improvement in survival [11-13]. The results of this study suggest that optimizing sedation management using RASS may reduce the risk of VAP. Muscle weakness and functional impairments, such as cognitive/mental function disorder, are known complications after artificial respiratory management and have been labeled as ICU Acquired Weaknesses [14]. To prevent these conditions, it is necessary to appropriately manage the risk factors in the acute phase, with particular attention to the appropriate management of sedatives. RASS assessments are thus an important component of the PICU VAP prevention bundle. Previous studies have also shown that proper sedation management with RASS reduced the incidence of VAP in the PICU [15]. COMFORT scale has been reported for the sedation scale targeted for children [16]. However, because this scale itself shows the patient's discomfort, pain is also included, which we cannot distinguish between analgesia and sedative. Assessment results are indicated by each item's total points (8-40 points), so it is difficult to set the target value in advance as a drawback. The reliability and validity of the State Behavioral Scale have been established, a Japanese version is also being developed [17]; however, its application in the PICU is complicated by the number of evaluation items. We assessed the sedation in PICU using RASS. It was a high concordance rate among physicians and nurses so that it could be easily assessed. Previous studies have also shown that RASS is quick, intuitive, and an excellent tool for use in the PICU [18]. In adults, RASS is used as part of the CAM-ICU for delirium evaluation. On the other hand, there is also pCAM-ICU in children [19, 20]. pCAM-ICU is to be evaluated using RASS. However, assessing the consciousness level by eye contact and gaze used in RASS may be difficult in infants, evaluating sedation and excitement using RASS may develop delirium evaluation in the future.

Limitations of the study

This study has several limitations. First, this was a single-center study. Second, it is considered that we could not sufficiently examine the influence of the medical care experience and RASS assessment proficiency level of nurses and physicians. In fact, it has been suggested that RASS can be an evaluation tool for pediatric patients through educational intervention [21]. Further, the validity of the RASS for children has not been adequately evaluated. The RASS is adapted for children by developing evaluation

criteria according to their age and conscious levels, and the validity of this scale needs to be assessed with more patients.

Conclusions

Though RASS's concordance rate between physicians and nurses in PICU was mostly high, there was still room for improvement. Moreover, the physicians assessed the sedation depth deeper than the nurses in the shallower sedation degree area from aptitude.

Acknowledgment

A part of this research result was presented at the 17th Joint Scientific Congress of the KSCCM and JSICM held in Seoul, South Korea, using posters. Addition, this study received research funding from the policy-based Medical Services Foundation in 2017.

Conflict of Interest

There are no conflicts of interest in this study. This study was conducted following the Ministry of Health, Labour and Welfare's "Ethics Guidelines for Medical Research involving Human subjects" with the proper ethical considerations. I also obtained approval from the Research Ethics Committee at each relevant institution before commencing my study.

References

1. Brook AD, Ahrens TS, Schaiff R, et al. Effect of a nursing implemented sedation protocol on the duration of mechanical ventilation. *Crit Care Med* 27 (1999): 2609-2615.
2. Deeter KH, King MA, Ridling D, et al. Successful implementation of a pediatric sedation protocol for mechanically ventilated patients. *Crit Care Med* 39 (2011): 683-688.
3. Smith HAB, Brink E, Fuchs DC et al. Pediatric delirium: monitoring and management in the pediatric intensive care unit. *Crit Care Pediatr Patient* 60 (2013): 741-760.
4. Rello J, Diaz E Roque M, et al. Risk factors for developing pneumonia within 48 hours of intubation. *Am J Respir Crit Care Med* 159 (1999): 1742-1746.
5. da Silva PS, Fonseca MC. Unplanned endotracheal extubations in the intensive care unit: systematic review, critical appraisal, and evidence-based recommendations. *Anesth Analg* 114 (2012): 1003-1014.
6. Barr J, Fraser GL, Puntillo K, et al. American College of Critical Care Medicine. Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit. *Crit Care Med* 41 (2013): 263-306.
7. Sessler CN, Gosnell MS, Grap MJ, et al. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. *Am J Respir Crit Care Med* 166 (2002): 1338-1344.
8. Ely EW, Truman B, Shintani A, et al. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). *JAMA* 289 (2003): 2983-2991.
9. Vet NJ, Ista E, de Wildt SN, et al. Optimal sedation in pediatric intensive care patients: a systematic review. *Intensive Care Med* 39 (2013): 1524-1534.
10. Playfor S, Jenkins I, Boyles C, et al. United Kingdom Pediatric Intensive Care Society Sedation, Analgesia and Neuromuscular Blockade Working Group. Consensus guidelines on sedation and analgesia in critically ill children. *Intensive Care Med* 32 (2006): 1125-1136.
11. Girard TD, Kress JP, Fuchs BD, et al. Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomized controlled trial. *Lancet* 371 (2008): 126-134.
12. Robinson BR, Mueller EW, Henson K, et al. An analgesia-delirium-sedation protocol for critically ill trauma patients reduces ventilator days and hospital length of stay. *The Journal Trauma* 65 (2008): 517-526.
13. Nakatani A, Tazaki O, Yoshiya K, et al. Examination on reduction of incident rate after introduction of RASS. *Journal of the Japanese Society of Intensive Care Medicine* 24 (2017): 47-48.
14. Needham DM. Mobilizing patients in the intensive care unit: improving neuromuscular weakness and physical function. *The Journal of the American Medical Association* 300 (2008): 1685-1690.
15. Haraguchi M. Evaluation of the Validity of the Richmond Agitation Sedation Scale in Critically Illness Infants and Children: A Retrospective Cohort Study. *Integr J Nurs Med* 3 (2022): 1-4.
16. Ambuel B, Hamlett KW, Marx CM, et al. Assessing distress in pediatric intensive care environments: the COMFORT scale. *J Pediatr Psychol* 117 (1992): 95-109.
17. Hoshino H, Sakuramoto H, Matsuishi Y, et al. Development of the Japanese version of the State Behavioral Scale for critically ill children. *Acute Medicine & Surgery* 6 (2019): 101-108.
18. Kerson AG, DeMaria R, Mauer E, et al. Validity of the Richmond Agitation Sedation Scale (RASS) in critically ill children. *J Intensive Care* 4 (2016): 65.
19. Traube C, Silver G, Kearney J, et al. Cornell Assessment of Pediatric Delirium: a valid, rapid, observational tool

- for screening delirium in the PICU. *Crit Care Med* 42 (2014): 656–663.
20. Smith HAB, Boyd J, Fuchs DC, et al. Diagnosing delirium in critically ill children: validity and reliability of the pediatric confusion assessment method for the intensive care unit. *Crit Care Med* 39 (2011): 150–157.
 21. Kihlstrom M J, Ashley P, Edge AP, et al. Multi-modal Educational Curriculum to Improve Richmond Agitation-sedation Scale Inter-rater Reliability in Pediatric Patients. *Pediatric Quality & Safety* 3 (2018).
 22. Curley MA, Harris SK, Fraser KA, et al. State Behavioral Scale: a sedation assessment instrument for infants and young children supported on mechanical ventilation. *Pediatr Crit Care Med* 7 (2006): 107-114.
 23. Smith HAB, Gangopadhyay M, Goben CM, et al. Delirium and benzodiazepines associated with prolonged ICU stay in critically ill infants and young children. *Critical Care Medicine* 45 (2017): 1427-1435.