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Comparison of the Efficacy of Comfort Scale with State Behavioral Scale in Critically Ill Pediatrics Patients Under Mechanical Ventilation for Developing Sedation Protocol and Reducing Ventilator-Associated Pneumonia

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Abstract

Background: Proper sedation in ill children can enhance treatment outcomes, provide comfort, control pain, reduce delirium, and prevent self-extubation. This study aimed to compare the "Comfort Scale" with the "State Behavioral Scale" (SBS) in children under mechanical ventilation in the ICU to develop a sedation protocol.

Methods: This study assessed 50 children, ranging from one month to 15 years of age, who were hospitalized in the ICU of Mofid Hospital for over four months. The convenience sampling method was used to select participants, who were then divided into two groups of 25 each (one for the Comfort Scale and one for the SBS). Data were analyzed using SPSS version 20, with a P-value of less than 0.05, which is considered statistically significant.

Results: The mean age of the patients was 30.3 months (ranging from 1 to 150 months), with 19 female patients (38%) and 31 male patients (62%). The time taken for scoring by hospital staff was significantly shorter in the SBS group than in the Comfort Scale group ($P < 0.0001$). There were no significant differences between the two groups in terms of hospitalization duration and the amounts of benzodiazepines and opiates used ($P > 0.05$). Both tools were associated with a decrease in the length of hospitalization.

Conclusions: The findings suggest that the SBS requires less time to administer than the Comfort Scale and can be considered a rapid method. Utilizing both the SBS and Comfort Scale can reduce the length of hospital stays and, consequently, the incidence of ventilator-associated pneumonia.

Keywords: Comfort Scale, State Behavioral Score, PICU, Ventilator-Associated Pneumonia, Pneumonia, Pneumonia; Sedation

1. Background

Children in the ICU, facing ill health, encounter an unfamiliar and unpredictable environment filled with audible and painful stimuli, making them susceptible to sleep disorders and delirium (1). Proper sedation can significantly enhance treatment outcomes, ensure comfort, control pain and delirium, and prevent self-extubation, thereby potentially reducing the length of ICU hospitalization and decreasing the risk of hospital-acquired infections. Patients in intensive care are particularly vulnerable to nosocomial infections due to factors such as general bodily weakness, compromised immune systems, extended hospital stays, and, specifically, the use of tracheal tubes and mechanical ventilation (2). Pneumonia is notably the most common nosocomial infection reported in ICUs, affecting 27% of all patients (3-5). Dasgupta et al.'s study found that 62.1% of ICU infections were cases of pneumonia (6), with ventilator-associated pneumonia (VAP) occurring more

frequently than non-ventilator-associated pneumonia (3). Research also indicates that patients on mechanical ventilation face a 10 to 20 times higher risk of developing pneumonia than those not ventilated (7, 8). In developing countries, VAP incidence rates range from 20% to 41.7% (9), with the situation in Iranian ICU units potentially exacerbated by multi-drug resistant pathogens and less stringent infection control measures (10).

Over-sedation of a child can increase the risk of infection, prolonged admission, weaning failure, and higher rates of morbidity and mortality (11), underscoring the need for precise sedation assessment protocols in children. The well-known Comfort Scale and State Behavioral Scale (SBS) have been employed in clinical and randomized studies as criteria for selecting the most effective sedation level (12, 13). The Comfort Scale incorporates not only consciousness and physical movement standards but also physiological components like blood pressure and heart rate (12). Currently, these criteria are not applied in ICUs, with decisions often based on theoretical experience rather than standardized protocols. Optimizing sedation in children on mechanical ventilators is crucial for improving treatment outcomes and patient comfort, as well as for controlling pain (14). Sedation, according to the comfort scale, may be useful for children under mechanical ventilation (15). Exceeding sedation limits can lead to longer hospital stays and increased risks of infection, morbidity, and mortality. While adults have various protocols for sedation level assessment, precise control and complication prevention in sedated children have received less attention (16).

2. Objectives

The absence of suitable protocols in our pediatric ICU within the pediatric emergency department highlighted the necessity for this study. Thus, we aimed to compare the Comfort Scale with the SBS in mechanically ventilated children in the ICU, with the goal of developing a sedation protocol and reducing the incidence of ventilator-associated pneumonia.

3. Methods

This study focused on ill children, ranging from one month to 15 years of age, who were hospitalized in the ICU of Mofid Hospital for four months. The inclusion criteria specified patients under mechanical ventilation for more than 24 hours who were receiving sedation therapy. Exclusion criteria included death within the first 24 hours, the use of muscle relaxants (neuromuscular blocking drugs), and transfer to another ward. We employed the convenience sampling method to select participants, dividing them into two groups of 25 children each (one for the Comfort Scale and one for the SBS). After the study's objectives were explained, written informed consent was obtained from all parents.

In the first group, variables such as sedation, drug use, self-extubation, and scoring time were assessed using the Comfort Scale. In the second group, these variables were measured by the SBS, allowing for the selection of the most effective criteria. The relevant forms were included in the patient's files, and nurses received training on how to complete these forms accurately, reducing the likelihood of data entry errors. The Comfort Scale comprises eight items (with a score range of one to five points), including alertness, calmness, respiratory response or crying (for spontaneously breathing children), body movements, facial tension, and muscle tone. The SBS is graded according to motor activity evaluation, covering agitation, restlessness, calm and cooperation, response to sound or touch, response to painful stimulation, and lack of response, with scores ranging from -3 to 2 (3, 4).

3.1. Ethical Issues

This research adhered to the principles of the Declaration of Helsinki. The Ethics Committee of Shahid Beheshti University of Medical Sciences approved the study (IR.SBMU.RETECH.REC.1397.698).

3.2. Statistical Analysis

Data were analyzed using SPSS-20. Descriptive statistics such as mean, standard deviation, and frequency, alongside chi-square, independent *t*-test, and Mann-Whitney U test, were utilized to examine the study's results. The Kolmogorov-Smirnov test verified the normal distribution of variables. A significance level of $P < 0.05$ was established.

4. Results

In this study, the average age of the patients was 30.3 months, with a range from 1 to 150 months. The gender distribution included 19 female patients (38%) and 31 male patients (62%). The average duration of hospitalization, sedation scores, amounts of benzodiazepines (BZD) and opium used, and scoring times for all patients were 19.04 ± 12.94 days, 10.10 ± 12.56, 0.13 ± 0.05 mg/kg, 1.67 ± 0.74 mg/kg, and 5.19 ± 3.61 minutes, respectively (Table 1). Reasons for admission

varied, including pneumonia (n = 15), resistant seizure (n = 10), hernia (n = 2), myopathy (n = 2), infection (n = 2), diabetic ketoacidosis (DKA) (n = 1), emphysema (n = 1), hydrocephaly (n = 4), esophagus perforation (n = 2), nephritic syndrome (n = 4), craniosynostosis (n = 2), lowered consciousness (n = 3), and cardio-surgery (n = 2).

Table 1. Quantitative Variables of Patients Participating in the Study

Variables	Minimum	Maximum	Mean ± Standard Deviation
Hospitalization duration (day)	3.00	60.00	19.04 ± 12.94
Age (month)	1.00	150.00	30.30 ± 41.12
Amount of opium (mc/kg)	1.00	3.00	1.67 ± 0.74
Amount of benzodiazepines (mg/kg)	0.10	0.30	0.13 ± 0.05
Scoring time	1.00	10.00	5.19 ± 3.61

Table 2 presents a comparison between the two groups in terms of sedation score, scoring time, amounts of BZD and opium used, and the duration of hospitalization. It indicates that the sedation score was significantly lower in the SBS group compared to the Comfort Scale group ($P < 0.0001$). Additionally, the average time taken for scoring by hospital staff was significantly shorter in the SBS group than in the Comfort Scale group ($P < 0.0001$). There was no significant difference between the two groups regarding the duration of hospitalization and the amounts of BZD and opium used ($P > 0.05$).

Table 2. Comparison of Sedation Score, Scoring Time, Amount of Benzodiazepines and Opium, and Hospitalization Duration in the Two Groups

Variables and Groups	N	Mean ± Standard Deviation	P-Value
Scoring time			< 0.001 [a]
SBS	25	1.71 ± 0.38	
Comfort	25	8.68 ± 1.10	
Hospitalization duration			0.780 [b]
SBS	25	18.52 ± 13.08	
Comfort	25	19.56 ± 13.05	
Amount of opium			0.825 [b]
SBS	25	1.65 ± 0.74	
Comfort	25	1.70 ± 0.77	
Amount of benzodiazepines			0.974 [b]
SBS	25	0.13 ± 0.05	
Comfort	25	0.13 ± 0.06	

[a] Using Mann-Whitney U test.

[b] Using independent *t*-test.

Concerning the frequency distribution of opium or BZD use and incidents of self-extubation between the SBS and Comfort Scale groups, no significant differences were observed ($P > 0.05$) (Table 3).

Table 3. Frequency Distribution of Opium, Anesthetic Agent or Benzodiazepine Use and Self-extubation Between the Two Groups

Variables	Groups [a]		Statistic
	SBS	Comfort	
Opium use			$\chi^2 = 0.439$; P = 0.371
Yes	20 (80)	18 (72)	
No	5 (20)	7 (28)	
Benzodiazepine use			$\chi^2 = 1.087$; P = 0.305
Yes	22 (88)	24 (96)	
No	3 (12)	1 (4)	
Anesthetic agent use			$\chi^2 = 1.174$; P = 0.160
Yes	4 (16)	8 (32)	
No	21 (84)	17 (68)	
Self-extubation			$\chi^2 = 1.500$; P = 0.472
No	18 (72)	14 (56)	
One time	6 (24)	10 (40)	
Two times	1 (4)	1 (4)	

[a] Values are expressed as No. (%).

5. Discussion

Establishing appropriate sedation for children admitted to the ICU can enhance treatment outcomes, provide comfort, control pain and delirium, and prevent self-extubation, thereby indirectly decreasing the mortality rate among hospitalized children. There is a critical need for precise protocols to assess sedation levels in children. In clinical and randomized studies, the well-known Comfort Scale and the SBS are utilized to select the most effective criteria (1, 11-13). This study compared the Comfort Scale with the SBS in children under mechanical ventilation in the ICU to develop a sedation protocol. In summary, the majority of patients were male (62%), with various causes of admission including pneumonia, resistant seizure, hernia, myopathy, infection, DKA, emphysema, hydrocephaly, esophageal perforation, nephritic syndrome, craniosynostosis, low level of consciousness, and cardio-surgery. Regarding the sedation score, the SBS group had lower scores than the Comfort group. Additionally, the SBS required less time than the Comfort Scale and can be considered a rapid method. There was no significant difference between the two groups in terms of hospitalization duration and the amount of BZD and opium used. Notably, there was no significant difference between the two groups in the frequency of opium,

anesthetic agents, or BZDs, and self-extubation, indicating that the two groups were approximately identical.

In a study by Ista et al., focusing on the assessment of sedation levels in child patients using the Comfort "behavior" scale, results indicated that a Comfort-B score ≤ 10 suggests oversedation, while ≥ 23 indicates undersedation (17). In this study, 11% exhibited undersedation, and 3% exhibited oversedation. Similarly, Valkenburg et al. found that the Comfort-Behavior Scale (Comfort-B) and the face, legs, activity, cry, consolability (FLACC) scale were effective in evaluating pain and distress severity in children (18). The pain was concurrently scored using a Visual Analog Scale and the nurse interpretation of sedation (NIS) score, with FLACC scores obtained before and after administering analgesics. The Comfort-B scale proved to be more precise and reliable for measuring children's sedation levels than the FLACC scale. Clinical practice from this study suggests that COMFORT-B may enhance pain and sedation management in intubated children in the ICU. Furthermore, a study by Wensley et al. (19) conducted a thorough review of comfort, incorporating 14 theoretical and 48 qualitative studies. This review offered a new perspective on comfort as a highly personal and contextual experience influenced by different factors in different individuals, highlighting its multidimensional and dynamic nature (13, 19-22).

Recently, Hoshino et al., in 2019, developed a Japanese version of the SBS. Following tests for reliability and validity, the SBS proved effective for evaluating sedation levels in critically ill children (20). The study included 31 patients ranging from 0 weeks to 8 years of age. During validity testing, the SBS and Visual Analog Scale (VAS) scores given by nurses showed a strong correlation with the researcher's SBS scores and the researcher's Richmond Agitation-Sedation Scale scores. Additional validation by another researcher yielded consistent results with the SBS (13, 21, 22).

In terms of VAP, our observational findings suggest that both the SBS and Comfort Scale can contribute to shortening hospital stays in the post-anesthesia care unit, thereby reducing the incidence of VAP. This is in line with the findings of the Dasgupta et al. study, which identified pneumonia as accounting for 62.1% of infections in the ICU, mirroring our observations (6).

Jin et al. assessed the efficacy of the Comfort Scale for determining optimal sedation in children under mechanical ventilation. Utilizing the Seoul sedation protocol alongside the Comfort Scale, the intervention group, as opposed to the control group, experienced significant reductions in total use of sedatives and analgesics, duration of mechanical ventilation, and length of hospital stay. Thus, a Comfort Scale-based protocol may be considered for children on mechanical ventilators (14).

5.1. Conclusions

Our results indicate that the SBS requires less time to administer than the Comfort Scale, making it a quicker method. There was no notable difference between the SBS and Comfort Scale regarding the use of anesthetic agents. For protocol development, the SBS is a suitable choice due to its simplicity, efficiency, and lack of impact on heart rate and blood pressure. Employing the SBS and Comfort Scale can reduce hospitalization duration and, consequently, the risk of ventilator-assisted pneumonia.

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Footnotes

Authors' Contribution: It was not declared by the authors.

Conflict of Interests: The authors declared no conflicts of interest in this study.

Data Reproducibility: The dataset presented in the study is available on request from the corresponding author during submission or after publication.

Ethical Approval: The Ethics committee of Shahid Beheshti University of Medical Sciences approved this study (IR.SBMU.RETECH.REC.1397.698).

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Informed Consent: After explaining the objectives of the study, written informed consent was obtained from all parents.

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