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Development and Validation of a Fall Risk Assessment Scale for Hospitalized Children in Korea

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Purpose: This study aims to develop a pediatric fall risk assessment scale and examine its validity and reliability. **Methods:** The study was conducted in two phases. First, we developed a preliminary fall risk assessment scale based on a literature review and an evaluation by 10 expert panels. Second, we tested the validity and reliability of the scale through in a retrospective case-control study. The dataset included 102 reported falls and 306 non-falls in one hospital over approximately 9 years (2005~2014). We performed a conditional logistic regression analysis to determine significance and predictability and a receiver operating characteristic (ROC) curve analysis to test the validity of the scale's final version. **Results:** The pediatric fall risk assessment scale included five factors: age, level of consciousness, gait ability, medication, and use of equipment. The area under the curve of the ROC was .75 (95% Confidence Interval [CI]: .70~.80; $p<.001$) at the time of hospital admission and .76 (95% CI: .70~81; $p<.001$) within 24 hours of a fall. The scale had high inter-rater reliability, with kappa values ranging from 0.89 to 1.00. **Conclusion:** We developed a fall risk assessment scale with high reliability and validity through a systematic process by accurately predicting the risk of falls among pediatric inpatients to reduce fall incidence rates.

Key Words: Falls; Assessment scale; Children; Validity; Reliability

INTRODUCTION

Inpatient falls are among the most common adverse events observed in healthcare facilities [1]. The global incidence rate of falls in hospitalized children ranges from 0.51 to 1.0 per 1,000 hospital days [2], which is lower than the rate in Korea alone at 0.63 to 2.45 per 1,000 hospital days [3]. Falls cause various injuries, ranging from minor soft tissue injuries to fractures, dislocations, brain injuries, and life-threatening physical injuries [4], which result in an increased hospital stay duration and medical costs [5,6]. Particularly, pediatric patients are considered at a high risk of falls owing to developmental characteristics such as immature physical coordination, curiosity, and impulsivity [7,8]. Moreover, children are less able to react in the moment when falling by relying on surrounding devices or protecting their own bodies, which can be devastating [7]. An analysis of the patient safety reporting system in the United Kingdom revealed that 30% of child safety accidents have resulted in critical consequences including permanent functional disability or death [9]. Therefore, it is critical to identify the risk factors for falls in pediatric inpatients and proactively intervene to prevent incidents.

Several personal, environmental, and systemic factors have been reported to influence the incidence of falls in pediatric patients [10]. Some studies have reported that preexisting medical conditions, medications, and unfamiliar environments may increase the risk by decreasing the child's perception and understanding of the surrounding setting [2,11]. Other studies have identified child mobility, impaired mental status, and an increased duration of hospital stay as risk factors for falls in hospitals [2,12,13]. Notably, most falls occur in boys between the age of 1 and

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5 years [14] and most probably occur in the presence of a parent [12,15] as children feel more comfortable and active with the presence of a family member [16,17]. However, the association between a history of falls and the risk of falls has been inconsistent [2].

Thus, assessment tools to predict the fall risk of hospitalized children have been developed, including the change in mental status, history of falls, age < 36 m, mobility impairment, parental involvement, and safety (CHAMPS) system [13], I'm SAFE [18], Humpty Dumpty Fall Scale (HDFS) [11], General Risk Assessment for Pediatric Inpatient Falls (GRAF-PIF) [12], and Little Schmidy [1]. These scales comprise from four to seven items, including diagnosis, drug use, and cognitive ability. Other items used to assess fall risk include age, sex, and response to surgery in HDFS; duration of hospital stay and physical therapy in GRAF-PIF; and sedation, anesthesia, fall history, and environment in I'm SAFE (comprehensive patient fall-risk assessment tool). The medicine categories included in each scale differ according to the drug used, the diagnosis timing, and disease category [1,7,11,12]. Given the differences in the assessment items and criteria between the scales, it is necessary to determine which items and criteria can most accurately predict the fall risk in inpatients. In addition, patient safety policies and regulations, hospital environment, and patient characteristics may vary from a country to another and should be considered while developing and testing fall risk assessment scales.

Several previous studies have consistently reported insufficient evidence on the validity and reliability of the fall assessment scales for pediatric inpatients [19-22]. Moreover, a systematic literature review of pediatric fall prevention programs revealed the limited use of pediatric fall assessment scales and indicated the necessity to develop a reliable scale [7], and a meta-analysis of diagnostic test accuracy, including nine studies on pediatric fall risk assessment scales, revealed a high sensitivity (0.79) and a low specificity (0.36; [23]); therefore, it is crucial to develop a scale that can concurrently improve sensitivity and specificity and to evaluate its effectiveness in a clinical setting. Therefore, this study aims to develop a valid and reliable systematic scale to assess the risk of falls in children.

METHODS

This study was conducted in two phases: 1) the development of a fall risk assessment scale, and 2) the modification and validation of the developed scale.

1. Phase 1: Development of a Preliminary Fall Risk Assessment Scale for Hospitalized Children

First, we reviewed the literature to determine risk factors associated with falls in pediatric inpatients. We searched using the terms "falls, child, hospital, and inpatient" to search for articles without publication date limitations. The search was conducted from October 13th to 29th, 2014. PubMed, CINAHL, and Google Scholar were used as international databases, and DBpia, Korean Studies Information Service System, Research Information Service System, and National Digital Science Library were used as Korean databases. The definition, specific criteria, and scoring method for each risk factor were then detailed based on the results of the literature review and were modified by experts with experience in pediatric care and risk management (Supplementary Table 1).

Second, we constructed initial pediatric fall risk assessment items based on the identified risk factors. They (n=11) were grouped into three categories: general factors, including age and history of falls; physical/behavioral factors, including level of consciousness, gait ability, sensory deficits, and activity status; and clinical factors, including medication, physical and occupational therapy, equipment, surgery, and anesthesia. Each of the ten items except for age, was scored with 1 or 2, and age was scored from 1 to 3. The total score for all the 11 items ranged from 11 to 23.

Third, the content validity of the preliminary items was evaluated by a 10-member expert panel comprising two pediatricians, two pediatric nursing professors, four nurses with more than 10 years of experience of working in a pediatric unit, and two hospital risk managers. The materials, including an overall introduction to the tool, items, definitions, and scoring methods, were provided. Each expert evaluated the relevance of the preliminary items. Content Validity Index (CVI) scoring was performed to rate each item using a 4-Likert scale (1: irrelevant; 2: somewhat relevant; 3: quite relevant; and 4: highly relevant) [24]. Item-level CVI (I-CVI) was calculated as the proportion of all the "quite relevant" and "highly relevant" ratings divided by the number of respondents. Items with an I-CVI score of ≥ 0.78 were considered as valid content [25]. "Physical and occupational therapy" and "anesthesia and sedation" items with a CVI score of < 0.78 were excluded from the assessment scale. Four out of the ten medications: diuretics, muscle relaxants, nootropics, neurotics, and other central nervous system drugs, were removed from the medication list that increased the risk of falls because their CVI score was .70 (Supplementary Table 2). In addition,

each item was revised to reflect additional expert opinions regarding ambiguous assessment criteria, explanations prone to misinterpretation, and practical applicability. Thus, a preliminary 9-item scale was developed based on the overall review opinions of the expert panel.

2. Phase 2: Modification and Verification of the Fall Risk Assessment Scale for Hospitalized Children

1) Design

This retrospective case-control study was designed to test the validity and reliability of a fall risk assessment scale for pediatric inpatients.

2) Participants

The data of pediatric inpatients aged <19 years who had been hospitalized and discharged from a tertiary hospital in Gyeonggi-do between May 1, 2005, and November 19, 2014 were collected to determine the validity and reliability of the developed preliminary scale. During this period, the hospital's risk management system was established, and data on falls were collected. The case group included 102 pediatric inpatients who had fallen as reported to the hospital's risk management system during the data collection period. The control group included patients admitted to the same unit in the same year as of the case group and were matched at a ratio of 1:3 based on sex and hospital stay duration in days. Moreover, the matching criteria used in this study (hospital ward, sex, hospitalization year, and duration of stay) were used to enroll controls in other case-control studies on pediatric inpatient falls. Based on these criteria, 306 controls were randomly selected from a target population of 17,787. In addition, the 1:3 matching ratio was applied because the power of the study increased as the ratio of the cases to controls increased; however, when the ratio exceeded 1:4, the power became small [26]. Therefore, 408 pediatric inpatients (102 patients and 306 controls) were included in the assessment.

3) Data collection

The researchers extracted the data from the entire EMR and Order Communication System for this retrospective study covering the participants' hospitalization period. To reduce the variance between researchers, two researchers who were familiar with the hospital's medical records system, comprehensively understand each survey item, and had > 3 years of experience in risk management in the hospital, extracted the data independently after thoroughly familiarizing themselves with each indicator's definition, assessment standards, and scoring systems. A history of falls was obtained from the appropriate items in the nursing information records. Data on the level of consciousness was obtained from the nursing information records, nursing notes, and progress notes. If no record of the level of consciousness during this period was found, it was assessed based on the last record of consciousness among the previous records. Gait ability was assessed through reviewing information in the developmental status section of the nursing information records, physician's developmental status assessment reports, and the gait ability section of the hospital's patient safety assessment record. If no record of gait ability within 24 h of the fall was found, it was assessed based on the last record before the stipulated period. Data on sensory deficits were collected from the nursing information records, physician admission notes, progress notes, and medical diagnoses. Activity status was assessed based on the "emotional state" item in the nursing information records and the "cooperation assessment" item in the progress notes. Furthermore, we reviewed the contents of the nursing and progress notes. Clinical factors were assessed through reviewing physicians' orders, progress notes, and nursing notes.

Regarding the case group, medical records were reviewed upon admission and within 24 h of the fall, whereas for the control group, medical records were reviewed upon admission and during the same hospitalization period of collecting data on the paired case participants. Only the first fall event was included in this analysis if two or more falls occurred during the hospital stay.

3. Statistical Analysis

The general and clinical characteristics of the participants were summarized using descriptive statistics. A conditional logistic regression analysis was performed to determine the significance and predictability of fall risk for each indicator in the preliminary scale. To validate the final version of the scale, a receiver operating characteristic (ROC) curve analysis was performed to calculate the area under the curve (AUC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). The optimal cutoff value was set based on the inflection point, where the sensitivity almost matched the specificity. Sensitivity is the proportion of individuals who experienced fall events among the population and were classified as the high-risk group, whereas specificity is the proportion of individuals who did not experience fall events among the population and were classified as the low-risk group. PPV refers to the proportion of chil-

dren classified as the high-risk group among pediatric inpatients who experienced a fall, whereas NPV refers to the proportion of children classified as the low-risk group among pediatric inpatients who did not experience a fall [27]. The reliability of the scale developed in this study was tested by calculating inter-rater reliability using the kappa coefficient of agreement. The data collected in this study were analyzed using the PASW 26.0 program (IBM Co., Armonk, NY, USA).

4. Ethical Considerations

The study protocol was approved by the Institutional Review Board (IRB) of the hospital where the data collection was conducted (AS 13144). The IRB reviewed the study protocol, including the research purpose, methods, and data collection process. The requirement of an informed consent was waived by the IRB because no personally identifiable information was included, and data were only collected from medical records. All personal information was anonymized for privacy protection; the collected data were only used for research purposes and were consequently destroyed upon study completion.

RESULTS

1. Development of a Preliminary Fall Risk Assessment Scale for Hospitalized Children

Based on the literature and expert panel reviews, we developed a preliminary fall risk assessment scale for hospitalized children comprising 10 items and 3 categories (Table 1).

The first category, general factors, comprised two items: age and fall history. Participants were assigned 1, 2, or 3 points if they were aged >6, ≥3 to <6, and <3 years, respectively. Children who had experienced a fall (2 points) were considered to be at a higher risk than that of those who had not (1 point).

The second category, physical and behavioral factors, comprised four items: level of consciousness, gait ability, sensory deficits, and activity status. The level of conscious-

Table 1. Preliminary Pediatric Fall Risk Assessment Scale for Hospitalized Children

Factors	Variables	Categories	Score
General factors	Age (year)	<3	3
		3~<6	2
		≥6	1
	History of falls	Yes	2
		No	1
Physical and behavioral factors	Level of consciousness	Confusion, delirium, drowsy, lethargy	2
		alert, stupor, coma	1
	Gait ability	Developmental stage; after walking	
		- Independent gait, immobility	1
		- Impaired gait, uses of ambulatory aids	2
		Developmental stage; before walking	
		- Immobility	1
		- Over rolling, crawling, standing, holding	2
	Sensory deficit	Vision or hearing impairment	2
		No	1
	Activity status	Hyperactivity, attention deficit, irritability, agitation	2
		None of the above	1
Clinical factors	Diagnosis	Musculoskeletal, neurological, psycho, and behavioral disorders	2
		Not applicable to the above diagnosis	1
	Medication (within 24 h)	Hypnotics and sedative, anticonvulsants and antiseizure, anxiolytics, anesthetics, antipsychotics, and antidepressants	2
		None of the above drugs	1
	Equipment	Yes	1
		No	2

ness item was divided into two groups based on children's ability to communicate verbally. Children who could communicate verbally were classified into seven consciousness state groups (alert, lethargy, confusion, delirium, drowsiness, stupor, and coma); confusion, delirium, drowsiness, and lethargy states were assigned 2 points (high risk), and stupor, coma, and alert states were assigned 1 point (low risk). Those unable to communicate verbally, such as newborns and infants, were classified according to their specific behavioral and response characteristics, i.e., the high-risk group for falls (2 points) comprised those with a history of persistent inappropriate crying, irritability, restlessness, agitation, delayed response to stimuli, or constant sleepiness (obtained from medical records). An adequate response to stimuli or unconsciousness was associated with a lower risk of falling; therefore, we assigned them a score of 1. Gait ability was assessed according to the walking status at the developmental stage. For children unable to walk at the developmental level, a score of 2 was assigned to children who crawled, held, stood, or rolled over, and a score of 1 was assigned to immobile children. If children could walk at the developmental level, 2 points were assigned if they had a gait disorder or used a walker. Regarding the sensory deficit item, children with visual or hearing impairments were considered at a high risk of falling (2 points). Regarding the activity status item, 2 points (high risk) were assigned if hyperactivity, attention deficit, irritability, or restlessness were detected in the medical records.

Finally, clinical factors included diagnosis, medications, equipment, anesthesia, and sedation therapy. Patients with diagnoses related to musculoskeletal, neurological, psychological, or behavioral disorders were considered at a high risk (2 points). Patients who used any of the following six types of medications (hypnotics and sedatives, anticonvulsants and antiepileptics, anxiolytics, anesthesia, antipsychotics, or antidepressants), anesthesia, or sedation therapy were considered at a higher risk (2 points) than that of those who did not (1 point). The use of equipment (e.g., urinary catheters, intravenous lines, restraints, or oxygen therapy equipment) was associated with a lower risk of falls (1 point) as it limited the child's movement and increased the caregiver's attention.

2. Modification and vErification of the fall Risk Assessment Scale for Hospitalized Children

1) General characteristics

Table 2 presents the general characteristics of the participants. The case and control groups comprised more males (60.8%) than females (39.2%). Children aged <3 and ≥3 to <6 years accounted for 81.4%(n=83) and 15.7% (n=16) in the case group and 63.1%(n=190) and 20.9% (n=64) in the control group. The mean duration of hospital

Table 2. General Characteristics of Participants (*N*=408)

Variables	Categories	Cases group (n=102)	Control group (n=306)
		n (%) or M±SD	n (%) or M±SD
Sex	Male	62 (60.8)	186 (60.8)
	Female	40 (39.2)	120 (39.2)
Age (year)	<3	83 (81.4)	190 (62.1)
	3~<6	16 (15.7)	64 (20.9)
	≥6	3 (2.9)	52 (17.0)
Length of stay		5.41±2.55	5.41±2.56
History of falls	Yes	2 (2.0)	9 (2.9)
	No	100 (98.0)	297 (97.1)
Level of consciousness	Alert, stupor, coma	97 (95.1)	302 (98.7)
	Drowsy, lethargy	0 (0.0)	3 (1.0)
Department	Confusion, delirium	5 (4.9)	1 (0.3)
	Pediatrics	91 (89.2)	273 (89.2)
	Neurosurgery	5 (4.9)	15 (4.9)
	Orthopedics	2 (2.0)	6 (2.0)
	Otorhinolaryngology and ophthalmology	2 (2.0)	6 (2.0)
	Obstetrics	2 (2.0)	6 (2.0)

M=Mean; SD=Standard deviation.

Table 3. Results of the Conditional Logistic Regression Analysis for Fall-related Risk Factors

Variables	At the time of hospitalization			Within 24 h prior to the fall event		
	Odds ratio	95% CI	*p*	Odds ratio	95% CI	*p*
1st model						
Age (year)			.034			.014
3~<6	14.59*	1.85~114.70	.011	26.63	2.67~265.73	.005
<3	3.27†	1.10~9.65	.032	2.75	0.80~9.41	.107
History of falls	0.73	0.11~4.65	.737	0.63	0.07~5.94	.684
Level of consciousness	9.31	2.82~30.74	<.001	8.98	1.73~46.47	.009
Gait ability	5.48	2.81~10.71	<.001	10.88	5.12~23.11	<.001
Sensory deficit	8.26	0.68~100.11	.097	3.71	0.36~38.41	.272
Activity status	0.72	0.02~20.40	.846	3.98	0.32~48.82	.280
Diagnosis	0.56	0.16~1.91	.355	0.45	0.15~1.34	.149
Medication (within 24 h)	7.10	1.35~37.19	.020	19.80	2.59~151.21	.004
Equipment	69.39	1.44~3,334.47	.032	13.62	2.10~88.43	.006
Final model						
Age (year)			.047			.023
3~<6	7.31	1.38~38.79	.019	12.59	2.05~77.39	.006
<3	2.56	1.04~6.34	.042	2.30	0.86~6.14	.097
Level of consciousness	8.70	2.68~28.20	<.001	7.26	1.56~33.71	.011
Gait ability	5.15	2.71~9.80	<.001	9.42	4.65~19.09	<.001
Medication (within 24 h)	2.11	0.72~6.14	.171	3.53	1.22~10.22	.020
Equipment	30.88	2.09~455.45	.012	13.66	2.26~82.63	.004

*Compared to those aged six years; †Compared to those aged 3~<6 years; CI=Confidence interval.

stay was 5.41±2.55 days. Two (2.0%) and nine (2.9%) children among the case and control groups, respectively, were categorized as having had a fall (falling within 1 m before hospitalization). The level of consciousness was mostly "alert" in both groups, and most of the children (89.2%) were admitted to the pediatric ward.

2) Modification of the pediatric fall risk assessment scale

A conditional logistic regression analysis was conducted to determine the predictive factors of fall risk in pediatric inpatients, which is one of the assessment items in the preliminary scale. Consequently, 5 out of the 10 items: age, consciousness level, gait ability, medication, and presence/absence of equipment, were confirmed as fall risk factors in pediatric inpatients (Table 3). The fall risk for pediatric inpatients aged 3 to <6 years was higher than that for those aged ≥6 years: 7.31-fold (95% Confidence Interval [CI]: 1.38~38.79; p=.042) at the time of hospitalization and 12.59-fold (95% CI: 2.05~77.39; p=.006) within 24 h of the fall. Regarding pediatric inpatients aged <3 years, the fall risk was 2.56-fold higher at the time of hospitalization (95% CI: 1.04~6.34; p=.042) and 2.30-fold higher within 24 h of the fall (95% CI: 0.86~6.14; p=.097) than that of those aged 3 to < 6 years; however, the difference within 24 h of the fall was not statistically significant. Regarding the level of consciousness, those who were in a state of confusion, experienced drowsiness, or were lethargic were at a higher risk of falling than that of those in a state of alertness, stupor, or coma: 8.70 (95% CI: 1.46~32.82; p<.001) at the time of hospitalization and 7.26 (95% CI: 1.56~33.71; p=.011) within 24 h of fall. Regarding gait ability, the fall risk of those lacking ambulatory ability, i.e., those walking with ambulatory aids or those still in the developmental stage of rolling over, crawling, standing by holding on to furniture, or walking with support, was 5.16-fold higher (95% CI: 2.71~9.80; p<.001) at the time of hospitalization and 9.42-fold higher (95% CI: 4.65~19.09; p<.001) within 24 h of a fall than that of those capable of independent gait or those in the stage of immobility. The fall risk in pediatric inpatients under medication, receiving at least one of the

Table 4. Final Version of Pediatric Fall Risk Assessment Scale

Items	Criteria	Score
Age (year)	- ≥6	1
	- 3~<6	2
	- <3	3
Level of consciousness	Communicative competence; possible	
	- Alert, stupor, coma	1
	- Confusion, delirium, drowsy, lethargy	2
	Communicative competence; impossible	1
	- Age-appropriate response to stimuli, unconscious state, and no response	
	- Persistent inappropriate crying, irritability, restless, and agitated, delayed response to stimulus, and constantly sleepy	2
Gait ability	Developmental stage; after walking	
	- Independent gait, immobility	1
	- Impaired gait, uses of ambulatory aids	2
	Developmental stage; before walking	
	- Immobility	1
	- Over rolling, crawling, standing, holding	2
Medication (within 24 h)	- Use of others medication or none	1
	- Use of the following medications: hypnotics and sedatives, anticonvulsants and antiseizure, anxiolytics, anesthetics, antipsychotics, antidepressants	2
Equipment	- Use of the following equipment: urinary catheter, intravenous line, restraint, oxygen therapy device, hemovac, tube, etc.	1
	- None	2
Total score	Highest score	11
	Lowest score	5

six drug categories, was 2.11-fold higher at the time of hospitalization, but without statistical significance, and 3.53-fold higher (95% CI: 1.22~10.22; p=.020) within 24 h of fall than that of those who did not receive medication. Lastly, pediatric inpatients who did not require any equipment, such as an intravenous line, nasal cannula, or urinary catheter, were at a higher risk of falls than that of those who required; 30.88-fold (95% CI: 2.09~455.45; p=.012) at the time of hospitalization and 13.66-fold (95% CI: 2.26~82.64; p=.004) within 24 h of fall.

Based on the above results, five items (age, level of consciousness, gait ability, medication, and equipment) were included in the final version of the fall risk assessment scale for pediatric inpatients (Table 4). The total score ranged from 5 to 11 points.

3) Validity of the final version of the assessment scale

The AUC of the ROC used for evaluating the overall validity of the proposed scale was .75 (95% CI: .70~.80; p<.001) at the time of hospitalization and .76 (95% CI: .70~81; p<.001) within 24 h of the fall (Figure 1). The discriminant power was established for both items because the values exceeded .7. Based on the sensitivity, specificity, and accuracy while varying the cutoff points, the optimal discriminability was identified at 8 points. Therefore, classifying pediatric inpatients with a total score of ≥8 as the risk group had the highest predictive power.

Table 5 shows the sensitivity, specificity, PPV, and NPV at each time point, depending on the occurrence or absence of a fall, through applying the cutoff point of eight to the fall risk classification. The sensitivity, specificity, PPV, and NPV at the time of hospitalization and within 24 h of the fall were 62.7%, 79.1%, 50.0%, and 86.4% and 65.7%, 81.0%, 43.2%, and 98.0%, respectively.

4) Reliability of the final version of the assessment scale

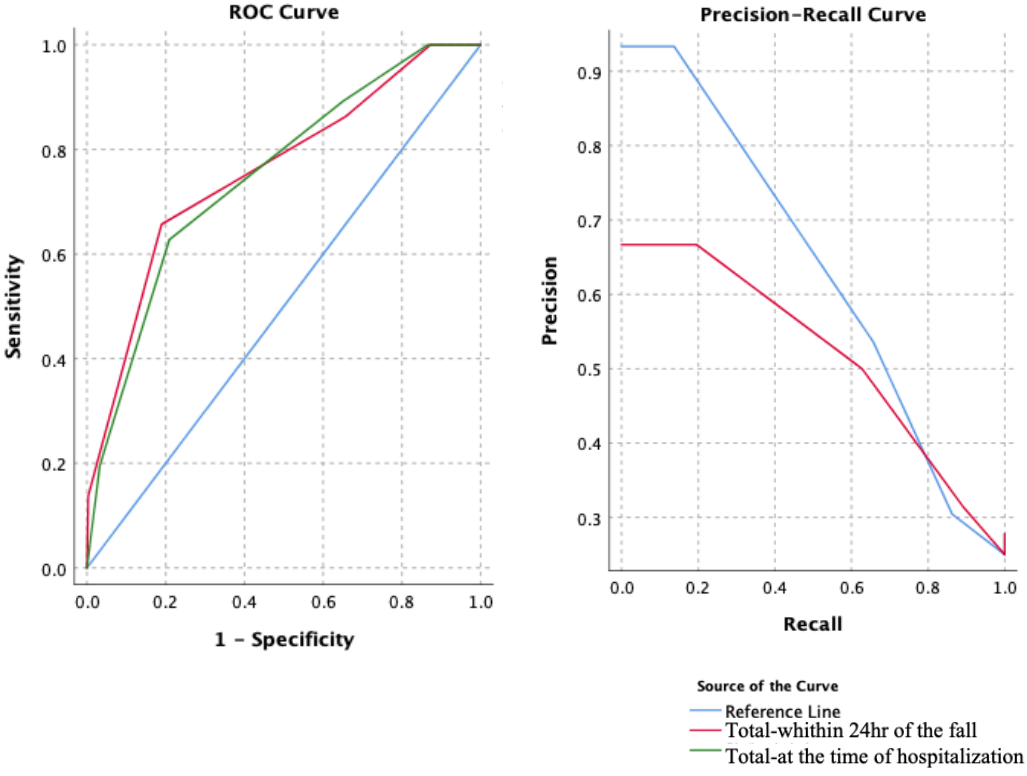
Two evaluators independently reviewed the participants' medical records during the same period to test the inter-rater reliability, and the independent results were compared. The comparison revealed high inter-rater reliability of the assessments conducted during hospitalization, with kappa values ranging from .89 to 1.00 for all the five assessment items. Within 24 h of the fall, kappa values ranged from .80 to 1.00 for all the five assessment items.

Additionally, when the analysis was established based on the total score for all the items through applying the cutoff point of eight, those with <8 and ≥8 points were classified into borderline and risk groups, respectively, and the kappa values at the time of hospitalization and within 24 h of the fall were .93 and .98, respectively.

DISCUSSION

In this study, a fall risk assessment scale was developed to accurately predict fall risk in pediatric inpatients, and its validity and reliability were verified. It included five factors: age, level of consciousness, gait ability, medication, and use of equipment, and it showed high validity and reliability.

First, age was classified into three categories: <3 years, 3~6 years, and 6 or older, which were assigned 3, 2, and 1 points, respectively, because younger children have a higher risk of fall incidence as identified in the HDFS and CHAMPS scoring systems [11,13], with the highest score assigned to children aged <3 year; in Little Schmidy, the highest score is assigned to children aged <5 years [1]. This finding is consistent with the findings of other studies that have shown that falls in pediatric inpatients are most common in those aged ≤35 m [28] or ≤24 m [29]. However, children aged <3 years, classified as the highest fall risk group, scored higher on the fall risk assessment upon admission than those aged 3~6 years; however, the results



AUC=area under the curve; ROC=receiver operating characteristic.

Figure 1. AUC-ROC values at the time of hospitalization and within 24 h of the fall.

Table 5. Validity of the Pediatric Fall Risk Assessment Scale

Variables	Cut-off point	Fall		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Yes (n=102)	No (n=306)				
At the time of hospitalization	≥8	64	64	62.7	79.1	50.0	86.4
	<8	38	242				
Within 24 h of the fall	≥8	67	58	65.7	81.9	43.2	98.0
	<8	35	248				

NPV=Negative predictive value; PPV=Positive predictive value.

obtained within 24 h were not statistically significant. In addition, while patients aged <3 years in this study had the highest fall incidence rate of 86.4%, a recent study reported that fall risk was the highest in children aged 3~6 years [19]. In a meta-analysis of pediatric fall scales, Kim et al.(2019) proposed a review of the HDFS scoring system, which assigned the highest score to children aged <3 years, given that children aged 3~5 years showed the highest fall incidence rate [20]. The age range and distribution of participants might explain the differences in these results. Most of the participants in the validation of the tool developed in this study aged <3 years (81.4%). Additionally, this study included data from 2005 to 2014; therefore, hospital environment might have changed throughout the years. Therefore, further validation of the critical age for an increased fall risk is necessary.

The assessment criteria for the level of consciousness were based on whether communication was possible. When communication was possible, the states of confusion, delirium, drowsiness, and lethargy were associated with a higher risk of falling than that in the states of alertness, stupor, and coma. When communication was impaired, pediatric inpatients with persistent inappropriate crying, irritability, restlessness and agitation, delayed response to stimuli, and persistent sleepiness had a higher incidence of falls than that of those with an age-appropriate response to stimuli or those in an unconscious state. These findings are consistent with the findings of previous studies that have reported a high incidence of falls in pediatric patients with cognitive abilities significantly lower than these of age-matched children or of children with hypersensitivity reactions, such as anxiety, agitation, and fear, and a lower fall risk in children with age-appropriate reactions or immobility with little voluntary movements, such as those detected in an unconscious state [1,11,12]. These states of consciousness are influenced by several factors such as underlying medical conditions, unfamiliar environments, and current conditions [30]. Furthermore, significant fall-related injuries, such as skull fractures and intracranial hemorrhages [31], may further compromise a child's level of consciousness and require careful assessment.

In the item "gait ability," children using ambulatory aids or experiencing gait impairment were considered at a high risk. Moreover, before reaching the walking developmental stage, infants capable of rolling over, crawling, and standing by holding onto furniture were considered at a high risk. These results were consistent with those of the HDFS, CHAMPS, and Little Schmidy, which assessed fall risk based on the use of ambulatory aids [1,11,13]. These are similar to the assessment criteria in other studies that included orthostatic hypotension (I'M SAFE) or physical disability (PFRA) as risk factors for falls [18,22]. However, the current study presented assessment criteria in two mobility categories of developmental stages (after and before walking), given the fall risk, even for those unable to walk, based on their movements in bed. Therefore, this study is significant as it reduces ambiguity in clinical application and enables an accurate assessment of fall risk for each developmental stage.

Regarding medications, the use of any of the six types of drugs: hypnotics and sedatives, anticonvulsants and antiseizure drugs, anxiolytics, anesthetics, antipsychotics, or antidepressants, was identified as a significant risk factor for falls among pediatric inpatients. While most of the previous studies used the same inclusion criteria of medication use among fall risk factors, the specific types of medications vary from a study to another [12,13,18,32]. In particular, some scales include antihypertensives, laxatives and diuretics, or hypoglycemics, which are not included in the proposed scale [1,13,32,33]. These differences may depend on considering the effects of each medication on children and the extent to which it is used. Thus, further studies are required to clarify these discrepancies. The HDFS assigns scores based on a different criterion, the number of co-medications: 3 points for two or more dangerous co-medications, 2 points for one drug type, and 1 point for no medication [11]. In addition, some scales assess surgery or anesthesia as a risk factor, apart from drug use [11,18,32]. However, since fall risk does not depend on the performance of the surgery itself, but on the effects of the intraoperative use of agents, such as anesthetics or sedatives, surgery was excluded from the proposed scale to avoid overlapping with the drug use indicator. However, it is necessary to determine which indicator is more important, surgery or medication use.

Regarding the use of devices that limit the mobility of pediatric patients, such as urinary catheters, intravenous lines, restraints, oxygen therapy, and drainage bags, children who did not use these devices had a higher fall risk than that of those who did. This finding is consistent with the findings of a study by Cho et al. (2013), which revealed an increased incidence of fall in instances where no intravenous line was used [28]. Similarly, the GRAF-PIF scale assesses the absence of an intravenous line or heparin lock as a risk factor for falls [12]. In contrast, some studies have evaluated the use of these devices as factors that increase the fall risk (I'M SAFE and PFAS;[32]). In addition, the widely used HDFS and CHAMPS do not assess the use of equipment as a predictor of fall risk [11,13]. These discrep-

ancies might be owing to the aspect of equipment use that each study focuses on; studies that considered that equipment use is not a risk factor may have depended on the fact that equipment use reduces child mobility and increases caregiver attention. However, other studies have emphasized the harmful effects of the devices, rather than the mobility reduction. Thus, future studies using clinical data are required to address these conflicting issues.

Finally, the proposed scale comprised five items, each with kappa coefficients ranging from .89 to 1.00. In addition, the AUC-ROC values, calculated to assess the overall validity of the scale at the time of hospitalization (.75) and within 24 h of the fall (.76), exceeded the cutoff point of .7 and were higher than the .65 point [23], as reported in a meta-analysis of existing pediatric fall scales. Considering that AUC-ROC values ranging between .7 and .9 generally indicate moderate diagnostic accuracy while those of ≥ 0.9 indicate high diagnostic accuracy, the diagnostic accuracy of the proposed scale is considered reasonable [34]. Furthermore, its sensitivity was 62.7% at the time of hospitalization and 65.7% within 24 h of the fall, with a specificity of 79.1% at the time of hospitalization and 81.9% within 24 h of the fall. Compared with the sensitivity (61~79%) and specificity (24~58%) of the existing scales [1,11,35,36], higher specificity and similar sensitivity were observed in the proposed scale. Because the goal of a fall risk assessment scale is to accurately screen high-risk groups to reduce the fall incidence rate by selection and concentration, further analysis is required to enhance sensitivity.

In summary, this study systematically developed a fall risk assessment scale with high validity and reliability for pediatric inpatients. As the five items of the scale were only core factors, it can be used more efficiently and conveniently in clinical practice. Special care was taken to enhance the accuracy by providing concrete criteria that were differentially applicable to young children's developmental stages. This study helps in providing a safer and healthier environment for pediatric inpatients by early screening high-risk groups for falls in each clinical setting and carrying on fall prevention interventions. Based on the results of this study, future research is required to develop effective fall prevention programs for children with a high fall risk. In addition, a study investigating the characteristics and causes of fall incidence in low-risk groups of children may help improve the accuracy of the scale. Finally, the finding that the fall risk assessment score within 24 h of a fall had a greater predictive power than that at the time of hospitalization emphasizes the need for regular assessment of fall risk. Thus, a follow-up study is needed to determine the optimal fall risk assessment cycle and appropriate reassessment intervals.

Despite the strengths mentioned above, this study had three limitations. First, because the data were collected from pediatric inpatients at one university hospital in one region, caution is warranted when generalizing the results to other regions or clinical settings. To enhance the generalizability of the results, it is necessary to conduct follow-up studies in hospitals in different areas to test the stability of the scale or in many different types of healthcare facilities to compare its reliability and validity. Second, because of the retrospective nature of the study which used participants' medical records, the records for the assessment items were not clearly described in some cases; thus, the scores were estimated by combining multiple records. Therefore, the validity of the tool might have been overestimated depending on the fidelity of the medical records. In addition, we were unable to investigate primary caregiver factors reported to be associated with the occurrence of falls in pediatric inpatients [37]. Future studies are required to investigate and analyze the effects of caregiver-related factors, such as the absence of a caregiver or the caregiver's perception of a fall event. Third, we tested the validity and reliability of the proposed scale; however, we did not directly compare and analyze its relation to the existing scales. A follow-up study should be conducted to examine the efficacy and accuracy of the proposed scale by directly comparing its results with those of widely used scales.

CONCLUSION

The assessment of fall risk in pediatric inpatients is a core nursing care strategy and a basis of preventive nursing interventions to safeguard patients' health and safety. In this study, we developed a fall risk assessment scale with high reliability and validity through a systematic process to reduce fall incidence rates by accurately predicting the risk of falls among pediatric inpatients. Using this scale allows more accurate screening of high-fall-risk groups in clinical settings, thus preventing injuries and losses to the hospital owing to unexpected incidents. Moreover, these findings provide important baseline data for developing efficient intervention programs to reduce the risk of falls in pediatric inpatients. Finally, it is necessary to compare the validity and reliability of the existing tools to identify more effective and accurate tools and to explore caregiver-related factors that increase the risk of falls.

CONFLICTS OF INTEREST

The authors declared no conflict of interest.

AUTHORSHIP

Study conception and design acquisition - PY and JS; Data collection - PY and JS; Analysis and interpretation of the data - PY and JS; Drafting and critical revision of the manuscript - PY and JS.

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Supplementary Table 1. Description of the Initial Items of the Fall Risk Assessment Scale for Hospitalized Children

Risk factor	Criteria	Score	Definition
Age (year)	< 3 3~< 6 ≥ 6	3 2 1	1. Age of the patient at the time of assessment 2. Childhood classification 1) Neonate: Birth~1 month 2) Infant: 1 month to 1 year old 3) Toddler: 1 to 3 years old 4) Preschool: 3~6 years old 5) School: 6 to 12 years 6) Adolescent: 12~18 years old [Reference: 1, 2, 3, 4, 5, 6, 7]
History of fall (within a month)	Yes No	2 1	• A history of falling within one month of the assessment, regardless of where it occurred, including home, playground, preschool, hospital, etc. • A fall is defined as an unplanned descent to the floor, either with or without injury (American Nurses Associations National Database of Nursing Quality Indicators) [Reference: 8, 11] [Previous Fall Risk Assessment Tools: GRAF_PIF, HDFS, CHAMPS, Cummings PFAS, I'M SAFE]
Level of consciousness	Confusion, delirium Drowsy, lethargy Alert, obtundation, stupor, coma	3 2 1	1. Consciousness is the state of being awake and able to appropriately perceive external stimuli in response to oneself and one's environment. It is determined by comprehensively considering the child's eye-opening, verbal, and motor responses at the assessment. 2. Level of consciousness 1) Alert: Awake or readily aroused; oriented, fully aware of external and internal stimuli and responds appropriately; conducts meaningful interpersonal interactions. 2) Lethargic: Not fully alert; drifts off to sleep when not stimulated; can be aroused to name when called in normal voice but looks drowsy; responds appropriately to questions or commands but thinking seems slow and fuzzy; inattentive; loses train of thought; spontaneous movements are decreased. 3) Confusion: typically indicates a state of disorientation, cognitive impairment, or mental fogginess. They may exhibit behaviors such as restlessness, agitation, incoherent speech, or impaired judgment. 4) Delirium: Clouding of consciousness (dulled cognition, impaired alertness); inattentive; incoherent conversation; impaired recent memory and confabulatory for recent events; often agitated and having visual hallucinations; disoriented, with confusion worse at night when environmental stimuli are decreased. 5) Obtunded: Sleeps most of time; difficult to arouse—needs loud shout or vigorous shake; acts confused when is aroused; converses in monosyllables; speech may be mumbled and incoherent; requires constant stimulation for even marginal cooperation. 6) Stupor: Spontaneously unconscious; responds only to persistent and vigorous shake or pain; has appropriate motor response (i.e., withdraws hand to avoid pain); otherwise, can only groan, mumble, or move restlessly; reflex activity persists. 7) Coma: Completely unconscious; no response to pain or any external or internal stimuli (e.g., when suctioned, does not try to push the catheter away); light coma has some reflex activity but no purposeful movement; deep coma has no motor response. [Reference: 8, 9, 10, 11, 19] [Previous Fall Risk Assessment Tools: HDFS, CHAMPS, Cummings PFAS]
Gait ability	1. Developmental stage; ambulatory - Independent gait, immobility - Impaired gait, uses of ambulatory aids 2. Developmental stage; before walking - Immobility - Over rolling, crawling, standing, holding	 1 2 1 2	1. Ambulatory: a condition in which a person can normally walk independently without assistance according to their developmental stage and has no limitations in their ability to balance, etc. 1) Using a walking aid; currently requires assistance with a wheelchair, crutches, cane, walker, etc., due to physical or mental problems. 2) Immobilized; unable to move around voluntarily 2. Unable to walk; unable to walk independently due to developmental stage 1) Standing with a device or holding, walking with assistance; depending on the stage of motor development, the child can move on their own using hands, knees, stomach, etc. (9~10 months), stand while holding onto objects such as furniture and walls around them (12 months), or walk with the help of objects or people around them (12~13 months). 2) Immobilized; unable to move voluntarily [Reference: 8, 12, 13, 14, 18] [Previous Fall Risk Assessment Tools: HDFS, CHAMPS, Cummings PFAS]
Sensory (vision or hearing) Impairment	Yes No	2 1	1. Visual impairment: Includes blindness with a corrected visual acuity of 0.05 or less or low vision with a corrected visual acuity of 0.04 to 0.3, in which the person cannot read normal-sized print in a book. However, they can perform basic activities of daily living as comfortably as possible. 2. Hearing impairment: A situation in which a person cannot hear the sound or understand the meaning of the sound due to an abnormality of the auditory transmission system, resulting in an obstacle to communication [Previous Fall Risk Assessment Tools: CNMC, Cummings PRAS]
Activity status hyperactivity, attention deficit, irritability, agitation	Yes No	2 1	• Hyperactivity/attention deficit: Inappropriately distracted (inattention), impulsive (impulsivity), and hyperactive (hyperactivity) for developmental level. Behavioral characteristics include hyperactivity such as a lot of movement or activity, "pacing back and forth," "inability to concentrate on task," and "difficulty controlling behavior (difficulty carrying out instructions from caregivers or nurses)" • Often unable to maintain attention on one thing, easily distracted by external stimuli, and unable to listen to others • Easily agitated, impulsive, cries frequently and easily, and has mood swings • Cannot sit still and is constantly active or acts as if something is chasing them; excessive running or climbing in inappropriate situations. [Reference: 7, 11, 14, 15, 16] [Previous Fall Risk Assessment Tools: Cummings PFAS]

Supplementary Table 1. Description of the Initial items of the Fall Risk Assessment Scale for Hospitalized Children (Continued)

Risk factor	Criteria	Score	Definition
Diagnosis	Yes No	2 1	• Orthopedic (Musculoskeletal) disorder • Neurologic disorder • Psycho & Behavioral disorder [Reference: 1, 11, 17] [Previous Fall Risk Assessment Tools: HDFS, I'M SAFE]
Medication (within 24 h)	Yes No	2 1	Hypnotics & Sedative; Anticonvulsants & Antiseizure; Antipsychotics; Antidepressants; Anxiolytics; Diuretics; Anaesthetics-Local & General; Muscle Relaxants; Nootropics & Neurotronic; Other CNS Drugs & Agents for ADHD [Reference: 1, 7, 11, 14] [Previous Fall Risk Assessment Tools: HDFS, I'M SAFE, Cummings PFAS]
Physical/ occupational therapy	Yes No	2 1	Patients scheduled to receive the following treatments: • Pediatric therapy: Vojta (for children with cerebral palsy) • Sling therapy: Exercise, Manual Therapy, Traction Therapy • Exercise therapy: Complex Decongestive Physical, EST, Exercise, FES Therapy, Gait Training, Manual Muscle Test, Mat exercise, NDT • Occupational Therapy: ADL training, Simple/Complex/Specialized therapy • Includes bedside exercises. [Reference: 11, 12] [Previous Fall Risk Assessment Tools: GRAF PIF, I'M SAFE
Equipment	Yes No	2 1	• Foley catheter (Urinary catheter etc.) I • V, Heparin locking, Chemo port, PICC • Restraint • Oxygen Therapy (Tracheostomy, Intubation, Ventilator, Mask, Nasal cannula) • Hemovac, Chest tube etc. [Reference: 7, 11, 17] [Previous Fall Risk Assessment Tools: GRAF PIF, Cummings PFAS, I'M SAFE
Anesthesia/ sedation (within 24 h)	Yes No	2 1	• General Anesthesia • Minimal Sedation, Anxiolysis • Moderate Sedation • Deep Sedation [Reference: 18] [Previous Fall Risk Assessment Tools: HDFS, I'M SAFE, CNMC]

[Previous Fall Risk Assessment Tools]

1. (GRAF-PIF) General Risk Assessment for Pediatric Inpatient Falls Scale (Graf 2005)
2. (CHAMPS) CHAMPS Pediatric Fall Risk Assessment Tool (Razmus et al. 2006),
3. (Cummings PFAS) Cummings Paediatric Fall Assessment Scale (Cum-mings 2006)
4. (HDFS) Humpty Dumpty Falls Risk Assessment Scale (Wood et al. 2006),
5. I'M SAFE (Neiman 2009) of The Children's Hospital Denver
6. (CNMC) Children's National Medical Center's instrument (CNMC, 2005)

[Reference]

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Supplementary Table 2. CVI of Initial Items for the Pediatric Fall Risk Assessment Scale

Categories	Items	Criteria (score)	CVI
General factors	Age (year)	<3 (3) 3~<6 (2) ≥6 (1)	1.00
	History of falls (within a month)	Yes (2) No (1)	1.00
Physical and behavioral factors	Level of consciousness	Confusion, delirium, drowsy, lethargy (2) alert, stupor, coma (1)	.90
	Gait ability	Developmental stage; after walking - Independent gait, immobility (1) - Impaired gait, uses of ambulatory aids (2) Developmental stage; before walking - Immobility (1) - Over rolling, crawling, standing, holding (2)	.90
	Sensory deficit	Vision or hearing impairment (2) No (1)	1.00
	Activity status	Hyperactivity, attention deficit, irritability, agitation (2) None of the above (1)	.90
Clinical factors	Diagnosis	Musculoskeletal, neurological, psycho, and behavioral disorders (2) Not applicable to the above diagnosis (1)	1.00 1.00 1.00
	Medication (within 24 h)	Hypnotics and sedative, anticonvulsants and antiseizure, anxiolytics, anesthetics Antipsychotics, antidepressants, diuretics* Muscle relaxants*, nootropics, and neurotics* Other CNS drugs* (2) None of the above drugs (1)	1.00 .90 .70 .70 .70
	Physical/occupational therapy*	Yes (2), No (1)	.70
	Equipment	Yes (1), No (2)	1.00
	Anesthesia/sedation (within 24 h)	Yes (2), No (1)	.70

*Excluded items; CVI=Content validity index; CNS=Central nervous system.