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A new tool for assessing the risk of fall in children with severe disability: development of the ALICE scale

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Key words: Fall, tool, disability, children
Parole chiave: Cadute, scale di valutazione, disabilità, bambini

Abstract

Introduction. *It is known in the literature that the main cause of physical impairment in children with severe disabilities is falling, which can worsen their already compromised condition. There are no specific scales for this population in the literature, neither in Italian nor in other languages. We created and validated a scale for assessing the risk of falling in children with severe disabilities.*
Study design. *Observational prospective study.*
Methods. *We enrolled children (inpatients or day-hospital) admitted to the "Santa Maria Bambina Centre" of the "Fondazione Onlus Sacra Famiglia" in Cesano Boscone, Milan; the Content Validity Index of the Scale was calculated to assess the content validity of a new scale (ALICE). Cronbach's alpha coefficient (α) was used to examine internal consistency, Spearman's rho coefficient to test inter-rater reliability. Sensitivity, specificity, positive and negative predictive values were calculated.*
Results. *Out of 48 patients enrolled, 14 fell (29.2%). The ALICE scale, with cut-off set at 16, showed a sensitivity of 100%, a specificity of 88.2%, a positive predictive value of 77.8% and a negative predictive value of 100%. The Content Validity Index of the Scale (=0.93), inter-rater reliability (rho=0.91, p<0.001) and Cronbach's alpha (=0.72) were satisfactory.*
Conclusions. *The ALICE scale seems reliable and valid in the disabled population and can be applied by nurses. Further studies with larger samples and a multicentre design are needed.*

Introduction

Disability is defined as a long-term reduction in the ability to carry out normal activities, due to the presence of a physical or mental impairment. Disability includes neurological, cognitive and motor deficits (1). There are approximately 200 million children living with disabilities, 10% of the world's population. Despite the lack of data, the incidence of injuries in children with disabilities, regardless of the degree

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of severity, is 10.2%, which is significantly higher than in children without disabilities, 4.4%, and increases to 11.2% in the presence of multiple disabilities (2).

The main cause of injury in children with severe disabilities are falls (3). Falls can have important repercussions on these patients, worsening their already compromised clinical condition, increasing the time spent in hospital and increasing the costs for the hospital hosting them. There is a growing need to address injury prevention and improve safety standards for this group; in particular, it is very important to prevent falls in this population, as the injuries sustained can be very serious (4-6).

Falls in hospital are relevant adverse events, due to their frequency and potential consequences (7, 8); their incidence varies between 10 and 17 per 1,000 patient/bed/day, with physical consequences in 30% of cases (9); however, to date, no information is available on children with disabilities (10). Nursing assessment, as a central part of broader prevention policies, is oriented towards identifying patients at risk of falling, and consequently implementing effective preventive strategies (11).

The Joint Commission on Accreditation for Health Care Organisations (JCAHO) (12) recommends the use of a standardized and validated fall risk assessment tool to prevent patient falls; despite this, there are no validated fall risk assessment tools suitable for this population category in the literature, either in Italian or in other languages. A correct assessment of this risk would make it possible to reduce the incidence of this phenomenon and to prevent the onset of complications, even serious ones, that could further compromise and aggravate the health status of this type of patients and increase the length of stay in the ward, as well as the costs for the hospital structure. It would therefore be desirable to produce and validate a suitable and appropriate fall risk assessment tool for children with severe disabilities, admitted to or residing in long-term care facilities.

The aim of this study is to create a new tool by adapting an existing fall risk assessment scale (the Edmonson Psychiatric Fall Risk Assessment Tool – EFRAT) to the needs of this population. The EFRAT in the validation study (13) showed adequate psychometric properties in the assessment of fall risk in the acutely ill psychiatric population, and was taken into consideration because it presents assessment elements that can be associated not only with the adult psychiatric population, but also with this type of patients, who, in most cases, manifest significant cognitive-behavioural problems.

Methods

Study setting and sample characteristics

A prospective, single-center, observational study was conducted to investigate the validity and reliability of a new fall risk assessment tool. The study was carried out at the "Santa Maria Bambina Centre" of the "Fondazione Onlus Sacra Famiglia" in Cesano Boscone, Milan, from 15 September to 15 October 2017. We enrolled a convenience sample of 48 patients aged 4 to 17 years (Mean=11 [8-14]) with a medical diagnosis of intellectual disability in their health records, admitted to long term care and those attending the Day Centre of the institute. These age discrepancies actually correspond to situations of cognitive impairment that are overall comparable, also in terms of comorbidity, for the purposes of falls risk. This hypothesis is supported by the fact that all patients are housed in a single ward. Moreover, even in the construction of the scale, it was decided to consider the clinical variables that contribute to the definition of the developmental age, rather than the anagraphic age, that in these patients does not have the same clinical relevance

that it has in non-disabled subjects. It was therefore decided to proceed to an overall analysis, without dividing the sample by age. From the point of view of diagnosis, all 48 subjects had a severe intellectual disability.

All falls that occurred during hospitalization were recorded.

The scale

The instrument (called ALICE) was built on the basis of the Edmonson Fall Risk Assessment Tools, whose items were adapted to the clinical condition and the peculiarities of this category of patients. Furthermore, it is easy to use and the administration time is very short (<5 minutes). The instrument was created by adapting the Edmonson scale to the needs and peculiarities of these patients. This scale was chosen as the starting point for the creation of a new fall risk scale for children with severe disabilities, because it contains many assessment parameters that can also be used for this population. Subsequently, a further literature review was carried out, through the same databases, on the general clinical conditions of children with severe disabilities, which may be more relevant for the risk of falling, in order to adequately establish the parameters to consider in the scale.

Initially a literature review was conducted through PubMed, to search for material on the risk of falls in children with severe disabilities and to check for the presence of a scale for the assessment of this risk already validated in Italian or other languages. In order to carry out this research, a MesH string was constructed for childhood disability and risk factors for falls in this population: ((“Accidental falls”[Mesh]) AND “Risk factors”[Mesh]) AND “Disabled children”[Mesh]). In addition to PubMed, other databases were consulted, such as CINAHL and Cochrane Library, thus confirming the inexistence of specific fall risk assessment scales for the paediatric population with severe disabilities, neither in Italian nor in other languages.

The scale we created includes eleven items: basic diagnosis, mental status, physical status, epilepsy, falls (3-6 months before), gait/balance, bowel/urinary elimination, sleep disorders, intake of benzodiazepines and/or hypnotic sedatives, intake of antiepileptics, intake of atypical antipsychotics (Table 1). The scores of the new scale have a theoretical range between 0 and 35, based on the sum of the minimum and maximum scores for each item.

Dividing the range from 0 to 35 into four theoretical quartiles, 14 patients had a score in the first quartile, 15 between the first and the median, 8 between the median and the third quartile and 11 between the third and the highest score. 14 patients fell (29.2%), all at one time during the hospitalizations; all had a score of ≥16 (calculated by adding up the scores of each item). In view of the problems presented by these patients, all subjects are potentially at risk of falling, so the cut-offs effectively serve to distinguish between residents at low/medium and high risk of falling. This is the reason why the maximum likelyhood was chosen. Based on the reasoning described above, it was considered correct to identify low/medium risk patients with scores <16. Within this range, no patients fell or presented near misses. From 16 points onwards, the patient is considered to be at high risk.

The ALICE scores obtained by the examined patients ranged from 3 to 27, with a median of 15, IQR [12;17].

The scale was administered to 6 nurses with >5 years of experience in the center of the study in order to assess its content validity; the nurses were asked to evaluate the relevance of each item by assigning a score ranging from 0 (“not at all relevant”) to 10 (“very relevant”); this allowed the calculation of the Content Validity Index of each item (CVI-I) and the Content Validity

Table 1 - The Tool ALICE

Items	Score
Diagnosis	0 = Moderate intellectual disability 2 = Medium intellectual disability 3 = Severe intellectual disability
Mental health	0 = Spatial and temporal orientation 2 = Episodic mental confusion/Mild cognitive impairment/Slight psychomotor agitation 3 = Severe mental confusion/Spatial and temporal disorientation/Severe psychomotor agitation/ Cognitive and judgment impairment
Physical health	0 = Healthy, wellbeing 2 = Weakness/asthenia 3 = Dizziness /Hortostatic hypotension/Weight loss (>5 kg in the last 3 months)/Obesity
Epilepsy	0 = None 2 = 1 episode/month 3 = More than 1 episode/month
Previous fall/near fall (3 Months)	0 = None 2 = Yes, one episode 4 = Yes, more than one
Walk/Step/Balance	0 = Postural stability/ walking without help, step activities 2 = Walking with aids (crutch, walker...) or assistance 4 = Gait and balance impairment, gait instability/Non compliances, wheelchair
Elimination	0 = None 1 = Use of diuretics and/or laxatives 3 = Impaired elimination (nicturia, urge incontinence, diarrhea)
Sleep disorders	0=None 1 = Already present 3 = New onset
Benzodiazepine/ Sedatives/ Hypnotics	0 = None 2 = Started before hospitalization 3 = New prescription/dosage
Anti-epileptics	0 = None 2 = Started before hospitalization 3 = New prescription/dosage
Anti-psychotics	0 = None 2 = Started before hospitalization 3= New prescription/dosage

Index of the scale as a whole (CVI-S); in agreement with the international literature, values of CVI-I ≥ 0.80 and values of CVI-S ≥ 90 were considered acceptable (14). The scale was administered separately by two advanced practice nurses (>10 years of experience in this setting), to 15 patients to enable inter-rater reliability to be assessed. Before the start of the study, all nurses at the centre involved underwent a training session by the creators of the instrument, to learn how to carry out the assessment).

Predictive properties of the new scale were compared with those of the Conley scale, a widely used tool for assessing the risk of falling for general inpatients; this

scale is a widely used tool for assessing the risk of falling for general inpatients and consists of three sections with six items in all. The total score of the tool ranges from 0 to 10 and a score of 2 or higher identifies patients at risk.

Statistical analysis

Descriptive statistics were used to summarize patient characteristics. Spearman's rho coefficient was calculated to assess interval-rater reliability; internal consistency was assessed by measuring Cronbach's Alpha coefficient. Sensitivity, specificity, positive predictive value and negative predictive value, as well as the area under the ROC curve were then calculated to identify a cut-off.

The cut-off was chosen considering the highest possible level of sensitivity, since the main purpose of this screening tool is to correctly identify the subjects at higher risk of falling; however, after having also calculated the corresponding sensitivity value, the maximum Youden's J statistic (J=sensitivity+specificity−1) was used to confirm the best possible combination of sensitivity and specificity.

The statistical significance threshold was set at 5%. All calculations were performed with SAS® University Edition software (SAS Inc., Cary, USA).

Ethics

This study was conducted in accordance with the principles of the Declaration of Helsinki and complied with the Italian law on data protection. Authorization to conduct the study was requested by the nursing director of the "Fondazione Sacra Famiglia Onlus" in Cesano Boscone and the nursing coordinator of the "Santa Maria Bambina O.U." of the same facility. The rules established by the local ethics committee were followed.

Results

Psycometric properties

All 11 items showed a CVI-I >0.80, the CVI-S of the ALICE scale was 0.93. The scores given by the two experienced nurses showed a strong correlation (rho=0.91, p=0.009). The value of Cronbach's alpha coefficient was 0.72, indicating acceptable internal consistency.

All 14 patients fell within 10 days of assessment.

Using the data collected through the study and the application of the two scales on the sample, preliminary calculations of sensitivity, specificity, positive predictive value and negative predictive value were made.

Conley Scores

The Conley scale identified all patients (n=48) as "at risk", as they all had a picture of cognitive disability. The scale achieved a sensitivity of 100% (all 14 fallen patients were classified as at risk), a specificity and negative predictive value of 0% and a positive predictive value of 29.2%.

ALICE Scores

To perform calculations of sensitivity, specificity, positive and negative predictive value, the initial cut-off was 16, which is the minimum score obtained by patients who had a fall during the observation period. The sensitivity was thus 100%, since all patients who fell belong to the population at high risk of falling, having obtained a score greater than or equal to the cut-off; the negative predictive value was also 100%, since none of the patients considered by the scale as not at risk of falling actually fell. 14 out of 16 children found to be at high risk fell (PPV=77.78%). On the other hand, the specificity was 88.23% (30 out of 34 patients who did not fall were found to have a "low/medium risk score for falls"). The maximum value of the *Youden index* is 1 (perfect test)

and the minimum is 0, when the test has no diagnostic value. At the set cut-off (=16), the Youden index of the tool was 0.88.

Subgroup analysis

Since the sample chosen for the investigation was clinically very heterogeneous, a new analysis was carried out, considering only patients with similar clinical characteristics, in detail we considered only patients who were able to walk. In this way the data of 17 children were used and the results of specificity, sensitivity, positive predictive value and negative predictive value were produced again. In this subgroup, 9 children fell. The sensitivity was always 100% for the reasons given in the previous case; the same applies to the negative predictive value. On the other hand, in this case, the specificity was 87.5%, since only 1 patient of those who did not fall had a high risk, and the positive predictive value was also 90.0% (9 out of 10 patients at risk then fell). On the basis of the results obtained, the ROC curve was constructed, which describes the result obtained from the scale in terms of the relationship between sensitivity and specificity, as shown in figure 1.

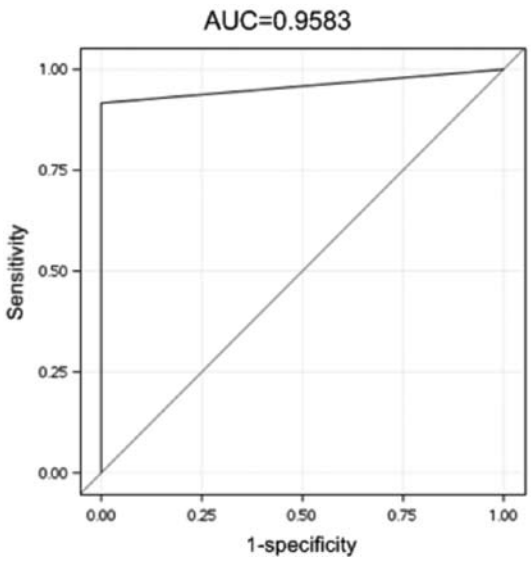

Figure 1 - Confidence interval of the AUC.

The scale used to detect the risk of falling in these patients obtained a value of 0.96, 95% IC = [0.94 - 0.99], which is a very good result; furthermore, when only patients who were able to walk we.

Discussion

The problem of falls has been widely studied and the literature shows that falls lead to increased disability and hospitalisation. The JCAHO pays great attention to the issue of patient safety and "reducing the risk of patient harm due to falls" is among its six stated objetives. One of the "bold" requirements (written in bold in the manual and considered indispensable) for JCAHO certification is to "assess and reassess the patient's risk, including the potential risk associated with the drug regimen being taken, and also to take steps to reduce or eliminate any identified risk". This point underlines the importance of always using validated tools in clinical practice also for fall risk assessment. In children with intellectual disabilities, falls are a frequent event and lead to a further worsening of their clinical picture, with repercussions on their quality of life (15-17); however, to date there is no detailed information on this phenomenon with regard to children with severe disabilities. The 14 falls observed during our study period confirm the frequency and therefore the importance of this event, moreover in this context. The aim of this study was to create and validate an effective fall risk assessment tool for these children based on an existing scale. The instrument we created gave more than satisfactory results, not only from a statistical point of view, but also from a clinical point of view. Furthermore, the construction of the instrument included a modification of the items of the starting scale on the basis of the clinical conditions of these children, such as epilepsy, spastic tetraparesis,

taking antiepileptic drugs; the values of the single scores were also modified, giving prominence to the most frequent clinical events that can be considered risk factors. From a practical point of view, considering the characteristics of these patients, it is not possible to establish the classic cut-off to determine the presence and absence of the risk of falling; in fact, given the great clinical variability of the sample, it is more useful to stratify the risk by distinguishing patients at high risk of falling from those at medium risk. This consideration was done because these patients would always be considered to be at risk of falling (as described by the results of the Conley scale), due to their extremely compromised clinical condition and the presence of a moderate or profound intellectual disability, which significantly limits their ability to act and modify their surroundings to their own advantage. We conducted a separate analysis considering only patients who are able to walk independently, with a stable and unstable gait; in this way; this and the result obtained on the entire sample can be considered very good at the current cutoff set at 16 in terms of sensitivity, specificity, positive predictive value and negative predictive value, with no significant differences.

This study has some limitations: the small number of these cases suggests that the preedictivity of the ALICE should be checked on a larger scale; furthermore, the scale has limitations, the main one being, as already mentioned, the influence of the clinical variability of the sample, which makes it necessary to categorize the patients on the basis of their clinical characteristics, in order to carry out a correct statistical analysis. In reality, this is not a problem of the scale, but of a clinical characteristic of the patients, which, however, must be taken into account if the practical usefulness of this instrument is to be maximized during the validation phase. As a limitation of this study, we only tested the scale in one centre; it would therefore be desirable to investigate falls in other clinical care settings.

The scale is only a small step towards lowering the incidence of the fall event. Nurses have an important role in prevention, contributing to the promotion of improved care safety and participating in clinical risk management activities and monitoring of adverse events such as falls in every clinical setting. The development of a screening tool, such as the ALICE that we proposed in our study, represents the first step to be included within any management pathway of children with intellectual disabilities.

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CRediT author statement
Stefano Terzoni: Methodology, Software, Writing- Reviewing and Editing; **Anne Destrebecq***:* Supervision; **Letizia Cristina Bianchi**: Visualization, Investigation, Validation; **Alessandra Di Bari:** Software, Conceptualization; **Paolo Ferrara**: Data curation, Writing- Original draft preparation.

Riassunto

Un nuovo strumento per la valutazione del rischio di cadere nel bambino affetto da disabilità severa: creazione della Scala ALICE

Premessa. È noto in letteratura che la principale causa di danno fisico nei bambini con disabilità severa è la caduta, che può peggiorare una condizione clinica già compromessa. Ad oggi Non esistono scale di valutazione specifiche per questa popolazione, né in italiano, né in altre lingue. L'obiettivo di questo studio è stato quello di creare e validare una scala per la valutazione del rischio di caduta nei bambini con grave disabilità.

Disegno dello studio. E' stato condotto uno studio prospettico osservazionale.

Metodi. Sono stati arruolati bambini (ricoverati o assistiti in regime di Day Hospital) ricoverati presso il centro dell'U.O. Santa Maria Bambina della Fondazione Onlus Sacra Famiglia di Cesano Boscone, Milano; il Content

Validity Index of the Scale è stato calcolato per valutare la validità di contenuto di una nuova scala (ALICE). Il coefficiente alfa (α) di Cronbach è stato utilizzato per esaminare la consistenza interna, il coefficiente rho di Spearman per verificare l'affidabilità inter valutatore. Sensibilità, specificità, valore predittivo positivo e negativo sono stati calcolati per indagare le proprietà predittivite dello strumento.

Risultati. Sono stati arruolati 48 pazienti; durante il periodo di osservazione 14 sono caduti (29.2%). La scala ALICE, con cut-off fissato a 16 ha mostrato una sensibilità del 100%, una specificità dell'88.2%, un valore predittivo positivo del 77.8% e un valore predittivo negativo del 100%. I punteggi di Content Validity Index of the Scale (0.93), l'affidabilità intervalutatore (rho=0.91, p<0.001) e alpha di Cronbach (0.72) sono risultati soddisfacenti.

Conclusioni. La scala ALICE si è dimostrata uno strumento valido ed affidabile a support della valutazione infermieristica del rischio di cadere nella popolazione pediatrica disabile. Ulteriori studi multicientrici e su campioni più ampi sono necessari.

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