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Pressure Ulcers in Hospitalized Children: Prospective Observational Study and Italian Linguistic and Cultural Validation of the Glamorgan Pediatric Pressure Ulcer Risk Assessment Scale

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Abstract

***Background**: Pressure Ulcers (PU) in hospitals are a major problem, including in pediatric settings. Knowledge of the epidemiology and risk factors of PUs is important, as is the use of a specific tool for the assessment of PU risk, which would allow the identification of subjects at risk. No Pediatric PU Risk Assessment Scales are currently validated in Italian. The goals of this study were: to perform the linguistic and cultural validation of the Glamorgan Pediatric Pressure Ulcer Risk Assessment Scale (GS) in Italian, to estimate its predictive performance and to estimate the frequency of PUs of hospitalized children.*

***Methods:** The study consists of two steps. First, linguistic and cultural validation of the GS in Italian. Second, evaluation of the Italian GS's performance on 1500 hospitalized children and estimate of PU frequency in hospitalized children.*

***Results**: The Italian version of the scale (GS-ita) has satisfactory validity (SCVI=0.93) and inter-rater reliability (Cohen's kappa=0.95). The second step is ongoing. So far 1212 subjects have been recruited. Preliminary analysis shows a frequency of PUs in hospitalized children of 5.8 ‰ (CI 95% 2.5–11.4). Based on the subjects recruited so far, the sensitivity of the GS-ita is 100% (CI95% 59 to 100) and the specificity is 44.5% (CI95% 41.6 to 47.3)*

***Conclusions:** Based on preliminary data, the performance of GS-ita is similar to those of the original English version. The frequency of PUs estimated on the basis of preliminary data is consistent with previous studies. Italian speaking pediatric nurses have now a novel tool to evaluate the risk of PUs in children and, consequently, to better prevent the onset of PUs. The study will continue until 1500 patients are recruited*

Keywords: *Pressure Ulcers, children, risk assessment scales, pediatric hospitals, risk management.*

Background

A pressure ulcer *(PU)* is defined as alocalized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear (1). PUs are a relevant problem in healthcare because they are associated with higher mortality and morbidity and determine an increase in health care costs (2).

While the scientific literature is rich of studies on prevention and treatment of PUs in adults, the problem of PUs in children has received less interest.

There are several aspects that differentiate the child

from the adult and that therefore determine different risk profiles and the need for a different approach to the problem of PUs. In newborns and infants the skin is thinner and has less hair; the stratum corneum is less developed and there is less cohesion between the dermis and the; the child produces less sweat and less sebaceous secretions; in the newborns the skin pH is neutral (3,4); Furthermore, in children, the proportions between the parts of the body are different: the head bears more pressure than the rest of the body and the heaviest part of the body is represented by the upper districts. Even the reduced voluntary mobility of children is a characteristic that affects the risk of PU more than in adults (3, 5).

The areas of the body which are most affected by PUs in children are the occiput, especially in newborns and infants, ears, nose, the points where medical deviceslay on skin (up to 19%) (3, 6, 7). The PUs located in the lower parts of the body are about 15% of the total (mainly heels and sacro-coccygeal area) (6). Other data show a 31% of PU on the head, 20% on the gluteal area, 19 % on the feet (7).

Available epidemiological studies show that the phenomenon of PU among children is far from negligible. A 2009 study on hospitalized children up to age 11 identified 65% of them as at risk of developing PU(8).

The prevalence of PUs in hospitalized children reported by available studies is variable: some studies report high prevalences, from 131 to 277 ‰ although for the most part they were PU category 1 PUs according to the NPUAP / EPUAP guidelines (3, 4, 9).

A recent study regarding patients aged 0 to 18 years hospitalized in the United States showed PU prevalence rates of 14‰ and of hospital-acquired pressure injuries of 11‰. Higher prevalences were found among patients in pediatric intensive care units (37‰) and pediatric rehabilitation (46‰), while in general pediatric units there was a lower prevalence (5.7‰) (10).

In a 2018 epidemiological study the prevalence of pressure ulcers was 17.2‰. A higher prevalence was observed in children younger than 3 years (28.9‰) and in particular children at age 1 year (47.7‰)(11).

Regarding the annual incidence of new PUs, values ranging from 4% to 18% have been reported among children in intensive care units (9, 12).

For an effective prevention of PUs it is necessary for healthcare professionals to have reliable, validated PUs risk assessment scales (1, 13). There are many scales for assessing the risk of PU in adults but the research has given little attention to similar tools for children. The Pediatric PU risk assessment scales (PPURAS) that have undergone a rigorous validation process are of two types: those derived from adult scales and those originally developed for children. The first group includes Braden Q (9), Braden Q Modified (12), Starkid Skin Scale (14), Neonatal Skin risk assessment scale-NSRAS (15) and PPUPET (16); in the second group there is the Glamorgan Pediatric Pressure Ulcer Risk Assessment Scale (GS) (17). The GS can be used on children of all ages; it has an excellent sensitivity (93.4%), a good specificity (50.2%) and a 0.912 ROC's area under the curve. Eleven variables are considered in the GS; the higher the score awarded for each variable, the higher is the risk. The final score, obtained summing up the scores of each variable, classifies the child in one of four risk categories (<10 = non-risk,> 10 ≤ 15 = risk,> 15 ≤ 20 = high risk,> 20 = very high risk)(18, 19).

Aim

In order to be used effectively in healthcare systems other than the original one, a risk assessment tool must be validated for each different linguistic and cultural context. The purpose of this study was therefore to carry out the linguistic and cultural validation of the GS in Italian, and to estimate its predictive performance.

Material and Methods

The study consists of two steps. The first step consisted of the forward-backward translation of the GS into Italian. The translated version was then analyzed in terms of validity and reliability, resulting in the validated linguistic-cultural Italian version of the GS, called GS-ita. This step was completed,

The second step is ongoing and it consists in a prospective observational study on a large population of hospitalized children. In this step, we record the PU that actually occurr in the observed population, also collecting biometrical and clinical data of the subjects, and measuring the risk for PUs using the GS-ita. This will allow us to estimate the GS-ita's predictive performance and to compare it with the original GS. The frequency of new PUs in hospitalized children

will be also estimated. Finally, we will analyze the biometrical and clinical data obtained during the observational study to estimate the association of the former with the PU onset.

The study was set up on request of and in collaboration with the Tuscan Healthcare System's Clinical Risk Center.

Methods of Step 1

Translation

The original English text of the GS and its compilation instructions were translated into Italian by two English mother tongue professionals (forward translation) who produced two independent translations. These two translations were then compared by a third translator. The three translators and the principal investigator together produced a consensual Italian translation of the GS. This Italian translation was then independently translated into English (backward translation) by two other translators, without knowing the original English version of the GS. The two new English versions were then compared with the original GS by all five translators together.

Analysis of Intelligibility of the Translated GS

To evaluate its intelligibility, the above Italian translation of the GS was administered to 30 Italian mother tongue pediatric nurses according to the procedure proposed by Sousa and Rojjanasrirat (20). The 30 nurses were asked to define each item of the scale and each correspondent item of the compilation instructions as "clear" or "not clear". When stating "not clear", the nurse had to suggest a more understandable alternative. All elements resulting as "not clear" by more than 20% of the sample were re-formulated.

Analysis of the Validity of the Translated GS

The Content Validity Index was used to evaluate the validity of the Italian translation of the GS, both at the item level (ICVI) and for the entire scale (SCVI) (21). A group of 10 experienced pediatric nurses evaluated the relevance of each item for purpose of the scale with a 4-point Likert scale, where 1=not relevant, 2=little relevant, 3=fairly relevant, and 4=very relevant. The ICVI value for each item is defined as the number of experts that give a value of 3 or 4 to items divided by the number of total experts. The SCVI is defined as the sum of ICVI values divided by the number of items. To be considered valid, a scale has to reach a minimum SCVI score of 0.9 and a minimum ICVI score of 0.78 for each item.

Analysis of The Reliability of the Translated GS

An estimation of the translated GS reliability was obtained by calculating the inter-rater concordance. To estimate the inter-rater concordance of the translated GS, two nurses used the scale on 100 hospitalized children, assessing them independently. The concordance of the classification of each child by two raters as at risk or not at risk according to the cut-off of the GS was calculated with Cohen's kappa.

Methods of Step 2

To determine the predictive performance of a risk assessment scale, it is necessary to compare the results of the given scale with another scale considered as the best available in that moment for the evaluation of that specific risk, i.e. the Gold Standard.

In the case of the GS, another PPURAS validated in Italian was unavailable and – because of the anatomical and physiological differences between adults and children – it would not be correct to use an assessment tool for risk for PUs designed for the adult population. In this case, the only possibility is to use as reference standard the actual occurrence of the event for which the predictive test was conceived. Therefore, we decided to prospectively collect an adequate number of assessments of hospitalized children with the Italian version of GS and to consider the PUs that actually occur during the observation time.

Inclusion Criteria

All hospitalized children from 0 to 18 years old admitted to the Meyer Children Hospital of Florence, Italy and to the pediatrics units of other Tuscan General Hospitals, whose parents give consent for participation in the study are eligible. A minimum sample size of 1,500 subjects is set.

Collected Data

For every child included in the study, the risk for PUs is assessed with the Italian version of GS. The PUs that occur during the hospital stay are registered. Also, we collect the biometric and clinical information of each child as possible risk factors for PUs. The variables of recruited subjects for which we collect dataare:diagnosis; gender; age; weight and height

(BMI centiles were then calculated); presence of cognitive alterations, treatment with antitumoral drugs, steroids or immunosuppressants; length of stay in Hospital; presence of diabetes; admittance to a single room; tubes, probes or wires connecting the child to diagnostic or therapeutic devices (oxygen, saturimetry, monitors, feeding tubes, urinary catheter, drainage bags, etc.); ongoing IV therapy; and bed rest prescription.

The collected GS-ita forms will be checked, and those presenting gross compilation errors or are incomplete will be discarded.

Sampling and Recruitment

The recruitment started on January 2018 and will last until the sample size of 1500 subjects is reached.

Statistical Analysis

Accuracy, sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios and ROC Area Under the Curve (AUC) of the Italian version of GSwill be calculated. For each of the independent variables observed on the subjects, we will estimate the association with the occurrence of PU. For qualitative variables, we will use the Chi-square test (or Fisher test if one of the values is less than 5), and for the quantitative variables the ANOVA test, with a threshold value of statistical significance of $p<0.05$.

In case of missing data relative to the examined variable in the record, the subject will be excluded from the analyses involving that variable.

Ethics

The study was approved by the Regional Pediatric Research Ethics Committee of the Tuscan Healthcare System (Deliberation n. 102/2016). The parents of children recruited for this study, as well as children themselves from the age of 7, are informed about the research according to the Guidelines of the Regional Pediatric Research Ethics Committee of the Tuscan Healthcare System. For each participant child, written informed consent is collected from the parents.

Results of Step 1

The two forward translations into Italian of both the GS and of the compilation instructions did not show discrepancies or ambiguities in regard to vocabulary and meaning. The two backward translations showed some minor differences compared to the original English version. These were examined by the group of translators together with the principal investigator, and the initial Italian version was changed accordingly, obtaining the consensus of an Italian translation, which was called GS-ita.

As for the intelligibility of the GS-ita, no item was considered "not clear" by more than five nurses. Since the fixed limit of 20% of "not clear" assessments was not reached, it was not necessary to reword any item.

In regard to GS-ita's validity, the ICVI values resulted between 0.99 and 0.8, whereas SCVI was 0.93; both values are above the minimum considered acceptable, that is 0.90 for SCVI and 0.78 for ICVI.

The calculated Cohen's Kappa of the GS-ita's researchers blinded observations resulted in 0.95. This value is above the minimum threshold of acceptability of Cohen's Kappa, which is 0.7.

Preliminary Results of Step 2

So far 1212 subjects have been recruited. Of these, 38 % are females (n=461) and 62 % males (n=751).

So far, 7 PUs occurred. Therefore, a prevalence of 5.8 PUs for every 1000 hospitalized children can be estimated(CI 95% 2.5–11.4).

The subjects classified as at risk for PU with the GS-ita have been 676 (55.8%), while those classified as not at risk have been 536 (44.2%). All the subjects who developed a PU had been classified at risk and no false negatives have been recorded. The false positives were 669 out of 1212 subjects (55.2%).

Based on the available data, the sensitivity of the GS-ita is 100% (CI95% 59 to 100) and the specificity is 44.5% (CI95% 41.6 to 47.3).

Discussion

This study aims to validate the GS scale into Italian and to evaluate its predictive performance. Moreover, with this study, we want to collect data on the onset of new PUs in hospitalized children and to evaluate possible associations between PUs and other clinical, biometric, and sociodemographic factors of the subjects.

The first step of the study resulted in an Italian translation of the GS. This translation was tested for comprehensibility, validity, and inter-rater

concordance, all of which were satisfactory. Therefore, the Italian validated version, called GS-ita, is now available for Italian-speaking nurses and other healthcare professionals.

The values of Sensitivity and Specificity of the GS's Italian version (Sensitivity: 100%, Specificity: 44.5%) aresimilar to those of the original English version (Sensitivity: 93.4 %, Specificity: 50.2%).

While on one hand the GS-ita has not produced false negatives, on the other hand it produced a high number of false positive subjects (55.2% of the total).

These values may suggest a limited clinical and operational utility of the GS. As a matter of fact, a risk assessment tool with a low Specificity might be useless to clinicians: if the number of subjects not at risk who screen positive is a large proportion of it, the aim of the tool -which is to discriminate among subjects- is not achieved and a large number of subjects receive unnecessary treatments (22).

The second aim of the study was to estimate the frequency of new PUs in hospitalized patients in pediatric hospitals.

To our knowledge, in this study, the number of recruited children is much higher than in any other study for the validation or evaluation of a PPUAS.

In our study, the prevalence of PUs was 5.8‰ hospitalized children. This prevalence is quite similar to that reported in the study by Razmus et al (5.7‰) in general pediatrics units (10), but much lower than those reported in other studies (3,4, 9, 11). This may be explained by the fact that in the Hospital where the study was carried out, a protocol for prevention of PUs had already been introduced in clinical practice.

Regarding the used research design, the advantage of a prospective study, compared to the retrospective design, is that prospective data are not affected by incompleteness and inconsistency of data that often characterize studies based on the examination of past clinical records. A retrospective design, however, could have allowed us to consider a higher number of PUs. Unfortunately, this was not possible due to the lack or incompleteness of previous records of children's PUs.

Conclusions

The study is ongoing. The subjects recruited so far represent 80% of the sample needed to complete the study, therefore the final results may differ in part from those presented in this paper.

Our study allowed the validation of the GS for the Italian health care system. Italian pediatric nurses have now a novel tool to evaluate the risk of PUs in children and, consequently, to better prevent the onset of PUs. However, the specificity of the GS-ita seems to be rather low, causing a high number of false positives.

Upon completion, this study will provide useful data for scholars about PUs frequency in children and about the clinical and biometric variables possibly associated with PUs.

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Multicenter observational study on falls of hospitalized children and Italian, linguistic-cultural validation of the "Humpty Dumpty Fall Scale"

Authors

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ABSTRACT

BACKGROUND. Falls in hospitals are a major problem, including in pediatric settings. Knowledge of the epidemiology and risk factors of falls is important, as is the use of a specific tool for the assessment of fall risk, which would allow the identification of subjects at risk. No Pediatric Fall Risk Assessment Scales (PFRAS) are currently validated in Italian. The goals of this study were: to perform the Italian validation of the Humpty-Dumpty Falls Scale (HDFS); to assess its predictive performance; and to estimate the frequency of falls of hospitalized children and to analyze the existing associations between the children's clinical variables and the fall event.

METHODS. The study consisted of four steps. First, linguistic and cultural validation of the HDFS in Italian. Second, evaluation of the Italian HDFS's performance on 1500 hospitalized children. Third, modifications of the Italian HDFS to improve its performance. Fourth, analysis of falls frequency and associations between falls and patients' clinical variables.

RESULTS. The Italian version of the scale (HDFS-ita) has satisfactory validity (SCVI=0.92) and inter-rater reliability (Cohen's kappa=0.965). The predictive performance is poor (Sensitivity=77.8%, Specificity=36.6%), which led us to create a new version of the HDFS-ita (HDFS-ita-M) with only three items and a cut-off of 7, to be used only for subjects between 1 and 15 years old. Although better, the HDFS-ita-M's predictive performance remains poor (Sensitivity=77.8%, Specificity=53.3%, AUC of the ROC curve=0.670). The frequency of falls of hospitalized children

was 6.38 ‰ children (CI95% 3.36–12.08) with a maximum frequency in children aged 3 to 6 years (11.28‰ children, CI95% 3.84–32.63). Variables associated to falls were motor or walking disorders (p=0.005), enuresis (p=0.0002), being in a single room (p=0.04), admittance to pediatric neuropsychiatry or neurology wards (p=0.001), and a diagnosis of neurological disorders (p=0.02).

CONCLUSIONS: HDFS-ita-M has a better performance than HDFS-ita, although this remains poor. Due to the inconsistency among PFRAS, further studies are necessary to determine an adequate panel of risk factors to predict the risk for falls of hospitalized children.

Keywords: Accidental falls, children, risk assessment scales, pediatric hospitals, risk management.

Introduction

A fall is defined as "An unplanned descent to the floor (or extension of the floor, e.g., trash can or other equipment) with or without injury. All types of falls are included, whether they result from physiological reasons or environmental reasons." (1).

Falls of hospitalized patients are of great concern for health systems: according to the data of the British National Health System, in the 2015/2016 period, 3.3% of patients were involved in falls within the healthcare settings; 25.5% of falls caused some harm to the patients and a burden for the health system of 2,600 £ for each fall (2). The Italian national healthcare system considers the fall of a hospitalized patient a "sentinel event" (3). Joint Commissions International underlined the importance of falls prevention in healthcare settings, including the reduction of risk for falls among the International Patient Safety Goals (4). In pediatric settings, falls are a frequent phenomenon and are the major cause of trauma in hospitalized children under 5 years of age (5). While there are many studies on the incidence and risk factors of falls in adult hospitals (6-9), unfortunately, there is little epidemiologic data available on falls in hospitals regarding pediatric patients.

Nimityongskul et al. estimate an incidence of 8.5 falls for every 1000 admissions (10). Cooper et al. show an incidence of 0.8 falls for every 1000 days of hospitalization (11) which, multiplied by the average length of pediatric admittance in the USA in the same period, which is 3.6 days (12), leads to an estimation of an incidence of about three falls for every 1000 admissions. Hill-Rodriguez et al. estimate an incidence of between 1 and 0.56 falls for every 1000 days of hospitalization, equivalent to 3.6 and 2 falls for every 1000 admissions (13). Schaffer et al. report an incidence of 0.84 falls for every 1000 days of hospitalization, that is, about three falls every 1000 admissions (14).

To minimize the risk for falls in pediatric patients, it is fundamental to have at one's disposal reliable Pediatric Fall Risk Assessment Scales (PFRAS) that can identify those patients that need prevention actions. Numerous tools exist for the assessment of risk for falls in adults, such as the Downton Scale (15), the Morse Fall Scale (MFS) (16), the St. Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY) (17), the Tinetti test (18), the Conley Scale (19), the Hendrich Fall Risk Model (HFRM) (20), and its latest version, the HFRM II (21). However, these scales are not adequate for the use in pediatric age, as shown in studies where two validated Adult Fall Risk Assessment Scales (the HFRM II and the MFS) were used on children (22, 23). Pediatric patients need different prevention strategies than the ones used for adults because the causes and risk factors concurring in the fall are different (22).

At present, few PFRAS are available in the scientific literature: the CHAMPS scale (acronym for Change in mental status, History of falls, age > 36 months, Mobility impairment, parental involvement and safety) which showed a Sensitivity of 75% and Specificity of 79% (24); the GRAF-PIF (25-27); the Cummings scale (23); the Children's National Medical Center (CNMC) Pediatric Fall Scale (28); the I'M SAFE scale (acronym for Impairment, Medications, Sedation/anaesthesia, Admitting diagnosis, Fall history, and Environment) (29); the Pediatric Fall Risk Assessment Tool (PFRAT), with a Sensitivity of 49.7% and Specificity of 40% (30); and the Humpty Dumpty Fall Scale (HDFS) (13, 31, 32). This last tool classifies patients as at "high risk" or at "low risk" according to the presence or absence of seven risk factors: age, sex, diagnosis, presence of cognitive impairment, environmental factors, answer to sedation or anesthesia sessions, and administered therapy. The final score, which can vary from a minimum of 7 to a maximum of 23, is obtained by adding the score for every item. The child is considered at high risk if the total score is 12, whereas the risk is considered low if the scores are less than 12. The English version on the HDFS has a Sensitivity of 85% and a Specificity of 24%. Of the seven PFRAS mentioned above, only four followed a formal process of validation and underwent a peer-review followed by publication in a scientific journal: CHAMPS, HDFS, PFRAT, and I'M SAFE. Nevertheless, only CHAMPS, HDFS, and PFRAT have an estimation of their Sensitivity and Specificity (13, 24, 30), and of these only HDFS shows data that supports its ability to reduce risk incidence if implemented in clinical practice (31).

When we started our study, no PFRAS for risk for falls in children was validated for the Italian linguistic-cultural context. It was, therefore, necessary to start with the linguistic-cultural validation of a PFRAS that was already validated in the original language to develop an assessment tool for the risk for falls in hospitalized children available for Italian health care professionals.

The HDFS was chosen because it is the only validated and published scale with known Sensitivity and Specificity with data available of its efficacy in falls prevention. However, it is necessary to underline that after we started our study, another PFRAS was validated in English and published, the Little Schmidy Pediatric Hospital Fall Risk Assessment Index, which has a Sensitivity of 79% and a Specificity of 49% (33).

Starting from the validated HDFS in English, the aims of this study were: 1) the linguistic-cultural validation of the HDFS in Italian and evaluation of its predictive performance; 2) if necessary, to modify the Italian validated HDFS to improve its performance; and 3) to estimate the frequency of falls of hospitalized children in pediatric settings and to analyze the existing associations between the different observed epidemiologic and clinical variables of recruited subjects and the fall event.

Patients and methods

The study consisted of four steps. The first step consisted of the forward-backward translation of the HDFS into Italian. The translated version was then analyzed in terms of validity and reliability, resulting in the validated linguistic-cultural Italian version of the HDFS, called HDFS-ita.

In the second step, we conducted a prospective observational study on a large population of hospitalized children. In this study, we recorded the falls that actually occurred in the observed population, collected biometrical and clinical data of the subjects, and measured the risk for falls using the HDFS-ita. This allowed us to estimate the HDFS-ita's predictive performance and to compare it with the original HDFS. The falls frequency of hospitalized children was also estimated.

In the third step, we checked the various hypotheses of modifications of the HDFS-ita, eliminating some items and/or limiting it to some age groups, to create a modified version of the HDFS-ita with better performance (HDFS-ita-M).

The fourth step consisted of the analysis of biometrical and clinical data obtained with the HDFS-ita administered to the second phase participants to estimate the association of the former with the fall event.

The study was set up on request of and in collaboration with the Tuscan Healthcare System's Clinical Risk Center.

Step 1

Translation – The original English text of the HDFS and its compilation instructions were translated into Italian by two English mother tongue professionals (forward translation) who produced two

independent translations. These two translations were then compared by a third translator. The three translators and the principal investigator together produced a consensual Italian translation of the HDFS. This Italian translation was then independently translated into English (backward translation) by two other translators, without knowing the original English version of the HDFS. The two new English versions were then compared with the original HDFS by all five translators together.

Analysis of intelligibility of the translated HDFS – To evaluate its intelligibility, the above Italian translation of the HDFS was administered to 30 Italian mother tongue pediatric nurses according to the procedure proposed by Sousa and Rojjanasrirat (34). The 30 nurses were asked to define each item of the scale and each correspondent item of the compilation instructions as "clear" or "not clear". When stating "not clear", the nurse had to suggest a more understandable alternative. All elements resulting as "not clear" by more than 20% of the sample were re-formulated.

Analysis of the validity of the translated HDFS – The Content Validity Index was used to evaluate the validity of the Italian translation of the HDFS, both at the item level (ICVI) and for the entire scale (SCVI) (35). A group of 10 experienced pediatric nurses evaluated the relevance of each item for purpose of the scale with a 4-point Likert scale, where 1=not relevant, 2=little relevant, 3=fairly relevant, and 4=very relevant. The ICVI value for each item is defined as the number of experts that give a value of 3 or 4 to items divided by the number of total experts. The SCVI is defined as the sum of ICVI values divided by the number of items. To be considered valid, a scale has to reach a minimum SCVI score of 0.9 and a minimum ICVI score of 0.78 for each item.

Analysis of the reliability of the translated HDFS – An estimation of the translated HDFS reliability was obtained by calculating the inter-rater concordance. To estimate the inter-rater concordance of the HDFS-ita, two nurses used the scale on 100 hospitalized children, assessing them independently. The concordance of the classification of each child by two raters as at risk or not at risk according to the cut-off of the HDFS was calculated with Cohen's kappa (minimum accepted value = 0.7).

Step 2

To determine the predictive performance of a risk assessment scale, it is necessary to compare the results of the given scale with another scale considered as the best available in that moment for the evaluation of that specific risk (the Gold Standard).

In the case of the HDFS-Ita, another PFRAS validated in Italian was unavailable and – because of the anatomical and physiological differences between adults and children – it would not have been correct to use an assessment tool for risk for falls designed for the adult population. In this case, the only possibility was to use as reference standard the actual occurrence of the event for which the predictive test was conceived. Therefore, we decided to prospectively collect an adequate number of HDSF-ita

assessments of hospitalized children and to consider the falls that actually occurred during the observation time.

Sample Size – To determine the adequate number of children to include in the study, it was first necessary to have an estimation of the incidence of the observed phenomenon (i.e., the falls of hospitalized children). Assuming an intermediate incidence between the maximum and the minimum incidence described in the literature (10, 11, 13, 14), we determined a sample size of 1170 participants, in accordance with Abrahamson (36). Assuming that up to 20% of collected records could have to be excluded (e.g., because of incompleteness or errors), we prudentially decided to recruit at least 1500 subjects.

Inclusion criteria – All hospitalized children from 0 to 18 years old admitted in low and medium care wards of participating hospitals and whose parents gave consent for participation in the study were considered eligible. Subjects older than 18 years and admitted to intensive or sub-intensive care settings were excluded.

Participating hospitals – The following pediatric hospitals or general hospitals with pediatric wards of the Tuscan Regional Healthcare System participated in the data collection: Meyer University Children Hospital of Florence, the General Hospitals of Arezzo, Barga, Lucca, Massa, Pisa, Pistoia, Siena, Valdarno, Versilia, and two specialty Hospitals [IRCCS Stella Maris (Neuropsychiatry) and Monasterio Foundation's Heart Hospital (Cardiology)].

Collected data – For every child included in the study, the risk for falls was assessed with the HDFS-ita. The falls that occurred during the hospital stay were registered. Moreover, to collect data to be used in step 4 of the study, we asked participating hospitals to also collect the biometric and clinical information of each child as possible risk factors for falls. The variables of recruited subjects for which we collected information were: type of ward where the child was admitted; gender; age; weight and height (BMI centiles were then calculated); presence of cognitive alterations, autistic spectrum disorders, behavioral disorders or mood disorders; presence of sight impairments; presence of hearing impairments; if sports are practiced in a regular way; presence of motor or walking disorders; presence of prosthesis, aids, tractions, splints or casts; presence of enuresis; treatment with antitumoral drugs; suffering from seizures or epilepsy; antiepileptic or anticonvulsant therapy; presence of pain in lower limbs; recurrent or prolonged pain; presence of diabetes; admittance to a single room; tubes, probes or wires connecting the child to diagnostic or therapeutic devices (oxygen, saturimetry, monitors, feeding tubes, urinary catheter, drainage bags, etc.); ongoing IV therapy; and bed rest prescription.

Sampling and recruitment – Each participating hospital proposed the participation in the study to all parents of admitted children in a period of 3 months, between May 2015 and October 2016. Each hospital chose a different period for data collection.

Statistical analysis – Accuracy, Sensitivity, Specificity, and Area Under the Curve (AUC) of the ROC curve were calculated.

Step 3

Next, we explored how removing one or more items for the scale would affect performance. Since in the literature the ability to walk without support is considered a relevant component in the assessment of the risk for falls in children (23, 24, 33), we also evaluated the tool's performance, limiting the sample on which to assess HDFS's performance only to children of walking age groups and, in order to reduce the internal variability of the sample, limiting the sample until the age of adolescence. A dataset which included only children from 12 months to 16 years and all corresponding data collected with the HDFS-ita was, therefore, extracted from the principal database. Accuracy, Sensitivity, Specificity, number of false negatives and false positives, and AUC of the ROC curve were calculated on the datasets, eliminating one or more items at a time.

In order to consider a new item combination as ameliorative compared to the integral HDSF-ita, all following conditions had to be met: increase of Specificity; a less or equal number of false negatives; and an increase of the AUC of the ROC curve.

Step 4

For each of the independent variables observed in step 2, we estimated the association with the fall event recorded. For qualitative variables, we used the Chi-square test (or Fisher test if one of the values was less than 5), and for the quantitative variables the ANOVA test, with a threshold value of statistical significance of $p<0.05$.

Wherever possible, we chose to transform quantitative variables into dichotomous qualitative variables. We also included in the analysis as qualitative independent variables the items of HDFS-ita dichotomized as the maximum score versus all other possible scores.

In case of missing data relative to the examined variable in the record, the subject was excluded from the analyses involving that variable.

Ethics

The study was approved by the Regional Pediatric Research Ethics Committee of the Tuscan Healthcare System (Deliberation n. 427/2014). The parents of children recruited for this study, as

well as children themselves from the age of 7, were informed about the research according to the Guidelines of the Regional Pediatric Research Ethics Committee of the Tuscan Healthcare System. For each participant child, written informed consent was collected from the parents.

Results

Results of step 1

The two forward translations into Italian of both the HDFS and of the compilation instructions did not show discrepancies or ambiguities in regard to vocabulary and meaning. The two backward translations showed some minor differences compared to the original English version. These were examined by the group of translators together with the principal investigator, and the initial Italian version was changed accordingly, obtaining the consensus of an Italian translation, which was called HDFS-ita.

As for the understanding of the HDFS-ita, no item was considered "not clear" by more than five nurses. Since the fixed limit of 20% of "not clear" assessments was not reached, it was not necessary to reword any item.

In regard to HDFS-ita's validity, the ICVI values resulted between 1 and 0.8, whereas SCVI was 0.92; both values are above the minimum considered acceptable, that is 0.90 for SCVI and 0.78 for ICVI.

The calculated Cohen's Kappa of the HDFS-ita's researchers blinded observations resulted in 0.965. This value is above the minimum threshold of acceptability of Cohen's Kappa, which is 0.7.

Results of step 2

Participating subjects – The study included 1508 children. The collected HDFS-ita forms were selected, eliminating those who presented gross compilation errors or were incomplete. This left 1411 forms suitable for statistical analysis. Of these, 41.4% were females (n=585) and 58.6% males (n=826).

Table I shows the distribution of subjects according to age range and ward type.

Frequency of falls – During the observed period, nine falls occurred. Therefore, 6.38 falls occurred for every 1000 hospitalized children (CI 95% 3.36–12.08). Five girls and four boys fell, corresponding to 8.55 falls for every 1000 hospitalized girls (CI 95% 3.66–19.85), and 4.84 falls for every 1000 hospitalized boys (CI 95% 1.88–12.38).

Table II shows the number of falls for age range and ward type, and per thousand hospitalized children, with a 95% confidence interval.

Seven out of nine falls occurred within the first 48 hours from admission. Six falls happened in the afternoon, two during the night, and one in the morning. The fall did not result in an injury for the child in three cases. Four fallen children incurred a mild head or face injury (one needed a lip suture), two incurred a limb injury (one radial and one ulnar fracture).

Subjects classified at risk for falls by the HDFS-ita – Table III shows the subjects classified as at risk and not at risk for falls according to HDFS-ita and the number of fallen and not fallen subjects in both groups.

The classification resulted in 63.5% of subjects at risk and the remaining 35.5% not at risk. False negatives were two out of nine (22.2%). False positives were 889 out of 1402 (63.4 %), that is, 63% of the whole sample.

Table IV shows the percentage of subjects identified as at risk for age range and type of unit.

Predictive performance for HDFS-ita – Table V shows the predictive performance indicators of HDFS-ita; they are slightly better than those of the original version (Sensitivity: 85%; Specificity: 24%).

Results of step 3

Table VI shows the performance indicators of HDFS-ita calculated on total records of the whole dataset versus the same indicators calculated on the dataset limited for age range 12 months to 16 years (1192 subjects).

Table VII shows the performance indicators of HDFS-ita based on the 12 months to 16 years dataset after removing each item, one-by-one. For brevity, some names of the items of the HDFS-it were abbreviated as follows: “environmental factors”=environment; “underwent surgical intervention, sedation or anesthesia”= surgery; and “use of drugs”= drugs.

The options that satisfy all three preventively set conditions for considering a new combination of items as ameliorative are those where the items “cognitive alteration”, “surgery”, and “drugs” were removed. However, the item for which its removal determines the greatest increase of the AUC is “surgery”. Moreover, it can be noted that the removal of the item “diagnosis” greatly worsened the AUC. Therefore, in the analysis of possible modifications, we decided to remove the item “surgery” and to maintain as fixed in every subsequent hypothesis the item “diagnosis”.

Proceeding empirically, we have progressively removed other items in various combinations. The best performance was obtained when removing simultaneously the items “surgery”, “sex”, “cognitive alterations”, and “drugs” (Table VIII).

The results show that by removing the four items “surgery”, “sex”, “cognitive alterations” and “drugs” and using the scale only on children that can already walk and until the age of adolescence, it is possible to achieve a clear improvement in the performance of the HDFS-its, although this remains far from the levels of acceptability that are usually required of a risk assessment scale.

Results of step 4

The statistical tests regarding the association between observed qualitative dichotomic variables and fall events, both on the entire observed population (1411 subjects) and on the 12 months to 16 years dataset (1192 subjects), showed a statistically significant association between falls and, respectively: enuresis; motor or walking disorders; admittance to a single room; being admitted to a Pediatric Neurology or Neuropsychiatry ward; and having a diagnosis among those described in the HDFS-ita’s guide with a score equal to 4 (Table IX).

Besides these, we found the variable “to have prosthesis, aids, splint or immobilization devices” to be close to statistical significance, both in the total population (OR 5.13, CI95% 1.05-25.11, Fisher Test’s 2-tailed p=0.08) and in the 12 months to 16 years dataset (OR 4.98, CI95% 1.01-24.45, Fisher Test’s 2-tailed p=0.08).

With regard to the association between the observed quantitative variables and the fall event on the entire population, the mean age of children who fell was 98.4 months vs. 88.9 months of children who did not fall (ANOVA test p=0.3). The mean BMI centile was 47.6 in children who fell vs. 61.8 in children who did not fall (ANOVA test p=0.33).

On the 12 months to 16 years dataset, the mean age of children who fell was 74.4 months vs. 89.9 months of children who did not fall (ANOVA test p=0.38). The mean BMI centile was 47.4 in children who fell vs. 61.8 in children who did not fall (ANOVA test p=0.33).

A possible new scale - In light of these results, proceeding by speculation, we simulated the predictive performance of a theoretical PFRAS in which the variables observed on the patients were the six mentioned above (the five statistically significant ones and the ones close to statistical significance) and in which for every variable the assigned score was: 1=condition not present; or 2=condition present. The simulations were carried out on the database with only patients from 12 months to 16

years. Table X shows the predictive performance indicators calculated on the simulated PFRAS described as above, with a cut-off of 7.

The performance of the simulated PFRAS with six items is better compared to those of HDFS-Ita and reaches the minimum reliability value of the AUC of the ROC curve, that is 0.8.

Discussion

This study aimed to validate the HDFS scale into Italian, to evaluate its predictive performance, and to make changes to improve its performance, if needed. Moreover, with this study, we wanted to collect data on falls frequency of hospitalized children and to evaluate possible associations between falls and other clinical, biometric, and sociodemographic factors of the subjects.

The first step of the study resulted in an Italian translation of the HDFS. This translation was tested for comprehensibility, validity, and inter-rater concordance, all of which were satisfactory. Therefore, the Italian validated version, called HDFS-ita, is now available for Italian-speaking health operators.

Although there are no substantial variations, the values of Sensitivity and Specificity of the scale's Italian version (Sensitivity:77.8%, Specificity: 36.6%) were slightly better than those of the original English version (Sensitivity:85%, Specificity:24%) (23)

These values suggest a poor clinical and operational utility of the HDFS. In fact, its poor Sensitivity – there were two false negatives out of nine, that is 22.2% of fallen children – is paired with a low Specificity and a high number of false positives.

For this reason, we examined the possibility to improve HDFS-ita's predictive performance. The performance of HDFS-ita is improved by leaving out the four items "Surgery", "Sex", "Cognitive alterations" and "Drugs" and reducing its use to children from 12 months to 16 years of age with a cut-off of 7. Nonetheless, it remains far from the levels of acceptability usually required for a risk assessment tool.

The denomination proposed for this version of the HDFS-ita with only three left items ("Age", "Diagnosis" and "Environmental factors") is: Humpty Dumpty Fall Scale Italian Modified, abbreviated HDFS-ita-M. The expected advantages from the use of HDFS-ita-M compared to HDFS-ita are, considering an equal Sensitivity (=77.8%) together with a not negligible increase of Specificity (=53.3%), a decrease of false positives with subsequent cost reduction thanks to the lower number of patients that need preventive measures, as well as its ease of use for nurses. However, due to the small number of falls observed and, consequently, to the large Confidence Intervals, the estimates of Sensitivity should be considered with caution.

Despite the improvements obtained with the HDFS-ita-M, the scale's predictive performance remains poor. As a matter of fact, a risk assessment tool with a low Specificity might be useless to clinicians: if the number of subjects not at risk who screen positive gets close to the total of a population or is a large proportion of it, the aim of the tool (which is to discriminate among subjects) is not achieved and a large number of subjects receive unnecessary treatments (37).

We are, therefore, still lacking a PFRAS in Italian with a good predictive performance, that is easy to use, and with an AUC of the ROC curve that is at least higher than 0.8 (the value above which the scale can be considered "good").

The performance of a speculative PFRAS that we simulated using the collected data, suggest that the data we collected can be used as the basis for the creation of a new easy to use PFRAS with satisfying performances. To do so, more studies are necessary.

On the other hand, the poor performance of HDFS is shared by other PFRASs. Along with the English HDFS (which has a Sensitivity of 85% and a Specificity of 24%) and HDFS-ita-M (with a Sensitivity of 77.8% and Specificity of 53.3%), in the literature we can find the CHAMPS (with Sensitivity 75% and Specificity 79%) (24), the Little Schmidy (with Sensitivity 79% and Specificity 49%) (33), and the PFRAT (with Sensitivity 49.7% and Specificity 40%) (30).

The poor performance of these PFRASs not only makes it unlikely to identify subjects at risk, but it also leads to identifying as at risk such a high number of subjects that they lose their usefulness in clinical settings. For example, along with the 63% of subjects identified as at risk by the HDFS-ita, in the literature, we find 68% by CHAMPS (28) and 65% by Little Schmidy (33). As a matter of fact, a scale aims to adequately discriminate subjects who are really at risk from subjects that are not, which should allow the implementation of prevention measures only to those who really need them. The use of a scale with poor predictive performance could also represent an unnecessarily high cost for the health system because it leads to adopting additional preventive measures on subjects that do not need them.

Some authors questioned the quality of existing PFRAS and the possibility to create scales able to detect the risk for falls in children. Harvey (28) compared five PFRAS (CHAMPS, GRAF-PIF, HDFS, Cumming, and CNMC) and concluded that all instruments had poor accuracy and presented a considerable discordance among them in regard to the definition of risk factors. Moreover, the authors argue that there is a lack of studies regarding the implementation and development of universal and consistent criteria for accurately assessing pediatric patients for falls and injury risk (28). Degirolamo et al., in a review of 2017, come to similar conclusions. They also argue that the poor accuracy and predictive performance of the PFRAS could be due to the fact that risk factors in

such tools do not match the clinical characteristics seen in a hospitals' patient population that fall; the authors, while underlining the importance of accurate PFRAS, state that the use of these tools should not replace nursing clinical judgment (38). Ryan-Wenger et al. also noted the inadequacy of PFRAS available in the literature and proposed that a broader perspective on the risks, causes, circumstances, and prevention of falls and related injuries is sorely needed. Moreover, they underline that authors of popular risk for falls assessment scales for the adult population have, afterward, concluded that adult fall risk assessment tools should be abandoned because they are inaccurate and provide a false sense of security that the clinical problem of patient falls is being addressed. (30). The same authors, in two more papers, indicate the need to overcome the actual paradigm of scales based on biological and clinical characteristics of the children that are going to be assessed, going over to a "momentary confluence of events model", that takes into account the complexity of a fall event, and illustrates how several intrinsic and extrinsic factors might converge at the moment in time to cause a hospitalized child to fall, focusing future research on the detection of circumstances in which the children fell in hospital, instead of the biological and clinical characteristics of fallen children (39,40).

The third aim of the study was to estimate the frequency of falls of hospitalized patients in pediatric hospitals and wards and to analyze the existing association between the different epidemiological and clinical observed variables of recruited subjects and the fall event. The participation in the study by one third-level pediatric hospital and 11 pediatric wards of general hospitals allowed the inclusion of a considerable number of subjects. To our knowledge, in this study, the number of recruited children is much higher than in any other study for the validation or evaluation of a PFRAS.

In our study, the frequency of observed falls was 6.38 falls for every 1000 hospitalized children. The few existing other available studies on the epidemiology of falls of hospitalized children show incidences that vary from a maximum of about 8.5 falls for every 1000 admittances (10), and a minimum of about two falls every 1000 admittances (13). Our finding appears, therefore, to be consistent with prior literature.

Our data show the presence of statistical significance in the association of some clinical factors with the fall event. These clinical variables are: presence of motor or walking disorders; presence of enuresis; the child being admitted to a single room; the type of admitting ward (pediatric neuropsychiatry or neurology versus all other); and the diagnosis of "Neurological problems" as defined by HDFS's operational guide for the assignment of a score 4 in the item "Diagnosis".

Our findings are in contrast with one of the studies by Harvey et al., who questions the idea that neurological patients are at increased risk for injury compared with other patients (28).

Also, it is interesting to note that among the seven variables included in the HDFS, only one (Diagnosis) was significantly associated with falls in our study. In particular, our study does not show a significant difference of risk for falls when comparing the two genders; this is in contrast with the presence, in the HDFS scale, of a higher risk score for males (13).

While there are differences among operational definitions of the different PFRAS items, it is interesting to note that among the 23 variables that are observed by the seven main PFRASs (CHAMPS, HDFS, I'M SAFE, GRAF-PIF, Cumming, CNMC and Little Schmidy), only two are present among the five that were identified as significantly associated to falls in our study: motor issues (present in CHAMPS, Little Schmidy e CNMC) and the neurological diagnosis (present in HDFS, Cumming, I'M SAFE and GRAF-PIF). Harvey et al. detected a statistically significant correlation with falls for only three variables: length of admittance, presence of problems due to blood loss, and temperament/behavior of the child (28).

The huge diversity and inconsistency among the findings of the different studies suggest that further studies are necessary to determine an adequate panel of risk factors for the prediction of risk for falls of hospitalized children and that also the statistically significant associations between falls and clinical variables found in our study should be interpreted with caution.

Limits and strengths – Although, to our knowledge, the sample size of this study is far higher than that of any other validation or evaluation study of a PFRAS (13, 23-25, 29, 30, 33), the small number of falls observed might be a problem. Therefore, we should interpret with caution the associations found between falls and clinical variables in our population, even though these were statistically significant.

Regarding the used research design, the advantage of a prospective study, compared to the retrospective design that was used by other studies (13, 11, 22- 24, 28, 29, 30, 32, 33), is that prospective data are not affected by incompleteness and inconsistency of data that often characterize studies based on the examination of past clinical records. A retrospective design, however, could have allowed us to consider a higher number of falls. Unfortunately, this was not possible due to the lack of previous records of children's falls in the participating hospitals.

Being a multicenter study might represent a strength. Indeed, according to some authors, one limitation of research dealing with the validation of different PFRAS is that initial testing is restricted to a single institution (28).

A limit of our study is that for the analysis of the association between falls and each clinical and biometric variable, some subjects were excluded because their records were lacking information relative to one variable. However, it should be noted that the percentage of subjects excluded from

the analysis exceeded 10% in only four cases, and it never exceeded 15%; these attrition percentages are considered largely acceptable in cohort studies (41).

Another limitation of the study is the differences among the participating Hospitals in regard to the clinical management of the child at risk for falls. When the study started, there was no common protocol for all participants regarding the implementation of fall prevention measures. This might have resulted in biases in the estimation of falls prevalence across different clinical settings.

Conclusions

Our study allowed the validation of the HDFS for the Italian health care system, in a reduced version that increases its predictive performance and easy to use. Moreover, the study provided useful data for scholars on children's fall frequency and possible associated factors. However, the predictive performance of the modified HDFS remains unsatisfactory, as it is for all other existing validated PFRAS, which are also inconsistent among them regarding considered risk factors. More studies are necessary to determine an adequate panel of risk factors to predict the risk for falls of hospitalized children.

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Notes

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Authors' contributions – SA, GD, KB, FF, and DC contributed to the conception and design of the study; DC, MF, and CG organized the database; FF performed the statistical analysis; FF, DC, and SN wrote the first draft of the manuscript; All authors contributed to manuscript revision, and read and approved the submitted version.

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Ethics – The study was approved by the Regional Pediatric Research Ethics Committee of the Tuscan Healthcare System (Deliberation n. 427/2014). The parents of children recruited for this study, as well as children themselves from the age of 7, were informed about the research according to the Guidelines of the Regional Pediatric Research Ethics Committee of the Tuscan Healthcare System, and gave written consent.

Tables

Table I. Distribution of subjects according to age range and type of Unit

Age (months)	n	%
Newborns (up to 1)	22	1.58
Infants (1 +1 day to 12)	164	11.61
Toddlers (12 +1 day to 36)	237	16.80
Pre-schoolers (37+1 day to 72)	266	18.84
School age (72+1 day to 156)	498	35.27
Adolescents (156 +1 day to 216)	224	15.90
Type of Unit		
Pediatric Surgery	173	12.26
Pediatric Neurosurgery	79	5.60
Neuropsychiatry & Paediatric Neurology	257	18.21
Paediatric Medicine	902	63.93

Table II. Number of falls occurred for age range, type of unit, and per thousand admissions.

Age (months)	n	‰	CI 95%
Newborns (up to 1)	0	0	-
Infants (1 +1 day to 12)	0	0	-
Toddlers (12 +1 day to 36)	2	8.44	2.32-30.24
Pre-schoolers (37+1 day to 72)	3	11.28	3.84-32.63
School age (72+1 day to 156)	3	6.02	2.05-17.56
Adolescents (156 +1 day to 216)	1	4.46	0.79-24.85
Type of Unit			
Pediatric Surgery	0	0	-
Pediatric Neurosurgery	0	0	-
Neuropsychiatry & Paediatric Neurology	6	23.35	10.74-49.99
Paediatric Medicine	3	3.32	1.13-9.73

Table III. Subjects at risk and not at risk, fallen, and not fallen.

	Fallen	Not fallen	Total
HDFS-ita at risk	7	889	896
HDFS-ita not at risk	2	513	515
Total	9	1402	1411

Table IV. Percentage of subjects resulted at risk for age range and type of unit.

Age (months)	% at risk
Newborns (up to 1)	85.7
Infants (1 +1 day to 12)	96.7
Toddlers (12 +1 day to 36)	95.5
Pre-schoolers (37+1 day to 72)	63.1
School age (72+1 day to 156)	46.3
Adolescents (156 +1 day to 216)	22.3
Unit	
Pediatric Surgery	49.7
Pediatric Neurosurgery	81.0
Neuropsychiatry & Paediatric Neurology	79.0
Paediatric Medicine	60.1

Table V. Predictive performance indicators of the HDFS-ita.

	Value	CI 95%
Accuracy (%)	36.9	34.33-39.4
Sensitivity (%)	77.8	39.9-97.2
Specificity (%)	36.6	34.1-39.2
False negatives	2	
False positives	889	
ROC curve AUC	0.604	

Table VI. Performance indicator of HDFS-ita on the 12 months-16 years dataset

	Value	CI 95%
Accuracy (%)	40.4	37.6-43.3
Sensitivity (%)	77.8	39.9-97.2

Specificity (%)	40.2	37.3-43
False negatives	2	
False positives	708	
ROC curve AUC	0.634	

Table VII. HDFS-ita performance indicators in the 12 months to 16 years dataset when removing each item.

	With all items	Without						
		Age	Sex	Diagnosis	Cognitive impairments	Environment	Surgery	Drugs
Accuracy (%)	40.4	44.8	46.7	36	49.6	40.6	44.9	42.5
Sensitivity (%)	77.8	66.7	66.7	77.8	77.8	77.8	77.8	77.8
Specificity (%)	40.2	44.6	46.7	35.7	49.4	40.3	44.6	42.3
False negatives	2	3	3	2	2	2	2	2
False positives	708	655	631	761	599	706	655	683
ROC curve AUC	0.634	0.614	0.637	0.556	0.638	0.635	0.659	0.644

Table VIII. HDFS-ita performance indicators in the 12 months to 16 years dataset without the items "surgery", "sex", "cognitive alterations", and "drugs."

	Value	CI 95%
Accuracy (%)	53.7	50.8-56.6
Sensitivity (%)	77.8	39.9-97.2
Specificity (%)	53.5	50.6-56.4
False negatives	2	
False positives	550	
ROC curve AUC	0.694	

Table IX. Statistical tests of associations between the observed dichotomic qualitative variables and the fall event, both on the entire observed population and on the 12 months to 16 years dataset.

Entire population					
Variables	% of fallen subjects in the group of subjects with variable	% of fallen subjects in the group of subjects without variable	OR	OR CI 95%	Fisher Test's 2-tailed p
Motor or walking disorders	2.7	0.38	7.29	1.94-27.41	0.005
Enuresis	4.11	0.48	8.83	2.07-37.7	0.01
Admittance to a single room	1.74	0,42	4.16	1.11-15.62	0.04
Type of ward (Neuro vs other)	2.33	0.26	9.15	2.27-36.82	0.001
HDFS-ita item Diagnosis (score 4 vs other scores)	1.69	0.36	4.79	1.28-17.96	0.02
12 months-16 years dataset					
Variables	% of fallen subjects in the group of subjects with variable	% of fallen subjects in the group of subjects without variable	OR	OR CI 95%	Fisher Test's 2-tailed p
Motor or walking disorders	2.86	0.89	7.44	1.98-27.99	0.004
Enuresis	4.17	0.5	8.57	2-36.62	0.01
Admittance to a single room	1.93	0.51	3.86	1.03-14.51	0.04
Type of ward (Neuro vs other)	2.49	0.32	8.04	1.99-32.39	0.003
HDFS-ita item Diagnosis (score 4 vs other scores)	1.96	[17] .43	4.66	1.24-17.5	0.02

Table X. Performance indicators of a simulated PFRAS on the dataset limited to the age range of 12 months to 16 years.

	Value	CI 95%
Accuracy (%)	55.1	52.2-57.9
Sensitivity (%)	88.9	51.7-99.72
Specificity (%)	54.7	51.9-57.7
False negatives	1	
False positives	534	
ROC curve AUC	0.8	