Open Access Journal of Nursing

ISSN: 2639-1783

Volume 2, Issue 2, 2019, PP: 05-10

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

Daniele Ciofi[1], Giulia Gori[2], Ilenia Castrogiovanni[2], Francesca Busi[2], Andrea Grappolini[2] Klaus Peter Biermann[1], Angela Savelli[1], Gabriele Frangioni[1], Stella Neri[2], Carlotta Gheri[2] Giulia D'Agliana[3], Sara Albolino[3]

[1]Meyer Children Hospital, Florence, Italy.

[2]Department of Health Sciences,University of Florence, Italy.

[3]Regional Center for Patient Safety and Clinical Risk, Regional Health Service of Tuscany, Florence, Italy.

daniele.ciofi@meyer.it

***Corresponding Author:** Daniele Ciofi, Meyer Health Campus Via Cosimo il Vecchio 26, 50139, Florence, Italy.*

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.

References

[1] National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014

[2] Saha S, Smith MEB, Totten A, et al. Pressure Ulcer Treatment Strategies: Comparative Effectiveness [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 May

[3] García Molina P, Balaguer López E. Special therapeutic surfaces for handling pressure in pediatrics (I). Characteristics and competency. Rev Enferm. 2009 Feb;32(2):17-24.

[4] Roques C. Prevention of decubitus ulcers in children. Soins Pediatr Pueric. 2009 Aug; (249):36-40.

[5] Solis I, Krouskop T, Trainer N, Marburger R.Supine interface pressure in children. Arch Phys Med Rehabil. 1988 Jul;69(7):524-6.

[6] Groeneveld A, Anderson M, Allen S, Bressmer S, Golberg M, Magee B, Milner M, Young S. The prevalence of pressure ulcers in a tertiary care pediatric and adult hospital. J Wound Ostomy Continence Nurs. 2004 May-Jun;31(3):108-20.

[7] McLane KM, Bookout K, McCord S, McCain J, Jefferson LS.The 2003 national pediatric pressure ulcer and skin breakdown prevalence survey: a multisite study. J Wound Ostomy Continence Nurs. 2004 Jul-Aug;31(4):168-78.

[8] Schlüer AB, Cignacco E, Müller M, Halfens RJ.The prevalence of pressure ulcers in four paediatric institutions. J Clin Nurs. 2009 Dec;18(23):3244-52

[9] Quigley SM, Curley MA. Skin integrity in the pediatric population: preventing and managing pressure ulcers. J Soc Pediatr Nurs. 1996 Apr-Jun;1(1):7-18.

[10] Razmus I, Bergquist-Beringer S. Pressure Injury Prevalence and the Rate of Hospital Acquired Pressure Injury Among Pediatric Patients in Acute Care. J Wound Ostomy Continence Nurs. 2017; 44(2):110-7.

[11] Sánchez-Lorente MM, Sanchis-Sánchez E, García-Molina P, Balaguer-López E, Blasco JM. Prevalence of pressure ulcers in the paediatric population and in primary health care: An epidemiological study conducted in Spain. J Tissue Viability. 2018 Nov;27(4):221-225.

[12] Curley MA, Razmus IS, Roberts KE, Wypij D. Predicting pressure ulcer risk in pediatric patients: the Braden Q Scale. Nurs Res. 2003 Jan-Feb;52(1):22-33.

[13] Kottner J, Hauss A, Schlüer AB, Dassen T. Validation and clinical impact of paediatric pressure ulcer risk assessment scales: A systematic review. Int J Nurs Stud. 2013 Jun;50(6):807-18

[14] Suddaby EC, Barnett S, Facteau L. Skin breakdown in acute care pediatrics. Paediatric Nursing 2005; 31(2): 132-138.

[15] Huffines B, Logsdon MC. The Neonatal Skin Risk Assessment Scale for predicting skin breakdown in neonates. Issues Compr Pediatr Nurs. 1997Apr-Jun;20(2):103-14.

[16] Sterken DJ, Mooney J, Ropele D, Kett A, Vander Laan KJ. Become the PPUPETMaster: Mastering Pressure Ulcer Risk Assessment With the Pediatric PressureUlcer Prediction and Evaluation Tool (PPUPET). J Pediatr Nurs. 2015

[17] Willock J, Baharestani MM, Anthony D.The development of the Glamorgan paediatric pressure ulcer risk assessment scale. J Wound Care. 2009Jan;18(1):17-21.

[18] Willock J., Anthony D., Richardson B. Inter-rater reliability of the Glamorgan Paediatric Pressure Ulcer Risk Assessment Scale. Paediatric Nursing 2008; 20(7): 14-19.

[19] Baharestani MM, Ratliff C. Pressure ulcers in neonates and children: an NPUAP white paper. Advances in skin & wound care 2007; 20(4): 208-220.

[20] Sousa V, Rojjanasrirat W. Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline. J Eval Clin Pract. 2011;17:268-74.

[21] Polit DF, Tatano Beck C. The Content Validity Index: are you sure you know what's being reported ? Critique and recommendations. *Res Nurs Health*. 2006;29:489-97.

[22] Maxim LD, Niebo R, Utell MJ. Screening tests: a review with examples. *Inhal Toxicol*. 2014; 26(13): 811-28.

Citation: **Daniele Ciofi, Giulia Gori et al.** *Pressure Ulcers in Hospitalized Children: Prospective Observational Study and Italian Linguistic and Cultural Validation of the Glamorgan Pediatric Pressure Ulcer Risk Assessment Scale. Open Access Journal of Nursing. 2019; 2(2): 05-10.*