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A simple tool to measure procedural restraint intensity in children: validation of the PRIC (Procedural Restraint Intensity in Children) scale

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ABSTRACT

Purpose: Restraint is often used when administering procedures to children. However, no metrologically scale to measure the restraint intensity had yet been validated. This study validated the metrological criteria of a scale measuring the restraint intensity, Procedural Restraint Intensity in Children (PRIC), used during procedures in children.

Design and methods: The PRIC scale performance was measured by a group of 7 health professionals working in a children's hospital, by watching 20 videos of health care procedures. This group included 2 physicians, 1 pediatric resident, and 4 nurses. The intra-class correlation coefficients were calculated to evaluate the inter-rater and test-retest reliability and the construct validity with the correlation between PRIC scale and a numerical rating scale.

Results: One hundred and forty measurements were made. Inter-rater and test-retest correlation coefficients were 0.98 and 0.98, respectively. The 2 scales were positively correlated with a Spearman coefficient of 0.93.

Conclusions: This study validated the Procedural Restraint Intensity in Children (PRIC) scale in metrological terms with some limitation. However, there is not gold standard scale to precisely validate the reliability of this tool and this study has been conducted in "experimental" conditions. Nevertheless, this is the first scale measuring the intensity of physical restraint with a metrological validation. The next step will be to validate it in real clinical situations.

1. Introduction

Restricting a child's movements in order to provide health care, although poorly quantified, seems quite common and is often implicit in pediatric health care [1]. Indeed, children often undergo procedures for diagnostic or therapeutic purposes, which can be painful, stressful, and potentially traumatic [2, 3, 4, 5, 6, 7]. Health professionals are sometimes required to hold them more or less firmly [4, 5] to be able to carry out these procedures [8], especially in the youngest patients. It is worth pointing out that some health professionals consider that restraint is acceptable if applied in the child's best interests [9, 10]. Hull et al. refer to the Department of Health [11] to define restraint as: '*the positive application of force with the intention of overpowering the child.*' [12]. According to Kirwan [13] who refers to the NCN's recommendations [14]: *"Restraint is described as a force that is reasonably or unreasonably applied by one person against another's resistance"*.

However, some authors suggested that frequent restraint by nurses could be compared to a form of abuse [9]. Restraint is also a practice that worries and stresses out the parents [7, 15, 16]. Furthermore, it has been shown that restraint was experienced as more stressful than the pain caused by the treatment [16].

The restraint should be quantified for three main reasons. Firstly, the

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use of restraint is a professional situation with ethical risks linked to an unreasonable and excessive use of force. Without a specific tool, it is difficult for health professionals to identify when restraint becomes unreasonable. Secondly, completing the first reason, it is necessary to document and quantify high-risk situations of strong restraint. The objective is to prevent these situations. Documenting restraint by health professionals is difficult during the care, so it is necessary to have a simple and handy tool. We demonstrated in a study the applicability of the PRIC scale (data not yet published) though we had to make sure it measured it right. Finally, the third reason is the necessity to quantify restraint practices. Indeed, the PRIC scale could provide opportunities to assess further the use of restraint, leading to an epidemiological assessment of this phenomenon. For all these reasons, it was essential to have a tool validated following metrological rules, measuring reliability and reproducibility.

1.1. Background

Several situations when children became agitated were described, such as during the induction of anesthesia or in case of emergency [17, 18, 19, 20, 21, 22, 23]. A research over one year identified 433 cases of agitation during painful procedures out of 5,045 procedures [24].

One study carried out in the emergency department among 124 preverbal and early-verbal children showed that physical restraint had been used for 72% of them. For some procedures like nasogastric tube insertion and intravenous cannulation, a moderate or forceful restraint had been used in 79 and 48% cases, respectively [25]. In this study, Crellin et al tried to categorize restraint in a very thorough manner and introduced the concept of "forceful restraint" [25].

We provided further explanations for the various terms used to refer to the restraint or holding of children during procedures. As pointed out, various terms correspond to physical restraint in the literature [26]. The word "restraint" was used in several publications [13, 27, 28], along with "supportive holding", "clinical holding", "therapeutic holding", "restrictive physical intervention", "restricting movement", "physical holding" and "immobilization" [7, 29, 30]. The notion of force associated with physical restraint is not the same according to the term used. Hull and Clarke considered that the definition of the restraint given by the department of Health[11] [1], implied "that restraint involved using force, and consequently was applied without consent" [28]. The assessment of the restraint intensity was based on two criteria measured independently: number of body parts held by health professional and force needed (mild, moderate or vigorous) for this holding. The level of restraint was assessed as follows: no restraint; targeted restraint (focusing only on the part affected by the procedure); partial restraint (including the part affected by the procedure and, either the torso or at least two limbs) or total restraint (with either the four limbs or at least two limbs and the torso) [25]. In this study, authors proceeded in two steps: they witnessed the care procedures and analyzed their video-recording [25]. This measurement method has not been metrologically validated nor presented as a scale by the authors.

In a study comparing general anesthesia and midazolam sedation during bone marrow smears and/or lumbar punctures in children in onco-hematology, the degree of restraint was the main criterion [31]. The scale used was the 0 to 5 Likert scale from 0-5 (from "not held" to "impossible to hold"). This scale was not specifically validated in this context.

To date, there is no validated scale to assess the restraint and measure its intensity in a reliable and reproductible way. This was the whole point of validating a scale. A scale has to take into account both the concept of force and the extent of the restraint in accordance with definitions seen above and has to be clinically relevant.

[1] 'the positive application of force with the intention of overpowering the child.

The objective of this study was to validate of the metrological criteria (i.e validity and fidelity [32, 33, 34]) of a scale measuring the intensity of restraint, the Procedural Restraint Intensity in Children (PRIC) scale. The objective of a metrological evaluation is to ensure that the evaluated tool works in a reproducible and reliable way. We tested the feasibility of the PRIC scale in clinical situation. It was a prospective survey conducted in 24 care units of a pediatric hospital. During 5 days, health professionals recorded the physical restraint with the PRIC scale during the health procedures. We included 599 children with a median age of 3 years and the level of contention was measured for 963 procedures (93%) [35]. The conclusion was that the PRIC scale was feasible in clinical practice, though we didn't test had not tested its reproducibility and reliability in this study.

2. Methods

2.1. Design

The items, the score modalities and the format of the scale were selected by a group of nine health professionals working in a children's hospital, including three physicians, two nurses, two psychologists, a clinical research nurse and a methodologist. This first step aimed to develop a practical, user-friendly scale in clinical practices. In this first study, the aim was to assess the feasibility of using a restraint scale in clinical situations. We had tested the feasibility of our scale during a first prospective evaluation of restraint [35].

So, we eventually chose two indicators from simple observations for their clinical relevance: on the one hand, the number of adults holding the child and the number of body parts held down; on the other hand, the behavioral responses of the child during the holding.

Five levels of restraint were then defined (see Table 1). The metrological validation included the determination of inter-rater agreement, the agreement between the two tests by the same observer (test-retest), and the construct validity with the correlation between the PRIC and Numerical Rating Scale (NRS). In this situation, the NRS documented by observers, had measured the restraint intensity between 0 and 10 (0 representing no restraint at all, and 10 the most forceful restraint imaginable). The inter-rater agreement evaluated the stability of scores assessed by at least two different observers in the same subject. The "test-retest" evaluated the stability of scores assessed by the same observer in the same individual at two different times. In this study, the two measurements were done several weeks apart to reduce the risk of remembering the first measurement.

2.2. Data collection

These evaluations were made from watching 20 videos representing health care procedures in children. These 20 health care procedures were carried out in children with a median age of 4 and interquartile ranges 25–75: 2 months -7 years (extremes: 1 month - 13 years old) and of whom 12/20 were boys. No children had cognitive impairment. Procedures were lumbar punctures (2), venipunctures for blood sample (12),

Table 1
Scale measuring restraint intensity: Procedural Restraint Intensity in Children scale (PRIC).

- **Level 0**: no restraint, the child is calm and relaxed
- **Level 1**: "mild restraint": part of the child's body is just lightly held (by one person) without a withdrawal reaction by the child
- **Level 2**: "medium restraint": one or two parts of the child's body are held (by one person) with a withdrawal reaction by the child
- **Level 3**: "forceful restraint": one or more parts of the body are held firmly (by several people), the child protests, screams, cries
- **Level 4**: "extremely forceful restraint": one or several parts of the child's body are held (by several people) with a withdrawal reaction, significant agitation from the child, who struggles strongly despite the restraint.

intravenous cannulation (3), nasogastric tube insertions (3) (see Table 2). All children were at rest and calm before the procedure. The video recorded their restlessness occurring during the procedure. Moreover, the physical restraint often occurred before the agitation started.

The study protocol was approved by Robert Debré hospital's ethics committee (n°2015/201). Written information and written consent were provided to parents to record the videos and use them for the study.

Following training on the PRIC scale, 7 health professional-observers, all working in pediatrics, watched these videos and attributed to each of them a restraint score on a specific collection sheet. These health professional-observers had a median age of 41 (interquartile ranges 25–75: 35–57) and their seniority concerning their activity in children department was in average 12 years (11–32). The distribution of their activity was as follows: four nurses and two doctors all specialized in management of children and their pain, one third-year pediatric resident. Unfortunately, the latter was not available for the second phase of the test-retest assessment. Participants were guided to evaluate the videos of children less than one year old. They were invited to give priority to the number of body parts that were held firmly even when restraint was applied by a single person.

They were required to watch the videos without expressing any comments among themselves and to assess physical restraint with the PRIC scale after viewing twice each clinical situation.

2.3. Analysis

The inter-rater reliability and "test-retest" were evaluated with the intra-class correlation (ICC) coefficient (satisfactory if > 0.8). The validity construct was assessed by calculating the correlation between the PRIC scale and the Numerical Rating Scale.

Quantitative variables were presented as medians and their interquartile range and qualitative variables as percentage with confidence interval at 95% (IC 95).

Data analysis was performed with SPSS 17.0 (SPSS Inc, Chicago, Illinois, USA).

3. Results

3.1. Measurement of the inter-rater reliability of the scale

The seven health professionals gave a PRIC score to each of the 20 procedures they watched. A total of 140 measurements were made. The average intra-class correlation coefficient was 0.98 [95% CI = 0.96–0.99] ($p < 0.0001$).

Table 2
Details about children, procedures and intensity of restraint.

	Care procedures	Age	Strong restraint*, **
Video 1	Intravenous cannulation	10 months	3.5
Video 2	Nasogastric tube insertion	5 months	3.0
Video 3	Venipuncture for blood sample	6 years old	3.5
Video 4	Venipuncture for blood sample	2 months	1
Video 5	Venipuncture for blood sample	2 months	2
Video 6	Venipuncture for blood sample	12 years old	1
Video 7	Venipuncture for blood sample	12 years old	0
Video 8	Intravenous cannulation	1 month	1
Video 9	Venipuncture for blood sample	10 months	1
Video 10	Venipuncture for blood sample	6 years old	1
Video 11	Venipuncture for blood sample	13 years old	0
Video 12	Venipuncture for blood sample	2 months	2
Video 13	Nasogastric tube insertion	1 months	3
Video 14	Venipuncture for blood sample	7 years old	2
Video 15	Intravenous cannulation	8 years old	1
Video 16	Venipuncture for blood sample	4 years old	1
Video 17	Lumbar puncture	8 years old	3.5
Video 18	Lumbar puncture	7 years old	2
Video 19	Venipuncture for blood sample	5 years old	3
Video 20	Nasogastric tube insertion	3 years old	4

*Strong restraint = level 3 or 4 for children older than 1 year old or level 2 or more for children less than 1 year old. ** median score.

3.2. Test-retest

Six health professionals evaluated the 20 procedures filmed twice several weeks apart, which accounted for 120 measurement pairs. The resident did not take part. The intra-class correlation coefficient was 0.98 [95% CI = 0.97–0.99] ($p < 0.0001$).

3.3. Construct validity

A total of 140 measurements were made with the PRIC and NRS scales. There was a positive correlation between the two scales with a Spearman coefficient of 0.93 [95% CI = 0.89–0.97] ($p < 0.0001$).

4. Discussion

This study validates the PRIC scale work in metrological terms. The good results of the inter-rater evaluation and the test-retest validated the reproducibility and reliability of the PRIC scale. This is currently the only validated scale, but the next step would be a validation in clinical practice, in real life. However, as other teams had done with different scales without any kind of metrology validation, we already used this practical scale to describe child restraint in a hospital [25, 31, 35].

This study did not validate the PRIC scale in real situations with patients and nurses providing health care. However, it was the first but fundamental step of the validation.

The lack of a gold standard scale for the construct validity was an important limitation of this study. We chose the Numeric Rating Scale as reference because that was pragmatic. The NRS is a commonly used scale and we made the hypothesis that it could be considered as a gold standard if used by health professionals with extensive experience in child management. In addition, the NRS' nurse has often been used as a reference score to validate different scales in pediatric medicine [36, 37].

Our scale differs from the one used by Crellin et al. They measured the perception of the forcefulness of restraint used on 3 levels (gentle, moderate, forceful) and divided the extent of the restraint into 4 categories, from no use of restraint to full restraint (all 4 limbs or 2 or more limbs and torso) [25].

We considered the number of adults, implied in the restraint, in our scale based on our clinical experience. In fact, our observations during children management led us to think that it was a relevant point in relation with the fact that it could be associated with the intensity of physical restraint for the older children at least. Indeed, the number of adults could determine the number of body parts to hold down restrain during physical restraint of the child. It could also determine the intensity of the restlessness and so the power needed to restraint the child. The advantage of this item was that it was objective, easy to record. It was obvious that this point was less important for younger children (less than one year old) because their bodies were smaller, so a single adult could restraint their body parts can be provided by a single adult. It is the reason why there was a weighing for this population.

The weighting for children less than one year old weakens the validation of the PRIC scale. Further refinement for this age group will have to be considered in the future. The number of body parts restrained will probably be the predominant criterion in this case.

We chose to analyze four procedures – venipuncture, intravenous cannulation, nasogastric tube insertion and lumbar puncture – to assess the scale. These procedures represented both the most common and the most technically challenging ones. Moreover, Crellin et al studied three of these four procedures (nasogastric tube insertion, venipuncture and intravenous cannulation) and determined that they were associated with forceful restraint [25]. We found similar results with the PRIC scale: according to the type of procedure (nasogastric tube insertion,

cannulation etc..) and frequency [1].

Brenner and al. suggested that "Many terms are used to describe restricting a child's movement, depending on the perceived degree of force used" [1] and hypothesized "that nurses have a common understanding of what constitutes the use of force in the clinical setting" [1]. However, the quantification of force remains vague. The nurses' approach to this practice varies and this can be a source of tension between nurses, parents and other professionals [15]. The PRIC scale aimed to assess both force and extent of the restraint.

Therefore, this scale appears to meet the clinical needs of assessing this practice. It should help improving professional knowledge about the use of restraint in pediatric care.

5. Conclusion

This study validated the PRIC scale, a tool enabling to measure the intensity of physical restraint in children during health care, in a reliable and reproducible way. However, one of the main limitations of this validation was the lack of a gold standard scale to measure the intensity of the physical restraint so we are still questioning the measuring precision of the PRIC scale (reliability). Another limitation was the "experimental" conditions of this study, but this is the first scale measuring the intensity of physical restraint with a metrological validation. The next step will be to validate it in real clinical situations.

Declarations

Author contribution statement

Bénédicte Lombart: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Daniel Annequin: Conceived and designed the experiments.

Patricia Cimerman, Carla De Stefano: Analyzed and interpreted the data.

Odile Perrin, Barbara Tourniaire: Contributed reagents, materials, analysis tools or data.

Celine Bouchart, Marie-Claire Schommer, Laura Ramelot, Céline Petit, Elisabeth Fournier-Charriere, Anne Caron, Solène Trebosc: Performed the experiments.

Michel Galinski: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

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Competing interest statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

References

[1] M. Brenner, A need to protect: parents' experiences of the practice of restricting a child for a clinical procedure in hospital, Issues Compr. Pediatr. Nurs. 36 (1-2) (2013) 5–16.
[2] L. Bray, B. Carter, K. Ford, A. Dickinson, T. Water, L. Blake, Holding children for procedures: an international survey of health professionals, J. Child Health Care 22 (2018) 205–215.
[3] L. Bray, B. Carter, J. Snodin, Holding children for clinical procedures: perseverance in spite of or persevering to be child-centered, Res. Nurs. Health 39 (2016) 30–41.
[4] L. Bray, S. Sinha, Developing an information leaflet for children having planned procedures in hospital, Nurs. Child. Young People 29 (2017) 30–34.
[5] M. Brenner, Development of a factorial survey to explore restricting a child's movement for a clinical procedure, Nurse Res. 21 (2) (2013) 40–48.
[6] I. Coyne, P. Scott, Alternatives to restraining children for clinical procedures, Nurs. Child. Young People 26 (2014) 22–27.
[7] M. Brenner, Child restraint in the acute setting of pediatric nursing: an extraordinarily stressful event, Issues Compr. Pediatr. Nurs. 30 (1-2) (2007) 29–37.
[8] M. Brenner, J. Drennan, M. Pearl Treacy, G.M. Fealy, An exploration of the practice of restricting a child's movement in hospital: a factorial survey, J. Clin. Nurs. 24 (2014) 1189–1198.
[9] L. Kirwan, I. Coyne, Use of restraint with hospitalized children: a survey of nurses'perceptions of practice, J. Child Health Care 21 (2017) 46–54.
[10] K. Hull, D. Clarke, Restraining children for clinical procedures: a review of the issues, Br. J. Nurs. 19 (2010) 346–350.
[11] P. McGrath, K. Forrester, S. Fox-Young, N. Huff, "Holding the child down" for treatment in paediatric haematology: the ethical, legal and practice implications, J. Law Med. 10 (2002) 84–96.
[12] M. Kangasniemi, O. Papinaho, A. Korhonen, Nurses' perceptions of the use of restraint in pediatric somatic care, Nurs. Ethics 21 (2014) 608–620.
[13] J. Selekman, B. Snyder, Nursing perceptions of using physical restraints on hospitalized children, An. Pediatr. Nurs. 21 (1995) 460–464.
[14] S. Robinson, J. Collier, Holding children still for procedures, Paediatr. Nurs. 9 (1997) 12–14.
[15] J. Thomas, Brute force or gentle persuasion? Paediatr. Anaesth. 15 (2005) 355–357, 2005.
[16] J. Benger, "Brutacaine" vanquished, but pain remains, Emerg. Med. J. 23 (2006) 823.
[17] E. Christiansen, N. Chambers, Induction of anesthesia in a combative child; management and issues, Pediatric Anesthesia 15 (2005) 421–425.
[18] B. Loryman, F. Davies, G. Chavada, T. Coats, Consigning "brutacaine" to history: a survey of pharmacological techniques to facilitate painful procedures in children in emergency departments in the UK, Emerg. Med. J. 23 (2006) 838–840.
[19] M.L. Sønderskov, P. Hallas, The use of 'brutacaine'in Danish emergency departments, Eur. J. Emerg. Med. 20 (2013) 370–372.
[20] R.G. McGlone, S. Ranasinghe, S. Durham, An alternative to" brutacaine": a comparison of low dose intramuscular ketamine with intranasal midazolam in children before suturing, J. Accid. Emerg. Med. 15 (1998) 231–236, 1998.
[21] J.R. Lightdale, C. Valim, L.B. Mahoney, S. Wong, J. DiNardo, D.A. Goldmann, Agitation during procedural sedation and analgesia in children, Clin. Pediatr. 49 (2010) 35–42.
[22] D. Crellin, F.E. Babl, T.P. Sullivan, J. Cheng, R. O'Sullivan, A. Hutchinson, Procedural restraint use in preverbal and early-verbal children, Pediatr. Emerg. Care 27 (2011) 622–627.
[23] K. Folkes, Is restraint a form of abuse? Paediatr Care 17 (2005) 41–44.
[24] K. Hull, D. Clarke, Are paediatric oncology nurses acknowledging the effects of restraint? A review of the current policy and research, Eur. J. Oncol. Nurs. 15 (2011) 513–518.
[25] K. Jeffery, Supportive holding or restraint: terminology and practice, Paediatr Care 22 (2010) 24–28.
[26] K. Lambrenos, E. McArthur, Introducing a clinical holding policy, Paediatr Care 15 (2003) 30–33.
[27] H.J. Przybylo, S.E. Tarbell, G.W. Stevenson, Mask fear in children presenting for anesthesia: aversion, phobia, or both? Paediatr. Anaesth. 15 (2005) 366–370.
[28] Royal College of Nursing, Restraining, Restrictive Physical Intervention and Therapeutic Holding for Children and Young People. Guidance for Nursing Staff, RCN, London, 2010. https://www.rcn.org.uk/professionaldevelopment/publications/pub-003573.
[29] S.G. Stacey, W. Ames, A. Petros, Sedation and restraint practices in UK paediatric intensive cares: a telephone survey, Paediatr. Anaesth. 10 (2000) 702.
[30] K. Jeffery, Therapeutic restraint of children: it must always be justified, Paediatr. Nurs. 14 (2002) 20–22.
[31] A. Page, A. McDonnell, Holding children and young people: defining skills for good practice, Br. J. Nurs. 22 (2013) 1153–1158.
[32] C. Darby, P. Cardwell, Restraint in the care of children, Emerg. Nurse 19 (2011) 14–17.
[33] M. Hardy, G. Armitage, The child's right to consent to x-ray and imaging investigations : issues of restraint and immobilization from a multidisciplinary perspective, J. Child Health Care 6 (2002) 107–119.
[34] C. Crock, C. Olsson, R. Phillips, G. Chalkiadis, S. Sawyer, D. Ashley, S. Camilleri, J. Carlin, P. Monagle, General anaesthesia or conscious sedation for painful procedures in childhood cancer: the Family's perspective, Arch. Dis. Child. 88 (2003) 253–257.
[35] B. Lombart, D. Annequin, P. Cimerman, P. Martret, A.C. Chary-Tardy, B. Tourniaire, M. Galinski, Using Restraint during Painfull Cares in Children. 18th Daytime Child' Pain. Which Answers? Paris, 2011. http://www.pediadol.org/IMG/pdf/U2011_lombart.pdf.
[36] C.H. Elliott, S.M. Jay, P. Woody, An observation scale for measuring children's distress during medical procedures, J. Pediatr. Psychol. 12 (1987) 543–551.
[37] M. Brenner, M.P. Treacy, J. Drennan, G. Fealy, Nurses' perceptions of the practice of restricting a child for a clinical procedure, Qual. Health Res. 24 (8) (2014) 1080–1089.