

Title: Feasibility and clinical utility of the Finnish version of the FLACC pain scale in PICU

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Conflict of interest

None

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Abstract

Purpose: To evaluate the feasibility and clinical utility of the Finnish FLACC scale when assessing children's pain in a Pediatric Intensive Care Unit (PICU).

Design and Methods: A non-experimental, descriptive cross-sectional study design, evaluating the feasibility and clinical utility was conducted in a Finnish PICU between May and August 2018. The nurses were asked to complete a data collection questionnaire about the feasibility and clinical utility of the Finnish FLACC every time they used the scale to assess pain in children. In total, the data consisted of 157 pain assessments cases. Quantitative data were analyzed statistically and responses to open-ended questions were analyzed using content analysis.

Results: In most cases, the nurses agreed that the Finnish FLACC scale was clearly structured (97%), easy to use (98%), helpful in assessing pain intensity (77%), and useful when reassessing pain after interventions (67%). Nurses found the scale more useable for children over one year old than for younger children. When assessing *cry* and *consolability*, pain was easier to score if the child was not intubated.

Conclusions: The Finnish FLACC scale exhibits adequate feasibility and clinical utility when assessing pain in children in a PICU. However, more information is needed about its use during painful short-term procedures and with children under one year old.

Practice implications: The Finnish FLACC scale is a helpful tool for nurses when assessing children's pain in a PICU. However, the Finnish version of the modified FLACC is needed for use with intubated children in the future.

Keywords: Pain, Pain assessment, Pediatric intensive care, Child, FLACC pain scale

Highlights

- The Finnish FLACC scale was clearly structured and easy to use for assessing children's pain in a PICU.
- Nurses agreed that the total pain scores generated with the Finnish FLACC scale helped them to assess the intensity of pain in children.
- Nurses found the FLACC more useable for children over one year old.
- Scoring *cry* and *consolability* was more difficult in intubated children.

INTRODUCTION

The assessment of a child's pain experience in any pediatric intensive care unit (PICU) presents unique challenges for health care providers. Most children requiring intensive care cannot quantify their own pain themselves: not only do they differ in their ability to communicate and their level of development, but the critical nature of a child's illness must also be considered (Harris et al., 2016; Ismail, 2016). Children in a PICU often have to undergo a series of painful and stressful events: as well as experiencing post-operative pain, they may also be subjected to many painful procedures such as venipuncture, insertion of intravenous and arterial cannulation, airway suctioning, intubation, and chest drain insertion. Even routine daily care, e.g. turning, can be painful for critically ill children (Harris et al., 2016).

Pain can be defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (IASP, 2017). The most recent definition of pain (William & Craig, 2016) also includes cognitive and social components. A child's pain experience is influenced by previous experiences, the expectation of pain, and sociocultural factors (Pope et al., 2017). Children who lack the verbal and cognitive ability to self-report pain because of their age (Thrane et al., 2016), cognitive impairments (CI), or illness are more likely to suffer untreated pain (Andersen et al., 2017; Herr et al., 2011).

Pain has several physiological and psychological consequences that can affect a child both at the time and later in life (Saxe et al., 2001; Taddio et al., 2002). Unrelieved pain in infancy and childhood can lead to a hypersensitivity to pain and life-long changes in pain perception (Fitzgerald & Walker, 2009). Accurate and evidence-based pain assessment is therefore essential for effective pain

management. Self-reporting is the primary method of assessing pain (Thrane, Cohen & Danfor, 2016), but children in a PICU are often unable to self-report their pain. Therefore, to accurately assess a critically ill child's pain, nurses need a valid, reliable, and responsive structured pain assessment tool (Herr et al., 2011). Despite the recent development of several pain assessment tools (Andersen et al., 2017; Harris et al., 2016), they are still used inconsistently with children. (Twycross & Collis, 2013.) In Finland, the Faces pain scale and the Visual Analogue Scale (VAS) are used for children who can self-report their pain, while the Neonatal Infant Acute Pain Assessment Scale (NIAPAS) is used to assess pain in infants requiring intensive care (Pölkki et al., 2014). However, there is no pain scale in the Finnish language for older children who cannot self-report their pain.

The Face, Legs, Activity, Cry, Consolability (FLACC) scale is a widely used behavioral observational pain scale for children who cannot communicate their pain (Andersen et al., 2017; Crellin et al., 2015). This scale was originally designed to measure postoperative pain in infants and children between two months and seven years old. It has five items, each of which is scored on an integer scale ranging from 0 to 2, giving a total range of 0-10, where 0 indicates no pain and 10 reflects the maximum level of pain (Merkel et al., 1997.) More recently, the FLACC scale has been used to assess procedural pain (Crellin et al., 2018; Gomez et al., 2013) as well as pain experienced by infants younger than two months and children older than seven years (Crellin et al., 2015). It was originally written in English but has since been translated into several languages including Chinese, Portuguese, Swedish, Danish, and Thai. The revised FLACC scale (r-FLACC) was developed in 2006 to enable more accurate assessment of pain in cognitively impaired children. The five categories of the original FLACC scale (Face, Legs, Activity, Cry, and Consolability) are retained in r-FLACC, but some descriptors associated with pain in cognitively impaired individuals were added together with open-ended descriptors for each of the five categories, allowing caregivers or parents to record individualized pain behavior the patient may exhibit (Malviya et al., 2006).

According to the systematic review of Crellin et al. (2015) there are adequate data on postoperative pain assessment in infants and children using the FLACC scale. However, more information is needed concerning the feasibility and clinical utility of the FLACC scale when assessing other painful events such as procedural pain. At present, it seems that there are insufficient data to support the use of the FLACC scale in all circumstances and populations to which is currently applied. In addition, there was a need to translate the scale into Finnish. Therefore, the aim of this study is to describe the feasibility and clinical utility of the Finnish FLACC scale for assessing pain in a PICU from the viewpoint of nurses.

METHODS

Finnish version of the FLACC scale

The process towards describing the feasibility and clinical utility of the FLACC scale in a Finnish PICU included forward translation (Finnish), back translation (English), and a pretest procedure. In the first step the FLACC scale was translated from English into Finnish by a professional translator. Then the authors (TP and HL) assessed and modified the translated version to include the specific terminology used in Finnish PICUs. The goal of translation was to achieve equivalence between the original and translated versions of the scale. Because the research environments and research questions always differ, there is no gold standard for translation techniques. However, it is important to use appropriate translation procedures and to employ a combined translation technique (Cha, Kim & Erlen, 2007). We made contact with the researchers who developed the original FLACC pain scale (Merkel et al. 1997), and received permission to translate the scale and apply it in research and practice from Terri Voepel-Lewis in January 2018.

In the second step, another professional translator translated the Finnish version back into English, and the original English and back-translated Finnish versions were compared by the researchers. Finally, in the third step, nurses responsible for pain management in the PICU evaluated the Finnish version and their suggestions for improvement were discussed. This procedure was continued until the authors and nurses all agreed on a Finnish version of the FLACC scale. This resulted in minor changes to the Finnish version of the FLACC scale. For example, where the original scale used the words "consolability", "legs", and "tone", the initial forward translation used the words "lohduteltavuus", "jalat", and "lihasjänteys". After consultation with the nurses, these words were changed to "rauhoiteltavuus", "alaraajat", and "lihasjänteisyys", which were back-translated as "consolability", "legs", and "muscle tone". The Finnish version was then validated by eight nurses specializing in pain management, from two University Hospitals to verify its understandability. The Finnish FLACC scale was brought into use in the PICU in February 2018 and was integrated into PICUs patient record system (Table 1).

Insert Table 1. The Finnish version of the FLACC scale.

Data collection

To describe the feasibility and clinical utility of the Finnish FLACC scale, we collected data from nurses working in one of the PICUs in Finland between May and August 2018. In Finland, PICUs are departments of university hospitals, and most of their employees are Registered Nurses (RNs). The official language in the studied PICU is Finnish, and a total of 50 nurses were working there during the data collection period. The PICU usually has ten beds, and the ages of its patients range from newborns to 16-year-olds. In 2018, the average treatment time in the PICU was 2.42 days. Patients at the PICU are classified into one of three groups depending on the severity of their illness. The most critically ill patients include intubated children, labile children who require demanding medications and sedatives, and children who need other demanding treatments. Less severely ill patients include stable infants with CPAP, restless children who cannot be left alone, and children needing postoperative pain management. Finally, patients requiring follow-up care include children with stable vital functions who don't need constant monitoring, babies recovering from infections, and children waking up after anesthesia.

The data examined in this work consist of 157 pain assessment cases in which nurses used the Finnish FLACC scale to assess the pain of pediatric patients in the PICU. Nurses were instructed to use the scale for all child patients when they considered it appropriate, irrespective of the patient's population or circumstances. Assessments were thus performed on patients at rest, post-operation, during routine care, and during short-term painful procedures. Children with cognitive impairment were excluded from this study. After the nurses had assessed pain using the Finnish FLACC, they completed a data collection questionnaire about the scale's feasibility and clinical utility. Nurses were asked to complete the questionnaire immediately after performing a pain assessment because the pain assessments were not videotaped. Nurses posted the completed questionnaires into a sealed box in the unit after completing each pain assessment.

Data were collected using a validated questionnaire based on questionnaires used in previous studies evaluating the scale's feasibility and clinical utility (Crellin et al., 2018; Gibbins et al., 2014; Pölkki et al., 2014; Stevens et al., 2014; Taddio et al., 2011). In addition, the questionnaire was piloted with ten nurses to evaluate its content validity and ensure that all the items were understandable. Some minor changes were made to the questionnaire after the pilot and a feasibility question about the written instructions concerning the use of the Finnish FLACC scale was clarified. To ensure nurses

knew where to find written guidance on completing the FLACC the whereabouts of such information was added to the questionnaire. Some words were altered to improve clarity.

The data collection questionnaire had four sections. Section one contained questions about the pain assessment cases: two questions about the children's characteristics (age and intubation or non-intubation) and one question about the context in which pain was assessed (at rest, postoperative, during routine care, during short-term painful procedures) (Table 2). Section two included nine questions about the feasibility of the Finnish FLACC: four questions relating to its clarity and six relating to ease of scoring (Table 3). Nurses were also asked two questions about the scale's usability when assessing pain in children of specific ages and in specific pain assessment contexts. Section three consisted of three questions about the clinical utility of the Finnish FLACC scale (Table 4). Finally, section four included one open-ended question about the nurse's response to any further proposed development of the Finnish FLACC scale. Questions relating to the feasibility of the FLACC scale were scored using a five-point Likert scale (1 = strongly disagree, 5 = strongly agree) (Polit & Beck, 2012) and one was an open question asking respondents to specify factors that made scoring difficult. Questions about the clinical utility of the FLACC scale were also scored using a five-point Likert scale. Most of the questions about the pain assessment cases were multiple choice and dichotomous (yes/no).

Data analysis

Data from the 157 pain assessment cases collected with the questionnaires were analyzed using SPSS Statistics for Windows (version 24.0). The data from sections one, two and three of the questionnaire were first analyzed by computing descriptive statistics including frequencies and percentages. After that, differences between background variables (pain assessment cases) and main variables (feasibility and clinical utility) were analyzed using the χ^2 - and Fisher's exact tests. For the analysis, sum variables were formed from the main variables and divided into two categories based on means, histograms, and boxplots: disagree (indicated by scores of 1–3.49) and agree (3.5–5.0). The results presented below are all statistically significant at $p < 0.05$ (Polit & Beck, 2012.)

Open-ended questions were analyzed using the principles of content analysis (Elo & Kyngäs, 2008; Kyngäs et al., 2011). First, written answers to open-ended questions were read repeatedly and a key word, sentence, or sentence fragment was identified and selected as the unit of analysis. The units were then grouped into subcategories and the subcategories were further grouped together into main

categories (Elo & Kyngäs, 2008). Results of open questions are presented using q, which describes the number of times a certain word or sentence appeared in the responses.

Ethical considerations

Permission to conduct this study was granted by the Oulu University hospital in Finland. Nurses were informed about the study and its purpose by email before and during the study. The researcher (HL) also visited the unit to provide further information about the study's implementation in practice. Participation in the study was voluntary, and the anonymity of all participants was ensured; questionnaires were anonymous and names were not recorded. The researcher had no access to the patients' medical records at any time during the study (Polit & Beck, 2012.)

RESULTS

Pain assessment cases

Most of the pain assessments were performed on children aged seven or under (65%), and only a few children were intubated (6%). In most cases (47%), pain levels were assessed when the child was at rest; 24% of cases were assessments of post-operative pain; 23% were cases of pain experienced during routine caring; only 5% of the pain assessments were conducted during a short-term painful procedure (Table 2).

Insert Table 2. Pain assessment cases: children's characteristics and contexts in which pain was assessed.

The feasibility of the FLACC scale

In most of the cases, nurses agreed (strongly agreed/agreed) that the structure of the FLACC scale was clear (97%), it was technically easy to use (98%), and filling the questionnaire did not take too much time (87%). In half of the cases, the nurse checked the written instructions and most of them (86%) agreed that the instructions were clear (Table 3).

Insert table 3. The feasibility of the Finnish FLACC as evaluated by the nurses.

In almost 80% of the pain assessments, nurses agreed (strongly agreed/agreed) that the Finnish FLACC scale was usable for assessing a child's pain. There were no statistically significant differences in usability between the different pain assessment cases. Usability did however differ between patient age groups: nurses agreed that the FLACC scale was usable for assessing pain in 94% (n = 43) of cases involving children between one and seven years old, and in 81% (n = 42) of cases involving children over seven years old. However, if the child was under one year old, only in 69% (n = 37) of cases did the nurses consider the FLACC scale to be suitable. The differences between the age groups were significant (χ^2 ; p= 0.008).

Scoring was considered 'easy' in all five categories (Table 3). However, intubation of the child was associated with a difference in ease of scoring *cry* and *consolability*. If the child was not intubated, nurses agreed scoring *cry* to be easy in 92% (n = 127) of cases. However, if the child was intubated, nurses only found scoring *cry* to be easy in 70% (n = 7) of cases (p = 0.022). Similar results were found when scoring *consolability*: nurses found scoring *consolability* easy in 95% (n = 131) of cases involving non-intubated children, but only in 70% (n = 7) of cases involving intubated children (χ^2 ; p = 0.002).

Reasons why scoring was not 'easy' were given in 18 % (n = 28) of the cases. The responses were grouped into three main categories: reasons related to the FLACC scale (q = 8), reasons related to the child (q = 17), and reasons related to the child's medication (q=3). The reasons related to the FLACC scale were: inappropriate descriptions, scale is too large for pain assessment, and vital sign values are missing when scoring pain. *Leg* could be defined more comprehensively by stating that the score should be increased if the child's hands are tensioned but their legs are not. A child's disease or condition may affect his or her movement directly, or a child may move restlessly and almost continuously. Additionally, muscle tension may differ between sick and healthy children. Scoring *face* can be difficult if a child's face is swollen or covered, or their eyelids are sewn. Scoring *cry* can be difficult if the child is intubated. Sometimes it is hard to differentiate between pain and fear. Moreover, medicines and local anesthetics such as epidural anesthesia can make scoring *activity* and *legs* difficult. Some illustrative responses to the open questions relating to factors that made scoring difficult include:

"Surgical patient having a medicine infusion that affects to activity and movement"

“The child had epidural anesthesia which paralyzed their legs, making it difficult to assess lower limb activity.”

“Child was anesthetized in the operating room and underwent an operation on the lumbar region. Normal movement of the lower limbs can presumably not be expected in such a situation.”

Clinical utility of the FLACC scale

In 77% of the pain assessment cases, nurses agreed (strongly agreed/agreed) that the total pain scores helped them assess the intensity of the pain (mild discomfort, discomfort, moderate pain, or severe pain). In 55% of cases, scores affected the decisions nurses made about managing the child’s pain, while in 67% of cases, the FLACC scores were found to be useful when reassessing the pain after an intervention (Table 4). There were no statistically significant differences in clinical utility between children who were and were not intubated.

Insert table 4. The clinical utility of the Finnish FLACC as evaluated by the nurses.

Development proposal

In a few cases (15%; n = 24), the nurses offered suggestions for further development of the Finnish FLACC scale. Common suggestions were that the scale should account for changes in patients’ vital signs, include instructions relating to pain scores, and account for individuality. The development proposals (q = 10) related to the need to include vital sign values in the Finnish FLACC scale. Nurses felt that changes in heart rate, O₂ saturation, blood pressure, and respiratory rate should be considered when scoring pain.

“I think the vital sign values could be taken into account in the pain scale (BP, pulse)”

“I would like the blood pressure and possible changes in pulse to be taken into account.”

Instructions on treating pain at specific pain scores (q = 1) were also mentioned.

“It would be good, if there were some instructions about effective ways of treating pain at specific pain scores, like in NIAPAS and VAS”

Individuality ($q = 4$) means that there could be different instructions and values for children of different ages. The psychological state of the child was also considered to be an important factor that should receive more attention.

DISCUSSION

The current lack of evidence concerning the feasibility and clinical utility of the Finnish FLACC scale in different populations and circumstances prompted us to describe the feasibility and clinical utility of the Finnish FLACC pain scale in the PICU. Our findings show that PICU nurses consider the FLACC scale to have good feasibility and clinical utility for assessing a child's pain in diverse pain assessment cases, including cases where the patient is rest, post-operative, undergoing routine daily nursing care, and undergoing short-term painful procedures.

The translated versions of the FLACC scale (e.g. Japanese and Portuguese version) have shown high degree of reliability and validity (Batalha et al. 2009, xx.) A Danish version of the r-FLACC is assessed to have a high clinical feasibility in Danish children with cerebral palsy. Although FLACC have been translated into several languages, the feasibility and clinical utility of the translated versions of the FLACC scale have not been published. Our results are consistent with those of Taddio et al. (2011), who suggest that implementing the FLACC scale is feasible. The nurses who participated in our study agreed that the structure of the Finnish FLACC scale is clear, it is technically easy to use, that it can be completed in a reasonable amount of time, and that the instructions are clear. Clinical utility was also considered good: the total pain scores were helpful for assessing the intensity of pain, and Finnish FLACC scores were useful when reassessing pain after interventions.

It should be noted that few of the pain assessments included in this study were conducted during short-term painful procedures. Therefore, any generalization of the results relating to such procedures should be made cautiously. Although short-term painful procedures are common in PICUs, pain assessments were not always conducted during such procedures, possibly because nurses were unaccustomed to assessing pain during such operations. Another reason may be that it is probably easier to concentrate on assessing the pain when a child is at rest, although pain assessment should

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be a systematic task performed by nurses during their working shifts. In addition, if pain can only be assessed after a procedure has been completed, it might be harder for a nurse to remember to do it.

Although scoring was considered ‘easy’ in all five categories, nurses found it harder to score *cry* and *consolability* when a child was intubated rather than not intubated. This may be because the Finnish FLACC scale does not provide different instructions for intubated and non-intubated children. Some other behavioral scales such as COMFORT use different scales for mechanically ventilated and spontaneously breathing children. In addition, Johansson & Kokinsky (2009) demonstrated the construct validity of a modified FLACC scale (in which the *cry* item was modified) that was designed to measure post-operative pain in intubated children. As an alternative, behavioral signs of pain such as facial expressions (moaning or crying) can be observed. While further development of the instructions appears to be needed, we suggest using the Finnish modified FLACC for intubated children in the future.

Additionally, in some of the cases, the nurses found that medicines and local anesthetics made scoring *activity* and *legs* difficult. It should be noted that if the child is deeply sedated or receiving a neuromuscular blockade, behavioral scales such as the FLACC may be inappropriate for assessing pain: the medication may render the child unable to exhibit pain behaviors, resulting in a pain score of “0” even though it is impossible for the nurse to know whether the child would exhibit pain behaviors in the absence of the medication (Laures et al., 2019). More research is needed to understand how nurses in Finnish PICU assess pain when self-reports and behavioral scales cannot be used. It is important to ensure that nurses use FLACC correctly: it is only applicable if the child can display all the behaviors on the scale.

The results presented here show that nurses find the Finnish FLACC scale to be more useable for older children than for children under one year old, although the FLACC scale was originally designed for use in infants and children aged between two months and seven years (Merkel et al., 1997). In our study, most of the children under one year old were over two months old and thus belong to the age group for which the FLACC scale was originally designed. Previous studies have shown that infants, toddlers, and older children each express their experience of pain in different ways and might need different pain scales (Thrane et al., 2016). In Finnish PICUs, the NIAPAS pain scale is available for assessing pain in infants under 2 months (Pölkki et al., 2014). Further research could explore whether nurses consider NIAPAS to be better than the Finnish FLACC scale for all children under one year old.

Most of the proposed developments suggested by nurses in the present study related to a perceived need to incorporate vital signs (pulse, O₂ saturation, blood pressure and respiratory rate) into the Finnish FLACC scale. Nurses using the Finnish FLACC scale might consider its non-reliance on vital signs problematic partly because PICU nurses routinely observe the vital signs of critically ill children requiring intensive care. Moreover, LaFond et al. (2015) report that nurses used a child's vital signs as a part of their pain assessment and consider changes in vital signs to be expected consequences of pain. However, other studies have shown that physiological signs are not necessarily good indicators of pain in toddlers (Buttner & Finke, 2000; Thrane et al., 2016). This is partly because physiological variables can be influenced by factors other than pain, for example the administration of vasoactive drugs or direct symptoms of the underlying illness (Ismail 2016). Instead, in infancy, physiological signs may be reasonable indicators of pain when combined with observations of crying, facial expression, and body movement (Thrane et al., 2016). It thus appears that Finnish PICU nurses may need more education about physiological indicators of pain and related factors to avoid over- or under-estimating the severity of children's pain.

LIMITATIONS

Our study has several limitations. One relates to data collection: some of the 157 pain assessment cases comprising the study's dataset may relate to the same child, and we had no way of controlling the number of nurses participating. Secondly, most of the pain assessments were conducted when the child was at rest, and only a few were conducted during short-term painful procedures. Consequently, great care is necessary when attempting to generalize the results presented here. The third limitation is that the participating nurses had only been using the Finnish FLACC scale for a few months before this study began. Different results might be obtained in future when nurses have accumulated more experience of using the Finnish FLACC scale to assess children's pain. The fourth limitation concerns the responses to the open questions and their analysis. The nurses' responses were mostly short, consisting of only a couple of words or short paragraphs. It would be important to conduct interviews with the nurses to better understand why they found scoring with the Finnish FLACC scale to be difficult in some circumstances, and to clarify their proposals for the scale's future development.

CONCLUSIONS

The accurate assessment of pain is essential for its effective management. However, assessing the pain experienced by children in a PICU is not always easy. Our study suggests that using the Finnish version of the FLACC pain scale is feasible, and that it exhibits good clinical utility for assessing the pain experienced by children in a PICU. However, future studies should aim to acquire more information about using the scale to assess a child's pain during short-term painful procedures.

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