# MedPharmRes

Original article

# Validity and Reliability of the Comfort Behavior Scale in Children Undergoing Wound Dressing Replacement in Vietnam

Huong Lan Thi Tran[a], Katrina Einhellig[b], Linh Thuy Khanh Tran[c], Oanh Hoang Thi Pham[d], Cuc Thu Thi Tran[d], Kien Gia To[e]*

[a]*Binh Duong Medical College, 529 Le Hong Phong Street, Phu Hoa Ward, Thu Dau Mot City, Binh Duong Province, Viet Nam;*
[b]*School of Nursing - University of Northern Colorado, Campus Box 125, 501 20th St, Greeley, CO 80639, USA;*
[c]*Faculty of Nursing and Medical Technology, the University of Medicine and Pharmacy at Ho Chi Minh City, 201 Nguyen Chi Thanh, Ward 12, District 5, Ho Chi Minh City, Vietnam;*
[d]*The Nhi Dong 1 Hospital, 341 Su Van Hanh, Ward 10, District 10, Ho Chi Minh City, Viet Nam;*
[e]*Faculty Public Health, the University of Medicine and Pharmacy at Ho Chi Minh City, 217 Hong Bang, Ward 11, District 5, Ho Chi Minh City, Vietnam.*

**Abstract:** *Background:* This study translated and culturally adapted the Comfort Behavior Scale (Comfort-B) into Vietnamese using a standard protocol guided by the World Health Organization. *Methods:* The Comfort-B was translated into Vietnamese and then English back-translated by independent translators. These versions were reviewed and assessed by a Vietnamese expert's panel and an English expert's panel. Thirty-four nurses of the Nhi Dong 1 Hospital were invited to use the Vietnamese Comfort-B to assess pain while watching five videos recorded before, during and after wound dressing replacement. The eight characteristics of the Vietnamese Comfort-B were assessed by 34 nurses. Fifteen nurses agreed to do the second assessment two weeks from the first assessment. The content validity index was used to assess the relevance and clarity of all items and the whole scale. Agreements between raters were explored using Kappa statistics. Intraclass correlation coefficients (ICC) were used to assess intra-rater and inter-rater reliability. Multi-level linear regression was used to assess changes in the Vietnamese Comfort-B before, during and after wound dressing replacement between two assessments. *Results:* The Vietnamese Comfort-B was accredited by the Vietnamese expert's panel. The English-back translated version was approved by the English expert's panel. The nurses agreed that the Vietnamese Comfort-B can be used in clinical practice and research. Kappas of all items were ≥0.96 indicating excellent agreement between raters. Alpha coefficients of two assessments were ≥0.97 indicating excellent internal consistency. All ICCs ≥ 0.79 indicated good intra-rater and inter-rater reliability. *Conclusions:* The study suggested that the Vietnamese Comfort-B can be used for future studies assessing children's pain in the local hospital context.

**Keywords:** Comfort-B, validity and reliability, tool validation, pediatric ICU, Vietnam.

# 1. INTRODUCTION

Pain is a serious health problem worldwide; however, it is often underestimated. A study conducted in a Brazilian teaching hospital found that pain relief was delivered to 80% of surveyed inpatients but only a half of them showed signs of pain [1]. A study found that nearly 80% of pediatric inpatients experiences at least one painful procedure per day; however, only 30% of those painful procedures were managed and documented [2]. Children suffer worse pain than adults do, particularly in those admitted in Pediatric Intensive Care Units (PICU) where painful medical procedures are performed daily [3]. Children admitted to PICUs were younger, stayed longer in PICUs and in hospitals, suffered more serious ills and mortality rate compared to those admitted to the general Intensive Care Units (ICU) [4].

Surgeries and burns are the leading causes of admission in children to ICUs and PICUs [4-6]. Pediatric surgical admission rate at PICU was reported at 25%, of which 52% was due to post-surgical admission [4, 5]. Pediatric surgical mortality was recorded at 34% in the ICU [5]. A prospective cohort study found that one pediatric patient suffered 11 distressful and painful procedures per day in surgical PICU [7]. Burn is the leading cause of hospital admission for injury in children with a report of 20% of admission and associated with painful and distressful experiences [6, 8, 9]. Medical advances have helped reduce mortality rate of burned children [9, 10]. Those who do not die still suffer painful burn care procedures such as wound dressing replacement, physiotherapy practice, skin grafts, and surgery to remove scar tissue [9, 11-13]. However, pain of burned children was improperly managed [14]. Effective pain management, including continuously monitoring and reporting, regularly and accurately assessing, and successfully addressing, would help patients recover more quickly and keep complications at the minimum rate [9,10,14].

A valid and reliable tool is needed to manage pain effectively. There are two main types of pain assessment tools: self-reporting and behavioral scales [15]. Self-reporting scales are considered the gold standard in assessing children's pain; however, behavioral scales are more effective in assessing pain of children with verbal or visual impairments [16-18]. The Comfort Behavior Scale (Comfort-B) was adapted by Monique van Dijk et al in 2005 [19] from the original version developed by Ambuel et al. in 1992 [20]. The Comfort-B consists of six items including alertness, calmness/agitation, crying (spontaneously breathing children)/ respiratory response (mechanically ventilated children), physical movement, muscle tone, and facial tension. Each item is scored from 1 to 5, making the possible pain score of 6 (no pain) to 30 (severe pain). The Comfort-B is a valid and reliable tool and has been used globally for assessing pediatric pain in ICUs [19,21-29]. Users are not required to have any special skills but suggested to attend an online training module for sufficiently assessing pain [30].

Assessing pain in PICUs has not been a routine practice in many Vietnamese hospitals as few studies have been conducted to provide supporting evidences. Moreover, few valid and reliable tools were available in Vietnamese [31]. Therefore, this study cross-culturally adapted the Comfort-B into Vietnamese clinical settings and assessed its psychometric properties. Findings of this study provide a useful reference for practitioners to manage pain in PICUs, and for students and researchers to do their studies.

# 2. METHODS

## 2.1. Study setting

This study was conducted at the Burn Intensive Care Unit (BICU) and Surgical Intensive Care Unit (SICU) of the Nhi Dong 1 Hospital, a provincial pediatric hospital, located in Ho Chi Minh City. The BICU and SICU have 61 beds and 57 nurses. There are 30 burned children and 120 critically ill children admitted in BICU and SICU monthly.

This study was approved by the Ethics Committee of the University of Medicine and Pharmacy at Ho Chi Minh City (506/DHYD-HDDD, October 17, 2019) and the Executive Board of the Nhi Dong 1 Hospital (2882/QD-BVND1, October 29, 2019).

## 2.2. Translation procedure

After getting a permission for translation and use of the Comfort-B, the translation process followed the process of translation and adaptation of instruments from World Health
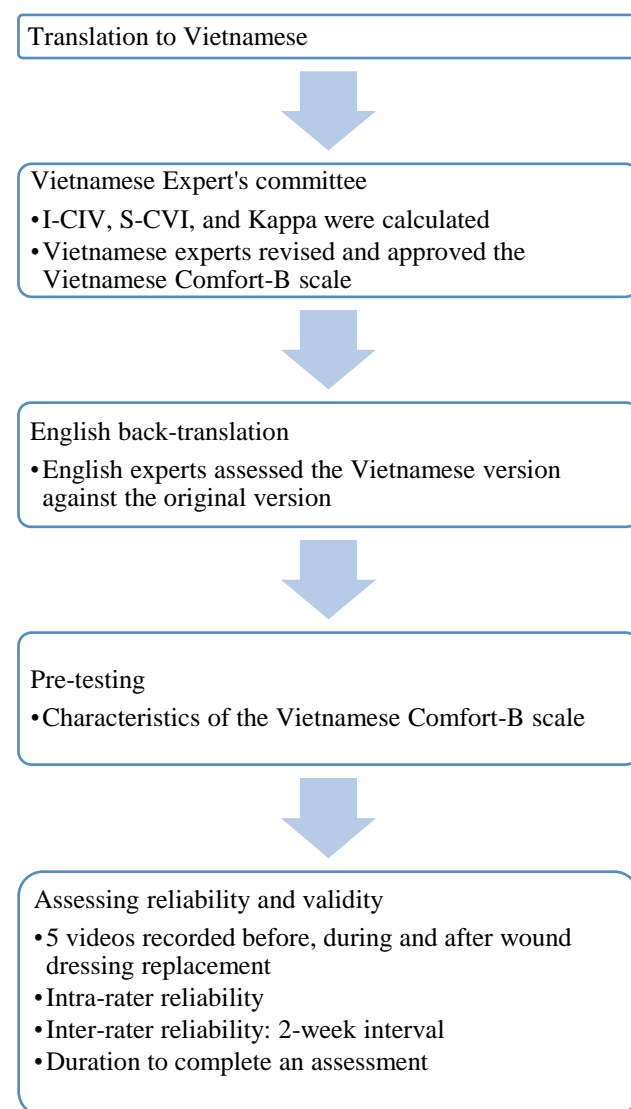
Translation to Vietnamese

Vietnamese Expert's committee
- I-CIV, S-CVI, and Kappa were calculated
- Vietnamese experts revised and approved the Vietnamese Comfort-B scale

English back-translation
- English experts assessed the Vietnamese version against the original version

Pre-testing
- Characteristics of the Vietnamese Comfort-B scale

Assessing reliability and validity
- 5 videos recorded before, during and after wound dressing replacement
- Intra-rater reliability
- Inter-rater reliability: 2-week interval
- Duration to complete an assessment

**Figure 1:** The process of translation and adaptation of the COMFORT-B

Organization including forward translation to Vietnamese, Expert's Committee Review, English-back translation, and pretesting [32]. The study process is presented in Figure 1.

A registered nurse and an English professor independently translated the Comfort-B into Vietnamese. The two Vietnamese versions were discussed among researchers for a unified version which were then reviewed by an expert panel consisting of 23 doctors and nurses of the Nhi Dong 1 Hospital as suggested by Lynn et al. [33]. Experts were asked to rate the relevance and clarity of 30 items of the Comfort-B Vietnamese version. Relevance was a 4-point Likert scale including 1 (cannot be used, not relevant), 2 (cannot be used, item needs some revisions), 3 (relevant, may be used with minor revisions) and 4 (very relevant). Clarity was a 4-point Likert scale including 1 (cannot be used, not clear), 2 (cannot be used, item needs some revisions), 3 (clear, may be used with minor revisions) and 4 (very clear).

Experts were also asked to comment on the language to improve the clarity of the scale. Any comment was noted then discussed among researchers for a final Vietnamese version. This version was then translated back to an English version separately by another registered nurse and English professor. This English-back translated version was assessed against the original version by an expert panel consisting of five English-native healthcare professionals. Differences were reviewed and discussed between researchers and the expert panel until a consensus was reached.

### 2.3. Pre-testing phase to assess characteristics of the Vietnamese Comfort-B

Registered nurses, who are working at the BICU and the SICU of the Nhi Dong 1 Hospital and responsible for caring for children, were invited for the pilot study that assessed whether the Comfort-B was 1) clear, 2) understandable, 3) easy to use, 4) convenient for use, 5) not time-consuming, 6) helpful for nurses to decide medical care, 7) feasible and applicable to clinical settings, and 8) able to classify pain level. Each item, a 5-point Likert scale, was rated from 1 (strongly disagree) to 5 (strongly agree). The mean and standard deviation of eight items were calculated. These items had been successfully used in previous studies [34-36].

Eligible nurses were excluded if they were probationary or experienced less than one working year at the hospital. All nurses of the BICU and SICU were approached and screened for their eligibility by a researcher. Eligible nurses who agreed to attend the study were asked to sign an informed consent after receiving an information sheet explaining the study. They were trained to use the Vietnamese Comfort-B following the instruction of Monique van Dijk et al. (https://www.comfortassessment.nl/web/index.php) [19] before using it in the pilot.

### 2.4. A final phase to assess validity and reliability of the Vietnamese Comfort-B

Five children hospitalized in the BICU and prescribed wound dressing replacement were consecutively selected for video-recording. They were not recruited if they were mechanically ventilated, had unstable vital signs, had hearing impairment, or were unconscious. A researcher approached and explained the purpose of the study to parents of eligible children and asked their permissions for video-recording their children at three periods before, during and after wound dressing replacement. If parents permitted their children to join the study, they were asked to sign an informed consent before researchers recorded videos.

Nurses of the BICU and SICU were invited to watch 15 recorded videos and used the Vietnamese Comfort-B to assess pain at two time-points which were two weeks apart from each other. The two-week interval was considered appropriate to assess intra-rater reliability as it had been selected by previous studies [34,37]. The inclusion criteria were nurses working at the BICU or SICU of the Nhi Dong 1 Hospital and responsible for caring for children. Participants were excluded if they were probationary or experienced less than one working year. Thirty-four nurses agreed to participate in the first assessment but only 15 nurses agreed to do the second assessment. A laptop was used to show videos and record duration to complete an assessment. All informed consents were signed before any data was collected.

### 2.5. Statistical analysis

All content validity measures including the item content validity index (I-CVI), the scale content validity index universal agreement (S-CVI/UA), the scale content validity index average (S-CVI/Ave), and Kappa (K) were calculated.

$I\text{-CVI} = \frac{A}{N}$, where A is the number of experts rating 3 or 4 for relevancy/clarity, and N is the total number of experts [38, 39]. I-CVI was appropriate if it is higher than 0.8 as suggested by previous studies [33, 38, 39]. S-CVI/UA was "the proportion of items on an instrument that achieved a rating of 3 or 4 by all the content experts" [33,38,40]. S-CVI/Ave was the average of all I-CVIs [33,38,40].

$K = \frac{(I\text{-CVI}) - P_c}{(1 - P_c)}$ , where $(P_c) = \left[ \frac{N!}{A!(N-A)!} \right] * 0.5^N$ is the probability of chance agreement. K should be above 0.6 for accepting an inter-rater reliability [38,41].

All nurses were asked to use the Vietnamese Comfort-B for assessing pain of 15 videos of five children recorded before, during and after wound dressing replacement. Two weeks after the first assessment, they were asked to re-assess the videos. The Cronbach's alpha coefficients were calculated at the first and second assessment separately. The alpha coefficients were acceptable if they were above 0.7 [42].

Intra-rater reliability was calculated to assess a difference in the Comfort-B mean score of 15 raters between two assessments (first and second assessment) at three periods (before, during and after wound dressing replacement) using group-average intra-class correlation coefficient (ICC) with two-way mixed-effects absolute agreement model [43]. Intra-rater reliability of each of 15 raters between two assessments at three periods was also calculated using individual ICC with two-way mixed-effects absolute agreement model [43].

Inter-rater reliability was assessed using individual ICC with two-way random-effect absolute agreement model [31,43-46]. ICC was classified as poor (ICC <0.5), moderate (0.5 ≤ ICC ≤ 0.75), good (0.75 < ICC ≤ 0.9), and excellent (ICC > 0.9) reliability [43].

### 3. RESULTS

### 3.1. Translation and cultural adaptation of the Vietnamese Comfort-B

The Comfort-B was successfully translated into Vietnamese. One out of 23 Vietnamese members of the experts' committee suggested that "ngủ không sâu" (item A2) and "tỉnh táo và hoạt bát" (item A4) should be replaced by "ngủ gà" and "tỉnh và chơi". However, all members agreed to keep the original wording after the discussion. The experts' committee suggested that "vận động" in items D1 to D5 should be replace by "cử động" and "phản ứng" in item A1 to A5 replaced by "đáp ứng", "phản ứng quá mức" in item A5 should be replaced by "tăng đáp ứng", "trẻ" replaced by "trẻ tỏ vẻ" in item B1, B3 and B4, "đau đớn" replaced by "lo lắng" in item B5, "thở êm" replaced by "thở đều" in item C1, "giãn hoàn toàn" replaced by "hoàn toàn thư giãn" in item E1, "sức kháng giảm" replaced by "kháng lực giảm" in item E2, "co

gấp" replaced by "gấp chặt" in item E4, "gồng cứng" replaced by "co cứng" in item E5, "căng cơ ở vài vị trí cơ mặt" replaced by "căng cơ ở vài nhóm cơ mặt" in item F3, and "các cơ khắp mặt" replaced by "toàn bộ nhóm cơ mặt" in item F4.

All five English members of the experts' committee agreed that the English-back translated version has similar meanings to the original version and can be used for research and clinical practice. An explanation "*clearly noticeable during the 2 minutes observation*" should be added to F3 and F4.

The I-CVIs of the Vietnamese Comfort-B for the relevance and clarity were above 0.95 for all items. S-CVIs/Ave were 1 for the relevance and 0.99 for the clarity. S-CVIs/UA was 0.93 (28/30) for the relevance and 0.87 (26/30) for the clarity. Modified Kappas of all items were above 0.95.

**Table 1:** The item content validity (I-CVI) and modified Kappa of the Vietnamese Comfort-B

| Item | | Relevance | | | | Clarity | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | A | I-CVI | Pc | K | A | I-CVI | Pc | K |
| *Sự tỉnh táo* | | | | | | | | | |
| A1 | Ngủ sâu (mắt nhắm, không đáp ứng với những kích thích của môi trường) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| A2 | Ngủ không sâu (hầu như nhắm mắt, thỉnh thoảng có đáp ứng) | 22 | 0.96 | 2.74 | 0.96 | 22 | 0.96 | 2.74 | 0.96 |
| A3 | Lơ mơ (trẻ nhắm mắt thường xuyên, đáp ứng ít với môi trường) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| A4 | Tỉnh táo và hoạt bát (trẻ đáp ứng với kích thích của môi trường) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| A5 | Tỉnh táo và quá khích (tăng đáp ứng với kích thích của môi trường) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| *Bình tĩnh / kích động* | | | | | | | | | |
| B1 | Bình tĩnh (trẻ tỏ vẻ yên lặng và không lo lắng) | 22 | 0.96 | 2.74 | 0.96 | 23 | 1 | 0.12 | 1 |
| B2 | Lo lắng nhẹ (trẻ thể hiện một chút lo lắng) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| B3 | Lo lắng (trẻ tỏ vẻ kích động nhưng vẫn còn kiểm soát được) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| B4 | Rất lo lắng (trẻ tỏ vẻ rất kích động, và rất khó khăn trong việc kiểm soát) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| B5 | Hoảng sợ (rất lo lắng và mất kiểm soát) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| *Khóc (đánh giá trên trẻ thở tự nhiên)* | | | | | | | | | |
| C1 | Thở đều, không có tiếng khóc | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| C2 | Thỉnh thoảng khóc nấc, rên rỉ nhẹ | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| C3 | Khóc rên rỉ (từng tiếng riêng lẻ) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| C4 | Khóc thành tiếng | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| C5 | Khóc thét hoặc la hét | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| *Cử động* | | | | | | | | | |
| D1 | Không có cử động | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| D2 | Thỉnh thoảng, (3 lần hay ít hơn) cử động nhẹ | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| D3 | Thường xuyên, (nhiều hơn 3 lần) cử động nhẹ | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| D4 | Cử động mạnh nhưng chỉ giới hạn ở tứ chi | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| D5 | Cử động mạnh bao gồm cả đầu và thân mình | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| *Trương lực cơ* | | | | | | | | | |
| E1 | Các cơ hoàn toàn thư giãn, không có trương lực cơ | 23 | 1 | 0.12 | 1 | 22 | 0.96 | 2.74 | 0.96 |
| E2 | Giảm trương lực cơ, kháng lực giảm nhẹ | 23 | 1 | 0.12 | 1 | 22 | 0.96 | 2.74 | 0.96 |
| E3 | Trương lực cơ bình thường | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |

| Item | | Relevance | | | | Clarity | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | A | I-CVI | Pc | K | A | I-CVI | Pc | K |
| E4 | Tăng trương lực cơ, các ngón tay và ngón chân gấp chặt lại | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| E5 | Cơ gồng cứng mạnh, các ngón tay và ngón chân co cứng gấp chặt lại | 23 | 1 | 0.12 | 1 | 22 | 0.96 | 2.74 | 0.96 |
| *Căng cơ mặt* | | | | | | | | | |
| F1 | Các cơ mặt hoàn toàn thư giãn thoải mái | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| F2 | Trương lực cơ mặt bình thường | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| F3 | Có dấu hiệu cho thấy sự căng cơ ở một vài nhóm cơ mặt (không duy trì liên tục trong khoảng thời gian 2 phút quan sát) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| F4 | Có dấu hiệu căng toàn bộ nhóm cơ mặt (duy trì liên tục trong khoảng thời gian 2 phút quan sát) | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |
| F5 | Cơ mặt méo mó và nhăn nhó | 23 | 1 | 0.12 | 1 | 23 | 1 | 0.12 | 1 |

A: the number of experts raing 3 or 4; N: the total number of experts; I-CVI: item-content validity index; Pc: probability of occurrence $= [N!/A!(N-A)!]*0.5^N*10^6$; K: modified Kappa $= (I\text{-}CVI\text{-}Pc)/(1\text{-}Pc)$

### 3.2. Characteristics of the Vietnamese Comfort-B

Table 2 shows the characteristics of the Vietnamese Comfort-B. All characteristics were rated 4 and above by 34 nurses of the hospital. Nurses take 1.6 (SD=0.6) minutes on average to complete the Comfort-B. They need more time to complete the Comfort-B during wound dressing replacement (2 minutes (SD=0.5)) compared to before (1.2 minutes (SD=0.4)) and after (1.5 minutes (SD=0.5)) wound dressing replacement.

**Table 2:** The characteristics of the Vietnamese Comfort-B were assessed by 34 nurses of the Nhi Dong 1 Hospital

| Characteristics of Comfort-B | Mean | SD |
|---|---|---|
| Comfort-B is clear | 4.12 | 0.41 |
| Comfort-B is understandable | 4.15 | 0.44 |
| Comfort-B is easy to use | 4.03 | 0.52 |
| Comfort-B is convenient for use | 4.09 | 0.57 |
| Comfort-B is not time-consuming | 4 | 0.65 |
| Comfort-B helps nurse decide medical care | 4.12 | 0.59 |
| Comfort-B is feasible and applicable to clinical settings | 4 | 0.55 |
| Comfort-B is able to classify pain level | 4.09 | 0.45 |

### 3.3. The reliability of the Vietnamese Comfort-B

The Cronbach's alpha coefficients were 0.97 at the first and second assessment. The inter-rater reliability between 34 nurses was measured at the first assessment, ICCs indicated good agreement before (ICC=0.82; 95%CI: 0.61 to 0.97) and during wound dressing replacement (ICC=0.79; 95%CI: 0.56 to 0.97) and excellent agreement after wound dressing replacement (ICC=0.91; 95%CI: 0.78 to 0.99). The inter-rater reliability between 15 nurses was measured at the second assessment, ICCs indicated good agreement before (ICC=0.86; 95%CI: 0.66 to 0.98) and during (ICC=0.90; 95%CI: 0.74 to 0.99) and excellent agreement after wound dressing replacement (ICC=0.98; 95%CI: 0.94 to 1.00).

The intra-rater reliability of 15 nurses between the first and second assessment was measured using group-average ICCs indicating good agreement during wound dressing replacement (ICC=0.90; 95%CI: 0.78 to 1.01), but excellent agreement before (ICC=0.94; 95%CI: 0.78 to 1.10) and after (ICC=0.97; 95%CI: 0.92 to 1.02) wound dressing replacement (Table 3).

**Table 3:** The intra-rater and inter-rater reliability of the Comfort-B Vietnamese version between nurses before, during and after wound dressing replacement at the first and second assessment

| | Before (n=5) ICC (95%CI) | During (n=5) ICC (95%CI) | After (n=5) ICC (95%CI) |
|---|---|---|---|
| First assessment (n=34)[*] | 0.82 (0.61; 0.97) | 0.79 (0.56; 0.97) | 0.91 (0.78; 0.99) |
| Second assessment (n=15)[*] | 0.86 (0.66; 0.98) | 0.90 (0.74; 0.99) | 0.98 (0.94; 1.00) |
| Average-group intra-rater (n=15)[**] | 0.94 (0.78; 1.10) | 0.90 (0.78; 1.01) | 0.97 (0.92; 1.02) |

*ICC: Intraclass Correlation Coefficient; 95%CI: 95% Confidence Interval*

*[*]Two-way random-effects absolute agreement model was used to assess inter-rater reliability between 34 nurses at the first assessment and between 15 nurses at the second assessment with before, during and after wound dressing replacement.*

*[**]5 videos were assessed by 15 nurses assessed at two times; the second assessment was two weeks away from the first assessment. Average-group intraclass correlation coefficient was reported for the group intra-rater using two-way mixed effects absolute agreement model.*

*All p-value <0.01*

**Table 4:** Multi-level linear regression assesses changes in mean score of the Vietnamese Comfort-B between first and second assessment with before, during and after wound dressing replacement (n=450)

|  | Coef. | p-value | 95%CI |
|---|---|---|---|
| Second vs. First assessment | -0.05 | 0.86 | -0.61; 0.51 |
| During vs. Before wound dressing replacement | 14.45 | <0.01 | 13.77; 15.13 |
| After vs. Before wound dressing replacement | 4.75 | <0.01 | 4.07; 5.43 |

*Coef.: regression coefficient; 95%CI: 95% Confident Interval*
*Multi-level linear regression random effect.*
*15 nurses rated 5 videos before, during and after wound dressing replacement at first and second assessment (n=15\*5\*3\*2=450).*

### 3.4. The validity of the Vietnamese Comfort-B

The multi-level linear regression generated no statistical difference in the Vietnamese Comfort-B mean score between the first and second assessment (b=-0.05; 95%CI: -0.61 to 0.51; p=0.86), but higher scores during (b=14.45; 95%CI: 13.77 to 15.13; p<0.01) and after (b=4.75; 95%CI: 4.07 to 5.43; p<0.01) compared to before wound dressing replacement (table 4).

## 4. DISCUSSION

This study translated and adapted the Comfort-B into Vietnamese using the standard process guided by the World Health Organisation [32]. The standard process used forward and back-translation with Vietnamese-English bilingual and English-native expert committees that has been highly recommended [47]. This process has been used sucessfully in a previous study validating Neonatal Infant Pain Scale (NIPS) conducted in Tien Giang General hospital, 70 km away from the south of Ho Chi Minh City [34].

The Vietnamese Comfort-B scale was strictly reviewed and approved by experienced nurses and doctors of the Nhi Dong 1 Hospital. Any disagreement on the Vietnamese Comfort-B between raters were carefully discussed to reach agreement. The English-back translation of the Comfort-B was strictly reviewed and approved by the English-native experienced healthcare professionals, including authors of the original Comfort-B, to ensure clear and correct meanings. The I-CVIs were all above 0.95 indicating relevance and clarity of translated items [33,38,39]. S-CIV/Aves and S-CIV/UAs were above 0.8 indicating that the scale was appropriately validated [33,38,39]. All modified Kappas were above 0.95 indicating an excellent agreement between raters [38,41]. All content validity and agreement measures of the Vietnamese Comfort-B indicating satisfactory translation.

All 57 nurses, working at BICU and SICU of the Nhi Dong 1 hospital, had at least one working year of experience and satisfied the study's eligibility, of which 23 refused to participate. Nearly 60% (34/57) of nurses did the first assessment and 26% (15/57) did both first and second assessment that met the sample size requirement for a reliability study [38,39,43]. The sample nurses (34) agreed that the Vietnamese Comfort-B is clear, understandable, easy to use, convenient for nurses, and not time-consuming. Moreover, it helps nurses classify pain level and make decisions on medical care. Those nurses agreed that the Vietnamese Comfort-B is applicable and feasible in the hospital context. The Comfort-B is applicable to assess children's pain in ICUs as suggested by previous studies [22,23,48]. A previous study showed that nurses might spend 30 seconds to complete the Comfort-B due to heavy workloads that lead to underscore the Comfort-B [49]. It was

suggested that nurses should take two minutes to complete the Comfort-B [19,49]. This study found that nurses took two minutes to complete the Comfort-B during wound dressing replacement but shorter time before and after wound dressing replacement.

The Vietnamese Comfort-B scale provides Cronbach's alpha coefficients of 0.97 for the first and second assessment indicating that the scale has appropriate internal consistency. Tavakol and Dennick recommended that the scale should be shortened if its alpha coefficient is higher than 0.9 [50]. However, Bland and Altman noted that alpha coefficient should be 0.95 as a minimum value for clinical application [51].

The average ICCs of 34 nurses at the first assessment and 15 nurses at the second assessment indicated good inter-rater reliability before, during and after wound dressing replacement (ICCs ≥0.79). The average-group ICCs of 15 nurses in a 2-week interval indicated good intra-rater reliability before, during and after wound dressing replacement (ICCs ≥0.9). The Vietnamese Comfort-B scale had 14.45 points (95CI%: 13.77 to 15.13) higher during wound dressing replacement compared to before wound dressing replacement indicating that the scale can classify the pain level at the cut-off point of 15. Its narrow confidence interval implies that the result is reliable [52]. Previous studies suggested the cut-off point of 17 for the Comfort-B to classify pain and no pain [19,23,53], however, the Chinese Comfort-B suggested a cut-off point of 13 [22].

The original Comfort-B was developed to assess children's pain and distress in PICUs, including those with mechanical ventilation; however, this study did not validate the 'respiratory response' category. There are various care procedures done in ICUs, this study focused only on wound dressing replacement in children, a burn care procedure. Another limitation of this study was that the Comfort-B can be used to assess pain in critically ill children, however, this study excluded children who had hearing impairment, unstable vital signs, or were unconscious. Further studies should be conducted to address these limitations. This study was conducted in one of three pediatric hospitals in Ho Chi Minh City, including Nhi Dong 1, Nhi Dong 2 and City Children's Hospitals. The Nhi Dong 1 Hospital is one of the four best pediatric hospitals in Vietnam, the generalizability of the findings to other hospitals in the city and other provinces should be cautiously considered.

## 5. CONCLUSION

In conclusion, this study showed that the Vietnamese Comfort-B can detect pain at a cut-off point of 15 in burned children undergoing wound dressing replacement. As few Vietnamese pain assessment tools have been validated, this

study provides preliminary evidences to support the Vietnamese Comfort-B for use in clinical practices and research at the local context.

## CONFLICT OF INTEREST

The authors declare that they have no competing interests.

## AUTHOR CONTRIBUTIONS AND ACKNOWLEDGEMENT

## REFERENCES

1. Linhares MB, Doca FN, Martinez FE, Carlotti AP, Cassiano RG, Pfeifer LI, et al. Pediatric pain: prevalence, assessment, and management in a teaching hospital. Brazilian journal of medical and biological research = Revista brasileira de pesquisas medicas e biologicas. 2012;45(12):1287-94. Epub 2012/09/18. doi: 10.1590/s0100-879x2012007500147. PubMed PMID: 22983181; PubMed Central PMCID: PMCPMC3854228.

2. Stevens BJ, Abbott LK, Yamada J, Harrison D, Stinson J, Taddio A, et al. Epidemiology and management of painful procedures in children in Canadian hospitals. CMAJ. 2011;183(7):E403-E10. Epub 04/04. doi: 10.1503/cmaj.101341. PubMed PMID: 21464171.

3. Ismail A. The Challenges of Providing Effective Pain Management for Children in the Pediatric Intensive Care Unit. Pain Manag Nurs. 2016;17(6):372-83. Epub 2016/10/21. doi: 10.1016/j.pmn.2016.08.005. PubMed PMID: 27756590.

4. Ibiebele I, Algert CS, Bowen JR, Roberts CL. Pediatric admissions that include intensive care: a population-based study. BMC Health Serv Res. 2018;18(1):264-. doi: 10.1186/s12913-018-3041-x. PubMed PMID: 29631570.

5. Embu HY, Yiltok SJ, Isamade ES, Nuhu SI, Oyeniran OO, Uba FA. Paediatric admissions and outcome in a general intensive care unit. African journal of paediatric surgery : AJPS. 2011;8(1):57-61. Epub 2011/04/12. doi: 10.4103/0189-6725.78670. PubMed PMID: 21478588.

6. Barcellos LG, Silva APPd, Piva JP, Rech L, Brondani TG. Characteristics and outcome of burned children admitted to a pediatric intensive care unit. Revista Brasileira de terapia intensiva. 2018;30(3):333-7. Epub 10/04. doi: 10.5935/0103-507x.20180045. PubMed PMID: 30304085.

7. Baarslag MA, Jhingoer S, Ista E, Allegaert K, Tibboel D, van Dijk M. How often do we perform painful and stressful procedures in the paediatric intensive care unit? A prospective observational study. Australian critical care : official journal of the Confederation of Australian Critical Care Nurses. 2019;32(1):4-10. Epub 2018/05/22. doi: 10.1016/j.aucc.2018.04.003. PubMed PMID: 29779912.

8. Peck MD, Jeschke MG, Ciollins KA. Epidemiology of burn injuries globally. UpToDate. 2019.

9. Li J, Zhou L, Wang Y. The effects of music intervention on burn patients during treatment procedures: a systematic review and meta-analysis of randomized controlled trials. BMC Complement Altern Med. 2017;17(1):158. Epub 2017/03/18. doi: 10.1186/s12906-017-1669-4. PubMed PMID: 28302117; PubMed Central PMCID: PMCPMC5356403.

10. Lorente JA, Amaya-Villar R. Update in the management of critically ill burned patients. Med Intensiva. 2016;40(1):46-8. Epub 2016/01/10. doi: 10.1016/j.medin.2015.10.009. PubMed PMID: 26746126.

11. de Jong AE, Middelkoop E, Faber AW, Van LNE. Non-pharmacological nursing interventions for procedural pain relief in adults with burns: a systematic literature review. Burns. 2007;33(7):811-27. Epub 2007/07/04. doi: 10.1016/j.burns.2007.01.005. PubMed PMID: 17606326.

12. Latarjet J, Choinere M. Pain in burn patients. Burns. 1995;21(5):344-8. Epub 1995/08/01. PubMed PMID: 7546255.

13. Summer GJ, Puntillo KA, Miaskowski C, Green PG, Levine JD. Burn injury pain: The continuing challenge. The Journal of Pain. 2007;8(7):533-48.

14. Gandhi M, Thomson C, Lord D, Enoch S. Management of pain in children with burns. Int J Pediatr. 2010;2010:825657. Epub 09/16. doi: 10.1155/2010/825657. PubMed PMID: 20885937.

15. Tsze DS, von Baeyer CL, Bulloch B, Dayan PS. Validation of self-report pain scales in children. Pediatrics. 2013;132(4):e971-9. Epub 2013/09/04. doi: 10.1542/peds.2013-1509. PubMed PMID: 23999954; PubMed Central PMCID: PMCPMC3784298.

16. Khin HT, Hegarty M, Russell P, Drake-Brockman TF, Ramgolam A, von Ungern-Sternberg BS. Perception of pediatric pain: a comparison of postoperative pain assessments between child, parent, nurse, and independent observer. Paediatr Anaesth. 2014;24(11):1127-31. Epub 2014/07/31. doi: 10.1111/pan.12484. PubMed PMID: 25074484.

17. Van HVC, Wilkie DJ, Wang E. Pediatric Nurses' Beliefs and Pain Management Practices:An Intervention Pilot. Western Journal of Nursing Research. 2011;33(6):825-45. doi: 10.1177/0193945910391681. PubMed PMID: 21172923.

18. Ljungman G, Kreuger A, Gordh T, Sörensen S. Pain in Pediatric Oncology: Do the Experiences of Children and Parents Differ from Those of Nurses and Physicians? Upsala Journal of Medical Sciences. 2006;111(1):87-96. doi: 10.3109/2000-1967-023.

19. van Dijk M, Peters JW, van Deventer P, Tibboel D. The COMFORT Behavior Scale: a tool for assessing pain and sedation in infants. Am J Nurs. 2005;105(1):33-6. PubMed PMID: 15659992.

20. Ambuel B, Hamlett KW, Marx CM, Blumer JL. Assessing distress in pediatric intensive care environments: the COMFORT scale. J Pediatr Psychol. 1992;17(1):95-109. doi: 10.1093/jpepsy/17.1.95. PubMed PMID: 1545324.

21. Amoretti CF, Rodrigues GO, Carvalho PR, Trotta EA. Validation of sedation scores in mechanically ventilated children admitted to a tertiary pediatric intensive care unit. Rev Bras Ter Intensiva. 2008;20(4):325-30. Epub 2008/12/01. PubMed PMID: 25307235.

22. Bai J, Hsu L, Tang Y, van Dijk M. Validation of the COMFORT Behavior scale and the FLACC scale for pain assessment in Chinese children after cardiac surgery. Pain Manag Nurs. 2012;13(1):18-26. doi: 10.1016/j.pmn.2010.07.002. PubMed PMID: 22341137.

23. Boerlage AA, Ista E, Duivenvoorden HJ, de Wildt SN, Tibboel D, van Dijk M. The COMFORT behaviour scale detects clinically meaningful effects of analgesic and sedative treatment. Eur J Pain. 2015;19(4):473-9. Epub 2014/07/30. doi: 10.1002/ejp.569. PubMed PMID: 25070754.

24. de Jong A, Baartmans M, Bremer M, van Komen R, Middelkoop E, Tuinebreijer W, et al. Reliability, validity and clinical utility of three types of pain behavioural observation scales for young children with burns aged 0-5 years. Pain. 2010;150(3):561-7. Epub 2010/07/14. doi: 10.1016/j.pain.2010.06.016. PubMed PMID: 20619968.

25. Kuhlmann AYR, Lahdo N, Staals LM, van Dijk M. What are the validity and reliability of the modified Yale Preoperative Anxiety Scale-Short Form in children less than 2 years old? Paediatr Anaesth. 2019;29(2):137-43. Epub 2018/10/27. doi: 10.1111/pan.13536. PubMed PMID: 30365208.

26. Latina R, Di Maglie V, Sili A, D'Angelo D, Marucci AR, Di Ettore B, et al. Pain assessment in Down Syndrome patients: a narrative review of the literature. Prof Inferm. 2018;71(4):209-20. Epub 2019/04/14. doi: 10.7429/pi.2018.714209. PubMed PMID: 30980706.

27. Marianne JE, van der Heijden, Johannes J, Heinz R, Sharon C, Joost van R, et al. Music in Medicine. South Africa: The Department of Paediatric Surgery of Red Cross War Memorial Children's Hospital in Cape Town; 2018. 87-104 p.

28. Valkenburg AJ, Boerlage AA, Ista E, Duivenvoorden HJ, Tibboel D, van Dijk M. The COMFORT-behavior scale is useful to assess pain and distress in 0- to 3-year-old children with Down syndrome. Pain. 2011;152(9):2059-64. doi: 10.1016/j.pain.2011.05.001. PubMed PMID: 21640484.

29. Maaskant J, Raymakers-Janssen P, Veldhoen E, Ista E, Lucas C, Vermeulen H. The clinimetric properties of the COMFORT scale: A systematic review. Eur J Pain. 2016;20(10):1587-611. Epub 2016/10/25. doi: 10.1002/ejp.880. PubMed PMID: 27161119.

30. Monique van Dijk EI, et al. Comfort assessment Netherlands: Erasmus MC; 2020 [cited 2020 February 08]. Available from: https://www.comfortassessment.nl/web/index.php/about/contact-us/.

31. Yoon PJ, Starr JR, Perkins JA, Bloom D, Sie KCY. Interrater and Intrarater Reliability in the Evaluation of Velopharyngeal Insufficiency Within a Single Institution. Archives of Otolaryngology–Head & Neck Surgery. 2006;132(9):947-51. doi: 10.1001/archotol.132.9.947.

32. World Health Organisation. Process of translation and adaptation on instruments 2020 [cited 28/04/2020]. Available from: https://www.who.int/substance_abuse/research_tools/translation/en/.

33. Lynn MR. Determination and quantification of content validity. Nurs Res. 1986;35(6):382-5. Epub 1986/11/01. PubMed PMID: 3640358.

34. Ngo HT, Fitzsimmons K, To KG. Validity and Reliability of Neonatal Infant Pain Scale (NIPS) in Neonatal Intensive Care Unit in Vietnam. MEDPHARMRES. 2019;3(2):1-7. doi: http://dx.doi.org/10.32895/UMP.MPR.3.2.1.

35. Taddio A, Hogan ME, Moyer P, Girgis A, Gerges S, Wang L, et al. Evaluation of the reliability, validity and practicality of 3 measures of acute pain in infants undergoing immunization injections. Vaccine. 2011;29(7):1390-4. doi: 10.1016/j.vaccine.2010.12.051. PubMed PMID: 21195076.

36. Suraseranivongse S, Kaosaard R, Intakong P, Pornsiriprasert S, Karnchana Y, Kaopinpruck J, et al. A comparison of postoperative pain scales in neonates. Br J Anaesth. 2006;97(4):540-4. doi: 10.1093/bja/ael184. PubMed PMID: 16885171.

37. Motta GC, Schardosim JM, Cunha ML. Neonatal Infant Pain Scale: Cross-Cultural Adaptation and Validation in Brazil. J Pain Symptom Manage. 2015;50(3):394-401. doi: 10.1016/j.jpainsymman.2015.03.019. PubMed PMID: 26025270.

38. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar AR. Design and Implementation Content Validity Study: Development of an instrument for measuring Patient-Centered Communication. J Caring Sci. 2015;4(2):165-78. Epub 2015/07/15. doi: 10.15171/jcs.2015.017. PubMed PMID: 26161370; PubMed Central PMCID: PMCPMC4484991.

39. Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. Res Nurs Health. 2007;30(4):459-67. Epub 2007/07/27. doi: 10.1002/nur.20199. PubMed PMID: 17654487.

40. Polit DF, Beck CT. The content validity index: Are you sure you know what's being reported? critique and recommendations. Research in Nursing & Health. 2006;29(5):489-97. doi: 10.1002/nur.20147.

41. McHugh ML. Interrater reliability: the kappa statistic. Biochemia medica. 2012;22(3):276-82. PubMed PMID: 23092060.

42. Taber KS. The Use of Cronbach's Alpha When Developing and Reporting Research Instruments in Science Education. Research in Science Education. 2018;48(6):1273-96. doi: 10.1007/s11165-016-9602-2.

43. Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med. 2016;15(2):155-63. doi: 10.1016/j.jcm.2016.02.012. PubMed PMID: 27330520; PubMed Central PMCID: PMCPMC4913118.

44. Eliasziw M, Young SL, Woodbury MG, Fryday-Field K. Statistical methodology for the concurrent assessment of interrater and intrarater reliability: using goniometric measurements as an example. Physical therapy. 1994;74(8):777-88. Epub 1994/08/01. PubMed PMID: 8047565.

45. Stata.com. icc — Intraclass correlation coefficients [cited 2019 12 December]. Available from: https://www.stata.com/manuals/ricc.pdf#riccRemarksandexamples.

46. McGraw KO, Wong SP. Forming Inferences About Some Intraclass Correlation Coefficients. Psychological Methods. 1996;1(1):30-46.

47. Maneesriwongul W, Dixon JK. Instrument translation process: a methods review. J Adv Nurs. 2004;48(2):175-86. Epub 2004/09/17. doi: 10.1111/j.1365-2648.2004.03185.x. PubMed PMID: 15369498.

48. Tamvaki E, Efstratiou F, Nteli C, Matziou V, Pavlopoulou I, Myrianthefs P, et al. Validation of the Greek Version of Comfort-B, FLACC, and BPS Scales in Critically Ill Children and Their Association with Clinical Severity. Pain Manag Nurs. 2019. Epub 2019/12/22. doi: 10.1016/j.pmn.2019.10.004. PubMed PMID: 31862298.

49. Boerlage AA, Ista E, de Jong M, Tibboel D, van Dijk M. The COMFORT behavior scale: is a shorter observation period feasible? Pediatr Crit Care Med. 2012;13(2):e124-5. Epub 2011/04/19. doi: 10.1097/PCC.0b013e3182192d92. PubMed PMID: 21499179.

50. Tavakol M, Dennick R. Making sense of Cronbach's alpha. Int J Med Educ. 2011;2:53-5. doi: 10.5116/ijme.4dfb.8dfd. PubMed PMID: 28029643.

51. Bland JM, Altman DG. Cronbach's alpha. BMJ (Clinical research ed). 1997;314(7080):572. Epub 1997/02/22. doi: 10.1136/bmj.314.7080.572. PubMed PMID: 9055718; PubMed Central PMCID: PMCPMC2126061.

52. Clarke J. What is a CI? Evidence Based Nursing. 2012;15(3):66-. doi: 10.1136/ebnurs-2012-100802.

53. Caljouw MAA, Kloos MAC, Olivier MY, Heemskerk IW, Pison WCR, Stigter GD, et al. Measurement of pain in premature infants with a gestational age between 28 to 37 weeks: Validation of the adapted COMFORT scale. Journal of Neonatal Nursing. 2007;13(1):13-8. doi: 10.1016/j.jnn.2006.11.007.