



# Reliability and Validity of the Chinese Version of the Critical Care Pain Observation Tool for Pediatric Patients

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**Background:** Appropriate assessment of pain is not only associated with analgesic use in clinical settings, but also helps improve the quality of pain management. However, only a limited number of tools are available to assess pain in children who cannot express pain verbally. The current study aims to validate the Chinese version of the Pediatric Critical-Care Pain Observation Tool (P-CPOT).

**Methods:** The P-CPOT scale was translated into Chinese. We obtained approval from the guardians before recruiting the participating children. The research staff assessed the pain response at three stages: pre-test, during pain stimulation, and post-test. The pain responses were recorded with the P-CPOT and the Face, Leg, Activities, Cry, and Consolability (FLACC) scales. Inter-rater reliability, construct validity, and discriminant validity were thereafter calculated.

**Results:** A total of 22 participants (13 males and 9 females) were recruited over 8 months of study. Participants aged between 0 and 27 months old (mean = 6.77 months). The mean hospitalization day of ICU stay was 15.09 days. Statistical analysis showed that the Chinese P-CPOT has satisfactory inter-rater reliability and construct validity. Elevated pain responses were recorded during the pain stimulation, which showed the discriminant validity of this validated scale.

**Conclusion:** Using this new tool, clinicians can have an alternative option for pain assessment in children, thereby improving the quality of pain control in Taiwan's pediatric intensive care units.

**Keywords:** *intensive care units, pain management, pediatric*

## Introduction

Pain management is an important task in clinical settings. Past research has indicated that many patients in critical care settings lack the ability to verbally communicate their discomfort, which can make effective pain management a challenge [1]. Inadequate pain assessment can result in unrecognized suffering, increased stress responses, and potentially lead to prolonged recovery times, which ultimately impact treatment outcomes and quality of life [2]. Accordingly,

researchers have strived to develop pain assessment tools to effectively evaluate pain in these patients. For example, the Behavioral Pain Scale (BPS) is an observational tool that clinicians use to assess pain in patients who cannot verbally express their pain [1]. There are only three items, each can be scored from 1 to 4. Clinicians rate according to the patient's facial expression, muscle activity of the upper limbs, and compliance with ventilation to decide whether pain is present. Later, a more elaborate scale, the Critical-Care Pain Observation Tool (CPOT), was developed

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Received: 23 April 2025; Received in revised form: 1 July 2025; Accepted: 10 July 2025.

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[3]. The CPOT is another validated behavioral pain assessment instrument for nonverbal critically ill adults. It evaluates pain through four domains: facial expression, body movement, muscle tension, and ventilator compliance. The CPOT demonstrates superior sensitivity and offers a more comprehensive pain assessment than the BPS [4]. It was originally implemented in the intensive care unit (ICU) and has shown positive effects on pain assessment. Since the administration of this scale, increased frequency of pain assessments and reduced administration of analgesics and sedatives have been reported [3]. Further, the CPOT has demonstrated satisfactory reliability and validity in general critical care populations, with strong inter-rater reliability and significant associations with other pain scales [5]. It was later adapted to assess pain in infants and children aged 2–104 weeks [6]. In the adapted version of the CPOT, P-CPOT, where P stands for pediatric, an additional category of consolability was added to the four categories in the original scale. The total score was expanded from 0–8 to 0–10, with a total score over 2 indicating the presence of pain, and higher scores indicating more severe pain. The P-CPOT also demonstrates strong convergent validity and interrater reliability. The Chinese version is shown in Table A1 in the Appendix.

Pain assessment is vital to achieve high-quality

pain care. A study included 15 pediatric ICU (PICU) across 12 children's hospital documented the use of several behavioral assessment scales for pain, such as Faces, Legs, Activity, Cry, and Consolability (FLACC) scale, Comfort B, Neonatal Infant Pain Scale (NIPS), Neonatal Pain, Agitation and Sedation Scale (NPASS), and CRIES (Crying, Requires oxygen, Increased vital signs, Expression, and Sleeplessness) scale [7]. Other studies also documented the use of the Premature Infant Pain Profile (PIPP) [8]. A general overview of the scales mentioned above is listed in Table 1 [7,9-16].

Although many existing scales have been validated to assess pain in pediatric patients, only three were recommended in a previous meta-analysis review: the Faces Pain Scale-Revised (FPS-R), FLACC scale, and Pediatric Pain Profile (PPP) [17]. The FPS-R has been well validated in children as young as 4 years old and is very easy to administer [18]. However, this requires self-reporting by children, which may be a challenge for some patients in the ICU setting. The PPP demonstrated good interrater reliability between clinicians and parents and acceptable internal consistency of the scale [19]. However, it contains 20 items and requires a detailed collection of children's pain history, which makes it less efficient in an ICU setting. The FLACC is one of the most widely used behavioral observation scales for pain assessment

**Table 1. General Overview of Pain Assessment Scales for Pediatric Patients [7,9-16]**

	FLACC	NIPS	NPASS	CRIES	PIPP
Age	0–7 years	Preterm to full-term neonates	23–40 weeks	≥ 32 weeks	28–40 weeks (gestational ages)
Types of pain	Procedural and post-OP pain	Procedural pain	Procedural pain and prolonged pain	Procedural and surgical pain	Procedural and post-OP pain
Variables assessed	Facial expression, leg movement, activity, cry, and consolability	Facial expression, cry, breathing patterns, arms, legs, state of arousal	Crying irritability, behavior state, facial expression, extremities tone, vital signs, heart rate, RR, BP, SaO <sub>2</sub>	Crying, SpO <sub>2</sub> , increased blood pressure and heart rate, expression, and sleeplessness	Heart rate, SaO <sub>2</sub> , brow bulge, eye squeeze, nasolabial furrow, behavioral state
Scoring	0–10	0–7	0–10	0–10	0–21
Reliability data	Yes	Yes	Yes	Yes	Yes
Validity data	Construct validity	Construct validity	Construct validity	Construct validity	Construct validity

Abbreviations: BP, blood pressure; CRIES, Crying, Requires oxygen, Increased vital signs, Expression, and Sleeplessness scale; FLACC, Faces, Legs, Activity, Cry, and Consolability scale; NIPS, Neonatal Infant Pain Scale; NPASS, Neonatal Pain, Agitation and Sedation Scale; PIPP, Premature Infant Pain Profile; post-OP, postoperative; RR, respiration rate.

[10,20]. This scale was originally validated in children aged two months to seven years. Later, a Chinese version of it was validated in Chinese children between 0.5 and 72 months [21]. This scale evaluated five categories of pain behaviors in children, including facial expression, leg movement, activity, cry, and consolability. The FLACC has been widely translated and validated in different languages [22]. Although a systematic review pointed out several limitations of the FLACC, such as the difficulty in differentiating fear, pain, and the biases in previous studies that validated this scale in young children, the review also pointed out that the FLACC is commonly used as a scale for the construct validity of newly developed pain scales [23].

To improve the quality of pain care and expand the choice of pain assessment tools in the PICU, this study aimed to validate the Chinese version of the P-CPOT. Compared with several commonly used pain assessment tools for pediatric patients, P-CPOT demonstrated some advantages. For example, NPASS is more complex, so it requires extensive training for clinicians. NIPS is easy to use, but it showed low sensitivity to changes in pain score [24]. PIPP was originally developed to assess pain in preterm infants, and it also showed good validity for evaluating pain in term infants [25]. However, there is a lack of documentation of well-established inter-rater reliability [26].

To expand our options in choosing an appropriate tool for pain assessment in PICU, we examined the discriminant validity of the Chinese version of the P-CPOT when exposed to a common nociceptive procedure, as well as the construct validity of this scale, and the inter-rater reliability of clinicians' rating this scale at the bedside.

## Methods

This cohort study was approved by the Institutional Review Board of the Changhua Christian Hospital on July 25, 2024 (reference number: 240612).

### Participants

Participants were recruited from the PICU between July 25, 2024, and March 31, 2025. The inclusion criteria for participants were children under the age of 3 years, whose guardians consented to participate. Children in a coma with hypoxic-ischemic encephalopathy, neuromuscular disease, under neuro-

muscular blockade, or those who should not be repositioned were excluded from recruitment. In the year before, there were 528 patients under the age of three admitted to the PICU of this hospital. This brings the estimated ideal sample size with  $\pm 5\%$  measurement error to  $n = 223$ . Based on a previous study on power and sample size estimation [27], to conduct parametric statistical tests, such as correlations, a reasonable sample size should be approximately  $n = 50$ .

### Psychometric Properties of the Test Material

To validate the Chinese version of the P-CPOT, we used the FLACC for construct validity. The FLACC was designed to assess postoperative pain in infants and children aged 2–7 years [10]. FLACC is a 5-item pain assessment scale with good inter-rater reliability and satisfactory construct validity. It is well-validated and widely used in clinical settings as a construct for developing new pain assessment scales [5,28].

### Study Procedure

Before the study, a pain physician and a clinical psychologist translated and back-translated the P-CPOT. A nurse compared the original text and the back-translated scale to determine consistency between the two. The wordings of the translated scale were then fine-tuned by a speech therapist who has 18 years of clinical experience working with children in an outpatient clinic. The Chinese version of the P-CPOT is shown in Table 1.

Before the study, the study research staff reviewed the NIPS scores recorded in the electronic medical record system. During the study, P-CPOT and FLACC scores were assessed at three stages: pre-test, during the test (pain stimulation), and post-test. Two trained raters recruited participants from the PICU and obtained the necessary consents from their guardians. Both raters were nurse practitioners currently working in the department of anesthetic technology. One of them used to work in the neonatal ICU (NICU), while one did not have experience working with pediatric patients. They received lessons on research ethics, how to score the scales, and the standardized study procedure. Before the test, the raters set up cameras to film the participants' responses during each stage of the study. In the pre-test, the raters rated the two scales to assess whether pain was present in the resting state. In the second stage of the study, pain

stimulation involved a light pad on the participants' backs and upper arms, and then we adopted the Peri-ungual Pressure Technique. The conduction of this technique involves the application of pressure to the area around the fingernail to induce pain. The nailbed soft tissues are innervated by dorsal branches of paired digital nerves. This stimulus to the peripheral nerve follows the typical ascending pathway for pain [29,30]. The raters recorded pain presentation using two scales. Approximately 15 minutes later, the raters returned and completed the post-test assessment. The raters ensured that no participant was left with pain or other discomfort from the test. When records from the two raters differed, a third rater would watch the video and assess the two scales to determine which score was closer to the participant's pain response.

### Plans for Statistical Analysis

Data were analyzed using R Studio. Consistent with previous validation on P-CPOT, the current study reports inter-rater reliability between two raters, construct (or convergent) validity between the P-CPOT and FLACC, and discriminant validity [6].

Inter-rater reliability was assessed using intraclass correlations of the assessments completed by the two trained scorers. Construct validity was assessed using Spearman's test between the FLACC and the P-CPOT. Discriminant validity was assessed using Friedman tests for the scores at pre-test, during test, and post-test for the nociceptive procedures, followed by post hoc Wilcoxon signed rank tests.

## Results

Participants included 13 males and 9 females, with a mean age of 6.77 months (SD = 7.51). Details of demographic characteristics and the rated FLACC and P-CPOT scores are presented in Table 2. According to the electronic medical record, the NIPS score for each participant was 0.

### Inter-Rater Reliability

Intraclass correlations were calculated for the P-CPOT scores rated by two scorers at each stage of the assessment. Only three recorded entries: two from pain stimulation and one from the post-test, involved ratings from the third rater. Intraclass correlations

**Table 2. Demographic Characteristics**

Patients characteristic	Total patient sample (n = 22)
Demographic variables	
Age (month), mean (SD)	6.77 (7.51)
Gender (male : female)	13:9
Height, cm (SD)	62.28 (11.76)
Weight, kg (SD)	6.48 (2.67)
Intensive care variables	
Sedation	0
Ventilator	0
Total ICU stay, days (SD)	15.09 (17.65), ranged 3–54
Pain assessments	
P-CPOT, score (SD)	
Pre-test	1.00 (2.20)
During test	5.18 (2.15)
Post-test	0.86 (1.86)
FLACC, score (SD)	
Pre-test	1.00 (1.97)
During test	5.55 (1.99)
Post-test	0.95 (1.96)

Abbreviations: FLACC, Faces, Legs, Activity, Cry, and Consolability scale; ICU, intensive care unit; P-CPOT, Pediatric Critical-Care Pain Observation Tool; SD, standard deviation.

were 0.99 for the scores at pre-test and post-test, and 0.97 for the scores obtained during pain stimulation (all  $P < 0.001$ ), indicating a strong agreement between the scorers at all stages of the assessment.

### Construct Validity

Spearman’s test between the FLACC and P-CPOT at pre-test showed significant correlations ( $\rho = 0.91, P < 0.001$ ). The two scales were also strongly positively correlated during pain stimulation ( $\rho = 0.55, P < 0.001$ ) and post-test ( $\rho = 0.84, P < .001$ ).

### Discriminant Validity

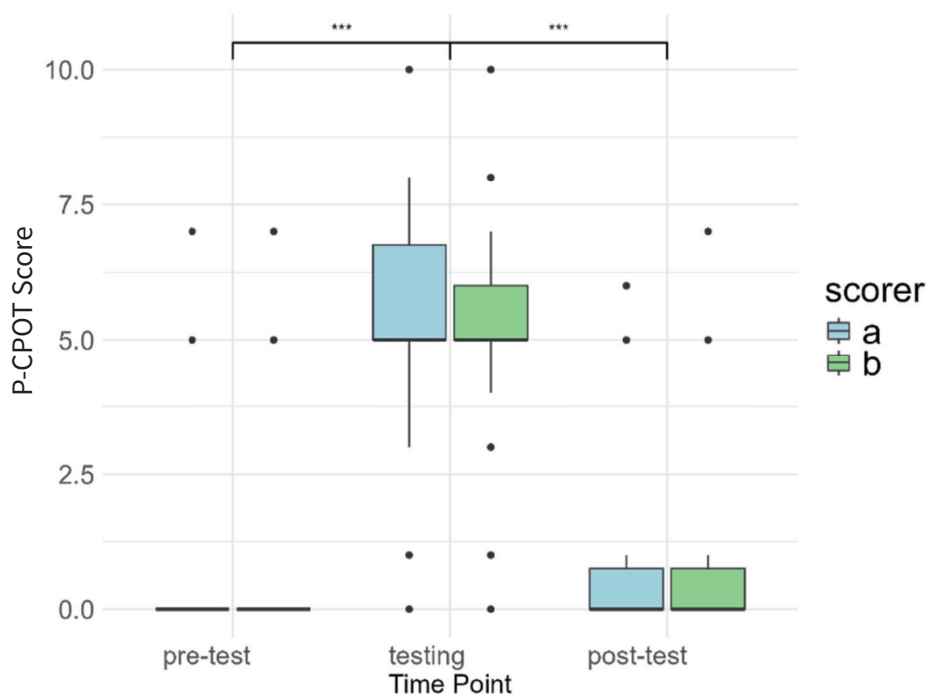
P-CPOT scores were tested for normality using the Shapiro-Wilk test. The scores before and after pain stimulation did not conform to normal distribution (all  $P < 0.05$ ). Similarly, the scores during pain stimulation did not conform to normal distribution ( $W = 0.91, P = 0.047$  for scorer A;  $W = 0.91, P = 0.042$  for scorer B). Therefore, we adopted Friedman tests for assessments before, during, and after the nociceptive procedures, followed by post-hoc Wilcoxon signed-rank tests.

A significant change in P-CPOT scores at the

three stages of the pain stimulation was observed ( $\chi^2 = 29.83, P < 0.001$  for both scorers). Following that, post hoc Wilcoxon signed-rank tests showed significant differences between P-CPOT scores at pre-test and during pain stimulation ( $P < 0.001$ ), and between P-CPOT scores during pain stimulation and at post-test ( $P < 0.001$ ). P-CPOT scores at pre- and post-tests showed no significant differences ( $P = 1.0$ ) (Figure 1).

### Discussion

Providing quality pain care has been a very important task for many hospitals nowadays, even in a critical care unit [31,32]. Appropriate assessment of pain is an essential first step in pain management, as it is linked to the following: titration of analgesic doses, detection of complications in ICU stays, and treatment outcome [33]. The current study validated an observational scale that has been suggested by previous studies as a suitable tool to assess pain in patients in the ICU [3,5,6]. It was reported that the majority of patients admitted to the PICU were under three years old (around 70%) [34]. Our study validated this new scale in this major group. Consistent with previous studies, the Chinese validated P-CPOT has satisfying



**Figure 1. Discriminant Validity**

Abbreviation: P-CPOT, Pediatric Critical-Care Pain Observation Tool.

\*\*\* $P < 0.001$

inter-rater reliability and construct validity [6]. The Chinese version of the P-CPOT also demonstrated good discriminant validity. It can effectively differentiate the participants' pain responses from those without pain.

According to a study that included 38 participating PICUs from 15 European countries, pain is one of the top 10 factors hindering mobilization [34]. This indicates the importance of pain control in PICUs. However, a systematic review pointed out that pain was absent from the outcome measurements of PICU stays in many studies [35]. This not only contradicts the expert consensus statement on physical rehabilitation after hospital discharge from serious illness [36] but also creates a confounding factor for other factors related to the care of patients in PICUs. For example, sedation and the use of analgesics are correlated with sedation levels and pain. The lack of appropriate pain assessment could therefore be a potential confounder [35].

Nevertheless, validation of a pain assessment tool is only a rudimentary step in pain management. There are still ideological and instrumental barriers in reality that can hinder the use of pain assessment tools. From a recent study that interviewed 30 clinicians who work in different specialism units of ICU (i.e., general and burn, liver, cardiac, cancer, or trauma), common issues faced by these clinicians in conducting effective pain assessments in ICU included: (1) lack of awareness of accessible pain assessment tools used specifically in ICU, and (2) lack of consensus on conducting pain assessment. For example, the timing and frequency of assessment, or who should conduct the assessment, and (3) mistrust the validity of assessment tools, and so on [37].

The validation of the Chinese version of the P-CPOT has clinical merits. Clinicians can have an alternative in the choice of pain assessment tools. However, there are several limitations to the current study. First, this study included a relatively small sample size, which can compromise the power of the statistical analysis. However, we have managed to overcome this problem by adopting a non-parametric statistical analytical method. Second, although unintentionally, this study included only participants who were not sedated and who did not use a ventilator. Third, although we reported the inter-rater reliability, construct validity, and discriminant validity as previous studies did, there is a lack of data on other vital signs, such as blood pressure, during the pain stimulation to serve

as another potential comparator of construct validity. Fourth, the relatively small sample size also prohibited us from conducting a confirmatory factor analysis for the factor structure of the validated scale. Fifth, although the translated scale was agreed upon by the research team, there is a lack of consultation on the comprehensibility and clinical relevance from health-care professionals working in PICUs or NICUs. Future studies should strive to include more participants and data from a variety of monitoring sources.

In conclusion, the P-CPOT scales can potentially improve the quality of care for individuals who are unable to report their pain verbally. We hope that, with appropriate citations, the P-CPOT scale validated in this study can be more widely used in clinical settings in Taiwan.

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## Appendix

**Table A1. Chinese Version of the Pediatric Critical-Care Pain Observation Tool**

小兒重症照護疼痛觀察工具 Pediatric Critical-Care Pain Observation Tool		
指標 Indicator	描述 Description	評分 Score
顏面表情 Facial expression	<ul style="list-style-type: none"> <li>觀察不到肌肉張力，沒有特別表情或笑容</li> <li>No muscle tension observed, no particular expression, or smile</li> </ul>	<ul style="list-style-type: none"> <li>放鬆，自然狀態</li> <li>Relaxed, neutral</li> </ul> <p>0</p>
		<ul style="list-style-type: none"> <li>緊張</li> <li>Tense</li> </ul> <p>1</p>
		<ul style="list-style-type: none"> <li>掙掙</li> <li>Grimacing</li> </ul> <p>2</p>
<p style="text-align: center;"> <span>Relaxed, neutral</span>                      <span>Tense</span>                      <span>Grimacing</span>  <span>0</span>    <span>1</span>    <span>2</span> </p>		
肢體動作 Body movements	<ul style="list-style-type: none"> <li>完全不動，或維持正常姿勢，不會去撫摸或保護疼痛部位</li> <li>Does not move at all or normal position (movements not aimed toward the pain site or not made for the purpose of protection)</li> </ul>	<ul style="list-style-type: none"> <li>無動作或正常姿勢</li> <li>Absence of movements or normal position</li> </ul> <p>0</p>
	<ul style="list-style-type: none"> <li>緩慢而小心的蠕動</li> <li>Slow, cautious movements, squirming</li> </ul>	<ul style="list-style-type: none"> <li>不安</li> <li>Restlessness</li> </ul> <p>1</p>
	<ul style="list-style-type: none"> <li>拉扯管路，試圖坐起來，揮動四肢打人，不聽從指令，僵直或抽搐</li> <li>Pulling tube, attempting to sit up, moving limbs/ thrashing, not following commands, arched, rigid or jerking</li> </ul>	<ul style="list-style-type: none"> <li>躁動</li> <li>Agitation</li> </ul> <p>2</p>

指標 Indicator	描述 Description	評分 Score		
右項兩者擇一 聲音表達程度（自發性呼吸病人） vocalization (extubated patients)  呼吸器順應程度（插管病人） Compliance with the ventilator (intubated patients)	<ul style="list-style-type: none"> <li>• 正常聲音語調，咕咕聲，牙牙學語，或不發聲</li> </ul> Talking in a normal tone, cooing, babbling, or making no sound	<ul style="list-style-type: none"> <li>• 正常聲音</li> </ul> Talking in a normal tone	0	
	<ul style="list-style-type: none"> <li>• 嘆氣，呻吟，用氣音說話，偶爾哭或抱怨</li> </ul> Sighing, moaning, whimpers, occasional cries or complaints	<ul style="list-style-type: none"> <li>• 嘆氣，呻吟</li> </ul> Sighing, moaning	1	
	<ul style="list-style-type: none"> <li>• 不斷哭泣，大哭，尖叫，呻吟，頻繁的抱怨</li> </ul> Crying out steadily, sobbing, screams, groans, frequent complaints	<ul style="list-style-type: none"> <li>• 哭泣或大哭</li> </ul> Crying out, sobbing	2	
		<ul style="list-style-type: none"> <li>• 適應呼吸器</li> </ul> Tolerating a ventilator or movement	0	
	<ul style="list-style-type: none"> <li>• 呼吸器警示響起但可自行停止</li> </ul> Coughing, alarms may be activated, but stop spontaneously	<ul style="list-style-type: none"> <li>• 咳嗽但可忍耐</li> </ul> Coughing but tolerating	1	
	<ul style="list-style-type: none"> <li>• 無法配合，對抗呼吸器，呼吸器警示頻繁響起</li> </ul> Asynchrony: blocking ventilation, alarms frequently activated	<ul style="list-style-type: none"> <li>• 對抗呼吸器</li> </ul> Fighting ventilator	2	
	肌肉張力（透過評估病人的被動式屈曲及伸展） Muscle tension	<ul style="list-style-type: none"> <li>• 被動運動無阻力</li> </ul> No resistance to passive movements	<ul style="list-style-type: none"> <li>• 放鬆</li> </ul> Relaxed	0
		<ul style="list-style-type: none"> <li>• 被動運動有輕微到中度的阻力</li> </ul> Minimal to moderate resistance to passive movements	<ul style="list-style-type: none"> <li>• 緊繃，僵硬</li> </ul> Tense, rigid	1
		<ul style="list-style-type: none"> <li>• 強烈抵抗被動運動，或被動運動無法完成</li> </ul> Strong resistance to passive movements or incapacity to complete them	<ul style="list-style-type: none"> <li>• 非常緊縮僵硬</li> </ul> Very tense or rigid	2
可否被安撫 Consolability	<ul style="list-style-type: none"> <li>• 平靜且不需要安撫</li> </ul> Calm and does not require consoling	<ul style="list-style-type: none"> <li>• 安適且放鬆的</li> </ul> Content, relaxed	0	
	<ul style="list-style-type: none"> <li>• 需要偶爾透過撫摸或說話分散患者注意力</li> </ul> Reassured by occasional touching or being talked to, distractable	<ul style="list-style-type: none"> <li>• 可被安撫</li> </ul> Consolable	1	
	<ul style="list-style-type: none"> <li>• 很難被安撫</li> </ul> Difficult to console or comfort	<ul style="list-style-type: none"> <li>• 無法被安撫</li> </ul> Inconsolable	2	
總分 TOTAL (> 4 分即表示有疼痛存在)	positive P-CPOT threshold score of greater than 4	0-10		