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Review Article

Evaluation of Observational and Behavioural Pain Assessment Tools in Nonverbal Intubated Critically Adult Patients after Open - Heart Surgery: A Systematic Review

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Abstract

BACKGROUND: Over 70% of patients hospitalised in an intensive care unit (ICU) often experience moderate to severe pain due to pre-existing diseases, trauma, surgery, aggressive procedures, and routine ICU care. Many patients hospitalised in ICU are not able to speak and express their pain due to various causes, including mechanical ventilation, reduced consciousness, and administration of sedative drugs. Therefore, the use of observational and behavioural pain tools is recommended in this group of patients given their inability to express pain.

AIM: To examine the existing observational and behavioural tools for assessment of in Nonverbal Intubated Critically Adult Patients after Open-Heart Surgery.

METHODS: A systematic review of available observational and behavioural tools for assessment of pain was undertaken using the COSMIN checklist. A literature search was conducted using the following databases: Ovid, Science Direct, Scopus, PubMed, and CINHAL databases, Google Scholar search engine as well as Persian resources Sid, Magiran, Iran doc, and IranMedex up to the end of 2017 were reviewed.

RESULTS: A total of 47 studies that had examined five tools used in intensive care units after cardiac surgery in patients under mechanical ventilation were reviewed. Each of the five tools included behavioural and observational items, and only one tool had physiological items. All the tools had been evaluated regarding validity and reliability. In the three tools, sensitivity, specificity, responsiveness, and satisfaction were considered.

CONCLUSION: Based on available evidence and investigations, CPOT and BPS tools have good validity and reliability to be used in pain assessment in Nonverbal Intubated Critically Adult Patients after Open-Heart Surgery. The NVPS tool requires more studies to be further confirmed before the assessment of pain in this group of patients.

Introduction

Pain is an unpleasant sensation recognised as an important physiological and psychosomatic stressor, which is experienced by many patients in some degree during hospitalisation [1]. More than 71% of patients admitted to hospital wards have memories of pain [2]. For example, in the intensive care unit, over 30% of patients experience a degree of Pain during rest, and more than 50% of them feel significant pain during routine care, including position change, endotracheal suction, and dressing [3], [4]. Untreated pain can have negative effects on various systems of the body such as endocrine, cardiovascular, immune, neurological, and musculoskeletal systems as well as affecting the mental health of patients admitted to ICU [5].

In addition to the mentioned physiological and mental consequences, failure to control pain leads to delayed postoperative recovery, prolonged hospitalisation, restlessness due to inability to communicate [1], chronic pain, and decreased the quality of life after the operation, leading to increased medical expenses for the patient and society [6]. Moreover, poor or inadequate assessment of pain is associated with increased mortality in ICU [7].

Pain after open-heart surgery has various reasons, including sternum incision, tissue excision, pain in the site of saphenous vein removal, the presence of chest tube as well as various factors

related to the type of operation [8], [9]. The occurrence of acute pain can trigger autonomic reactions and lead to the emergence of stress responses causing an imbalance between the supply and demand of oxygen in cardiac tissue, ischemia, infarction and eventual increase in morbidity and mortality [10].

Pain assessment is the first and most important step in the care and cure of these patients [11]. According to a general definition, the expression of pain by a patient is known as the golden standard for pain assessment. However, a large number of patients admitted to ICU cannot speak and report their pain for various causes like mechanical ventilation, decreased consciousness, and administration of sedative drugs which has placed this group of patients at maximum risk of inadequate pain assessment and management [12]. For this reason, some tools have been proposed as an alternative for assessment of pain in patients who cannot speak. American Society for Pain Management Nursing (ASPMN) recommends observational and behavioural pain tools as an alternative to self-reported pain in patients who are not able to communicate verbally for any reason. Studies on observational and psychometric tools for pain assessment in patients who are not capable of verbal communication have been the focus of research in recent years [10], [13]. Vital signs, which can be easily quantified in intensive care units, are another criterion to assess pain in patients admitted to intensive care units. According to a study, more than 70% of nurses use vital signs to assess pain in patients [14]. However, current evidence does not support the validity of vital signs to assess pain in these patients. ASPMN guidelines in 2006 stated that the application of changes in vital signs is not recommended for pain assessment in patients who are not able to speak [15] and that vital signs should not be considered as the only pain assessment tool but rather can be used as a guide when other pain assessment tools are not applicable in the long term [16], [17].

In this study, we aimed to review the studies on behavioural and observational pain assessment tools in patients admitted to ICU (especially after open-heart surgery) that were not able to communicate verbally.

Methods

Research questions

1. What behavioural and observational do tools have appropriate validity and reliability to be used in intensive care units for patients under mechanical ventilation?

2. Which of these tools has been used in the intensive care unit after cardiac surgery?

3. What are the best tools used in the intensive care unit after cardiac surgery?

Objective

The goal of this review study is to investigate and explain existing observational pain tools and compare them with each other to assess pain in patients not capable of verbal communication admitted to intensive care units. Also, in reviewing these tools, studies evaluating patients admitted to intensive care units after cardiac surgery have been emphasised.

Search method

In this review study, the keywords of pain assessment, behavioural pain tool, nonverbal pain scale, observational pain tool in intensive care, and post-cardiac surgery pain assessment were searched in Ovid, Science Direct, Scopus, PubMed, and CINHAL databases, Google Scholar search engine as well as Iranian resources such as Sid, Magiran, Iran doc, and IranMedex up to the end of 2017. Based on the significance of papers for the research topic and comments expressed by research team members, appropriate and relevant papers were selected and evaluated. Papers citing pain assessment indicators or non-verbal pain assessment in intensive care units, especially among non-verbal patients, will be subject to final analysis. The inclusion criteria of papers are as follows:

1. The language of the texts in English or Persian.

2. The words pain, non-verbal pain, tool or instrument, index, scale, non-conscious patient, patients with an endotracheal tube, and open-heart surgery are present in the title, abstract, and keyword.

3. The study is of quantitative, qualitative, combined, and instrumental type.

4. The study is conducted on patients over 18 years of age.

5. Tools are investigated in at least one study concerning the intensive care unit following cardiac surgery in unconscious and mechanically ventilated patients.

6. The studies published in languages other than English and Persian, editorial and commentary papers, as well as a book review, will be eliminated.

7. The number of samples study is > 30.

Search results

A total of 1216 papers were found in the initial search of databases based on keywords. After studying the titles, 70 papers were selected. The difference in the clinical conditions of patients and the presence of one keyword in the title without the proximity of the content to this review study resulted in the exclusion of papers. Then, 54 studies were selected from among the nominated papers according to a review of abstract and methodology. Finally, considering the number of patients under study and other inclusion criteria, 47 papers were selected from among the tools as follows: BPS (14 papers), CPOT (22 papers), NVPS (8 papers), FLACC (2 papers), and PBAT (1 paper).

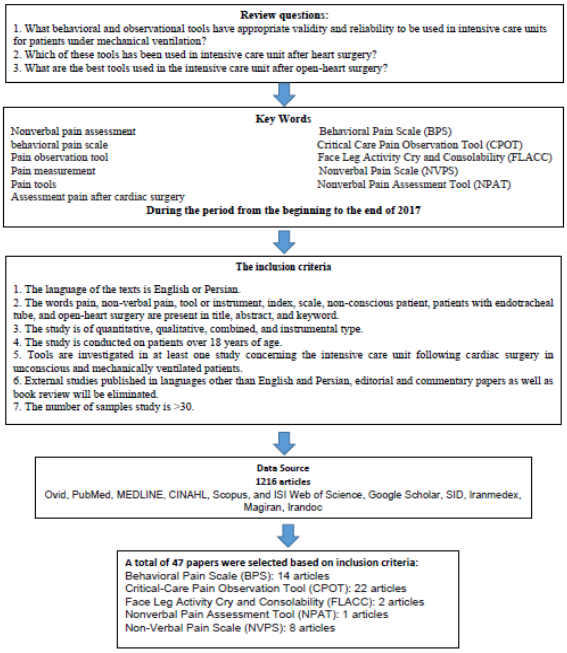

Figure 1: Flow chart of the review process

Design

This study was designed to systematically review the published papers on observational and behavioural pain assessment tools, progression and testing of these tools, as well as evaluation of their validity and reliability for pain assessment among patients with endotracheal tube admitted to ICU who were not able to communicate. In this research, the quality of studies and their methodology have been assessed and reported based on the COSMIN checklist [18]. Following consideration of the reported psychometric properties of the tools alongside COSMIN ratings, conclusions are drawn as to the established psychometric properties of each tool.

Quality of Methodology

Each reported study was assessed for methodological quality by an author using the COSMIN checklist with 4-point [18]. A rating of excellent, good, fair or poor was assigned separately to the evaluated measurement properties of each study.

Results

Behavioural Pain Scale

The Behavioral Pain scale was originally in the French language, which was translated into English [19], Chinese [20], Finnish [21], Brazilian Portuguese [22], Swedish [23], and Persian [24]. The behavioural pain scale has three parts: facial expression, upper limb movement and Compliance with mechanical ventilation, each graded with scores 1-4. The sum of minimum scores is 3 from 3 parts (no pain) and a top score of 12 (maximum pain). In 14 studies investigated, the validity and reliability of this tool were assessed on 1082 mechanically ventilated adult patients in the intensive care unit [19], [20], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35].

Reliability

BPS reliability was investigated in 13 studies [19], [20], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [35]. Of these, in test-retest procedure the reliability of tool was re-tested in three studies [19], [20], [24], and in all of them satisfactory results relative to primary test were obtained ($r = 0.50$-0.84, $p < 0.001$). Internal consistency of the tool was calculated in 8 studies [24], [27], [29], [30], [31], [32], [33], [35], and Cronbach's alpha in the range of 0.59-0.80 indicated moderate to high internal reliability. The inter-rater agreement percent was over 85% in studies [19], [20], [30], which was statistically ideal. However, in one study, when the patient felt no pain, the inter-rater agreement percent was 82-91%, and after a non-painful stimulation (oral care), the agreement percent was 64-73%, which was 36-46% during painful stimulation (change of position) [35]. Based on Kappa coefficient, the inter-rater agreement percent was in the range of $k = 0.67$-0.83 [19], [25], [26], [29], which was good because it was > 0.60. The inter-rater agreement percent for each item of tool was investigated in one study according to Kappa coefficient, and the results were as follows: face expression item ($k = 0.78$-0.80), upper limb movement item ($k = 0.67$-0.72), and Compliance with mechanical ventilation item ($k = 0.61$-0.62)(25). ICC ranged from 0.74 to 0.95 in the studies [24], [27], [31], [32], [33]. In one study, the highest value of ICC was related to face expression item (ICC = 0.90) [27]. also, ICC had a higher value at the time of painful stimulation (suction and position change) in the upper limb

movement item (ICC = 0.85-0.94) [27]. In Chinese version of the tool, ICC was reported 0.98-1.00 [30]. Inter-rater reliability was reported in the range of r = 0.65-1.00 (p < 0.001) based on Pearson correlation coefficient [20], [28]. In correlation analysis of items with total score, the highest and lowest correlation was related to face expression and Compliance with mechanical ventilation, respectively (r = 0.92, 0.65).

Validity

BPS validity was evaluated across in 13 studies [19], [20], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35]. To assess construct validity, average changes in final BPS scores were evaluated at the time of stimulation compared to the base time. In these studies, significant changes were observed in an average score of the tool at the time of painful stimulation (change in position, endotracheal suction), and the average changes were reported in 3.0 versus 6.8 range. The significant difference in BPS score at the time of painful stimulation (3.0 vs. 6.8) compared to the time of non-painful stimulation (3.0 vs. 3.5) in studies confirmed a good differential validity of the tool [19], [25], [27], [31], [33], [35]. Moreover, in two studies, the increase by two points in the score of the tool was reported at the time of painful stimulation compared to baseline [32], [33]. In three studies, the criterion validity was also examined [20], [24], [30]. Higher BPS scores in subjects confirming the presence of pain indicated the validity of the tool (P < 0.001). In one study, BPS score was observed to increase in 97.1% of patients under painful stimulation (endotracheal suctioning), but only 2.9% of subjects underwent non-painful stimulation (body temperature measurement) [30]. For convergent validity, BPS tool was investigated using the NVPS tool, and the correlation between the two tools at rest and during the painful procedure was ρ = 0.69 and ρ = 0.77, respectively [31]. According to the analysis performed in two studies, 55-65% of pain expression variance is determined by the initial factor (face expression: 0.78-0.90, upper limb movement: 0.79-0.85, Compliance with mechanical ventilation 0.63-0.64) [19], [27]. Also, in one study, the correlation between tool items was reported, which indicated moderate to high correlation between the items (face expression with upper limb movement: 0.70, face expression with ventilation challenge 0.40, and upper limb movement with ventilator challenge 0.29) [27]. Concurrent validity was instated by comparison between BPS scores and patients' self-reports of pain intensity [25], and showed a positive and statistically significant correlation (ρ = 0.67; *p* = < 0.001).

Responsiveness

Responsiveness refers to the ability of the tool to detect important changes in measurement unit over time, even if the changes are small [36]. In four studies, BPS has been found to be responsive [25], [27], [28]. The effect size on responsiveness was large for the scores of three tool items as well as for total BPS score. The responsiveness for the final score of this tool has been reported to be excellent (1.8-3.4). The largest effect size was related to face expression item in the range of 2.3-5 [27]. Also, in a study, the responsiveness of BPS, CPOT, and NVPS tools was compared, indicating the size effect factor and therefore the response of BPS tool (1.99 vs 1.55 and 1.46, respectively). Moreover, in one study, the highest responsiveness was reported during painful stimulation (suctioning r = 1.20, position change r = 1.87) [28].

Feasibility

The Feasibility and utility of the tool were investigated in two studies [19], [29]. In the first study, 24 out of 28 nurses participating in the research were satisfied or highly satisfied with the use of tool [19]. In the second study, out of 20 nurses participating in the study, the scores 7-8 were assigned regarding accuracy, usability, and convenience from a score range 0 (worst) to 10 (best). Also, 33% of participants preferred BPS to other study tools [29].

Sensitivity and specificity of the tool were also investigated in two studies [20], [34]. In the Chinese version of the tool, the cutoff point was reported to be 6.5, and it was stated that when BPS score was > 6.5, 75.9% of the area under the curve had a splitting property with a sensitivity and specificity of 52.4% and 87.5%, respectively [20]. Another study also found that in a score > 5, 76% of the area under the curve had splitting property, with a general sensitivity of 84.8% and specificity of 52.3% for the tool. At the time of painful stimulation, the sensitivity and specificity of the tool was 62.8% and 91.7%, respectively [34].

Limitations

There were still limitations to the tool after reviewing and verifying the validity and reliability of BPS in several studies, including the lack of a practical definition of some items such as upper limb movement that may be interpreted differently between nurses. In different studies, repeated and frequent observations of patients under study may lead to more results, so the results should be interpreted with more cautiousness [37], [38].

Critical-Care Pain Observation Tool (CPOT)

Critical-Care Pain Observation Tool (CPOT) is designed to assess pain in both verbal and non-verbal adult patients admitted to ICU [39]. The tool has four items of facial expression, body movements, muscle

tension, and Compliance with a ventilator in intubated patients or Vocalization in non-intubated patients. Scoring range of this tool is 0-2 per item with a total score of 0-8. The pain observation tool in intensive care was originally provided in French and then translated into English [40], Spanish [41], Danish [42], Finnish [21], Swedish [43], Dutch [44] and Turkish [45].

This tool has been reviewed and investigated in 22 studies on 1249 patients in various intensive care units such as medical, surgical, open-heart surgery, and neurosurgery [10], [15], [28], [29], [32], [33], [34], [39], [40], [41], [42], [43], [44], [45], [46], [47], [48], [49], [50], [51], [52], [53].

Reliability

The reliability of the tool was examined in 18 studies [28], [29], [32], [33], [34], [39], [40], [41], [42], [43], [44], [45], [47], [49], [50], [51], [52], [53]. A test-retest procedure was then performed in one study with non-parametric Spearman correlation coefficient of 0.81-0.93, indicating the reliability of the primary test [49]. Internal consistency of the tool was investigated in 10 studies [28], [29], [32], [33], [42], [43], [44], [45], [49], [51], with Cronbach's alpha reported in 0.31-0.81 range. However, in one study, Cronbach's alpha was 0.95 [28]. In the Dutch version of the tool, the internal consistency of the tool was 0.56, which increased to 0.60 by eliminating the Compliance with ventilator item [44]. The inter-rater agreement per cent has been reported 97-100%. Moreover, the kappa coefficient has been calculated in 0.79-0.94 range in one study [50]. The inter-rater agreement per cent was reported in the range of 0.52-0.88 using weighted kappa coefficient [39]. Moderate to high measures of inter-rater reliability from two or more raters were found was calculated using the Kappa coefficient in three studies, which ranged 0.79-0.94 [29], [43], [50]. In the Turkish version of the tool, inter-rater reliability has been reported in the range of 0.55-1.00 [45]. inter-rater reliability of the CPOT was found to be lower during patient turning as painful procedures when compared to the BPS (0.90) and NVPS (0.92) [29]. ICC rate was studied in eight studies [32], [33], [42], [43], [44], [49], [52], [53], which was reported in the range of 0.62-0.93, and in the Dutch version of tool, ICC has been recorded in 0.56-0.98 range. In the Danish version, the ICC was also reported to be > 0.90. In a study, the agreement between CPOT and facial expression after open-heart surgery was considered, and the highest level of agreement was reported during consciousness of patients (k = 0.787) [39]. In a research conducted on patients admitted to intensive care units after cardiac surgery, CPOT tool was compared with BIS monitoring and vital signs, in which there was positive and strong correlation between CPOT and BIS before ($r = 0.666$, $p < 0.001$), during ($r = 0.612$, $p < 0.001$), and after painful stimulation ($r = 0.738$, $p< 0.001$) [46].

Validity

The validity of the tool was evaluated in 17 studies [28], [29], [32], [33], [34], [39], [40], [41], [42], [43], [44], [45], [49], [50], [51], [52], [53]. To assess content validity, in the study by Gelinas et al., [39], 4 physicians and 13 nurses in ICU reviewed the tool as specialists and scored the tool in 0.88-1.00 range based on four-point Likert scale. Content validity in the translated version into Turkish [45] was also evaluated by five experts in the field of intensive care using a four-point Likert scale and was reported to be satisfactory. Also, in another study, content validity was approved by experts [52]. In order to investigate the construct validity, changes in average CPOT scores during painful stimulation (repositioning, endotracheal suction) were investigated compared to baseline in the studies, and it was shown that the average CPOT score was significantly increased during painful stimulation (0.48 vs 3.38) [39], [43], [45]. Discriminant validity of tool was also reviewed in 11 studies [29], [32], [33], [34], [39], [40], [42], [43], [45], [49], [53], and significant increases in pain during painful stimulation relative to non-painful stimulation indicated a good Discriminant validity of the tool. In one research, average CPOT score at painful stimulation (position change) was 3.04, that is higher than baseline, while at non-painful stimulation (dressing change), only 0.25 points increase compared to baseline was observed, which indicated a non-significant finding [50]. Furthermore, in two studies, it was stated that the average score increase during painful stimulation compared to baseline was 2 points, but it was 0-0.5 points during non-painful stimulation [32], [33]. The criterion validity was measured by comparing CPOT and self-reporting of pain by the patient [39], [53]. Moderate correlation with Spearman correlation coefficient of ($r = 0.40$-0.49, $p < 0.05$) was observed as well as higher correlation ($\rho = 0.59$, $p < 0.001$) during painful stimulation among 105 patients [39]. In another study, Spearman correlation between CPOT and mean arterial pressure was $\rho = 0.35$ ($p < 0.001$) during painful stimulation [43]. In one research on 55 patients, criterion validity was reported $r = 0.71$ ($p < 0.05$) by comparing CPOT and self-reported pain by the patient during painful stimulation [40]. A strong correlation was found between CPOT and VAS tools ($r = 0.48$, $p < 0.0001$) [26]. CPOT was also compared with PIAND and NVPS tools ($r = 0.86$, $p < 0.001$), and in all the three tools, the increase in score was observed in the case of painful stimulation compared to baseline [51]. In a comparison of the Turkish version of CPOT with BPS tool, the correlation between the two tools at painful stimulation was 0.89. Moreover, in a study on patients admitted to intensive care units after cardiac surgery, CPOT score increased by 3 points during painful stimulation (change of position) compared to baseline [45].

Responsiveness

The responsive rate of the tool was reviewed in one study, in which the effect size of CPOT between baseline and during the painful procedure was reported to be 1.55 [29].

Feasibility

The Feasibility and utility of the tool were investigated in two studies [29], [39]. In the study of Gelinas et al., over 90% of 33 nurses participating in the study described the use of CPOT as satisfactory regarding understanding, learning, and ease of use. Moreover, 72.7% of the participants in the study considered the use of CPOT as useful and recommended it. In the study of Chanques et al., 20 nurses participating in the study gave the score 7-8 from 0 (worst) to 10 (best) range regarding accuracy, utility, and ease of use. Also, 24% of these people preferred BPS tool to other study tools.

Sensitivity and specificity of the tool

In two studies, the sensitivity and specificity of the tool were studied [44], [47]. During painful stimulation, the sensitivity and specificity was 66.7-86% and 78-83.3%, respectively, with a cutoff point of 2-3 scores [47]. Also, in the Dutch version of the tool, at a cut-off point of > 2, sensitivity and specificity of the tool was 39% and 58%, respectively [44].

Limitations

Limited review of some items of the tool (including Vocalization item) is a limitation of CPOT, which has been studied only in patients without endotracheal tube after heart surgery, while the purpose of this item has been to assess pain in non-intubated patients who are not able to express their pain. Furthermore, in some studies, it has been stated that the face expression item in patients with brain injuries or face trauma is different from other patients hospitalised in ICU. However, it seems that the validity and reliability of CPOT should be considered in various patient groups, including delirium patients as well as those with mental problems and brain injuries [37], [38], [54].

Non-Verbal Pain Scale (NVPS)

In 8 studies, non-verbal pain scale (NVPS) was investigated [28], [29], [31], [55], [56], [57], [58], [59], which was originally designed based on FLACC tool. This tool has 5 items for assessment of pain: face expression, activity (movement), and guarding as the item's behavioral section, and physiological section in original version of NVPS, including physiological item I (blood pressure, heart rate, respiratory rate) and physiological item II (pupil size, skin color and temperature, sweating) [57], and in the revised version includes a physiological item (blood pressure, heart rate) and a respiration item (based on SPO2 and Compliance with ventilator). Each item is scored in 0-2, with the score range calculation of 0 (painless) to 10 (maximum pain). The revised version of the tool is based on studies by Odhner et al., in which the respiration item has replaced the physiological item II. To assess validity and reliability, the original and revised versions of the tool were reviewed among 213 and 401 patients admitted to ICU, respectively [28], [29], [31], [55], [56], [57], [58], [59].

Reliability

The reliability of tool was examined in seven studies [28], [29], [31], [55], [56], [57], [58], and A test-retest procedure was then performed in one study. The re-test was conducted 8-12 hours after the initial test among 37 out of 60 patients, and the correlation coefficient between the two tests for original and revised versions of the tool was r = 0.51-0.75 and r = 0.55-0.86, respectively(55). Internal consistency of the tool was reported using Cronbach alpha, which was 0.62-0.78 during painful stimulation [31], [55], [56], [57], [58]. Moreover, in the revised version of NVPS, Cronbach alpha value was reported to be in 0.72-0.86 range during painful stimulation [28], [55], [56]. Also, in a study by Odhner et al., if FLACC and the original version of NVPS were combined, the internal consistency of the tool would increase to 0.90 [57]. Inter-rater agreement percent for both tools was reported > 90% (90.8-94.7%) in 72 observations(56). Inter-rater reliability was 0.71 for the final score using kappa coefficient [29], and the highest value of it was related to the face expression item (k = 0.70) and the lowest for the physiological item II (k = 0.02) [29]. ICC has also been reported at a range of 0.62-0.95 at different times of study [28], [31]. The inter-rater reliability based on the Pearson correlation coefficient was also reported 0.89-0.96 for the revised version and 0.80-0.87 for the original version [55]. The highest correlation level of items with a final score was reported to be r = 0.708 during the painful stimulation associated with face expression item in the original version and guarding item (r = 0.663) in the revised version [56].

Validity

The validity of the tool was also reviewed in seven studies [28], [29], [31], [55], [56], [57], [58]. The discriminant validity was confirmed through increasing average score by at least 2 points at painful stimulation (endotracheal suction, position change) compared to basic time (P < 0.001) [28], [55], [58]. To evaluate the convergent validity, NVPS was compared with FLACC tool, which showed a correlation between the two tools (r = 0.86, p < 0.05) [57]. Comparison of

patient self-reports to NVPS scores demonstrated a moderate statistically correlation (ρ = 0.313; *p* = < 0.001) [59].

Also, to assess the criterion validity of the tool, NVPS was measured using self-report by the patient (yes/no). The higher NVPS scores in patients who confirmed the presence of pain indicated the validity of the tool (p < 0.001) [55]. The correlation of NVPS with numerical scores of pain (NRS) was ρ = 0.559 during painful stimulation and ρ = 0.405 during non-painful stimulation [58].

Responsiveness

In a study, the Responsiveness of the tool was investigated by reporting the effect size [29]. The effect size for average final score was 1.01 during suction, and it was 1.20 during repositioning. The maximum effect size was related to respiration item during suction (0.22), and the maximum effect size was related to the face expression item (1.68) during repositioning.

Feasibility

In a study, the utility and usefulness of this tool were evaluated before and after implementation in the intensive care unit [59]. 78% of participants (out of 32) stated that the application of this tool was easy or very easy. Also, 80% were satisfied with the training and implementation of this tool. 81% of nurses also stated that NVPS was a reliable tool for pain assessment in non-conscious patients, while 57% of nurses participating in the survey were ensured of the tool to assess pain in non-conscious patients before NVPS training and implementation (from 53 people) [59].

Sensitivity and specificity

In one study, the sensitivity and specificity of the tool were reported to determine the cut-off point of pain. In the original version of the tool, cutoff point in 1.5 scores had 95.6% sensitivity and 97.4% specificity. In the revised version of the tool, the pain cutoff point in 1.5 scores had sensitivity and specificity of 95.6% and 96.3%, respectively [55].

Limitations

There are limitations in NVPS design and study. For example, in physiological item II, the definition of pupillary dilation and sweating is not standardised [38]. In behavioural items, the expression of a smiley state or normal position of body and hands cannot indicate a painless situation [54]. In the study of Topolovec-Vranic et al., the number of nurses participating in a post-implementation survey of the tool (32 subjects) was less than those participating before the implementation of the tool (53 subjects), which could affect the final results [54].

Faces, Legs, Activity, Cry and Consolability Scale

This tool was originally designed to assess pain among children with cognitive impairment [60]. Each item of the tool is scored 0-2, and finally, for the five items, the score range of 0-10 is expected. This tool has been evaluated in two studies on 88 adult patients admitted to intensive care units [57], [61].

Reliability

The reliability of the tool was examined in both studies [57], [61]. Internal consistency of the tool was measured using Cronbach's alpha coefficient, which was high in both studies and was reported in 0.84-0.88 range, which would increase to 0.934 by eliminating the cry item [61]. However, internal consistency was reduced by eliminating any of the other items. Inter-rater reliability had a high final score (k = 0.98), which was lower for the cry item (k = 0.72). Also, the inter-rater agreement per cent for tool items ranged 84-93%. Moreover, to calculate the variance of score, participation of each tool item was calculated using factor analysis method, with minimum level related to cry item (68.9%) compared to the items of face (0.86), legs (0.94), activity (0.90), and consolability (0.95) [57], [61].

Validity

A significant reduction in the score of FLACC after administration of an analgesic drug or decrease in scores in non-painful situations relative to painful situations (mean, 5.27; SD, 2.3 vs mean, 0.52; SD, 1.1; P < .001) indicates construct validity [61]. Also, to verify the criterion validity, the correlation between FLACC and Checklist of Nonverbal Pain Indicators (CNPI) was investigated, indicating high correlation as a sign of excellent reliability of tool (ρ = 0.963; P < 0.01). Furthermore, the high correlation of final FLACC score with that of NVPS tool represents excellent validity of the tool (r = 0.86, p < 0.0001). The highest correlation among FLACC and NVPS items is related to the face expression item (r = 0.78, p < 0.0001). The correlation of FLACC items with the final score of NVPS is in r = 0.65-0.75 range (p < 0.0001) [57].

Responsiveness/Accessibility

In none of the studies conducted on adult patients admitted to the intensive care unit were responsiveness, accessibility, and utility of the tool examined.

Limitations

The number of samples used in the studies is limited, and the tool should be used in more patients and in other wards to achieve better and more robust results. Moreover, for further verification of validity, the comparison of the tool with the patient's self-report seems to be more beneficial [38].

Non-Verbal Pain Assessment Tool (NPAT)

This tool was developed and introduced in 2010 to assess pain in people who could not communicate verbally [2]. NPAT has been studied in patients hospitalised in internal intensive care, general surgery, cardiac and chest surgery units. The initial version of this tool has five items, each of which scored 0-2, with 0 representing the lowest score and 10 the top score. The tool includes emotion (effective response to a situation), movement (change in the placement and positioning of the body), verbal cues (vocalization from the patient other than speech), facial cues (expressions of the face), and positioning/guarding (body response that imply a protection of the body from contact with external touch), which has been studied in three phases in the initial research. The first and second phases of the study were conducted to verify the validity and reliability of the tool, and the third phase focused on assessment of criterion validity in comparison with patient's self-reported pain. In the first and second phases of the study, five teams each involving two nurses were present, and the third phase was attended by a team of two nurses [2], [54].

Reliability

In the first phase of the study, 68 non-verbal patients in intensive care units were evaluated. To assess the inter-rater reliability, the concordance correlation coefficient was used that was reported 0.69 in this study, indicating a moderate to high reliability among assessors. The internal reliability of the tool for the final score was reported using Cronbach α, which was 0.82. The internal reliability of the tool items was also reported at 0.79-0.77. The correlation of the average score of each item with the total score is also in 0.60-0.63 range, except for the verbal item, which is equal to 0.55. Also, in this phase of the study, the kappa value was 0.35, indicating minimal strength of agreement.

In the second phase of the study, 39 patients who were not able to communicate verbally were evaluated. The concordance correlation coefficient was 0.72 (95% confidence interval), demonstrating strong interrater reliability [2], [54].

Validity

In the second phase of the study, the criterion validity of the tool was evaluated in 42 patients, showing tool validity of 0.21 indicative of poor validity and concern over the utility of the tool. In the third phase of the study, to review the criterion validity of the revised NPAT version, 50 patients admitted to a post-operative ward who were able to self-report pain were examined. In this phase of the study, two nurses separately and blindly attempted to record the degree of pain among patients based on the patient's self-report as well as the revised version of NPAT. The correlation coefficient was 0.66 ($P < 0.05$), which showed a moderate to high correlation [2].

Limitations

In this study, the responsiveness, satisfaction, sensitivity, and specificity of the tool were not considered. In this research, the time to evaluate pain has not been clearly expressed, which is a major weakness. Furthermore, unlike the first and second phases of the study, the tool was investigated in patients undergoing surgery, the results of which are not reliable in our case [2], [54].

Discussion

In this study, a review of psychometric and appropriateness of tools as well as the adequacy of tools has been used to assess pain. In this systematic review, five pain assessment tools for patients admitted to post-cardiac surgery ICU have been investigated.

At least 100 samples have been recommended for review according to instrumentation and psychometric papers [18]. However, in most studies, the number of samples is usually < 100 patients, and in some studies, < 50 patients have been evaluated [27], [29], [35], [43], [61] and in some studies > 100 [2], [11], [26], [30], [31], [34], [39], [44], [47], [62]. Nevertheless, in most studies, at least two assessments were done for patients. The test-retest procedure was conducted to express the per cent of missing items as well as data management for CPOT, BPS, and NVPS tools, and a majority of studies were related to BPS tool [19], [20], [24]. One of the limitations in validity assessment of tools was that in a small number of studies, the tools were compared with self-reported pain. In these studies, BPS, CPOT, and NPAT tools were compared in different groups with patients' self-report of pain. NPAT tool was evaluated only in one study [2] in which the validity and reliability of tools were assessed in three phases; however, further studies are needed to ensure the validity of the tool. In the third phase of the study, in contrast to the first and second phases, the tool was examined among patients in the surgical ward, the

results of which were not reliable for our review. Also, the validity of the tool cannot be verified, and there seems to be a need for further studies [54].

An important point in this review was nurses' attitude to the need for observational tools and how to use these tools. In previous studies, there has been a positive correlation between the ability of nurses to assess pain in patients admitted to intensive care units with the adequacy of treatment and pain control. Furthermore, the lack of timely diagnosis of pain or accurate assessment of patient's pain as well as following a treatment course not based on patient's actual pain hurts improvement of the disease and clinical and psychological conditions of the patient. Therefore, implementation of tools among nurses can be effective in changing the viewpoints of nurses in this regard [63].

Based on our analysed in all of the tools examined, immobilisation of patient was considered as indicative of no pain in the patient, while in some painful situations, immobilisation of patient is regarded as a measure to reduce and control pain [54]. Another probable drawback of observational pain tools is that various items of these tools could be a function of causes other than pain such as restlessness. Another problem with these tools is the lack of proper performance in patients with spinal cord injuries, patients receiving muscle relaxants, and those having facial trauma.

In NVPS, physiological signs (including vital symptoms) have been used as items assessing the tool. In the original version of the tool, there is no standard definition of pupil dilation and sweating in physiological item II. Also, the use of vital signs, including heart rate, is unlikely to be effective in pain assessment among patients [38].

According to research, over 70% of nurses use vital signs to assess pain in patients [62]. However, current evidence does not support the validity of critical signs to assess pain among the patients. American Society for Pain Management Nursing (ASPMN) in a 2006 guideline stated that the use of vital signs changes is not recommended for the assessment of pain in patients not able to speak [15] and that vital signs should not be considered as the only pain assessment tool but rather as a guide when other pain assessment tools are not applicable for a long time [17]. In some studies, the convergence of CPOT and MAP tools has been shown [28], [46], which represents the convergence of MAP and CPOT changes. However, further supplementary studies can be helpful in this respect. Overall, considering the clinical conditions of each patient, general conditions, the course of the disease, and provision of treatment based on individual changes of vital signs should not be ignored among patients admitted to the intensive care unit.

In one study [57], the FLACC tool was considered as the gold standard to evaluate the validity of NVPS, while FLACC was originally designed to assess pain among children. Based on our study FLACC tool was implemented in two studies on adults with a low sample number [57], [61], which does not seem to be able to confirm the validity of tool in adults. Moreover, the responsiveness rate and utility of the tool have not been reviewed, which is a disadvantage by itself. Another possible drawback is that FLACC has not been evaluated and compared with self-reported pain of adults. In the FLACC tool, the cry item looks non-specific for adults, which reduces the value of this tool to assess pain among adults. It seems to Comparison of CPOT and NVPS tools in patients admitted to ICU after cardiac surgery indicated that CPOT tool in these patients was superior for assessment of pain and that the nurses participating in the study had more consensuses on scoring and use of CPOT. Also, the items have not been clearly explained in the CPOT tool.

Among these tools, BPS and CPOT had the highest adequacy to be used in pain assessment among adult patients admitted to these wards. According to our research, CPOT and BPS tools have higher validity and reliability and appear to be the best choice for pain assessment in post-cardiac surgery intensive care units among patients with mechanical ventilation. In the case of BPS tool, the base score (painless) is 3, which is sometimes misleading [54]. It seems that changing the painlessness score from 3 to 0 eliminates the wrong impression of the base score. CPOT tool is likely to be an appropriate tool for pain assessment in patients admitted to post-cardiac surgery intensive care units under mechanical ventilation not able to express their pain according to examined validity, reliability, responsiveness rate, and utility. Nevertheless, to confirm this conclusion, further studies in these patients and comparison with other available tools are warranted.

The results obtained in this systematic review are in line with those related to previous studies [37], [38], [54]. Examining the versions of tool translated to various languages have confirmed similar findings in previous studies, although further confirmation of the reliability and validity of the investigated tools requires more studies. More clinical studies with higher sample sizes and elimination of limitations in previous studies are needed to develop more functional and specialised observational tools, which can be used as a stable component in patient assessment and recording by nurses as well as treatment based on these assessments.

Limitation: In our research, studies examining < 30 patients, those written in a language other than English and Persian, and letters to the editor were excluded, although there were researchers among them that were noteworthy to be considered. Another limitation of our study was that only one researcher extracted data from studies, which was error-prone, although the overall review was under the supervision of other researchers. Similar to any systematic review,

other relevant tools subject to thorough and unannounced testing may not be included in this review.

Conclusion

Application of behavioural and observational pain tools in unconscious and non-verbal adults patients in an intensive care unit is essential for pain assessment and timely treatment. In patients undergoing open-heart surgery, lack of well-timed diagnosis and treatment of pain can cause irreparable consequences and complications, increase hospitalisation time, lead to mental health problems, raise medical expenses, and eventually result in death. Therefore, familiarisation and training of nurses working in intensive care units with behavioural and observational tools of pain assessment are necessary. Nurses' skills and experience in using these tools to identify and cure pain promptly can lead to a new experience by patients when admitted to intensive care units.

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