



## The Validity and Reliability of Pain Instruments In Patients With Decreased Level Of Consciousness: A Literature Review

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### ABSTRACT

Pain is an unpleasant experience that produces a detrimental effect on patients. The quality of pain management is influenced by an accurate pain assessment. However, a pain assessment in patients with a decreased level of consciousness is still a big challenge for nurses. Currently, there is no standard instrument for assessing pain in this population. This study aims to determine a valid and reliable pain instrument for pain assessment in patients with a decreased consciousness level. Our study was a literature review guided by Preferred Reporting Items for Systematic Reviews and Meta-Analysis. The Systematic search was conducted in PubMed, Science Direct, Scopus, SAGE, Taylor & Francis, dan ProQuest using the keywords of "Pain Assessment" and "Loss of Consciousness". The inclusion criteria were observational or experimental design articles, adult patients, and studies of patients with a decreased level of consciousness but not in a coma. The bibliography search yielded 861 articles. Through the selection process, seven articles were found to meet the eligibility. The results of the study show that pain instrument based on behavioral observations has better validity than the physiological indicator. All studies using pain instruments recommend the Critical-Care Pain Observational Tool as a valid and reliable instrument for pain assessment in patients with verbal communication disabilities. Facial expression is the most relevant indicator in assessing pain intensity changes. The results of this study increase the opportunity for nurses to build scientific evidence to improve the quality of pain management.

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#### Kata kunci:

penurunan tingkat kesadaran  
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### ABSTRAK

Nyeri merupakan sebuah pengalaman tidak menyenangkan yang mengakibatkan efek buruk pada pasien. Kualitas penatalaksanaan nyeri dipengaruhi oleh penilaian nyeri yang akurat. Penilaian nyeri pada pasien dengan penurunan tingkat kesadaran masih menjadi tantangan besar bagi perawat. Saat ini belum terdapat instrumen standar yang digunakan dalam penilaian nyeri pada populasi pasien dengan penurunan tingkat kesadaran. Penelitian ini bertujuan untuk menentukan validitas dan reliabilitas instrumen nyeri pada pasien dengan penurunan tingkat kesadaran. Penelitian ini merupakan literature review yang mengacu pada pedoman Preferred Reporting Items for Systematic Reviews and Meta-Analysis. Penelusuran sistematis dilakukan melalui database jurnal PubMed, Science Direct, Scopus, SAGE, Taylor & Francis, dan ProQuest menggunakan kata kunci "Pain Assessment" and "Loss of Consciousness". Kriteria inklusi penelitian meliputi artikel dengan metode observasi atau eksperimen, melibatkan pasien dewasa, dan penelitian dilakukan terhadap pasien dengan penurunan tingkat kesadaran, namun bukan dalam keadaan koma. Penelusuran pustaka menghasilkan 861 artikel. Melalui proses seleksi,

didapatkan tujuh artikel yang memenuhi kriteria kelayakan review. Hasil review artikel menunjukkan bahwa instrumen nyeri berbasis observasi perilaku memiliki validitas lebih baik dibanding indikator fisiologis. Semua artikel penelitian yang menggunakan instrumen nyeri merekomendasikan Critical-Care Pain Observation Tool (CPOT) sebagai instrumen yang valid dan reliabel dalam penilaian nyeri terhadap pasien dengan ketidakmampuan komunikasi verbal. Ekspresi wajah merupakan indikator paling relevan dalam menilai perubahan intensitas nyeri. Hasil review ini meningkatkan peluang perawat dalam membangun bukti ilmiah guna meningkatkan kualitas penatalaksanaan nyeri.

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## INTRODUCTION

Pain is a disagreeable subjective and emotional experience that generally occurs within a certain period (Jie et al, 2019; cit. Sengkeh and Chayati (1). A research conducted by Asadi-Noghabi, Gholizadeh (2) shows that 64% of patients experienced pain while receiving treatment in the Intensive Care Unit (ICU). Pain sensation was felt when patients at rest and increased by up to 50% when they underwent treatment procedures, such as changing body position, suctioning endotracheal mucus, removing drainage tube, wound care, and insertion of intra-venous or intra-artery catheter (3).

Pain sensation that is not managed properly results in various adverse effects on patients, including higher incidence of Ventilator-Associated Pneumonia (VAP), medical errors related to drugs administration, interference in the recovery process, longer duration of treatment, and higher mortality (3). Pain management is still a major problem in various health care centers, especially in the ICU (4).

Inadequate pain management is often associated with the inability of health care providers to identify and assess pain in patients (5). Systematic pain assessment becomes an essential component that plays a role as a guidance for pain intervention (6). The pain assessment method using verbal patient reports is the most valid standard in the identification and assessment of pain (7). However, this assessment method cannot always be performed on ICU patients who experience a decreased level of consciousness, are on mechanical ventilator, receive sedative therapy, or are in critical illness (Alderson and McKechnie, 2013; cit. Birkedal, Larsen (3). This condition becomes an obstacle for health care providers to assess pain based on verbal reports from patients (8).

Pain assessment in the ICU patients has become a major challenge for nurses and other health care professionals (9). Health care providers may consider the use of behavioral observation strategies and physiological indicators as alternative methods to assess pain in the ICU patients (Gelinas et al., 2006; cit. Birkedal, Larsen (3). A study carried out by Gregersen, Melin (10) and Lin, Wang (11) shows that pupil size, facial expression, Skin Conductance Index (SCI), heart rate, and brain electrical activity can be significant indicators in detecting pain. Another study recommends the use of video pupillometry as an objective indicator of pain assessment in patients with critical illness (Li et al., 2009; cit. Bernard, Delmas (12).

Some recommended pain assessment instruments to use in the ICU patients are Nonverbal Pain Scale (NVP), Critical-

Care Pain Observation Tool (CPOT), Behavioral Pain Scale (BPS), COMFORT Scale, and Face Legs Activity Cry and Console (FLACC)(Rose et al, 2013; cit. Birkedal, Larsen (3). Shan, Cao (7) mentions that CPOT and Bispectral Index (BIS) are valid and reliable pain instruments to assess pain in patients with severe head injuries. Another experimental study suggests that the BPS, Nociception Coma Scale for Intubated Patients (NCS-I), and Nociception Coma Scale Revised Version (NCS-RI) are valid, reliable, and easy-to-use instruments for mechanically ventilated head injury patients (12).

Various research studies have been conducted to compare pain assessment methods in the ICU patients. Several research articles provide different recommendations concerning the validity of pain assessment instruments and the use of various physiological indicators of pain. This literature review is an important study for health care providers in the clinical practice activities to identify valid, reliable, and easy-to-use pain instruments for patients experiencing a decreased level of consciousness during hospitalization.

The main objective of this literature review is to identify the most valid and reliable pain instrument in assessing pain intensity in patients with critical illness and a decreased level of consciousness. The specific purpose of this review is to determine the validity of the behavioral observation-based pain instrument compared to physiological indicators. In addition, this review aims to determine the most relevant indicators in assessing pain level changes in patients with critical illness and with a decreased level of consciousness.

## RESEARCH METHODOLOGY

### *Research Design*

This study was a literature review of research articles about pain assessment in patients with critical illness and a decreased level of consciousness.

### *Inclusion and Exclusion Criteria*

The inclusion criteria as the feasibility indicator of an article to be included in the review process were: a). Articles with an observational or experimental quantitative design; b). Research involving adult patients (age 16 years and above); and c). Studies conducted on patients experiencing a decreased level of consciousness.

The criteria of research articles excluded in the review process were: a). Research conducted outside a hospital setting; b). Reviews or preliminary studies; c). Researches on coma patients, patients with motor paralysis of the limbs, and those using drugs that block the nervous system; d). Studies on patients with various types of cognitive deficits and psychiatric conditions; and e). Non-English or non-Indonesian research articles.

#### *Article Search*

The search for literature was carried out on international journal databases, such as PubMed, Science Direct, Scopus, and SAGE using Pain Assessment, Pain Measurement, Pain Scale, Loss of Consciousness, Consciousness State, and Unconsciousness as the keywords. The strategy for searching was built on PubMed using Medical Subject Heading (MeSH) resulting in the following search formula (((((Pain Assessment\* [Title/Abstract]) OR (Pain Measurement\* [Title/Abstract])) OR (Pain Scale\* [Title/Abstract])) AND (Loss of Consciousness [Title/Abstract])) OR (Consciousness State [Title/Abstract])) OR (Unconsciousness [Title/Abstract])). This formula was also used as a literature search strategy in other journal databases. The search for literature was limited to articles published from 2011 to 2021. The other limitations included languages, types of articles, and academic publications.

#### *Article Selection*

All articles obtained from various journal databases and relevant to the topic of the literature review were screened to eliminate duplicate articles. Then, the articles were selected based on the suitability for the title, abstract, and inclusion criteria for the literature review.

#### *Article Quality Assessment*

The selected research articles in the literature review were assessed for the methodological quality. The assessment used the Critical Appraisal Tools (CAT) checklist for Analytical Cross-Sectional Studies from the Joanna Briggs

Institute (JBI). This checklist consists of 8 question items to assess the quality of the methodology and the extent to which a study overcomes possible bias. The researchers decided that an article would have the feasibility of being included in the review process if it met the 'Yes' answer of at least 6 items.

#### **RESULTS**

The researcher used the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines to carry out a systematic search for articles through the journal databases, to screen the articles, and to determine those that met the eligibility criteria for the review (13). The articles were collected from 4 journal databases: PubMed, Science Direct, Scopus, and SAGE journal. A total of 706 research articles were found based on the keywords. The articles were then screened using the Reference Manager: EndNote application to eliminate duplicate articles (n:9).

The researchers screened the articles to assess whether the titles and abstracts met the literature review questions. The screening process resulted in 2 duplicate articles and 11 potential articles for further reviews. The researchers then searched for more articles in 2 other journal databases, namely Taylor & Francis and ProQuest and managed to collect 110 articles. In the next screening process, the researchers identified 4 additional potential articles. Then, the researchers screened the articles to assess whether the titles and abstracts met the literature review questions. Based on the number of articles screened, the researchers decided to search for additional articles from 2 journal databases: ProQuest and Taylor & Francis, which resulted in an additional number of 110 articles. Through the screening process, the researchers managed to identify 15 potential articles for further study. However, there were only 7 articles that met the feasibility and eligibility criteria. The process is shown in Chart 1.

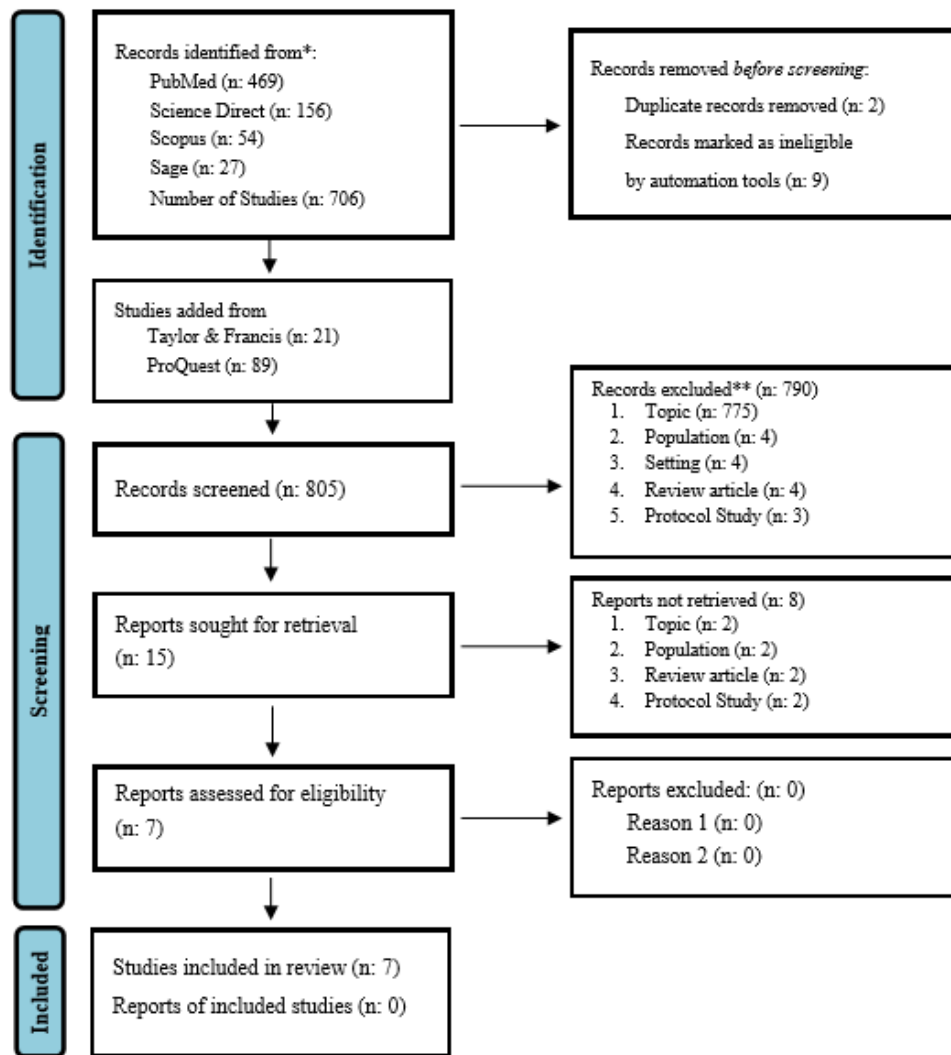


Chart 1. The Process of Reviewing and Analyzing the Articles using PRISMA Diagram

At the next stage, the researchers conducted a full text review and evaluated the quality of the articles using the JBI Critical Appraisal Tools for Analytical Cross-Sectional Studies instrument. Seven articles were found to meet the quality criteria. Then, a synthesis process was carried out to draw conclusions from all the articles reviewed (Higgins et al., 2019; cit. Wibowo and Putri (14). The data extraction process for each article is shown in Table 1.

The review of the seven articles that met the eligibility criteria showed that all studies were conducted on patients who experienced a decreased level of consciousness due to either disease (Topolovec-Vranic, Gélinas (15); Arbour, Choinière (16); Severgnini, Pelosi (17); Gélinas, Bérubé (18); Fratino, Peluso (19) or the administration of sedative drugs (Khanna, Chandralekha (20); Khanna, Pandey (21); Fratino, Peluso (19). All research studies were conducted on patients being treated in the ICU, including trauma and neuro-surgery ICU, in hospitals in various countries, such as Canada (Topolovec-Vranic, Gélinas (15) and Arbour, Choinière (16), Italia (17), India (Khanna, Chandralekha (20) and Khanna, Pandey (21), Canada and US (18), and Belgium (19).

The review of the articles shows that pain assessments in patients with a decreased level of consciousness can be evaluated using pain instruments based on behavioral observations (9) and observations of physiological indicators of pain, such as skin conductance, pupil size, blood pressure,

and heart rate (11). This literature review also shows that facial expression is the most relevant indicator used to identify changes in pain intensity in this patient population.

#### Patient Characteristics

Patient characteristics including age and medical condition were identified in this review. All studies in this literature review employed adult patients as research objects, although there were slight differences in the age criterion. The research conducted by Topolovec-Vranic, Gélinas (15), Khanna, Chandralekha (20), and Khanna, Pandey (21) used the age of  $\geq 16$  years old, while a research carried out by Arbour, Choinière (16), Severgnini, Pelosi (17), Gélinas, Bérubé (18), and Fratino, Peluso (19) used the age of  $\geq 18$ . The mean of age of the patients ranged from  $\pm 43.7$  years (20) to  $\pm 65$  years (17). The majority of patients involved in this literature review study were male ranging from 54.5% (15) to 76% (19). The age and sex characteristics of the patients did not affect the assessment of pain in patients with a decreased level of consciousness.

Nonetheless, the patients' medical condition could affect the identification and assessment of pain. The studies were conducted on patients with a decreased level of consciousness with various backgrounds. Several studies

used surgical patients, such as those with brain trauma and neuro-surgery (Topolovec-Vranic, Gélinas (15); Arbour, Choinière (16); Gélinas, Bérubé (18)), with post-thoracic, abdominal, vascular surgery, and with multiple trauma (Severgnini, Pelosi (17)). The other backgrounds were internal diseases, such as respiratory failure, sepsis, and chronic obstructive pulmonary disease as well as cases requiring intubation and mechanical ventilation (Khanna, Chandralekha (20); Khanna, Pandey (21); Fratino, Peluso (19)). All of the research projects excluded patients with such cases as coma and brainstem death, spinal cord trauma or various diseases causing paralysis of the limbs, those undergoing treatment using neuromuscular blocking drugs, and those with the history of cognitive deficits or psychiatric problems. The study of Fratino, Peluso (19) used slightly different inclusion criteria. This study involved patients in the state of deep sedation (the value of or RASS Score -5).

*Pain assessment using behavioral observation-based pain instruments*

The accuracy of pain assessment in patients with a decreased level of consciousness is influenced by the pain instrument used. A study conducted by Topolovec-Vranic, Gélinas (15) used CPOT and NVPS-R pain instruments to assess pain in patients with trauma and neurosurgery who were unable to verbally communicate their pain. The pain assessment was carried out during the turning procedures and the non-invasive blood pressure measurement. The results were compared with those of patients whose pain was assessed using the Faces Pain Thermometer pain instrument. The findings show that the CPOT pain instrument has better validity than the NVPS-R (p CPOT = 0.019; p NVPS-R = 0.025).

Another study carried out by Severgnini, Pelosi (17) used the CPOT and BPS instruments to assess pain in patients experiencing a decreased level of consciousness. Both instruments show good validity to assess pain, but the CPOT instrument shows better sensitivity than the BPS (BPS = 62.7% vs CPOT = 76.5%). The validity of the CPOT instrument was tested by comparing it with the method of reporting pain from patients using the Visual Analog Scale (VAS) pain instrument. Similar results are shown by research conducted by Gélinas, Bérubé (18) confirming that the CPOT-Neuro instrument has good validity and reliability in assessing pain

in patients with a decreased level of consciousness due to brain trauma.

The CPOT instrument is also more meaningful in assessing pain in critically ill patients who are unable to communicate their pain compared with the physiological indicators, such as blood pressure and heart rate changes (21). Facial expression is the most relevant indicator in assessing changes in pain intensity in a population of patients with a decreased level of consciousness (Arbour, Choinière (16); Severgnini, Pelosi (17); Khanna, Chandralekha (20); Gélinas, Bérubé (18).

*Pain assessment based on observations of physiological indicators of pain*

Pain often results in changes in physiological functions, namely agitation, insulin and cortisol hormone secretion as well as changes in the immune system, in the cardiac and respiratory functions, and in the mental status (Smeltzer et al., 2011; cit. Sedighie, Bolourchifard (4)). Research by Khanna, Chandralekha (20) shows that there was a significant increase in blood pressure and heart beat rate when patients received tracheal suctioning and body turning procedures, except for heart beat rate during the turning procedure. The results of the study also show that the Skin Conductance Index (the SCI Index) is able to detect noxious stimulation better than the blood pressure and heart rate parameters. These results indicate that the SCI Index is more significant in assessing pain in critically ill patients who experience limitations in communicating their pain.

The SCI index is a physiological indicator that has a fairly good sensitivity and specificity to detect pain in patients with inability to communicate pain. This indicator requires further study to assess its efficacy in improving pain management in critical care rooms (20). Khanna, Pandey (21) does not really support the use of physiological indicators for pain assessment in patients with a decreased level of consciousness. The researcher states that the CPOT pain instrument has good psychometric test results for assessing pain in this patient population. The statement of Khanna, Pandey (21) is consonant with a study by Fratino, Peluso (19) showing that there is no correlation between the SCI Index and pupillometry index. Both methods are considered less valid for pain assessment in patients with critical illness and with a decreased level of consciousness.

**Table 1. Evaluation and Extraction of Review Articles**

Researcher	Research Design	Characteristic of Participants	Factors	Results	Strength and Limitations	Others Information
Topolovec-Vranic, J.B.P., et al., 2013	Prospective descriptive study with repeated measures	The participants were: <ul style="list-style-type: none"> <li>Trained nurses in using CPOT (n: 12) and BPS (n:11)</li> <li>Adult patients aged ≥ 16 (n: 66) treated with indications of trauma or neuro-surgery ;</li> </ul> The patients were divided into: able to communicate (n: 34) and unable to	<ul style="list-style-type: none"> <li>Patient demographic characteristics</li> <li>Assessment of consciousness level and analgesic status</li> <li>Assessment of pain</li> <li>Nociceptive and non-nociceptive procedures</li> <li>Assessment of discriminant validity, criterion</li> </ul>	<ul style="list-style-type: none"> <li>The CPOT instrument has better validity than the NVPS-R in assessing pain in critically ill patients unable to verbally communicate (CPOT; p = 0.019 vs NVPS-R; p = 0.025)</li> <li>The majority of nurses (60%) prefer CPOT as an instrument in practical activities.</li> </ul>	<p><u>Strength:</u></p> <ul style="list-style-type: none"> <li>The research has provided the training process for nurses</li> <li>The researchers seek feedback from the participants (nurses) regarding the use of the instrument</li> </ul> <p><u>Limitation:</u></p>	<ul style="list-style-type: none"> <li>The pain assessment used the NVPS-R and CPOT instruments</li> <li>The study did not compare the observation-based instrument with the observation of physiological indicators of pain</li> </ul>

Arbour, C., et al., 2014	Descriptive subjective with repeated measures	<p>communicate (n: 32)</p> <p>The participants were:</p> <ul style="list-style-type: none"> <li>• Adult patients aged <math>\geq 18</math> years (n: 45); with a severe head injury</li> </ul>	<p>validity, and reliability</p> <ul style="list-style-type: none"> <li>• Patient demographic characteristics</li> <li>• Assessment of disease severity</li> <li>• Assessment of consciousness level, sedation level, and analgesics status</li> <li>• Assessment of pain</li> <li>• Nociceptive and non-nociceptive procedures</li> <li>• Assessment of discriminant validity, criterion validity, and reliability</li> </ul>	<ul style="list-style-type: none"> <li>• There is a significant difference between pain behavior in nociceptive procedures (turning the body position) and non-nociceptive procedures (non-invasive blood pressure measurement)</li> <li>• There is a strong positive correlation between changes in pain behavior during nociceptive procedures and report of the patient. Pain behavior was observed in 25% of head trauma patients during nociceptive procedures and in 22.2% - 66.7% of patients who reported pain.</li> <li>• Facial expressions and limb movements are relevant indicators to identify the pain</li> </ul>	<p>The research areas are limited</p> <p><u>Strength:</u> The research focuses on assessing pain behaviors</p> <p><u>Limitation:</u></p> <ul style="list-style-type: none"> <li>• The assessment of pain behaviors using video recordings is subjective</li> <li>• The number of patients observed with varying degrees of consciousness is limited. This affects the exploration of the researchers and the results of the analyses</li> </ul>	<ul style="list-style-type: none"> <li>• The severity of diseases was assessed using APACHE Score</li> <li>• The pain was assessed using behavior checklist and recorded using video</li> <li>• The study did not use any pain instrument as a pain assessment method</li> </ul>
Severgnini, P., et al., 2016	Prospective observational	<p>The participants were:</p> <ul style="list-style-type: none"> <li>• Doctors (n: 12) and Nurses (n:28)</li> <li>• Adult patients aged 18 years (n: 101); patient requires mechanical ventilation; patient divided into: conscious (n: 41), unconscious (n: 60);</li> </ul>	<p>validity, and reliability</p> <ul style="list-style-type: none"> <li>• Patient demographic characteristics</li> <li>• Assessment of prognostic predictor</li> <li>• Assessment of consciousness level and sedation level</li> <li>• Assessment of pain</li> <li>• Nociceptive and non-nociceptive procedures</li> <li>• Assessment of discriminant validity, criterion validity, and reliability</li> </ul>	<ul style="list-style-type: none"> <li>• The CPOT and BPS show good criterion validity and discriminant validity in assessing pain. The BPS scale is more specific (91,7%) than the CPOT (70,8%), but has lower sensitivity than the CPOT (BPS: 62,7% vs CPOT: 76,5%)</li> <li>• Both instruments have a significant correlation to the Visual Analog Scale (VAS) (BPS r: 0.56 dan CPOT r: 0.48; <math>p &lt; 0.0001</math>)</li> <li>• The combination of the BPS and</li> </ul>	<p><u>Strength:</u> The research has involved multidisciplinary professions</p> <p><u>Limitation:</u></p> <ul style="list-style-type: none"> <li>• The number of certified assessors is limited</li> <li>• The number of research samples is small</li> </ul>	<ul style="list-style-type: none"> <li>• The pain assessment used the CPOT and BPS instruments</li> <li>• The criterion validity was found by comparing pain assessment using the CPOT and BPS instruments with the VAS instrument</li> <li>• The study did not compare the observation-based instrument with the observation of physiological indicators of pain</li> </ul>

Khanna, P., et al., 2018	Quantitative Prospective Observational with repeated measures	The participants were: Adult patients aged 16 years (n: 60) with Ramsay Score $\pm$ 3.6. Patient requiring intubation and mechanical ventilation with various background: Sepsis, COPD, and ARDS; majority patients were post operative (n: 21)	<ul style="list-style-type: none"> <li>• Patient demographic characteristics</li> <li>• Assessment of sedation level</li> <li>• Nociceptive and non-nociceptive procedures</li> <li>• Observation of physiological indicator using skin conductance algometer</li> <li>• Observation of invasive hemodynamic parameters: including blood pressure and heart rate</li> </ul>	<p>CPOT has resulted in a higher level of sensitivity in assessing patient pain, that is 80.4%.</p> <ul style="list-style-type: none"> <li>• Facial expression is the most relevant parameter in evaluating changes in pain level</li> </ul> <ul style="list-style-type: none"> <li>• The analyses show that there is no correlation between the SCA (Skin Conductance Algesimeter) index and the variables of blood pressure and heart rate (p: &gt;0.005), as well as with the patient's level of sedation</li> <li>• The SCA index is able to detect noxious stimulation better than blood pressure and heart rate variables. This indicate that the SCA index may have good sensitivity and specificity in detecting pain in patient with decreased level of consciousness</li> </ul>	<p><u>Strength:</u></p> <ul style="list-style-type: none"> <li>• The samples vary</li> <li>• The research has used a tool so that the assessment of the variables becomes more objective</li> </ul> <p><u>Limitation:</u></p> <ul style="list-style-type: none"> <li>• The research area is limited</li> <li>• The number of research participants is small</li> </ul>	<ul style="list-style-type: none"> <li>• The assessment of sedation levels used Ramsay Scale</li> <li>• The study did not use any pain instrument as a pain assessment method</li> <li>• Blood pressure is a better physiological indicator in assessing pain than heart rate</li> </ul>
Khanna, P., et al., 2018	Quantitative Prospective Observational with repeated measures	The participants were: Adult patients aged 16 years (n: 60) with Ramsay Score $\pm$ 3.6. Patient requiring intubation and mechanical ventilation with various background: Sepsis, COPD, and ARDS; majority patients were post operative (n: 21)	<ul style="list-style-type: none"> <li>• Patient demographic characteristics</li> <li>• Assessment of sedation level</li> <li>• Nociceptive and non-nociceptive procedures</li> <li>• Assessment of pain</li> <li>• Assessment of invasive hemodynamic parameters, including blood pressure and heart rate</li> </ul>	<ul style="list-style-type: none"> <li>• The Analyses show that there is no strong correlation between the CPOT scores and the physiological indicators (p: &gt;0.005)</li> <li>• The results of the study show that the CPOT instrument is significant in assessing pain in critical patients who are unable to verbally communicate</li> <li>• Facial expressions make a big contribution as a valid indicator in</li> </ul>	<p><u>Strength:</u></p> <ul style="list-style-type: none"> <li>• The samples vary. This study identifies pain behavior and physiological indicators of patients with different levels of consciousness</li> </ul> <p><u>Limitation:</u></p> <ul style="list-style-type: none"> <li>• The research area is limited</li> <li>• The researchers have not measured the criterion validity</li> </ul>	<ul style="list-style-type: none"> <li>• The assessment of sedation levels used Ramsay Scale</li> <li>• The pain assessment employed the CPOT instrument</li> <li>• Blood pressure increases when patient undergo painful procedures</li> </ul>

Gélinas, C., et al., 2021	Prospective cohort with repeated measures	The participants were: Adult patients who had a brain trauma (n: 226); GCS score $\geq 4$ . More than 55% a diagnosis brain injury, either with trauma, ischemia, hemorrhagic, brain tumor, or no trauma; majority of patients had a RASS score of -1	<ul style="list-style-type: none"> <li>• Patient demographic characteristics</li> <li>• Assessment of consciousness level and sedation level</li> <li>• Assessment of pain</li> <li>• Nociceptive and non-nociceptive procedures</li> <li>• Assessment of discriminant validity, criterion validity, and reliability</li> </ul>	<p>assessing changes in pain intensity</p> <ul style="list-style-type: none"> <li>• The CPOT-Neuro has a moderate positive correlation with patient's verbal report of pain during the body-turning procedure (S rho 0.63; <math>p &lt; 0.001</math>) and other nociceptive procedures (S rho 0.64; <math>p &lt; 0.001</math>)</li> <li>• The CPOT-Neuro has good validity and reliability in assessing pain in ICU patients with various types of brain injuries with different levels of consciousness and sedation</li> <li>• Facial expression is an indicator that changes more often when a patient experiences pain</li> </ul>	<p><u>Strength:</u></p> <ul style="list-style-type: none"> <li>• The research was conducted across countries</li> <li>• The number of sample is quite big (n: 226)</li> </ul> <p><u>Limitations:</u></p> <ul style="list-style-type: none"> <li>• The CPOT-Neuro cannot be used in unresponsive patients (GCS 3 or RASS -5)</li> </ul>	<ul style="list-style-type: none"> <li>• The assessment of sedation level used the RASS score</li> <li>• The pain assessment used the CPOT instrument and Faces Pain Thermometer (FPT)</li> <li>• The study did not compare the observation-based instrument with the observation of physiological indicators of pain</li> </ul>
Fratino, S., et al., 2021	Prospective Observational	The participants were: Adult patients with a diagnosis of brain injury (n: 51); GCS score $\leq 9$ with response motoric $\leq 5$ ; majority of comorbid disease were hypertension (n: 27)	<ul style="list-style-type: none"> <li>• Patient demographic characteristics</li> <li>• Assessment of consciousness level and sedation level</li> <li>• Nociceptive procedures in the form of tetanic stimulation</li> <li>• Assessment of physiological indicators using quantitative pupillometry and skin conductance algometer</li> </ul>	<ul style="list-style-type: none"> <li>• There is no correlation between the SCA index and pupillometry in 25 of 51 patients</li> <li>• Six patients showed the presence of skin conductance with a pupillometric index value of 4, while 19 patients showed a high pupillometric index value in the absence of skin conductance</li> <li>• The SCA index and video pupillometry are not valid in assessing pain in critically ill patients with decreased level of consciousness</li> </ul>	<p><u>Strength:</u></p> <ul style="list-style-type: none"> <li>• The research has employed a device so that the assessment of the variables becomes more objective</li> </ul> <p><u>Limitation:</u></p> <ul style="list-style-type: none"> <li>• The number of research samples is limited</li> <li>• The administration of sedative drugs and analgesic dose not have a standard protocol</li> <li>• The pain stimuli vary in duration and intensity</li> </ul>	<ul style="list-style-type: none"> <li>• The study did not use any pain instrument as a pain assessment method</li> <li>• Pupillometry indicators are more effective for critically ill patients with no brain trauma</li> <li>• The SCA index is less effective in patients with deep sedation</li> </ul>

## DISCUSSION

Pain is a multidimensional experience involving sensory, emotional, cognitive, and social aspects of an individual

(William and Craig; cit. Herr, Coyne (22)). Pain is not only a manifestation of the physical dimension, but is holistic, making it easier for health care providers to understand the existence of pain in patients with critical illness who are



unable to convey pain complaints (23). The results of the literature review explain that pain assessment in patients with a decreased level of consciousness can be done with pain instruments based on behavioral observations and observations of physiological indicators of pain. Gelinas et al. (2006; cit. Birkedal, Larsen (3) stated that patient behaviors and physiological indicators are important indices in pain assessments of ICU patients with verbal communication disabilities. Some behaviors that can be observed from patients include facial expressions, body movements, muscle stiffness, as well as breathing patterns or compliance with the ventilator (Herr, Coyne, and McCaffery, 2011; cit. Arbour, Choinière (16). As for physiological indicators of pain, they can be blood pressure, heart rate, respiratory rate, changes in pupil size, skin conductance, and electroencephalography (EEG) (11).

Pain assessment using behavioral observation-based pain instruments is recommended in patients with a decreased level of consciousness (2). This statement is consonant with the recommendation of The American Society for Pain Management Nursing (ASPMN) that behavioral pain instruments that show validity and reliability to a certain groups or context can be used as pain assessment methods if verbal pain reporting instruments are not possible to be applied (9). Currently, there are various pain assessment instruments that can be used in adult patients in the ICU, namely the Nonverbal Pain Scale (NVP), Critical-Care Pain Observation Tools (CPOT), Behavioral Pain Scale (BPS), COMFORT Scale, and Face, Legs, Activity, Cry, and Console (FLACC) Scale (Rose et al., 2013; cit. Birkedal, Larsen (3).

The CPOT and BPS instruments are considered to have better validity and sensitivity in detecting pain responses in patients with decreased verbal communication skills or in those receiving sedative therapy (Gelinas, 2007; Ahlers et al., 2008; Barr et al., 2013; cit. Birkedal, Larsen (3). The CPOT instrument was developed by Gelinas to assess pain behavioral indicators in patients with critical illness and unable to communicate their pain (15); while the BPS instrument was developed to assess pain in patients with a decreased level of consciousness and with mechanical ventilation installed (Payen et al., 2001; cit. Birkedal, Larsen (3). The main difference between the two instruments lies in the aspect of the evaluation of the patient's body movement and muscle stiffness (17).

Several studies in this literature review reported the results that the CPOT instrument showed good discriminant and criterion validity and good reliability values when used to detect pain in critically ill patients and in those with decreased levels of consciousness (Topolovec-Vranic, Gélinas (15); Severgnini, Pelosi (17); Khanna, Pandey (21); and Gélinas, Bérubé (18). The validity and reliability of the instrument was found by testing the CPOT instrument on the patient's response when receiving a nociceptive procedure, such as turning the body (repositioning) and suctioning tracheal mucus, compared with the results when they receive a non-nociceptive procedure, namely the non-invasively blood pressure measuring. In line with the results of research in this literature review, Cooney and Quinlan-Colwell (24) stated that the majority of patients in the ICU experience pain due to endotracheal mucus suctioning procedures, turning/changing body positions, removing drainage tubes, wound care, and insertion of venous/arterial catheters.

The CPOT instrument is reported to have several advantages. The majority of nurses of approximately 60%, stated that they prefer the CPOT instrument in a clinical application on the grounds that it is a fairly easy instrument

to use to detect and assess pain indicators in patients with verbal communication disabilities, sedation, decreased consciousness, or with endotracheal tube installed (Topolovec-Vranic, Gélinas (15); Gelinas, 2010; cit. Georgiou, Hadjibalassi (25). The CPOT instrument carries feasibility since it has a short mean time, which is about 4 minutes, to complete a pain assessment in a population of patients with verbal communication disabilities (21). The average completion time of filling out the instrument provides an advantage for nurses in terms of time efficiency of service to patients. The research of Severgnini, Pelosi (17) suggested that the CPOT instrument have a beneficial impact on improving the quality of pain management obtained through the accuracy of pain assessment, collaborative action with the physician, and re-evaluation of pain. These advantages have a positive impact on improving the quality of patient nursing care.

One of the limitations of the CPOT pain instrument is that it is not suitable to use in patients with paralysis due to the administration of Neuromuscular Blocking Agents (NMBA), or patients who cannot show a behavioral response to pain, such as in a coma or severe sedation. The CPOT instrument is also not suitable for patients experiencing a decreased level of consciousness due to severe head injuries (22). Therefore, the CPOT instrument needs to be adapted or modified to accommodate changes in pain behaviors in patients with severe head injuries (18).

Arbour, Choinière (16) reported that more than 25% of patients with head injury exhibited painful behaviors during nociceptive procedures; whereas in patients who are able to communicate, they show pain complaints with a percentage of 22,2% to 66,7%. The pain behavior most frequently shown by patients is a change in facial expression (Arbour, Choinière (16); Severgnini, Pelosi (17); Khanna, Pandey (21); and Gélinas, Bérubé (18). Patients who experience a decreased level of consciousness due to head trauma cause a reduced neuromuscular response to external stimuli, so that the response to muscle contractility and limb movement decreases (16). Compliance with the ventilator can be quite effective in assessing pain, but it is not valid because it can be influenced by various factors that are not related to pain, such as hypoxemia, bronchospasm, retention of respiratory tract mucus, and mechanical ventilation disturbances (21).

Pain sensation affected by hemodynamic parameters, including blood pressure and heart rate, shows a significant increase when the patient received nociceptive procedures, such as turning the body position and suctioning tracheal mucus. Khanna, Chandralekha (20) and Khanna, Pandey (21) gave slightly different results that higher hemodynamic parameters were not accompanied with an increase in heart beat rate when the patient underwent changes in body position. The results of the measurement of other physiological indicators, the SCI using an Algesimeter, did not show a correlation with changes in hemodynamic parameters (20).

Changes in the patient's vital signs provide clues for the nurse to initiate a further assessment of pain or other stressors (Devlin et al., 2018; dalam Herr, Coyne (22). However, changes in vital signs cannot be used as a single indicator in the assessment of pain in patients experiencing critical illness and a decreased level of consciousness. Scientific evidence does not support changes in vital signs as sensitive or specific indicators in assessing the presence of pain, especially in critically ill patients with homeostatic instability (22). The changes in vital signs can be affected by various types of drugs, such as vasopressors, adrenergic blockers, anti-arrhythmias, and sedatives; and influenced by

the pathophysiology of the underlying disease, such as sepsis, shock, hypoxia, and anxiety (Hamill-Ruth and Marohn, 1999; cit. Khanna, Chandralekha (20).

Khanna, Chandralekha (20) stated that the SCI has better sensitivity and specificity in detecting painful stimuli in critically ill patients than the hemodynamic parameters. The SCI has lower inter-individual variability, reacts immediately to stimuli, and is not affected by changes in homeostasis, cardioactive or vasoactive drug classes, and neuromuscular blocking agents (21). The opposite result is reported by Fratino, Peluso (19), stating that the SCI and pupillometry were not valid in detecting pain in patients with critical illness accompanied by a decreased level of consciousness. The sensitivity between two instruments was affected by the administration of sedative and analgesics drugs. Other factors that may have an influence on the validity of the instrument's assessment results are critical illness conditions, inflammatory processes, or brain damage. Further research on the observation of physiological indicators needs to be carried out on patients with acute or chronic pain in order to assess their efficiency (11).

## CONCLUSION

Pain is an unpleasant sensory experience and has become the main complaint of many patients visiting health care facilities. Poor pain management produces detrimental effects on patients and it remains a major problem in health care facilities, especially in the Intensive Care Unit (ICU). Various factors can affect the quality of patient pain management, including pain assessment using accurate pain instruments.

The results of this literature review show that behavioral observation-based pain instrument: Critical-care Pain Observation Tool (CPOT) has better validity than physiological indicators of pain, especially the hemodynamic parameters. The CPOT instrument shows good psychometric results for assessing pain in critically ill patients who are unable to communicate verbally. As for facial expressions as behavioral responses, they prove to be the most relevant indicator in assessing changes in pain. The use of CPOT instrument as a behavioral observation-based pain assessment method can improve nurse performance and various aspects of pain management.

## CONFLICT OF INTEREST

The author declared there was no conflict of interest regarding publication of this article.

## ETHICAL APPROVAL

Not applicable

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