Sensitivity and Specificity of the Comfort Scale to Assess Pain in Ventilated Critically Ill Adult Patients in Intensive Care Unit

Indah Sri Wahyuningsih¹, Awal Prasetyo², Reni Sulung Utami³

¹Faculty of Nursing, Sultan Agung Islamic University, Semarang, Indonesia
²Faculty of Medicine, Diponegoro University, Semarang, Indonesia
³Department of Nursing, Diponegoro University, Semarang, Indonesia

Corresponding Author: Indah Sri Wahyuningsih (indah.undip@gmail.com)

ABSTRACT

Background: Pain is a common phenomenon experienced by ventilated and critically ill adult patients. It is urgent to measure the pain among these patients since they are unable to report their pain verbally. Comfort Scale is one of the instruments used to measure pain in adult patients. The scale is used to measure pain among children patients with fairly high sensitivity and specificity.

Purpose: This study aimed to examine the sensitivity and specificity of the Comfort Scale to measure pain in the ventilated critically ill adult patients in the ICU.

Methods: This study employed a cross-sectional design with 66 ventilated adult patients in the ICUs of two hospitals in Semarang. The pain assessment was administered to the patients in 2 duplo periods by two observers comparing with the Comfort Scale and Critical Care Pain Observational Tool (CPOT) as a gold standard instrument during the pre and post positioning procedures. The data were analyzed using the receiver operating curve (ROC).

Result: The results showed that in the pre-positioning procedure, the Comfort Scale had the sensitivity value of 69% and the specificity value of 81%. Meanwhile, in the post-positioning procedure, the values were decreasing (the sensitivity of 45%, the specificity of 67%). This indicated that the sensitivity value of the comfort scale decreased and could be interpreted that the ability of the instrument to detect pain remained low. Meanwhile, the decrease of the specificity value of the instrument between the pre and post administration was not far different, so it could be interpreted that the instrument can correctly identify the patient without pain.

Conclusion: The Comfort Scale had a lower value of sensitivity and specificity in the post-positioning than that in the pre-positioning procedure. It is recommended that further studies should focus on the relationship between sedation and pain by using instruments of pain studies for adult patients (CPOT). Additionally, the hospital policy makers, that is Pain Task Force is expected to give education and training through workshops and seminars about the nurse skills in pain management on critical areas as part of the multidisciplinary team.

Keywords: Comfort scale; sensitivity; specificity
BACKGROUND

The critically ill patients admitted to the ICU often experience anxiety and pain. Pain is a major stressor for patients undergoing treatment in the ICU (Gelinas et al., 2011; Gelinas et al., 2014). The pain experienced by patients is varied and characteristically acute of moderate to severe level (Gelinas et al., 2014). A prior study showed that from nearly five millions of patients admitted to the ICUs annually, 71% of them experienced the pain during the treatment (Stites M, 2008).

The pain experienced by patients in the ICU is due to several reasons, such as the pathophysiological diseases and side effects of therapies and the procedures performed for the patients (Cade, 2008). These procedures include the medical and nursing procedures. The surgery, endotracheal installation and use of drain are some medical procedures causing the pain in the patients. Meanwhile, some nursing procedures such as positioning, suction of mucus from the trachea in the patients with mechanical ventilation, wound dressing, and installation or release of catheter also cause the pain (Alderson et al., 2013; Dunn & Murphy, 2009; Puntillo et al., 2004; Sutari et al., 2014).

The nursing procedures and medical actions which are improperly administered may cause the pain for patients undergoing treatment in the ICU. This pain can be minimized through the pain management so that the tolerance towards ventilator use and length of stay in the ICU can be enhanced (Alderson & McKechnie, 2013). The first step of the pain management in critically ill patients is to assess the pain accurately. In a study involving 1,144 patients in the ICUs, the pain assessment was administered to 513 patients, and no assessment was carried out in the remaining 631. The results revealed that patients with pain assessment showed a decrease in the use of ventilator (8 days vs. 11 days, p <0.01) and the length of stay at the ICU (13 days vs. 18 days, p <0.01) (Chanques et al., 2009; Kollef et al., 1998).

The assessment of pain in the critically ill patients is used as guidance in the clinical decision-making related to the pain management (Cade, 2008). Considering the pain management in the critically ill patients at the ICU, the nurses play a role as a caregiver that is to perform an effective pain assessment as an integral part of the nursing process (Poter & Perry, 2006). In addition, the nurses also play a role as an advocate for the accurate assessment by collaborating with doctors regarding analgesic medication administered to the patients according to their needs. A comprehensive approach is needed to assess the pain in the critically ill patients in the ICU who are unable to communicate verbally as seen in their behavioral indicators (Blenkharn A., 2002; Herr et al., 2006). An observation in the ICU showed that such expressions as a grimacing face, rigidity, closed eyes and clenched hands were the behavioral indicators of pain as indicated by the patients for pain assessment (Gelinas et al., 2014).

Some pain assessment instruments which are based on the behavioral indicators for the critically ill adult patients have been developed, such as the Pain Assessment Algorithm, Pain Assessment and Intervention Notation (PAIN), Nonverbal Adult Pain Scale (NVPS), Behavioral Pain Scale (BPS) and the Critical-care Pain Observational Tool (CPOT) (Payen et al., 2001; Young et al., 2006). Several studies related to the pain...
measurement tools showed that the CPOT has a higher score of validity and reliability than the Pain Assessment Algorithm, P.A.I.N, NVPS, and BPS (Tahka et al., 2009). This is also supported by the American Society for Pain Management Nursing (ASPMN) which recommended the use of CPOT as a valid and reliable instrument for assessing the pain in critically ill adults who were unable to verbally report their pain (Americas Association of Critical-Care Nurses, 2013).

Several hospitals in Semarang, Indonesia, have used the behavioral-based instruments for assessing the pain in the critically ill adult patients who are unable to communicate verbally. The comfort scale is an example of such instrument which has been used by two hospitals in Semarang. In particular, this instrument was developed by Ambuel et al. in 1992 and was used to assess the pain in critically child patients under the age of 18. This instrument had been tested for its validity and reliability for use in the adult patients. The results showed the value of 0.49 to 0.74 for its validity, and the Cronbach alpha of 0.60- 0.66 for its reliability (Ashkenazy & DeKeyser-Ganz, 2011). The Comfort Scale has never been tested for its sensitivity and specificity in the critically ill adult patients with ventilators. According to the American Association of Critical-Care Nurses (AACN), it was reported that 2 of the 8 items in the Comfort Scale (blood pressure and pulse) could not be used as the pain indicators with an evidence level of C (Americans Association of Critical-Care Nurses, 2013; Chanques, et al., 2009).

One of the hospitals in Semarang has used the Comfort Scale as a measure of the pain assessment for critically ill adult patients in the ICU who are unable to report their pain verbally. Based on the data in January 2016, it was reported that the total number of patients with ventilators in the last three months was 93. Some problems were reported regarding the use of the instrument, such as the length of time for its administration since two items in the instrument (blood pressure and pulse) are not appropriate for the patient’s clinical condition. Furthermore, the instrument has never been tested for its sensitivity and specificity for the critically ill adult patients with ventilators. For all those reasons, it is very necessary to examine the sensitivity and specificity of the Comfort Scale to assess the pain in critically ill adult patients with ventilators in the ICU.

PURPOSE
This study aimed to investigate the sensitivity and specificity of the Comfort Scale as an assessment the pain in critically ill adult patients with a ventilator in the ICU.

METHODS
The present study employed a non-experimental quantitative design with a cross-sectional approach. The non-probability sampling with a consecutive sampling technique was used. The samples were the critically ill adult patients admitted to the ICUs of two hospitals in Semarang. The inclusion criteria were the patients of age ≥ 18 years old, received mechanical ventilator of >24 hours to <72 hours, and had a decreased consciousness of GCS 7-10. Meanwhile, the exclusion criteria were the patients with paralysis of all limbs and with head trauma. In this study, 66 patients who met the criteria were recruited. The data were collected in three months by two observers (one researcher, one enumerator) who had been tested for the inter-observer
reliability with a Kappa value of 0.87. The face validity of the instrument used in this study was already tested. Before the face validity of the comfort scale instrument was tested, the English version of the comfort scale instrument was translated into the Indonesian language. The translation was done by referring to the WHO standards, where the process involved four experts: two experts in critical nursing, one Intensive Care (IC) consultant and one expert in the English Language. The instrument was back translated by the expert in English Language and was found to be not much different from its original instrument. Hence, the instrument was valid to collect the data.

The data collection was performed simultaneously by the observers before and after the positioning procedure for 30 minutes by using the Comfort Scale and CPOT measures. The first assessment was administered by measuring the pain baseline in the patients based on the indicators on each instrument. The second assessment was carried out after the positioning procedure by using the Comfort Scale and CPOT measures. The assessment was performed by observing the changes that existed in each item of the instruments. The Receiver Operating Curve (ROC) was employed to analyze the data.

RESULTS
The results showed that the majority of patients were of age 41-60 years old (39.4%), males (65.2%), received a medical diagnosis of respiratory disorder (45.5%) and did not receive the procedure of sedation (84.8%). The characteristics and demographic data of respondents were described in Table 1.

Table 1. Characteristics of respondents (n= 66)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-40 years old</td>
<td>15</td>
<td>22.7</td>
</tr>
<tr>
<td>41-60 years old</td>
<td>26</td>
<td>39.4</td>
</tr>
<tr>
<td>&gt;60 years old</td>
<td>25</td>
<td>37.9</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>43</td>
<td>65.2</td>
</tr>
<tr>
<td>Female</td>
<td>23</td>
<td>34.8</td>
</tr>
<tr>
<td>Medical diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory disorders</td>
<td>30</td>
<td>45.5</td>
</tr>
<tr>
<td>Neurological disorders</td>
<td>5</td>
<td>7.6</td>
</tr>
<tr>
<td>Gastrointestinal, haematological disorders</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td>Cardiovascular disorders</td>
<td>18</td>
<td>27.3</td>
</tr>
<tr>
<td>Kidney disorders</td>
<td>9</td>
<td>13.6</td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td>Sedation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non sedation</td>
<td>56</td>
<td>84.8</td>
</tr>
<tr>
<td>Sedation</td>
<td>10</td>
<td>15.2</td>
</tr>
</tbody>
</table>
Figure 1. Sensitivity and specificity of the instrument before the positioning procedure (n = 66)

Figure 1 is a ROC curve which depicts the sensitivity and specificity of the instrument. The intersection point of both lines resulted in a sensitivity value of 69% and a specificity value of 81%.

Figure 2. Sensitivity and specificity of the instrument after the positioning procedure (n= 66)

Figure 2 is also a ROC curve which indicates the sensitivity and specificity of the instrument. The point of intersection of both lines resulted in a sensitivity value of 45% and a specificity value of 67%.

Figure 3. Sensitivity and specificity of the instrument before the positioning procedure of non-sedating patients (n = 56)
Figure 3 is also a ROC curve which shows the sensitivity and specificity of the instrument. The point of intersection of both lines resulted in a sensitivity value of 66% and a specificity value of 82%.

![ROC Curve](image)

Figure 4. Sensitivity and specificity of the instrument after the positioning procedure of non-sedating patients (n = 56)

Figure 4 is another ROC curve which depicts the sensitivity and specificity of the instrument. The point of intersection of both lines resulted in a sensitivity value of 44% and a specificity value of 67%.

Table 2. Mean difference between the sensitivity value before and after the positioning procedure without the MAP and heart rate domains (n= 66).

<table>
<thead>
<tr>
<th>Sensitivity value</th>
<th>Positioning procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
</tr>
<tr>
<td>Sensitivity A</td>
<td>76%</td>
</tr>
<tr>
<td>Sensitivity B</td>
<td>69%</td>
</tr>
<tr>
<td>Δ Sensitivity value</td>
<td>7%</td>
</tr>
</tbody>
</table>

Table 2 shows the sensitivity value of A (without MAP and heart rate domains) and the sensitivity value of B (with MAP and heart rate domains). The mean difference of sensitivity when the MAP and heart rate domains were excluded increased by 7% before the positioning procedure, whereas after the positioning procedure, the sensitivity also increased by 13%.

**DISCUSSION**

The sensitivity and specificity of the Comfort Scale in this study after the positioning procedure showed the value of 45% and 67% consecutively. This is lower than that before the procedure, in which the value was 69% for sensitivity and 81% for specificity. A decreased value of sensitivity of an instrument describes that the ability of the instrument to detect the presence or absence of the pain is weak. A high value of sensitivity is necessary to identify the level of pain in a patient. The specificity value of the instrument was also decreased after the positioning procedure, but it was still in a tolerable range. The specificity value of a pain instrument indicates that the instrument...
can correctly identify the absence of pain within the patients. A pain instrument with high sensitivity value has good ability to detect the pain whereas an instrument with high specificity is interpreted indicates that the instrument can correctly identify the absence of pain within the patients. Pain assessment instruments should have a good sensitivity and specificity value which can be used to assess pain before or after the implementation of any procedures causing pain. High sensitivity and specificity values give implications for an appropriate pain management, as well as for administering analgesic doses. Pain instruments that have a high sensitivity value demonstrate a good ability to detect the pain, whereas instruments with a high specificity value have a good ability in detecting the absence of pain.

The sensitivity and specificity values of the Comfort Scale decreased after the positioning procedure. It could be caused by several factors such as the domain of physical movement, MAP, and heart rate. First, the physical movement is one of the indicators of the rating of the instrument. The domain is more appropriate to assess the pain in children than the adult patients (Holsti et al., 2010). The result of sensitivity and specificity tests in infants showed the high scores with AUC value of 0.95, a sensitivity value of 100% and a specificity value of 77% with a cut-off point of 20 (Wielenga et al., 2004). This is in line with a study by Holsti et al. (2010) which stated that the physical movement is an indicator which is related to the scale of pain in children. This study showed that the physical movement in children becomes more specific to assess the pain if the children are given a procedure that stimulates the pain. The procedure affects changes in the foot, knee, and hip regarding flexion and extension which affects the assessment of pain. The changes in physical movement indicate a distress in infants or children.

The present study showed different findings regarding the physical movement. The response of pain in the physical movement domain was different from that in the pediatric patients when measured before or after the positioning procedures. The physical movement item on the Comfort Scale is difficult to use as a response to pain in the adult patients. Normally in adult patients, the physical movement tends to localize the pain by such movements as pulling the tube and trying to sit up if given a stimulus that stimulates the pain. In fact, the physical movement domain in the Comfort Scale only describes the presence or absence of spontaneous movement, the movement of the extremities, and the strong movement in the head and pelvis. This is also congruent with a study by Gelines et al. (2009) which stated that the movement of the body in adult patients is indicated by touching the location of pain, trying to pull the endotracheal tube and agitation. Thus, the domain of physical movement in the instrument is not appropriate when used to assess the pain response in adult patients.

The domain of Mean Arterial Pressure (MAP) and heart rate can also play a role in decreasing the sensitivity and specificity values of the Comfort Scale. The results of the present study showed that there were no changes of values on the comfort scale instrument domains, namely the MAP and heart rate. The researchers had calculated the mean difference in the sensitivity values without including the MAP and heart rate domains. The result indicated an increased value before and after excluding the MAP and heart rate domains from the calculation. The mean difference of sensitivity
increased by 7% before the positioning procedure, and 13% after the positioning procedure (see figure 5). This suggests that the presence of MAP and heart rate domains could decrease the sensitivity value on the comfort scale. It is evident as by eliminating those domains, the sensitivity value was increasing. Some studies stated that there was a weak relationship between the vital sign assessment (MAP and heart rate) and the behavioral assessment towards the pain. It was characterized by the absence of changes in the value of MAP and heart rate, including the declining, increasing and even stable status, when the assessment was carried out before, during and after the positioning procedure. Therefore, both domains could not be used as an accurate indicator of pain (Americans Nurses Association of Critical-Care, 2013; Chanques et al., 2009; Gelinas et al., 2014). The MAP and heart rate in the assessment of pain cannot be used as the indicator of the changes in vital signs can be affected by some factors such as fear, anxiety, and psychological stress in the patients (Gelinas et al., 2014). Furthermore, studies on the validation of pain assessment instrument in the adult patients also mentioned that changes in vital signs were affected by the health conditions, medications, changes in hemostatic and anxiety (Gelinas et al., 2009; Herr et al., 2006).

Results of another study examining the pain in critically ill patients with sedation before and during the provision of pain procedures indicated that there was no relationship between the hemodynamic changes such as blood pressure and heart rate, and the pain with the r² value of <0.10 (Payen et al., 2001). Furthermore, in a study by Young et al. (2006), it was revealed that the hemodynamic change was not associated with the response to pain and was not a reliable indicator for assessing pain. This study is also supported by the clinical practice guidelines related to the management of pain, agitation and delirium which stated that the vital signs are not recommended as an indicator in the assessment of pain in adult patients in the ICU (Barr et al., 2013). Thus, it can be concluded that the MAP and heart rate are not appropriate to use as the indicators of pain assessment in adult patients.

The pain assessment instruments should have a good value of sensitivity and specificity when used to assess the pain before and after the procedure that causes the pain in the patients. The value of sensitivity and specificity has implications for the appropriate pain management, as well as the dosage of the analgesics. Nurses are part of a multidisciplinary team in the management of pain, and therefore, the knowledge and skills regarding the pain are required for the nurses to achieve an effective pain management. The roles of nurses in the pain management, among others, are providing information for patients and families, assessing the pain, administering and monitoring the side effects of analgesics, and documenting the pain. One of the principal keys to the effective pain management is the assessment of pain. The role of nurses in this stage is to comprehensively assess the pain of the patients who are able to report the pain verbally and non-verbally. The knowledge that the nurses should have includes the use of the pain assessment instrument and the theory and physiology of pain. Meanwhile, the skills that the nurses should acquire involves the ability to use a reliable pain assessment instrument and the ability to interpret the pain in patients who are unable to report verbally, as well as the ability to conduct a holistic pain assessment (Lellan, 2006).
Qualitative studies which examined the challenges of nurses in the management of pain in critical nursing also showed that nurses as decision-making personnel have an obligation and ethical responsibility in performing the pain management using the appropriate instruments (Morton & Fontaine., 2013; Subramanian et al., 2012). Nurses also play a role in deciding the appropriate pain management by collaboration with the physicians to provide the analgesics according to the prescribed dosage. Another study stated that there was a positive correlation between the education and the effectiveness of the pain management performed by the nurses. If the nurses obtained the training of pain management, they would be able to provide effective pain interventions for the patients comprehensively (Manias, Botti, & Bucknall, 2002). If the instruments used to assess the pain do not have the good value of sensitivity and specificity, the patient’s pain will not be properly handled. The pain assessment instruments, which are sensitive, are required to detect the presence of pain that affects the decreased duration of the use of ventilator and length of stay in the ICU (Payen et al., 2009).

The present study also assessed the pain in the sedating patients with a total number of 10 respondents. The researchers conducted a separate analysis of the 56 non-sedating respondents with a consideration that this group could cause a bias in the results. The results of the analysis showed that the sensitivity and specificity of the 56 non-sedating respondents were not much different from the value of the sensitivity and specificity of a total number of 66 respondents. A chi-square analysis was employed to the 66 respondents to examine the relationship between the sedation and the pain and obtained a p-value of >0.05. Therefore, it was concluded that there was no significant relationship between the sedation and pain. This could be due to the small number of the respondents (10 patients).

The comfort scale can also be used in patients with sedation and non-sedation by excluding the MAP and heart rate as the indicators of pain assessment in the adult patients. It is because the present findings found no hemodynamic changes in the patients with sedation. The value of reliability of the comfort scale in the adult patients (α = 0.6) (Ashkenazy & DeKeyser, 2011) was lower than its use in children (α = 0.9). In short, the comfort scale can be used to detect the pain in adult patients, but some indicators in the instrument need to be eliminated since they affect the value of the sensitivity.

CONCLUSION
The sensitivity and specificity values of the comfort scale decreased in the post positioning procedure but remained high in the pre-positioning procedure. In the pre-positioning procedure, the sensitivity and specificity values were 69% and 81% consecutively. Meanwhile, in the post-positioning procedure, the sensitivity and specificity values were 45% and 67%.

Based on the findings, the study recommends that the policy makers in the ICU should reconsider the use of the comfort scale to assess the pain in adult patients with ventilators. Planning to include nurses in the pain management training should also be considered to improve the knowledge of nurses in the use of appropriate pain assessment instruments for critically ill adult patients. Further studies which involve
more samples by carrying out a multicenter study in several hospitals in Semarang are required. In addition, a modification of the comfort scale with other pain assessment instruments is also necessary to develop a new pain assessment instrument for adult patients with a high value of sensitivity and specificity.

REFERENCES


