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**A PRELIMINARY VALIDATION OF THE PERSIAN VERSION OF THE CRITICAL-CARE PAIN OBSERVATION TOOL IN ADULT PATIENTS ADMITTED IN INTENSIVE CARE UNIT**

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**ABSTRACT**

Background: Pain has important physiologic and psychological effects that can change the outcome of the patients. It remains as a mystery in Intensive Care Unit admitted patients that are not able to communicate. Although different tools for assessment of pain were offered, a few of them are taken into consideration. Critical -care Pain Observational Tool seem to be more reliable, valid, and easy to use.

Methods: Patients observed for assessment of pain at three steps of rest, during, and 15 minutes post nociceptive and non-nociceptive procedures (overall 396 assessments). For each step, patients were evaluated by using the Critical-care Pain Observational Tool.

Result: A good total cronbach  $\alpha$  (0.86) for internal consistency and moderate to good internal consistency variable 0.39 - 0.85 for 6 measures of each patient was observed. We also found moderate to good Intraclass Correlation Coefficient variable 0.39 - 0.85 and good discriminant validity by peak Critical-care Pain Observational Tool scores during nociceptive procedures support verification of Persian version of Critical-care Pain Observational Tool.

Conclusion: Persian version of Critical-care Pain Observational Tool has the psychometric property similar to previous studies in most of its parts.

**Keywords: ICU, Noncommunicative, Pain assessment, Pain behavior, Reliability, Tool, , Validity**

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**INTRODUCTION**

Pain is one of the most common stressors in critically ill patients (1). The cause of pain can be due to surgery, trauma, intubation/mechanical ventilation, invasive procedures, and routine nursing care of patients (2). Poor assessment and management of pain have physical and psychological effects that can change outcomes of patients (3). Different studies have reported moderate to severe pain among the ICU admitted patients varying between 50-71% (4). Clinical researches show that pain in ICU is often under diagnosed, under assessed(5) and undertreated(1) and thus pain management is highly challenging in ICU(6). While pain management is a priority, its' assessment is the first step to provide appropriate patients care in ICU(2) and patient's self-report of pain intensity is the most valid assessment and is the gold standard(7).

There are two important barriers for appropriate assessment and treatment of pain in ICU patients. First, many of these patients are unable to communicate and second, there is no generally accepted assessment tool for this kind of patients.(8). The reason that many of patients in ICU are unable to communicate are cognitive, developmental and physiologic (7) due to

sedative medication, mechanical ventilation, and change in level of consciousness (2). When the patient is alert with intact cognitive functioning, even though she/he is intubated, we can use Numeric Pain Scale (NPS) or Visual Analog Scale (VAS)(1). When patients admitted in ICU are not able to self-report their pain intensity, comprehensive pain assessment and objective evaluation by observation of pain behavior indicators is the key of success.(4) Professional organization of American Association of Critical-Care Nurses, the American College of Chest Physicians, the Society for Critical Care Medicine and the American Society for Pain Management advocated for implementation of standardized pain assessment tools that include behavioral indicators in patients who cannot communicate (9). A variety of tools are available for assessing pain in ICU patients. Observing patient behavior is a common method of assessing pain (10). Although these indicators are used to detect the presence of pain and response to analgesia, these elements are not able to show the exact intensity of pain(1). Relying on changes in vital signs to predict pain may be misleading because they may be related to other factors(11).

To achieve patient safety and to avoid under-estimation or excessive use of analgesics we need validated and standardized tools that are easy to use, precise, accurate and sufficiently robust to assess pain (12,1). Critical-care Pain Observational Tool (CPOT) has been suggested by critical care experts in recent reviews and American Society of Pain Nursing Management (13). In this study, we tried to evaluate the Persian version of the CPOT in critically ill adult patients.

#### **MATERIAL AND METHOD:**

**study design;** This prospective observational study was designed to do a preliminary validation of the Persian version of the Critical-care Pain Observational Tool(CPOT) in adult ICU patients.

**Study setting;** The study was conducted over a 6 month period from January to June 2013 in Emergency, General and Central ICUs, 30-bed medical, surgical ICUs at 600-bed Nemazee University base teaching and referral facility hospital of Shiraz University of Medical Science. These 3 ICUs are staffed by 5 intensivists, 2 ICU fellowships, 12 anesthesiology residents, and 66 nurses and admit more than 1000 patients annually.

**Study sample;** A convenient sample of 66 ICU patients were enrolled in this study. Patients were considered for inclusion in the

study if 1) they were 18 years or older, 2) stay in ICU more than 24h, 3) had a definitive source of pain, and 4) were fluent in Persian. Patients were excluded if 1) they had noninvasive ventilation, 2) brain damage, 3) facial injury, 4) arm damage, 5) use of neuromuscular blocker, and 6) any disease that affect skeletal muscle or caused paralysis.

**Research Ethics;** The protocol of this study was approved by the Local Research Ethics Committee and University Institutional Review Board before beginning to educate investigators.[Ethical Committee Approval Number: CT-P-91-4808 , 18/11/2012]

Consent was obtained from patients, or if the patients were not able to give their own consent, the consent was obtained from the patient's next of kin (family member). The study was explained in detail to the patients or the decision maker.

**Study instrument;** to assess the presence of pain and its' intensity, we used the Persian version of CPOT (originally described by Gelinas et al) to assess pain in ICU patients. The CPOT is an observational rating scale of pain behavior that showed good psychometric qualities, is easy to use, and is well accepted by nurses. CPOT is a 4-item tool, each item with different behavioral category that scored from 0 to 2 for each

section and therefore the total scores ranges from 0 to 8. ( Appendix tables I,II )

In addition to the CPOT scores, systolic and diastolic blood pressures, mean arterial pressure, heart rate, and respiratory rate were measured with the monitoring equipment available in the ICUs. The patient sedation-agitation levels were assessed by Richmond Agitation Sedation Scale (RASS). The RASS scale, rates sedation level of patients on scale from -5 to 4.

study procedure; The study was organized in 4 steps; obtain permission from the pioneer of CPOT, get an appropriate translation of CPOT in Persian, educate the researcher team about CPOT, and start study and data gathering.

After written permission from Gelinas et al, we translated the original version of CPOT to Persian step by step by this instruction: preparing Persian translation of CPOT, correcting it and translating it to English again, reviewing, correcting, and writing the final version.

The first group consists of 3 ICU nurses independently translating the CPOT by using a dictionary of English to Persian. Then, these three translations were compared to each other. The second group consists of one physician and one ICU nurse that were fluent in English with no previous

knowledge about CPOT, translating the Persian version of CPOT to English again.

The first group compared this new English text to the original text of CPOT.

We also evaluated the Persian version of CPOT efficiency with think aloud protocol. 3 nurses learned to express their thought during use of CPOT and all this expressed has been recorded and evaluated to find out any difficulties that need to be resolved from the Persian version of CPOT. The last corrections were performed and the Persian version of CPOT was prepared for our study.

We had only one nurse volunteer at this time to take part in this study. The nurse was trained in two 2-hour sessions by the research team member to make sure she had enough knowledge and qualification to use CPOT practically. After this theoretical education, the next step was practical education and using CPOT by observing the patients and recording of data for 1 month. When she was completely able to use CPOT and able to have at least 95% agreement with research trainer, she was eligible to start study.

We started our study by observing the patients during Nociceptive Procedures (NP) and Non-Nociceptive Procedures (NNP) . In non-nociceptive process, the nurses cleaned

the face and hands of the patients by using a warmed wet towel. Nociceptive procedure was performed by turning the patients to change the sheets. The observation of the patients were done three times for each patient during these processes: at rest (NP1, NNP1), during the process (NP2, NNP2), and 15 minutes after the process (NP3, NNP3). The choice of 15 minutes was needed to eliminate stress hormones release during the process.

#### **DATA ANALYSIS**

Data were collected and analyzed by version 19.0 of SPSS statistical program.

Based on similar studies with correlation coefficient of  $r = 0.35$ ,  $\alpha = 0.05$ , and 80% power, the sample size required was 61 patients. We selected 66 patients and 6 pain assessments for each (non-nociceptive and nociceptive procedures), overall we used CPOT 396 times for pain assessment in our patients.

Descriptive data analysis were completed for all variables that we obtained, mean and SD for continuous variables, and frequency and percentage for categorical data. (Table 1) Our strategies to verify CPOT was psychometric properties of internal consistency, Intraclass Correlation Coefficient (ICC), criterion validity, and discriminant validity.

Internal consistency explains how much agreement is there between each item and total items in a questioner. We calculated correlation of each item with value of total items. We also calculated Cronbach  $\alpha$  for total items of questioner to show reliability of Persian version of CPOT.

Criterion validity explains how much correlation is there between each procedure and physiologic parameters and show them as  $r$  and  $p$ .

Intraclass reliability shows percent agreement in CPOT score when we have only one rater.

Discriminant validity shows if there is different in CPOT score during nociceptive and non-nociceptive procedures and was calculated by Paired-T Test and Wilcoxon Signed Rank Test.

#### **RESULTS**

##### **DESCRIPTIVE STATISTIC**

Demographic data of the patients based on quantitative and qualitative variable are presented in Tables 1. Most of patients were male, average age of more than 50 and under mechanical ventilation and intubated. All the patients were under infusion of analgesic and sedative medication based on our hospital standard.

According to RASS, more than half of our patients had score -1 to 1, almost 20% had score of less than -1 and 20% more than 1.

*Reliability:* As we had only one rater we calculated Cronbach  $\alpha$  for internal consistency and Intra Class Correlation (ICC) to show reliability. The Cronbach  $\alpha$  for internal consistency of CPOT was 0.86 and for each of procedures are shown in Table 2.

As can be seen in Table 2, the range of Cronbach  $\alpha$  varies from the lowest of 0.39 at NNP3 to highest of 0.85 at NP1, indicating a remarkable variation in the internal consistency of CPOT for assessment of pain. Also for internal consistency of CPOT items we assessed correlation between each item of CPOT (24 items = 3x4x2 of pre, during and post procedure of face, body, vocal, muscle in nociceptive and non-nociceptive procedure) with total Cronbach  $\alpha$  of CPOT. We calculated the highest ( $P < 0.001$ )  $r = 0.68$  related to muscle tone during nociceptive procedure and the lowest  $r = 0.30$  related to body movement after nociceptive procedure ( $P = 0.015$ ).

*Criterion validity:* As most of the patients were intubated and most of extubed patients were not able to communicate, we were not able to calculate criterion validity by comparing the CPOT score and self-

reporting pain score. We did it by comparing the COPT score during six assessments with physiologic parameters of HR, MAP and RR that can be seen in Table 3.

Our findings show that there was no correlation between physiologic indicators and each of 6 phase of CPOT assessment. All P values were greater than 0.05 and most of correlation coefficients are very low.

*Discriminant validity:* We assessed the discriminant validity of CPOT to see if there is any change in CPOT score during nociceptive and non-nociceptive procedure. Table 4 shows the means and standard deviation of CPOT score at each phase of CPOT assessment.

The most values of CPOT are during the nociceptive procedures and all scores of nociceptive procedure are greater than non-nociceptive procedure respectfully. We used Paired T-Test and Wilcoxon Singend Rank Test to show the difference between COPT scores during nociceptive and non-nociceptive procedure. The result for both tests had  $P < 0.001$  and showed a meaningful difference.

Table 5 shows that face is the most common item that reflected our patients' pain, and body movement and muscle tone are the next and vocal response has the lowest percent of use among the items. There was

no difference between use of CPOT items when we compared nociceptive with non-nociceptive procedure ( $p > 0.05$ )

Additional statistical analysis showed no meaningful difference between CPOT score at pre and post procedures (NNP1-NNP3, NP1-NP3) but a great meaningful difference were detected between pre vs during and during vs post procedures ( NNP1-NNP2, NNP2-NNP3, NP1-NP2, NP2-NP3 ) and for all of these P value was less than 0.001 . These differences demonstrate the specific designing of CPOT for pain assessment and also show how accurate this new tool of pain assessment can be used in Persian language.(Table 6)

## DISCUSSION

The present study verifies the Persian version of CPOT and according to our best knowledge is the first Persian version of pain assessment tool in ICU patients that we have ever had access to it in the literature. The verification of Persian version of the CPOT was done base on internal consistency for reliability and Intra Class Correlation (ICC), Criterion Validity, and Discriminant Validity. This study is consistent with some of the previous studies (14,15,16,17) and its results recommends the CPOT as an suitable behavioral pain assessment tool for critical patients admitted

in ICU that are not able to express their pain severity.

The total Cronbach  $\alpha$  for internal consistency of CPOT is 0.86 and for each six assessment (three painful and three non-painful) had the range of 0.39 for NNP3 and 0.85 for NP1(Table 3). This range shows a remarkable variation of CPOT internal consistency. The two lowest Cronbach  $\alpha$  are related to non-nociceptive (NNP) procedures and the two highest changes in Cronbach  $\alpha$  are after procedure(NNP3,NP3). These variations can be related to unsteady value of some items of CPOT in some specific conditions. Total Cronbach  $\alpha$  coefficient (0.86) is exactly compatible with some other studies, Nurnberg et al(17), 0.89 in Marmo et al(18), and 0.76 in Paulson-Conger et al(19).

Intraclass Correlation Coefficient (ICC) also demonstrates range of 0.39 - 0.85. Criterion validity of Persian version of the CPOT shows no correlation between CPOT scores and the physiologic parameters. This finding is inconsistent with some studies (17) in some points, but consistent with some other studies (20, 16). At this time, recommendations regarding physiologic indicators for assessing pain is limited to considering them as a cue for further assessment, because they are not sensitive

and absence of increased HR and BP does not indicate that there is no pain(20). While physiologic indicators can be affected by many factors other than pain, many factors can affect the behavior of the patients(20). However, attention to pain-related behaviors has received much more support than physiologic indicators(16).

Discriminant validity of Persian version of CPOT was supported by significant increase in CPOT score during nociceptive procedure(NP) comparing with non-nociceptive procedure(NNP) and also with comparing of NNP2-NNP1, NNP2-NNP3, NP2-NP1, NP2-NP3 (P value were <0.001 for all of these comparisons). There was no significant difference in CPOT scores comparing NNP3-NNP1 and NP3-NP1 with  $P= 0.1$ , that is supported by Gelinas et al(16). These findings are consistent and supported by many other studies (21,16,22,8,14,15,16,17). Payen et al (4) also showed a higher behavioral score during nociceptive procedure than at rest in unconscious patient by a scaling score similar to CPOT.

There is some controversy regarding discriminant validity and the consciousness level of the patients. Linde et al (14) showed that their patients had significantly higher scores during turning even though patients

received more analgesic and sedative medication before turning(  $P<0.001$ ). Topolovec-Vranic et al (15) showed that mean score during nociceptive procedure was significantly higher for non-communicative patients than communicative, but another study (21) showed higher scores in conscious patients. Vasquez et al (15) showed no difference between the scores of conscious and unconscious patients.

Although the type of the patient admission (medical or surgical) can affect the CPOT scores that patients obtain, significant changes in scores for nociceptive procedure are confirmed by all these studies. Additional findings in our study was regarding quality and quantity of CPOT domains that our patients used during our rater observation ( Table 5). These findings are compatible with findings of Gelinas et al(23) and Puntilo et al(10).

Similar to other studies, this study is not without limitations. Even though our patients consisted of a wide range of critically ill patients, we didn't have post cardiac surgery patients. The most important limitation of this study was the number of raters that was only one volunteer nurse. The second limitation was the absence of patients that were able to communicate and express their severity of pain as the gold

standard of pain scale. In order to reach more accurate findings we suggest more study with this version of CPOT, in more various medical conditions, more raters, in a multicentric design.

In conclusion, the Persian version of CPOT seems to have enough criteria as a tool for assessment of pain in patients who are not communicative, but at the same time it looks

that it is not a pure estimator of pain and may be in some part under influence of emotional and Psychological condition of patients. Further studies with more and different patients and in multicentric studies are needed to figure out which item(s) of CPOT are mixed and affected by other variables.

**Table 1: Patients characteristics (Quantitative and Qualitative variable)**

Variables	Mean or number(standard deviation or percentile)	
Age( year)	53.5(21.1)	
Weight( Kg)	73.1(10.6)	
Heart Rate	92.9(20.7)	
Systolic BP	129.5(20.5)	
Diastolic BP	75.9(13.9)	
MAP	90.4(16.3)	
APACHE	75.3(26.8)	
Respiratory Rate	19.5(6.5)	
ICU stay(day)	8.4(7.7)	
Gender	52(78.8%) Male	
Ventilator therapy	45(69.3%)	
Intubation	47(71.2%)	
RASS	-4	6(9.4%)
	-3	4(6.3%)
	-2	3(4.7%)
	-1	7(10.9%)
	0	17(26.6%)
	1	13(20.3%)
	2	10(15.6%)
	3	4(6.3%)

BP: Blood Pressure, MAP: Mean Arterial Pressure, RASS: Richmond Agitation Sedation Scale, APACHE: Acute Physiology and Chronic Health Evaluation, ICU: Intensive Care Unit

**Table 2: Cronbach  $\alpha$  and Intra Class Correlation(ICC) for 6 assessments of CPOT**

	ICC for 95% CI	Cronbach $\alpha$
NNP1	0.56( 0.37-0.71 )	0.57
NNP2	0.65( 0.49-0.77 )	0.68
NNP3	0.39( 0.10-0.60 )	0.39
NP1	0.85( 0.78-0.90 )	0.85
NP2	0.69( 0.45-0.80 )	0.72
NP3	0.58( 0.39-0.73 )	0.59

CPOT: Critical-care Pain Observational Tool, NNP: Non-Nonceptive Procedure, NP: Nonceptive Procedures,

**Table 3: Spearman's correlation for CPOT and physiological indicators**

	HR	MAP	RR
NNP1	P= 0.71 r= -0.05	P= 0.87 r= -0.02	P= 0.84 r= 0.03
NNP2	P= 0.79 r= -0.04	P= 0.81 r= -0.03	P= 0.08 r= -0.22
NNP3	P= 0.32 r= -0.13	P= 0.31 r= -0.14	P= 0.39 r= 0.11
NP1	P= 0.65 r= -0.06	P= 0.73 r= 0.05	P= 0.62 r= 0.06
NP2	P= 0.59 r= 0.07	P= 0.91 r= 0.02	P= 0.57 r= 0.07
NP3	P= 0.68 r= 0.05	P= 0.51 r= 0.09	P= 0.46 r= 0.09

CPOT: Critical-care Pain Observational Tool, HR: Heart Rate, MAP: Mean Arterial Pressure, RR: Respiratory Rate, NNP: Non-Nociceptive Procedure, NP: Nociceptive Procedure

**Table 4: Means and Standard Deviation of the CPOT and physiologic indicators at each phase of CPOT assessment.**

	NNP1	NNP2	NNP3	NP1	NP2	NP3
CPOT	0.37(0.76)	1.20(1.38)*	0.23(0.55)	0.79(1.47)	3.85(1.96)*	0.73(1.03)

CPOT: Critical-care Pain Observational Tool, NNP: Non-Nociceptive Procedure, NP: Nociceptive Procedure

**Table 5: Mean and Standard Deviation of CPOT items at each phase**

	Face pain	Face nonpain	Body pain	Body nonpain	Vocal pain	Vocal nonpain	Muscle pain	Muscle nonpain
% of Pts who used this item	93.90	42.40	74.20	30.30	65.20	12.10	74.20	30.30
Mean	1.74	0.67	1.23	0.41	1.00	0.15	1.39	0.55
SD	1.04	0.95	1.00	0.70	1.04	0.51	1.32	1.00

SD: Standard Deviation, CPOT: Critical-care Observational Tool

**Table 6: Comparison of all steps of CPOT**

Procedures	NP-NNP	NNP1 vs NNP2	NNP2 vs NNP3	NNP1 vs NNP3	NP1 vs NP2	NP2 vs NP3	NP1 vs NP3
P value	< 0.001	< 0.001	< 0.001	0.10	< 0.001	< 0.001	0.10

CPOT: Critical-care Pain Observational Tool, NNP: Non-Nociceptive Procedure, NP: Nociceptive Procedure

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