MemorialCare Health System
Excellence in Health Care

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- The Speaker has No Disclosures or Conflict of Interest related to this educational topic.

Objectives

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At the completion of this session, the participants will be able to:

1. Understand the clinical elements of the utility of the CPOT tool in assessing non-verbal ICU patients.
2. Discuss the feasibility and interrater reliability when comparing the CPOT to PAINAD tools
3. Identify gaps in implementation of the CPOT in various ICU setting.
4. Identify future areas for research related to pain assessment among critically ill patients.

Background: Pain in the ICU

- A patient's self-report of pain – gold standard (American Society Pain Management Nursing - ASPMN/ American Association of Critical Care Nurses -AACN)
- Many patients in ICU, are nonverbal, unable to self report pain. E.g., altered level of consciousness, aphasia, receiving sedation or analgesia, or placed on a mechanical ventilator.
- **Pain assessment in these patients poses a challenge – many may not have good pain control.**

Background: Pain in the ICU

Definitions
Scope of the problem
Barriers
Consequences
Assessment tools
Approach

American Society Pain Management Nursing

- Unpleasant sensory and emotional experience associated with actual or potential tissue damage
- Can only be reported by the person experiencing it

Background: Pain in the ICU

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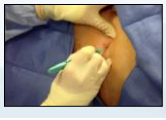
SCCM

- 50% (or more) of ICU patients
- Many types of pain
  - Rest pain
  - Surgical/trauma/cancer pain
  - Procedural pain

Society of Critical Care Medicine
The Intensive Care Professionals



Background: Pain in the ICU

Definitions
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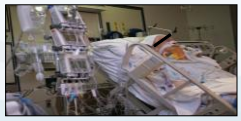
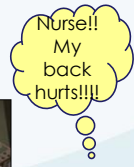
Impediments to pain reporting

- Unable to self report pain
- Altered level of consciousness
- Mechanical ventilation
- Sedation





Background: Pain in the ICU

Definitions
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Consequences of unrelieved pain

- Inefficient sleep [1]
- Memories
  - Pain of ETT [1]
  - Most recount moderate to severe pain
  - Persist up to 6 months

1. Gelinas, C. Crit Care Nurs, 2007; 23:298-303

Background: Pain in the ICU

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The Ideal Pain Assessment

- Reproducible across disciplines
- Enables monitoring over time
- Assesses adequacy of interventions
- Easily implemented and monitored

Background: Pain in the ICU

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Pain Scales

- Most valid and reliable
  - Behavioural Pain Scale
  - Critical-care Pain Observation Tool
- Useful for all; except brain injury
- Designed for the following
  - Unable to self-report
  - Intact motor function
  - Observable behaviours
- **Further research was needed to validate CPOT**

STUDY PURPOSE/AIMS

Purpose:

- **To compare the Pain Assessment in Advanced Dementia (PAINAD) (standard care) Tool vs the Critical-Care Pain Observation Tool (CPOT) scores for assessment in nonverbal ICU patients.**

Primary Aim/Hypotheses

1. **Examine the comparative efficacy of the use of CPOT vs. PAINAD screening tools, as measured by improved pain assessment frequency and quality.**
   1a. Hypothesis: The CPOT provides more accurate pain assessment for the nonverbal critically ill patient.

Secondary Aim

- **Examine the nurse's perception of the use of the CPOT in their clinical practice (Feasibility and Clinical Utility of CPOT Questionnaire) (2-Items -Likert scale 0-4), Online via survey monkey**

Orem's Self-Care Model Provided Framework for the Study

Figure 1. Orem's Model and Nursing Process, adapted from http://grandtheoryroyandorem.weebly.com[3]

Methods

- A prospective, descriptive, comparative design guided this study.
- A convenience sample of **(N=65)** ICU/CCU non-verbal, adult patients of varying medical diagnoses, requiring pain evaluation, were included.

STUDY CLINICAL OUTCOMES
- ❑ Improved pain assessments & reassessments
- ❑ Increased appropriate pain management

Secondary Outcomes * Decreased LOS and * Mortality

- **Repeated measures were used to examine behavioral responses, using within-subjects and crossover techniques.**

First Testing Period			Second Testing Period			Third Testing Period		
T1	T2	T3	T4	T5	T6	T7	T8	T9
R	P/PR	REC	R	P/PR	REC	R	P/PR	REC

Abbreviations: R, rest (1 minute), P, repositioning/turning; PR, procedure (suctioning, insertion of vascular access device or tube); REC, recovery (20 minutes after position change or suctioning or vascular access device or tube insertion).

PATIENT FLOW THROUGH STUDY

Eligible for Consent (screen daily)
Screen & enroll within 48 hours of ICU/CCU Admission

Inclusion Criteria
- Age 18 years and older
- Enrolled within 48 hours after admission
- Sedation level of less than -2 on Richmond Agitation Sedation Scale [RASS]**
- Unable to self- report a pain score using a numeric pain scale
  Unable to self- report using a Visual Analog scale or nonverbal indicators such as finger pointing or being able to indicate one for yes two for no, nodding or blinking of eyes.

Exclusion Criteria
- Awake, alert and can self-report verbally
- Receiving neuromuscular blocking agents
- Spinal cord injured patients with paralysis
- Brain injured patients with intracranial pressure monitoring (ICP) or sedation to decrease ICP
- Unstable hemodynamics that precludes turning in bed.
- Dialysis patients undergoing acute dialysis treatment during ICU.
- Undergoing comfort care & are actively dying.

Investigational Procedures

1. On a daily basis, the study team will screen all newly admitted patients for enrollment in the study.
2. Verbal consent will be obtained and a copy to patient/surrogate. An enrollment study note is made in Epic per good clinical practices (GCPS). All subjects will be assigned a study ID No.
3. Demographic data will be collected at this time and recorded on the investigator developed demographic log.

First Testing Period			Second Testing Period			Third Testing Period		
T1	T2	T3	T4	T5	T6	T7	T8	T9
R	P/PR	REC	R	P/PR	REC	R	P/PR	REC

Abbreviations: R, rest (1 minute); P, repositioning/turning; PR, procedure (suctioning, insertion of vascular access device or tube); REC, recovery (20 minutes after position change or suctioning or vascular access device or tube insertion).

CLINICAL OUTCOMES
1. **Improved pain assessments & reassessments**
2. **Increased appropriate pain management**
3. **Secondary Outcomes**
4. **Decreased length of stay**
5. **Decreased mortality**

Figure 1. Modified CONSORT diagram of patient flow through the study

Patient Instrument(s): PAIN IN ADVANCED DEMENTIA (PAINAD)

- **PAINAD looks at Five behaviors (Breathing; Facial Expression; Verbalization/Vocalization' Body Language; Consolability;**
- Used in advanced dementia patients that cannot verbally communicate levels of pain. Found to be valid and reliable in LTC and in other hospitalized patients

Pain Assessment in Advanced Dementia (PAINAD) Scale

Items*	0	1	2	Score
Breathing independent of vocalization	Normal	Occasional labored breathing. Short period of hyperventilation.	Noisy labored breathing. Long period of hyperventilation. Cheyne-Stokes respirations.	
Negative vocalization	None	Occasional moan or groan. Low-level speech with a negative or disapproving quality.	Repeated troubled calling out. Loud moaning or groaning. Crying.	
Facial expression	Smiling or inexpressive	Sad. Frightened. Frown.	Facial grimacing.	
Body language	Relaxed	Tense. Distressed pacing. Fidgeting.	Rigid. Fists clenched. Knees pulled up. Pulling or pushing away. Striking out.	
Consolability	No need to console	Distracted or reassured by voice or touch.	Unable to console, distract or reassure.	
			Total**	

Standard of Care

Total scores range from 0 to 10 (based on a scale of 0 to 2 for five items), with a higher score indicating more severe pain. **(0="no pain" to 10="severe pain").

Pain Assessment
Critical Care Pain Observation Tool* (CPOT)

Based on Four domains (Range 0-8, cutoff >3 is significant)
Facial expressions, body movements, muscle tension, compliance with ventilation for intubated patients and vocalization for extubated patients.

The Critical Care Pain Observation Tool

Indicator	Description	Score	
Facial expression	No muscular tension observed Presence of frowning, brow lowering, orbit tightening, and levator contraction All of the above facial movements plus eyelid tightly closed	Relaxed, neutral Tense Grimacing	0 1 2
Body movements	Does not move at all (does not necessarily mean absence of pain) Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements Pulling tube, attempting to sit up, moving limby/ thrashing, not following commands, striking at staff, trying to climb out of bed	Absence of movements Protection Restlessness	0 1 2
Muscle tension Evaluation by passive flexion and extension of upper extremities	No resistance to passive movements Resistance to passive movements Strong resistance to passive movements, inability to complete them	Relaxed Tense, rigid Very tense or rigid	0 1 2
Compliance with the ventilator (intubated patients) OR Vocalization (extubated patients)	Alarms not activated, easy ventilation Alarms stop spontaneously Asynchrony: blocking ventilation, alarms frequently activated Talking in normal tone or no sound Sighing, moaning Crying out, sobbing	Tolerating ventilator or movement Coughing but tolerating Fighting ventilator Talking in normal tone or no sound Sighing, moaning Crying out, sobbing	0 1 2 0 1 2
Total, range			0-8

RESULTS:
Table 1. Study Characteristics

Mean (SD) or N (valid %)	N=65 (all patients)
Age, years mean (SD)	71.3
Gender:	
Male	**40 (61.5%)**
Female	25 (38.5%)
Family:	
Married	6 (9.4%)
Single	18 (28.1%)
Widowed	**23 (35.9%)**
Divorced	16 (25.0%)
Race:	
White/Caucasian	**31 (47.7%)**
African American	12 (18.5%)
Latin/Hispanic	12 (18.5%)
Asian/Pacific Islander	6 (9.2%)
Native American	4 (6.2%)
Mortality	24 (36.9%)
Hospital (LOS), mean (SD)	18.0 (12.9)
ICU (LOS), mean (SD)	9.1 (7.7)
Average pain score across 9 time points:	
PAINAD	1.2 (1.0)
CPOT	1.2 (0.9)

Table 1. Study Characteristics cont…

Co-Morbidities	N (%)
Hematological	**23 (35.4%)**
Immunological	**5 (7.7%)**
Cardiac (HTN, AMI, HF)	**49 (75.4%)**
Gastrointestinal	**18 (27.7%)**
Shock	**13 (20.0%)**
Diabetes	**26 (40.0%)**
CVA	**23 (35.4%)**
Liver Failure	**9 (13.8%)**
Respiratory Failure	**34 (52.3%)**
Trauma	**6 (9.2%)**
MODS	**2 (3.1%)**
Cardiac Arrest	**6 (9.2%)**
Spinal Cord Injury	**2 (3.1%)**
UTI	**5 (7.7%)**
Neurological	**16 (24.6%)**
Infection/Sepsis	**24 (36.9%)**
Pneumonia	**18 (27.7%)**
Chronic Kidney Disease	**21 (32.3%)**
Cancer	**6 (9.2%)**

Inter-Rater Reliability of CPOT VS PAINAD

Table 2. Assessment of number (N) of patients with values on both scales at each time point, distributional differences in average scores across time points within each tool, reliability of CPOT (interchangeability with PAINAD) by calculation of percent agreement and weighted kappa.

Study	PAINAD	CPOT	# Scale Levels Represented in Data	% Agree Unweighted	Weighted Kappa[b] (SE)	p-value	Landis-Koch Interpretation of weighted kappa coefficient	
	N	Median (IQR)	Median (IQR)				Threshold [c]	Direct [d]
T1	59	0 (0-0.5)	0 (0-1)	6	71.1%	0.80 (0.09)	P<.001	Substantial	Almost Perfect
T2	59	2 (0-5)	3 (0-5)	10	28.8%	0.67 (0.09)	P<.001	Moderate	Substantial
T3	59	0 (0-0)	0 (0-0)	5	76.3%	0.56 (0.16)	P<.001	Moderate	Moderate
T4	34	0 (0-0)	0 (0-0)	4	82.4%	0.67 (0.16)	P<.001	Moderate	Substantial
T5	34	1 (0-3)	2 (0-3)	9	38.2%	0.62 (0.16)	P<.001	Moderate	Substantial
T6	32	0 (0-0.5)	0 (0-0)	4	62.5%	0.43 (0.18)	P=.027	Fair	Moderate
T7	19	0 (0-0)	0 (0-0)	3	89.5%	0.52 (0.38)	P=.018	Slight	Moderate
T8	19	2 (0.5-3.0)	3 (1.5-3.5)	7	47.4%	0.69 (0.10)	P<.001	Substantial	Substantial
T9	18	0 (0-0)	0 (0-0)	5	83.3%	0.29 (0.25)	P=.025	Slight	Fair
Test of difference across time points [a]	P<.001	P<.001						

Table 3. Bland-Altman analyses assessed statistical significance of difference between the two measurement tools and whether proportional bias present PAINAD and CPOT (Study nurse data).

	Both Tools	Test of difference between scores on two tools at each time point		Test of proportional bias [c]	
Study	N	Mean difference (SD) [a]	P-value [b]	β	P-value [c]
T1	59	-0.07 (0.76)	P=.497	β = -0.093	P=.303
T2	59	0.07 (1.95)	P=.790	β = 0.103	P=.406
T3	59	-0.05 (0.64)	P=.635	β = -0.231	P=.090
T4	34	0.06 (0.42)	P=0.42	β = 0.294	P=.039 *
T5	34	-0.41 (1.86)	P=0.21	β = 0.040	P=.802
T6	32	-0.09 (0.14)	P=0.52	β = -0.347	P=.097
T7	19	0.05 (0.52)	P=0.67	β = 0.286	P=.253
T8	19	-0.47 (1.35)	P=0.14	β = 0.131	P=.523
T9	18	-0.28 (1.07)	P=0.29	β = -0.930	P=.002 *

[a] PAINAD-CPOT scores
[b] P-value based on one sample t-test run to test the null hypothesis of zero difference between tools.
[c] P-value based on linear regression with difference score as dependent variable and average score on two tools the predictor. Testing the null hypothesis of no proportional bias (β=0).

STUDY SECONDARY AIM

- **Critical Care Nurses Response to the 'Feasibility and Clinical Utility of the Critical-Care Pain Observation Tool (CPOT) Questionnaire**
- **Sample N = 19/75 (25% response rate)**

Gelinas also reported on the Registered Nurses Evaluation of the feasibility and the clinical utility of the CPOT. If RN's don't feel the tool is useful will they not incorporate it into their practice.

RN Demographics: Feasibility and Clinical Utility of the CPOT Questionnaire.

- N=19 nurses completed the CPOT Questionnaire.
  - (72.5%) were aged between 26–65 years old.
- The majority of subjects (83.3%) were female, and more than half (58.8%) were married.
- > Half of the nurses had < than five years of experience.
- Educational Level:
  - (67%) BSN
  - (30%) MSN
  - (2%) ADN.
- Position in ICU
  - (84.8%) Staff Nurse
  - (11%) Assistant nurse manager
  - (3%) Clinical educator
  - (3%) Clinical nurse specialist
- Have Received Education in Pain
  - (100%)

Table 4. Nurses' Responses to the Questionnaire About the Feasibility and Clinical Utility of the Critical-Care Pain Observation Tool (CPOT)

	Frequency (n)				
	1	2	3	4	
Question	Not At All	A Little	Sufficiently	Very	% Frequency
1. Was the length of time sufficient to train to use the CPOT accurately?	0	5	8	6	31%
2. Were the directives about the use of the CPOT clear?	0	4	8	7	36.84%
3. Is the CPOT quick to use?	0	5	6	8	47.37%
4. Is the CPOT simple to understand?	1	3	6	9	47.37%
5. Is the CPOT easy to complete?	0	1	9	9	47.3%
6. Would you recommend to use the CPOT routinely?	0	5	5	9	47%
7. Is the CPOT helpful for nursing practice?	0	4	7	8	42%
8. Has the CPOT influenced your practice in assessing the patient's pain?*	6	2	3	8	40%

Discussion

- Over 47% of the nurse participants found the CPOT to be easy to use and relevant for clinical practice. Only 5% of the nurses criticized the CPOT as long or complex to use, compared with 74% of the nurses felt the CPOT was easy and they would recommend the CPOT use routinely, particularly compared to the PAINAD tool currently in use.
- 31% of the nurses felt the education was inadequate, thus an opportunity exists to improve our education and use of the CPOT tool for all nurses staff. Others report that the CPOT should include operational definitions.
- Criticisms of the nurse participants of the CPOT need to be addressed.
  - "Some indicators of the CPOT, such as body movements, may lack specificity to pain. A score of 0 is attributed when the patient is not moving or immobile." Yet, the absence of movements may not necessarily mean an absence of pain. According to Puntillo et al, 1997), nurses have identified the absence of movements as an indicator of the presence of pain in ICU patients.
- Furthermore, some nurses reported also that unconscious patients are also more likely to exhibit fewer pain behaviors compared with conscious patients (Gélinas & Arbour, 2015; Gélinas & Johnston, 2007).

Discussion

- **Statistically the CPOT Tool was highly significant in accurate pain assessment, and had high Inter-rater Reliability (Kappa >70%) compared to PAINAD.**

future research

- Further research is warranted in this field to establish the specificity of behavioral parameters as a pain response in ICU patients. Meanwhile, the CPOT should be used in nonverbal patients who have intact motor function so that they can respond to the tool's requisite behaviors.
- **Further studies with other painful procedures should be continued to be tested with the CPOT. (i.e. mediastinal chest tube removal MTR).** (14)

Limitations of Study

- Sample size was small and the participation rate was moderate. The majority of the Time-1 assessments were completed, however, Timed-2 and Time-3 assessments fell drastically, most likely to patient awakening; reversal of sedation, or patient improvement, and discharge from unit.
- Gap in education and practice with CPOT was noted. They may not have felt that they had enough exposure to the CPOT to evaluate its clinical characteristics.
- Second, nurse participants were provided only with paper documents for the CPOT training. Many nurses did not take advantage of the training patients' videotapes.
- CPOT was used for research purposes in this study, so that nurse participants used it for enrolled patients only. Of note, the range of patients evaluated by the nurse participants varied from one to four patients per nurse.

Conclusions

- To date, the CPOT has demonstrated acceptable results of reliability and validity in both conscious and unconscious ICU adults. Its feasibility and clinical utility have also been positively evaluated by ICU nurses who used it for the purpose of research. The use of a valid behavioral pain scale is recommended in clinical guidelines for pain assessment in nonverbal patients (Herr et al., 2006), and the CPOT is suggested by many experts in critical reviews (Li et al., 2008; Sessler et al., 2008).
- **At MemorialCare Health System – Study findings were presented at executive level (nurses/MDs) to our entire health system, and there was enthusiastic support and adoption for using the CPOT tool, and integrating this into our EMR.**
- Even if further research is warranted to improve the specificity of some indicators of the CPOT and to evaluate its feasibility and clinical utility in routine care, the CPOT appears to support ICU nurses in the assessment of their patients' pain and could contribute to better pain control in the critically ill adult.

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