The effects of the Critical-Care Pain Observation Tool on pain assessment/management nursing practices in an intensive care unit with brain-injured critically ill patients

Gli effetti della scala Critical-Care Pain Observation Tool nella valutazione e gestione del dolore nei pazienti con lesioni cerebrali ricoverati in terapia intensiva

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ABSTRACT

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Acknowledgement:

The authors received no financial support for this study. The authors gratefully acknowledge the support of the medical staff, the nursing staff, and the Charge Nurse of the Anaesthesiology and Critical Care Service of Lecco Hospital (formerly A. Manzoni Hospital). **INTRODUCTION.** Accurate pain assessment and management in critically ill patients with cognitive alterations who are unable to communicate constitute a major challenge for the medical and nursing staff of Intensive Care Units (ICUs). This study want assess the impact of Critical Care Pain Observation Tool (CCPOT) scale in ICU practice and evaluate the effects on pain assessment and management in brain-injured critically ill adult patients.

METHODS. This before-and-after study was carried out in an Italian ICU, where data were collected before (T0) and after (T1) implementation of the CCPOT in brain-injured critically ill adults.

RESULTS. The study population consisted of 81 patients (35 before and 46 after intervention). The use of propofol fell significantly (propofol: t(80) = 1.83, p =.03) and at the same time the use of morphine increase significantly (morphine: t(80) = 1.51, p =.02) after intervention. Analysis of the data with respect to pain relief and prevention during some nursing care activities revealed a significant increase in the use of fentanyl citrate (x2(1)= 4.04, p =.04) and paracetamol (x2(1)= 5.30, p =.02). Pain management was in line with the protocol, which envisaged administration of pain medications to patients with CCPOT scores > 3 in 76.8% of cases.

CONCLUSION. The present findings strongly support the value of the CCPOT scale in managing ICU patient pain in conjunction with medical and nursing staff training. However, further studies of larger patient samples should be performed.

KEY WORDS: Intensive care, pain, assessment, pain management

RIASSUNTO

INTRODUZIONE. Una valutazione e gestione accurata del dolore nei pazienti in condizioni critiche con alterazioni cognitive non in grado di comunicare, costituiscono una grande sfida per il personale medico e infermieristico delle Terapie Intensive (TI). Questo studio vuole valutare l'impatto della scala CCPOT in TI, valutandone gli effetti sulla valutazione e gestione del dolore nei pazienti adulti con lesioni cerebrali.

METODI. Questo studio before-after è stato condotto in una terapia intensiva italiana, in cui i dati sono stati raccolti prima (T0) e dopo (T1) l'implementazione dello strumento.

RISULTATI. La popolazione di studio era composta da 81 pazienti (35 prima e 46 dopo l'intervento). L'uso di propofol è diminuito in modo significativo (propofol: t(80) = 1.83, p = .03) e allo stesso tempo, l'uso della morfina è aumentata in modo significativo (morfina: t(80) = 1,51, p = .02) dopo il nostro intervento. L'analisi dei dati relativi al sollievo dal dolore e alla prevenzione durante alcune attività di assistenza infermieristica ha rivelato un aumento significativo dell'uso di fentanil citrato (x2(1) = 4.04, p = .04) e paracetamolo (x2(1) = 5.30, p = .02). La gestione del dolore era in linea con il protocollo, che prevedeva la somministrazione di antidolorifici a pazienti con punteggi CCPOT > 3 nel 76.8% dei casi.

CONCLUSIONE. I risultati supportano fortemente il valore della scala CCPOT nella gestione del dolore dei pazienti in terapia intensiva unitamente alla formazione del personale medico e infermieristico. Tuttavia, devono essere eseguiti ulteriori studi su campioni di pazienti di dimensioni maggiori.

PAROLE CHIAVE: Terapia intensiva, dolore, valutazione, gestione del dolore

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INTRODUCTION

Accurate pain assessment and management in critically ill patients with cognitive alterations who are unable to communicate constitute a major challenge for the medical and nursing staff of ICUs (Damico et al., 2018).

In 85% of cases, intensive care unit (ICU) patients are administered sedatives to relieve pain, anxiety, and the agitation resulting from mechanical ventilation (Bambi et al., 2015). Oversedation may be the result of inappropriate or careless pain management, whereas undersedation involves the risks of self-extubation, cardiovascular problems, and physical injury (Jarzyna et al., 2011; Bambi et al., 2015). Sedation levels should match patient characteristics and their disease state (Jarzyna et al., 2011; Johansson et al., 2012).

Evidence has shown that brain-injured patients in the neurological intensive care unit (NICU), such as postcraniotomy patients, experience a higher than expected incidence of moderate or intense pain (Echegaray-Benites et al., 2014). Validated scales are strongly recommended to determine whether patients whose clinical condition prevents them from reporting their suffering, feel pain (Barr et al., 2013).

The Critical-Care Pain Observation Tool (CCPOT) is currently considered one of the best scales, both for psychometric properties and clinical feasibility (Gélinas et al., 2011). In 2006, the American pain management nursing association recommended the CPOT for evaluating pain in tracheal intubated and unconscious patients (Kerr et al., 2006; Gélinas et al., 2011). The CCPOT was also validated for pain assessment in brain surgery patients. Validation of the Italian version of the Critical Pain Observation Tool in brain-injured critically ill adults was done in 2017 by Sulla and colleagues (Sulla et al., 2017).

Before this study, the common practice in our ICU was informal observational assessment of non-communicative patients, which was inconsistent with international guidelines. Therefore, we decided to implement the CCPOT in our routine ICU practice and evaluate the effects on pain assessment and management in brain-injured critically ill adult patients.

METHODS

Design

This before-and-after study was carried out in an Italian ICU, where data were collected before (T0) and after (T1) implementation of the Critical Care Pain Observation Tool in brain-injured critically ill adults. The study protocol was in line with the Declaration of Helsinki, as revised in 2013, and was

approved by the institutional ethics committee (No. 621 of 2018). All participants provided their

informed written consent to participate during their ICU stay or at the time of discharge. Consent was obtained from patients and/or caregiver before study recruitment, by the nursing staff. If patients were unable to give it because of sedation or intubation or for a cognitive impairment, the request was passed on to their relatives (spouse, offspring).

Setting

The study was conducted in an Italian adult 10-bed ICU in a 950 bed secondary hospital. Common conditions that are treated within ICU include acute respiratory distress syndrome (ARDS), post-operative surgical, neurosurgical, trauma, multiple organ failure and sepsis. The unit is comprised of dedicated full-time staffs (physicians and nurses) trained in adult multidisciplinary critical care medicine; 30 nurses and 16 medical anesthetists work fulltime in the department, (5 nurses on each shift, 2 medical anesthetists morning-afternoon and 1 on night shift).

Sample

All brain-injured critically ill adult patients with impaired consciousness aged at least18 years, who were admitted to Lecco Hospital ICU from 1 June 2019 to 15 June 2020 and were unable to communicate, were eligible to be included in the study. Patients with curarization or quadriplegia (any cause) and those who were alert and oriented and did not require sedation, and were thus capable of reporting the level of the pain they experienced using the common scales, were excluded.

Intervention

The nursing guidelines folders and ICU flow charts were redesigned to incorporate the CCPOT, and a pain assessment of brain-injured critically ill adults in ICU guideline document was uploaded to the hospital intranet, establishing the CCPOT as the standard pain assessment tool for non-communicative ICU patients. These were made available immediately before the implementation phase.

Introduction of the CCPOT scale in ICU nursing practice was supported by a pain management protocol, approved by Comitato Ospedale Senza Dolore (Committee Against Hospital Pain), that involved (Damico et al., 2018) pain assessment with the CCPOT scale, which rates observed patient behavior, and (Bambi et al., 2015) administration of pain medications to patients whose CCPOT score was > 3 (moderate pain). The adoption of the CCPOT scale was prompted by the numerous validation studies found in the literature. Before implementation of the therapeutic intervention, there was no protocol envisaging the assessment and rapid management of the pain in brain-injured critically ill adult patients by the nursing staff. Nurses always asked the physician before administering an analgesic, which significantly delayed the intervention and prolonged suffering. After CCPOT implementation, a prescription by the medical staff authorized the administration of analgesics "to patients whose CCPOT score was > 3 or PRN (as needed)," such as in the case of painful procedures. This reduced the delay in analgesic administration and increased the autonomy of the nursing staff.

Support for the CCPOT implementation nurses received a 120-minute standardized training that included

To establish whether the intervention was delivered in line with the protocol, two nurses who had received specific training reviewed the patients' charts at daily or weekly intervals to check how many times pain was assessed, whether it was managed according to the protocol, and how many times a CCPOT score was > 3 followed by the administration of pain medications.

Outcome Measures

The primary outcome of this study was the observed difference in proportions on which analgesic drugs were given, and quantities of analgesics administered.

Secondary outcome measures were the number of pain assessments made, and a comparison of the sedation and analgesia administered before and after adoption of the CCPOT based on the amounts of morphine, remifentanil, propofol, midazolam, ropivacaine, fentanyl citrate, nonsteroidal anti-inflammatory drugs (NSAIDs), and paracetamol administered. A greater use of sedation (e.g., propofol, midazolam) rather than analgesia (e.g., morphine, NSAIDs, paracetamol) post-CCPOT would have reflected inappropriate pain management.

 Table 1. Demographic and clinical characteristics of 81 patients included in the study.

	Group Before (n= 35)	Group After (n= 46)	p-value
Age, mean (+) y	54.9 (12.3)	52.3 (14.6)	.83
Gender, n (%)			
Male	15 (42.9)	21 (45.6)	.80
Female	20 (57.1)	25 (54.4)	
Weight, mean (+), kg	73.49 (9.9)	71.9 (8.2)	.42
BMI, mean (+)	26.5 (2.1)	26.2 (1.1)	.16
APACHE II, mean (+)	12.5 (1.6)	12.9 (1.2)	.39
Diagnosis, n, (%)			
Intracranial aneurysm	19 (54.3)	25 (54.4)	.99
Trigeminal nerve resection	2 (5.7)	4 (8.7)	.61
Cyst excision-resection	3 (8.6)	3 (6.5)	.72
Micro-vascular decompression	2 (5.7)	3 (6.5)	.88
Tumour resection	4 (11.4)	6 (13)	.82
More than one type	5 (14.3)	5 (10.9)	.64

BMI (Body mass index); APACHE II (Acute Physiology and Chronic Health Evaluation II) it is applied within 24 hours of admission of a patient to an ICU.

Instrument

The CCPOT scale was developed to evaluate pain in mechanically ventilated as well as non-intubated ICU patients. It assesses four behavioral domains: (a) facial expressions, (b) body movements, (c) muscle tension, and (d) compliance with the ventilator (mechanically ventilated patients) or vocalization (non-intubated patients) (Gélinas & Arbour, 2009; Gélinas et al., 2009; Stefani et al., 2011). Each domain is scored from 0 to 2, and the total score can range from 0 to 8. The discriminant validity of the CCPOT scale has been documented by significantly higher scores during repositioning (mean: 1.85) compared with rest (pre mean: 0.60, post mean: 0.65) (Buttes et al., 2014). In critically ill conscious and unconscious patients, pain assessment with the CCPOT has a specificity of 70.8% (Severgnini et al., 2014). In patients exposed to nociceptive stimuli, the scale has been reported to have a sensitivity of 86%, a specificity of 78%, a positive likelihood ratio of 3.87 (1.63-9.23), and a negative likelihood ratio of 0.18 (0.09-0.33), whereas in patients not exposed to nociceptive stimuli, it showed effectiveness in pain screening and had fairly high specificity (83% and 97%), but suboptimal sensitivity (47% and 63%) (Gélinas et al., 2009).

Based on the literature (Severgnini et al., 2014) and on the Italian validation study (Stefani et al., 2011), scores of 0 to 2 were considered to indicate no or minimal pain; a score of 3 was considered to indicate moderate pain. The department operating procedure, inspired by the Committee Against Hospital Pain, envisaged the administration of analgesic medications to patients with scores > 3.

Data collection

Data were collected at 2 points. At T0 (1 June 2019 to 10 November 2019), patients' clinical data were obtained from their electronic medical records (Margherita3 2010 form) stored at the ICU. Only the data from brain-injured patients who had been sedated or intubated or had received mechanical ventilation are included in this study. T1 (11 November 2019 to 15 June 2020) data were collected after implementation of the intervention, and were compared with the CCPOT data.

Data Analysis

Data analysis was performed blindly by a staff member who was not involved in the study and who was aware neither of its aim nor of the patient group to which the data belonged. Descriptive statistics, means and standard deviations, and absolute and relative frequencies were calculated.

Between-group comparisons were performed with the x2 test (nominal variables) and Student'st test (ratio level variables). Statistical analysis was performed with SPSS (IBM SPSS Statistics for Windows, Version 22.0 Armonk, NY: IBM Corp). The level of significance was set at p < .05. **Table 2.** Use of Continuous drug infusion: numbers of patients who received sedation and analgesia before and after implementation of the critical-care pain observation tool.

Outcome measures	Group Before	Group After	Statistical	- p-value	
	(n= 35)	(n= 46)	test		
Morphine consumption mcg/kg/h mean, (+)+	11.3 (2.8)	12.1 (1.9)	1.51	.02	
N. of treated patients (morphine) (%)*	29 (82.8)	38 (82.6)	0.001	97	
Remifentanyl consumption mcg/kg/h mean, (+)+	3.1 (0.6)	3.3 (0.5)	0.75	.23	
N. of treated patients (remifentanil) (%)*	4 (11.4)	9 (19.5)	0.977	.32	
Propofol consumption mg/kg/h mean, (+) +	2.3 (0.5)	1.9 (0.8)	1.83	.03	
N. of treated patients (propofol) (%)*	26 (74.3)	35 (76.1)	0.035	.85	
Dexemetomedine consumption mcg/kg/h mean, (+) +	0.29 (0.01)	0.26 (0.1)	0.86	.20	
N. of treated patients (dexemetomedine) (%)*	6 (17.1)	4 (8.7)	1.226	.26	
Midazolam consumption mg/kg/h mean, (+) +	14 (4)	15 (1)	0.77	.24	
N. of treated patients (midazolam) (%)*	3 (8.6)	3 (6.5)	0.122	.72	

+ p-value: Student's test, significance set at p < .05.

* p-value: x2 test, significance set at p <. 05.

Table. BMI (Body mass index); APACHE II (Acute Physiology and Chronic Health Evaluation II) it is applied within 24 hours of admission of

Characteristics	Group Before	Group After	p-value
	(n= 35)	(n= 46)	
Age, mean (+) y	54.9 (12.3)	52.3 (14.6)	.83
Gender, n (%)			
Male	15 (42.9)	21 (45.6)	.80
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RESULTS

Patient characteristics

Admissions during both audit periods were well matched for age, gender, severity, and diagnosis, with no significant baseline differences between groups (Table 1). The study population consisted of 81 patients. The proportion of non-communicative patients was 43.2% (n= 35) in the pre-implementation phase and 56.8% (n= 46) in the post-implementation phase.

No patients included in the study deceased during the study observation.

Management of Sedation and Analgesia

The use of continuous infusion sedation and analgesia in the pre- and post-intervention groups was compared in terms of the mean number of grams, milligrams, or micrograms pro Kilograms hours of drugs administered and of the number of patients who received treatment (Table 2).

The use of sedation (propofol) fell significantly in

terms of both dose administered per patient (propofol: t(80) = 1.83, p =.03). At the same time the use of strong opioids (morphine) increase significantly in terms of both dose administered per patient (morphine: t(80) = 1.51, p =.02). The use of strong opioid (remifentanil), and sedation like midazolam or dexemetomedine, did not significantly differ between the two patient groups (Table 2).

Analysis of the data with respect to pain relief and prevention during some nursing care activities revealed a significant increase in the use of fentanyl citrate (administered in 2 patients before versus 10 patients after) (x2(1)= 4.04, p =.04) and paracetamol (administered in 24 patients before versus 41 patients after) (x2(1)= 5.30, p =.02). However the use of ketorolac and ketoprofen (intravenous) and morphine sulfate (enteral) did not significantly differ.

The overall use of anti-inflammatory drugs and analgesics on an as needed basis also increased significantly (x2(1)=4.51, p=.03) from 77.1% of patients (n= 27) in pre-implementation phase to 93.5% (n=43) after implementation.

Frequency of pain assessment

After adoption of the clinical therapeutic intervention, pain was assessed with the CCPOT scale 812 times. Pain management was in line with the protocol, which envisaged administration of pain medications to patients with CCPOT scores > 3 in 76.8% of cases. The mean CCPOT score of the post-intervention group was 1.2. All 46 patients in this group received pain assessment with the CCPOT scale; in 82 (10.1%) of the 812, at least 1 assessment had a score > 3 (Table 3). The mean number of assessments per patient was 17.6 +7.3 (range: 4 - 32).

DISCUSSION

This study was devised to assess the efficacy of a clinical therapeutic intervention aimed at improving pain assessment and management in patients admitted to Lecco Hospital ICU. The intervention involved the introduction into routine clinical practice of a new pain assessment and management directed at all brain-injured critically ill adult patients with impaired consciousness, and was preceded by ad hoc training of the ICU staff. Our data suggest that before CCPOT adoption, patients received excessive sedation and insufficient analgesia. The implementation of decision-making algorithms and protocols in intensive care can have a positive effect on patient outcomes (Olsen et al., 2015).

Reduction of sedation and more effective pain management have the potential to exert beneficial effects on the post-ICU course (Barr et al., 2013; Damico et al., 2018). Recent studies report that the adoption of behavioral pain scales has favorable effects on ICU pain, by improving the use of analgesics and sedatives, and on clinical outcomes, by reducing the duration of mechanical ventilation and hospital stay (Grap et al., 2012; Resnick et al., 2016). The validity and reliability of the CCPOT scale have also been documented in patients undergoing elective neurosurgery (Echegaray-Benites et al., 2014; Joffe et al., 2016). The aforementioned considerations make it possible for the results of the present study to be extended to specialized ICUs.

Our results indicate that a significant barrier to pain assessment in this ICU was the lack of a suitable tool for non-communicative patients. When provided with such a tool, nurses assessed pain more frequently and appropriately, as seen in the Canadian studies (Rose et al., 2013).

The adoption of the CCPOT scale at our ICU seemed to have favorable effects on pain assessment and management, as noted in previous studies (Jones et al., 2004). The protocol involved both the medical and nursing staff, who found the CCPOT scale useful and reliable. Indeed, it continues to be used, as also stressed by other researchers (Damico, Murano, Cazzaniga, & Dal Molin, 2018).

The improved pain management achieved in the present study is in line with reports describing pain reduction after staff training (Barr et al., 2013). Using a valid pain assessment tool can improve patient management and analgesia.

In our study, nurses carried out a clinical intervention in 76.8% of patients with CCPOT scores > 3. Of the 812 times pain was assessed with the CCPOT scale, the score was > 3 in 82 (10.1%) cases, but in 23.2% of them, the ICU staff failed to adopt an intervention or to monitor pain evolution (Table 3).

It would be beneficial if the reasons for these decisions were addressed in a focus group. Use of a behavioral pain scale helped nurses in discriminating pain from other symptoms, for instance, anxiety. Now that valid behavioral pain scales for nonverbal, brain-injured critically ill adult patients are available and can be easily taught and implemented in the ICU, it is urgent for the clinical recommendations to be adopted. The high rate of interventions (76.8% of cases with CCPOT scores > 3) and large number of assessments (mean for patient= 17.6) made according to the protocol at our ICU underscore the effectiveness of staff training.

Study Limitations

The main limitations of the study are that the study was interrupted from February 20th to May 15th for the Covid-19 emergency. However during this period no patient with Brain-Injured has been admitted in our ICU.

This study was undertaken in an ICU with a specific patients subpopulation and cannot be generalized to all brain surgery patients. The presence of the head bandage may have limited the observation of the facial expression item in the CCPOT scale, especially of the forehead region for some patients.

We did not examine interrater reliability of the CCPOT; however, this has been demonstrated in other studies. In one study of patients in a burns unit, the investigators reported poor interrater reliability for the CCPOT, and other observational tools, after brief education on the tools.

In addition, no information is provided on how often assessments were to be performed or whether there was an expectation in this regard. Although we feel that at least one pain assessment per shift is desirable, patients' clinical conditions and sedation levels change over time.

Therefore, the nursing staff were not asked to conduct pain assessments at pre-established intervals, but only whenever they deemed it necessary based on their experience. This explains why a mean number of pain assessments per shift could not be calculated, as patients who were deeply sedated were not assessed on a per shift basis.

Implications for Nursing Education, Practice, and Research

The CCPOT is a promising pain assessment tool in ICU neuro-surgical patients. Research conducted on its practical use, including the present study, supports its clinical value. Staff training is critical for its success. Nurses play a key role in implementing programs aimed at improving pain management because pain symptom detection is a specific task of their job. There is a great need for interdisciplinary education on pain assessment in the critical care setting. Suitably trained ICU nurses have the potential to exert a favorable influence on sedation and analgesia and on the adoption of pain relief interventions during nursing care activities. Awareness of such issues is crucial for the adoption of novel tools enabling increasingly better management of ICU sedation and analgesia.

CONCLUSIONS

The intervention described in this study proved effective in increasing the number of clinical therapeutic interventions directed at relieving patient pain and indirectly contributed to reducing sedation levels. The present findings strongly support the value of the CCPOT scale in managing ICU patient pain in conjunction with medical and nursing staff training. The scale seems to have a greater discriminant validity in assessing pain in brain-injured critically ill adults nonverbal patients. However, further studies of larger patient samples should be performed to monitor the stability of results over time and to explore the efficacy of the approach in other populations, such as pediatric and neonatal ICU patients.

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