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Research paper

Impact of implementing the critical-care pain observation tool in the adult intensive care unit: A nonrandomised stepped-wedge trial

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ABSTRACT

Background: Approximately 70% of patients in intensive care units (ICUs) experience untreated pain, often due to severe patient conditions and communication barriers.
Aim: The aim of this study was to implement the Critical-Care Pain Observation Tool (CPOT) to improve pain assessment in patients unable to self-report pain in the ICU.
Method: A stepped-wedge trial was conducted in six adult ICUs in Saudi Arabia between February and June 2022. The sequential transition of ICU clusters occurred in February 2022, from control to intervention, until all ICUs were exposed to the intervention. The primary outcome was the number of pain assessments, whereas the secondary outcomes were reassessments. Other outcomes were length of stay, mechanical ventilation duration, and administered doses of sedatives and analgesic agents. Statistical analyses were performed using the Statistical Analysis Software v9.4.
Results: A total of 725 patients unable to self-report pain were included; 65% (n = 469) were male with an average age of 55 years. Implementing CPOT showed a significant increase in the number of pain assessments (rate ratio: 1.77, 95% confidence interval: 1.45, 2.16, $p < 0.001$) and reassessments (rate ratio: 13.99, 95% confidence interval: 8.14, 24.02, $p < 0.001$) between intervention and control conditions. There was no significant effect on the ICU length of stay, mechanical ventilation duration, and the amount of sedation (midazolam, propofol, and ketamine) and analgesia (fentanyl) administered.
Conclusion: The study indicates that the implementation of the CPOT increased the frequency of pain assessment and reassessment. However, the impact on patient outcomes remains inconclusive. Further investigations focussing on CPOT as the primary pain scale are necessary to determine its holistic impact on patient outcomes over the long term.
Trial registration: NCT05488834.
Clinical trial registration number: This study was registered with the U.S. National Library of Medicine (ClinicalTrial.gov, NCT05488834).

1. Background

Pain is a common symptom experienced by patients admitted to the intensive care unit (ICU).[1] Furthermore, patients in the ICU experience pain at rest and during a procedure, and those who undergo certain procedures without prior analgesia are more likely to experience high levels of pain.[2] Despite decades of study and efforts to improve pain management, 50–70% of patients experience moderate to severe pain during their stay in the ICU.[3,4] It has

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also been reported that pain remains or is untreated in adult ICU patients.[5] The consequences of untreated pain in this population are profound and can lead to posttraumatic stress disorder,[6,7] high healthcare costs, and increased use of healthcare services.[8,9]

2. Importance of pain assessment

The efficacy of pain management relies significantly upon the quality of systematic pain assessment, using validated and appropriate instruments.[10] The evidence suggests that pain assessment in patients unable to self-report pain in ICU settings plays a pivotal role in pain management as it assists nurses in identifying pain among patients and guiding pain management.[11] However, reassessment, which is measuring pain score after administration of analgesic, holds equal importance in pain management within adult ICUs as an initial assessment. Systematic pain assessment, which includes reassessment post analgesic administration in patients unable to self-report pain, can enable nurses to promptly recognise fluctuations or changes in pain levels[12] and facilitate quicker adjustments to pain management strategies.[13] Pain treatment is an evolving practice that emphasises frequent and precise pain assessment to tailor treatments effectively. Utilising validated and appropriate pain assessment tools is crucial as it ensures standardised and reliable evaluations, enhancing the accuracy of pain identification and management in clinical settings.[14] These validated tools offer a structured framework that assists nurses in effectively assessing and monitoring pain, enabling tailored interventions for patients' specific needs. Despite the availability of these measures, pain tends to be underassessed and consequently undermanaged, making it a significant issue in ICU clinical practice.[15]

3. Barriers to pain assessment

Assessing pain in ICU patients presents several challenges. Limited communication between the ICU nurse and the patient due to the patient's inability to self-report pain due to a decreased level of consciousness or intubation is one of the major challenges. Additionally, nurses encounter their own set of challenges to pain assessment. In a recent systematic review,[16] the barriers to pain assessment were examined using the Behavioural Change Wheel framework that is centred on the Capability, Opportunity and Motivation Behaviour model.[17] These barriers encompassed factors including lack of knowledge, improper attitude, lack of education, and high workload.[16] Moreover, there is often a lack of adherence to evidence-based practices, hindering effective pain assessment. However, implementing evidence-based guidelines has the potential to improve pain assessment practices, leading to optimal pain management.[12,18]

Several professional bodies have recommended the use of behavioural pain assessment methods to evaluate pain among ICU patients who are unable to self-report their pain.[19,20] Various behavioural pain assessment instruments, such as the Nonverbal Pain Scale,[21] Behavioral Pain Scale,[22] and Critical-Care Pain Observational Tool (CPOT), have been developed for assessing pain in patients who are unable to self-report.

The CPOT has been validated in various medical, surgical, and trauma ICUs[23] due to its demonstrated high reliability and validity in pain assessment.[24] The CPOT assesses various aspects, including facial expressions, body movements, muscle tension, and ventilator compliance or vocalisation, to provide a concise evaluation of pain in patients unable to self-report. The use of CPOT helps nurses effectively manage pain in critical care settings, improving patient care and increasing the chance of theoretically improving patient care and detecting pain.[25] A change in pain scale was necessary, despite the use of the Face, Legs, Activity, Cry, Consolability (FLACC) scale, as the FLACC was originally designed for paediatric patients. In an adult ICU, the CPOT, which is validated for adult patients, offers a more accurate pain assessment and better aligns with the clinical needs of these patients.

4. Pain management in Saudi Arabia

Pain management within the ICU settings in Saudi Arabia where this study was conducted faces multifaceted challenges. These challenges include a scarcity of standardised protocols tailored to ICU settings, the absence of specific guidelines for behavioural pain tools,[26,27] insufficient emphasis on specialised training programs focussing on assessing pain in the ICU for nurses and healthcare staff, and a lack of policies and protocols dedicated to pain management strategies.

The purpose of this study was to assess the implementation of the CPOT by using strategies formulated by the investigators, informed by the barriers identified in the integrative review.[16]

The hypothesis was that the implementation of CPOT in the ICU will result in a higher frequency of pain assessment and reassessment among patients unable to self-report, ultimately leading to improved pain management outcomes and enhanced patient comfort.

5. Methods

5.1. Study design

A nonrandomised stepped-wedge design[28] was used for the sequential roll-out of CPOT implementation in six adult ICUs. This study was registered with the U.S. National Library of Medicine (ClinicalTrial.gov, NCT05488834), and the reporting has adhered to the Consolidated Standards of Reporting Trials guidelines.[29] A nonrandomised stepped-wedge design was chosen because the inclusion of several units from a single site made it difficult to randomise.[30]

5.2. Ethical consideration

Ethical approval was granted by the Human Research Ethics Committee at the University of Newcastle, Australia (H-2021-0298) and King Abdullah International Medical Research Centre Saudi Arabia (IRB/2704/21).

5.3. Study settings

This study was conducted at King Abdul-Aziz Medical City Hospital in the Ministry of National Guard (NGHA) in Riyadh, Saudi Arabia. King Abdul-Aziz Medical City Hospital is a tertiary referral hospital with six adult ICUs (medical, surgical, respiratory, trauma, neurological, and progressive care), totalling 120 ICU beds and employing approximately 207 registered nurses. The average length of stay in these ICUs was between 4 and 7 days, and the average number of admissions ranged from 70 to 110 patients per month in each ICU.

5.4. Participants

Eligible participants included as per the following criteria: aged 18 years and older admitted to one of the six ICUs between February 2022 and June 2022 and who had a Richmond Agitation Sedation Scale score ranging from −1 to −5, indicating an inability to self-report state.[31] Consent for patients included in this trial was obtained from patients' relatives or next of kin after providing them

with detailed information about the study and before any data were collected.

5.5. Control condition (usual care)

The usual care for pain assessment in ICU patients unable to self-report pain was conducted every 2 h using the FLACC pain scale.[32] The results were documented in the medical record system. It is important to note that pain management decisions are not within the scope of nursing practice in Saudi Arabia. Therefore, the FLACC results were reported to physicians for pain management.

5.6. Intervention condition

During the intervention period, all participants received the usual care and the implementation of the CPOT.

The CPOT instrument evaluates four subscales: facial expression, body movement, muscle tension, and compliance with ventilator or vocalisation to evaluate an individual's pain. Each item is rated on a 3-point descriptive scale from 0 to 2, and the total score ranges from 0 to 8, where 8 indicates the highest intensity of pain behaviours.[23] Patients are observed for 60 s while resting and during standard care procedures, such as turning or wound dressings, to detect any change in behaviour that could indicate pain. For reassessments, patients must be observed before and 30 min after analgesia medications are administered to evaluate the effectiveness of the pain treatment.[33] The CPOT has shown the most robust psychometric properties for ICU pain assessment and was validated in the Saudi Arabian context.[34] CPOT was selected as it is specifically tailored for use in critical care settings. It is sensitive to subtle nonverbal cues indicative of pain, such as facial expressions, body movements, muscle tension, and compliance with mechanical ventilation. It provides a standardised approach to pain assessment, ensuring consistency among healthcare providers.[31]

5.7. Implementation strategies of the CPOT

The implementation strategies of the CPOT included four main components that address distinct barriers to pain assessment in patients unable to self-report pain in the ICU: (i) education; (ii) training; (iii) enablement; and (iv) persuasion. These strategies were developed using the Behavioural Change Wheel framework that centred around an individual's capability, opportunity, and motivation and how these elements influence behaviour.[17] The education was delivered to enhance nurse staff members' knowledge and skills, using prerecorded videos to present topics covering the CPOT, pain assessment, reassessment, and documentation. The training strategy focussed on "train-the-trainer" model to empower head nurses and nurse educators for effective knowledge dissemination within ICUs and to ensure knowledge sustainability. Enablement strategy addressed opportunity-related barriers by introducing CPOT and establishing an implementation team for crucial support. The persuasion element was delivered by presenting evidence of undetected pain in ICUs, emphasising the essential role nurses play in pain assessment in the ICU and the consequences of untreated pain such as prolonged hospital stay and psychological distress.[4]

5.8. Sequence of stepped-wedge trial

Six ICUs were recruited and grouped into three clusters (two ICUs in each cluster) based on their geographical proximity to each other. The number of included ICUs and the 5-month duration of the study were intentionally selected to increase engagement of all sites and to enhance nurse retention to the implementation strategy.[35] In addition, the selected duration was decided based on the sample size calculations related to the number of patient admissions monthly. The CPOT was sequentially implemented. The allocation sequence for the intervention was determined in consultation with the Director of Clinical Nursing, taking into consideration the impact of the COVID-19 pandemic on each ICU's readiness for the implementation. A transition period of 1 month was specified for the full implementation of the intervention. In the first month (February 2022) of the study, all three clusters were in the control condition and received the usual care. In the second month, CPOT implementation commenced and was delivered to the first cluster over 1 month (no data were collected during this period), while other clusters continued to receive the usual care. In the third month, the first cluster sequenced to the intervention condition and started using CPOT in addition to the FLACC, and the second cluster commenced the implementation, while the third cluster stayed in the control condition. Implementation then proceeded through the clusters, following the sequence as outlined in Fig. 1.

5.9. Outcomes

5.9.1. Primary outcome

The primary outcome was the number of pain assessments documented in a 24-h period post ICU admission, starting at midnight on the admission day and finishing at midnight 24 h later.

5.9.2. Secondary outcomes

The secondary outcomes were the number of pain reassessments (assessments undertaken within 30 min following the administration analgesic and/or sedation) in a 24-h period, length of stay, and length of intubation.

5.10. Data collection

During the intervention period, nurses were provided with a structured data collection form for documenting both the assessments and reassessments. This was in accordance with the instructions outlined by the developer of the CPOT. If the CPOT score was 3 or more, interventions were initiated, followed by reassessment within 30 min post intervention. During the control period, data were collected from the electronic medical records.

The following data were collected: (i) Richmond Agitation Sedation Scale score; (ii) the number of pain assessments and reassessments in 24 h; (iii) patient demographics, i.e., age, gender, nationality, and principal diagnosis (based on the Australian and New Zealand Intensive Care Society, Adult Patient Database, and patient general medical information); (iv) ICU length of stay (days) and mechanical ventilation duration (days); and (v) the total amount of sedatives and analgesic agents administered to patients (total administered amount to patients during intervention condition compared to total administered amount to patients during control condition). Data were collected from each ICU per month, with a total of 725 patient records over the 5-month period. The principal author extracted data from the electronic medical record called "BESTCare". Additional information was obtained from the paper copy of the medical records.

5.11. Sample size calculation

A sample of 30 patient records per ICU per month (excluding the implementation month) was drawn from all six ICUs, totalling 720 participants in total (6 ICUs $\times$ 30 records per ICU per month $\times$ 4 months). Assuming a type 1 error rate of 5%, an intracluster correlation of 0.05, and a difference of 0.5 standard deviation (SD, a

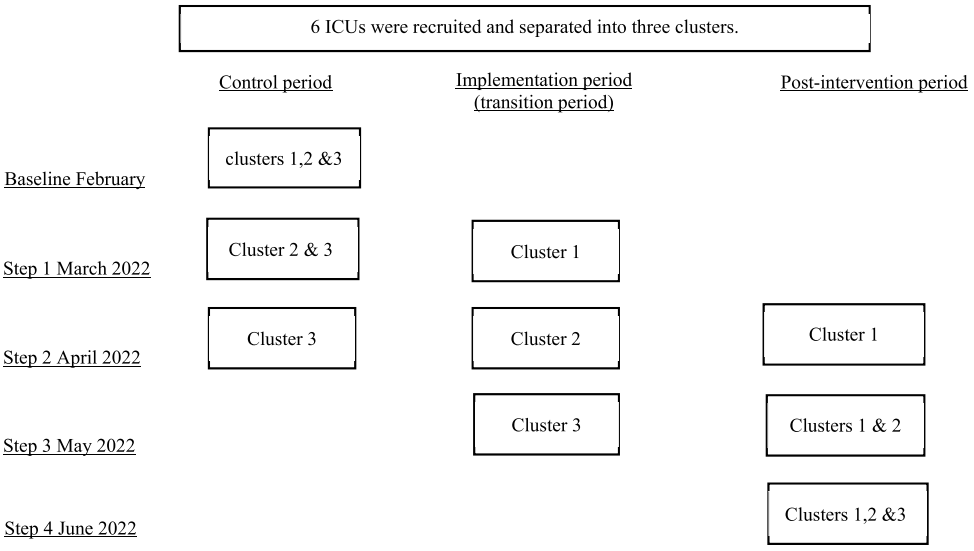

Fig. 1. Recruitment and stepped-wedged during the 5-months period. Note: ICU: intensive care unit; CPOT: Critical-Care Pain Observation Tool; Control period: preintervention period when patients cared for received the standard care. Implementation period: CPOT was implemented on the cluster ICUs and the nurses working on the specific cluster received the implementation strategies (education, training, persuasion and enablement). Cluster 1: medical ICU and trauma ICU; Cluster 2: general ICU and neurology ICU; Cluster 3: respiratory ICU and surgical ICU. No patient data were collected from the ICUs during the implementation period. The transition period of 1 month was specified for the full implementation of the intervention.

medium Cohen's d effect size) between preintervention and post-intervention periods, this study achieved approximately 69% power computed using Power Analysis & Sample Size software (PASS) 2023, version 23.0.2. The reduction in power from the original plan (80%) is attributed to the complexities of the stepped-wedge design, an area of ongoing research where power calculation approaches have evolved since the initial sample size determination.

5.12. Data analysis

Descriptive statistics for categorical data were presented as count (%), and in the absence of sufficient skew, the mean and SD for continuous variable were reported. Outcome measures in the form of discrete counts and overdispersed continuous measures were modelled using mixed-effect negative binomial regression. Random effects for ICU type were included in the modelling to account for correlated observations on the ICU cluster level. Relative risk (RR) is presented for Poisson and negative binomial regressions, which were used to model count- based outcomes. Differences in counts are reported as RRs with 95% confidence intervals (CIs) and corresponding p values. Odds ratios are presented for logistic regressions, which were used to model binary outcomes (such as whether or not patients received analgesia). The differences in proportions between the control and intervention groups for these outcomes were reported as odds ratios with 95% CIs. All statistical analyses were programmed using SAS v9.4 (SAS Institute Inc. Cary, NC, USA). Statistical significance was set a priori at $p < 0.05$.

Missing data were collected by auditing the paper-based medical records of the patients. However, if data were not available from either the electronic or paper-based records, the participants' records were removed from analysis as a result of this process. The total dose of each sedative and analgesic for every patient was calculated separately. This was done by combining the total dose administered via infusion and bolus. Infusion doses were calculated using the product of dose rate (provided in mg/hour) and length of infusion.

6. Results

A total of 725 patients were included, of whom 469 (65%) were male. The average age of the patients was 55.7 (SD: 20.78) years, and the majority (n = 683; 95%) were of Saudi nationality. Viral pneumonia was the most common condition, affecting a total of 247 patients (34%), followed by chronic obstructive pulmonary disease affecting 141 patients (19%), and 47 patients (6%) were admitted for stroke. There was no statistically significant difference in the baseline characteristics during the intervention and control conditions across the entire period of the study (Table 1).

6.1. Number of pain assessments and reassessments

The mean number of pain assessments was 9.72 during the control condition and 13.46 in the intervention period. The mean number of pain reassessments was 1.87 in the control condition and 7.65 in the intervention condition. The impact of implementing the CPOT has resulted in a statistically significant increase in the number of pain assessments (RR: 1.77, 95% CI: 1.45, 2.16, $p < 0.001$) and reassessment (RR: 13.99, 95% CI: 814, 24.02, $p < 0.001$).

6.2. Other patient outcomes

The mean length of ICU stay and intubation was 7.24 and 5 days, respectively. The mixed-effect negative binomial regression showed no statistically significant difference between intervention and control conditions in length of stay (RR: 1.35, 95% CI: 0.94, 1.93, $p < 0.097$) and intubation (RR: 0.96, 95% CI: 0.62, 1.48, $p < 0.846$). The mean amount of propofol administered across all patients during the control condition was 12 1191.6 mg, whereas the mean amount of propofol administered across all patients in the intervention condition was 7587.3 mg. The mean total amount of midazolam administered across all patients in the control period was 424.4 mg, whereas 276.3 mg was administered in the intervention condition. The mean of the total amount of fentanyl administered

Table 1
Demographics of the patient participants.

Demographic	Total (n = 725)	Control (n = 370)	Intervention (n = 355)	P value
Age (years mean ± SD)	55.77 (±20.78)	56.52 (±20.31)	54.99 (±21.27)	0.32
Gender (n, %)				
Male	469 (65%)	236 (64%)	233 (66%)	0.98
Female	253 (35%)	133 (36%)	120 (34%)	0.38
Nationality (n, %)				
Saudi	683 (95%)	341 (93%)	342 (97%)	0.33
Other	37 (5.1%)	26 (7.1%)	11 (3.1%)	0.02
Primary diagnosis				
Viral pneumonia	247 (34%)	128 (34%)	119 (33%)	0.87
COPD	141 (19%)	83 (22%)	58 (15%)	0.30
Multiple trauma	128 (17%	77 (20%)	51 (14%)	0.38
Cancer	109 (15%)	37 (10%)	72 (20%)	0.18
Stroke	47 (6%)	29 (7%)	18 (5%)	0.78
Other	47 (6%)	8 (2%)	39 (10%)	0.46

Note: Continuous variables are expressed as mean (±standard deviation); categorical variables are presented as number (percentage). Abbreviation: COPD: chronic obstructive pulmonary disease, n: number of patients; SD: standard deviation.

during the control and intervention conditions was 24 698.8 mcg and 13 439.7 mcg, respectively. There was no statistically significant difference in the mean total amount of sedation administered including midazolam (RR: 1.25, 95% CI: 0.09, 17.16, $p < 0.866$) and propofol (RR: 0.99, 95% CI: 0.13, 07.84, $p < 0.966$) between the intervention and control conditions. Similarly, there was no statistically significant difference in the mean total amount of fentanyl administered (RR: 0.89, 95% CI: 0.57, 1.40, $p < 0.583$) between the intervention and control conditions.

7. Discussion

This study aimed to implement the CPOT to improve pain assessment and patient outcomes in patients unable to self-report pain using the education, training, enablement, and persuasion implementation strategy in six ICUs in Saudi Arabia. To our knowledge, this study is the first stepped-wedge trial designed to evaluate the impact of implementing the CPOT in critical care settings. Specifically, the study demonstrated that the CPOT improved pain assessment and reassessment in patients unable to self-report pain. This study highlighted the need for using strategies in the implementation and dissemination of evidence-based practices within the critical care setting.

Our results showed a significant increase in the frequency of pain assessment post implementation of the CPOT in adult ICUs. These findings are similar to those of previous studies[33,36,37] that found the use of the CPOT increased mean total pain assessment. Phillips et al. conducted a before-and-after study to implement CPOT; the authors audited 441 charts retrospectively for 49 days, and charts were audited post implementation; then, the frequency of pain assessment and length of ICU stay were compared between the two groups.[37] They found that the frequency of pain assessment in 24 h increased, with the mean total assessment increasing from 3.0 to 8.9. These results suggest that prior to the introduction of the CPOT, there was a lack of a suitable tool for assessing pain in patients unable to self-report pain. With the provision of an appropriate tool, nurses demonstrated increased vigilance in pain assessment.[33] However, it should be noted that although the primary outcome was statistically significant, this level of power of 69% is viewed post hoc and should be interpreted cautiously.

Adherence to pain assessment is known to improve patient outcomes in the ICU.[37] Increased and more frequent behavioural assessment, for example, using CPOT, have previously had a direct effect on lowering the administration of analgesics and decreasing the length of stay and mechanical ventilation duration.[38] However, the results we obtained did not align with our expectations. One explanation is the potential impact of COVID-19. Since the trial hospital was assigned as a referral centre in the Riyadh region during the COVID-19 pandemic, most patients admitted to the ICUs during the trial period were either COVID-19-positive or suspected COVID-19 cases. The hospital implemented a COVID-19 protocol that provided uniform guidelines for mechanical ventilation in addition to sedative and analgesic agent administration. Consequently, similar patient care was provided under this protocol, potentially masking the specific effects of using CPOT on patient outcomes. In this trial, we collected data on the causes of admission for all patients, and it was observed that more than half (specifically 388 patients, which constitutes 53% of the sample) had respiratory problems, of whom some could be COVID 19 cases. This led to the same protocol being applied to both groups, resulting in no significant changes in the length of stay or length of intubation among patients in the control and intervention conditions.

Our findings support other studies that have identified the importance of using an implementation strategy to promote adherence to established guidelines.[39,40] Despite the inherent challenge of assessing pain in patients unable to self-report, our intervention period exhibited higher rates of assessment and reassessment, indicating nurses' commitment to utilising CPOT-related documentation. In addition, despite the additional workload, the improvement in assessment rates underscores nurses' commitment to evidence-based practice. Our study revealed an increase in the frequency of pain assessment and reassessment within a 24-h period, suggesting a potential lack of suitable assessment tools for patients unable to self-report pain, which, when provided, led to more frequent pain assessments by nurses in the ICUs.[33] This aligns with prior findings that implementing evidence-based pain tools alongside effective education and training can significantly influence nurses' practice and usage of such tools.[37,41]

7.1. Limitation

This stepped-wedge trial is not exempt from limitations. It is important to note that this study was conducted during the COVID-19 pandemic at a hospital that served as a referral centre for COVID-19 critical care cases throughout Saudi Arabia. The implementation of COVID-19 protocols could be a confounding factor in the study's secondary outcomes. Several factors could serve as a confounding factor to patient outcomes, particularly in the administration of analgesics and sedations. Firstly, gaining patient consent posed challenges due to the complex process of involving next of kin or

relatives, resulting in delays of up to 5 days due to restricted visiting times. Secondly, the participating hospital pain management is not nurse-led, and nurses rely on physician orders to manage pain and provide pain relief. COVID-19 protocols often caused deviations from usual patient management practices. Despite CPOT scores being reported, they were not consistently used to guide sedative and analgesic titration. Physicians prioritised managing the primary respiratory effects of COVID-19, including prone position and adjusting sedation for comfort during mechanical ventilation, often independent of CPOT scores. This inconsistency in sedation and analgesia administration likely introduced variability that may have skewed the secondary outcomes of the study's results. Furthermore, it is important to note study biases, including the selection of a single centre, which could introduce internal contamination. The absence of randomisation and lack of blinding can impact the reliability and generalisability of the findings. These biases should be taken into account when evaluating the study's conclusions and considering its implications for clinical practice.

8. Conclusion

In this study, we focus on implementing the CPOT to improve pain assessment in patients unable to self-report pain in the ICU. This study reveals that the CPOT significantly increased the number of pain assessments and reassessments documented in a 24-h period. These findings cannot be generalised, and further research is required to replicate this study using an experimental design when fewer impacts related to the COVID-19 pandemic are evident. Future research should also consider evaluating the effectiveness of analgesia by analysing how systematic pain assessment correlates with pain management outcomes. This would help to determine whether the increased frequency of assessments leads to better pain control. Nevertheless, the findings underscore the importance for nurses to diligently adhere to systematic pain assessment methods such as the CPOT to enhance the quality of care for patients unable to self-report in intensive care settings.

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CRediT authorship contribution statement

Majid Alotni: data curation, writing—original draft writing, data collection; **Michelle Guilhermino**, **Ritin Fernandez Jenny Sim and Ginger Chu:** writing—reviewing and editing, supervision, investigation, validation. **Daniel Barker and Stuart Szwec:** data analysis.

Conflict of interest

The authors declare no conflicts of interest related to this manuscript.

Data availability statement

The data that support the findings of this study are available from the corresponding author, Majid, upon reasonable request.

Availability of data and materials

All data in this study are included in this published article (and its supplementary information files).

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