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DEVELOP AND VALIDATE PAIN INTENSITY SCALE FOR PATIENTS WITH DISTURBED CONSCIOUSNESS ON MECHANICAL VENTILATOR

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Abstract:

Introduction: Critical ill patients with disturbed consciousness may suffer from pain and discomfort, which affects their functional and hemodynamic status, so utilizing a valid pain assessment tool is critical for pain management in all critically ill patients, especially those with disturbed conscious levels. Aim: This study aimed to develop and validate the pain intensity scale for patients with disturbed consciousness on a mechanical ventilator. **Methods:** A methodological research design on 300 patients in the general surgical and neurosurgery intensive care unit (ICU). The study included 25 experts from critical care medicine and nursing to validate the scale. The patient assessment record was used to assess the demographic data, medical data, and Glasgow Coma scale. The Critical Care Pain Observation Tool was used as a valid and reliable tool to judge the concurrent validity of the developed tool. The Mechanically Ventilated Disturbed Consciousness Pain Assessment Scale (MV-DCPAS) was used as a developed tool to assess pain intensity in disturbed-conscious patients on mechanical ventilation. Face and Content Validation Opinionnaire. **Results:** The results show excellent face and content validity, high reliability with the internal consistency of >0.9(Cronbach's alpha), and a good to excellent interrater reliability with a weighted Cohen's kappa minimum of 0.780 to maximum 0.819, higher sensitivity than specificity with AUC= >0.8, with significantly less than 0.01** in all procedure. **Conclusion:** The developed scale shows excellent face and content validity, high reliability, high sensitivity, and specificity for detecting pain in patients with disturbed consciousness on mechanical ventilation.

Keywords: Pain intensity scale, mechanical ventilator, disturbed consciousness patient

INTRODUCTION

According to (Srinivasa et al., 2020), who participate in the International Association for the Study of Pain (IASP) describe, pain as 'An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage''. Pain varies from one person to another and has different dimensions: sensory, emotional, cognitive, physiological, and behavioral. Critical ill patients with disturbed consciousness may suffer from pain and discomfort, which affects the functional and hemodynamically status of these patients.

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Adult intensive care unit (ICU) patients frequently experience pain as a result of acute and chronic illnesses, as well as from positioning and treatments that are typical of ICU care. In addition to being morally right and humane, treating pain efficiently helps the patient with mechanical ventilation, avoiding agitation and delirium. Acute pain can lead to various physiological changes that can impact patient care in the ICU, such as tachycardia, hypertension, increased breathing effort, increased cortisol release, and increased risk of infection. ICU patients are thought to feel pain at a rate of 50% or more, and the fact that they cannot communicate because of mechanical breathing does not negate the possibility that they are suffering (Devlin et al., 2018).

Pain diagnosis in a patient who cannot communicate relies on objective and subjective measurements. This two-pronged approach can and should be tailored to the individual patient, clinical picture, and healthcare setting. Nursing Clinical judgment and behavioral observation comprise the second branch of diagnosis and may elicit a more accurate assessment of the pain levels of a patient (Abd-El Sayed, 2019).

The effective assessment of pain is possible through one reliable and authentic evaluation method, which requires accurate measurement of pain for guiding the treatment team toward decision-making for the selection of the type and accurate dose of the drug. Although accurate evaluation of pain has been emphasized, its execution is not as possible as the evaluation of other vital signs because pain is a subjective and mental experience, and there are no objective tools to measure it (Rafiei et al., 2016).

Adequate pain assessment requires dependable tools that aid in its detection and measurement. Recent international guidelines recommend the utilization of scales based on behavioral markers of pain for patients who are incapable of self-report, provided that their motor function is preserved and behaviors are observable (Latorre-Marco et al., 2016).

Practice guidelines for pain recommend individualized and goal-directed pain management. This incorporates an efficient assessment of pain with a proven pain scale appropriate to the patient’s level of consciousness (Rijkenberg et al., 2016). The diagnosis of pain in patients with low consciousness is a major challenge in the intensive care unit. Nurses are the cornerstone in this evaluation, as ICU nurses are attending for 24 hrs, observing meticulously, recording the onset, intensity, duration, radiation, drug response, using many alternatives for pain relief, and following it up.

Aim of the study

To develop and validate the pain intensity scale for patients with disturbed consciousness on a mechanical ventilator

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Materials and methods

Research design

A methodological research design was used for the development of a tool according to (Nilsson, et al., 2014), it is a process used to develop instruments' validity and reliability to measure constructs.

Setting and sample

This study was conducted at three critical care units affiliated with Ain Shams University (the general surgical ICU, which consists of fifty beds; the neurosurgery, which consists of six beds; and the emergency neurosurgery, which consists of ten beds). These units had high patients flow rates for those with a possibility for change in their conscious level either postoperatively or after trauma or neurological, metabolic disorders, or other causes. A purposive sample of (300) patients for scale validation as a rule of thumb (Clark & Watson, 1995).

It includes two groups:

Group 1: include a panel of experts, they were (25) experts from critical care medicine and nursing, to validate the scale

Group 2 included patients in general surgical, neurosurgery, and emergency intensive care unit (ICU). Those were selected according to the following criteria: Adult patients from both genders, patients on a mechanical ventilator for more than 24 hours, and patients with a Glasgow coma scale ranging from 3 T- 8 T.

Exclusion criteria:

Patients were considered eligible for the exclusion if they met the following criteria: Above 65 years, patients with a motor disorder such as quadriplegia, extensive damage to the face and arms, and muscular, functional disorders, hemodynamically unstable patients at the time of observation and patient who received neuromuscular blocking drugs, sedation, and analgesics at the time of observation.

Measurement and data collection

Data were collected using the following tools:

Patient assessment record: it was written in English language and filled by the researcher based on the patient's health record after a review of relevant recent related literature. It includes (demographic data, medical data, and the Glasgow coma scale). The patient is evaluated only based on an eye-opening, and motor scores and the suffix (T) are added to their score to indicate intubation; the maximum GCS score is 10T, and the minimum score is 2T.

Face and Content Validation Opinionnaire: It consisted of the preliminary self-assessment Opinionnaire developed by the researchers; the jury members were asked to agree/disagree with each item regarding face, content validity, and comments.

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Critical Care Pain Observation Tool: it was a valid tool used to assess the level of patient comfort and pain among critically ill mechanically ventilated; it has four sections, each with different behavioral categories (facial expression, body movement, compliance with ventilator or vocalization for the extubated patients, and muscle tension) (Gélinas, 2016).

The mechanically Ventilated Disturbed Consciousness Pain Assessment scale (MV-DCPAS) was developed by the researcher and used to measure pain intensity among mechanically ventilated disturbed consciousness patients; it was validated by a panel of experts and reliability tested by alpha coefficient test. It is composed of two main sections, the first is concerned with assessing behavioural changes, and the second is concerned with altering vital signs. The first section (behavioural changes assessment) is composed of four assessment categories. The first category assesses facial expression (relaxed or neutral, tightened/tense, grimacing). The second category is assigned to assess the body movements; (absence of movement/normal position, protection, and restlessness/agitation). The third category assessed the patient's compliance with the ventilator (tolerating the ventilator, coughing but tolerating, and fighting the ventilator). The fourth category assessed muscle tension (relaxed, tense/rigid, very tense/rigid). Variables from category one to category four were scored from 0 to 2.

The second section was concerned with assessing the vital signs alteration. The first sign is the respiratory rate. The respiratory rate was categorized as the baseline respiratory rate or alteration in respiratory rate. The second sign is oxygen saturation (SpO2). It was categorized as the baseline oxygen saturation or alteration in SpO2. The third sign was the heart rate, categorized as baseline heart rate or alteration in heart rate. The fourth sign was blood pressure. It is categorized as the baseline blood pressure or alteration in blood pressure. Variables in section two were scored from 0 to 1. These variables were tested during painful procedures. The selected procedures used to assess the MV-DCPAS were wound dressing and turning. The total score for MV-DCPAS ranged from 0 (no pain) to 12 (the most pain). The total scores were categorized into three levels as follows:

- No pain = 0
- Mild pain = 1-4,
- Moderate pain = 5 – 8 and
- Severe pain = 9-12 score

Fieldwork

Testing validity of the proposed tool using face, content validity by using factor analysis Face validity aimed to inspect the items to determine whether the face of the tools measures what it is supposed to measure. Content validity was conducted to determine whether the tool covered the aim. Validity was tested through a jury of twenty-five experts from the critical and medical-surgical nursing department, faculty of nursing, Ain Shams University, and Anesthesia and critical care medicine, specializing in pain management

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(5 professors in nursing, seven assistant professors and 3lecturers in nursing) and (4 professors, three assistant professors, and three lecturers in anesthesia and critical care medicine). Testing the reliability of proposed tools was done statistically by the alpha Cronbach test.

Pilot study

A pilot study was conducted to test the feasibility and applicability of the study tools used in this study. It was carried out on 10% of the total study subjects (30 patients). Necessary modifications were done for the tools used, and patients included in the pilot study were excluded from the main sample.

Data were collected from October 2021 to March 2022

The researcher visited the study setting three days/a week (Saturday, Tuesday, and Wednesday) and filled the tools in the morning and afternoon shifts. The patients' files were screened for eligibility. The demographic and medical data were obtained from the patient file. The consciousness level of the patient was assessed first by the Glasgow coma scale. Then the patient was assessed for pain intensity for the non-painful procedure (measuring blood pressure) and for the painful procedure (wound dressing and turning) at different observation times.

The pain was assessed twice by a valid and reliable tool (Critical Care Pain Observational Tool) which was taken for 1:3 minutes for each patient, and the developed tool (Mechanically Ventilated Disturbed Consciousness Pain Assessment scale) at the same time (it was taken from 1:3 minutes for each patient).

Data analysis

The data were collected, coded, and analysed with the program (statistical package for social science) (SPSS) under Windows 27. The number and percentage for qualitative variables were done. Quantitative data were presented as mean and standard deviation. ROC curves compare the diagnostic performance of two or more laboratory or diagnostic tests. Sensitivity (with optional 95% Confidence Interval): Probability that a test result will be positive when the pain is present (true positive rate). Specificity (with optional 95% Confidence Interval): Probability that a test result will be negative when the pain is not present (true negative rate). Cohen's kappa coefficient (κ) is a statistic used to measure inter-rater reliability for qualitative (categorical) items and can account for the degree of congruence of measurements that have multiple items on a scale. Cronbach's alpha, α (or coefficient alpha), was used to quantify the degree to which a set of items of the MV-DCPAS measure the same general construct (internal consistency). The chi-square test ($\chi 2$) was used to compare proportions between two qualitative parameters. A test of significance was used and regarding the significance of the result, the observed differences and associations were considered as follows: Probability (p-value)

- Non-significant (NS) $p > 0.05$
- Significant (S) $p < 0.05$

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- Highly significant (HS) $p < 0.001$

Ethical considerations

Ethical approval was obtained from the Scientific Ethical Committee of the faculty of nursing of Ain Shams University before starting the study. The purpose of the study was explained to the patient's guards and oral consent was obtained from them to participate in this study. They assured that anonymity, confidentiality, and the right to withdraw from the study at any time would be guaranteed. Ethics, values, culture, and beliefs were respected.

RESULTS

Table 1: Experts' group opinions regarding the face validity of Mechanically Ventilated Disturbed Consciousness pain Assessment scale (N = 25).

					N	%
Content is comprehensive					25	100
Representative					25	100
Steps are in a logical consequence					25	100
Appropriate					25	100
Accurate					25	100
Clear					25	100
Content is related to objective						
	Agree		**Disagree**		**Agree with modification**	
	N	**%**	**N**	**%**	**N**	**%**
Facial expression	25	100	0	0	0	0
Body movements	24	96	1	4	0	0
Muscle tension	24	96	0	0	1	4
Compliance with the ventilator	23	92	0	0	2	8
Respiratory rate	25	100	0	0	0	0
Oxygen saturation	18	72	7	28	0	0
Heart Rate	23	92	2	8	0	0
Blood Pressure	19	76	5	20	1	4

Values expressed as N: number and % percent

Table 1 shows that all of the expert members (100%) agreed regarding the content validity as it was comprehensive, representative, in logical consequence, appropriate, accurate, and clear. All of them 100% of the experts agreed on assessing facial expression and respiratory rate, 96.0% agreed to assess body movement and muscle tension, 92.0% of them agreed to assess compliance with the ventilator and heart rate 76.0% of them agreed on assessing the blood pressure item. The least element was that 72% of them agreed on the oxygen saturation item.

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Table 2: Internal consistency of Mechanically Ventilated Disturbed Consciousness pain Assessment scale in different stages of all tested procedures

	Alpha score	Interpretation
Turning		
Before	0.913	Excellent
During	0.908	Excellent
After	0.902	Excellent
Wound dressing		
Before	0.910	Excellent
During	0.917	Excellent
After	0.911	Excellent
Blood pressure		
Before	0.902	Excellent
During	0.915	Excellent
After	0.921	Excellent

*0.9 ≤. Excellent. 0.8 ≤ α < 0.9 good. 0.7 ≤ α < 0.8 Acceptable. 0.6 ≤ α < 0.7 Questionable. 0.5 ≤ α < 0.6 poor. α< 0.5 Unacceptable

Table 2 presents that the internal consistency was excellent, with a score that is > 0.9 (Cronbach's alpha) for all procedures; internal consistency achieved the best results during wound dressing and after blood pressure measurement, whereas Cronbach's α = (0.917 and 0.921), respectively.

Table 3: Inter-rater reliability of Mechanically Ventilated Disturbed Consciousness pain Assessment scale and critical care observational tool

	Kappa score	Interpretation
Turning		
Before	0.780	Good
During	0.792	Good
After	0.810	Excellent
Wound dressing		
Before	0.783	Good
During	0.819	Excellent
After	0.791	Good
Blood pressure		
Before	0.801	Good
During	0.779	Good
After	0.800	Good

*>0.81. Excellent. 0.80-0.61 good. 0.60-0.41 moderate. 0.40-0.21poor. <0.021bad

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Table 3 indicates that the interrater reliability of the Mechanically Ventilated Disturbed Consciousness Pain Assessment scale and critical care observational tool revealed a good to an excellent agreement for the developed scale with the Critical Care Observation Tool with a weighted Cohen's kappa minimum of 0.780 to a maximum of 0.819, a k-value larger than 0.6 showed a good correlation.

Table 4: The area under the curve ROC score for the Mechanically Ventilated Disturbed Consciousness pain Assessment scale

	Area	Sig	95% confidence interval	
			Lower	Upper
Turning				
Before	0.881	<0.000	.839	.923
During	0.864	<0.000	.827	.897
After	0.857	<0.000	.818	.874
Wound dressing				
Before	0.824	<0.000	.793	.863
During	0.836	<0.000	.802	.859
After	0.850	<0.000	.820	.883
Blood pressure				
Before	0.833	<0.000	.811	.862
During	0.821	<0.000	.799	.847
After	0.852	<0.000	.824	.893

AUC – area under the ROC curve. CI: confidence interval; ($p<0.05$).

Table 4 reveals that accurate pain detection with the MVDC-PAS was found during the turning procedure (AUC = 0.864; 95% CI 0.827– 0.897), during the wound dressing procedure (AUC = 0.836; 95% CI 0.802–0.859), and during measuring blood pressure procedure (AUC = 0.821; 95% CI 0.799– 0.847). Indicating good discriminative properties and diagnostic efficiency of the MVDC-PAS for pain.

Table 5: The Sensitivity and specificity score for the developed tool (MV-DCPAS) in measuring pain intensity for patients with disturbed consciousness on mechanical ventilation

	Sensitivity	Specificity
Turning		
Before	.796	.660
During	.742	.610
After	.813	.690
Wound dressing		
Before	.761	.630
During	.801	.650
After	.845	.702
Blood pressure		
Before	.820	.681
During	.824	.652
After	.810	.643

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(MV-DCPAS): Mechanically ventilated disturbed conscious pain assessment scale

Table 5 shows the sensitivity score for the developed tool to assess the pain intensity in the disturbed conscious patient on mechanical ventilation was 0.742 during turning (painful procedures), 0.801 during wound dressing (painful procedures), and 0.824 during measuring blood pressure (non-painful procedures). The specificity score was 0.610 during turning, 0.650 during wound dressing and for blood pressure was 0.652.

Table 6: Comparison of Mechanically ventilated disturbed conscious pain assessment scale (MV-DCPAS) and Critical Pain Observation Tool (CPOT) in assessing the pain intensity before, during and after wound dressing.

Wound dressing		Mechanically Ventilated Disturbed Consciousness pain Assessment scale		Critical care observation tool		X^{2*-}	P value
		N	%	N	%		
One minute before	No pain	67	22.5%	66	22.1%	1.013	0.071
	Mild pain	170	57.0%	211	70.8%		
	moderate pain	61	20.5%	21	7.0%		
	Severe pain	0	0.0%	0	0.0%		
During	No pain	0	0.0%	0	0.0%	1.998	0.064
	Mild pain	26	8.7%	24	8.1%		
	moderate pain	62	20.8%	109	36.6%		
	Severe pain	210	70.5%	165	55.4%		
10 minutes after	No pain	22	7.3%	24	8.0%	4.657	0.041*
	Mild pain	117	39.0%	180	60.0%		
	moderate pain	112	37.4%	89	29.3%		
	Severe pain	49	16.3%	5	1.7%		

X2: The chi-square test, Significant (S) $p < 0.05$

(Table 6) shows a similarity in pain intensity assessment ability between the two tools, as there was a statistically non-significant difference between them one minute before, during the most painful procedure (wound dressing), while there was a statistically significant difference between the two tools after 10 minutes of the procedure, as the developed tool (MV-DCPAS) could detect the severe pain intensity level in 16.3% of patients pain compared to 2.3% detected by the COPT, and also can detect moderate pain in 37.4% among patients pain, compared to 29.7% detected by COPT.

DISCUSSION

In the intensive care unit environment (ICU), patients are subjected to several procedures that can be painful, and not always healthcare professionals are alert to pain in these patients, especially those with disturbed conscious levels. Ineffective assessment of pain is associated with negative patient outcomes that can include: an increased need for mechanical ventilation, increased length of hospitalization, and increased mortality. Appropriate pain assessment is an important part of quality care for critically ill patients, and the use of validated measures of pain could aid in evaluating multidisciplinary pain management techniques for nonverbal critically ill patients. This study aimed to develop

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and validate the pain intensity scale for patients with disturbed consciousness on a mechanical ventilator.

The results of the current study show excellent face and content validity, high reliability, high sensitivity, and specificity of the developed scale (MV-DCPAS), all of the experts agree on the face validity of the Mechanically Ventilated Disturbed Consciousness Pain Assessment scale as it was comprehensive, representative, arranged in a logic consequence, appropriate, accurate and clear. Regarding the content validity of the developed scale, the present study findings indicated that most of the jury groups agreed upon all items; this high level of the agreement demonstrates that the new scale items adequately represent the content's universe. The only element that obtained the agreement of less than three-quarters of the experts was oxygen saturation, although this element was added to the developed tool based on an extensive review of literature that supports the idea of the effect of pain on oxygen saturation. This relationship was discussed by Høiseth et al. (2015), who stated that in the presence of pain, tissue oxygen saturation and perfusion index are further reduced by hypovolemia (lower body negative pressure, -60 mm Hg). Thus, pain must be considered when evaluating tissue oxygen saturation and perfusion index as markers of hypovolemia in trauma patients.

Also, it was supported by Tetzlaff (2012), who stated that the direct effects of pain include increased heart rate, stroke volume, and peripheral resistance, which increase myocardial oxygen demand. The increased heart rate decreases diastolic filling time, which can decrease coronary blood flow and oxygen delivery.

Internal consistency reveals an excellent score for painful and non-painful procedures. This high internal consistency provides evidence of the reliability of the MC-DCPAS in detecting pain and determining the pain intensity level efficiently in disturbed consciousness patients on mechanical ventilators.

Reliability and validity are the two most important and essential features in evaluating any measurement instrument or tool for good research. Validity concerns what an instrument measures and how well it does so. Reliability concerns the confidence that one can have within the data obtained from the use of an instrument, that's, the degree to which any measuring tool controls for random error (Hardan, 2017). They are utilized for improving the accuracy of the assessment and evaluation of research work (Tavakol & Dennick, 2011).

The good values for internal consistency for CPOT were illustrated by the Italian version (Cronbach's alpha 0.78) for the nociceptive procedure and 0.86 after the nociceptive procedure (Sulla et al., (2017), the Chinese version (Cronbach’s alpha 0.57–0.86 (Li et al., 2014), the Danish version (Cronbach’s alpha with all scores >0.70, (Frandsen et al., 2016), and the german version (Cronbach's alpha 0.59–0.94 (Kiesewetter et al., 2019).

The Inter-rater reliability testing revealed a good to excellent agreement of the developed scale (MV-DCPAS) with COPT, which indicates a high degree of congruence of measurements between items in the developed scale (weighted Cohen’s kappa of 0.779–

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0.819) of the MVDC-PAS that was also comparable with those reported in previous studies: in the Japanese version for CPOT showed kappa coefficients ranged from 0.48 to 0.94 (Yamada & Ikematsu, 2021). In the German version of the Critical-Care Pain Observation Tool for critically ill adults, the weighted kappa coefficients ranged from 0.54–0.89 (Kiesewetter, 2019).

Our study found that scores of the area under curve ROC of all studied procedures (painful and non-painful) at all stages of observation, the ROC was >0.8, with significantly less than 0.01**, which indicates good discriminative properties and diagnostic efficiency of the developed scale for pain detection. This result was in agreement with (Emsden et al., 2019), whose results concluded that the scores of the area under curve ROC were 0.97 for CPOT. . Also (Li et al., 2014), in a study of Pain Assessment Using the Critical-Care Pain Observation Tool in Chinese Critically Ill Ventilated Adults" found the area under curve ROC was .849 to 0.902.

In our study, the sensitivity was higher than the specificity in all procedures. This implies that the MV-DCPAS is sensitive in identifying pain when the pain is actually present. Although the specificity was also accepted, that mean the developed tool probability detects that a test will be negative when the pain is not present (true negative rate). This result was in agreement with Emsden et al., (2019), whose results concluded that the CPOT has high sensitivity and specificity. This study is congruent with Wongtangman et al., (2017), who found that the Specificity for CPOT 0.847 was higher than sensitivity 0.643.

A statistically non-significant difference between the previously validated tool (COPT) and the newly developed tool (MV-DCPAS) regarding the most painful procedure (wound dressing) before and during the procedure. At the same time, the new tool shows efficiency in detecting the intensity (the moderate and severe pain level) more than the compared tool (COPT) after 10 minutes of the procedure, with a statistically significant difference between the two tools, which was evidence for the concurrent validity for the newly developed tool.

This result was in agreement with a study done by (Shan et al., 2018) who found that non-significant differences were found within the pre-stimulation CPOT and BIS values between the two stimulations. However, all post-stimulation values were significantly higher after suctioning than after touching.

CONCLUSIONS

A valid pain assessment tool is important for pain detection and management in critically ill patients, especially those with disturbed conscious levels. This study shows excellent face and content validity, high reliability, high sensitivity, and specificity of the developed scale (MVDC-PAS) to detect pain in a patient on a mechanical ventilator with disturbed consciousness.

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RECOMMENDATIONS

Recommend the tool to determine the pain intensity for mechanically ventilated disturbed conscious patients. Training of nurses on the developed tool is also recommended. The study should be replicated on a large probability sample and in different hospital settings to generalize the results. Replication of the current study on non-surgical patients is recommended to achieve generalization of the results, moreover, on sedated and analgesic patients.

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Author's contribution

All authors (NME, SYM, AMH, SFM) contributed to the study conception, design, data analysis, preparation, and revision of the manuscript.

Conflict of interest

The authors declare no conflicts of interest.

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