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The Effect of Implementation of a Pain Monitoring Protocol on the Pain Intensity in the Intensive Care Unit Semiconscious Patients

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Abstract

Background: Neglecting the pain assessment in intensive care unit (ICU) patients with decreased level of consciousness (LOC) can lead to inappropriate pain management. Implementation of a pain management protocol may contribute to avoiding such negligence.

Aim: This study aimed to determine the effect of using a pain monitoring protocol on the pain intensity of ICU patients with decreased LOC.

Method: This clinical trial was conducted on 60 nurses and 120 patients in the surgical ICUs of Imam Reza and Ghaem hospitals, Mashhad, Iran, 2016. The nurses in the intervention group were trained about pain management protocol in three 20-minute sessions (each session for 10 nurses). Before and after two weeks of training, the patients' pain intensity was monitored using the Nonverbal Pain Scale (NVPS) for three months during the resting-state, suctioning, and dressing change. The patients in the control group received routine nursery care. Data analysis was performed using independent and paired t-tests in the SPSS software version 22.

Results: The nurses in the intervention and control groups had a mean age of 38.1±6.4 and 41.2±7.1 years, respectively. The results of independent t-test demonstrated no difference between overall pain intensity (P=0.08), pain intensity during resting-state (P=0.11), suctioning (P=0.23), and dressing change (P=0.06) scores among two groups before the intervention, however after the intervention, there was a significant reduction in the intervention group in comparison to the control group in all mentioned aspects (P<0.001)

Implications for Practice: It was found that a satisfactory prediction of pain intensity during resting-state and painful procedures is obtained by using a pain management protocol, which enables the nurses to address the underlying causes of the pain and provide the necessary cares.

Keywords: Decreased consciousness, ICU, Pain intensity, Pain management

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Introduction

Pain as a mental state that cannot be expressed by anyone except the individual who experiences it, is a problem of almost all intensive care unit (ICU) patients. As a result, pain management in the intubated ICU patients with decreased level of consciousness (LOC) who cannot express their feelings is a difficult task, which can be neglected by physicians and nurses (1, 2).

Several characteristics of intensive care such as mechanical ventilation, LOC observation, and sedative administration make the patient unable to verbally communicate with the healthcare staff, which makes it extremely difficult to assess the patients' pain intensity. Consequently, instead of overlooking the pain, it is essential to carefully assess and manage it in patients with decreased LOC.

Certainly, unconscious patients have no perception of pain; therefore, a nurse may overlook a patient due to misestimating of the patients' pain intensity as a result of inadequate knowledge as to the appropriate pain assessment (1, 2). Insufficient pain assessment and management in the patients with decreased LOC increase their mortality rate.

A distressing issue is that 64% of these patients do not receive any medication before and during the painful procedures (3, 4). Further, 33% of intubated ICU patients experience pain and its prevalence during several procedures may increase up to 56% (1). According to another evidence, 63% of ICU patients might experience various degrees of pain (5).

Recently, the American Pain Society has described pain as the fifth vital sign (6). Pain assessment and documentation are primary stages of nursery and are as valuable as vital signs, because understanding the patient's pain provides the necessary insight to improve the treatment and patient condition (7). The American Society for Pain Management Nursing suggests that a pain measurement tool may be beneficial for those patients who cannot verbally express their feeling (8).

Proper pain assessment and management lead to decreased length of stay in ICU, duration of intubation, and subsequently the number of hospital-acquired complications (9, 10). To make fairly accurate pain intensity estimation, a simple and consistent assessment procedure must be regularly performed using a specialized and standardized pain assessment instrument (11, 12).

Regarding the literature, physicians prescribe drugs to alleviate pain in more than 89% of cases as a result of absence of an effective protocol to assess the causes and intensity of pain (9). In Iran, the clinicians used to prescribe as-needed (PRN) analgesics and delegate the task of time of need to the nurses, who administer the medicines without applying any pain assessment instrument. Accordingly, the Iranian patients with verbal communication problems are likely to be deprived or overridden of the proper pain management services (7).

The majority of previous studies in this field concentrated on efficacy of available pain assessment and management tools (13, 14). The communication problem of patients with decreased LOC necessitates proper access to effective behavioral scales for pain assessment such as Behavioral Pain Scale (BPS), Critical-Care Pain Observational Tool (CPOT), Face, Leg, Activity, Cry, Consolability (FLACC) for neonatal pain assessment, and NVPS (Nonverbal Pain Scale) for assessing the pain of critically ill ICU patients with impaired communicative abilities (15, 16).

In Iran, providing a pain management protocol for intubated patients is essential to enable the nurses to assess the causes of pain in patients before administration of analgesics and sedatives. Implementation of such protocol is particularly important in ICUs, where common causes of pain include incorrectly-applied compression bandages, tracheal tube cuff pressure, uncomfortable position of the patients' body, cuff of tracheostomy tube, and immobility. It is important to eliminate the causes of pain in the patients rather than administering high doses of medicines.

A pain management protocol which can cover such issues allows nurses to identify the source of discomfort, particularly in the cases where analgesics are ineffective, and eliminate the pain without administration of extra medicines. To determine the importance of pain management in the intubated nonverbal patients, this study sought to evaluate the effect of pain management protocol on the patients' pain intensity.

Multiple factors affect the pain management for ICU patients, commonly, the post-surgical pain and the trauma or condition that led to surgical operation, are the most reasons of pain among these patients [17]. Furthermore, immobility, patient's positioning and fixation, pressure of life-support devices on the patient's sensitive body parts, long term drainage, and inappropriate functioning of drains and catheters can cause pain in these patients.

It is a typical practice to alleviate the aforementioned pains by administration of analgesics without

adequate knowledge about the relevant etiologies. Systematic pain management of ICU patients can play a crucial role in reducing complications and hospitalization duration, as well as improving the curse of recovery and the patients' quality of life (18, 19).

The nurses should be able to accurately estimate the patient's pain intensity to provide a proper care. Pain has a subjective nature; thus, it is difficult to assess and estimate its intensity. Obviously, any misestimation negatively affects the effective pain relief (20, 21). Additionally, commonly administered sedatives have physical and mental adverse effects such as addiction, hypotension, depressed vital functions, drowsiness, nausea, vomiting, and even shock, which have significant expenses for the healthcare system (22).

Regarding the literature, assessment instruments have been exclusively used to determine the presence and intensity of pain while there is no pain management protocol to investigate the causes. Such protocol allows the nurses to identify the causes of these pains, which are unresponsive to analgesics, and soothe the patient's pain and discomfort following the intensive treatment. After confirmation of this protocol effectiveness, it could be promoted to improve the pain management performance in ICUs and mitigate the unpleasant experience of hospitalization in these units on a large scale.

Given the importance of pain management in intubated nonverbal patients, this study aimed to evaluate the efficacy of a pain management protocol with the ability to cover secondary causes of pain in surgical ICUs.

Methods

A parallel designed clinical trial was conducted on 60 nurses and 120 patients with decreased LOC under their care in surgical ICUs of Imam Reza and Ghaem teaching hospitals, Mashhad, Iran. The subjects were selected by convenience sampling method. The sample size (n=30 per group) was determined through a pilot study on 20 subjects (n=10 per group) based on the differences between means of two groups (control group: 6.1±3.2 and intervention group: 3.9±2.8) with 95% confidence interval and test power of 80%.

The surgical ICUs of Ghaem and Imam Reza teaching hospitals were randomly considered as control and intervention ones, respectively. The number of selected patients from both ICUs was equal considering the similar conditions of two ICUs in terms of number and condition of the patients and personnel.

The included nurses had a bachelor's degree in nursing or higher with more than one year of work experience in ICU, and those who were transferred to other wards, travelled, or were affected by stressful life events such as death of a close family member or severe financial problems were excluded.

After obtaining an informed consent from the patients' first-degree relatives, those ICU patients who were disabled to communicate and aged more than 18 years with the Richmond Agitation Sedation Scale (RASS) score of 2-3 within the first 72 hours were included in the study. Furthermore, they should have not received any relaxants.

Those patients who underwent cardiopulmonary resuscitation, their LOC changed, received relaxants and continuous infusion of sedatives, as well as those in whom the tracheal tube was removed were excluded from the study. Furthermore, the exclusion criteria comprised of having sepsis, hypovolemic or hemorrhagic shock, cardiac dysfunction (confirmed by a cardiologist), and any arrhythmia affecting the cardiovascular function or inducing hemodynamic instability such as ventricular tachycardia (VT) and atrial fibrillation (AF) with rapid ventricular response, as well as the denial of the patient's family.

The pain intensity of those patients who were admitted to the ICU in at least 24 hours and at most 72 hours was evaluated by Nonverbal Pain Scale (NVPS) during resting-state, dressing change, and suctioning. The nurses in the intervention group were instructed in 15-20-minute sessions held by the researcher about the NVPS, pain management protocol, and how it must be followed to investigate the cause of pain in unconscious ICU patients. Each session was held for seven to ten nurses at the research site. After each session, their questions were answered and the pain management protocol and NVPS sheets were distributed.

Data was collected using the demographic data form (consisted of five questions about the nurses' personal and occupational information and prepared and filled by the researcher) and the NVPS

(validity and reliability of which were confirmed by Marmo in 2010 and Wysong in 2014) (23, 24).
The NVPS consists of five dimensions of face, activity, guarding, physiological indicators (blood pressure and heart rate), and respiratory rate. Each dimension ranges from 0 (minimum pain) to 2 (maximum pain). The total pain scores of 0-2, 3-6, and 7-10 represent no, moderate, and severe pain, respectively.
The NVPS was translated into Persian by a linguist and edited by a specialist. Afterwards, its content validity was revised by 10 members of Faculty of Nursing and Midwifery of Mashhad University of Medical Sciences, Mashhad, Iran; and the reliability of the scale was confirmed by inter-rater agreement (r=0.8).
The pain management protocol for surgical ICU patients with decreased LOC is provided by the researcher to determine the pain intensity and its relevant biological mechanisms using the NVPS. In this protocol, it is essential to check all the patients with physiological and behavioral signs by the NVPS to determine the presence and intensity of pain. After identifying the cause of pain, the pain intensity must be reevaluated and this process should be continued until the pain subsides.
Since the pain is rarely limited to the surgical site and may involve the other organs, this protocol gives priority to the factors concerning the nursing care to prevent unnecessary sedation. The content validity of this protocol was confirmed by review of latest relevant publications and consultation with 10 faculty members and clinical experts.
The nurses were asked to respect the protocol and use NVPS to detect, measure, and manage the pain in their ICU patients. The nurses in the intervention group received two weeks of theoretical and practical instructions about the protocol and NVPS. Then, the protocol was fully implemented for three months under supervision of the researcher. Regular inspections were performed in the mornings and evenings to be ensured that the nurses follow the pain management protocol.
The patients in control group received routine nursery and medical care, in which the patients with low LOC were not subjected to any pain assessment and painful procedures such as suctioning and dressing change were not performed with sedation; however, to demonstrate the patient's resistance to ventilator, catheters, and intubation, PRN medications as restraint chemicals were to be administered. The nurses in this group were not instructed about pain management procedures. The pain intensity in the control group was measured using the NVPS. The pain intensity of the patients in both groups was measured during resting-state, dressing change, and suctioning by NVPS for three months.

Data analysis performed by applying independent t-test (to compare the quantitative variables such as age, work experience, and pain intensity between two groups), Chi-squared (to compare the qualitative variables), paired t-test (to compare pre- and post-intervention results of each group) with 95% confidence interval, and Mann-Whitney U test in SPSS software version 22. In all the measurements, the P-value less than 0.05 was considered statistically significant.

An informed consent was obtained from a patient's first-degree relative and they were assured of the confidentiality of the collected information. Prior to the study, the research plan was reviewed and confirmed by Khorasan's regional committee for medical and health research ethics, Mashhad, Iran, and an introduction letter was issued and sent to the authorities at the site of research. After coordination with authorities and personnel, the researcher attended the hospitals and chose the research units. This trial is registered and approved in Iranian Registry of Clinical Trials (IRCT Code: IRCT2016062526113N1).

Results

Out of 60 nurses participated in this study, 21 (70%) and 20 (66.7%) nurses, who assigned to the control and intervention groups were women, respectively. The mean age of nurses in the intervention and control groups was 38.1±6.4 and 41.2±7.1 years, respectively (P=0.08). Their mean work experience was 9.0±3.6 and 8.7±2.7 years, respectively (P=0.71). All the nurses in the control group and 96.7% of them in the intervention group had a bachelor's degree in nursing.
The mean and standard deviation (SD) of the patients' ages were 50.7±11.1 and 47.8±13.5 in the intervention and control groups, respectively. The results of applying independent t-test revealed no significant difference between the groups in terms of patients' age (P=0.36). On the other words, the groups were homogeneous in this respect. Prior to the intervention, the mean time of staying in ICU

was 45.6±15.2 and 38.8±14.7 hours, while after the intervention it was 47.2±14.8 and 44.0±15.5 hours in the control and intervention groups, respectively.

According to the results of Mann-Whitney U test, there was no significant difference between the groups in terms of mean length of staying in ICU (P=0.40). It is worth mentioning that, 86.7% and 96.7% of the patients in the intervention and control groups had tracheal tube, respectively, and the rest had tracheostomy tubes. According to the RASS, 76.7% and 70% of the patients in intervention and control groups had a LOC of 2. The Chi-squared and independent t-test demonstrated no significant difference in terms of the frequency and mean of aforementioned variables between two groups (P=0.56; Table 1).

Table 1. The demographic characteristics of nurses and patients

Variable	Group				P-value
	Intervention		Control		
	Frequency	Mean±SD	Frequency	Mean±SD	
Age of nurses (years)	30	38.6±1.4	30	41.7±2.1	P=0.08
Work experience of nurses (years)	30	9.0±3.6	30	8.7±2.7	P=0.71
Age of patients (years)	60	47.8±13.5	60	50.7±11.1	P=0.36
Patients' ICU length of stay (hours)	30	44.0±15.5	30	47.2±14.8	P=0.40
Patients' LOC** (RASS***)	Frequency (%) 23 (76.7) 7 (23.3)	Score -2 -3	Frequency (%) 21 (70.0) 9 (30.0)	Score -2 -3	P=0.56
Patients' way of inhalation	26 (86.7) 4 (13.3)	Tracheal tube Tracheostomy	29 (96.7) 1 (3.3)	Tracheal tube Tracheostomy	P=0.35

* Mean and Standard deviation, ** Level of consciousness, *** Richmond Agitation and Sedation Scale

Prior to the intervention, the mean pain intensity score was 7.2±0.7 and 6.9±0.7 in the control and intervention groups, respectively. The results of t-test revealed no significant difference between these scores among the groups (P=0.16). Nevertheless, after the intervention the results of t-test demonstrated that the mean pain intensity score significantly reduced in the intervention group (3.2±0.6) in comparison to the control group (7.2±0.7; P<0.001).

Applying the paired t-test in the control group showed no significant difference in terms of means of baseline and final pain intensity scores (P= 0.85), whereas in the intervention group, the mean of post-intervention pain intensity score was significantly low (P<0.001; Table 2).

In addition to the overall pain intensity score, the subscales of this score during resting-state, suctioning, and dressing change were investigated. According to the results of independent t-test, at the pre-intervention stage, there was no significant difference between the groups in terms of mean score of pain intensity during resting-state, suctioning, and dressing change (P>0.05); nonetheless, after the intervention, the mean score of pain intensity during resting-state was significantly lower in the intervention group (2.6±1.1) in comparison to the control group (5.1±1.3; P<0.001). Moreover, significant differences were observed in the final scores of pain intensity during suctioning (4.1±1.1

Table 2. Pre- and post-interventional pain intensity scores in the intervention and control groups

Stage	Pain intensity	Intervention group Mean ± SD* (n=30)	Control group Mean ± SD (n=30)	Inter-group analysis with independent t-test
	Pre-intervention	6.9±0.7	7.2±0.7	P=0.16
	Post-intervention	3.2±0.6	7.2±0.7	P<0.001
Intra-group analysis with paired t-test		P<0.001	P=0.85	

* Mean and Standard deviation

Table 3. Pre- and post-interventional pain intensity scores during resting-state, suctioning, and dressing change in the intervention and control groups

		Intervention group Mean ± SD* (n=30)	Control group Mean ± SD (n=30)	Inter-group analysis with independent t-test
Pre-intervention	During resting-state	4.5±0.9	5.3±1.0	P=0.11
	During suctioning	8.6±0.9	8.3±0.8	P=0.23
	During dressing change	7.7±1.3	8.3±1.1	P=0.06
Post-intervention	During resting-state	2.6±1.1	5.1±1.3	P<0.001
	During suctioning	4.1±1.1	8.4±0.9	P<0.001
	During dressing change	3.1±1.0	8.2±0.9	P<0.001
Intra-group analysis with paired t-test	During resting-state	P<0.001	P<0.001	
	During suctioning	P<0.001	P<0.001	
	During dressing change	P<0.001	P<0.001	

* Mean and Standard deviation

Table 4. The results of two-way ANOVA for the mutual effect of variables on the post-interventional pain intensity scores of ICU patients

Variable	Mutual effect	Effect of variable	Effect of group	Overall effect
	P–value	P–value	P–value	P–value
Age of nurses	0.18	0.54	P<0.001	P<0.001
Gender of nurses	0.10	0.66	P=0.04	P=0.01
Work experience of nurses	0.50	0.57	P<0.001	P<0.001
Patients' LOC*	0.94	0.21	P<0.001	P<0.001
Airway type (patients)	0.64	0.21	P=0.01	P=0.01

* Level of consciousness

and 8.4±0.9 in the intervention and control groups, respectively; P<0.001) and dressing change (8.2±0.9 and 3.0±1.0 in the intervention and control groups, respectively; P<0.001; Table 3).

According to an intra-group analysis of the control group, there was no significant difference in the mean scores of pain intensity during resting-state, suctioning, and dressing change before and after the study (P>0.05); however, the same analysis in the intervention group demonstrated a significant reduction in these scores (P<0.001; Table 3).

Two-way analysis of variance (ANOVA) represented no significant relationship between the nurses' demographic variables including age, gender, and work experience, and the patients' LOC and inhalation methods and the final pain intensity scores in both groups (P<0.05; Table 4).

Discussion

Regarding the results of this study, the ICU patients with decreased LOC, whose nurses were trained to employ pain management protocol, had 53.3% lower pain intensity scores in comparison to the control group. Topolovec-Vranic et al. performed a study in 2010 to evaluate pain assessment and management using NVPS and detect the pain severity during the painful procedures. They concluded that pain intensity was reduced from 55% to 35% by drug administration. These results were consistent with our findings although the pain reduction was higher in our study (1).

Consistent with our study, a study conducted by Marmo et al. in 2010 on pain assessment in the critically ill post-open heart surgery patients, the NVPS enabled 78% and 79% of the nurses to detect pain during suctioning and repositioning, respectively (23). In accordance with this study, Payen et al. conducted a study in 2007 on sedation and pain alleviation techniques for critically ill intubated patients, which reported that pain is felt in 30% of intubated ICU patients during resting-state (25).

Although the mean pain intensity score during the resting-state for 120 ICU patients was 4.9 out of 10 in the current study, Al Sutari et al. in 2014 determined this value among 301 ICU patients as 3 out of

10. The aforementioned results were in line with our study in terms of presence of pain; nonetheless, there was a disagreement in terms of intensity of pain. This inconsistency might be due to different studied units; as Al Sutari et al. study was conducted on the patients of general surgery, heart surgery, and neurosurgery departments (26).

Prior to the intervention, 90% of the patients in both groups had moderate pain intensity during the resting-state. However, after the intervention the final score of pain intensity during resting-state was 42% lower in the intervention group in comparison to the control group. In the study of Chanques et al. in 2007, pain is felt in 49% and 41% of trauma and medical ICU patients during resting-state, respectively.

The medical patients feel more pain due to immobility and their pain is located in the limbs and back. Our results are consistent with this report in terms of presence of pain during the resting-state, but not in terms of its intensity. This incontinency might be due to lack of any established pain management protocol in the selected ICUs (27).

In this study, prior to the intervention, all the patients had severe pain during suctioning; however, after the intervention, the pain intensity during suctioning was 53% lower in the intervention group in comparison to the control group. This is consistent with the results of Gelinas et al. study in 2007, which demonstrated that 65% of intubated hearth surgery patients in ICU experienced moderate to severe pain during suctioning (28).

In congruence with our study, Topolovec-Vranic et al. in 2013 showed that the mean pain intensity during suctioning was elevated by 21.6% (29). Furthermore, Payen et al. in 2007 reported that 56% of the subjects had severe pain during suctioning (25). Likewise, in a study by Arroyo-Novoa et al. in 2008, the majority of their patients (93%) had moderate to severe pain during common ICU procedures such as suctioning (as a truly painful procedure), drain extracting, and repositioning (30).

Given the results of this study, there was a significant enhancement in pain intensity of ICU patients during painful procedures. It is consistent with the results of Brocas et al. study in 2002, who determined a significantly higher mean pain intensity scores in the patients who did not receive any analgesic before painful procedures such as suctioning (31). In the present study, the mean pain intensity score during suctioning in 120 ICU patients was 8.45 out of 10.

This value was 6 in 301 ICU patients selected in Al Sutari et al. study in 2014. These results were consistent in terms of elevated pain intensity, but not in terms of magnitude of the elevation. This disagreement might be because of the studied patients, who included general surgery, heart surgery, and neurosurgery patients (26). Al Darwish et al. in 2016 investigated the utility of three pain assessment tools, namely BPS, CPOT, and NVPS, through a clinical study on 47 unconscious intubated patients. In the mentioned study, 60% of the patients received a combination of fentanyl and midazolam, and the rest did not receive any sedatives. They detected a significant difference in pain intensity during suctioning and resting-state by using NVPS ($P<0.001$). The patients of the mentioned study received sedatives; therefore they had lower levels of pain intensity (32).

Given the results of this study, prior to the intervention, 86.7% of all the participated patients had severe pain during dressing change; nonetheless, at the end of the intervention the pain intensity was 61% lower in the intervention group in comparison to the control group. To the best of our knowledge, there were a few studies regarding this subject. Pardavila et al. in 2011 reported that 40% of their subjects had been suffering during painful procedures such as dressing change, which was consistent with our results in terms of elevated pain during this particular procedure (33).

Moreover, Linde et al. in 2013 reported an increase in the mean pain intensity during painful procedures such as dressing change, even in patients who received analgesics and sedatives (17% and 30% of the patients received analgesic and sedatives, respectively). It was consistent with our study in terms of elevated pain intensity, but those patients experienced pain despite of medication administration, which probably implies the insufficient use of sedatives and inadequate pain management (34).

Despite our efforts to remove or control the effect of confounding variables, several factors such as the effects of other sources and media on research units were beyond our control.

Implications for Practice

Given the similarity of control and intervention groups in all aspects except for the use of pain management protocol, the difference in patients' final pain intensity scores could be due to use of this protocol. As a result, this protocol improved the patients' pain management during the resting-state

and painful procedures. Therefore the promotion of this protocol could contribute to efficacy of pain relieving efforts for nonverbal ICU patients. It seems that sensitizing the nurses to the presence of pain in nonverbal patients and enhancing their ability to detect and address such unexpressed discomfort could be a constructive step towards improving the performance of nursing staff in detecting, controlling, and mitigating pain intensity in all patients. Ultimately, further studies on the effect of this pain management protocol on the overall performance of nurses are recommended.

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Conflicts of Interest
The authors declare that there is no conflict of interest regarding the publication of this article.

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