ORIGINAL ARTICLE

Pain monitoring in intensive care: How does the nociception level index affect treatment and prognosis? A randomized, controlled, double-blind trial

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ABSTRACT

BACKGROUND: Effective pain management is vital in critical care settings, particularly post-surgery. Clinicians should maintain objective and efficient standards to assess pain in a patient-centered manner, in order to effectively manage this complex issue. A newer technology, the nociception level (NOL) index, shows promise in achieving this task through its multi-parameter evaluation.

METHODS: This study was a prospective, controlled, randomized trial involving two groups of patients (n=30 each) in a diverse intensive care unit. Participants were over 18 years old with American Society of Anesthesiology scores ranging from I to III and were scheduled for critical care follow-up after general anesthesia. All subjects followed a standard analgesia protocol that included rescue analgesia. Drug administration was guided by a numeric rating scale and the critical care pain observation tool in the Control Group, while it was guided by nociception level index monitoring in the NOL Group.

RESULTS: Pain scores between the two groups did not significantly differ. However, within the NOL Group, pain scores and nociception values displayed a strong positive correlation. Notably, total analgesic consumption was significantly lower in the NOL Group (p=0.036).

CONCLUSION: Monitoring pain using the nociception level index is an effective method for detecting pain compared to standard pain scores utilized in critical care. Its guidance facilitates personalized analgesic titration. Additionally, the potential of nociception level index guidance to reduce the duration of intensive care and hospital stays may be linked to its effects on delirium, a connection that awaits further exploration in future studies.

Keywords: Behavioral pain scores; delirium; nociception level index; pain monitoring; postoperative cognitive dysfunction; postoperative pain.

INTRODUCTION

Patients in the intensive care unit (ICU) are frequently subjected to painful stimuli. Pain in the ICU can have multifocal causes, not only stemming from disease-related factors such as critical illness symptoms or postoperative surgical pain, but also from treatments (e.g., endotracheal tube, drainage tubes, catheters) and routine care procedures (e.g., blood collection, patient positioning).[1] Inadequate pain management can significantly worsen clinical outcomes in the ICU. The exacerbation of pain can amplify the stress response, leading to hemodynamic and respiratory instability, which worsens the underlying pathophysiology and negatively impacts mortality and morbidity.[2] Furthermore, studies on the neuroimmune interaction of pain have demonstrated that while activated immunity can induce pain, pain itself can also cause immunosuppression.[3] Long-term effects of pain-related psychological stress can include persistent pain, sleep disturbances,

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delirium, and both acute or chronic cognitive impairments.[3,4] Effective pain management in the ICU is associated with better wound healing, shorter weaning times, reduced ICU stays, and improved quality of care.[3] Although pain in the intensive care unit is a multidimensional issue with significant consequences, the subjective nature of the pain experienced by patients makes it challenging to address with a single standard approach.[5] Therefore, it is crucial to provide individualized care and tailor pain monitoring strategies in intensive care.

In standard ICU settings, pain management typically employs pain intensity scales (e.g., Numeric Rating Scale (NRS)) for patients who can self-report, and observational behavioral scales (e.g., Critical Care Observation Pain Tool (CPOT)) for those who cannot.[6] However, for patients who are neither able to self-report nor express behavioral signs of pain, such as those who are deeply sedated or non-communicative, reliable monitoring methods are necessary.

Nociception monitors have been developed and are currently utilized for this purpose.[6] The nociception level (NOL) index represents a new generation of electrophysiological devices designed to assess pain-related nociception, distinguishing itself through its multi-parameter evaluation.[7] The NOL index is derived from five parameters: heart rate, heart rate variability, skin conductance level, photoplethysmography waveform amplitude, and the number and time derivatives of skin conductance fluctuations. Beyond pain monitoring, the NOL system can facilitate targeted analgesic titration in the ICU, as recommended by recent guidelines.[4] Thanks to its multi-parameter design, the NOL may also help differentiate individual perceptions of nociplastic pain.[3,7] Furthermore, contemporary pain assessment technologies are advised to supplement subjective and behavioral pain scales in the ICU as a validated component of the ABCDEFGHI bundle for delirium protection.[8] Based on these hypotheses, employing NOL guidance as a pain management tool could probably significantly impact treatment outcomes and prognosis in ICU practice.

Thus, our study aims to evaluate pain management under NOL guidance, focusing on the use of postoperative analgesics in intensive care follow-up and treatment, as well as the length of stay in the intensive care unit. Additionally, we investigated the potential effects of NOL on delirium.

MATERIALS AND METHODS

Study Design and Setting

Following approval by our Institutional Ethics Committee (dossier no: 212-2022), we conducted a double-blind prospective study involving 60 patients (2 groups; 1:1 allocation; n=30). Eligible patients were those who underwent general anesthesia for major surgery and required postoperative follow-up in the ICU for at least 24 hours as per our institutional protocol, to manage potential surgery-related complications. Inclusion criteria encompassed patients aged 18 and over with American Society of Anesthesiology (ASA) scores of I to III. We excluded patients from the study for several reasons: those who declined to participate; individuals with concurrent organ failures, particularly lung failure as indicated by a partial pressure of oxygen/fraction of inspired oxygen (PaO2/FiO2) ratio below 200; those with histories of allergies to the drugs used in our study protocol; patients undergoing deep anesthesia, characterized by a Richmond Agitation-Sedation Score (RASS) of -2, meaning they could not be awakened by loud sounds; individuals expected to have a low postoperative Glasgow Coma Score (GCS) due to head trauma; and patients experiencing surgical complications, arrhythmias, or sepsis during their hospital stay. We also excluded patients who required procedures associated with high pain intensity, such as chest tube removal, wound drain removal, endotracheal suctioning, frequent repositioning, and blood sampling (1). This study adhered to the Declaration of Helsinki, and written informed consent was obtained from all participants prior to surgery. The study was registered at ClinicalTrials.gov (NCT05762666). The progression of the study was illustrated using the Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Fig. 1).

Randomization

Randomization was achieved through a computer-generated algorithm at a 1:1 ratio, resulting in two groups: the NOL Group and the Control Group (n=30 each). Each group's allocation was sealed in opaque envelopes. On the day of the surgery, if the inclusion/exclusion criteria were satisfied, the anesthetist in the operating room selected one envelope to implement the designated protocol for each group. Data collected during the clinical follow-up were recorded by informed nurses in the ICU and by an independent anesthesiologist who was blinded to the group assignments. This anesthesiologist also assessed all post-surgical evaluations in the wards, focusing particularly on delirium and total analgesic use by the end of the ICU stay.

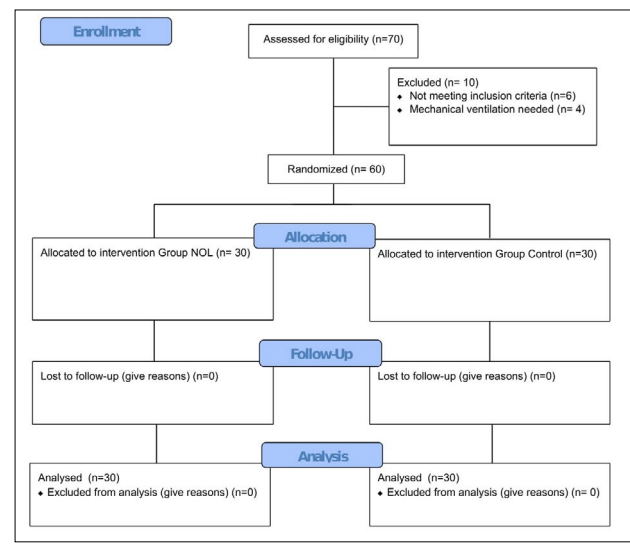

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the study.

Standardization

All patients adhered to a uniform intraoperative analgesia plan, receiving 2 mcg/kg of fentanyl without any monitoring of pain, and a standard postoperative analgesia regimen beginning immediately after surgery. This included 1 gram of paracetamol every six hours (with a maximum of four doses daily) and rescue analgesia of 1 mg/kg tramadol, also limited to four doses daily every six hours. If pain relief was inadequate, additional intervention of 0.05 mg/kg morphine intravenous (IV) boluses were administered based on elevated pain scale readings (NRS>4; CPOT>2; NOL>25 over 1 minute) or at the patient's request. ICU nurses evaluated pain using NRS and CPOT scales at 6, 8, 12, and 24 hours postoperatively, correlating these with NOL values at specific time points. The Control Group underwent standard monitoring, using pain scales, and received rescue analgesia based on these assessments.

Intervention

The experimental group (the NOL Group) was monitored postoperatively using only NOL values throughout their ICU stay, while also receiving rescue analgesia guided by these NOL values alongside traditional pain scales. Trained nurses administered the analgesia protocol when NOL values exceeded 25 for at least one minute. Additional analgesia was administered if NOL values were elevated outside these specified intervals.

Primary Outcome

The primary outcome was the total amount of analgesic consumption during the ICU stay, recorded before discharge.

Secondary Outcomes

The study investigated the correlation between reference pain assessment tools (NRS, CPOT) and NOL values. Additionally, delirium was assessed at the 24th hour before discharge using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) score and by the 4 'A's Test (4AT) at the surgical ward on the third postoperative day before hospital discharge. Additionally, to evaluate the potential secondary effects of NOL monitoring on patient prognosis, we compared the length of stay in the intensive care unit and the total hospital stay between the groups.

Statistical Methods

The primary endpoint was the total analgesic consumption during the ICU stay. The study was powered to detect a difference in this primary endpoint, but not in pain assessment tools. The required sample size was calculated using the

Table 1. Demographic and medical data of the study population

	Group NOL* (n=30)	Group Control (n=30)	p-value
Age (years) (median, range)	63.5 (20-80)	63.0 (24-84)	0.68
BMI (kg/cm²) (median, range)	26.8 (19.7-42.5)	27.27 (18-52.7)	0.71
ASA Status (I / II / III) (number)	4 / 13 / 12	10 / 14 / 7	0.11
Comorbidities** (number)			
Hypertension	13	11	
Diabetes Mellitus	4	10	
Coronary Artery Disease	8	11	
Cancer	1	8	
Epilepsy	2	-	
Respiratory Disease	9	6	
Chronic Renal Failure	2	3	
Type of Surgery (number)			0.28
Orthopedic	3	4	
Neurosurgery	13	10	
General Surgery	8	9	
Urologic	1	3	
Otorhinolaryngologic	5	4	
Length of Surgery (minutes) (median, range)	120 (20-607)	240.5 (69-510)	0.001***
Length of Hospital Stay (days) (mean, standard deviation)	10.03 (5.49)	15.23 (14.37)	0.016***
Length of ICU Stay (days) (mean, standard deviation)	1.07 (0.25)	1.23 (0.43)	0.01***
APACHE II Scores	8.3 (8)	8.7 (8)	0.51

*NOL: Nociception Level; **Comorbidites that were diagnosed and under treatment; ***p<0.05.

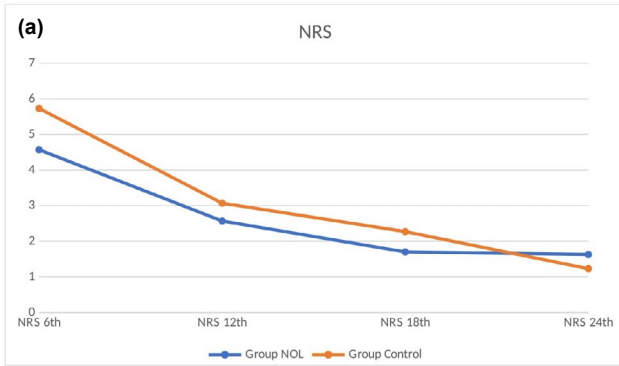

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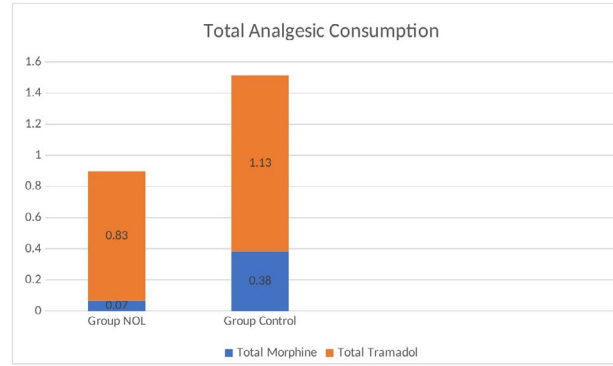
Figure 2. (a) Comparison of Numeric Rating Scale (NRS) scores between groups. **(b)** Comparison of Critical Care Observation Pain Tool (CPOT) scores between groups.

G*Power 3.1 analysis program, based on a study anticipating a 25% reduction in total analgesic consumption (8). The effect size was derived from preliminary clinical observations of mean daily morphine consumption to alleviate postoperative pain, targeting a power of 90% and a significance level of 8%. It was determined that a minimum of 24 patients per group was necessary to achieve statistical significance. To account for potential dropouts, we included 60 patients in the study. Statistical analyses were conducted using IBM SPSS (Statistical Package for the Social Sciences) Statistics for Windows (Version 26.0; IBM Corp., Armonk, NY, USA). Demographic variables such as age, Body Mass Index (BMI), ASA status, and length of surgery were not normally distributed, as indicated by the Shapiro-Wilk Test ($p<0.05$) and kurtosis and skewness indices exceeding ±2. Consequently, the Mann-Whitney U test was employed for analysis. Comparisons of normally distributed values (NRS, CPOT, and NOL; total tramadol and morphine consumption; lengths of hospital and ICU stays;



Values of graphic were given with mean; morphine as mg and tramadol as per times of 1 mg/kg administration.

Figure 3. Comparison of total tramadol and morphine consumption between groups.

4AT and CAM-ICU assessments) were analyzed using independent sample T-tests. Correlations were examined using Pearson's tests for parametric variables such as CAM-ICU and 4AT, and Spearman's tests for nonparametric variables such as NRS, CPOT, and NOL.

RESULTS

Characteristics of Study Subjects: The distribution of age, BMI, ASA status, Acute Physiology and Chronic Health Evaluation II (APACHE II) scores, and type of surgery were consistent across all groups. Notably, the length of surgery was significantly shorter in the NOL Group. Additionally, the lengths of hospital and ICU stays were significantly reduced in the NOL Group (Table 1).

Primary Outcome: No significant differences were observed in CPOT and NRS scores between the groups, except at the 18th hour, where both CPOT and NRS showed significant differences ($p=0.026$ and $p=0.027$, respectively) (Fig. 2). Upon examining the correlations between NRS and CPOT with NOL values within the NOL Group, a strong positive correlation was noted at each hour (Table 2).

However, as the primary outcome of the study, the total analgesic consumption during the ICU stay was found to be significantly different between groups in terms of morphine consumption ($p=0.036$). Tramadol consumption was lower in the NOL Group ($p=0.065$) (Fig. 3).

Secondary Outcome: There were no significant differences between groups concerning CAM-ICU and 4AT scores ($p=1$; $p=0.138$). Furthermore, correlations between NOL values

Table 2. Correlations between NRS and CPOT with NOL values

	NOL 6th (r)	NOL 12th (r)	NOL 18th (r)	NOL 24th (r)
CPOT	0.759	0.417	0.171	0.618
NRS	0.691	0.478	0.361	0.515

0.2<r<0.29: Weak relationship; 0.3<r<0.39: Moderate relationship; 0.4<r<0.69: Strong relationship; r>0.69: Very strong relationship.

and both CAM-ICU and 4AT scores were found to be negligible (0<r<0.2).

DISCUSSION

Our study demonstrates the effectiveness of NOL-guided pain management in intensive care, focusing on a population specifically selected to minimize pain factors. This population excludes individuals with complex disease diagnoses like sepsis or procedures known to produce high pain intensity. It is among the first studies to compare NOL guidance in the ICU with traditional pain scores such as NRS and CPOT. These tools have been standard for analgesic titration and are crucial in monitoring pain and stratifying risk for delirium and cognitive dysfunction.[9,10]

While there were no significant differences in CPOT and NRS scores between groups, a strong positive correlation was observed between these pain scales and NOL values within the NOL Group. Remarkably, total analgesic consumption varied between groups (Fig. 3). Given that NOL values primarily dictated analgesic administration in the NOL Group, this outcome underscores its effectiveness in reducing analgesic usage, even when traditional pain scores were similar.

The application of NOL-guided analgesia in anesthesia has recently been validated for perioperative use, demonstrating a reduction in analgesic consumption during major abdominal surgerie.[8] Moreover, when opioid administration is guided by intraoperative NOL values instead of blood pressure and heart rate, this approach has been shown to decrease postoperative pain scores.[11] A similar challenge exists in the ICU setting, where patients under deep sedation and neuromuscular paralysis cannot self-report or express behaviors. [6] Although video pupillometry, which measures changes in pupillary dimensions to indicate sympathetic and parasympathetic responses, was explored for this purpose, it proved unreliable.[12] Additionally, the Analgesia Nociception Index (ANI), based on heart rate variability, was found to be more sensitive to emotional stimuli and less specific to pain.[13,14]

As a result of these observations, the NOL index may prove more effective due to its design, which incorporates five physiologic variables related to nociception. This makes it particularly valuable as it has been shown to effectively discriminate between noxious and non-noxious stimuli in a clinical setting.[15]

Despite the existing research on NOL-guided anesthesia, further studies are needed to explore its impact in the ICU environment. Gélinas et al.[16] conducted a study validating the NOL index but only in the Postoperative Anesthesia Care Unit (PACU) population following cardiac surgery. Consequently, we selected a more diverse ICU setting to determine if NOL values correlate with NRS and CPOT scores in pain detection. Although previous findings indicated only modest performance in pain detection using NRS scores and no correlation with CPOT scores, our study observed a strong and positive correlation between pain scores and NOL values.

More importantly, while other devices like the Analgesia Nociception Index have been ineffective in guiding personalized opioid use, the potential of the NOL index in establishing opioid-free anesthesia and ICU management remains underexplored.[17] Our study has addressed a critical gap by demonstrating reduced opioid consumption under NOL guidance, contributing to the burgeoning field of personalized, opioid-free pain management in the ICU.

Delirium presents a major concern in qualified ICU care and represents a critical area for future improvements in ICU design.[8] Over time, it has been recognized that delirium can adversely affect patient prognosis, leading to prolonged anxiety, depression, cognitive dysfunction, and even post-traumatic stress disorder. Moreover, delirium has been associated with increased mortality, particularly among frail patients, and extended lengths of stay in both the intensive care unit and the hospital overall.[18,19] Consequently, a bundle has been developed to support a delirium-free ICU, which has improved the comprehensive A to F (A-F) bundle for managing delirium risk factors in the ICU.[20,21] An aspect of this bundle that requires further investigation is the assessment and management of pain using subjective (NRS) and behavioral tools (CPOT), complemented by innovative non-invasive pain assessment technologies such as NOL.[8] This issue prompted our examination of the impact of NOL-guided pain management on CAM-ICU and 4AT scores. Although no significant differences were found between groups regarding CAM-ICU and 4AT scores, the lengths of hospital and ICU stays were significantly shorter in the NOL Group (Table 1). This outcome may be attributed to our study's focus on an uncomplicated population that did not receive sedation and excluded patients with prolonged ICU stays beyond 48 hours. Further research could be invaluable in exploring the relationship between NOL-guided pain monitoring and the emerging concept of the new component in the bundle, G - gaining insight into patient needs for more personalized care in future ICU settings.[8]

Limitations

Our study was aimed at demonstrating the comparison of NOL-guided pain management in the ICU. We designed a standardized ICU environment where noxious stimuli were minimized. To confirm the effectiveness of the NOL index and its impact on analgesic titration in settings with more frequent and intense procedural pain, further research involving more complex critical patient populations is necessary. The types of surgeries involved in our study varied; consequently, the difference in surgical times between the two groups was unintentionally higher, with the control group experiencing longer surgery durations. To reduce ambiguity, conducting another study focused on a single type of surgery would yield more precise results. Additionally, we selected patients who were not sedated or mechanically ventilated; however, investigating the NOL index may be more effective in patients

experiencing deep sedation and paralysis, where other pain scores prove ineffective. Conducting a multicenter study with a larger and more diverse population could better demonstrate the significant benefits of NOL monitoring in standard care within intensive care units.

CONCLUSION

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Conclusion

NOL index monitoring correlates well with more traditional methods of detecting pain, such as the NRS and CPOT scales. NOL offers a superior, objective, and efficient technology for assessing pain in patients who cannot be evaluated using either subjective (NRS) or behavioral (CPOT) pain scales. Furthermore, NOL-guided analgesic titration could help reduce opioid use by facilitating personalized, opioid-free analgesia in critical care.

Ethics Committee Approval: This study was approved by the Haseki Training and Research Hospital Ethics Committee (Date: 30.11.2022, Decision No: 212-2022).

Peer-review: Externally peer-reviewed.

Authorship Contributions: Concept: B.C.; Design: B.C.; Supervision: B.C., Z.B.; Resource: O.S.; Materials: B.C., Z.B.; Data collection and/or processing: B.C., Z.B.; Analysis and/or interpretation: B.C.; Literature search: B.C.; Writing: B.C.; Critical review: B.C.

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ORİJİNAL ÇALIŞMA - *ÖZ*

Yoğun bakımda ağrı takibi: Nosisepsiyon düzeyi indeksi tedavi ve prognozu nasıl etkiler? Randomize kontrollü, çift kör bir çalışma

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AMAÇ: Özellikle ameliyat sonrası yoğun bakımda ağrı yönetimi önemlidir. Bu çok boyutlu sorunu yönetmek için klinisyenlerin ağrıyı hasta bazlı bir şekilde tespit etmeye yönelik objektif ve etkili standartlar sağlamaları gerekir. Yeni bir teknoloji olan nosisepsiyon düzeyi indeksi, çok parametreli değerlendirmesiyle bu görevi başarmak için umut verici bir adaydır.

GEREÇ VE YÖNTEM: Heterojen yoğun bakım ünitesindeki iki grubu (n=30) karşılaştırmak için prospektif, kontrollü, randomize bir çalışma tasarlandı. Genel anestezi sonrası yoğun bakım takibi için 18 yaş üstü ve Amerikan Anesteziyoloji Derneği skoru I-III olan hastalar seçildi. Tüm hastalara, kurtarma analjezisini de içeren standart analjezi protokolü verildi ve ilaç uygulaması, Grup NOL'de nosisepsiyon düzeyi indeksi monitörizasyonu tarafından yönlendirilirken Grup Kontrol'de sayısal bir derecelendirme ölçeği ve kritik bakım ağrı gözlem aracı tarafından yönlendirildi.

BULGULAR: Ağrı skorları açısından gruplar arasında anlamlı fark yoktu. NOL Grubu içindeki ağrı skorları ve nosisepsiyon değerleri güçlü bir pozitif korelasyon gösterdi. Toplam analjezik tüketimi NOL grubunda anlamlı derecede düşüktü (p=0.036).

SONUÇ: Ağrı için nosisepsiyon düzeyi indeksinin izlenmesi, yoğun bakımda kullanılan standart ağrı skorlarıyla karşılaştırıldığında ağrıyı tespit etmenin etkili bir yoludur. Rehberliğinde kişiselleştirilmiş analjezik titrasyonuna yardımcı olur. Nosisepsiyon düzeyi indeksinin yoğun bakım ve hastanede kalış süresini azaltma üzerindeki etkisi, daha fazla çalışma ile ortaya çıkarılmayı bekleyen deliryum üzerindeki etkisiyle bağlantılı olabilir.

Anahtar sözcükler: Ağrı takibi; davranışsal ağrı skorları; deliryum; nosisepsiyon düzeyi indeksi; postoperatif bilişsel işlev bozukluğu; postoperatif ağrı.

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