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ORIGINAL RESEARCH

qCON and qNOX-Guided Sedation Monitoring During Gastrointestinal Endoscopy: A Prospective Observational Preliminary Study

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Background: The depth of sedation during gastrointestinal endoscopy is predominantly assessed based on clinical experience due to the absence of a universally recognized objective standard. This study aimed to evaluate the utility of two novel electroencephalography-derived parameters, the quantitative consciousness index (qCON) and the quantitative nociception index (qNOX), for sedation and analgesia monitoring, and to determine the optimal qCON range correlated with optimal procedural stability.

Methods: In this prospective observational study, a total of 220 patients scheduled for elective gastroscopy or colonoscopy were enrolled. All patients received propofol and sufentanil for sedation and analgesia according to routine clinical practice. Depth of anesthesia and nociceptive responses were continuously monitored using qCON and qNOX. Hemodynamic parameters, body movement, and coughing were recorded at predefined time points. The primary outcome was defined as optimal procedural stability, characterized by hemodynamic fluctuations within 10% of baseline combined with the absence of body movement or coughing.

Results: A qCON range of 55–63 was observed to be associated with optimal procedural stability (95% confidence interval [CI]: 55.25–62.62 for gastroscopy; 55.25–62.52 for colonoscopy). A strong correlation between qCON and qNOX was observed (gastroscopy: qNOX = 0.78 × qCON + 26.1, R^2 = 0.714; colonoscopy: qNOX = 0.83 × qCON + 22.47, R^2 = 0.716; $p < 0.001$). The qNOX index demonstrated a more rapid response to noxious stimuli than qCON during recovery phases.

Conclusion: The qCON index appears to provide an objective approach to assessing sedation depth in sedated gastrointestinal endoscopy. Our findings suggest that qCON values within the range of 55 to 63 are associated with optimal procedural stability as defined in this study. Combined monitoring with qCON and qNOX may provide complementary information to support a balanced approach to intra-procedural sedation management, thereby potentially enhancing the safety and overall quality of sedation management.

Trial Registration: This study was registered at ClinicalTrials.gov (Registration Number: NCT06604156) on April 11, 2024.

Keywords: anesthesia depth, gastrointestinal endoscopy, nociception, qCON, qNOX, sedation monitoring

Introduction

Gastrointestinal endoscopy is a primary modality for the diagnosis and treatment of gastrointestinal diseases.[1–3] With the development of comfort-centered healthcare and increasing public awareness, most patients prefer diagnostic and therapeutic procedures to be performed under sedation.[4–7] In China, there is a particularly high demand for deep sedation to ensure complete amnesia and comfort during these procedures. However, deep sedation is associated with an increased risk of adverse events, particularly respiratory depression and Hypotension. At present, the assessment of sedation depth during gastrointestinal endoscopy predominantly depends on the clinical experience and judgment of anesthesiologists, as no universally accepted objective standard for monitoring sedation has been established.[8,9] Consequently, clinical parameters such as blood pressure, heart rate, and responses to nociceptive stimuli are typically used to titrate analgesic

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and sedative agents. However, these parameters may not reliably distinguish between the effects of analgesia or sedation, limiting their specificity, and they often fail to provide early warning signs of respiratory depression in deep sedation.

EEG-based monitoring systems such as Bispectral Index (BIS) and Narcotrend are occasionally utilized during gastrointestinal endoscopy, although their application remains infrequent in routine clinical practice. These indices predominantly assess the hypnotic depth rather than nociceptive responses.[10–15] Recently, two electroencephalography (EEG)-derived indices, the quantitative consciousness index (qCON) and the quantitative nociception index (qNOX), have been introduced as tools for assessing sedation and analgesia. These indices are computed using an adaptive neuro-fuzzy inference system and nonlinear EEG analysis, providing values ranging from 0 to 99. The qCON reflects hypnotic depth of anesthesia, while the qNOX reflects the probability of a motor response to noxious stimuli.[16–19] During general anesthesia, maintaining qCON values between 40 and 60 and qNOX between 30 and 50 is considered indicative of an appropriate balance between sedation and analgesia.[17,20,21] This unified EEG-based approach offers distinct advantages in differentiating hypnotic and nociceptive components, particularly during procedural sedation where the depth of hypnosis is shallower than in general anesthesia and spontaneous ventilation is maintained. Given the paucity of data characterizing these indices specifically in gastrointestinal endoscopy, establishing their correlation with clinical stability is essential to determine whether they provide incremental value over current monitoring standards.

Safe and effective sedation monitoring requires both direct visual observation and continuous physiological monitoring. Physiological monitoring encompasses vital parameters such as heart rate, blood pressure, electrocardiographic activity, oxygen saturation via pulse oximetry, capnographic evaluation of ventilation, and EEG-based sedation depth indices.[22–24] Visual monitoring encompasses observation of respiratory patterns, chest wall movement, changes in skin coloration, spontaneous movements, and facial expressions suggestive of discomfort or nociceptive stimulation.

In this study, qCON and qNOX indices were employed to evaluate sedation depth and nociceptive responses in patients undergoing sedated gastrointestinal endoscopy. These indices were used in conjunction with standard physiological monitoring and visual assessment, including cough reflex, respiratory depression, and body movement, with the aim of identifying an optimal sedation range conducive to procedural stability and patient safety.

Materials and Methods

Study Population

This study was approved by the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University (Approval No.: 2024–109-01) and was registered at ClinicalTrials.gov (NCT06604156) on April 11, 2024. Written informed consent for participation and publication was obtained from all participants before enrollment. Eligible participants included patients aged 18 to 60 years with a body mass index between 18 and 28 kg/m^2 and classified as American Society of Anesthesiologists physical status I or II. All participants were scheduled to undergo sedated gastrointestinal endoscopy at the outpatient department between September 1, 2024, and November 30, 2024.

Exclusion criteria included pregnancy or lactation; known allergy or contraindications to opioids or propofol; severe neurological disorders (such as stroke, hemiplegia, convulsion, or epilepsy); anticipated difficult airway (such as cervical spine fixation or restricted mouth opening); respiratory diseases that may increase airway sensitivity (eg., including tracheitis, bronchitis, asthma, chronic obstructive pulmonary disease, or acute respiratory infection); disorders affecting pharyngolaryngeal function (including chronic pharyngitis, laryngitis, laryngeal edema, or recurrent laryngeal nerve paralysis); esophageal disorders associated with dysphagia or gastroesophageal reflux (such as esophagitis, esophageal stenosis, or esophageal dysmotility); and severe uncontrolled cardiovascular diseases (such as poorly controlled hypertension, significant arrhythmia, or unstable angina).

Study Design

Participants were allocated to one of two groups based on the type of endoscopic procedure: gastroscopy group (n = 110) and colonoscopy group (n = 110). All participants received intravenous anesthesia induction using propofol combined with low-dose sufentanil. This was a prospective observational study in which the anesthesiologists were blinded to the

qCON and qNOX values throughout the procedure. The monitoring screen displaying these indices was covered. Anesthetic management was determined solely based on standard clinical signs according to routine practice.

Anesthesia Protocol

All participants adhered to standard preoperative fasting guidelines: fasting from solids for at least 6 hours and from clear fluids for at least 2 hours. Those undergoing gastroscopy received 10 mL lidocaine gel orally for topical pharyngeal anesthesia, whereas participants scheduled for colonoscopy received lidocaine gel applied to the anal region and colonoscope shaft. Participants were positioned in the left lateral decubitus position and received supplemental oxygen via nasal canula at a flow rate of 5 L/min.

Anesthesia induction was initiated with intravenous administration of sufentanil (5 μg; Yichang Renfu Pharmaceutical, China), followed one minute later by propofol (1.5–2.5 mg/kg; Chenxin Pharmaceutical, China) injected at a rate of 1 mL every 3 seconds. The Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale was used to assess clinical sedation depth. Endoscope insertion was initiated when the MOAA/S score reached ≤ 1. Anesthesia was maintained with propofol infusion at 4–6 mg/kg/h and discontinued at the initiation of endoscope withdrawal. Intraoperative events such as coughing or spontaneous body movement were managed with rescue doses of propofol (0.5 mg/kg).

Monitoring and Data Collection

Standard monitoring included non-invasive blood pressure, heart rate, and peripheral oxygen saturation (SpO_2). Depth of anesthesia was monitored using the qCON/qNOX system (Apollo-9000A, Chongqing Xider Medical Instrument Co., China), with three forehead electrodes positioned on the forehead to record raw EEG signals. Monitored EEG-derived parameters included the qCON index (representing the hypnotic component of anesthesia), qNOX index (indicating nociception), the burst suppression ratio, and the signal quality index.

Primary Outcome

The primary endpoint was optimal procedural stability, evaluated at the point of maximal noxious stimulation (pharyngeal passage for gastroscopy; splenic flexure traversal for colonoscopy). This state was defined as the simultaneous occurrence of hemodynamic stability (HR and SBP fluctuations ≤10% from baseline) and the absence of coughing or body movement.

Observation Indices

The following parameters were recorded at predefined time points: qCON, qNOX, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), SpO_2, and MOAA/S score. For gastroscopy, the observation time points were as follows: baseline (T0), loss of consciousness (T1), pre-insertion of the gastroscope (T2), passage through the pharynx (T3), one minute after intragastric placement (T4), completion of the procedure (T5), eye opening in response to verbal stimulation (T6), discharge from the procedure room (T7). For colonoscopy, the observation time points included baseline (T0), loss of consciousness (T1), pre-insertion of the colonoscope (T2), post-anal insertion (T3), upon reaching the sigmoid colon (T4), at the splenic flexure (T5), at the hepatic flexure (T6), completion of the procedure (T7), eye opening in response to verbal stimulation (T8), and discharge from the procedure room (T9).

Additional measurements were obtained during specific procedural events, including during coughing, spontaneous body movement, tissue biopsy, and polypectomy. All adverse events were recorded, including hypoxemia, respiratory depression, bradycardia, hypotension, injection site pain, coughing, and body movement. Post-procedure assessments included recovery time and the incidence of post-procedure complications such as dizziness, blurred vision, nausea, vomiting, abdominal pain, and abdominal distension.

Statistical Analysis

A previous study reported a hemodynamic instability rate of 22.39% during painless gastrointestinal endoscopy.[25] The incidence of hemodynamic instability was assumed to be 30% under standard conditions and 10% under sedation

monitoring. Using a two-sided test with a significance level (α) of 0.05, power (1–β) of 0.90, and an anticipated dropout rate of 10%, the required sample size was calculated using PASS 15.0 software, yielding a final sample size of 220 participants (110 per group).

All statistical analyses were conducted using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). All tests were two-sided, and a p-value ≤ 0.05 was considered statistically significant. Data distribution normality was examined via the Shapiro–Wilk test. Normally distributed data are presented as mean ± standard deviation (Mean ± SD) and compared between groups using the independent-samples *t*-test. Corresponding 95% confidence intervals (CIs) were also calculated. Non-normally distributed data are presented as median and interquartile range [median (IQR)] and were compared using the Mann–Whitney *U*-test; with 95% CIs estimated using the Hodges–Lehmann two-sample estimator. Correlations between qCON and qNOX were analyzed using Pearson correlation coefficients.

Results

Participant Characteristics

A total of 230 patients were screened in the study, including 114 undergoing gastroscopy and 116 undergoing colonoscopy. In the gastroscopy group, 2 patients had missing data, 1 experienced reflux aspiration, and 1 did not complete the procedure. In the colonoscopy group, 1 patient had missing data, and 2 procedures were not completed. The participant flow diagram, including reasons for exclusion, is presented in Figure 1. Baseline characteristics of the included participants are summarized in Table 1.

Trends in qCON and qNOX dynamics: Baseline values of qCON and qNOX were defined as the average values recorded during the 1-minute interval prior to anesthesia induction. Loss of consciousness (LOC) was determined by the absence of the eyelash reflex, marking the transition from wakefulness to sedation. At the point of LOC, the mean qCON was 69 in the gastroscopy group and 67 in the colonoscopy group.

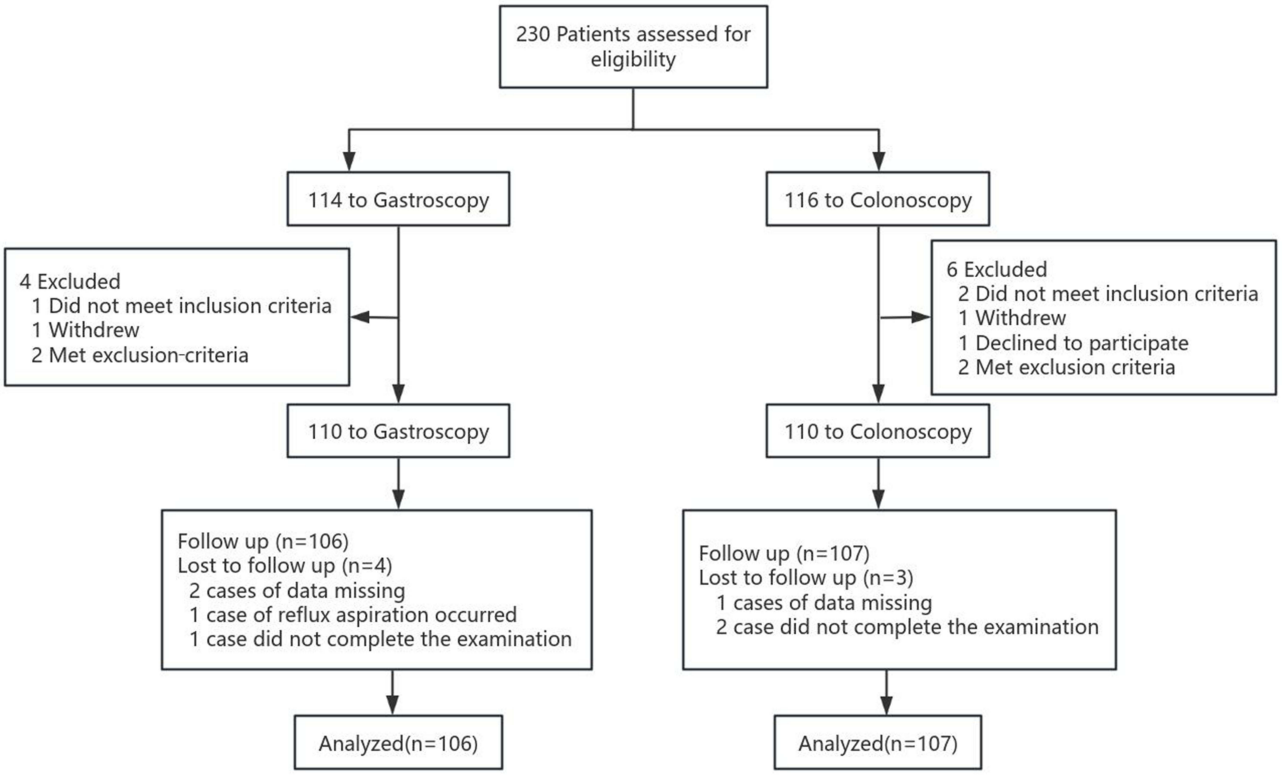

Figure 1 Study Flow Diagram.

Table 1 Patient and Intervention Characteristics

Characteristics	Gastroscopy	Colonoscopy
Age (yrs)	49(38,56)	49(38,56)
Gender (M/F)	33/73	48/59
Weight, kg	57(52.8,65.0)	60(53.0,67.5)
Height, cm	160.6±7.7	161.2±7.5
ASA classification score (I/II)	13/93	12/95
Propofol induction dose, mg (IQR)		
Induction dose	130.0(120.0,150.0)	125.0(120.0,150.0)
Total dose	150.0(130.0,180.0)	190.0(150.0,220.0)
Duration of procedures (min)	5.0(3.0,6.0)	9.0(6.0,13.0)
Anesthesia emergence time (min)	5.0(3.0,7.0)	4.0(2.0,7.0)
Duration of stay in PACU (min)	18.0(15.0,18.0)	17.0(15.0,20.0)

Notes: Results presented as mean ± SD, median [Q1–Q3].
Abbreviations: ASA, American Society of Anesthesiologists; PACU, postanesthetic care unit.

During the anesthesia maintenance phase, qCON values were maintained within the range of 45 to 60, whereas qNOX values stabilized between 60 and 70 (Figure 2). Notably, immediately following loss of consciousness (LOC), qCON values fluctuated between 66 and 69, while qNOX values exhibited a significantly higher range of 84 to 90. Conversely, upon response to verbal command (eye-opening), qCON values rose to 74–78, and qNOX values surged to 87–98. During induction, qCON decreased more rapidly than qNOX, whereas during emergence, qNOX increased faster than qCON. These findings are consistent with previously reported differences in response latency between the two indices.

Based on predefined criteria for optimal procedural stability. For gastroscopy (assessed at the pharyngeal passage) 30 participants met the criteria for optimal procedural stability, with a qCON 95% CI of 55.25–62.62. For colonoscopy (assessed at splenic flexure passage), 34 participants achieved optimal procedural stability, with a qCON 95% CI of 55.25–62.52 (Table 2). These results indicate that a qCON range of 55–63 is associated with optimal procedural stability during sedated gastrointestinal endoscopy. A strong linear correlation was observed between qCON and qNOX values. For gastroscopy, the relationship was defined by the equation: $qNOX = 0.78 \times qCON + 26.1$ ($p < 0.001$; $R^2 = 0.714$), and for colonoscopy, $qNOX = 0.83 \times qCON + 22.47$ ($p < 0.001$; $R^2 = 0.716$) (Figure 3).

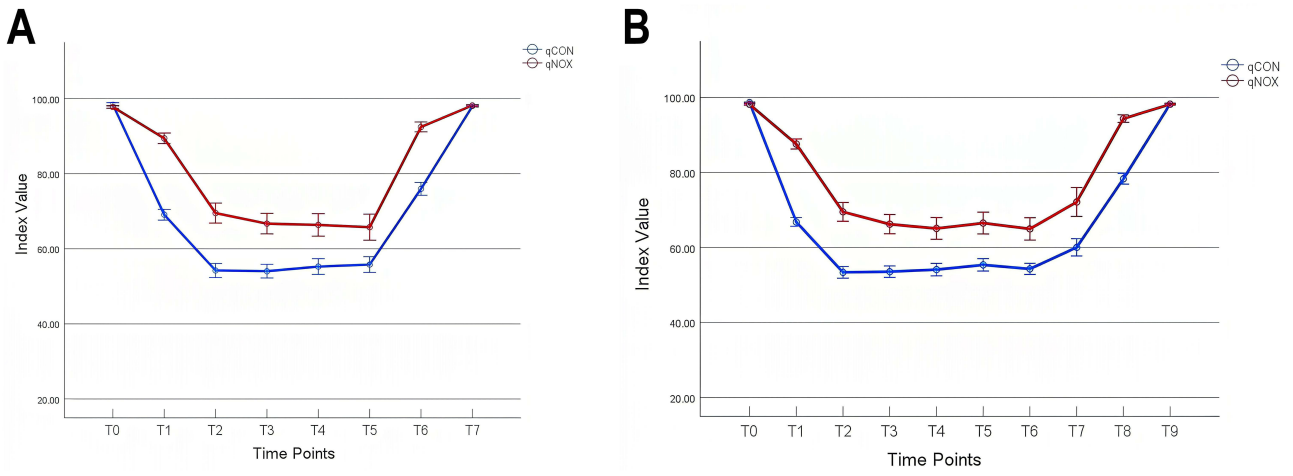

Figure 2 Variations of qNOX and qCON in gastroscopy (**A**) at the different time-points (T0 =baseline value, T1 = Loss of Consciousness, T2 = pre-insertion of the gastroscope, T3 = As Gastroscopy Passes Through the Pharynx, T4 = 1 minute after intragastric placement, T5 = procedure completion, T6 = eye opening upon verbal stimulation, T7 = room discharge and Variations of qNOX and qCON in colonoscopy (**B**) at the different time-points (T0 = Baseline value, T1 = Loss of Consciousness, T2 = pre-insertion of the colonoscope, T3 = post-anal insertion, T4 = at the sigmoid colon, T5 = At the Splenic Flexure, T6 = At the Hepatic Flexure, T7 = procedure completion, T8 = eye opening upon verbal stimulation, T9 = room discharge. Plain circles represent mean val-ues. Error bars represent standard deviations.

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Table 2 qCON Levels at the Time for Inadequate/Adequate Sedation

Variable	No.	Mean	SD	Median	Minimum	Maximum	95% CI
Gastroscopy							
Adequate sedation	30	58.93	9.87	61.00	41.00	72.00	55.25,62.62
Inadequate sedation	76	50.97	14.10	49.00	39.00	73.00	47.73,54.21
Colonoscopy							
Adequate sedation	34	58.88	10.07	62.50	41.00	73.00	55.25,62.52
Inadequate sedation	73	53.94	8.85	52.50	40.00	80.00	50.49,57.39

Notes: Hemodynamic fluctuations within ±10%, without coughing and body movement. The critical time points for sedation were evaluated during passage of the gastroscope through the pharynx and colonoscopy into the splenic flexure, as this may cause a strong physiological response.

Discussion

An optimal sedation monitoring strategy should minimize the risk of sedation-related adverse events and facilitate early identification of oversedation. Continuous monitoring that combines visual assessment, such as observation of coughing, cyanosis, and spontaneous limb movements, with physiological parameters, including vital signs and oxygen saturation, remains essential for ensuring patient safety during sedation.[7,26,27] This study is the first to evaluate the application of both qCON and qNOX monitoring during gastrointestinal endoscopy under intravenous sedation. The findings suggest that a qCON range of 55–63 is strongly associated with a state of optimal procedural stability, defined rigorously as hemodynamic fluctuations within 10% of baseline and the absence of motor responses. Notably, among patients who attained this ideal clinical state, qCON values exhibited concordant clustering within this narrow interval. These data suggest that maintaining qCON between 55 and 63 may optimize the probability of achieving optimal procedural stability, although this range should be interpreted as a probabilistic target rather than a deterministic guarantee for every individual. Furthermore, the differential responsiveness of qNOX to nociceptive stimuli underscores its potential utility as an early-warning indicator for analgesic titration, serving as a valuable adjunct to qCON-guided sedation.

Monitoring anesthetic depth is essential to avoid unintended consciousness during procedural sedation while preventing adverse effects associated with excessive anesthetic dosing. It is important to clarify that the term "awareness" in this context refers to procedural recall or arousal from sedation, which differs fundamentally from Accidental Awareness During General Anesthesia (AAGA) as defined in the NAP5 report, since our patients were not under general anesthesia with neuromuscular blockade. However, no standardized data currently exist for assessing anesthetic depth during sedated gastrointestinal endoscopy, and clinical practice often relies on anesthesiologists' subjective judgment. Previous investigations have explored the combined use of the BIS and the MOAA/S scale to define an optimal depth of anesthesia for endoscopic procedures.[28,29] However, the MOAA/S scale has limited utility at deeper levels of sedation due to its subjective nature.[30,31] There remains a lack of consensus on specific threshold values for the newer qCON and qNOX indices in this setting.

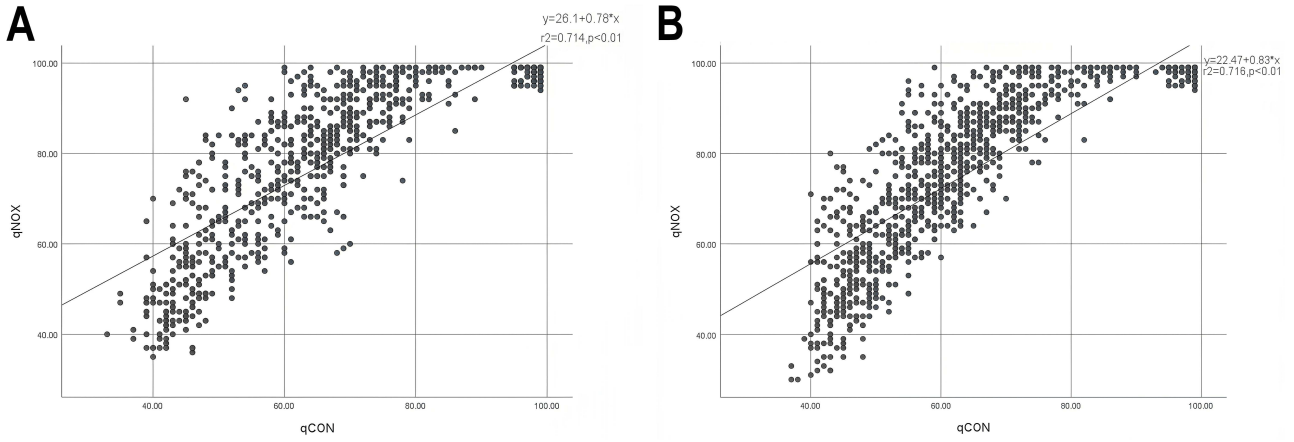

Figure 3 Relationship between (**A**) qCON and qNOX from T0 to T7 in gastroscopy, (**B**) qCON and qNOX from T0 to T9 in colonoscopy.

In this study, we explicitly distinguished between the hypnotic (qCON) and nociceptive (qNOX) components, avoiding their interchangeable use. qCON reflects the hypnotic depth, whereas qNOX reflects the probability of a motor response to noxious stimuli.[32] Although we observed a strong linear correlation between qCON and qNOX ($R^2 \approx 0.71$), reflecting their concordant behavior driven by the physiological interplay between sedation and analgesia, the uncoupling of these indices yields critical clinical insights.[20,33] Specifically, qNOX demonstrated a steeper slope of change in response to noxious events compared to qCON. Although Figure 2 depicts a generally concordant trajectory for both indices, qNOX exhibited temporal precedence, peaking earlier and with greater magnitude during periods of intense noxious stimulation.

We propose specific interpretive thresholds based on our observational data, while acknowledging these require prospective validation. A qNOX value above 70 was frequently observed in conjunction with signs of insufficient analgesia, suggesting a need for reassessment of analgesic depth. Values exceeding 80 correlated with a high probability of imminent return of consciousness. The observation that qNOX > 90 may predict arousal even when qCON remains near 60 warrants mechanistic explanation. This phenomenon likely occurs because intense nociceptive input can activate the reticular activating system and trigger arousal via subcortical pathways that may not be immediately reflected in the cortical EEG patterns processed by qCON. These data suggest that this range may serve as a promising target for future interventional validation.

This findings indicate that while both gastroscopy and colonoscopy share a similar optimal qCON range (55–63), their nociceptive profiles differ distinctly. Although traditional teaching emphasizes the intense but transient pharyngeal stimulation during gastroscopy as the primary noxious event, emerging evidence suggests that colonoscopy may impose comparable or even greater nociceptive demands. Specifically, colonic distension and mesenteric traction can evoke profound visceral nociception, necessitating deeper levels of analgesia.[34] This aligns with our observation of sustained qNOX elevations during the traversal of the splenic and hepatic flexures, likely reflecting pain secondary to luminal distension and traction. These data suggest that while the nature of the noxious stimulus differs (somatic/pharyngeal vs. visceral/traction), the magnitude of the required analgesic response in gastrointestinal endoscopy should not be underestimated. Consequently, vigilant, continuous monitoring of qNOX throughout the entire procedure is warranted to prevent inadequate analgesia and patient movement.

This study has several limitations. As a single-center observational study, the identified associations reflect the specific conditions of our cohort and do not establish causal guidelines. The relatively small proportion of patients meeting the strict "optimal" criteria limits the generalizability of the exact threshold, emphasizing the need for larger, multicenter interventional trials to validate whether targeting this range improves outcomes. Furthermore, despite the robust correlation between qCON and qNOX, the incremental utility of qNOX resides in its specific sensitivity to nociception. This distinct advantage warrants further investigation through study designs capable of dissociating hypnotic and analgesic drug effects.

Conclusion

This study is the first to evaluate the combined use of qCON and qNOX indices for monitoring sedation depth during gastrointestinal endoscopy. The findings suggest that maintaining qCON values between 55 and 63 is associated with hemodynamic stability and the absence of adverse motor responses. However, given the observational nature of this study, this range should be interpreted as a preliminary reference target that necessitates validation through future prospective trials.

Data Sharing Statement

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

This study was conducted with approval from the Ethics Committee of The First Affiliated Hospital of Chongqing Medical University (No.2024-109-01) and registered in the Chinese Clinical Trial Register website (clinicaltrials.gov, NCT06604156, April 11, 2024). This study was conducted in accordance with the declaration of Helsinki. Written informed consent was obtained from all participants.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests in this work.

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