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ORIGINAL RESEARCH

Triage for Early Recognition of Immune-Related Adverse Events in Patients Receiving Immune Checkpoint Inhibitors: A Multicenter Prospective Diagnostic Accuracy Study

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ABSTRACT

Background: Immune checkpoint inhibitors (ICIs) have transformed treatment across multiple solid tumors, but immune-related adverse events (irAEs) occur in approximately 40% of treated patients across all grades and require prompt recognition to limit morbidity. In settings with a high patient-to-oncologist ratio, nurse-led triage may extend safe monitoring capacity, but prospective validation against a physician reference assessment has been lacking in Indian cancer centers.

Objective: To evaluate the diagnostic accuracy of a structured Nurse-Led irAE Triage Checklist (NLITC) for identifying clinically significant irAEs (Common Terminology Criteria for Adverse Events [CTCAE] v5.0 grade ≥ 2) among patients receiving ICI therapy at two tertiary oncology centers in India.

Methods: In this prospective, two-center diagnostic accuracy study, consecutive adult patients receiving ICI monotherapy or combination therapy were assessed at infusion visits and through a 24-hour nurse-staffed helpline using the NLITC. Each nurse-triage assessment was compared with a blinded oncologist reference assessment; actionable encounters underwent same-day physician assessment, whereas non-actionable encounters underwent assessment at the next scheduled infusion visit. Sensitivity, specificity, predictive values, likelihood ratios, and Cohen's kappa were calculated.

Results: Of 262 enrolled patients, 258 completed at least one paired assessment (612 total encounters). A clinically significant irAE was confirmed by the reference standard in 94 of 258 patients (36.4%). Nurse-led triage showed a sensitivity of 94.7% (95% CI, 88.1–97.7) and specificity of 90.2% (95% CI, 84.7–93.9), with positive and negative predictive values of 84.8% and 96.7%, respectively. Agreement in actionable/non-actionable classification was high (κ = 0.83; 95% CI, 0.74–0.90). Median time from symptom report to completed nurse triage was 24 minutes (IQR, 15–40).

Conclusion: In this prospective two-center Indian cohort, a structured nurse-led triage checklist demonstrated high sensitivity and strong agreement with oncologist assessment for identifying clinically significant irAEs. Because the study used asymmetric verification timing and included repeated encounters, the findings should be considered hypothesis-generating. Further multicenter validation with symmetric reference-standard verification and analyses that account for repeated encounters is warranted.

Keywords: *immune checkpoint inhibitors; immune-related adverse events; oncology nursing; nurse-led triage; diagnostic accuracy; STARD*

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INTRODUCTION

Immune checkpoint inhibitors (ICIs) targeting programmed cell death protein-1 (PD-1), its ligand (PD-L1), and cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) have become standard therapy across a growing range of solid tumors [1–4]. Their distinct mechanism of action—restoring antitumor T-cell activity—produces a correspondingly distinct toxicity profile: immune-related adverse events (irAEs), which can affect virtually any organ system and range from mild, self-limiting symptoms to fulminant, occasionally fatal, immune-mediated organ injury. A systematic review pooling 272 studies and more than 300,000 ICI-treated patients reported an overall irAE event rate of 40.0% across all grades and 19.7% for high-grade (CTCAE grade ≥ 3) events [5]. Because irAEs can progress rapidly if unrecognized, major oncology society guidelines—from the American Society of Clinical Oncology (ASCO), the European Society for Medical Oncology (ESMO), the Society for Immunotherapy of Cancer (SITC), and the National Comprehensive Cancer Network (NCCN)—identify early symptom recognition, prompt grading, and timely escalation as cornerstones of safe ICI delivery [1–4].

Oncology nurses are frequently the first point of clinical contact for patients reporting new or worsening symptoms during ICI therapy, whether at scheduled infusion visits or through unscheduled telephone contact [6]. Structured, symptom-anchored triage tools administered by nurses have been used successfully to standardize assessment of treatment-related symptoms in other settings: the United Kingdom Oncology Nursing Society's 24-hour telephone triage framework has been incorporated into an eHealth-enabled model of care for irAE monitoring in a European ICI cohort [7], and the Pan-Canadian Oncology Symptom Triage and Remote Support (COSTaRS) group has developed and evaluated evidence-informed nursing protocols for remote assessment of cancer treatment-induced symptoms more broadly [8]. To our knowledge, no prospective study has validated a nurse-led, irAE-specific triage instrument against a blinded physician reference assessment in Indian tertiary-care oncology centers.

This gap is clinically material in India, where an estimated fewer than 1,000 formally trained medical oncologists serve a cancer population that yields a patient-to-oncologist ratio of approximately 2,000:1—roughly twenty-fold lower oncologist availability than in the United States—placing substantial day-to-day symptom-monitoring responsibility on oncology nursing staff who may have limited formal oncology-specific training [9,10]. As ICI use expands into Indian tertiary and regional cancer centers, a validated, low-cost, nurse-administered triage instrument could extend safe toxicity surveillance without requiring proportional growth in oncologist staffing.

We therefore developed the Nurse-Led irAE Triage Checklist (NLITC), a structured, organ-system-based instrument adapted from CTCAE v5.0 grade descriptors and modeled conceptually on the UKONS/COSTaRS triage frameworks, and conducted a prospective diagnostic accuracy study to determine whether nurse-administered triage using the NLITC could reliably identify clinically significant irAEs (CTCAE grade ≥ 2) when benchmarked against oncologist assessment in patients receiving ICI therapy at two tertiary oncology centers in India.

METHODS

Study design and reporting

This was a prospective, two-center diagnostic accuracy study conducted in the medical oncology day-care and ICI-infusion units of Fortis S. L. Raheja Hospital, Mumbai, Maharashtra, and VPS Lakeshore Hospital, Kochi, Kerala, India. The study is reported in accordance with the Standards for Reporting of Diagnostic Accuracy Studies (STARD 2015) guideline [11]. Written informed consent was obtained from all participants before enrollment.

Setting and participants

Consecutive adult patients (≥18 years) receiving single-agent or combination ICI therapy (anti–PD-1/PD-L1 monotherapy, anti–PD-1 plus anti–CTLA-4 combination, or ICI plus chemotherapy) for any solid tumor were screened for eligibility during the predefined enrollment period. Patients were excluded if they were unable to complete symptom-report telephone contact (for example, no access to a telephone, or significant hearing or cognitive impairment without a reliable caregiver proxy) or declined participation. Eligible patients were followed prospectively from enrollment through 90 days after the final administered dose or until treatment discontinuation, whichever occurred first.

Index test: Nurse-Led irAE Triage Checklist (NLITC)

The NLITC is a structured, organ-system-based checklist (dermatologic, gastrointestinal, endocrine, pulmonary, hepatic, renal, neurologic, cardiac, and "other/constitutional" domains) with symptom-anchor questions adapted directly from CTCAE v5.0 grade descriptors [12]. Item content was drafted from these CTCAE anchors and reviewed for face and content validity by a five-member multidisciplinary panel (two medical oncologists, two oncology nurses, and one clinical pharmacist) before nurse training. No formal psychometric validation (for example, exploratory factor analysis or a quantitative item-content validity index) was performed, which is acknowledged as a limitation.

At each scheduled infusion visit and at every unscheduled contact through a dedicated 24-hour nurse-staffed helpline, a trained oncology nurse administered the NLITC and assigned a Red–Amber–Green risk tier per organ system, together with an overall composite classification of either "actionable" (suspected CTCAE grade ≥2, requiring same-day physician review, urgent referral, or emergency assessment) or "non-actionable" (suspected grade ≤1 or no new symptom, managed with routine follow-up or self-care advice). Fourteen oncology day-care nurses completed an 8-hour structured training program before study initiation, with competency confirmed by ≥90% agreement with expert-rated case vignettes.

Reference standard and target condition

Within each clinical encounter, the treating medical oncologist independently assessed the patient while blinded to the nurse's triage classification and assigned a CTCAE v5.0 grade for any reported or examined toxicity. For infusion-visit encounters and helpline-triggered encounters classified by the nurse as actionable, the oncologist reference assessment was completed on the same day. For encounters triaged as non-actionable, the reference-standard assessment was completed at the next scheduled infusion visit (median 6 days later) rather than on the same day. This asymmetry in verification timing represents potential differential verification bias and is addressed in the Limitations section [13]. Nurse-triage and oncologist reference assessments were recorded on separate forms and reconciled post hoc by a data manager not involved in direct patient care, preserving blinding until data lock.

For the diagnostic-accuracy analysis, a clinically significant irAE was prespecified as CTCAE grade ≥2 in any organ system. This threshold was selected as a pragmatic severity threshold; however, the clinical urgency and management of grade 2 toxicities vary by organ system, and not all grade 2 events uniformly require corticosteroids or treatment modification [1–4]. Attribution of a qualifying event as an irAE was made by the oncologist reference assessment based on the clinical evaluation; organ system was categorized according to the primary system recorded in that assessment, with cases recorded as multisystem classified as other/multisystem.

Outcomes

The primary outcome was diagnostic accuracy (sensitivity, specificity, positive and negative predictive values, and positive/negative likelihood ratios) of the NLITC "actionable" classification against the oncologist reference-standard determination of grade ≥2, assessed at the patient level. Each patient contributed only the first completed paired assessment after enrollment to the primary analysis.

As a prespecified secondary exploratory analysis, the same accuracy measures were recalculated at the encounter level using all 612 encounters. Because multiple encounters were contributed by individual patients,

these encounter-level observations were clustered within patients and were not treated as independent confirmatory evidence. Further secondary outcomes were inter-rater agreement in actionable/non-actionable classification, overall and by primary implicated organ system; time from symptom report to completed nurse triage; and nurse-reported usability of the NLITC, assessed with a 10-item adapted System Usability Scale (SUS) [14] administered to all participating nurses at study completion. The adaptation of the SUS and scoring procedure were documented before analysis; no separate psychometric validation of the adapted scale was performed.

Sample size

Sample size was calculated using the Buderer method for diagnostic accuracy studies, which incorporates anticipated disease prevalence into precision-based estimates for sensitivity and specificity [15]. In the absence of pilot data specific to the NLITC, anticipated sensitivity and specificity were set a priori at 85% and 90%, respectively. A prevalence of clinically significant (CTCAE grade ≥2) irAE of 35% was used as a pragmatic planning estimate, informed by pooled literature reporting approximately 40.0% any-grade irAEs and 19.7% grade ≥3 events [5]. Using a 95% confidence-interval width of 10 percentage points, the Buderer calculation yielded a minimum of 140 evaluable patients; allowing for 10% attrition, the target enrollment was 154 patients [15]. The final enrollment of 262 patients therefore exceeded the prespecified minimum.

Statistical analysis

Diagnostic accuracy measures were calculated with 95% confidence intervals using the Wilson score method. Likelihood-ratio confidence intervals were calculated on the log scale. Inter-rater agreement was quantified using Cohen's kappa for the binary actionable/non-actionable classification and interpreted using the conventional categories proposed by Landis and Koch (κ 0.81–1.00, almost perfect; 0.61–0.80, substantial; 0.41–0.60, moderate) [16]. Continuous variables are summarized as mean ± standard deviation or median (interquartile range) according to distribution; categorical variables are summarized as frequencies and percentages. The primary patient-level analysis used the full analysis set of patients with at least one completed paired assessment. The encounter-level analysis was descriptive and accounted conceptually for within-patient clustering in interpretation rather than treating repeated encounters as independent observations.

RESULTS

Patient flow and baseline characteristics

Of 271 patients assessed for eligibility, 262 were enrolled and 258 completed at least one paired nurse-triage/oncologist reference-standard assessment, contributing 612 total encounters (median 2 per patient, IQR 1–3) (Figure 1).

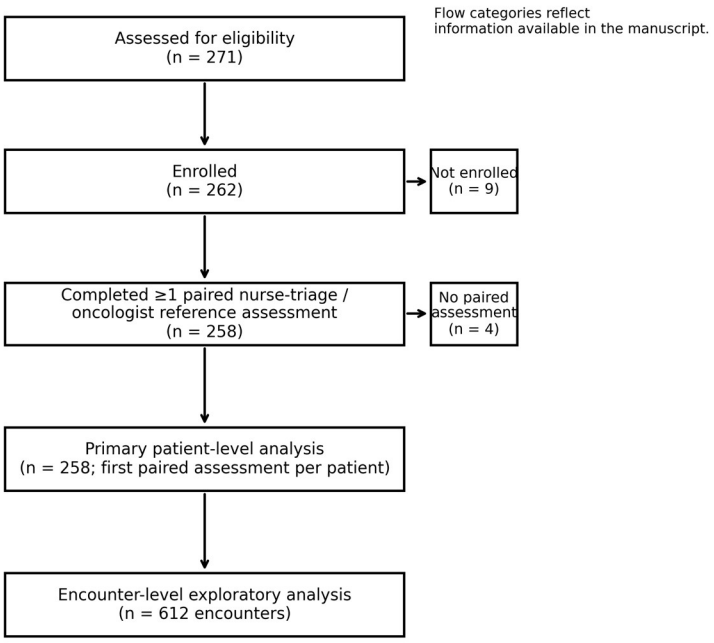


Figure 1. Patient flow through screening, enrollment, and paired nurse-triage/oncologist reference-standard assessment.

Baseline characteristics of the analysis set are summarized in Table 1. Mean age was 58.4 ± 11.2 years, 152 (58.9%) were male, and the most common tumor types were non–small-cell lung cancer (37.2%) and head and neck squamous cell carcinoma (18.6%). Most patients (76.0%) received anti–PD-1/PD-L1 monotherapy.

Table 1. Baseline demographic and clinical characteristics of the analysis set

Characteristic	Value (n = 258)
Age, years, mean ± SD	58.4 ± 11.2
Sex, male	152 (58.9)
Sex, female	106 (41.1)
ECOG performance status 0–1	231 (89.5)
ECOG performance status 2	27 (10.5)
Tumor type — non–small-cell lung cancer	96 (37.2)
Tumor type — head and neck squamous cell carcinoma	48 (18.6)
Tumor type — urothelial carcinoma	34 (13.2)
Tumor type — renal cell carcinoma	27 (10.5)
Tumor type — melanoma	21 (8.1)
Tumor type — gastric / gastro-esophageal junction adenocarcinoma	19 (7.4)
Tumor type — other	13 (5.0)
ICI regimen — anti–PD-1/PD-L1 monotherapy	196 (76.0)
ICI regimen — anti–PD-1 + anti–CTLA-4 combination	41 (15.9)
ICI regimen — ICI + chemotherapy	21 (8.1)
ICI cycles at enrollment, median (IQR)	3 (1–6)
Prior history of irAE	22 (8.5)

Diagnostic accuracy

A clinically significant irAE (CTCAE grade ≥2) was confirmed by the oncologist reference standard in 94 of 258 patients (36.4%). Nurse-led triage classified 89 of these 94 patients as actionable (true positive) and 5 as

non-actionable (false negative). Among the 164 patients without a clinically significant irAE, nurse-led triage correctly classified 148 as non-actionable (true negative) and 16 as actionable (false positive). This corresponded to a sensitivity of 94.7% (95% CI, 88.1–97.7) and specificity of 90.2% (95% CI, 84.7–93.9) (Table 2). Overall percentage agreement was 91.9% (237/258), with a Cohen's kappa coefficient of 0.83 (95% CI, 0.74–0.90) for actionable/non-actionable classification.

Table 2. Overall diagnostic accuracy of nurse-led triage versus the blinded oncologist reference standard

Diagnostic performance measure	Estimate (95% CI)
Sensitivity	94.7% (88.1–97.7)
Specificity	90.2% (84.7–93.9)
Positive predictive value	84.8% (76.5–90.5)
Negative predictive value	96.7% (92.5–98.4)
Positive likelihood ratio	9.70 (6.08–15.50)
Negative likelihood ratio	0.059 (0.025–0.139)
Overall percentage agreement	91.9% (237/258)
Cohen’s kappa (κ), actionable/non-actionable classification	0.83 (0.74–0.90)

Organ-system-specific performance

Sensitivity by primary implicated organ system ranged from 89.5% (gastrointestinal/colitis, n = 19) to 100% (pulmonary and other/multisystem categories, each n = 9), with corresponding kappa values from 0.76 to 0.84 (Table 3, Figure 2). Confidence intervals were widest for the pulmonary and hepatic subgroups, reflecting the small number of qualifying events in these categories; the point estimates of 100% sensitivity in the pulmonary and other/multisystem subgroups should be interpreted cautiously because a single additional missed case would lower the estimate to approximately 88.9%.

Table 3. Organ-system-specific diagnostic performance and inter-rater agreement

Primary implicated organ system	Qualifying events, n	True positive, n	Sensitivity, % (95% CI)	Cohen’s κ
Dermatologic	30	29	96.7 (83.3–99.4)	0.84
Gastrointestinal / colitis	19	17	89.5 (68.6–97.1)	0.78
Endocrine	16	15	93.8 (71.7–98.9)	0.76
Pulmonary / pneumonitis	9	9	100 (70.1–100)	0.81
Hepatic	11	10	90.9 (62.3–98.4)	0.80
Other / multisystem	9	9	100 (70.1–100)	0.83
Overall	**94**	**89**	**94.7 (88.1–97.7)**	**0.83**

Secondary outcomes

The encounter-level exploratory analysis of all 612 encounters yielded sensitivity of 93.9% and specificity of 91.4%. Because repeated encounters were clustered within patients, these estimates are presented as descriptive sensitivity analyses rather than as independent confirmatory estimates. Across all 612 encounters, the median time from symptom report to a completed nurse-triage decision was 24 minutes (IQR, 15–40). All 14 participating nurses completed the post-study usability assessment; the mean adapted SUS score was 83.6 (SD 7.9), and 12 of 14 nurses (85.7%) rated the NLITC as easy to integrate into existing workflow.

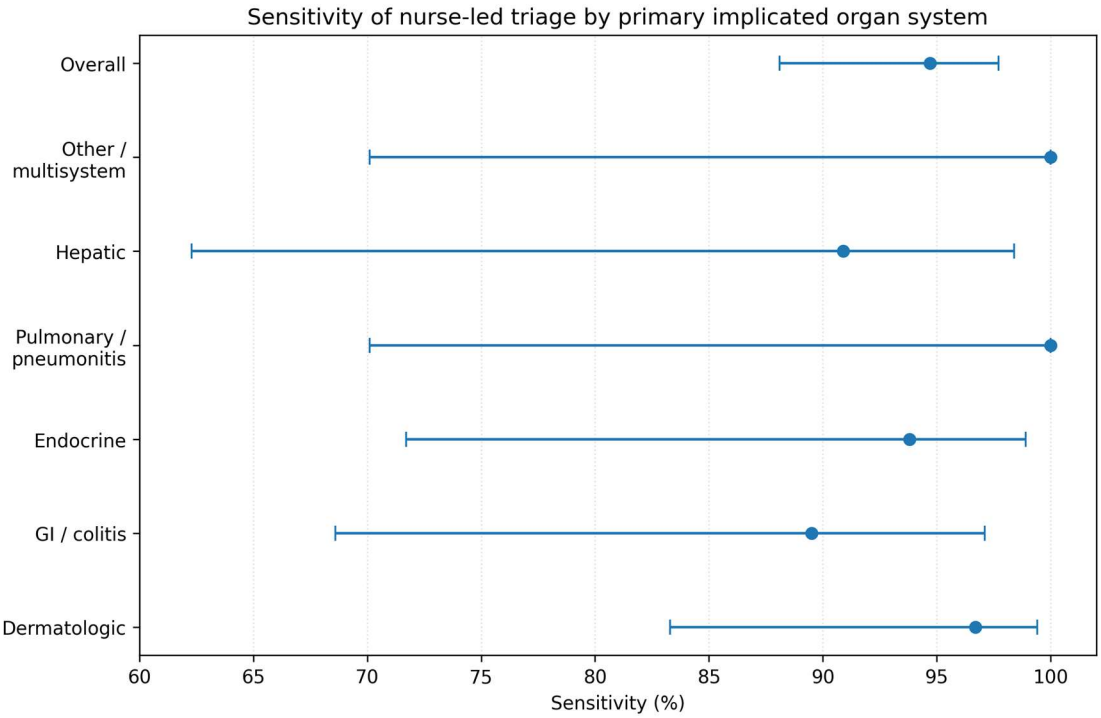


Figure 2. Sensitivity of nurse-led triage versus the oncologist reference standard, overall and by primary implicated organ system, with 95% confidence intervals.

DISCUSSION

In this prospective, two-center diagnostic accuracy study, a structured nurse-led triage checklist identified clinically significant irAEs with high sensitivity (94.7%) and good specificity (90.2%) when benchmarked against blinded oncologist assessment, with strong agreement in actionable/non-actionable classification (κ = 0.83). These findings are consistent in direction with prior nurse-led triage frameworks developed for treatment-related symptoms more broadly, including the UKONS 24-hour triage tool as incorporated into a European eHealth-enabled irAE monitoring model [7] and the COSTaRS remote symptom-triage protocols [8], and extend this evidence base specifically to irAE recognition in Indian tertiary-care settings.

The clinical relevance of these findings is amplified by the workforce context in which they were generated. India's constrained oncologist availability [9], combined with previously documented gaps in formal oncology training among nursing staff in Indian cancer centers [10], creates structural pressure toward nurse-extended monitoring models as ICI use expands beyond apex referral centers. A triage instrument with a negative predictive value of 96.7%, as observed here, could in principle allow oncologists to prioritize in-person review toward patients flagged as actionable while deferring most non-actionable patients to routine follow-up; however, such a workflow should be implemented only after external validation and with organ-specific escalation safeguards.

Several limitations warrant caution before broader adoption. First, this was a two-center study, and the nurses studied received structured training and close initial mentorship; performance may not generalize to settings without comparable training infrastructure. Second, because nurses were aware they were participating in a validation study, a Hawthorne effect may have inflated triage accuracy relative to unmonitored routine practice.

Third, non-actionable encounters were verified by the reference-standard oncologist at the next scheduled visit rather than on the same day, an asymmetry in verification timing that constitutes a form of differential verification bias; this could inflate apparent specificity if some misclassified non-actionable episodes resolved spontaneously before reference-standard review [13]. Fourth, a uniform CTCAE grade ≥2 threshold was applied across all organ systems despite differing clinical urgency; organ-specific action thresholds may be a more clinically meaningful target for future refinement of the tool. Fifth, subgroup sample sizes for less common irAE categories (pulmonary and hepatic) were small, yielding wide confidence intervals around otherwise favorable point estimates; the consequences of a missed high-grade pneumonitis event can be clinically severe, so these subgroup estimates should not be interpreted as reassurance [1–4]. Sixth, the NLITC has not undergone formal psychometric validation beyond the content-review process described in Methods, and its performance may not transfer to other item sets or organ-system weightings. Seventh, the study design did not include a contemporaneous comparator arm (for example, unstructured nurse assessment without the NLITC), so the incremental benefit of the structured checklist over existing informal practice cannot be quantified from these data alone. Finally, spectrum bias is possible if patients with obviously severe symptoms bypassed telephone triage and sought direct emergency care, potentially inflating apparent sensitivity [13].

Future work should prioritize external multicenter validation across centers with varying nurse-to-patient ratios and baseline oncology training levels, ideally using a stepped-wedge or cluster-randomized design that compares structured NLITC-guided triage against usual nursing practice. Future studies should also apply symmetric same-day reference-standard verification to actionable and non-actionable encounters when feasible, use statistical methods that account for repeated encounters within patients, and capture downstream clinical outcomes such as time to corticosteroid initiation, unplanned hospitalization rates, and ICI discontinuation rather than diagnostic accuracy alone.

CONCLUSION

A structured, CTCAE-anchored nurse-led triage checklist demonstrated high sensitivity and strong agreement with blinded oncologist assessment for identifying clinically significant immune-related adverse events among patients receiving immune checkpoint inhibitor therapy at two tertiary oncology centers in India. Given the asymmetric verification timing between actionable and non-actionable encounters, the repeated-encounter structure of the dataset, the absence of a contemporaneous comparator arm, and the single-country setting, these findings should be regarded as hypothesis-generating rather than confirmatory. Additional multicenter validation with symmetric reference-standard verification and appropriate accounting for repeated observations is needed before widespread adoption of nurse-led triage using the NLITC.

DECLARATIONS

Funding

This research received no external funding.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Author Contributions (CRediT)

ET: Conceptualization, Methodology, Investigation, Data curation, Formal analysis, Writing – original draft. AV: Methodology, Investigation, Data curation, Formal analysis, Writing – review & editing. SP: Investigation, Data curation, Validation, Writing – review & editing, Supervision. All authors reviewed and approved the final manuscript and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki. The study protocol was reviewed and approved by the institutional ethics committees of the participating hospitals. Written informed consent was obtained from all participants before enrollment.

Consent for Publication

Not applicable. No individually identifiable patient information is included in this manuscript.

Data Availability

The datasets generated and/or analyzed during the current study are not publicly available because they contain potentially identifiable clinical information but are available from the corresponding author upon reasonable request, subject to applicable ethics and data-protection requirements.

Artificial Intelligence Statement

The authors used AI-assisted tools solely for language editing, grammar correction, and proofreading during manuscript preparation. AI tools were not used to generate or analyze research data, perform statistical analyses, interpret findings, generate figures, or formulate scientific conclusions. The authors critically reviewed and verified all AI-assisted text and take full responsibility for the content, accuracy, originality, and integrity of the manuscript.

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