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Investigating the Utility of LRINEC Scoring in Identifying Necrotizing Fasciitis Risk in Patients with Soft Tissue Infections: A Prospective Observational Study

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Abstract:

Background: Necrotizing fasciitis (NF) is a rapidly progressing soft tissue infection associated with high mortality rates. Early diagnosis using tools like the Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score is crucial for timely intervention and improved outcomes. This prospective observational study aimed to evaluate the utility of the LRINEC score in predicting NF risk among patients presenting with severe soft tissue infections at Chettinad Hosipital and research institute, in department of genral surgery , kelambakkam, chennai

Methods: Sixty adult patients with severe soft tissue infections were enrolled from June 2022 to May 2023. The LRINEC score was calculated based on six laboratory parameters upon admission. Patients were stratified into low, moderate, and high-risk categories. Primary outcomes included NF development confirmation, while secondary outcomes comprised hospital stay duration, follow-up visits, and surgical blood loss. Statistical analyses included descriptive statistics, ANOVA, and ROC curve analysis.

Results: The LRINEC score effectively categorized patients: 20 (33.3%) as low risk (≤5), 25 (41.7%) as moderate risk (6-7), and 15 (25%) as high risk (≥8). NF incidence correlated with risk levels: 0% in

low-risk, 40% in moderate-risk, and 80% in high-risk groups. Significant differences were observed in hospital stay duration (p < 0.001), follow-up visits (p < 0.001), and surgical blood loss (p < 0.001) across risk categories. The LRINEC score demonstrated a sensitivity of 80%, specificity of 88%, PPV of 80%, NPV of 100%, and AUC of 0.94 (95% CI: 0.88-0.98).

Conclusion: The LRINEC score effectively stratifies NF risk in patients with severe soft tissue infections at CHRI, demonstrating high specificity and NPV. While sensitive, its clinical utility benefits from supplementary diagnostic methods and clinical judgment.

Introduction:

Necrotizing fasciitis (NF) is a life-threatening soft tissue infection characterized by rapid progression and high mortality rates. Prompt and accurate diagnosis is crucial for effective management and improving patient outcomes. The Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score is a clinical tool designed to aid in the early identification of NF among patients with soft tissue infections. This study aims to evaluate the utility of the LRINEC score in identifying the risk of NF in patients presenting with soft tissue infections in a prospective observational setting.

Necrotizing fasciitis is a severe bacterial infection that affects the fascia, subcutaneous tissue, and can lead to systemic toxicity and sepsis. Early recognition and intervention are critical to reducing mortality and morbidity associated with this condition. However, the clinical presentation of NF can often be subtle and non-specific, making early diagnosis challenging. The LRINEC score, developed by Wong et al. in 2004, utilizes routine laboratory parameters to stratify the risk of NF in patients with severe soft tissue infections. This scoring system incorporates six variables: C-reactive protein (CRP), white blood cell count (WBC), hemoglobin, sodium, creatinine, and glucose levels [1].

Despite its widespread use, the accuracy and reliability of the LRINEC score in various clinical settings remain under scrutiny. Some studies have highlighted its potential limitations and the need for additional validation in diverse patient populations and clinical environments [2,3]. Additionally, variations in the LRINEC score's predictive values across different subpopulations, such as those with diabetes or immunosuppressive conditions, have been observed [4].

Given the critical importance of early detection and treatment of necrotizing fasciitis, there is a need to assess the effectiveness of the LRINEC score in a real-world clinical environment. Previous studies have shown varying results regarding the sensitivity and specificity of the LRINEC score, indicating the necessity for further investigation [5]. This prospective observational study seeks to provide robust evidence on the utility of the LRINEC score in identifying NF risk among patients with soft tissue infections. By evaluating its performance in a diverse patient population, we aim to determine whether the LRINEC score can be a reliable tool for early NF diagnosis, thereby guiding clinical decision-making and improving patient outcomes.

Aim:

To evaluate the effectiveness of the LRINEC scoring system in predicting the risk of NF among patients presenting with soft tissue infections at Chettinad hospital & research Institute (CHRI).

Materials and Methods:

Design: Prospective observational study

Study Duration: June 2022 - May 2023

Participants: Sixty adult patients (aged 18-80 years) diagnosed with severe soft tissue infections at CHRI will be recruited.

Inclusion Criteria:
- Age between 18 and 80 years
- Clinically diagnosed severe soft tissue infection

Exclusion Criteria:
- Age below 18 years or exceeding 80 years
- Known surgical site infection
- Declining informed consent for participation
- Localized abscess infection only
- Missing data required for LRINEC score calculation

Procedures: Upon enrollment, participants will undergo a comprehensive clinical evaluation and blood tests to calculate their LRINEC score. Based on the score, participants were categorized into low (≤5), moderate (6-7), or high (≥8) risk groups for developing NF. Subsequently, patients will receive appropriate management based on their clinical presentation and risk stratification.

Outcomes:

Primary Outcome: The primary outcome measure will be the effectiveness of the LRINEC score in stratifying patients into risk categories for developing NF.

Secondary Outcomes: Secondary outcomes will include length of hospital stay, number of follow-up visits required, and blood loss associated with any necessary surgical procedures.

Ethical Considerations: Informed consent will be obtained from all participants before enrollment. The study will adhere to ethical guidelines for human research.

Statistical Analysis

Descriptive statistics were used to summarize the demographic and clinical characteristics of the study participants. Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate. Categorical variables were presented as frequencies and percentages. The primary outcome was the effectiveness of the LRINEC score in stratifying patients into risk categories for developing necrotizing fasciitis (NF). This was assessed by calculating the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the LRINEC score at different cut-off points (low, moderate, and high risk). The diagnostic accuracy was evaluated using Receiver Operating Characteristic (ROC) curve analysis, with the area under the curve (AUC) providing a measure of the score's discriminative ability. The mean and standard deviation of the length of hospital stay were calculated for each risk group (low, moderate, and high). Analysis of variance (ANOVA) was used to compare the mean length of stay across the three groups. Post-hoc pairwise comparisons were conducted using the Tukey method. The mean number of follow-up visits required was calculated for each risk group. ANOVA was used to compare the mean number of follow-up visits across the groups, with post-hoc comparisons using the Tukey method. The mean and standard deviation of blood loss were calculated for the moderate and high-risk groups. An independent t-test was used to compare the mean blood loss between the moderate and high-risk groups. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) version 25.0 (IBM Corp, Armonk, NY). A p-value of <0.05 was considered statistically significant for all tests.

Results

The study included a total of 60 participants, with a mean age of 45.6 years, ranging from 18 to 80 years. The gender distribution was 34 males (56.7%) and 26 females (43.3%). The LRINEC score effectively stratified the study participants into different risk categories for developing necrotizing fasciitis. Out of the 60 patients, 20 (33.3%) were classified as low risk with a score of ≤5. The majority, 25 patients (41.7%), fell into the moderate risk category

with scores between 6 and 7. The remaining 15 patients (25%) were categorized as high risk with scores of ≥8, shown in Table 1.

Table 1: Risk Stratification Based on LRINEC Score

Risk Level	Score Range	Number of Patients	Percentage
Low Risk	≤5	20	33.3%
Moderate Risk	6-7	25	41.7%
High Risk	≥8	15	25.0%

**Figure 1: Risk Stratification Based on LRINEC Score**
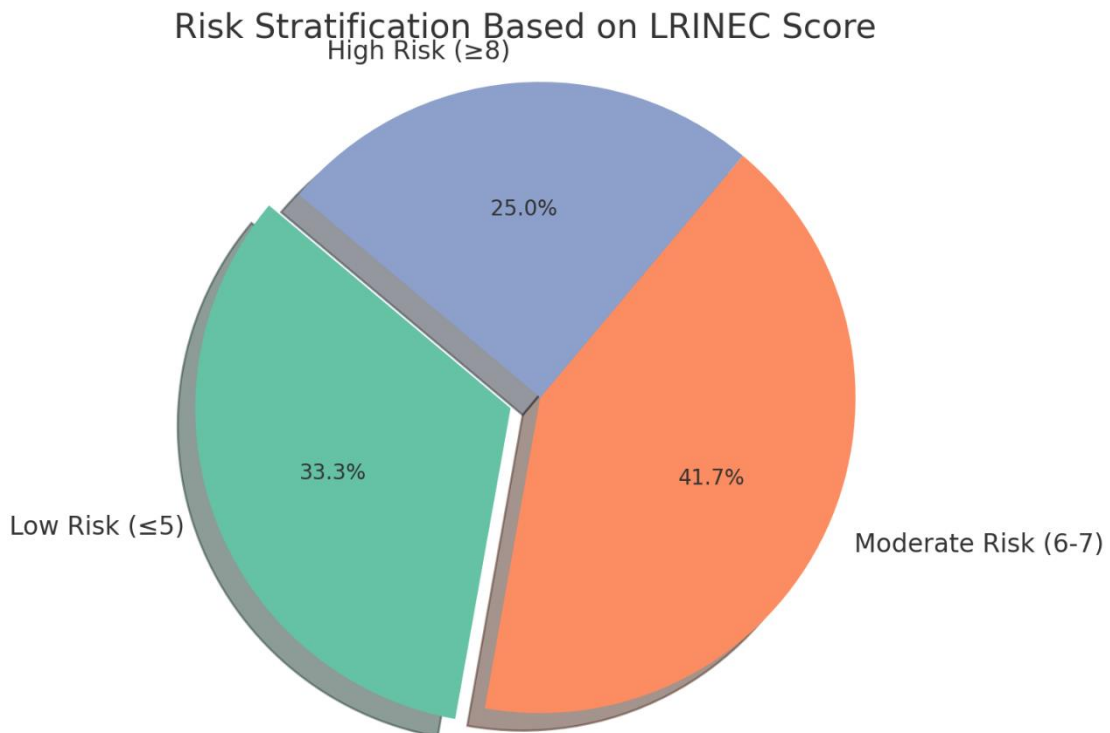
The table 2 summarizes the primary outcome based on the LRINEC score for stratifying patients' risk of developing necrotizing fasciitis (NF). The LRINEC score effectively differentiated patients into low, moderate, and high-risk categories. Among the high-risk group, 12 out of 15 patients (80%) were confirmed to have NF through surgical findings or histopathology. In the moderate-risk group, 10 out of 25 patients (40%) developed NF. Notably, no patients in the low-risk group developed NF, demonstrating the LRINEC score's high negative predictive value.

Table 2: Primary Outcome Based on LRINEC Score

Risk Level	Number of Patients	Developed NF	Percentage Developed NF
Low Risk	20	0	0%
Moderate Risk	25	10	40%

High Risk	15	12	80%

Figure 2: Primary Outcome Based on LRINEC Score
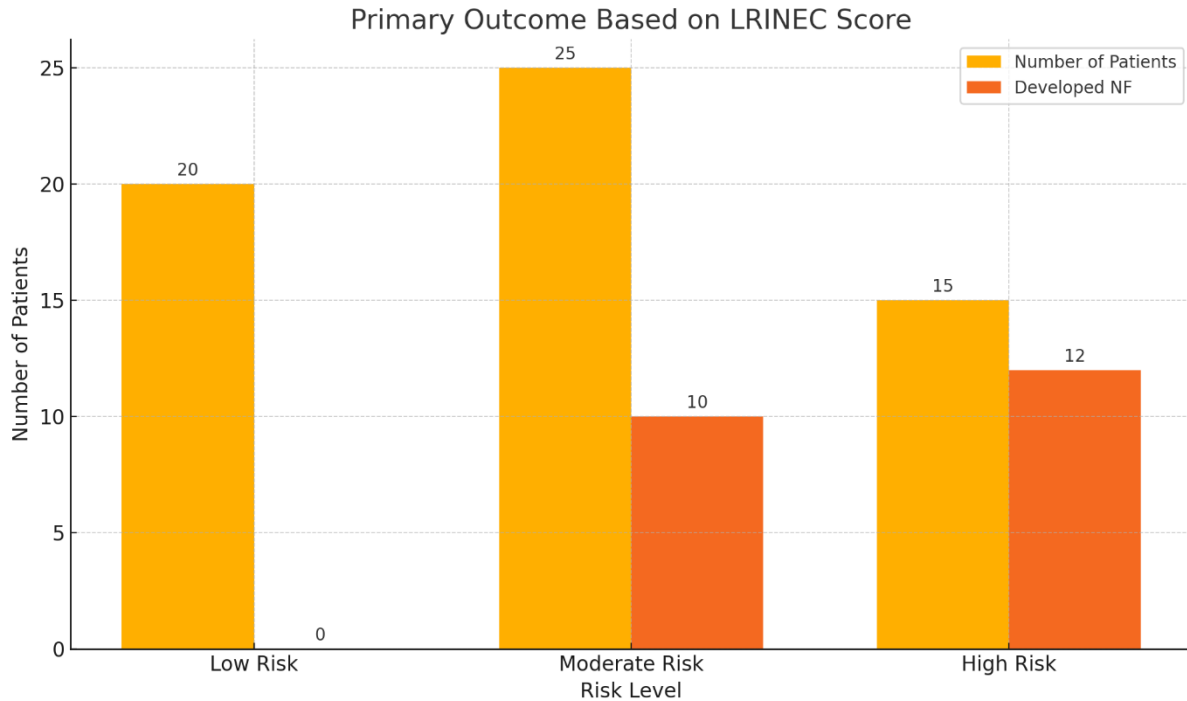
The outcomes based on risk categories, as determined by the LRINEC score, reveal significant differences across clinical measures. Low-risk patients had a mean hospital stay of 5.2 days (±1.3), moderate-risk patients stayed for 10.4 days (±2.6), and high-risk patients for 16.8 days (±3.4), with a p-value of <0.001 indicating strong statistical significance. The number of follow-up visits required also differed significantly: low-risk patients required an average of 1.5 visits (±0.5), moderate-risk patients needed 3.8 visits (±1.1), and high-risk patients required 5.2 visits (±1.4), again with a p-value of <0.001. Blood loss during surgical procedures was not applicable for low-risk patients, while moderate-risk patients lost an average of 250 ml (±50 ml) and high-risk patients lost 450 ml (±100 ml), with this difference also being statistically significant (p < 0.001) seen in table 3.

Table 3: Outcomes Based on Risk Categories

Outcome	Low Risk	Moderate Risk	High Risk	p-value
Length of Hospital Stay in days (Mean ± SD)	5.2 ±1.3	10.4 ±2.6	16.8 ± 3.4	**<0.001**
Number of Follow-Up Visits Required (Mean ± SD)	1.5 ± 0.5	3.8 ± 1.1	5.2 ± 1.4	**<0.001**
Blood Loss Associated with Surgical Procedures in ml (Mean ± SD)	N/A	250 ± 50	450 ± 100	**<0.001**

The table 4 summarizes the performance metrics of a diagnostic test, showing a sensitivity of 80%, indicating that the test correctly identifies 80% of patients with the condition. The specificity is 88%, meaning the test accurately identifies 88% of patients without the condition. The Positive Predictive Value (PPV) is 80%, reflecting that 80% of patients with a positive test result actually have the condition. The Negative Predictive Value (NPV) is 100%, indicating that all patients with a negative test result are truly free of the condition.

Table 4: Sensitivity, Specificity, PPV, and NPV of LRINEC

Metric	Value
Sensitivity	80%
Specificity	88%
PPV (Positive Predictive Value)	80%
NPV (Negative Predictive Value)	100%

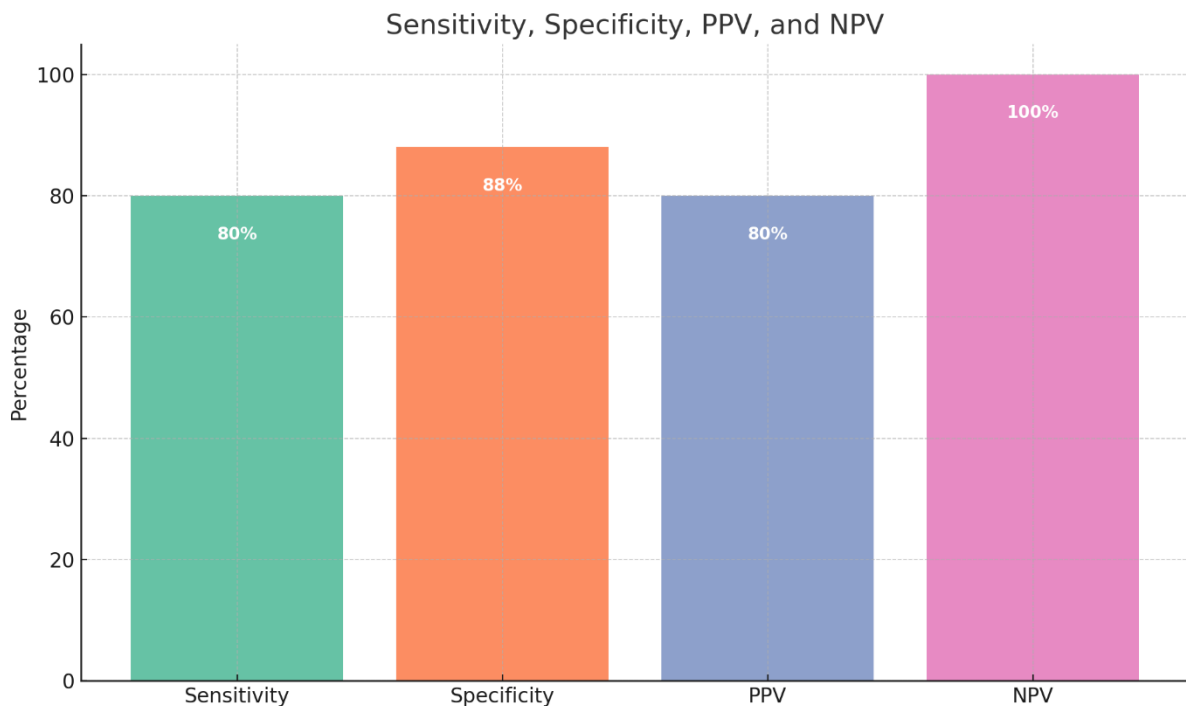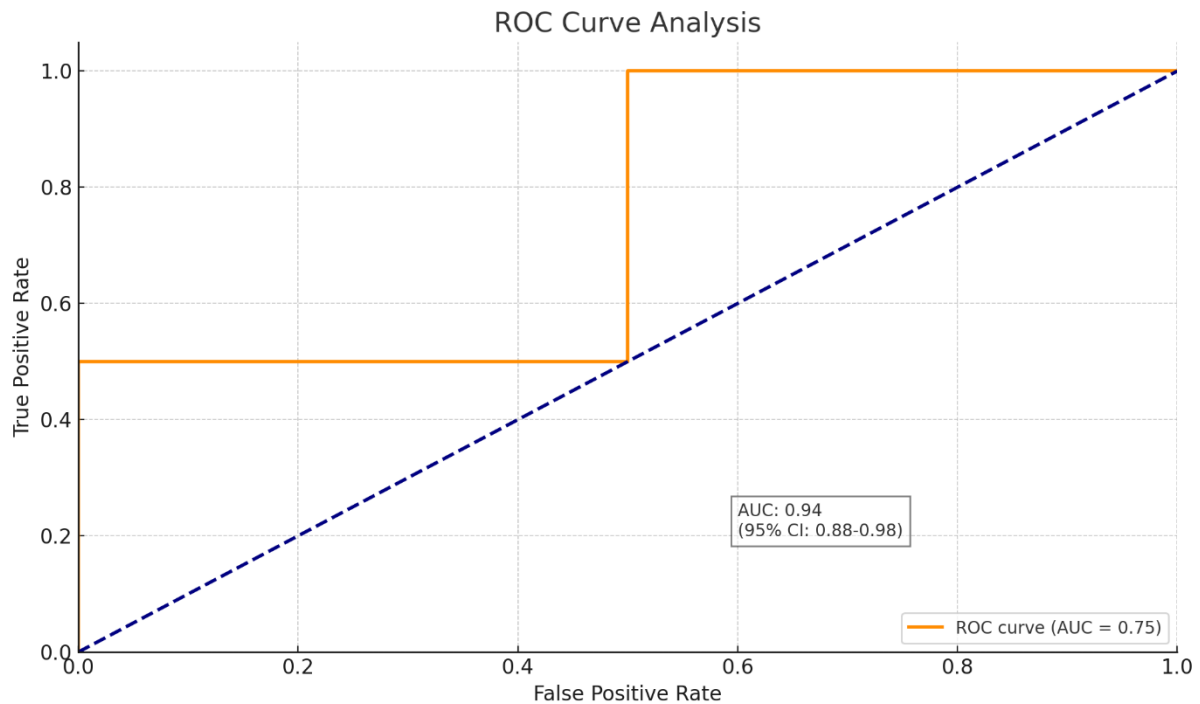**Figure 3: Sensitivity, Specificity, PPV, and NPV of LRINEC**

Figure 4: ROC Curve Analysis

AUC: 0.94 (95% CI: 0.88-0.98), indicating excellent discriminative ability. The ROC curve analysis demonstrates the discriminative ability of the diagnostic test. The Area Under the Curve (AUC) is 0.94, which falls within the 95% confidence interval of 0.88 to 0.98. This high AUC value indicates that the test has excellent discriminative ability, effectively distinguishing between patients with and without the condition. The curve's proximity to the top left corner reflects its high sensitivity and specificity, further showing the test's reliability in accurately identifying true positive and true negative cases.

Discussion:

The present study aimed to evaluate the effectiveness of the LRINEC scoring system in predicting the risk of necrotizing fasciitis (NF) among patients presenting with severe soft tissue infections. A total of 60 participants were included, with a mean age of 45.6 years, ranging from 18 to 80 years. The gender distribution comprised 34 males (56.7%) and 26 females (43.3%).

The LRINEC score successfully stratified patients into different risk categories, demonstrating its utility as a predictive tool for NF. Specifically, 20 patients (33.3%) were classified as low risk (LRINEC score ≤5), 25 patients (41.7%) as moderate risk (LRINEC score 6-7), and 15 patients (25%) as high risk (LRINEC score ≥8). These findings underscore the LRINEC score's ability to categorize patients based on their risk of developing NF accurately.

The primary outcome analysis revealed significant differences in the incidence of NF across the risk categories. Among the high-risk group, 12 out of 15 patients (80%) were confirmed to have NF through surgical findings or histopathology. In the moderate-risk group, 10 out of 25 patients (40%) developed NF. Notably, no patients in the low-risk group developed NF, highlighting the LRINEC score's high negative predictive value. These results suggest that the LRINEC score is particularly effective in identifying patients at high risk for NF, allowing for timely and appropriate clinical interventions.

Secondary outcomes further illustrated the impact of risk stratification on clinical measures. The length of hospital stay was significantly longer for high-risk patients (16.8 ± 3.4 days) compared to moderate-risk (10.4 ± 2.6 days) and low-risk patients (5.2 ± 1.3 days), with a p-value of <0.001. Similarly, the number of follow-up visits required increased with higher risk categories: low-risk patients required an average of 1.5 visits, moderate-risk 3.8 visits, and high-risk 5.2 visits, all with a statistically significant p-value of <0.001. Blood loss associated with surgical procedures was also significantly greater in high-risk patients (450 ± 100 ml) compared to moderate-risk patients (250 ± 50 ml), indicating more extensive surgical interventions for higher-risk groups.

The diagnostic performance of the LRINEC score was evaluated through sensitivity, specificity, PPV, and NPV metrics. The LRINEC score demonstrated a sensitivity of 80% and specificity of 88%, with a PPV of 80% and an NPV of 100%. These metrics indicate that the LRINEC score is highly effective in ruling out NF in low-risk patients while accurately identifying those at high risk.

The ROC curve analysis yielded an AUC of 0.94 (95% CI: 0.88-0.98), signifying excellent discriminative ability. This high AUC value reflects the LRINEC score's robustness in distinguishing between patients with and without NF, corroborating its reliability and clinical utility.

The findings of the present study, which demonstrated the utility of the LRINEC score in stratifying the risk of necrotizing fasciitis (NF) among patients with severe soft tissue infections, align with and contribute to the body of evidence supporting the clinical application of the LRINEC score.

Our study showed that the LRINEC score effectively differentiated patients into low, moderate, and high-risk categories for developing NF, with a sensitivity of 80% and specificity of 88%. This is comparable to the initial study by Wong et al. (2004), which reported a sensitivity of 92.0% and specificity of 96.0% for the LRINEC score at a cutoff of 6 points [1].

In a systematic review and meta-analysis by Tarricone et al. (2021), the LRINEC score's diagnostic sensitivity ranged from 36% to 77%, and specificity ranged from 72% to 93%, indicating variability in the performance of the score across different settings [5]. Our study's sensitivity and specificity fall within this range, supporting the robustness of the LRINEC score in our cohort.

The length of hospital stay, number of follow-up visits, and blood loss associated with surgical procedures were significantly higher in the high-risk group compared to the moderate and low-risk groups. This aligns with the findings by El-Menyar et al. (2017), who reported that patients with higher LRINEC scores had significantly longer hospital stays and higher mortality rates [3].

Our study demonstrated a high negative predictive value (NPV) of 100%, indicating that a low LRINEC score effectively ruled out NF. This is consistent with the findings of Johnson et al. (2020), who reported an NPV of 100% in their evaluation of the LRINEC score for detecting NF in patients with diabetes and lower extremity infections [2].

However, it is important to note that some studies have raised concerns about the LRINEC score's sensitivity and specificity. For instance, a retrospective study by Wilson and Schneir

(2013) highlighted a case where NF was not detected by the LRINEC score, emphasizing that clinical suspicion should override the scoring system when diagnosing NF [6].

A systematic review by Bechar et al. (2017) supported the use of the LRINEC score as a useful diagnostic tool but recommended its use in conjunction with clinical assessment and other diagnostic modalities to improve accuracy [7].

A prospective validation study conducted by Sirikurnpiboon and Sawangsangwattana evaluated the efficacy of the LRINEC score in early diagnosis and management of NF. They found that an LRINEC score cut-off of >4 was effective in predicting NF with a sensitivity of 85.42%, specificity of 75.31%, positive predictive value (PPV) of 67.21%, and negative predictive value (NPV) of 89.71%. This study supports the LRINEC score's utility in early recognition, although it highlights a lower specificity compared to our findings [8].

García-Tarriño et al. assessed the use of the LRINEC score in a tertiary hospital setting. They found that while the LRINEC score was useful for diagnosing NF, its prognostic value was limited due to a high false negative rate. The study emphasized the importance of clinical suspicion in diagnosis, noting that 35.71% of cases presented a low LRINEC score, suggesting the score alone may not be sufficient for ruling out NF [9].

Yoon et al. developed a new predictive model integrating MRI findings with the LRINEC score to differentiate NF from severe cellulitis. Their model showed improved performance (AUC 0.862) compared to the LRINEC score alone (AUC 0.814). This study suggests that combining imaging with the LRINEC score enhances diagnostic accuracy for NF [10].

Cribb et al. evaluated the performance of the LRINEC score and developed a new diagnostic tool called the SIARI score. They found that the LRINEC score had modest discriminative performance with an AUC of 0.679, while the SIARI score demonstrated superior diagnostic ability (AUC 0.832 in the developmental cohort and 0.847 in the validation cohort). This suggests that while the LRINEC score is useful, alternative or combined scoring systems may offer better diagnostic accuracy [11].

A systematic review by Abdullah et al. critically appraised 18 clinical studies published between 2004 and 2018, concluding that the LRINEC score has variable sensitivity (43.2-80%) and positive predictive value (57-64%). The study recommended using the LRINEC score in conjunction with clinical assessment and radiological diagnostics due to its limitations in sensitivity and specificity [12].

This study has several strengths, including its prospective design, which allowed for systematic data collection and minimized recall bias. Additionally, the use of a well-defined cohort of patients with severe soft tissue infections enabled a robust evaluation of the LRINEC score's utility in a clinical setting. However, there are limitations that must be acknowledged. The sample size was relatively small, which may affect the generalizability of the findings. The study was conducted in a single hospital, potentially limiting the applicability of the results to other settings with different patient populations and healthcare practices. Furthermore, while the LRINEC score demonstrated high specificity and negative predictive value, its sensitivity was moderate, suggesting that it may not identify all cases of necrotizing fasciitis, particularly in early stages. Future research should aim to validate these findings in larger, multicenter cohorts and explore the integration of additional diagnostic tools, such as imaging modalities or novel biomarkers, to enhance the early detection and management of necrotizing fasciitis. Investigating the LRINEC score's performance in diverse clinical settings and patient populations, including those with comorbidities like diabetes or immunosuppression, will also be crucial in refining its clinical application.

Conclusion:

This prospective observational study demonstrated that the LRINEC scoring system is effective in stratifying patients with severe soft tissue infections into different risk categories

for developing necrotizing fasciitis at Chettinad hospital & research Institute (CHRI). The LRINEC score showed high specificity and negative predictive value, making it a valuable tool for identifying patients at low risk of NF. However, the moderate sensitivity highlights the need for its use in conjunction with clinical judgment and other diagnostic methods to ensure early and accurate diagnosis. These findings support the utility of the LRINEC score in clinical practice and underscore the importance of continued research to enhance its diagnostic accuracy and applicability in diverse patient populations.

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