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Accuracy of the Laboratory Risk Indicator for Necrotizing Fasciitis Score for Diagnosis of Necrotizing Fasciitis

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ABSTRACT

Background: Necrotizing fasciitis (NF) is a fast-growing infection that mostly affects the subcutaneous tissue and fascia. The Laboratory risk indicator for necrotizing fasciitis (LRINEC) score was initially presented in 2004. **Objective:** This study aimed to assess the diagnostic accuracy of the laboratory risk indicator for necrotizing fasciitis (LRINEC) score for the diagnosis of necrotizing fasciitis, taking histopathology as the gold standard. **Study Design:** Cross-sectional validation study. **Settings:** General Surgery Department, Sahiwal Teaching Hospital, Sahiwal Pakistan. **Duration:** Six months from 13 February 2024 to 12 August 2024. **Methods:** A total of 165 adult cases with suspected necrotizing fasciitis were included. Patients with <48 hours of hospital stay, prior oral antibiotic use, or previous debridement were excluded. Clinical suspicion was based on rapidly spreading erythema with severe pain. LRINEC score, consisting of white blood cells, hemoglobin, sodium, glucose, creatinine, and C-reactive proteins, was calculated. Debridement findings and histopathology confirmed necrotizing fasciitis. Sensitivity, specificity, predictive values, accuracy, and likelihood ratios of LRINEC (≥6) were determined using histopathology as the gold standard. **Results:** Mean age was 42.4 ± 9.9 years, and 59.4% (n=98) were males. Diabetes mellitus was present in 73.9%. The mean leucocyte count, hemoglobin, serum sodium, blood sugar, and creatinine were 16.6±7.6/mm^3, 12.0±2.1 g/dL, 137.4±9.1 mmol/L, 147.3±45.9 mg/dL, and 1.4±0.6 mg/dL, respectively. Necrotizing fasciitis was diagnosed in 39.4% by LRINEC (≥6) and 60% by histopathology. The sensitivity, specificity, and accuracy of LRINEC (≥6) were 55.6%, 84.8%, and 67.3%, respectively. **Conclusion:** LRINEC score (≥6) showed moderate sensitivity but high specificity for necrotizing fasciitis. It can be useful as an adjunct assessment tool, but histopathology remains the gold standard to make a diagnosis.

Keywords: *Necrotizing Fasciitis, Laboratory risk indicator for necrotizing fasciitis LRINEC, Sensitivity, Specificity.*

INTRODUCTION

Necrotizing fasciitis (NF) is a fast-growing infection that mostly affects the subcutaneous tissue and fascia [1]. It is the most serious soft tissue infection, with a 50% fatality rate in the absence of surgery.[2] The fascial plane, which has a weak blood supply, is usually the site where the infection travels.[3] Any invasive technique, including basic procedures like phlebotomy, can cause necrotizing fasciitis.[4] Gas is produced by pathogenic microorganisms, which are typically mixed. Increasing age, resistant microorganisms, delayed treatment, multiple organ failure, and sites of infection are risk factors for unfavorable results.[5]

It is crucial to identify and aggressively debride all necrotic fascia and subcutaneous tissue as soon as possible. It has been demonstrated that a delay in surgical debridement raises the death rate.[6] When detecting soft tissue gases in necrotizing infections, computed tomography (CT) is more sensitive than plain film.[7] Wong *et al*. initially presented the laboratory risk indicator for necrotizing fasciitis (LRINEC) score in 2004.[8] For NF to be diagnosed early, laboratory data such as hemoglobin, creatinine, glucose, C-reactive protein (CRP) levels,

sodium, as well as the white blood cell counts (WBC), are utilized.[9] Six scores are associated with a 92% and 96% positive predictive value (PPV) and negative predictive value (NPV), respectively. A necrotizing infection is 75% likely if the score is 8 or above.[9]

Liao CI *et al*. recruited 3155 patients with severe cellulitis and 233 patients with NF. Sensitivity was 59.2%, specificity was 83.8%, PPV was 37.9%, NPV was 92.5%, and the area under the receiver operating characteristic curve was 0.77 for the LRINEC score of ≥6. NF diagnosed clinically by physicians in the emergency room was seen in 58.4% of patients.[10] A total of 825 patients with cellulitis and 106 (11.4%) individuals with necrotizing fasciitis were enrolled by Hsiao CT *et al*.[11]

The sensitivity and specificity were 43% and 83%, respectively, while the PPV and NPV were 25% and 92% when the LRINEC cutoff score was ≥6, and 69.6% was the area under the receiver's operating characteristic curve.[11]

We have planned this study to validate the role of LRINEC in the early diagnosis of NF in patients clinically suspected of soft tissue infections at our local setting. Clinical examination may not detect deep fascial involvement, making objective risk-stratification tools like LRINEC valuable. Early detection and differentiation of NF from other infections will lead to timely surgical debridement and appropriate antimicrobial therapy so that adverse outcomes associated with this condition will be reduced. Early risk stratification will prioritize high-risk patients for imaging (MRI/CT) and surgical exploration. It will also help avoid unnecessary surgeries in low-risk cases.

METHODS

This cross-sectional validation study was executed at the General Surgery Department of Sahiwal Teaching Hospital for six months, from 13 February 2024 to 12 August 2024, after approval from the ethics review committee (No: 187/IRB/SLMC/SWL). A total of 165 patients aged 18 - 60 years, either male or female gender, and admitted with suspicion of necrotizing fasciitis, ≤ 48-hour duration of illness, were consecutively included in the study after informed consent. Patients who had a duration of hospitalization <48 hours, were already on oral antibiotics, and had already had debridement done were excluded.

Patients presenting with erythematous, hot, or swollen skin that is rapidly progressing with intense pain (VAS≥ 6) were suspected of having necrotizing fasciitis. Baseline patient characteristics were recorded. All the patients underwent venous blood sampling before the first antibiotic dose and fluid resuscitation. The samples were sent to a single laboratory for the measurement of WBC count, hemoglobin, sodium, glucose, creatinine, and CRP levels as per hospital protocol. LRINEC score was determined. All the patients underwent debridement after initial resuscitation. Operative findings of necrotic fascia and pus collection were recorded, and tissues were sent for histopathological examination to the pathology Department. The presence of necrosis, polymorphonuclear infiltration, vasculitis, and thrombosis in the tissue and operative findings were used to make the final diagnosis of necrotizing fasciitis.

A minimum sample size of 165 was calculated using the online sample size calculator https://wnarifin.github.io/ssc/sssnsp.html, taking disease prevalence of 58%, 43% sensitivity of LRINEC, 83% specificity[11], and 10% absolute precision. Mean ± SD was calculated for normally distributed quantitative variables (median and IQR if not normally distributed). Frequencies and percentages were measured for categorical data. Keeping histopathological findings as the gold standard, the sensitivity, specificity, PPV, NPV, accuracy, and positive and negative likelihood ratios with a 95% confidence level were calculated for the LRINEC score ≥6.

RESULTS

The mean age of the patients was 42.4 ± 9.9 years, and there were 59.4% (n=98) males in the study. Diabetes mellitus was the underlying co-morbidity in 73.9% (n=122) of the cases. On admission, the mean leucocyte count, hemoglobin, serum sodium, blood sugar, and serum creatinine were 16.6 ± 7.6/mm^3, 12.0 ± 2.1 g/dl, 137.4 ± 9.1 mmol/L, 147.3 ± 45.9 mg/dl, and 1.4 ± 0.6 mg/dl, respectively. The median (IQR) C-reactive protein and LRINEC score were 100 (89) mg/dl and 2 (5), respectively. (Table 1)

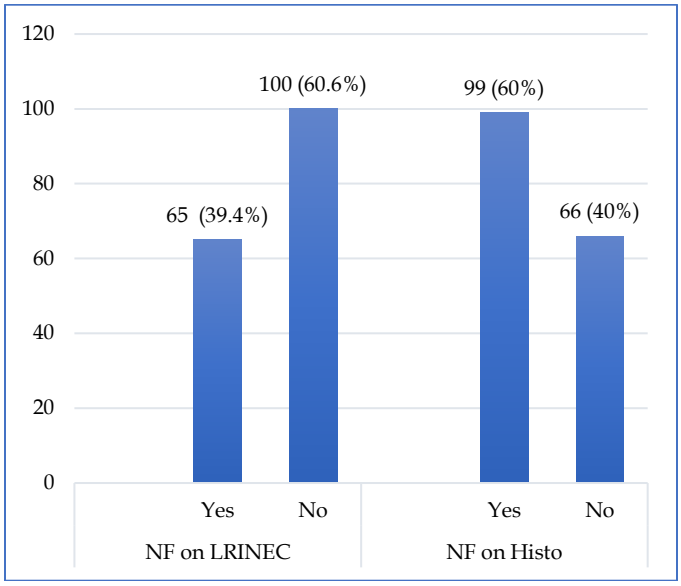
Table 1: Characteristics of patients presenting with suspected necrotizing fasciitis (N=165)

Age (years)		42.4 ± 9.9
Gender	Male	98 (59.4)
	Female	67 (40.6)
Diabetes Mellitus (yes)		122 (73.9)
Total leucocyte count (/mm^3)		16.6 ± 7.6
Hemoglobin (g/dl)		12.0 ± 2.1
Serum Sodium (mmol/L)		137.4 ± 9.1
Blood Sugar (mg/dl)		147.3 ± 45.9
Serum Creatinine (mg/dl)		1.4 ± 0.6
C-reactive protein (mg/dl)		100 (89)
LRINEC* score		2 (5)

**Laboratory Risk Indicator for Necrotizing fasciitis*

Necrotizing fasciitis on LRINEC score (≥6) was positive in 39.4% (n=65) and 60% (n=99) on histopathology. (Figure 1).

Figure 1: Frequency of necrotizing fasciitis diagnosed of LRINEC score and histopathology (N=165)



Taking histopathology as the gold standard, the sensitivity, specificity, and PPV were evaluated. NPV, accuracy, positive likelihood ratio and negative likelihood ratio were 55.6% (95% CI: 45.2 – 65.6), 84.8% (95% CI: 73.9 – 92.5), 84.6% (95% CI: 75.2 – 90.9), 56.0% (95% CI: 49.9 – 61.8), 67.3% (95% CI: 59.5 – 74.4), 3.7 (2.0 – 6.7) and 0.5 (0.4 – 0.7) respectively. (Table 2)

Table 2: Diagnostic accuracy of LRINEC score for necrotizing fasciitis taking histopathology as gold standard (N=165)

Necrotizing Fasciitis on LRINEC Score	Necrotizing Fasciitis on Histopathology	
	Yes	**No**
Yes	55	10
No	44	56
Sensitivity	55.6% (95% CI: 45.2 – 65.6)	
Specificity	84.8% (95% CI: 73.9 – 92.5)	
Positive Predictive Value	84.6% (95% CI: 75.2 – 90.9)	
Negative Predictive Value	56.0% (95% CI: 49.9 – 61.8)	
Accuracy	67.3% (95% CI: 59.5 – 74.4)	
Positive Likelihood Ratio	3.7 (2.0 – 6.7)	
Negative Likelihood Ratio	0.5 (0.4 – 0.7)	

DISCUSSION

Our work is the first prospective study reported from our local region on the validation of the LRINEC score with a sizable patient population. The LRINEC score showed sensitivity, specificity, PPV, NPV, and accuracy of 55.6%, 84.8%, 84.6%, 56.0%, and 67.3%, respectively, according to this study. Our findings imply that the LRINEC score is insufficient to differentiate between NF and severe cellulitis in the limbs. In the emergency room, one must be cautious while using the LRINEC score alone for diagnosing NF.

The LRINEC score was found to have moderate sensitivity, which was demonstrated by this prospective validation study. This is in line with findings from other research studies where the sensitivity varied between 30%-85%.[11,12,13] Since many individuals having NF are misinterpreted as cases of severe cellulitis, using the moderately sensitive LRINEC score to exclude individuals with necrotizing fasciitis may result in late diagnosis, late operative therapy, and more unfavorable consequences.

The meta-analysis and retrospective validation studies produced contradictory findings about the LRINEC score's accuracy. According to Liao *et al.*'s large retrospective validation study (the NF group included 233, while the severe cellulitis group included 1394 patients), the LRINEC score for NF had a moderate AUROC curve (0.77). The author concluded that NF cannot be identified early with the LRINEC score alone.[10]

In line with our findings, Neeki et al.'s retrospective validation research (NF group had 47 and the severe cellulitis group had 948 patients), which was the 2nd largest, showed 36% sensitivity and 89% specificity with LRINEC score ≥6.[14] Increased mortality and postponed surgical intervention could result from large false negative rate in actual NF cases confirmed on pathology.

The emergency room's clinical load and patients' financial burden are further increased by more than ten percent false positivity in cases diagnosed with severe cellulitis, which can result in needless clinical, laboratory, or radiological investigations for NF.

The association between the LRINEC score and amputation and mortality was evaluated by Fujinaga J *et al*. The results for patients, including amputation and mortality, did not correlate with the LRINEC score.[15] Forty-five patients participated in a prospective study by Adhil *et al*. With an AUC of 0.751, the ROC curve produced a cutoff limit of ≥6. The study's sensitivity was 85%, and its specificity was 52% at this cutoff threshold. Similarly, in the early diagnosis of NF, the PPV was 58.6%, the NPV was 81.2%, and the overall accuracy was 66.6%.[16]

The sensitivity of the LRINEC score was 86%, according to Daniels *et al.*'s study of both the traditional and modified LRINEC scores. The modified LRINEC score calculation revealed a 97% improvement in sensitivity.[17] In comparison to our observations, these investigations

demonstrate better sensitivity to LRINEC. A total of 220 patients were recruited in the analysis of another California study. All things considered, the sensitivity was 76%, the specificity was 52%, the PPV was 32%, and the NPV was 88%.[18] The diagnostic role of LRINEC score more than or above 6 was assessed by Thomas NM *et al*.; score of 8 or above had a sensitivity and specificity of 67% and 82% with PPV and NPV of 78% and 72%, respectively, while score 6 or above had a sensitivity of 85% and specificity of 62%.[19]

To differentiate NF from severe cellulitis, one retrospective study reported the LRINEC score with AUROC - 0.92, sensitivity - 76%, specificity - 93%, and PPV and NPV of 95% and 88%, keeping the LRINEC value of ≥6. The LRINEC score was found to be a reliable and practical scoring method that can be used as a supplement to diagnose NF earlier.[20] A meta-analysis consisting of sixteen research studies and 846 patients yielded an AUROC of 0.92. According to the study, one helpful clinical indicator to diagnose NF is the LRINEC score.[21] The LRINEC score's accuracy was moderate, according to our prospective validation results, and the LRINEC score might not be a reliable tool for stratifying the risk of NF and differentiating it from severe cellulitis in the emergency department despite the contradictory findings from these retrospective studies and meta-analyses.

Different patient characteristics (e.g., age and associated morbidities) in the study cohorts may have contributed to the discrepancy between our results and those of these studies. Second, because the score significantly depends on the affected body part, our study only included cases with NF involving the limbs, which may have skewed the validation results. Finally, the LRINEC score may vary based on the frequency of certain microorganisms in various geographic locations.

In order to increase the LRINEC score's sensitivity without sacrificing its specificity, one earlier study tried to modify it by including clinical factors and several laboratory markers.[22] The scoring system should not, however, be viewed as a stand-alone diagnostic technique. Age, gender, comorbid conditions, physical findings, blood tests, and radiological findings should all be taken into consideration when making a diagnosis.

CONCLUSION

According to our study, the LRINEC score is not a reliable method for stratifying the risks of NF and distinguishing between NF and cellular inflammation in an emergency setting. In the emergency room, the LRINEC score, if used cautiously, can prove to be a standard diagnostic tool for NF.

LIMITATIONS

Our study was conducted at a single tertiary care hospital, which may limit the generalizability of the findings to other settings or populations. As a cross-sectional validation study, it could not evaluate the impact of LRINEC scoring on patient outcomes or decision-making over time. Patients with prior antibiotic use, short hospital stays, or previous debridement were excluded, which may have led to selection bias and impacted the diagnostic accuracy of the LRINEC score.

SUGGESTIONS / RECOMMENDATIONS

Future research should include diverse geographic and institutional settings to enhance the external validity and generalizability of the LRINEC score's diagnostic utility. Longitudinal studies assessing patient outcomes based on initial LRINEC scoring can better determine its impact on early intervention and prognosis. Studies should be conducted to evaluate different LRINEC score thresholds to identify the most sensitive and specific cutoff points for various populations or risk groups.

CONFLICT OF INTEREST / DISCLOSURE

None.

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