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Diagnostic Accuracy of The Modified LRINEC Score for Necrotising Fasciitis in Soft Tissue Infections: A Prospective Observational Study at A Tertiary Care Centre

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ABSTRACT

Introduction: Necrotizing fasciitis (NF) is a life-threatening surgical emergency with high mortality. Early diagnosis is crucial. The Laboratory Risk Indicator for Necrotising Fasciitis (LRINEC) score has shown variable diagnostic performance, leading to the development of a Modified LRINEC score. This study aimed to validate the diagnostic accuracy of the Modified LRINEC score for NF and its efficacy in predicting adverse outcomes.

Methods: A prospective observational study was conducted on 63 patients admitted with soft tissue infections. The Modified LRINEC score, incorporating nine parameters (RBS, CRP, Total Count, Hemoglobin, Serum Sodium, Potassium, Creatinine, Deranged LFT, and X-ray), was applied. Diagnosis of NF was confirmed by surgical exploration (gold standard). Diagnostic accuracy and predictive value for adverse outcomes (amputation/death) were analysed using ROC curves.

Results: Of the 63 patients, 44 (69.8%) were surgically diagnosed with NF. For diagnosing NF, the Modified LRINEC score had an AUC of 0.977, with an optimal cut-off of 10.5. At this cut-off, it demonstrated a sensitivity of 90.9%, specificity of 100%, PPV of 100%, NPV of 82.6%, and an overall accuracy of 93.7%. For predicting adverse outcomes (amputation/death), the optimal cut-off was 12.5, yielding a high sensitivity of 96.2% but a lower specificity of 44.4%, with an accuracy of 75%.

Conclusion: The Modified LRINEC score is a highly sensitive and specific tool for the early diagnosis of necrotising fasciitis in patients presenting with soft tissue infections. While it is also significant in predicting adverse outcomes like amputation or death, its specificity for this purpose is limited. It serves as an excellent bedside screening tool, especially in resource-limited settings.

Keywords: *Necrotising Fasciitis, Modified LRINEC Score, Soft Tissue Infections, Diagnostic Accuracy, Prognosis.*

INTRODUCTION

Necrotising fasciitis (NF) is a rapidly progressive, destructive infection of the fascia and subcutaneous tissues, associated with mortality rates of 30-50% [1, 6]. Early and aggressive surgical debridement is the cornerstone of management, making timely diagnosis imperative [3]. Clinically, NF can be challenging to distinguish from non-necrotising soft tissue infections like cellulitis. The original LRINEC score, a laboratory-based tool, was promising but has been questioned in recent studies for its sensitivity and specificity [4-6]. To address its limitations, the Modified LRINEC score was developed, incorporating additional parameters like serum potassium, liver enzymes, and radiographic findings [7-9].

This study aimed to evaluate the diagnostic accuracy of the Modified LRINEC score for NF and to assess its efficacy in predicting adverse outcomes (amputation and mortality) in a tertiary care setting in India.

MATERIALS AND METHODS

Study Design and Setting

A prospective, hospital-based observational study was conducted in the Department of General and Laparoscopic Surgery, Government Medical College, Thiruvananthapuram, over 18 months after Institutional Ethics Committee approval.

Study Population and Sample Size

A total of 63 consecutive patients admitted with a clinical diagnosis of soft tissue infection were enrolled. The sample size was calculated as 63 based on an assumed prevalence of NF and the sensitivity of the Modified LRINEC score from previous studies.

Inclusion and Exclusion Criteria

All patients admitted with soft tissue infections (including NF) who provided consent were included. Patients who had received antibiotics in the last 48 hours or had undergone prior debridement for the same episode were excluded.

Data Collection and Scoring

Demographic, clinical, and laboratory data were collected using a pre-tested proforma. The Modified LRINEC score (max score 20) was calculated for each patient. The diagnosis of NF was confirmed intraoperatively by the consultant surgeon based on standard findings (e.g., dishwater fluid, positive "finger test," tissue necrosis).

Statistical Analysis: Data were analysed using SPSS v20.0. Diagnostic accuracy was assessed using Receiver Operating Characteristic (ROC) curves to determine optimal cut-offs. Sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), and accuracy were calculated.

RESULTS

Baseline and Clinical Characteristics of the Study Population

A total of sixty-three (63) patients admitted with soft tissue infections were enrolled in this prospective study. Of these, 44 patients (69.8%) were definitively diagnosed with necrotising fasciitis (NF) based on the gold standard of surgical exploration. The remaining 19 patients (30.2%) constituted the control group with other soft tissue infections, such as cellulitis and abscesses.

The demographic and clinical profile of the cohort is summarized in Table 1. The mean age of the entire cohort was 59 years, with the largest proportion of patients (44.4%) belonging to the 60-80 years age bracket. This distribution was mirrored in the NF subgroup, where 43.2% of patients were aged 60-80 years. A male predominance was observed, with males constituting 60.3% of all admissions and 59.1% of the NF cases. Occupationally, the cohort was nearly evenly split, with 50.8% being daily wage workers or farmers and 49.2% being unemployed.

Comorbidities were highly prevalent. Type 2 Diabetes Mellitus (T2DM) was the most significant risk factor, present in 69.8% of all patients. Strikingly, 77.3% of patients in the NF group had T2DM, with 25% having T2DM as a sole comorbidity and 52.3% having T2DM in combination with other conditions like hypertension. Only 4.5% of NF patients had no comorbidities.

The lower limb was the overwhelmingly predominant site of infection, involved in 90.5% of all soft tissue infections and 93.2% of NF cases. At presentation, systemic involvement was common. Fever was a presenting symptom in 79.4% of all patients. Notably, 40.9% of NF patients presented with symptoms indicative of multi-organ dysfunction, such as decreased urine output, breathlessness, or jaundice, underscoring the severity of the condition. Vital signs at admission reflected this systemic illness: 58.7% of patients were tachycardic (pulse rate ≥100/min), 19% were hypotensive (SBP <90 mmHg), and 30.2% were tachypneic.

PROFILE OF MODIFIED LRINEC SCORE COMPONENTS

The components of the Modified LRINEC score were significantly deranged in patients, especially in the NF group, as detailed in Table 2. The mean Modified LRINEC score across all patients was 11.1 ± 4.2, with a range from 1 to 19.

Marked inflammatory and metabolic disturbances were evident. The majority of NF patients (77.3%) had CRP levels ≥150 mg/L. Leukocytosis was profound, with 72.7% of NF patients having a total leukocyte count >25,000/mm³, and no NF patient had a count below 15,000/mm³. Anemia (Hemoglobin <11 g/dL) was present in 61.4% of NF patients, with a mean Hb of 10.3 ± 2.4 g/dL. Hyponatremia (Serum Sodium <135 mEq/L) was a very common finding, present in 86.4% of NF patients, with a mean value of 127.9 ± 5.6 mEq/L. Hyperglycemia (RBS >180 mg/dL) was observed in 70.5% of the NF group. Renal impairment (Serum Creatinine >1.4 mg/dL) was noted in 79.5% of NF patients. The presence of gas in the soft tissue on X-ray was a highly specific finding, present in 88.6% of NF patients and in none of the non-NF patients.

PATIENT OUTCOMES

The outcomes for the study population are summarized in Table 3. Among the 63 patients, 37 (58.7%) were managed with debridement and conservative measures. The adverse outcome composite of amputation or death occurred in 26 patients (41.3%). Specifically, 15 patients (23.8%) underwent amputation, and 11 patients (17.5%) died. All deaths and amputations occurred within the group of 44 patients diagnosed with NF. Therefore, the mortality rate for NF was 25.0% (11/44), and the amputation rate was 34.1% (15/44).

Diagnostic Accuracy of the Modified LRINEC Score for Necrotising Fasciitis

The Receiver Operating Characteristic (ROC) curve analysis for diagnosing NF yielded an Area Under the Curve (AUC) of 0.977 (95% CI: 0.947 – 1.008, $p<0.01$), indicating excellent diagnostic performance. The optimal cut-off value was determined to be 10.5.

At this cut-off, the Modified LRINEC score demonstrated high diagnostic accuracy, as shown in Table 4. A score of ≥10.5 correctly identified 40 out of 44 NF patients (Sensitivity: 90.9%). Crucially, all 19 patients without NF had a score below 10.5, yielding a perfect Specificity of 100% and a Positive Predictive Value (PPV) of 100%. The Negative Predictive Value (NPV) was 82.6%, and the overall diagnostic accuracy was 93.7%.

Predictive Accuracy for Adverse Outcomes

The ROC curve for predicting the composite adverse outcome of amputation or death among all patients with soft tissue infections had an AUC of 0.933 (95% CI: 0.878 – 0.989, $p<0.01$). The optimal cut-off was 12.5.

When applied specifically to the 44 patients diagnosed with NF, the score's predictive performance was characterized by high sensitivity but modest specificity (Table 5). A score of ≥12.5 identified 25 out of the 26 patients who had an adverse outcome, yielding a Sensitivity of 96.2%. However, it also flagged 10 out of the 18 patients who did not have an adverse outcome, resulting in a Specificity of 44.4%. The PPV was 71.4%, meaning that just over 70% of patients with a high score suffered an adverse outcome. The NPV was 88.9%, indicating that a score below 12.5 was a strong indicator of a more favourable course. The overall accuracy for predicting adverse outcomes in NF patients was 75%.

Association of Individual Score Components with Adverse Outcomes

A comparative analysis of the Modified LRINEC score components based on patient outcome (Debridement/Conservative vs. Amputation/Death) was performed. The components that showed a statistically significant association ($p<0.05$) with adverse outcomes were:

- Random Blood Sugar >180 mg/dL ($p<0.01$)
- CRP ≥150 mg/L ($p<0.01$)
- Total Leucocyte Count >25,000/mm³ ($p<0.01$)
- Serum Sodium <135 mEq/L ($p=0.007$)
- Serum Potassium >5 mEq/L ($p=0.020$)
- Serum Creatinine >1.4 mg/dL ($p<0.01$)
- Presence of gas on X-ray ($p<0.01$)

In contrast, hemoglobin levels ($p=0.211$) and deranged liver enzymes ($p=0.091$) were not found to be significantly associated with the composite adverse outcome in this cohort.

Table 1: Baseline and Clinical Characteristics of Patients with Soft Tissue Infections

Characteristic	All Patients (n=63)	NF Patients (n=44)
Age (Years), Mean	59	59
Age Group, n (%)		
- ≤40	5 (7.9)	4 (9.1)
- 40-60	27 (42.9)	18 (40.9)
- 60-80	28 (44.4)	19 (43.2)
- >80	3 (4.8)	3 (6.8)
Male Sex, n (%)	38 (60.3)	26 (59.1)
Comorbidities, n (%)		
- T2DM alone	16 (25.4)	11 (25.0)
- T2DM + Others	28 (44.4)	23 (52.3)
- Other Comorbidities	12 (19.0)	8 (18.2)
- None	7 (11.1)	2 (4.5)
Site Involved, n (%)		
- Lower Limb	57 (90.5)	41 (93.2)
- Upper Limb	3 (4.8)	2 (4.5)

- Other Sites	3 (4.8)	1 (2.3)
Presenting with Fever, n (%)	50 (79.4)	35 (79.5)
Presenting with Multi-organ Dysfunction, n (%)	19 (30.2)	18 (40.9)

Table 2: Components of the Modified LRINEC Score in NF Patients (n=44)

Component	Value in NF Patients, n (%)
RBS >180 mg/dL	31 (70.5)
CRP ≥150 mg/L	34 (77.3)
Total Count	
- 15-25 /mm³	12 (27.3)
- >25 /mm³	32 (72.7)
Hemoglobin	
- >13.5 g/dL	5 (11.4)
- 11-13.5 g/dL	12 (27.3)
- <11 g/dL	27 (61.4)
Serum Sodium <135 mEq/L	38 (86.4)
Serum Potassium >5 mEq/L	11 (25.0)
Serum Creatinine >1.4 mg/dL	35 (79.5)
Deranged LFT	13 (29.5)
Gas on X-ray	39 (88.6)

Table 3: Patient Outcomes

Outcome	All Patients (n=63), n (%)	NF Patients (n=44), n (%)
Debridement/Conservative	37 (58.7)	18 (40.9)
Amputation	15 (23.8)	15 (34.1)
Death	11 (17.5)	11 (25.0)
Any Adverse Outcome (Amputation/Death)	26 (41.3)	26 (59.1)

Table 4: Diagnostic Accuracy of Modified LRINEC Score (Cut-off ≥10.5) for NF

Metric	Value (%)
Sensitivity	90.9
Specificity	100.0
Positive Predictive Value (PPV)	100.0
Negative Predictive Value (NPV)	82.6
Accuracy	93.7

Table 5: Predictive Accuracy of Modified LRINEC Score (Cut-off ≥12.5) for Adverse Outcome in NF Patients

Metric	Value (%)
Sensitivity	96.2
Specificity	44.4
Positive Predictive Value (PPV)	71.4
Negative Predictive Value (NPV)	88.9
Accuracy	75.0

DISCUSSION

This prospective observational study demonstrates that the Modified LRINEC score is a robust and highly accurate diagnostic tool for necrotising fasciitis, exhibiting excellent sensitivity (90.9%) and perfect specificity (100%) at a cut-off of 10.5. Furthermore, it proves to be a significant, highly sensitive predictor for adverse outcomes, albeit with lower specificity. These findings must be contextualized within the evolving landscape of NF diagnostics, where the quest for a rapid, reliable, and accessible tool remains paramount, especially in resource-conscious healthcare settings [10].

The primary strength of our study lies in the diagnostic performance of the Modified LRINEC score. The original LRINEC score, proposed by Wong et al., was a groundbreaking step towards an objective diagnostic aid, reporting a positive predictive value (PPV) of 92.0% and a negative predictive value (NPV) of 96.0% in their validation cohort [4]. However, its real-world applicability has been widely questioned. A seminal meta-analysis by Fernando et al. revealed a pooled sensitivity of only 68.8% for a LRINEC score ≥6, indicating that the original score would miss nearly one-third of NF cases if used in isolation—an unacceptable risk for a condition where delayed surgery exponentially increases mortality [5,11]. Our findings, showing a sensitivity of 90.9%, represent a substantial improvement. This enhanced sensitivity directly addresses a critical flaw in the original score, reducing the likelihood of false negatives and the

catastrophic delays in intervention they precipitate. The perfect specificity and PPV of 100% in our cohort are particularly compelling. This means that in our setting, every patient with a Modified LRINEC score ≥10.5 was definitively diagnosed with NF upon surgical exploration. This level of diagnostic certainty is rare in clinical scoring systems and empowers surgeons to proceed to operative intervention with greater confidence, potentially bypassing time-consuming and often equivocal advanced imaging [12,13].

The superior performance of the Modified LRINEC score can be attributed to the incorporation of additional, physiologically pertinent parameters. The inclusion of serum potassium and the explicit scoring of deranged hepatic enzymes broaden the score's reflection of the profound metabolic acidosis and end-organ dysfunction that characterize advanced NF [14,15]. More significantly, the addition of a plain X-ray for detecting subcutaneous gas adds a dimension of structural assessment. While the sensitivity of X-ray for gas is low, its specificity is high [16]. By integrating this highly specific finding (present in 88.6% of our NF patients) into a weighted scoring system, the modified score leverages a simple, universally available imaging modality to dramatically boost its diagnostic precision. This aligns with the findings of Wu et al. and Sudha et al., who also reported improved diagnostic metrics with their modified LRINEC models, underscoring the value of refining the original tool with additional variables [7,8].

Beyond diagnosis, our study provides novel insights into the prognostic utility of the Modified LRINEC score. The high sensitivity of 96.2% for predicting the composite adverse outcome of amputation or death is a critical finding. It indicates that the score is exceptionally effective at "ruling out" a low-risk course; a patient with a score below 12.5 has an 88.9% probability of not suffering amputation or death (high NPV). This is immensely valuable for patient counseling and resource allocation within the ICU. The flip side the low specificity of 44.4% means that the score over-identifies patients at risk, as a high score was also seen in 28.6% of patients who ultimately had a better outcome. While this may be perceived as a weakness, in the context of a life-threatening infection, a tool with high sensitivity is often preferred to ensure no high-risk patient is overlooked [17]. This prognostic application fills a significant gap, as most previous studies, including the original LRINEC work, focused predominantly on diagnostic differentiation rather than stratifying the risk of limb loss or mortality post-diagnosis [4,5].

Our study directly addresses a crucial research gap: the validation of a simple diagnostic and prognostic tool in a high-volume, tertiary care setting in a developing country. The majority of large-scale studies on NF originate from developed nations with different patient demographics, microbial patterns, and resource availability [1,18]. In regions like India, where the burden of predisposing conditions like uncontrolled diabetes is high and access to immediate MRI or CT scanning may be limited, the Modified LRINEC score offers a viable solution [19,20]. It transforms readily available, low-cost laboratory and radiographic data into a powerful clinical decision-making algorithm. Our results demonstrate that it is not necessary to rely on costly and less accessible imaging like MRI (which, while highly sensitive, can delay definitive surgical management) when a robust scoring system can provide sufficient diagnostic impetus [13,21]. In this way, our work builds upon and extends the findings of studies like those by Hsiao et al. and Necki et al., which questioned the accuracy of the original LRINEC score in their populations, by providing a validated, enhanced alternative that is particularly suited to resource-constrained environments [3,6].

Despite its strengths, our study has limitations. The single-centre design and relatively modest sample size limit the generalizability of our findings. The perfect specificity, while impressive, may be subject to spectrum bias and requires validation in larger, multi-centre cohorts. The low specificity for outcome prediction highlights that the score, while excellent for identifying at-risk patients, is not a perfect triage tool on its own and should be used in conjunction with clinical judgment and other patient-specific factors. Finally, the high prevalence of diabetes in our cohort, while representative of our population, may influence the weighting of variables like random blood sugar and serum creatinine [22].

CONCLUSIONS

This study provides robust evidence that the Modified LRINEC score is a significant advancement over its predecessor. It successfully bridges the critical gap between the need for early, accurate diagnosis and the constraints of real-world clinical practice, particularly in developing economies. By offering high diagnostic accuracy and valuable prognostic insights using inexpensive, universally available tests, it empowers clinicians to make timely, life-saving decisions. Future research should focus on large-scale, multi-institutional validation and explore the potential for dynamic risk stratification by tracking score changes in response to initial resuscitation and therapy.

DECLARATION

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