

An Observational Study on The Effectiveness of LRINEC (Laboratory Risk Indicators For Necrotising Fascitis) Scoring System in The Diagnosis of Necrotising Fascitis Among Patient Presenting With Soft Tissue Infection

Appasaheb V Ingale*, Janhavi Telang, Inayat Tamboli

Department of General Surgery, Government Medical College, Miraj, Maharashtra, India

Corresponding author: Appasaheb V Ingale, Email: ingalep77@gmail.com

Abstract

Background: Necrotizing fasciitis (NF) is an aggressive, rapidly progressing life-threatening soft tissue infection that is associated with higher mortality if diagnosed late. Clinical signs of early NF are like cellulitis or an abscess, so an easy and cheap bedside tool is required. The Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score is based on six common laboratory values. Its diagnostic utility in the patient with soft tissue infections was tested.

Methods: This is a prospective, observational study of 50 consecutive patients with SSTIs over a period of two years at a tertiary care centre. At presentation, the LRINEC score was computed and the patients divided into low risk (≤ 5), intermediate risk (6-7) and high risk (≥ 8). Biopsy results were used as the reference standard. Patients with and without NF were compared, and a receiver operating characteristic (ROC) analysis was performed to evaluate the diagnostic performance.

Results: The mean age was 52.78 ± 14.12 years and 72% of patients were male. In the study, 17 patients (34%) were diagnosed with NF by biopsy. The mean LRINEC score was significantly higher in NF (9.65 ± 2.17 vs 3.73 ± 2.05 ; $p < 0.0001$). There were significant differences in C-reactive protein, total leukocyte count, serum creatinine, serum sodium and blood glucose levels but not in haemoglobin levels between the groups. The area under the ROC curve was 0.979 (95% CI 0.891–0.999). The ROC derived cutoff point of >6 had a sensitivity of 94.12% and specificity of 90.91%. The sensitivity was 100% and specificity 84.85% with positive predictive value of 77.27%, negative predictive value of 100% and accuracy of 90% at the conventional cut-off ≥ 6 .

Conclusion: LRINEC score was found to be a simple and reliable tool to differentiate NF from other soft tissue infections in this cohort. It must be used in conjunction, not in place of, clinical judgment.

Keywords: necrotizing fasciitis; LRINEC score; soft tissue infection; early diagnosis; diagnostic accuracy.

Introduction

Necrotizing soft tissue infections (NSTIs) are serious infections which may affect the skin and subcutaneous tissues, fascia and muscle. The local tissue destruction and the systemic inflammatory response is mediated by the action of toxins produced by bacteria; this can escalate to shock and multiple organ failure [1,2]. The most famous form is necrotizing fasciitis (NF), where the necrosis of the fascia and subcutaneous tissue spreads quickly. Although antimicrobial therapy and intensive care has improved, mortality is still reported as high as 10.9% to 76% and amputation rates are 15% to 30% [3]. Prognosis is largely dependent on early recognition and prompt debridement of all necrotic tissue – operative debridement was shown to increase mortality with delay [4]. Unfortunately, early NF is hard to diagnose. The blood supply to the fascial planes is poor, and the overlying skin may appear near normal for awhile and it is especially easy to confuse with cellulitis or an abscess. On admission, between 15 and 34% of NF patients have a correct diagnosis [5]. However, computed tomography, magnetic resonance imaging, and frozen section biopsy can help with early diagnosis, but are not routinely used because of their cost and the fact they are not widely available, especially in resource-limited facilities. Physical examination is not very sensitive, and can be enhanced by the addition of laboratory values [6]. The Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score was evolved from earlier studies by Wall et al. demonstrating the biochemical derangement can help differentiate NF from non-necrotizing infection [8] and was developed by Wong et al. in 2004 [7]. They use six variables that are common lab tests: C-reactive protein (CRP), total white cell count, haemoglobin, serum sodium, serum creatinine and blood glucose. A score of 5 or less is considered low risk, a score between 6 and 7 is considered intermediate risk, and a score of 8 or higher is considered high risk. In the initial cohort, a score of 6 or more had a positive predictive value of 92% and negative of 96% [7]. Later validation studies have yielded conflicting results. A systematic review has found that the evidence is not consistent [9] and a meta-analysis of its diagnostic accuracy has come to similar ambiguous conclusions regarding its use as an independent test [10]. Local validation is important due to the possibility of variations in performance with

population, case mix and referral pattern. There are only a few studies in India. In view of this, we performed a prospective study for the validity of LRINEC score for detecting NF of patients attending the tertiary care centre with soft tissue infections. The questions asked were: (1) is there a good separation of NF from other soft tissue infections by the use of the LRINEC? (2) can routine scoring be used to aid early debridement? (3) do the cut-off values used in this study apply to our study population.

Methods

Study design and setting

It was a descriptive, prospective and observational study carried out in the Government Medical College, Miraj (Tertiary care teaching hospital) in the Department of General Surgery. This study was conducted over a 2-year period. All participants gave informed consent and the study protocol was submitted for ethical approval prior to the start of the study with the Institutional Ethics Committee.

Participants and sampling

All consecutive cases, both males and females, with a soft tissue infection, admitted under the surgical department were taken. Consecutive sampling was employed and sample size was dependent on the length of the study. Patients were excluded if they: • did not have a soft tissue infection; • had an unclear or incomplete LRINEC score; or • takes an HIV test; and • had a known malignancy; or (Only one admission was recorded, all were re-admitted with NF).

Data collection

Demographic information, comorbidities, presenting symptoms, vital signs and laboratory findings were recorded on a pretested structured proforma for each patient. Transcription of data on a master chart for analysis. The six laboratory parameters that were used to calculate the LRINEC score were the same as described by Wong et al. [7] and included CRP, total leukocyte count (TLC), haemoglobin, serum sodium, serum creatinine and blood glucose. These patients were then classified as low risk (≤ 5), intermediate risk (6–7) and high risk (≥ 8). Thorough clinical examination and appropriate laboratory investigations were used to diagnose NF and biopsy was used as the reference standard against which the LRINEC score was evaluated.

Statistical analysis

The data are reported as descriptive statistics: mean and standard deviation for continuous data; and frequencies and percentages for categorical data. Patients with and without biopsy confirmed NF were compared with Student's t-test and $p < 0.05$ was regarded as statistically significant for continuous variables. The discriminatory power of the LRINEC score was evaluated by ROC curve analysis and the area under the curve (AUC), with a standard error and 95% confidence interval was computed. The best cut-off was determined using the ROC curve. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and overall accuracy were then calculated at the conventional threshold of 6 using a two-by-two comparison with biopsy results.

Results

Patient characteristics

There were 50 patients with soft tissue infection. The mean age was 52.78 ± 14.12 years (range 19–80 years). 72% of the patients were male and 28% were female. The mean pulse rate was 87.56 ± 15.42 beats per minute, mean systolic blood pressure 112.16 ± 25.21 mmHg and mean diastolic blood pressure 77.18 ± 8.33 mmHg. The mean LRINEC score of all participants was 5.74 ± 3.50 . Many patients had 1 or more comorbidities. Fifteen (30%) had diabetes mellitus, 13 (26%) had hypertension, five (10%) had ischaemic heart disease and three (6%) had bronchial asthma. Swelling was present in all patients (100%), discharge in 22 (44%) and crepitus in 16 (32%).

Distribution of laboratory parameters

Among all 50 patients, CRP exceeded 150 mg/L in 13 (26%). The total leukocyte count was below 15,000/cumm in 19 (38%), between 15,000 and 25,000/cumm in 19 (38%) and above 25,000/cumm in 12 (24%). Haemoglobin was below 11 g/dL in 22 patients (44%), 11–13.5 g/dL in 19 (38%) and above 14 g/dL in nine (18%). Serum creatinine exceeded 1.6 mg/dL in 23 patients (46%), serum sodium was below 135 mEq/L in 20 (40%), and blood glucose exceeded 180 mg/dL in 20 (40%).

Comparison between patients with and without necrotizing fasciitis

Biopsy-proven NF was present in 17 patients (34%) and in 33 patients (66%) there was other soft tissue infections. Demographic and clinical parameters are compared in table 1. The total LRINEC score was markedly higher in the NF group (9.65 ± 2.17) than in the non-NF group (3.73 ± 2.05 ; $p < 0.0001$). Diastolic blood pressure was significantly lower in patients with NF (72.94 ± 8.92 vs 79.36 ± 6.94 mmHg; $p = 0.0072$). There was no significant difference in age, pulse rate or systolic blood pressure. Patients with NF were slightly older, and had slightly lower levels of systolic blood pressure.

Table 1. Demographic and clinical parameters according to the presence of necrotizing fasciitis (mean $\pm$ SD)

Parameter	NF absent (n=33)	NF present (n=17)	p value
Age (years)	50.30 ± 13.53	57.59 ± 13.57	0.0777
Pulse (beats/min)	85.33 ± 13.66	91.88 ± 17.16	0.1479
Systolic BP (mmHg)	116.91 ± 28.07	102.94 ± 13.18	0.0586
Diastolic BP (mmHg)	79.36 ± 6.94	72.94 ± 8.92	0.0072
Total LRINEC score	3.73 ± 2.05	9.65 ± 2.17	<0.0001

Table 2 shows the distribution of the laboratory risk indicators by NF status. CRP, total leukocyte count, serum creatinine, serum sodium and blood glucose all differed significantly between the groups, whereas haemoglobin did not. Raised CRP (>150 mg/L) was seen in 10 of 17 patients with NF compared with three of 33 without. A total leukocyte count above 25,000/cumm was found in 11 of 17 patients with NF compared with one of 33 without, and no patient with NF had a count below 15,000/cumm. Hyponatraemia (<135 mEq/L) was present in 12 of 17 patients with NF but only two of 33 without.

Table 2. Laboratory risk indicators according to the presence of necrotizing fasciitis (number of patients)

Parameter	Category	NF absent	NF present	p value
CRP	<150 mg/L	30	7	0.0003
	>150 mg/L	3	10	
Total leukocyte count	$<15,000$ /cumm	19	0	<0.0001
	15,000–25,000/cumm	13	6	
	$>25,000$ /cumm	1	11	
Haemoglobin	<11 g/dL	11	11	0.0777
	11–13.5 g/dL	14	5	
	>14 g/dL	8	1	
Serum creatinine	<1.6 mg/dL	22	5	0.0275
	>1.6 mg/dL	11	12	
Serum sodium	>135 mEq/L	25	5	<0.0001
	<135 mEq/L	2	12	
Blood glucose	<180 mg/dL	24	6	0.0241
	>180 mg/dL	9	11	

Diagnostic performance of the LRINEC score

ROC analysis of the LRINEC score against biopsy results gave an AUC of 0.979 (standard error 0.0154; 95% CI 0.891–0.999; $p < 0.0001$ versus an AUC of 0.5), indicating excellent discrimination. The cut-off identified from the ROC curve was >6 , with a sensitivity of 94.12% and a specificity of 90.91%.

We then applied the conventional threshold, classifying a score of 6 or more as positive and a score below 6 as negative (Table 3). Twenty-two patients scored 6 or more and 28 scored below 6. All 17 patients with biopsy-confirmed NF were identified by the score. Of the 33 patients without NF, 28 were correctly classified and five were false positives. No false-negative result occurred.

Table 3. LRINEC score (threshold ≥ 6) compared with biopsy for the diagnosis of necrotizing fasciitis

LRINEC category	Biopsy positive	Biopsy negative	Total
Positive (≥ 6)	17	5	22
Negative (< 6)	0	28	28
Total	17	33	50

From these values the sensitivity was 100%, specificity 84.85%, PPV 77.27%, NPV 100% and overall accuracy 90%. The prevalence of NF in the study population was 34%.

Discussion

The progression from presentation to debridement is a critical time for necrotizing fasciitis, and will significantly impact survival [4]. One of the major problems is the non-specificity of the earliest features. The score derived from 6 routine blood tests discriminated between the 2 groups of patients with biopsy-proven NF and those with other soft tissue infections with a very high AUC (0.979) and failed to miss any 17 cases when the threshold was chosen at 6.

Patient profile

The patients were in middle to later life (mean age 52.78 years) and most of them were male (72%) and diabetes was the most common comorbid disease (30%). This profile is typical and in line with the literature. Hoesl et al. found the mean age of 70 patients with NF to be 58.4 years, with a predominance of males [11] and El-Menyar et al. found a mean age of 50.9 years in 294 patients with NF and a mean admission LRINEC score of 6.28 [12]. Similarly, Pratheek et al. reported that three-quarters of the patients with NF were male [13]. In a study of 209 patients, 69.2% were male and again diabetes was the most common comorbidity (55.5%) [14]. Reddy et al. and Duthaluri et al. reported a male predominance as well with diabetes being the most common comorbidity in the former [15,16]. The lower percentage of diabetics seen in our series than these reports is probably due to the fact that we included all soft tissue infections and did not include the patients with NF disease. The lower level of diastolic pressure in the patients with NF, and similar trend for systolic pressure, is physiologically plausible and is probably reflective of the early systemic inflammatory response. There was no discrimination value, as there was swelling in all our patients, and crepitus was seen in approximately one third of patients. This confirms the already mentioned fact that the classical "hard signs" are late and untrustworthy, and that is why objective laboratory support is appealing.

Laboratory parameters

Except for haemoglobin, each of the other components of the score was significantly different between the patients with and without NF. This is in line with the observations by Reddy et al. [15] and with the basis used in the development of the score [7]. The CRP and the leukocyte count are biologically indicative of the magnitude of the inflammatory response to deep tissue infection. Raised creatinine levels are believed to indicate early renal damage due to sepsis or hypoperfusion, raised blood glucose levels are believed to be from the stress response as well as underlying diabetes and hyponatraemia is a marker of systemic illness and fluid shifts. The absence of any meaningful haemoglobin difference could have been due to the small number of cases studied, and the high prevalence of anaemia in the region (44% of all of our patients had haemoglobin < 11 g/dL, regardless of diagnosis). It doesn't mean that haemoglobin should be axed from the score. In our data, the most discriminating individual parameters were the leukocyte count and the serum sodium. There were no patient with leukocyte count below 15,000/cumm in the NF group and the hyponatraemia was 5–6 times more common in the NF group. These simple observations can assist clinicians in a setting where a full scoring is postponed.

Diagnostic accuracy in context

The LRINEC score has a wide range of reported performance. In the first derivation study, the PPV and NPV achieved 92% and 96% respectively at a score of 6 or above [7]. Our sensitivity is comparable but higher than the other results with a lower PPV (77.27 %), which has resulted from the different prevalence of NF and false positive rates for the settings. Other large validation studies have not been as positive. The largest retrospective validation compared the score with 233 patients with NF with 1,394 patients with severe cellulitis, and the authors found the score to have only moderate AUC (0.779), and that it alone was not enough to make an early diagnosis [17]. A study by Neeki et al. reported on a sensitivity of 36% and a specificity of 89% at a score of 6 [18]. A prospective

study of extremity infections by Hsiao et al. resulted in a sensitivity of 43%, specificity of 80%, positive predictive value of 25% and a negative predictive value of 92% at the same cut-off [19]. Sensitivity at this level means that a false-negative result could potentially lead to a delay in surgery, and a false positive rate greater than 10% for severe cellulitis can create additional imaging and laboratory work-up resulting in increased workload and cost [19]. There may be some differences in case mix, as our comparison group included those admitted to a surgical service with soft tissue infection, and our biopsy-confirmed cases were often more advanced at presentation which may explain our higher score. Other studies, particularly from Asia and Australia, are more similar to our results. Narasimhan et al. tested the score in Darwin with an AUROC of 0.925, a sensitivity of 76.3%, a specificity of 93.1%, PPV of 95.5% and NPV of 88.1% [20, 36-44]. Nayak & Kattimani reported an AUC of 0.982 and sensitivity of 96.72%, specificity of 89.74% and accuracy of 95% [21] which are very close to our results. Pratheek et al. achieved a sensitivity of 90.90%, specificity of 87.5%, PPV of 95.23%, NPV of 77.78% and accuracy of 90% similar to our results [13]. Duthaluri et al. reported lower figures (sensitivity 79.4% and specificity 75.4%, PPV 65.9% and NPV 86%) [16] and Nirmal Kumar et al. reported even lower values (sensitivity 46% and specificity 98.33%) [22, 24-28] at the same cut-off point in their Indian series. Sophy and colleagues correlated the score with the histopathology and achieved an 81.82% sensitivity and a 97.44% specificity, and a 94% accuracy [23, 29-35]. All of these Indian studies imply that specificity is high, and sensitivity is variable and will substantially rely on the selection of the case and the stage of the disease.

Choice of cut-off

We found two thresholds in our analysis. The optimum that gave the highest value of sensitivity and specificity (ROC>6) was 94.12% and 90.91% respectively. The traditional cut-off of 6 or greater resulted in 100% sensitivity and 5 false positives. In a disease that could be life-threatening if misdiagnosed, the second approach (which will have a higher sensitivity) is clinically appealing. The score of less than 6 is not an exclusion criterion for NF, and a score of 6 or higher should be treated as a call for emergency surgical evaluation. El-Menyar et al. also reported that the score may have prognostic value with cut-off points of 5 for predicting septic shock and 8 for mortality, which were not investigated in our series [12]. Clinical implications Low cost, objective and uses hospital tests, the LRINEC score is inexpensive. It can be used in every patient with soft tissue infection to help identify those which require prompt surgical assessment, rapid imaging and exploration and may help to prioritize operating theatre and intensive care resources in limited availability. Does not replace clinical assessment. Patients with a high index of suspicion (e.g. severe pain out of proportion to findings, rapid progression, bullae, crepitus or systemic toxicity) should be explored regardless of the score.

Limitations

There are some limitations to this study. The sample size was small (50 patients) and the patients were drawn from one centre, limiting the extent to which the findings can be generalized and resulting in wide confidence intervals around the estimates, including an AUC interval of 0.891 to 0.999. There were relatively few patients with NF (n=17). This may limit applicability, as patients with malignancy or on immunosuppressive drugs were excluded, who are at particular risk of NF. A selection bias may have been introduced because of the use of a consecutive sample and a duration-based sample size rather than a calculated one. The clinical outcomes (time to debridement, amputation, length of stay, mortality) were not assessed and so we cannot draw conclusions on whether the routine scoring is associated with improved clinical outcomes. Lastly, both cut-off analyses were based on the same data set and could be confirmed in an independent set.

Conclusion

The LRINEC score had excellent discriminatory ability between necrotizing fasciitis and other soft tissue infections (AUC 0.979) with 100% sensitivity and 100% NPV at a threshold of 6. It is a simple, objective and inexpensive complement to clinical assessment, especially when high quality imaging is not immediately available. If the score is high, immediate surgical evaluation is warranted, while a low score is not a contraindication to surgical evaluation in those who are clinically suspicious of NF. Further multi-centre studies involving patients' outcomes are required to validate these results and establish the score in day-to-day practice.

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