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A Prospective Study to Assess the Diagnostic Efficacy of Laboratory Risk Indicator for Necrotising Fascitis (Lrinec) Scoring System in Patients with Soft Tissue Infection

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Abstract:
The LRINEC score is a measure of biochemical changes which accurately predicts the presence of necrotizing fasciitis and the outcome of necrotizing fasciitis. According to Wong et.al, the LRINEC score can characterize patients with soft-tissue infections based on the high-risk and moderate-risk categories.
The LRINEC score can enable an early diagnosis of NF, with risk stratification, and on-time appropriate surgical debridement which is an essential parameter for achieving the optimum clinical outcome. Studies have indicated that the LRINEC score is one of the useful diagnostic tests which can provide a potential prognostic value. The clinical findings from such studies revealed that patients with a high LRINEC score generally tend to have a poor prognosis in NF. These studies were conducted among patients ranging from 15-209 cases and revealed significant findings.

Introduction:
Necrotizing fasciitis (NF) is a rapidly progressive soft tissue infection necrosis that mainly affects the fascia and subcutaneous tissues with significantly high mortality and morbidity among patients. Data has suggested that 13 per million patients are hospitalized due to NF with a mortality rate of 20-30%.
NF is most commonly associated with diabetes mellitus, immunodeficiency disease, drug abuse, and malnutrition .The prevalence of infection can also be due to an undetermined etiology.
The necrotizing soft tissue infection requires a critical care approach to reach a favorable outcome in NF patients. An early diagnosis, prompt antibiotic treatment, and serial debridement are the methods adapted to improve the overall clinical condition in patients. [4]
The diagnosis of NF is depended on the Laboratory Risk Indicator for NF (LRINEC) which is a scoring system derived from the six major laboratory tests which were used initially for the diagnosis of NF. The scoring system enables early diagnosis of NF from other major soft tissue infections. [5]
Multiple studies have evaluated the efficacy of LRINEC for the early diagnosis of NF and discovered that it may be utilized for identifying and categorizing NF patients into distinct risk groups, facilitating the optimal management of hospital resources. [6] Necrotizing Fasciitis is considered a surgical

emergency. The diseased region should be debrided as soon as possible until viable healthy bleeding tissue is found.

Necrotizing Fasciitis can be caused by aerobic, anaerobic, or mixed bacteria. Necrotizing fasciitis can develop as a result of surgery, any invasive operation, or even a small treatment such as phlebotomy. Although the causative bacteria are typically mixed, they do create gas. [8] Previously, imaging techniques such as computed tomography, magnetic resonance imaging, and frozen section biopsies were used to differentiate necrotizing fasciitis from other soft tissue infections, but these procedures were restricted by cost and availability. Diagnostic scoring has the potential to prevent marked morbidity and mortality in the accurate diagnosis of necrotizing fasciitis .

The LRINEC score is calculated using regular laboratory tests such as C- reactive protein (CRP), white cell count, hemoglobin, serum sodium, serum creatinine, and glucose levels. [10]The current study aims to evaluate the use of the LRINEC score for the diagnosis of necrotizing fasciitis in hospitalized patients. The study will help in an early diagnosis of NF with prompt treatment which can provide better therapeutic outcome

Aim: To determine the diagnostic efficacy of LRINEC scoring in patients with soft tissue infections

Objectives: To correlate the LRINEC scoring with the progression and severity of necrotizing fasciitis.

Materials and methods:
Study design: Prospective study
Study period: 12 months (JUNE 2023 to JUNE 2024)
Sample size: 167 patients

Inclusion criteria:

- Patients above the age of 18 years of age..
- Patients with soft tissue infection involving the extremities.

Exclusion criteria:

- Patients less than 18 years of age.
- Patients who have undergone previous debridement.
- Pregnant women.
- Patients with craniofacial and cervical fasciitis.

Methodology:

- Patients fulfilling the inclusion and exclusion criteria were selected.
- After obtaining consent from the patient, detailed history, physical examination, vital signs, and laboratory blood investigations are to be documented.
- Patients will be stratified based on LRINEC score as low, intermediate, and high risk.
- All patients will be given empirical antibiotics and based on risk stratification conservative management or fasciotomy and surgical debridement will be done.
- The number of debridement, the need for amputation, and the mortality rate will be documented

- Later regular wound dressing, antibiotics according to culture and sensitivity, and supportive therapy will be given.

Statistical analysis:

LRINEC score with CRP positive proportion is 83% of p-value 0.001. Sample size calculated in open epi with confidence interval 90% and power 80%.

LABORATORY TESTS AND LRINEC SCORE:

Certain laboratory results can assist the clinician in distinguishing NF from other skin conditions like necrotizing soft tissue infection. White blood cell counts above 20,000/L are very suspicious, and leukocytosis is a prevalent symptom in NF patients. Continuous renal failure, which is frequently present in these individuals, is indicated by blood urea nitrogen >18 mg/dL and serum creatinine >1.2 mg/dL. Patients with severe sepsis and MODS also have elevated serum levels of creatine kinase (CK).Several laboratory-based scoring systems for NF early diagnosis have been suggested. The Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score can also facilitate the classification of patients into risk categories, and help in the allocation of diagnostic resources. The Fournier's Gangrene Severity Index (FGSI), a different grading system, has demonstrated exceptional efficacy in determining whether or not a patient needs surgical debridement·Patients with ambiguous clinical signs and a moderate to high risk of NF determined by the LRINEC score (>5) may also undergo imaging testing, such as CT or MRI, or a frozen section biopsy·

LRINEC score

S.No.	Variables	Value	Score
1.	C Reactive Protein (CRP)	< 150mg/L	0
		≥ 150mg/L	4
2.	Total Leucocyte Count (TLC)	$< 15x10^3$ per cubic mm	0
		$15\text{-}25x10^3$ per cubic mm	1
		$>25x10^3$ per cubic mm	2
3.	Haemoglobin (Hb)	> 13.5 g/dL	0
		11-13.5 g/dL	1
		< 11 g/dL	2
4.	Serum Sodium	≥ 135 mmol/L	0
		< 135 mmol/L	2
5.	Serum Creatinine	≤ 1.6 mg/dL	0
		> 1.6 mg/dL	2
6.	Blood Glucose	≤ 180 mg/dL	0
		> 180 mg/dL	1

Results : Gender distribution

The current study reports a high predominance of male patients with 126 participants (75.4%) and 41 female participants (24.6%).

Table 1 -Gender distribution

SEX	Frequency	Percent
FEMALE	41	24.6%
MALE	126	75.4%
Total	**167**	**100.0%**

Clinical presentation : All the participants were diagnosed with swelling in the affected area.However, the presence of ulcers was seen in 19 patients (11.4%).

Table 2 – Prevalence of swelling

SWELLING	Frequency	Percent
YES	167	100.0%

Table 3– Prevalence of ulcers

ULCER	Frequency	Percent
NO	148	88.6%
YES	19	11.4%
Total	167	100.0%

LRINEC score evaluation

A score of <5 was seen in the majority of the patients 52.1%, followed by a score of >8 in 24.6% of patients, and 23.4 individuals were diagnosed with a score of 6-7.

Table 4 – LRINEC scoring

LRINEC	Frequency	Percentage
<5	87	52.1%
6-7	39	23.4%
>8	41	24.6%
Total	167	100.0%

Debridement requirement

A majority of the patients 105 (62.9%) required the debridement procedure for their necrotising fasciitis. However, 62 patients (37.1%) were not reported to undergo any debridement procedure.

Table 5 – Debridement procedure in the patients

DEBRIDEMENT	Frequency	Percent
NO	62	37.1%
YES	105	62.9%
Total	167	100.0%

Treatment outcomes : Correlation of debridement with LRINEC score

The current study reports a significant difference (p-value of 0.0001) in assessing the need for debridement by using the LRINEC score in patients.

A total of 105 patients required debridement out of which; 26 patients were in a score of <5, 38 were in the score range of 6-7, and 41 patients were reported with a score of >8.

Table 13 – LRINEC score and debridement in patients

			LRINEC				
			<5	6-7	>8	Total	P value
DEBRIDEMENT	NO	Count	61	1	0	62	<0.0001
		% within LRINEC	70.1%	2.6%	0.0%	37.1%	
	YES	Count	26	38	41	105	
		% within LRINEC	29.9%	97.4%	100.0%	62.9%	
Total		Count	87	39	41	167	
		% within LRINEC	100.0%	100.0%	100.0%	100.0%	

A score of <5 in patients shows a lesser need for debridement, the score of 6-7 and >8 shows a higher need for debridement among the patients.

Comparison:

Outcome	p value
Success rate	0.038
Recurrence rate	0.063
Complication rate	0.139
Length of stay	0.021

Discussion:

This current study reports diabetes mellitus as a comorbid condition among 57 patients (34.1%) who presented with necrotizing fasciitis or cellulitis. Diabetes mellitus was one of the most common risk factors associated with necrotizing fasciitis however, other risk factors include immunodeficiency disease, illicit drug use, and malnutrition. [46] In addition, the clinical study has reported diabetes mellitus is the most common comorbidity in NF patients; with an incidence rate of 2 out of every 3 patients.

The LRINEC score of <5 was reported in 87 patients (52.1%), followed by a score of 6-7 in 39 patients (23.4%), and a score of >8 in 41 patients (24.6%). A score of <5 has been associated with less morbidity of the disease. In addition, the surgical intervention of debridement was only seen in 26 patients with an LRINEC score of <5 whereas, the need for surgical debridement was prevalent in the score of 6-7

(97.4%) and 41 patients with a score of >8. This indicates that the LRINEC score successfully predicts the need for a surgical method based on the clinical condition of the patient with NF. This data from our study can be correlated with the study conducted by Colak et.al. which revealed that a high LRINEC score predicts the requirement of debridement among patients with NF.

In addition to this study, Menyar et.al. also reported that a high LRINEC score can be associated with the need for debridement. [45] In our study, we report a

significant difference in predicting the requirement of debridement by comparison with the LRINEC score with a significant p-value of <0.0001.

The present study also reports the LRINEC score compared with the histopathological findings and the tissue infection. Patients with an LRINEC score of <5 were seen with no histopathological involvement in 61 patients (70.7%). In addition, patients with a score of 6-7 show various histopathological involvement such as coagulase necrosis (28.2%), necrosed skin fascia (43.6%), and neutrophil infiltration (25.6%). The LRINEC score accurately identifies the severity of the disease concerning a high score. The current study reports a significant difference with a p-value of <0.0001 which states a direct correlation between LRINEC score and histopathological involvement. The study by Menyar. et.al reports similar clinical findings where the majority of the individuals with a high LRINEC score were seen with histopathological findings.

The tissue culture involvement with the predictability of the LRINEC score was compared which stated a significant difference (p-value of <0.0001). The tissue infection involvement was predicted higher in the score between 6-7, where patients were mostly diagnosed with GAS infection (13 patients), followed by the polymicrobial infection with the LRINEC score of <5. However, the study by Menyer et al. found a high prevalence of pseudomonas aeruginosa infections with no statistical correlation difference between the study. The studyalso reported that LRINEC scores were able to categorize the score based on tissue infections.

The significant finding which shows the prognostic and predicting ability of the LRINEC score is the accurate diagnosis of severe necrotizing fasciitis. The current study reports that the LRINEC score identified 41 patients with a score

>8 who were diagnosed clinically with necrotizing fasciitis. In addition, the score of the 6-7 range also predicted necrotizing fasciitis (97.4% of patients). These statistical findings also show a significant difference with a p-value of <0.0001 which reveals the predicting ability of the LRINEC score for morbidity and mortality of soft tissue infections.Corbin et.al also reported similar findings for the predictive value of LRINEC to score among 50 patients, the study reported that patients with a high LRINEC score >6 were more prevalent with septic shock, ICU admission, and mortality. [43]

Hence the use of the LRINEC score can be beneficial in predicting an early diagnosis of necrotizing fasciitis with severe bacterial infection and mortality.

Conclusion:

The current study was conducted among 167 patients who presented with a clinical diagnosis of necrotizing fasciitis. The age range of 51-60 was the most prevalent age for necrotizing fasciitis with a male predominance (75.4%) and the presence of diabetes mellitus (34.1%). In addition, clinical symptoms such as edema (100%), ulcers (11.4%), fever (25.1%), and discolourization of the skin (11.4%) were reported. Patients were characterized based on the LRINEC scoring system out of which a score of <5 was seen in 87 patients (52.1%), 6-7 in 39 patients (23.4%), and a score of >8 (24.6%) of the

patients. The histopathological finding of necrosed skin fascia was prevalent in 50 patients (29.9%) followed by neutrophil infiltration in 31 patients (16.6%). Polymicrobial infection (14.4%) and GAS (17.4%) was the most prevalent tissue culture.

LRINEC score was able to detect severe necrotizing fasciitis with 100% accuracy in the score >8 and the 6-7 score range of 97.4%. The LRINEC score was able to detect the need for debridement among the patients presented with a score of >8 (100%), and 6-7 (97.4%) with a significant difference (p-value <0.0001). This shows the prognostic use of the LRINEC score for assessing the need for debridement among NF patients. The severity of the disease was successfully predicted by using the LRINEC score concerning the histopathological finding (p-value <0.0001) and tissue infection (p-value<0.0001). This signifies that the use of the LRINEC score can enable clinicians to predict the overall mortality of necrotizing fasciitis.

Besides the application of the LRINEC score in diagnosis, the scoring system can also be used to predict the mortality of necrotizing fasciitis, and identify high-risk patients. However, further studies large sample-size studies are needed to support the current study findings.

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