

PROSPECTIVE VALIDATION OF THE MODIFIED LRINEC SCORE FOR NECROTIZING FASCIITIS AT TERTIARY CARE CENTRE IN SALEM, TAMIL NADU

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Abstract

Introduction: Necrotizing fasciitis is an aggressive and swiftly advancing inflammatory illness that affects the fascia, leading to the death of the tissues beneath the skin. Necrotizing fasciitis spreads inside the fascial plane. Timely identification and prompt surgical intervention are the only determinants in reducing the adverse health outcomes and death in individuals with necrotizing fasciitis. **Aims and Objectives:** In order to assess the effectiveness of the modified LRINEC scoring system in promptly identifying necrotizing fasciitis in patients with soft tissue infections, the objectives of this study are as follows: 1. To diagnose necrotizing fasciitis at an early stage, 2. To apply the modified LRINEC scoring system to all patients with soft tissue infections, and 3. To determine the appropriate treatment plan based on the outcomes of the modified LRINEC scoring system. **Materials and Methods:** A prospective cohort study was undertaken on 100 patients from the Department of General Surgery at Vinayaka Mission's Kirupananda Variyar Medical College in Salem, Tamilnadu. The study took place from August 2022 to December 2023. This study covered patients who were diagnosed with a soft tissue infection. An initial evaluation and risk assessment were conducted using the LRINEC grading method, which was then followed by the appropriate choice of conservative or surgical treatment. **Results:** In individuals with low risk (<6) M-LRINEC score, 40% were involved. According to M-LRINEC scores, 20% of patients fell into the intermediate risk category (6–8), and 37% of patients fell into the high risk group (>8). M-LRINEC rating.86 Of the 100 patients, 60 underwent debridement; these patients included those with intermediate and high risk M-LRINEC scores. Patients with a low risk M-LRINEC score (<6) did not require debridement interventions. 46 individuals out of the 60 who had debridement had their NF diagnosis confirmed by histology, the gold standard for NF diagnosis. The M-LRINEC score's sensitivity on validation is 95.65%. With P value of 0.0600, the results show a specificity of 69.67%, positive predictive value of 85.56%, and negative predictive value of 91.5%. **Conclusion:** The LRINEC score system aids in early diagnosis and prognosis of necrotizing fasciitis (NF), facilitating prompt intervention and ensuring early therapy and debridement. It differentiates NF from other soft tissue infections, making it routinely recommended.

Keywords: Necrotizing Fasciitis, M-LRINEC Score, Soft Tissue Infections, Early Diagnosis.

INTRODUCTION

Necrotizing fasciitis (NF) is a fast spreading infection of the fascia that causes the death of subcutaneous tissue. The thickness of the subcutaneous layer is directly proportional to the rate of spread. Necrotizing fasciitis progresses along the fascial plane. The prevalence of NF varies from 0.4 to 7.7 cases per 100,000 individuals [1]. The speed of spread is directly proportional to the thickness of the subcutaneous layer. Necrotizing fasciitis moves along the fascial plane.

Multiple investigations have demonstrated an increase in occurrence within the recent decades [2].

The oldest documented mention of necrotizing fasciitis dates back to 500 BC, when Hippocrates provided a clinical account of problems arising from erysipelas illness, which closely resembled the current description of NF [3]. In 1952, Wilson introduced the name "necrotizing fasciitis" and provided a more precise explanation of the illness [3]. Knowledge of the condition significantly progressed during the late 1980s. Stevens documented that out of a group of 20 patients who exhibited streptococcal shock, 11 were specifically identified as having necrotizing fasciitis (NF).

The disease was commonly referred to by the general public as "flesh-eating bacteria syndrome [3]". The annual occurrence rate of Necrotizing fasciitis is believed to be between 500 and 1,000 cases per 100,000 individuals, and the estimated worldwide frequency is 0.40 occurrences of necrotizing fasciitis [4]. The male-to-female ratio is 3:1, which is mostly associated with the increased prevalence of Fournier's gangrene in males.

While the illness has the potential to impact individuals of all ages, it is particularly prevalent among individuals who are over the age of 50 and those in their middle years. Three Anaya et al.'s research indicates that the perineum, belly, and lower extremities are the most common locations for NF infection. Compared to neurofibromatosis (NF) affecting the lower limbs, NF in the upper limbs is infrequent [5].

Soft-tissue necrotizing infections can be classified into four categories based on the types of bacteria that invade the soft tissue. Paz Maya et al. extensively address this classification in their work on NF [6].

Necrotizing fasciitis (NF) refers to a severe infection that affects the subcutaneous soft tissues, particularly the superficial layers and often extending to the deep fascia. It frequently presents as a severe condition, however it may occasionally progress in a less severe form. Necrotizing fasciitis (NF) has the potential to invade any part of the body, although it commonly targets the extremities, specifically the legs. Other areas that are particularly prone to occur are the abdominal wall, perianal and groin regions, and surgical incisions.

Abrasions, lacerations, insect bites, burns, laparotomies performed in the presence of peritoneal soiling (such as in cases of penetrating abdominal trauma or perforated viscus), surgical procedures (such as hemorrhoidectomy or vasectomy), perirectal abscesses, decubitus ulcers, and intestinal perforations are the primary sources of infection entry points. Intestinal perforation can be caused by a foreign item, such as a chicken bone or toothpick, a rectosigmoid tumor, or concealed diverticulitis.

Neurofibromas originating from the intestines can present in the lower limbs, groin, or abdominal wall. Infection originating from the intestines can spread to the lower extremities by following the path of the psoas muscle. Additionally, if there is a col-cutaneous fistula, the infection can also reach the abdominal wall. Neurogenic fever (NF) can occur specifically in cases of parenteral drug addiction, diabetes mellitus, and alcoholism. This disorder is known by numerous labels, including progressive synergistic infection gangrene, NF, Fournier gangrene, cancrum oris, and Meloney's gangrene. All of these terms refer to different forms of bacterial diseases that cause the destruction of flesh [7].

Identifying the distinctive traits and the quickly advancing clinical development of the disease helps in diagnosing NF [8]. Olafsson et al. [9] show that the main characteristic of NF is the presence of intense pain and sensitivity in the affected skin and underlying muscle.

The routine utilization of computed tomography, magnetic resonance imaging, and frozen section biopsy is limited due to their high cost and limited accessibility in the evaluation of soft tissue infections.

Therefore, Wong et al. [10] developed a straightforward scoring system called the laboratory risk indicator for necrotizing fasciitis (LRINEC). This method utilizes common laboratory tests that are easily accessible in most medical facilities. Its purpose is to differentiate necrotizing fasciitis (NF) from other types of soft tissue diseases. The LRINEC score is constructed using six laboratory variables that are measured at the time of presentation: hemoglobin, total leukocyte count, serum glucose, serum sodium, serum creatinine, and serum C-reactive protein.

While Wong et al. [10] proposed that the LRINEC score can identify even early cases of NF, subsequent investigations [11-14] have not shown sufficient evidence to support the routine use of the LRINEC score.

The prompt identification and timely surgical intervention are the only decisive variables in averting the morbidity and mortality associated with necrotizing fasciitis. The scarcity of distinctive skin manifestations to differentiate necrotizing fasciitis from other types of soft tissue infections, such as cellulitis, poses a significant challenge in making the diagnosis. Therefore, there is a need for a scoring system that is both user-friendly and economical, while also having a high level of accuracy in predicting both positive and negative outcomes [1]. The LRINEC scoring system, developed by Wong et al. in 2005, is a scoring system that has been shown to have a positive predictive value of 92.0% and a negative predictive value of 96.0% [5]. Another scoring method, known as M-LRINEC (modified LRINEC), is reported to have a sensitivity of 91.8% and a specificity of 88.4% [15].

The Modified LRINEC (M-LRINEC) scoring system includes routinely used laboratory parameters such as age, immunocompromised state, total white cell count, hemoglobin, sodium, potassium, glucose, serum creatinine, and C-reactive protein. This robust scoring system is capable of detecting even clinically early cases of necrotizing fasciitis, using variables that are routinely measured to assess severe soft tissue infections. Patients with an M-LRINEC score greater than 6 should be carefully evaluated for the presence of necrotizing fasciitis. The maximum score for the M-LRINEC is 18.

Table 1: Modified LRINEC Scoring System

S.NO.	VARIABLE	RANGE	SCORE
1	AGE	18-45	1
		45-60	2
		>60	3
2	IMMUNO COMPROMISED STATE	ABSENT	0
		PRESENT	2
3	RANDOM BLOOD SUGAR	180 OR LESS	0
		>180	1
4	C-REACTIVE PROTEIN	NEGATIVE	0
		POSITIVE	2
5	TOTAL WBC COUNT /mm ³	<15000	0
		15000-25000	1
		>25000	2
6	HEMOGLOBIN	>13.5	0
		11-13.5	1
		<11	2
7	SERUM SODIUM	135 OR MORE	0
		<135	2
8	SERUM POTASSIUM	5 OR LESS	0
		>5	2
9	SERUM CREATININE	1.4 OR LESS	0
		>1.4	2

Aim of the Study:

The aim of the study is

1. To assess the efficacy of the modified LRINEC scoring system in promptly identifying necrotizing fasciitis in patients with soft tissue infections for the purpose of early diagnosis.
2. To apply the improved LRINEC grading system to patients with all types of soft tissue infections.
3. Treatment plan determined by the results of the modified LRINEC grading system.

MATERIALS AND METHODS

A prospective cohort study was conducted on 100 patients diagnosed with NF at Vinayaka Mission's Kirupananda Variyar Medical College in Salem, Tamilnadu. The study, conducted between August 2022 and December 2023. . This study was done in accordance with the Declaration of Helsinki and approved by Institutional Ethics Committee of Vinayaka Mission's Kirupananda Variyar Medical College in Salem, Tamilnadu and written informed consent from the patients. The study included patients aged 15 to 75, diagnosed with NF in the surgical wards of the college, which is linked to Vinayaka Mission's research foundation. The study received approval from the institutional ethics committee and all participants provided signed informed consent.

A total of 100 patients presenting with soft tissue infections, meeting the inclusion and exclusion criteria, were included in the study. The inclusion criteria required all patients to be above 18 years of age and diagnosed with soft tissue infections based on clinical evaluation, as well as willing to participate in the study. Exclusion criteria included patients under 18 years of age, those who had already undergone surgical

debridement for the current episode of soft tissue infections, patients with burns or furuncles without evidence of cellulitis, and those unwilling to participate in the study.

The sample for this study consisted of 100 patients who had a clinical diagnosis of soft tissue infections. The following parameters are assessed: C-reactive protein, total white cell count, hemoglobin, sodium, potassium, creatinine, and glucose. The demographic data was documented using a pre-designed form. The LRINEC scoring method was utilized and the scores were documented. The grading criteria for necrotizing fasciitis were used to determine the severity of the condition and guide the medical treatment. Wound debridement was performed as the ultimate procedure when necessary. The patients were subsequently treated with standard wound dressings, antibiotics, and supportive care to maintain blood pressure and renal function. In certain cases, vacuum aided dressings were utilized to expedite the healing process. In several instances, extensive amputations were necessary to effectively manage and prevent the spread of infection. Diabetic patients were treated with oral hypoglycemic medications and insulin.

Data Analysis:

The statistical analysis for the required sample size per group was carried out using Statistica version 9 (StatSoft, Inc, 1984-2009, USA). All other statistical analyses were performed using the Statistical Package for Social Sciences for Windows 8.0 software. The results are presented as means with their respective standard deviations. To make comparisons, analysis of variance (ANOVA) was employed, followed by Tukey's post hoc test for multiple comparisons and the independent samples Student's t-test. Pearson correlation analysis was used to calculate correlations between variables. The results were evaluated within a 95% confidence interval, and significance was determined with a probability level of less than 0.05.

RESULTS

The study included 100 patients with soft tissue infections. The age distribution showed that 24% were between 18-44 years, 19% were between 45-60 years, and 57% were over 60 years. Gender distribution indicated that 64% of the patients were male and 36% were female. Regarding immunocompromised status, 53% of the patients were immunocompromised, while 47% were not (Table 2).

Table 2: Patient Demographics and Clinical Characteristics

Characteristic	Category	Frequency (n = 100)	Percentage
Age Distribution			
	18-44 years	24	24%
	45-60 years	19	19%
	>60 years	57	57%
Gender Distribution			
	Male	64	64%
	Female	36	36%
Immunocompromised Status			
	No	47	47%
	Yes	53	53%

Table 3: Patient Laboratory Parameters

Characteristic	Category	Frequency (n = 100)	Percentage
Random Blood Sugar	<180 mg/dL	66	66%
	>180 mg/dL	34	34%
C-Reactive Protein	Negative	65	65%
	Positive	35	35%
Total Leucocyte Count	<15 /mm ³	49	49%
	15-25 /mm ³	41	41%
	>25 /mm ³	10	10%
Hemoglobin	>13.5 g/dL	11	11%
	11-13.5 g/dL	48	48%
	<11 g/dL	41	41%
Serum Sodium	>135 mEq/L	79	79%
	<135 mEq/L	21	21%

The laboratory parameters of the 100 patients with soft tissue infections revealed the following: 66% had random blood sugar levels below 180 mg/dL, while 34% had levels above 180 mg/dL. C-reactive protein was negative in 65% of the patients and positive in 35%. Total leucocyte count was less than 15 /mm³ in 49% of patients, between 15-25 /mm³ in 41%, and greater than 25 /mm³ in 10%. Hemoglobin levels were above 13.5 g/dL in 11% of patients, between 11-13.5 g/dL in 48%, and below 11 g/dL in 41%. Serum sodium levels were above 135 mEq/L in 79% of patients, while 21% had levels below 135 mEq/L (table 3).

In the current study, only 57 out of 100 patients underwent debridement, during which tissue samples were collected for histopathology examination to definitively diagnose Necrotizing fasciitis. Among these patients, 12 out of 21 in the intermediate risk group and 30 out of 36 in the high risk group were confirmed to have necrotizing fasciitis. Specimen for culturing and testing for antibiotic sensitivity

In this study, a total of 57 patients underwent debridement and tissue samples were collected for culture and sensitivity testing. A total of 44 out of 57 patients who underwent debridement exhibited the growth of germs. Among them, 30 patients in the high-risk group had bacterial growth, while 14 patients in the intermediate-risk group showed the growth of microorganisms. Out of the total number of patients (57%) who underwent debridement, 52% of them revealed the presence of microorganisms. Among these patients, 14% were classified as intermediate risk and 30% were classified as high risk.

Table 4: Validation of m-LRINEC Score in Relation to HPE for Diagnosing of Necrotizing Fasciitis

Parameter	Estimate	95% Confidence Interval
Sensitivity	95.45%	79.28% - 98.21%
Specificity	68.67%	45.37% - 82.81%
Positive Predictive Value	84.16%	64.97% - 90.25%
Negative Predictive Value	91.50%	63.98% - 96.51%

The diagnostic parameters for the study demonstrated high sensitivity at 95.45% (95% CI: 79.28% - 98.21%) and a specificity of 68.67% (95% CI: 45.37% - 82.81%). The positive predictive value was 84.16% (95% CI: 64.97% - 90.25%), and the negative predictive value was 91.50% (95% CI: 63.98% - 96.51%) (Table 4).

DISCUSSION

The majority of patients in the current study who presented with soft tissue infections were above the age of 60, which aligns with the findings of Wong et al.'s study [10]. In our study, the majority of the subjects were males with 64.%, whereas it was 51%, 73.10%, and 73.3% in Faucher et al. [16], Chowdary et al. [17], and Pratheek et al. [18], respectively.

In this study, out of the 100 patients examined, only 34 individuals had a random blood sugar level above 180 mg/dl, while the remaining 66% of patients had random blood sugar levels below 180 mg/dl. In comparison to the studies conducted by Johnson, L. J., Crisologo et al. [19], and Longmore et al. [3], the cutoff for random blood sugars was found to be less than 200 mg/dl. This cutoff resulted in 73% of the population having random blood sugars above 200 mg/dl, which does not align with the findings of the present study. However, the study conducted by Captain S. Nedunchezian et al. [20] revealed that 34 out of 50 patients in the study population had random blood sugars above 180 mg/dl, which is consistent with the results of the present study.

The LRINEC score, originally proposed by Wong et al., was modified to create the M-LRINEC score. In the present study of 100 patients, the M-LRINEC score had a total score of 18. Among the patients, 43 were classified as low risk (score<6), 21 were classified as intermediate risk (score between 6-8), and 36 were classified as high risk (score>8). In the study conducted by Captain S. Nedunchezian et al. [20], out of the 50 patients, 27 were classified as high risk, 8 as intermediate risk, and 15 as low risk. According to Po-Han Wu's study [21], out of the 25 patients, 12 were classified as low risk, 7 as high risk, and 6 as intermediate risk. In the study conducted by Hsiao CT et al. [22], out of the 303 patients, 123 were categorized as intermediate risk and 80 as low risk.

For high risk patients serial m-LRINEC score monitoring may be useful for stopping the progression of NF. An early aggressive surgical intervention may reduce mortality and related complications in high risk patients. A high index of suspicion, along with early diagnosis and aggressive surgical treatment, remains the supreme management strategy for NF. The adjunct risk evaluation model based on laboratory investigations may be useful in the early stages of NF.

CONCLUSION

Prompt recognition and treatment of necrotizing soft tissue infections, such as necrotizing fasciitis (NF), are crucial for patient outcomes given the potentially lethal nature of these illnesses. The LRINEC score, obtained from standard laboratory tests, is a useful tool for differentiating necrotizing fasciitis (NF) from other types of soft tissue diseases. The LRINEC score system, with its heightened sensitivity and statistically significant p-values, allows doctors to accurately categorize patients with severe soft tissue infections.

This approach helps in promptly implementing appropriate interventions and ultimately enhances the well-being of patients. Timely identification and classification of risk using the LRINEC score are crucial measures in guaranteeing timely and suitable treatment, ultimately resulting in improved outcomes for persons suffering from necrotizing soft tissue infections.

Limitations

The small sample size of 100 patients limits the generalizability of the findings. As this was a single center study with a comparatively short sample size, results of this study cannot be generalized. Generalization requires the support of results from similar large studies

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Conflicts of Interest: There are no conflicts of interest.

Ethical Statement:

Institutional ethical committee accepted this study. The study was approved by the institutional human ethics committee, Vinayaka Mission's Kirupananda Variyar Medical College in Salem, Tamil Nadu. Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and the voluntary nature of participation were explained to the participants before obtaining consent. The confidentiality of the study participants was maintained.

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Authors' Contributions:

Dr. Chiranjeevi. G & Dr. Praveen Kumar.S - conceptualization, data curation, investigation, methodology, project administration, visualization, writing—original draft, writing—review and editing; **Dr. E. M. J. Karthikeyan** -conceptualization, methodology, writing—original draft, writing—review and editing; **Dr. Shaikh Aaliah Naaz & Dr. Kumaran** - conceptualization, visualization, supervision, writing—original draft; **Dr. J Sridhar** - methodology, writing—original draft, writing, review and editing. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work. All authors have read and agreed to the published version of the manuscript.

Data Availability:

All datasets generated or analyzed during this study are included in the manuscript.

Informed Consent:

Written informed consent was obtained from the participants before enrolling in the study.

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