



Evaluation Of Efficacy Of Laboratory Risk Indicator Scoring System As A Diagnostic And Prognostic Tool In Necrotizing Fasciitis In A Tertiary Care Centre

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Abstract

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Introduction

Necrotizing soft-tissue infections (NSTI) represent a spectrum of severe skin and soft-tissue infections that are characterized by extensive, rapidly progressive soft tissue necrosis. due to end arteritis and systemic signs of sepsis. It has been defined as infections of any of the layers within the soft tissue compartment (dermis, subcutaneous tissue, superficial fascia, deep fascia) that are associated with necrotizing changes. Infection typically spreads along the muscle fascia due to its relatively poor blood supply, while muscle is usually spared because of its generous blood supply. It is a surgical diagnosis characterized by friability of superficial fascia, dishwater exudates and absence of pus.

The incidence of the disease is estimated which ranges from 0.3 to 15 cases per 1, 00,000 population.¹ The incidence is more common in those aged >50 years and with male preponderance (male to female ratio of 2-3:1).

NF is a surgical challenge because of combination of both difficulty in establishing the diagnosis and even more difficult to manage the associated morbidity and mortality. Early clinical suspicion, prompt and aggressive surgical debridement, appropriate antimicrobials, supportive care are key to improve survival rate. Despite advances in surgical and medical care, the mortality still remains high around 20-30 % (2-5)

Numerous scoring system have been studied for evaluation and prognosis of the patients with NF.LRINEC(laboratory risk indicator for necrotizing fasciitis),Acute Physiology and Chronic Health Evaluation II (APACHE II), Sequential Organ Failure Assessment (SOFA), Simplified Acute Physiology Score II (SAPS II), and Mortality in Emergency Department (MEDS) are some of the

Aims And Objectives Of The Study

To assess laboratory risk indicator in necrotizing fasciitis in early diagnosis and as a prognostic tool.

Materials And Methods

A prospective observational study of 70 patients with diagnosis of necrotizing fasciitis was done over a period of 3 years in a tertiary care medical college hospital in south India.

Data was collected as per proforma that included demographics, clinical presentations, site of infection, type of co-morbidities, microbiological (culture and sensitivity) and laboratory findings, surgical care (debridement) given and response to the treatment.

Ethical Clearance: Ethics clearance was obtained from Institutional Ethics Committee SIMS, Shivamogga.

Consent to participants : Consent was taken from participants and the objective and details of study was clearly explained.

A standard scientific treatment protocol was being followed with serial debridement, regular dressing, antibiotic therapy base on culture & sensitivity, skin grafting, amputations if required.

NF was diagnosed based on clinical and laboratory assessments on arrival and during the hospital stay. When the clinical assessment and surgical exploration is same, the final diagnosis of NF was confirmed by histo-pathological analysis. A gram staining was obtained during primary debridement. LRINEC was calculated at presentation using laboratory results of six variables C-reactive protein (CRP), white blood cell count, hemoglobin, sodium level, creatinine and glucose.

Inclusion Criteria:

All patients with age more than 18years with provisional diagnosis of necrotizing soft tissue infections were include in the study population.

Exclusion Criteria:

1. Patients diagnosed with abscess that were managed with incision and drainage.
2. Patients not full filling the six clinical parameters necessary to calculate the laboratory risk indicator in necrotizing fasciitis scores.

Sample Size Calculation:

Precision=9%

C.I=95%

Sample size=70

$$N = [Z^2 (1-\alpha)^2 P (1-P)] \div d^2$$

Where p = sensitivity of the test D= precision

$$Z (1-\alpha)^2 = C.I$$

Sample size = 70

Statistical Analysis:

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi- square test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation.

p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

Observation And Results

Total of 70 patients with soft tissue infection were included in the study. They were evaluated on the basis of Laboratory risk indicator for necrotizing fasciitis (LRINEC). Patients were appropriately managed and the results are shown below

Table 1: Age distribution of subjects in the study

		Count	%
Age	<40 years	13	18.6%
	41 to 50 years	17	24.3%
	51 to 60 years	14	20.0%
	61 to 70 years	17	24.3%
	>70 years	9	12.9%
	Total	70	100.0%

In the study majority of subjects were in the age group 41 to 50 years and 61 to 70 years (24.3% respectively) and 51 to 60 years (20)

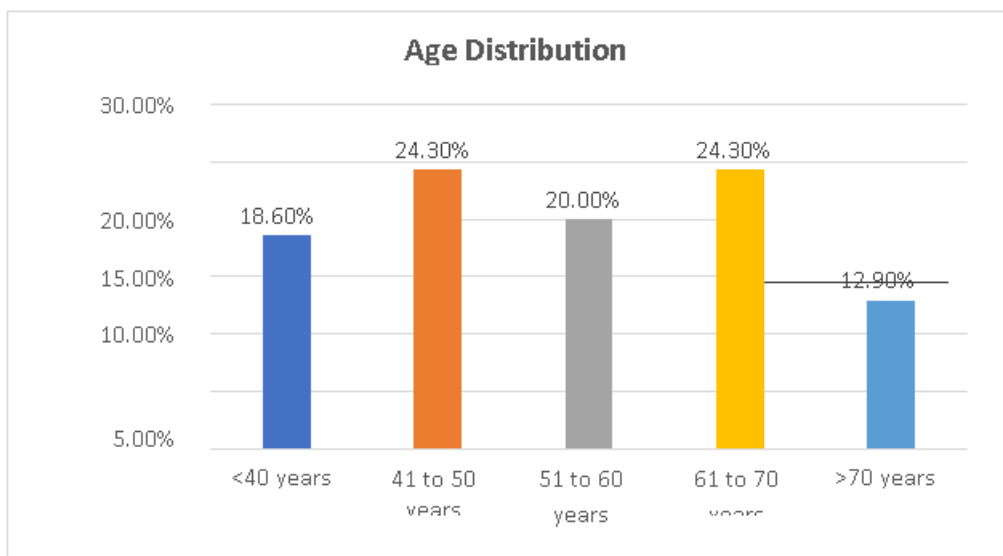


Table 2: Sex distribution of subjects:

		Count	%
Sex	Female	8	11.4%
	Male	62	88.6%

In the study 88.6% were males and 11.4% were females

Table 3: Parameters used for laboratory risk indicators

	Mean	SD	Minimum	Median	Maximum
CRP (mg/dl)	210.04	61.24	121.00	200.00	412.00
WBC (mm ³)	14.46	3.38	7.20	13.80	23.00
Hb (mg/dl)	10.79	1.73	6.90	11.00	15.00
Na (mmol/l)	129.70	3.94	119.00	130.00	137.00
Creatinine (mg/dl)	1.35	0.34	0.50	1.35	2.30
Glucose (mg/dl)	184.29	51.75	99.00	181.00	389.00

Mean CRP was 210.04 ± 61.24 mg/dl, mean WBC was 14.46 ± 3.38 mm³, and mean Hb was 10.79 ± 1.73 mg/dl, mean Na⁺ was 129.7 ± 3.94 mmol/l, mean Creatinine was 1.35 ± 0.34 mg/dl and mean Glucose was 184.29 ± 51.75 mg/dl.

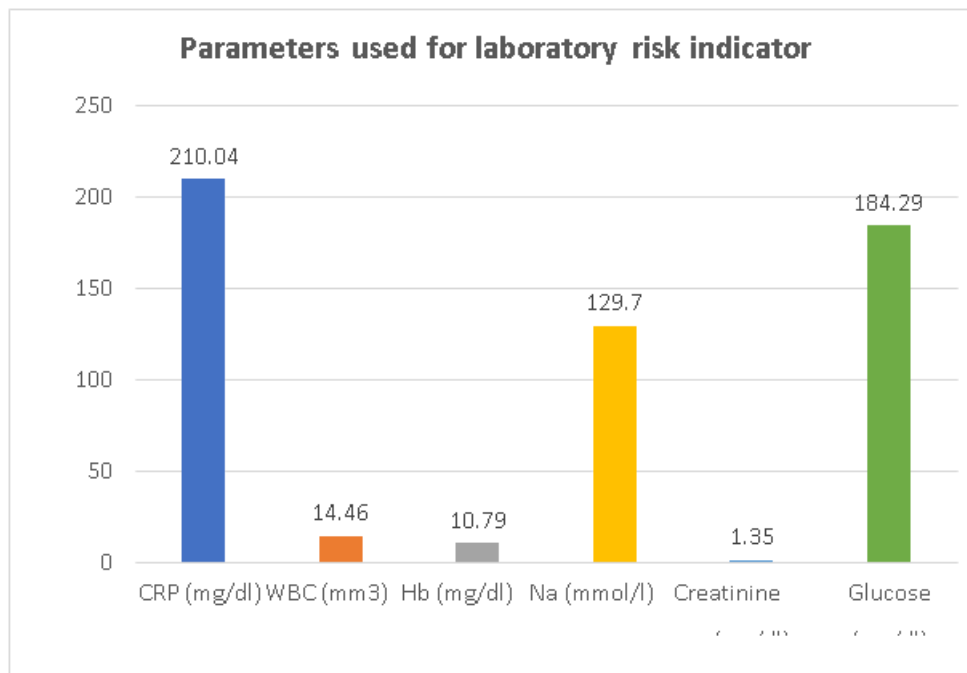


Table 4: Treatment given distribution

		Count	%
Treatment Given	Amputation	4	5.7%
	Debridement	57	81.4%
	Debridement With Tracheostomy	1	1.4%
	Debridement	1	1.4%
	Fasciotomy	6	8.6%
	Non-Surgical	1	1.4%

In the study 45.6% underwent Debridement, 25% underwent Fasciotomy, 13.3% non surgical treatment and others as shown in above table (graph plotted for 50%).

Out of seventy patients 46 patients histo-pathology reports showed evidence reports showed evidence of necrosis. In statistical analysis this was significant outcome with p value <0.0001.

At score of >6 the sensitivity was 91.3% and specificity 45.83% and negative predictive value of 73.3%.

Diabetes mellitus was most common (27.1%) comorbidity associated with necrotizing soft tissue infections followed by hypertension+diabetes (7.1%) chronic renal disease and others like COPD, heart disease in our study.

In our study most common organisms isolated was staphylococcus (24.3%) and streptococcus (22.9%). E.coli and pseudomonas were major organisms in gram negative cultures.

Table 5: Validity of Laboratory risk indicator Score in predicting Necrotizing Fasciitis Area under the ROC curve (AUC)

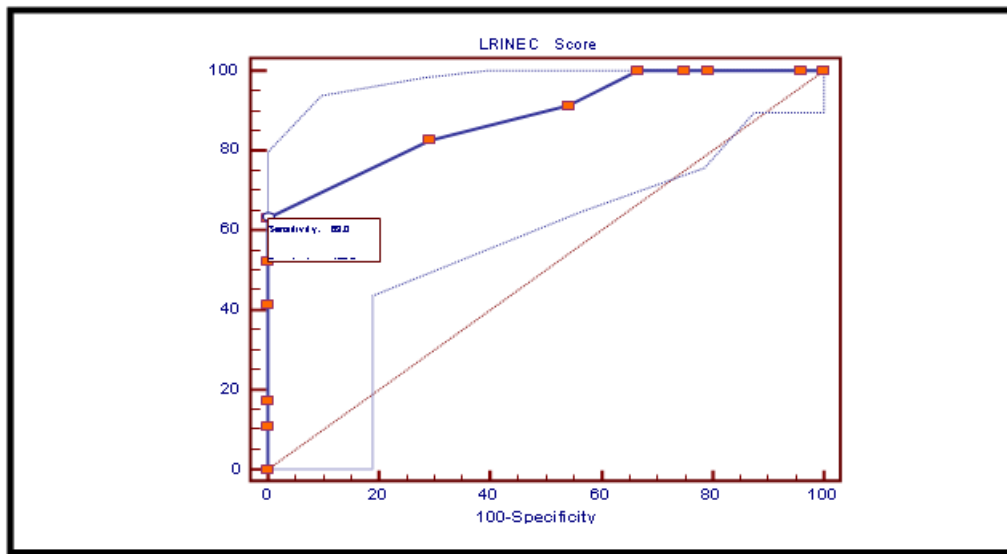
Area under the ROC curve (AUC)	0.883
Standard Error	0.0369
95% Confidence interval	0.784 to 0.947
z statistic	10.374
Significance level P (Area=0.5)	<0.0001

Youden index

Youden index J	0.6304
95% Confidence interval	0.4499 to 0.7391
Associated criterion	>8
95% Confidence interval	5 to 8

In the study Yourdon’s index was 0.6304, and Laboratory risk indicator Score >8 had highest sensitivity of 63.04%, Specificity of 100%, Positive Predictive value of 100% and negative predictive value of 58.5%.

ROC Curve showing Validity of Laboratory risk indicator Score in predicting Necrotizing Fasciitis



Discussion

Necrotizing fasciitis is a life threatening condition which needs early diagnosis with aggressive resuscitation, prompt and repeated surgical debridement, physiologic support, broad-spectrum antimicrobial therapy and nutritional support. In spite of all the above treatment modalities, the prognosis remains poor.

Our studies showed most of the patients were belonging to age group of 41-50(24.3%) and 61-70

(24.3%). Similar analysis was observed in study conducted by Pratheek KC et al ⁽⁶⁾ in terms of age distribution.

There are four types of NF depending on microbiological profiles.

They are Type I necrotising fasciitis (polymicrobial); Type II necrotising fasciitis due to group A streptococcus ;Type II necrotising fasciitis due to Staphylococcus aureus ; Type III necrotising fasciitis due to Vibrio vulnificus ; Type III necrotising

fasciitis due to *Aeromonas hydrophila* ; Type III necrotising fasciitis due to *Clostridium* ; Type IV necrotising fasciitis due to *Mucorales*

In the study most of the patients were male constituting 88.6%. Similar results were seen in study by Narayanaswamy *et al* ⁽⁷⁾ and Bansal *et al* ⁽⁸⁾. Male population have higher incidence of traumatic injury, also higher workplace hazards and alcoholism being common among male population become the predisposing factors for higher incidence of necrotizing fasciitis in males.. Minor injuries are common in workplace that requires physical labor. Lack of proper safety precautions and bad hygiene in the work place will form a perfect combination for the origin of infections. This pattern shows that with improving the hygiene, safety and the working environment and through proper training of manual labor, the incidence of necrotizing fasciitis can be reduced. Majority of the cases of necrotizing fasciitis follow minor injury due to trauma, RTA, insect bite, snake bite, thorn prick, etc. and poor care for the wound following the trivial trauma is the major cause for necrotizing fasciitis. The incidence of necrotizing fasciitis was highest following the trauma. The foreign body that might get lodged or the deep inoculation that occurs with trauma, thorn prick and other cause forms a perfect incubator for the organisms to flourish, this is complemented by lowered host defense due to alcoholism, and diabetes leads to fulminant local infection leading to necrotizing fasciitis. Causes of NF include Endotoxins and exotoxins produced by bacteria induce a fulminant inflammatory response, which leads to obliterating endarteritis; thrombosis; tissue Necrosis, Erythema and swelling which is spreading often, systemic illness with sepsis and multisystem organ failure.

Lower extremities were the most common organs involved in necrotizing soft tissue infections in the study with a frequency of 67.1% (right 35.7% +left 31.4%) followed by upper limb 5.7% (upper extremity right-2.9% left-1.4% .and right hand-1.4%), abdominal wall -2.9% and neck 1.4%. Other study done by Kumar *et al* showed lower limb involvement 68.3% ,scrotum/perineum 20% ,upper limb 8.3% and abdomen wall 3.3% which was comparable to our study⁽⁹⁾

In contrast, upper limb was most common site affected in study done by Wall *et al* ⁽¹⁰⁾ which was attributed to intravenous drug abuse. Host defense lost due to severe systemic illness of the patient like diabetic mellitus, hypertension, renal disease and chronic kidney disease will increase the chance of spread of infection and accelerate the morbidity. Diabetes mellitus was the most common (27.1%) co-morbidity associated with necrotizing soft tissue infections followed by hypertension +diabetes (7.1%) chronic renal disease and others like COPD, heart disease in our study. In a study conducted by Khamnaun *et al* ⁽⁴⁾, Diabetes was found in 25.6%, hypertension was found in 35.7%, CRD and cirrhosis were found in 2.9% and 4% of total number of patients.

Debridement was the primary procedure of choice for treatment of necrotizing fasciitis, 57 out of seventy patients (81.4%) underwent the procedure. Other procedures such as fasciotomy (8.6%), amputation (5.7%) in case of spreading infections to control the morbidity were performed. Early diagnosis and on time appropriate surgical debridement are crucial for the outcome of NF. Using the score and confirming the outcome by presence of necrosis in histopathology was the major principle of the study for LRINEC score validation. Out of seventy patients 46 patients histo-pathology reports showed evidence of necrosis. In statistical analysis this was significant outcome with p value <0.0001.

For validating the LRINEC score in diagnosing the necrotizing soft tissue infections ROC curve was plotted, where score of more than 8 with confidence interval from 5 to 8 with Youdens index 0.6304 had highest sensitivity of 63.04%, specificity of 100% ,positive predictive value of 100% and negative predictive value of 58.5% . At score of >6 the sensitivity was 91.3% and specificity 45.83% and negative predictive value of 73.3%. Our study was comparable to study by Bansal *et al* were LRINEC score >8 had specificity 95.04%, and negative predictive value 42% and positive predictive value 90% (8).

LRINEC scoring is a useful diagnosis tool to identify and diagnose necrotizing fasciitis. As the score went lower, the specificity was lower and negative predictive value was higher. Based on this correlation of statistics it can be said that soft tissue infections

such as cellulitis where internal milieu is less disturbed the score will be low, which makes use of score debatable.

A prospective observational study done by Hsiao C-T *et al* indicated that LRINEC score may not be an accurate tool in differentiating the severe cellulitis and necrotizing infections in emergency department setting⁽¹²⁾. In our study most common organisms isolated was staphylococcus (24.3%) and streptococcus (22.9%). E.coli and pseudomonas were major organisms in gram negative cultures. Anaya *et al*^(2, 13) found that staphylococcus and streptococcus were the most commonly isolated organisms in polymicrobial cultures which were similar in our study. The study by Narayanswamy *et al* and S Chitra *et al* had streptococcus as most common monomicrobial infections^{(7) (14)}. Wong *et al*. suggest a LRINEC threshold of ≥ 6 for patients with a suspicion of necrotizing fasciitis and a score of ≥ 8 for patients with a strong prediction for the disease⁽¹⁵⁾. The importance of using an evidence based approach has good role in early diagnosis, surgical intervention and improved morbidity and mortality. For assessing the LRINEC score as prognostication patients were grouped into low risk (<6), intermediate risk (6-8) and high risk (>8). Some of the patients required second surgeries like debridement and amputations. In the present study among subjects with low risk score, no re-do surgery was required, among subjects with intermediate risk score, 9.1% required second surgery and among subjects with high risk score, 27.6% required second surgery. But, there was no significant association between Second surgery and LRINEC Risk Score. These analysis shows that score <6 will perform well with expectant management were as score of >6 require aggressive serial debridement. However, in the study there was higher mean hospital stay in high risk group of 15.2 as compared to intermediate 8.9 and low risk group 8.2. On Scatter plot graph there was positive correlation between LRINEC score and duration of hospital stay i.e. with increase in LRINEC score there was increase in duration of hospital stay and vice versa. Pearson correlation was 0.652 with sig. (2-tailed) p value <0.001 . Similar results are comparable with study done by Bansal N *et al*⁽⁸⁾ Only 3 deaths were seen in high risk group with mortality rate of 10.3% in high risk group patients, but no mortality was seen in low and intermediate risk group.

Conclusion

Necrotizing soft tissue infections are often fatal, characterized by extensive necrosis of the fascia and subcutaneous tissues. It is perhaps the most severe form of soft tissue infection potentially limb and life threatening.

LRINEC - Laboratory Risk Indicator for Necrotizing Fasciitis score is based on routine laboratory investigations that are readily available, at most centers and is cheaper simple tool for predicting the need of early surgical intervention having good sensitivity and specificity.

Hospital stay and mortality was higher in score group of more than 8. A score of more than 8 should be treated aggressively with debridement and use of antibiotics as a treatment of choice, if required amputation in view to reduce the mortality and morbidity.

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