

Research Article

SIARI Score versus LRINEC Score for Diagnosis of Necrotizing Fasciitis- A Prospective Comparative Study

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Submitted: 22 May 2022**Accepted:** 07 November 2022**Published:** 10 November 2022**Copyright**

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ISSN: 2573-1017**OPEN ACCESS****Keywords**

- Necrotizing fasciitis
- SIARI score
- LRINEC score

Abstract

Background: Necrotizing Fasciitis is a rapidly progressive soft tissue infection that is life and limb threatening without prompt treatment. LRINEC score is the most commonly used scoring system for its diagnosis. This study aims to compare SIARI score with LRINEC score for diagnosis of NF.

Method: This was a prospective, comparative observational study of 42 patients admitted in Bir Hospital with provisional diagnosis of necrotizing fasciitis between August 2020 and March 2021. SIARI score and LRINEC score at admission were calculated and compared to final diagnosis on the basis of histopathology reports and with regards to sensitivity, specificity, positive predictive value, negative predictive value and C-statistic.

Results: Out of enrolled 42 patients, 32 had final diagnosis of NF. The mean age was 46.59 ± 15.58 years with male to female ratio being 2.2:1. The most commonly affected site was lower limb (59.4%) and polymicrobial infections (59.4%) were common. Trauma (40.6%) was the most common risk factor. The most common co-morbid conditions were chronic alcoholism (65.6%) and diabetes mellitus (34.4%). Mortality rate of 15.6% was noted. Sensitivity, specificity, PPV, NPV and C-statistic of SIARI score ≥ 3 and LRINEC score ≥ 6 were 78.1% vs. 62.5%, 70% vs. 60%, 89.3% vs. 83.3%, 50% vs. 33.3% and 0.827 ($p < 0.001$) vs. 0.650 ($p < 0.0962$) respectively.

Conclusion: SIARI score is an easy to use tool for diagnosis of Necrotizing Fasciitis exhibiting better sensitivity, specificity and diagnostic accuracy compared to LRINEC score.

ABBREVIATIONS

NF: Necrotizing Fasciitis; NSTIs: Necrotizing Soft Tissue Infections; DM: Diabetes mellitus; PPV: Positive Predictive Value; NPV: Negative Predictive Value

BACKGROUND

Necrotizing Fasciitis (NF) is one of the most severe soft tissue infections primarily involving the fascia and subcutaneous tissue [1]. The incidence of Necrotizing Soft Tissue Infections (NSTIs) is 0.04 cases per 1000 person-years in US and Canada [2-5]. NF is almost fatal without prompt treatment with mortality rare reported from 8.3% to as high as 73% [6-11]. Most NSTIs are polymicrobial seen in 80% cases, however monomicrobial infections are reported in 10-15% [11,12]. Trauma is the most common etiology of NF and the risk factors include old age, atherosclerosis, chronic alcoholism, peripheral vascular disease, diabetes mellitus (DM) and immunosuppression [2,4,13-16]. Early diagnosis of NF with prompt surgical intervention is the key to prevent morbidity and mortality. However, paucity of early pathognomic signs and lack of definite imaging characteristics make the early diagnosis of NF a challenge [4,7,8,17-19]. Different scoring systems have been developed to aid in early diagnosis

of NF. The Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) Score, devised by Wong et al. in 2004, is the most extensively used scoring system. This scoring system utilizes levels of C-reactive protein, WBC count, hemoglobin, serum sodium, Creatinine, and glucose. Wong et al., in their initial study, reported a PPV of 92% and NPV of 96% using 6 as a cut-off value for LRINEC score [1]. Though these results are encouraging, subsequent studies done across the globe have revealed poor results [1,19-21]. Cribb et al. proposed the SIARI score in 2019 which stands for Site of infection outside of lower limb, history of Immunosuppression, Age ≤ 60 years, Renal impairment (Serum Creatinine > 141 micro mol/L), Inflammatory markers (White cell count > 25 per mm [3], C-reactive protein ≥ 150 mg/L). Contrary to LRINEC score, this score had better diagnostic ability to detect NF, is easier to recall, uses fewer laboratory parameters and makes room for clinical variables in which laboratory values usually seen in profound sepsis may not be necessarily present [21]. A score with fewer laboratory variables and better diagnostic yield will help in early diagnosis of NF, which will ultimately reduce the treatment cost, morbidity and mortality. Therefore, this study was done to assess the validity of the SIARI score and compare it with the LRINEC score.

METHODS

Study Design and Patient Selection

Following the ethical clearance from the Institutional Review Board (IRB) of National Academy of Medical Sciences (NAMS), this prospective observational comparative study was conducted at Bir Hospital, Kathmandu, Nepal. The sample size was calculated using the test of hypothesis on the difference between 2 proportions. At test power of 80% with 95% confidence interval and considering 10% dropout cases, the required sample size came out to be 42 [21-23]. All adult patients presenting with provisional diagnosis of NF to the Emergency Department (ED) and Outpatient Department (OPD) of General Surgery, Bir Hospital were included in the study. The exclusion criteria were as follows: who did not consent, below 16 years of age, pregnant women, lactating mothers, with known skin infection other than NF and who were already managed surgically at other centers. After fulfilling the inclusion criteria, all patients were explained about the purpose of the study and the methods used. Informed written consent was taken. A total of 42 patients were included in the study from August 2020 to March 2021.

Intervention Details

A detailed clinical history, physical examination and appropriate investigations as per the hospital protocol were carried out at the emergency department or OPD and the data were recorded on a structured Performa. The SIARI score and LRINEC score were calculated. Cut-off values as suggested by the authors of these scores were taken for computation of sensitivity and specificity. On the basis of these scoring systems, the patients were divided into two groups; one as NF and the other as Non-necrotizing soft tissue infections. Final decision regarding management (operative, observation, discharge) of the case was done by surgeon on duty. Any surgical intervention if required was conducted by surgical team under the guidance and supervision of Consultant on duty. The patients were managed initially with broad spectrum antibiotics followed by culture-based antimicrobials along with debridement. The intra-operative findings were recorded and retrieved tissue specimen was sent for culture sensitivity and another tissue specimen, preserved in 10% Formalin, was sent for histological examination. Intraoperative findings were documented as necrotizing fasciitis or non-necrotizing soft tissue infections. Presence of gray necrotic tissue, lack of bleeding, thrombosed vessels, foul smelling 'dishwater' pus, non-contracting muscle and/or lack of resistance of normally adherent muscular fascia to blunt dissection gave the intraoperative impression of NF. The final diagnosis of NF was based on histopathological findings. Daily dressings were done and debridement repeated as needed till the dead and devitalized tissues were completely removed. Dressings were continued till the wound became suitable for grafting or secondary suturing. Every patient was followed till discharge, improved or mortality and outcome data was collected in terms of recovery, amputation and mortality. The patient was considered recovered when the wound became suitable for grafting or secondary suturing without the need for amputation.

Statistical Analysis

The collected data was stored in MS-Excel Sheet and then checked, organized, coded, and entered in Statistical Package for Social Science (SPSS) version 23 for analysis. ROC curve analysis was done using MedCalc Statistical Software version 19.6. Patients were stratified into different groups on the basis of cut off values suggested for each of SIARI and LRINEC score and their sensitivity, specificity, positive predictive value and negative predictive value were calculated. Histopathological reports were taken as the reference for comparison. ROC curves were obtained for these scores and area under the curves was compared for accuracy of the scores. All the meaningful statistics were worked out. Baseline categorical and continuous variables were compared using Chi-square test, McNemar test and pairwise DeLong test. Results were presented in tables, graphs and diagrams and expressed as percentages, and mean \pm standard deviation for variables. A 95% confidence interval was taken, and p value less than 0.05 were considered as statistically significant. Results obtained from the study were discussed with relevant available literature. Conclusions were drawn based on these results obtained.

RESULTS

The study was conducted with 42 patients suspected of Necrotizing Fasciitis. SIARI score and LRINEC score was calculated for each patient. Histopathological report was used as reference of comparison which confirmed 32 cases as NF. The mean age of patients with NF was 46.59 years with Standard Deviation of ± 15.58 . The youngest patient in the study was of 17 years and the eldest was of 72 years. Of the total 32 NF patients, 68.75% were male and 31.25% were female (Table 1). The most common site of lesion of NF seen in the study was lower limb which accounted for 59.4% cases followed by perineum and genitalia (Table 2). Polymicrobial infections were more common and were seen in 59.4% cases. The most common organism isolated in patients with NF was *Streptococcus spp* which was seen in 69.2% cases of monomicrobial infections and in 75% cases in total (Table 3). Trauma was the most common etiology seen in 40.6% cases. However, no identifiable causative factor was seen in 37.5% cases (Table 4). Chronic alcoholism (65.6%) was the most common co-morbidity seen in NF patients followed by DM (Table 5). Twenty three (71.9%) of 32 patients with NF recovered, 4 (12.5%) patients underwent amputation while mortality was seen in 5 (15.6%) patients.

Analysis of SIARI scores

Out of 28 patients with SIARI score ≥ 3 , 25 (89.3%) patients had positive HPE results and 3 (10.7%) had negative results. Out of 14 patients with SIARI score < 3 , 7 (50%) patients had negative HPE results. Thus, in this study, SIARI score revealed sensitivity, specificity, PPV and NPV of 78.1%, 70%, 89.3% and 50% respectively (Figure 1).

Analysis of LRINEC scores

Out of 24 patients with LRINEC score ≥ 6 , 20 (83.3%) had positive HPE reports whereas 6 (33.3%) patients out of 18

Table 1: Demographic data of patients diagnosed as Necrotizing Fasciitis.

Age(in years)	Male		Female		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
≤20	1	4.6	2	20	3	9.4
21-40	5	22.7	4	40	9	28.1
41-60	9	40.9	2	20	11	34.4
>60	7	31.8	2	20	9	28.1
Total	22	100	10	100	32	100

Table 2: Distribution of Site of lesion for Necrotizing Fasciitis.

Site of lesion	Number of Cases	Percentage (%)
Lower limb	19	59.4
Upper limb	4	12.5
Perineum and genitalia	5	15.6
Abdomen	4	12.5
Total	32	100

Table 3: Distribution of microorganisms causing NF based on C.S. report.

Organism	Number of Cases	Percentage (%)
I. Monomicrobial	13	40.6
a) <i>Streptococcus spp</i>	9	69.2
b) <i>Staphylococcus spp</i>	1	7.7
c) <i>Enterobacter spp</i>	1	7.7
d) <i>Klebsiella spp</i>	2	15.4
II. Polymicrobial	19	59.4

Table 4: Distribution of Etiological Factors causing Necrotizing Fasciitis.

Risk Factor	Number of Cases	Percentage (%)
Idiopathic	12	37.5
Trauma	13	40.6
Bites (Human/Insect/Animal)	3	9.4
Surgery	1	3.1
IVDA	3	9.4
Total	32	100

Table 5: Presence of Comorbidity in a patient with Necrotizing Fasciitis.

Co-morbid Condition	Number of Cases	Percentage (%)
DM-II	11	34.4
HTN	5	15.6
Immunosuppression	5	15.6
Obesity (BMI ≥25 kg/m ²)	6	18.8
Chronic Kidney Disease (CKD)	2	6.3
Chronic Alcoholism	21	65.6
Others	3	9.4

patients with LRINEC score <6 had negative HPE reports. LRINEC score had sensitivity of 62.5%, specificity of 60%, PPV of 83.3% and NPV of 33.3% in this study (Figure 2).

Comparison of SIARI and LRINEC score

In this study, area under the receiver operating curve of SIARI score was 0.827 (95% CI; 0.678-0.926) and that of LRINEC score was 0.650 (95% CI; 0.487-0.790). Pairwise comparison of ROC curves of these scoring systems revealed a p-value of 0.0902. On comparison of the SIARI and LRINEC score using McNemar test, p-value obtained was 0.454 which was statistically insignificant (Table 6, Figure 3).

DISCUSSION

Necrotizing Fasciitis, which was initially described as a rapidly spreading gangrene of the subcutaneous tissue caused by beta hemolytic streptococci group A, is now considered a separate clinical entity [4,24]. NF is often mistaken for cellulitis or abscess due to the paucity of cutaneous manifestations early in the course of the disease. Therefore, its early diagnosis is challenging leading to delay in surgical intervention with the ultimate cost of increased morbidity and mortality. It is a surgical emergency owing to the fact that it spreads rapidly through the fascial plane causing extensive tissue destruction. The outcome of the disease is not only debilitating but also fatal. Early recognition of this

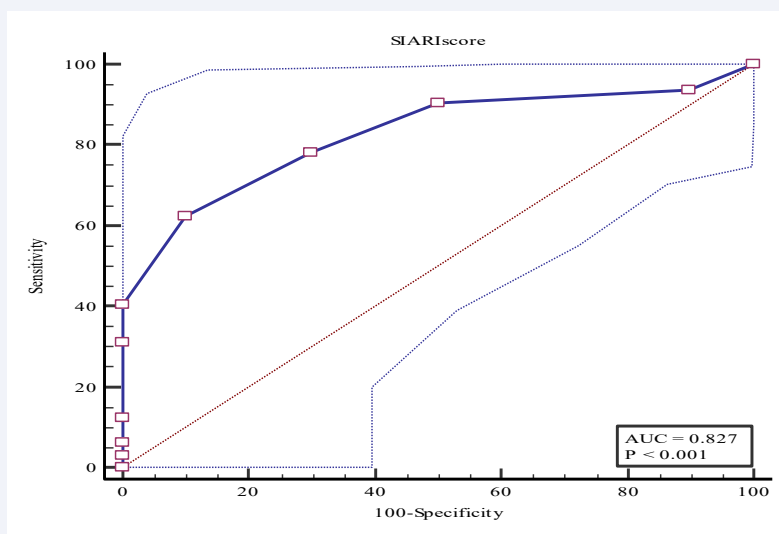


Figure 1 Analysis of SIARI scores.

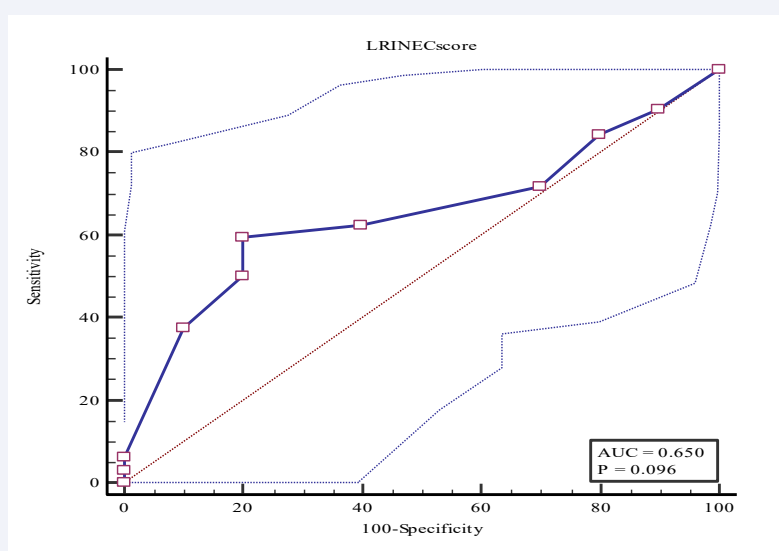


Figure 2 Analysis of LRINEC scores.

Table 6: Comparison of SIARI and LRINEC Scoring Systems.

Index	SIARI score	LRINEC score
Sensitivity (95% CI)	78.1% (60-90.7%)	62.5% (43.7-78.9%)
Specificity (95% CI)	70% (34.8-93.3%)	60% (26.2-87.8%)
PPV (95% CI)	89.3% (71.8-97.7%)	83.3% (61.8-94.5%)
NPV (95% CI)	50% (24-75.9%)	33.3% (14.3-58.8%)
C-statistic (95% CI)	0.827 (0.678-0.926)	0.650 (0.487-0.790)
p value	<0.0001	0.0964

entity and immediate aggressive surgical debridement is the cornerstone for favorable outcome [19,25,26].

In our study, the mean age of the patient suffering from NF was 46.59 years with male: female ratio being 2.2:1. Similar results are seen in studies by Pathak et al., Frazee et al., Anaya et al. and Kulasegaran et al [4,27-29]. This higher incidence of NF in

males may be attributed to the fact that men are indulged in more outdoor activities where they are more prone to trauma. Our study reveals that the lower limb was the most commonly affected site seen in 59.4% cases followed by perineum and genitalia (15.6%). 12.5% cases were seen each in upper limb and abdomen. Similar to our study, Pathak et al [27]. in 2016 noted the involvement

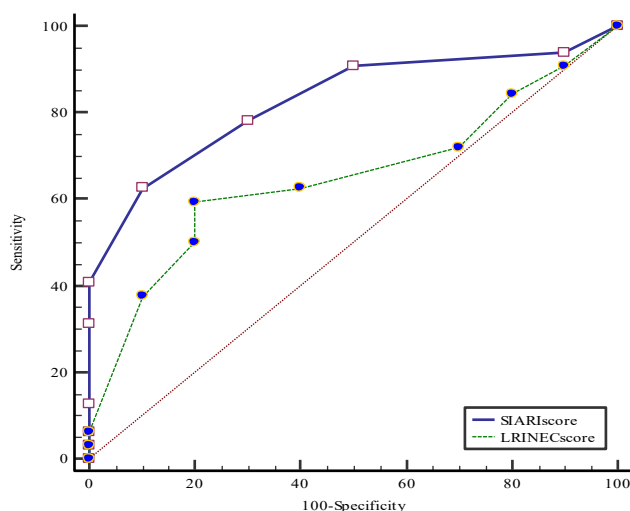


Figure 3 Comparison of ROC curve of SIARI and LRINEC scoring systems.

of lower limbs, perineum/genitalia, upper limb and abdomen in 62.2%, 15.56%, 13.33% and 8.89% cases respectively. A 11-year retrospective case review in South Auckland by Kulasegaran et al.²⁹ showed similar results with the lower limb being the most commonly affected site seen in 56.2% cases followed by perineum/genitalia (21.9%), upper limb (9.5%) and abdomen (8%). The reason for the lower limbs being the most common site of involvement in NF relates to the fact that these are more exposed to trauma and bites. The microbiological profile of NF in our study revealed the infection was polymicrobial in 59.4% (19) cases. Similar findings were noted in studies done by Anaya et al [30], Keung et al [31], and Pathak et al [27].

In our prospective study, trauma stood out to the most common cause of NF seen in 40.6% cases followed by bites and intravenous drug abuse seen in 9.4% cases each and surgery contributed to 3.1% of cases. However, in the remaining 37.5% cases, the inciting cause could not be identified and was labeled as idiopathic. In accordance with our study, Narasimhan et al [32], in 2018 and Borschitz et al [33], in 2015 also pointed out trauma as the main etiology of NF seen in 43.3% and 34.5% cases respectively. The relatively higher number of cases labeled as idiopathic may be linked to the reason that minor trauma suffered by the patient few days prior to the development of cutaneous manifestations of NF may have been forgotten. Also the social stigma of intravenous drug abuse may hinder the patients to disclose their history.

Chronic alcoholism (65.6%) was the most common co-morbidity seen in NF patients followed by DM (34.4%) in our study. Obesity, HTN, immunosuppression and CKD contributed as co-morbid factors in 18.8%, 15.6%, 15.6% and 6.3% cases respectively. This is similar to result seen in study conducted by Park et al [34], Misiakos et al [15], Cribb et al [21], Narasimhan et al [32], Keung et al [31], and Anaya et al [30]. The outcome distribution of NF in the present study revealed that 71.9% patients recovered, 12.5% patients underwent amputation while mortality was seen in 15.6% cases. The mortality rate of our study

was comparable with the rate seen in study done by Faraklas et al [35], Wong et al [1], Misiakos et al [15], and Harasawa et al [36]. Resuscitation and urgent radical surgical debridement has been the mainstay of our treatment and this has contributed to the low mortality rate seen in our study.

At a cutoff of LRINEC score ≥ 6 , sensitivity of 62.5%, specificity of 60%, PPV of 83.3%, NPV of 33.3% and area under the receiver operating characteristic curve of 0.650 was seen in our study. Thomas et al [37] in their study at Washington revealed that LRINEC score of ≥ 6 had a sensitivity of 56% and a specificity of 60% which is almost identical to our study. However, in the landmark study conducted by Wong CH et al [1] which was published in 2004, they reported that at a cutoff of LRINEC score ≥ 6 , it had a PPV of 92%, NPV of 96% and area under the receiver operating curve of 0.980 in the developmental cohort and 0.976 in the validation cohort. This is in contrast to the results we obtained in our study. The reason behind it is that as the LRINEC score takes in consideration the laboratory parameters only which include hematologic and biochemical changes that occur with sepsis and the associated systemic inflammatory response syndrome. These changes tend to be corrected with resuscitation efforts at health facilities and thus interfere with the diagnostic accuracy of this score. Also in patients with co-morbidities, the inflammatory response is blunted and the LRINEC score may not reflect the underlying pathology. In the retrospective case-control study done by Cribb et al [21], the LRINEC score at the cut-off of ≥ 6 had a sensitivity of 61%, specificity of 65%, PPV of 64% and NPV of 63%. The sensitivity and specificity of LRINEC score was similar to our study.

SIARI score had sensitivity of 78.1%, specificity of 70%, PPV of 89.3%, NPV of 50% and area under the receiver operating curve of 0.827 in our study. These values are higher than those observed with the LRINEC score. Cribb et al [21] in their study which was published in 2019 revealed that the SIARI score had sensitivity, specificity, PPV and NPV of 81%, 73%, 73% and 80% respectively in the developmental cohort. In the validation cohort,

their study reported a sensitivity of 84%, specificity of 70%, PPV of 74% and NPV of 81%. Our study had similar sensitivity and specificity.

In our prospective study, the area under the receiver operating curve for LRINEC score was 0.650 (95% CI; 0.487-0.790) and p value 0.0964. Comparing with the ROC curve analysis, the area under curve suggested 'poor' diagnostic accuracy. Similarly, the area under the receiver operating curve for SIARI score was 0.827 (95% CI; 0.678-0.926) and p value < 0.0001 which was statistically significant. Comparing with the ROC curve analysis, the area under curve suggested 'good' diagnostic accuracy. Study by Cribb et al [21] found area under curve for LRINEC score to be 0.691 (p value <0.001) and for SIARI score to be 0.832 (p value <0.001) in the developmental cohort. In the validation cohort, they reported area under curve for LRINEC score to be 0.667 (p value <0.001) and for SIARI score to be 0.847 (p value <0.001). These results are almost identical to our study.

In our study, SIARI score had better sensitivity, specificity, PPV, NPV and C-statistic compared to LRINEC score. As LRINEC score is based on laboratory parameters only, it has no room for clinical judgments. This score is essentially a marker of septic shock seen in NF. There are variants of this lethal condition that present without the typical phenomenon especially in immunosuppressed. In such cases, the laboratory values of sepsis may not be seen and a high index of clinical suspicion is needed. The variable discriminative performance of the LRINEC score raises questions over the utility of this score in distinguishing necrotizing fasciitis from other non-necrotizing soft tissue infections. The SIARI score, devised by Cribb et al. in 2019, incorporates clinical variables along with fewer laboratory parameters and has better diagnostic ability to detect NF.

CONCLUSION

Both SIARI score and LRINEC score are fast, simple, reproducible and safe scoring systems for the early diagnosis of Necrotizing Fasciitis. However a high degree of clinical suspicion is very essential to improve morbidity and mortality of the patients. The SIARI score is easier to recall, uses fewer laboratory parameters and takes into considerations the clinical scenario. Also, this score has higher sensitivity, specificity, PPV, NPV and C-statistic as compared to the LRINEC score. Hence, incorporation of SIARI score in daily clinical practice for the diagnosis of NF is justifiable. Similar studies with a larger sample size and multi institutional involvement are recommended.

DECLARATIONS

Ethics approval and consent to participate

The ethical approval was taken from Institutional Review Board of NAMS. Written informed consent was taken from the participants.

All methods were carried out in accordance with relevant guidelines and regulations.

Consent to publish

Not applicable in the declarations section.

Availability of data and materials

All data generated or analyzed during this study are included in its supplementary information file.

Competing interests

The authors have no competing interest for the publication of this research article.

Funding

All costs incurred during the collection of data and preparation of this manuscript has been covered by the authors.

Authors' contributions

SA: conception and design of the study, collection and analysis of data, drafting the manuscript.

KM: critically revised the manuscript and gave the final approval.

All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS

The authors would like to thank the patient and patient party who stood tough and gave permission for the publication of this research article.

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Cite this article

Srikant A, Kishor M (2022) SIARI Score versus LRINEC Score for Diagnosis of Necrotizing Fasciitis- A Prospective Comparative Study. *Ann Emerg Surg* 6(1): 1034.