Early Diagnosis of Necrotizing Fasciitis using Laboratory Risk Indicator of Necrotizing Fasciitis (LRINEC) Score

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Background: *Necrotizing fasciitis (NF) is a rapidly progressive inflammatory infection of the fascia. Early diagnosis of NF is essential, as delayed diagnosis leads to higher rates of amputation and mortality. The laboratory risk indicator for necrotizing fasciitis (LRINEC) score is used to obtain early diagnosis in order to reduce morbidity and mortality rates.*
Objective: *The laboratory risk indicator for necrotizing fasciitis (LRINEC) score was introduced in 2004 and is useful in achieving early recognition of necrotizing fasciitis. The authors investigated the efficacy of the LRINEC score inearly diagnosis and management of NF.*
Material and Method: *This prospective validation cohort study included patients admitted tothe Surgery Department of Rajavithi Hospital from December 2013 to December 2015. Medical records, microbiological tests and laboratory parameters were examined, and LRINEC score of all patients was calculated on admission.*
Results: *Of 164 patients examined, 61 were diagnosed with necrotizing fasciitis and the other 103 were confirmed as cases of cellulitis. The results showed that for patients who had duration of symptoms ≥8 hours, the optimal cut-off LRINEC score of ≥4 was effective in predicting NF. The sensitivity was 85.42%, specificity was 75.31%, positive predictive value (PPV) was 67.21%, negative predictive value (NPV) was 89.71% and accuracy was 79.07%. The overall amputation rate was significantly higher (p = 0.018) in NF patients.*
Conclusion: *The LRINEC score is a diagnostic tool which can assist in differentiating NF from cellulitis. Many adjuncts have been described which can help to achieve early recognition of the disease, and the LRINEC score is a reliable tool for use by surgeons in identifying diseases that can develop into NF.*

Keywords: *Diagnosis, LRINEC, Necrotizing fasciitis*

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Necrotizing fasciitis (NF) is an uncommon, rapidly progressive inflammatory infection of the fascia, involving secondary necrosis of the subcutaneous tissues[1]. The speed of its spread is directly proportional to the thickness of the subcutaneous layer at rates reaching 2-3 cm/hr[2]. The incidence of necrotizing fasciitis has been on the rise because of an increase in the number of immunocompromised patients with a variety of illnesses such as diabetes mellitus, cancer, alcoholism, vascular insufficiencies, organ transplants, HIV infection, and neutropenia[3-6]. Patients usually complain of excessive pain and with progress of the disease, often within hours, the tissues become swollen. The mortality rate is about 73% if not treated. Without surgery and antibiotics, the infection will progress rapidly, and early diagnosis of NF is therefore essential, as any delay could prove fatal, given its association with more extensive surgery, and higher rates of amputation and mortality. Furthermore, if left untreated, the infection could lead to systemic inflammatory response syndrome (SIRS).

Thailand is a developing country in which most people are agricultural workers in rural areas. Rajavithi Hospital is a tertiary health care center which admits referral patients from primary and secondary health care centers and also from other out-patient or emergency departments. The author found that the patients who had soft tissue infection needed early diagnosis to differentiate between cellulitis and necrotizing fasciitis, as thetwo conditions require different management. A review of patients who were admitted with soft tissue infection from the year 2004-

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2013 revealed that 362 were diagnosed with necrotizing fasciitis, while 256 were cases of cellulitis. About 70% of those diagnosed with NF underwent fasciotomy. The mortality rate was about 8.6%, and the total amputation rate was about 35.3% overall.

Rajavithi Hospital statistics showed that NF was very aggressive and caused high morbidity and mortality rates if clinical diagnosis was delayed. Lack of specific clinical features and characteristics in the initial stages of the disease may be the crucial reason for the failure of early recognition of NF. The laboratory risk indicator for necrotizing fasciitis (LRINEC) score was first introduce in 2004, and there have been a few reports of its subsequent use[5-8].

Laboratory data including hemoglobin (Hb), creatinine (Cr), glucose (BS), sodium (Na) and C-reactive protein (CRP) levels, and white blood cell (WBC) counts are used for early recognition of NF. This study collected data from Rajavithi Hospital, Bangkok, Thailand, from December 2013 to December 2015 to further validate whether the LRINEC score could be used effectively for early diagnosis of NF.

Material and Method

This was a prospective validation cohort study which included all patients treated for soft tissue infection at Rajavithi Hospital between December 2013 and December 2015. The inclusion criteria were all adult patients (≥20 years of age) admitted to hospital through the surgery department of Rajavithi Hospital having discharge diagnosis of necrotizing fasciitis or cellulitis. All patients were checked to see whether their diagnoses were correct. The following characteristics at operative exploration were used for definitive diagnosis: the presence of grayish necrotic fascia; lack of resistance of normally adherent muscular fascia to surgeon's blunt finger dissection; lack of bleeding of fascia during dissection; and the presence of foul-smelling turbid "dishwater" and pus. Tissue culture was sent for confirmation of diagnosis.

During the period of the study, 164 patients were admitted with clinical diagnoses of cellulitis or soft tissue infection. Control patients were selected from this pool of patients with intact laboratory data. Patients were excluded if they were less than 20 years old.

Sex, age, co-morbidities, clinical symptoms/signs at the site of infection, laboratory findings and medication being taken at the time of admission, probe test, wound culture and hemo-culture were recorded. The time from admission to operation, number of surgical procedures, need for amputation, duration of hospitalization and mortality rates were also documented. Data collections were made by a single abstractor who was blinded to the purpose of the study. Patients initially recognized as having necrotizing fasciitis by emergency physicians or general surgeons within 8 hours were considered to have had early diagnosis. Early operative treatment was defined as debridement or amputation being carried out within 24 hours of admission. The LRINEC score was calculated for each case based on points assigned for each of six laboratory variables at the time of patient presentation: C-reactive protein; total white cell count; hemoglobin; serum sodium; serum creatinine; and serum glucose, as shown in Table 1.

Statistical analysis

Statistical analysis was performed with the statistical program SPSS version 17.0. Data were presented as mean, standard deviation (SD) and median (minimum-maximum) for continuous variables, and number (%) for categorical variables. Student t-test/Mann-Whitney U test were used for continuous variables and Pearson Chi-square/Fisher's exact tests for categorical variables. A *p*-value of <0.05 was considered statistically significant. An ROC curve

Table 1. Laboratory risk indicator for necrotizing fasciitis (LRINEC) score

Variable	LRINEC score
C-reactive protein (mg/L)	
<15	0
≥15	4
WBC (cells/mm^3)	
<15	0
15-25	1
>25	2
Hemoglobin (g/dL)	
>13.5	0
11-13.5	1
<11	2
Sodium (mmol/L)	
≥135	0
<135	2
Creatinine (mg/dL)	
≤1.6	0
>1.6	2
Glucose (mg/dL)	
≤180	0
>180	1

was generated by plotting the sensitivity against 1-specificity, and the area under the curve with 95% confidence intervals (95% CI) was calculated. The optimal cut-off points for LRINEC score were selected based on ROC curve analysis. Sensitivity, specificity, and positive and negative predictive values were calculated using a 2x2 table of the collected data.

Results

Sixty-one patients were diagnosed as having necrotizing fasciitis and one hundred and three were diagnosed with cellulitis. To evaluate all the patients using LRINEC score, ROC curves were calculated to identify LRINEC score cut-off values for predicting outcomes of necrotizing fasciitis. The cut-off value was a LRINEC score of 4 with a 95% confidence interval (95% CI) of 0.77-0.90 with highest sensitivity and specificity as shown in Fig. 2 The mean, SD, median, min and max of different multiple imputations of LRINEC score was significant at *p*-value <0.001, as shown in Table 2.

The demographic characteristics and co-morbidities of the patients and controls were recorded and are shown in Table 3. Existence of co-morbidities was significantly related to necrotizing with *p*-value = 0.023.

In the Fasciitis (NF) group, the most common co-morbidity was diabetes mellitus with 20 (32.8%) patients. There were 2 (3.30%) cases of liver cirrhosis, 4 (6.6%) of renal disease, and 7 (11.4%) cases of others diseases. Table 4 shows the micro-organisms found in

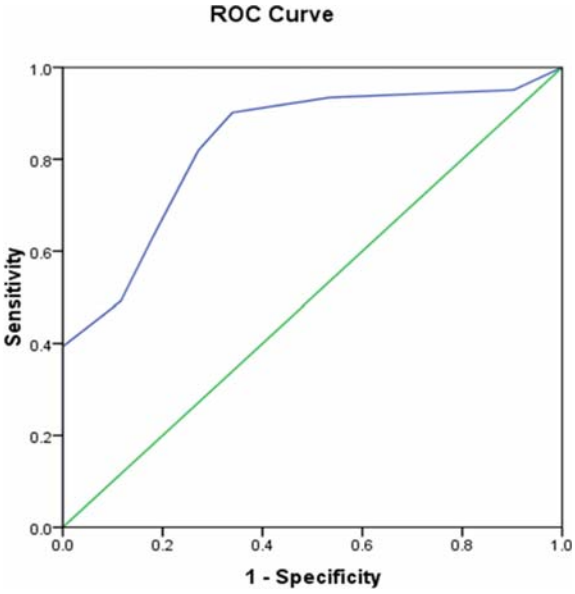

Fig. 2 Receiver-operator characteristic curve for laboratory risk indicator for necrotizing fasciitisin predicting early diagnosis of necrotizing fasciitis. Area under the curve was 0.83, cut-off value was 4.0.

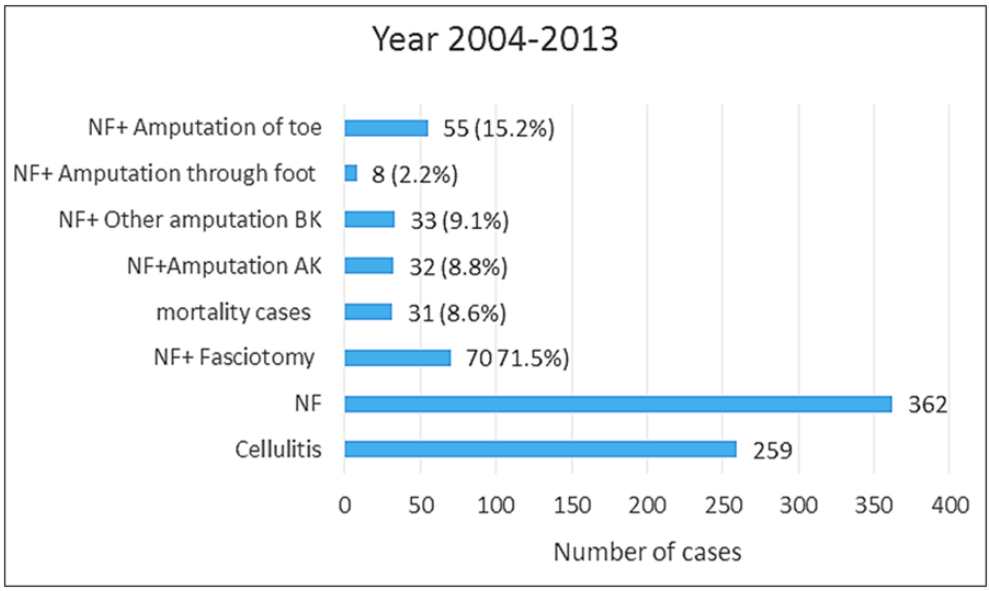

Fig. 1 Necrotizing fasciitis, cellulitis, fasciotomy, amputation rate and mortality rates in Rajavithi Hospital from Year 2004-2013.

Table 2. Mean, SD, median, min and max of six different multiple imputation methods in necrotizing fasciitis and cellulitis patients

	Necrotizing fasciitis (60)		Cellulitis (103)		*p*-value
	Mean ± SD	Median (min-max)	Mean ± SD	Median (min-max)	
CRP	17.12±15.44	15.1 (0.15-0.3)	6.73±10.94	1.8 (0.0-56.0)	<0.001*
WBC	14,220.33±7,370.05	12,800 (1,300-34,400)	10,535.34±5,242.97	9,300 (3,600-35,200)	0.001*
Hb	10.71±2.00	10.6 (6.9 -15.0)	11.84±1.93	11.9 (5.7-16.0)	0.001*
Na	132.82±5.58	134.0 (120.0-143.0)	137.07±4.62	138.0 (123.0-158.0)	<0.001*
Cr	1.49±1.21	1.1 (0.5-6.1)	0.96±0.51	0.8 (0.3-3.3)	0.002*
BS	171.05±111.43	116 (67-527)	125.97±58.58	108 (34-4.18)	0.004*

Values are presented as mean ± SD, median (max-min), * Significant at $p<0.05$

Table 3. Demographic and clinical variables and outcomes of patients

	Necrotizing fasciitis (n = 61)	Cellulitis (n = 103)	Total (n = 164)	*p*-value
Age (years)	55.89±18.08	55.11±18.21	55.39±18.11	0.791
Sex				0.146
Male	35 (57.4)	47 (45.6)	82 (50.0)	
Female	26 (42.6)	56 (54.4)	82 (50.0)	
Co-morbidities	33 (54.1)	37 (35.9)	70 (42.7)	0.023*
DM	20 (32.8)	20 (19.4)	40 (24.4)	0.054
Cirrhosis	2 (3.30)	2 (1.9)	4 (2.4)	0.629
CKD	4 (6.6)	4 (3.9)	8 (4.9)	0.442
Other	7 (11.4)	11 (10.7)	18 (11)	0.788

Values are presented as n (%), mean ± SD. * Significant at $p<0.05$

specimens of pus, hemo-culture and tissue culture.

In sub-group analysis of the duration of symptoms of patients and LRINEC score prior to admission, duration of symptoms ≤8 hours was considered to constitute early diagnosis of NF while duration of symptoms >8 hours was classified aslate diagnosis. In patients who had symptoms ≤8 hours, the optimal cut-off LRINEC score was ≥6 for predicting NF. The sensitivity was 61.5%, specificity was 81.8%, positive predictive value (PPV) was 66.6%, negative predictive value (NPV) was 78.2% and accuracy was 74.2%. In patients who had symptoms duration >8 hours, the cut off LRINEC score was ≥4. The sensitivity was 85.4%, specificity was 75.3%, positive predictive value (PPV) was 67.2%, negative predictive value (NPV) was 89.7% and accuracy was 79.0%. A cutoff point of 6 showed sensitivity of 49.2% (31.4-60.8%), specificity 88.3% (81.5-95.6%), PPV 71.4% (54.1-87.7%) and NPV 74.6% (63.9-82.1%).

Table 5 shows comparative LRINEC scores of NF and cellulitis patients, and Table 6 shows comparative mortality and morbidity rates.

A review of 10 years' data of NF at Rajavithi Hospital showed that a total of 362 patients were diagnosed with NF, and 128 (35.4%) of these cases resulted in amputation. After applying LRINEC scores to predict early diagnosis of NF for early management, 64 patients were diagnosed with NF, and 4 required amputation (6.3%). These results show that the amputation rate was reduced significantly. The relative risk (RR) was 5.66 (2.17-14.76, *p* value <0.001) as shown in Table 7.

Discussion

NF has high mortality rates even in developed countries, The LRINEC score is capable of detecting early cases of necrotizing fasciitis in patients diagnosed with cellulitis: a developmental study by Wong et al[5,9]

reported that a LRINEC score ≥6 had a sensitivity of 89.9%, specificity of 96.9%, positive predictive value of 92% and negative predictive value of 96.0%. In 2012, Chun-I Liao et al[8] studied a group of 233 patients in Taiwan using the LRINEC score ≥6 to evaluate its ability to discriminate NF from severe soft tissue infection. The results showed a sensitivity of 59.2%, specificity 83.8%, positive predictive value of 37.9% and negative predictive value of 92.5%[7,8].

This study showed that the LRINEC score

Table 4. Microorganisms of necrotizing fasciitis recovered

Microorganism	n (%)
Streptococcus species	19 (31.1)
Staphylococcus aureus	11 (18.0)
Enterococcus faecium	5 (8.2)
Acinetobacter baumannii	4 (6.6)
Pseudomonas aeruginosa	4 (6.6)
Eschericia coli	2 (3.3)
Proteus species	2 (3.3)
Bacteroides species	2 (3.3)
Candida species	2 (3.3)
Corynebacterium	1 (1.6)
Bacillus cerceus	1 (1.6)
No growth	5 (8.2)
Not performed	3 (4.9)

Values are presented as n (%)

Table 5. LRINEC scores of patients with necrotizing fasciitis and cellulitis

LRINEC score	Necrotizing fasciitis n (%)	Cellulitis n (%)
0	3 (4.9)	10 (9.7)
1	1 (1.6)	38 (36.9)
2	2 (3.3)	20 (19.4)
3	5 (8.2)	7 (6.8)
4	11 (18.0)	9 (8.7)
5	9 (14.8)	7 (6.8)
6	6 (9.8)	12 (11.7)
7	7 (11.5)	0 (0)
8	5 (8.2)	0 (0)
9	7 (11.5)	0 (0)
10	2 (3.3)	0 (0)
11	1 (1.6)	0 (0)
12	2 (3.3)	0 (0)

Values are presented as n (%)

Table 6. Mortality and amputation rates with laboratory risk indicator for necrotizing fasciitis (LRINEC) score in necrotizing fasciitis and cellulitis

	Necrotizing fasciitis	Cellulitis	Total	*p*-value
Overall (n)	61	103	164	
Mortality rate	4 (6.6%)	3 (2.9%)	7 (4.3%)	0.426
Amputation rate	4 (6.6%)	0 (0.0%)	4 (2.4%)	0.018*
LRINEC score <4 (n)	50	28	78	
Mortality rate	0 (0.0%)	1 (1.3%)	1 (1.2%)	1.000
Amputation rate	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA
LRINEC score ≥4 (n)	11	75	86	
Mortality rate	4 (8.0%)	2 (7.1%)	6 (7.7%)	1.000
Amputation rate	4 (8.0%)	0 (0.0%)	4 (5.1)	0.291

Values are presented as n (%), * = Significant at $p<0.05$

Table 7. Relative risk of amputation rate after applying LRINEC score

	n	Amputationn (%)	RR (95% CI)	*p*-value
Rajavithi from year 2004-2013	362	128 (35.4)	5.66 (2.2-14.8)	<0.001*
Rajavithi from year DEC 2013-2015 (using LRINEC score)	64	4 (6.3)		

Values are presented as n (%), * = significant at $p<0.05$

performed impressively in achieving early diagnosis of NF. ROC curves showed that the optimal cut off LRINEC score ≥4 had the highest sensitivity of 85.4.0% (72.2-93.9%) and specificity of 75.3% (64.5-84.2%) with positive predictive value (PPV) 67.2% (54.0-78.7%) and negative predictive value (NPV) 89.7% (71.0-85.7%) for predicting NF as compared to a previous study in which the optimal cut-off point of LRINEC score was 6 with sensitivity 49.2% (31.4-60.8%), specificity 88.3% (81.5-95.6%), PPV 71.4% (54.1-87.7%) and NPV 74.6% (63.9-82.1%). The possible explanation for these differences is that the duration of symptoms prior to admission was related to the LRINEC score. In patients who had symptoms for more than 8 hours prior to admission, the LRINEC score ≥4 predicted NF accurately. In a study of sepsis, non-specific or mild presentation led to delays in diagnosis and management, leading to increased morbidity and mortality[10,11]. This study found that patients with risk factors such as diabetes mellitus, liver cirrhosis, chronic kidney disease, vascular diseases, and those who were immunocompromised, were prone to NF, and this is in keeping with the findings of a previous report[12]; however, sub-group analysis did not find these factors significantly to be related because of the small sample size.

There is some controversy in relation to the various common organisms found in different continents andcountries, as well as the amputation rates, in previous reports. The microorganisms causing necrotizing fasciitis that weremost commonly found in pus cultures collected during the probe test and fasciotomy were polymicrobial or mixed aerobic and an aerobic infections; these accounted for approximately two-thirds of the cases. Monomicrobial organisms accounted for about one-third of cases, and the majority of the organisms found were gram positive cocci; this was in agreement with previous reports in different continents and socioeconomic classes[12-14]. However, a recent study by Chang NC et al[15] showed higher monomicrobial *Klebsiella pneumoniae* in NF coinciding with greater risk of amputation. Early management with antibiotics should be performed as soon as the patient isis suspected to have soft tissue infection[16], and initial treatments recommended have included a combination of intravenous antibiotics and surgical debridement[17,18]. This study found a significantly lower amputation rate after using LRINEC scores. The recommended antibiotics were penicillin or cephalosporin (Ceftriaxone or Ceftazidime) combined with clindamycin or fluoroquinolones (Ciprofloxacin)[18-23]. Cultures were taken to determine appropriate antibiotic coverage, and choice of antibiotic may change after cultures have been obtained. In this study the amputation rate fell significantly.

Limitations

One limitation of this study was that it used multiple imputations for missing CRP data. Another limitation is that a variety of different antibiotic treatmentswere used by emergency physicians before they consulted the surgeon; furthermore, the sample size of the population might not have been adequate.

Conclusion

Necrotizing fasciitis is a lethal infection with significant morbidity and mortality. In patients with clinical signs suspicious of severe soft tissue infection, the LRINEC score is an effectiveearly-diagnosis tool in distinguishing NF from other soft tissue infections in order to secure early management and debridement. In this study, the LRINEC score was used to evaluate early diagnosis of patients with co-morbidities such as diabetes mellitus, cirrhosis and chronic kidney disease which render them more susceptible than healthy patients to necrotizing fasciitis. Early debridement results in decreasesin morbidity, mortality rates, amputation rates, and number of hospital stays, resulting in lower financial costs for hospitals. This study might have been improved by enrolling more patients, and providing more details of patients' underlying diseases and medication history.

What is already known on this topic?

NF has high mortality rates even in developed countries.The LRINEC score has been introduced to achieve early diagnosis, but there is still some controversy in relation to the various common organisms found in difference continents, and amputation rates in previous reports.

What this study adds?

This study found that the lower cut point of 4 is sufficient to make an early diagnosis of NF in patients who delayed seeking medical services, and this resultedinsignificantly reduced amputation rates.

Potential conflicts of interests

None.

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การใช้ LRINEC score ในการวินิจฉัย necrotizing fasciitis

สิริพงศ์ สิริกุลพิบูลย์, ธันย์ชนก สว่างแสงวัฒนา

ภูมิหลัง: การติดเชื้อผิวหนังชนิด Necrotizing fasciitis (NF) เป็นการติดเชื้อที่มีความรุนแรงของโรคที่สูง การวินิจฉัยที่ล่าช้าส่งผลต่ออัตราการเสียชีวิตและอวัยวะของผู้ป่วยอย่างมีนัยสำคัญอย่างไรก็ตามอาการหรืออาการแสดงของโรคนั้น ในระยะแรกวินิจฉัยได้ยาก จึงมีการนำผลตรวจทางห้องปฏิบัติการมาพิจารณาร่วมในการวินิจฉัยโดยเรียกว่า The laboratory risk indicator for necrotizing fasciitis (LRINEC) score

วัตถุประสงค์: การศึกษา LRINEC score เพื่อช่วยในการวินิจฉัย ภาวะติดเชื้อผิวหนัง (Necrotizing fasciitis) โดยหวังผลลดภาวะแทรกซ้อน ลดอัตราการตัดอวัยวะ และอัตราการเสียชีวิต

วัสดุและวิธีการ: การศึกษาทำในลักษณะการศึกษาติดตามไปข้างหน้า (prospective validation cohort study) ในผู้ป่วยที่เข้ารับการรักษาในโรงพยาบาลราชวิถี ตั้งแต่เดือนธันวาคม พ.ศ. 2556 ถึง เดือนธันวาคม พ.ศ. 2558 โดยเก็บข้อมูลจากเวชระเบียน ผลตรวจทางห้องปฏิบัติการและผลตรวจทางจุลชีววิทยา

ผลการศึกษา: ผู้ป่วยรวมทั้งหมด 164 ราย โดย 61 ราย ได้รับการวินิจฉัย NF และ 103 ราย วินิจฉัย cellulitis พบว่าผู้ป่วยที่มีอาการนานกว่า 8 ชั่วโมงก่อนมาโรงพยาบาลนั้นการใช้ LRINEC score ที่มากกว่าหรือเท่ากับ 4 ช่วยในการวินิจฉัย NF โดยมี sensitivity ที่ร้อยละ 85.4, specificity ที่ร้อยละ 75.3, positive predictive value (PPV) ที่ร้อยละ 67.2, negative predictive value (NPV) ที่ร้อยละ 89.7 และ accuracy ที่ร้อยละ 79.1 นอกจากนี้อัตราการผ่าตัดตัดระยางค์ (amputation) นั้นมีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ($p = 0.018$)

สรุป: การใช้ LRINEC score เพื่อช่วยในการวินิจฉัย NF จากภาวะการติดเชื้อผิวหนังทั่วไป เช่น cellulitis พบว่าสามารถช่วยให้วินิจฉัยได้เร็วขึ้นและลดอัตราการสูญเสียอวัยวะของผู้ป่วยได้อย่างมีนัยสำคัญ