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Evaluation of laboratory risk indicator for necrotizing fasciitis (Lrinec) scoring system for diagnosis of necrotizing fasciitis in patients presenting with soft tissue infection

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ABSTRACT

Necrotizing soft tissue infection represents a diverse process; the term itself encompasses a con-tinuum ranging from pyoderma to life threatening infections (clostridial gas gangrene with my-onecrosis, anaerobic cellulitis, and severe, necrotizing vibrio infections). These can occur in any anatomical area but the commonest site is the extremities. Necrotizing fasciitis is often underestimated because of the lack of specific clinical findings in the initial stages of the disease. The paucity of specific cutaneous signs to distinguish necrotizing fasciitis from other soft tissue infections such as cellulitis makes the diagnosis extremely difficult. The first and most important consideration for an accurate, prompt diagnosis is to have a high index of suspicion. It has been shown by numerous studies in the past that early recognition and surgical interven-tion at the earliest is the sole factor in preventing the morbidity and mortality in patients with ne-crotising fasciitis [1-3]. So a scoring system which is easy to follow and cost effective with high positive and negative predictive value is required. One such scoring system is the LRINEC scoring system devised by Wong et al [4] in 2005 which claims to have a positive predictive value of 92.0% and negative pre-dictive value of 96.0%. The mortality in necrotizing fasciitis is as high as 34%. [5] We evaluated LRINEC scoring system in patients presenting with symptoms and signs sugges-tive of soft tissue infection that progresses to necrotizing fasciitis in Sri Ramachandra Medical College and Hospital, Porur, Chennai over a period of two years.

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MATERIALS AND METHODS

We performed this study on 91 consecutive patients in the ER over two years with symptoms suggestive of soft tissue infections atSri Ramachandra Medical College.

All the patients presenting with symptoms suggestive of soft tissue infections underwent clinical examinations and the investigations (Haemoglobin,total white cell counts ,random blood sugar,serum creatinine,serum sodium,serum C-reactive protein and a wound swab).

Information regarding the demographics & co-variates of soft tissue infections was collected using a pretested semi- structured profoma cum observational checklist.

LRINEC scoring system was applied to each of the study subjects (Table 1)

VARIABLE	SCORE
C-reactive protein (mg/dl)	
<1.5	0
>1.5	4
Total white cell count (cmm)	
<15000	0
15000-25000	1
>25000	2
Haemoglobin (g/dl)	
>13.5	0
11-13.5	1
<11	2
Sodium (mmol/l)	
>135	0
<135	2
Creatinine (mgs/dl)	
<1.4	0
>1.4	2
Glucose (mgs/dl)	
<180	0
>180	1

Table 1: The LRINEC (laboratory risk indicator for necrotizing fasciitis) score [4].
LRINEC score of 6 or greater is considered positive for necrotizing fasciitis.

The inclusion criteria included all the patients presenting to Sri Ramachandra Medical College and Hospital with symptoms suggestive of soft tissue infections during the study period.

The exclusion criteria were 1) Patients below 15 yrs or above 90 yrs of age. 2) Patients who have received antibiotic treatment in the last 48 hours or a minimum of 3 doses of antibiotic prior to presentation. 3) Patient who has undergone surgical debridement for present episode of soft tissue infection.

This was a hospital based observational study. The collected data were statistically analysed with IBM.SPSS statistics software 23.0 Version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. The performance of the final model was very good (Hosmer-Lemeshow goodness of fit test, $P= 0.492$) and discriminated well between patients with necrotizing fasciitis and those with other soft tissue infections. Area under the receiver operating characteristic curve for the developmental cohort was 0.795 (95% CI, 0.699–0.892) with Sensitivity, Specificity, NPV and PPV.The methods of analyses used in this study was multivariate analyses by backward stepwise (Wald) logistic regression procedure. In all the above statistical tools the probability value .05 is considered as significant level.

RESULTS

A Total of 91 consecutive patients with soft tissue infections who fulfilled the inclusion criteria were taken up for the study during a period of two years [after getting Institutional Research Ethics Committee clearance (REF: CSP-MED/15/AUG/24/07)] and LRINEC score was applied to validate the progression of any soft tissue infection into necrotizing fasciitis.

When we analyzed the patients with necrotizing fasciitis, we found that in the age group 41-50 years there were 8(23.5%) patients, 51-60 years there were 14 (41.1%) and in 61-70 years there were 7(20.5%) patients (Fig 1 depicts age distribution)
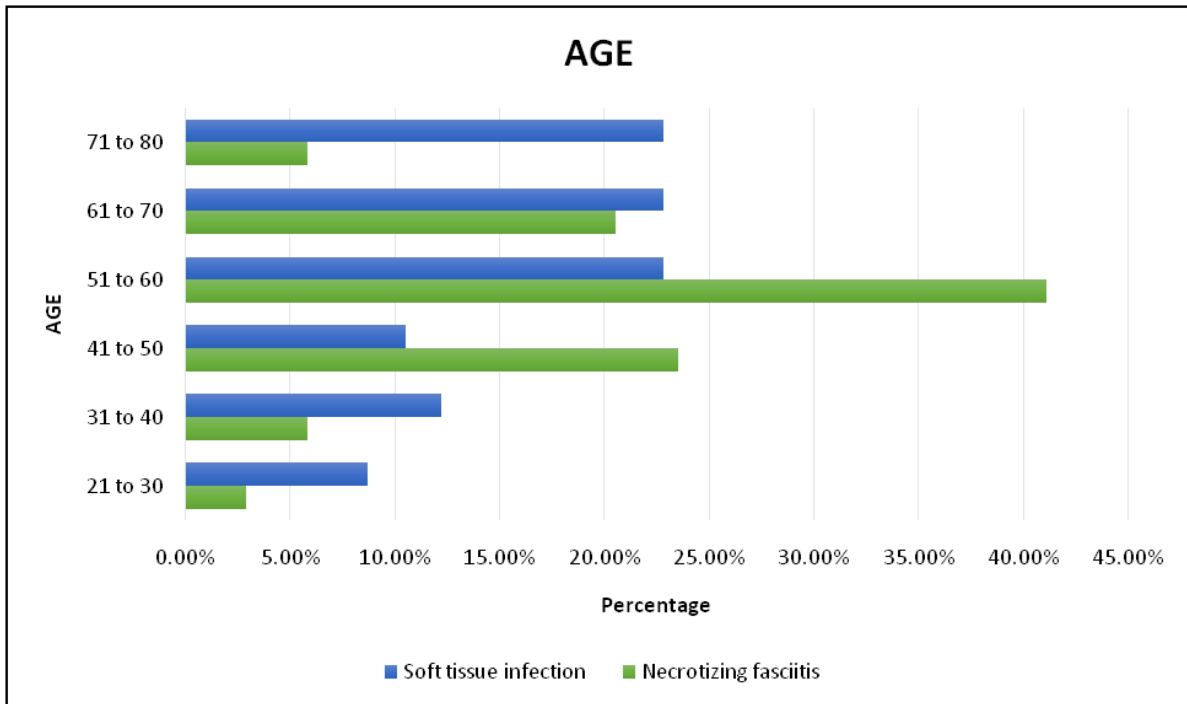

Figure 1: Demographic representation of Age distribution

In our study population of 91 patients the mean age was 55.59 years (SD±14.368) with a median of 57 years. With regards to the age distribution, maximum clustering was observed in the 45 to 65 years age group, with 49 patients constituting 53.8% of the group.

When we looked at the gender distribution of the total number of patients presenting with soft tissue infection we found that 76 patients were males which is 83.5% while 15were females (16.5%).

A diagnosis of necrotizing fasciitis was made if patients presented with the following characteristics: acute pain, extensive fascial necrosis sparing the muscles, foul smelling fluid and signs of systemic toxicity.

57 out of the 91(62.6%) patients had soft tissue infection. Out of the 34 patients (37.4%) diagnosed with necrotizing fasciitis majority of them were males accounting to 91.2%.

C- REACTIVE PROTEIN

C- Reactive Protein is a nonspecific parameter for any inflammatory process. In our study, the patients were divided into two groups lesser than 1.5mg/dl and greater than 1.5mg/dlas seen in Table 2

	Necrotizing fasciitis (n/%)	Soft tissue infection (n/%)
> 1.5	20 (58.8%)	8 (14.0%)
<1.5	14 (41.1%)	49 (85.9%)

Table2: CRP in total population (mgs/dl)

Among 34 patients with necrotizing fasciitis, 20 patients had CRP greater than 1.5mgs/dl and 14 patients had CRP less than 1.5mgs/dl. Whereas in soft tissue infection group, 8 patients had

CRP greater than 1.5mg/dl and 49 less than 1.5mgs/dl.

Mean C- reactive protein of the total population was 1.315mg/dl (SD±0.6931). In the necrotizing fasciitis group mean C- reactive protein was 1.80mg/dl as compared to soft tissue infection group which was 1.026mg/dl. This was statistically significant (p value 0.001) as seen in table 3.

	Group	Number of Patients	Mean	Std. Deviation
CRP	Soft tissue infection	57	1.026	0.6143
	Necrotizing fasciitis	34	1.80	0.5326

Table 3: Mean of the total population of CRP (mg/dl)

WHITE BLOOD CELL COUNTS

Increased white blood cell count is a direct contribution to the under lying infection. The patients were categorized into three groups (<15,000cmm, 15000cmm to 25,000cmm and > 25000cmm) as seen in table 4

	Necrotizing fasciitis (n/%)	Soft tissue infection (n/%)
< 15000	16 (47%)	35 (61.4)
15000-25000	13 (38.2%)	19 (33.3%)
>25000	5 (14.7%)	3 (5.2%)

Table 4: WBC in the total population (cmm)

Among 34 patients with necrotizing fasciitis, 16 patients had WBC less than 15000cmm, 5 patients had WBC greater than 25000cmm range and 13 patients had WBC ranging from 15000cmm to 25000cmm. Where in soft tissue infection group, 35 patients had WBC less than 15000cmm, 3 patients had WBC greater than 25,000cmm and 19 patients had WBC ranging from 15000cmm to 25000cmm.

In the total population white blood cell count mean was 14837.36cmm (SD ± 7275.219). The mean white blood cell count in soft tissue infection group was 13668.42cmm as compared to necrotizing fasciitis group which was 16797.06 cmm as seen in table 5. This was significant statistically with p value of 0.047.

	Group	Number of Patients	Mean	Std. Deviation
WBC	Soft tissue infection	57	13668.42	6518.851
	Necrotizing fasciitis	34	16797.06	8119.169

Table 5: Mean of white blood cell count (cmm)

HEMOGLOBIN

The level of hemoglobin was categorized into, less than 11gm/dl, 11gm/dl to 13.5gm/dl and greater than 13.5gm/dl and the whole group was divided accordingly. Among 34 patients with necrotizing fasciitis, 14 patients had hemoglobin less than 11gm/dl, 2 patients had hemoglobin greater than 13.5gm/dl and 18 patients had hemoglobin ranging between 11gm/dl to 13.5gm/dl. Wherein soft tissue infection group 23 patients had hemoglobin less than 11gm/dl, 9 patients had hemoglobin greater than 13.5gm/dl and 25 patients had hemoglobin between 11gm/dl to 13.5gm/dl. Mean hemoglobin in the total population was 11.481gm/dl (SD ± 1.96). The mean hemoglobin in necrotizing fasciitis group was 11.6gm/dl while in soft tissue infection group it was 11.8gm/dl. However, this was not statistically significant (p value - 0.265)

SODIUM

Sodium range was categorized into greater than 135mmol/l and lesser than 135mmol/l, the whole group was divided accordingly.

Among 34 patients with necrotizing fasciitis, 17

patients had sodium greater than 135mmol/l and 17 patients had sodium less than 135mmol/l. Whereas in the soft tissue infection group, 40 patients had sodium greater than 135mmol/l and 17 less than 135mmol/l. Mean sodium in the total group was 135.45mmol/l (SD ± 4.65). The mean sodium in necrotizing fasciitis group was 134.74mmol/l as compared to soft tissue infection group which was 135.8mmol/l. However, this was not statistically significant (p value 0.260)

CREATININE

Creatinine range was categorized into greater than 1.4mgs/dl and lesser than 1.4mgs/dl, the whole group was divided accordingly. Among 34 patients with necrotizing fasciitis, 10 patients had creatinine greater than 1.4mgs/dl and 24 patients had creatinine less than 1.4mgdl. Wherein soft tissue infection group, 12 patients had creatinine greater than 1.4mgs/dl and 45 patients had creatinine less than 1.4mgs/dl. Mean creatinine in the total population was 1.24mgs/dl (SD ± 1.01). The mean sodium in necrotizing fasciitis group was 1.23mgs/dl as compared to soft tissue infection group which was 1.26mgs/dl. However, this was not statistically significant (p value - 0.902).

RANDOM BLOOD SUGAR

Random blood sugar range was categorized into greater than 180mgs/dl and lesser than 180mgs/dl, the whole group was divided accordingly.

Among 34 patients with necrotizing fasciitis, 22 patients (64.7%) had random blood sugar greater than 180mgs/dl and 12 patients (35.3%) had random blood sugar less than 180mgs/dl. Wherein soft tissue infection group, 15 patients (24.6%) had random blood sugar greater than 180mgs/dl and 42 patients (75.4%) had random blood sugar less than 180mgs/dl

Mean random blood sugar in the total group was 159.35mgs/dl (SD ± 94.77). The mean random blood sugar in necrotizing fasciitis group was 154.86mgs/dl as compared to soft tissue infection group which was 166.88mgs/dl. However, this was not statistically significant (p value - 0.561)

Of the total 91 patients, fourteen patients with necrotizing fasciitis had a LRINEC score greater than 8, seven patients had a score less than 5 and thirteen patients were within the range of 6-7. In soft tissue infection group there were six patients with a score greater than 8, forty three patients had a score less than 5 and eight patients were within the range of 6-7. Fig 2 depicts LRINEC score distribution.
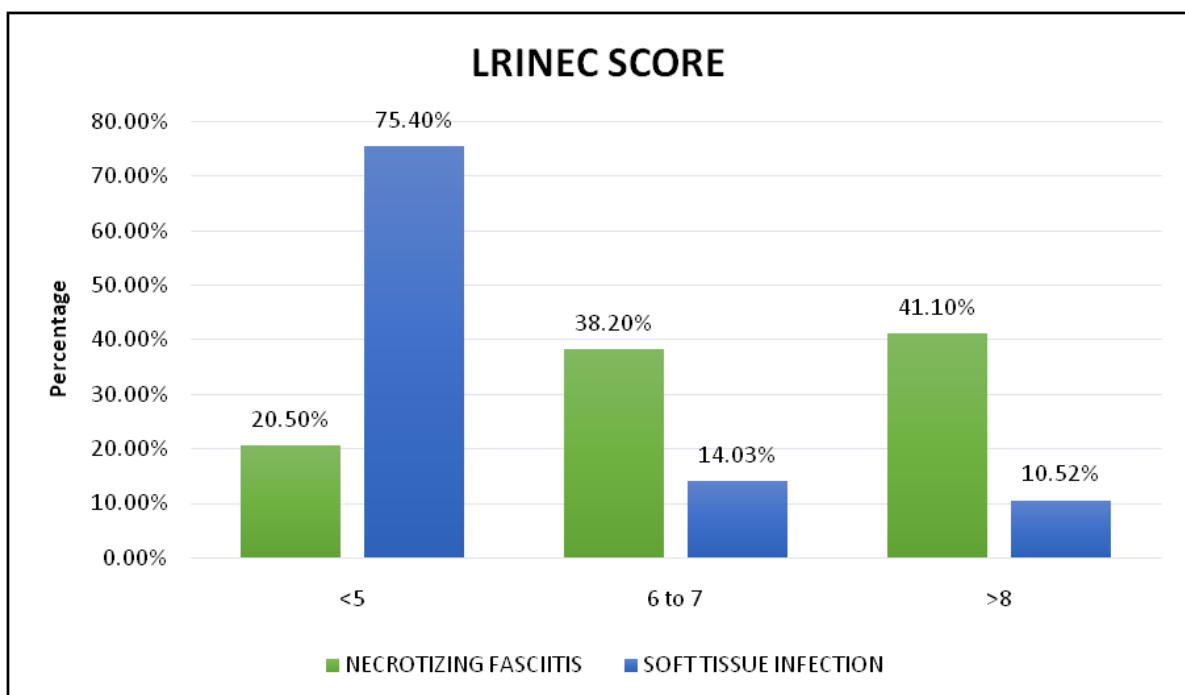

Figure 2: Distribution for LRINEC SCORE

CO-MORBIDITIES IN THE STUDY POPULATION
DIABETES MELLITUS:
Out of the 91 patients in my study 39 patients (42.9%) had previous history of diabetes mellitus and 52 of them (57.1%) did not have previous history of diabetes mellitus.

SYSTEMIC HYPERTENSION
Out of the 91 patients in my study 13 patients (14.3%) had previous history of hypertension and 78 of them (85.7%) were not hypertensive. When analyzing 34 patients with necrotizing fasciitis 15 patients were diabetic (44.1%) and 2 patients were hypertensive (5.9%).

Kidney injury was defined as patient on admission had signs of decreased urine output of lesser than 300ml and creatinine of greater than 1.6mg/dl. In our study of the total population 27.5% (25 patients) were diagnosed with kidney injury.

Multi organ failure was defined as patient who had presented with one or more of systemic diseases such as diabetes mellitus/ systemic hypertension/ liver disease/ kidney injury.

Of the 34 patients with necrotizing fasciitis, 11 patients had kidney injury and 7 patients had multi organ failure.

MICROBIOLOGY
In our study we had analyzed the organism grown in the culture as single organism growth or poly microbial. Of the 91 patients 68 patients (74.7%) had single organisms in the culture, wherein 23 patients (25.2%) had poly microbial organism in the culture.

In my 34 patients with necrotizing fasciitis 24 patients (70.6%) had single organism growth in the culture wherein 10 patients (29.4%) had poly microbial organisms in the culture

MORTALITY
5 patients of the 91 patients (5.5%) in the study population succumbed to their illness. In the necrotizing fasciitis group, 5 out of 34 patients (14.7%) died and all these patients had a LRINEC score of greater than 8.

In the subgroup of patients with LRINEC greater than 8, nine patients with necrotizing fasciitis survived their infection. Table 6 shows the LRINEC score in both groups

		Necrotizing Fasciitis	Soft tissue Infection	Total
Score range	>6	27	14	41
	< 6	7	43	50
Total		34	57	91

Table 6 shows the the LRINEC score in both groups.
Odd's Ratio: 0.375

	True Positive	False Positive	False Negative	True Negative	Total	P value of score
Observation	27	14	7	43	91	<0.001
	Sensitivity	Specificity	PPV	NPV	Accuracy	
Evaluation (%)	79.4	75.4	65.9	86.0	76.9	

Table 7 showing the summation of accuracy.

Sensitivity of the LRINEC score was 79.4%, its specificity was 75.4%, positive predictive value was 65.9% and negative predictive value 86%. This is statistically significant with p value of 0.001as seen in table 7.

According to our study, LRINEC score of greater than 6 had a 4.3 times greater risk (Relative risk Ratio) of progression into necrotizing fasciitis.

ROC allows to create complete sensitivity/specificity report. The ROC is fundamental tool for diagnostic test evolution. In a ROC the true positivity rate (sensitivity) is plotted in function of the false positive rate (1-Specificity) for different cut off points of a parameter. Each point on the ROC represents a sensitivity/specificity pair corresponding to a particular decision threshold. The

area under the ROC curve (AUC) is a measure of how well a parameter can distinguish between two diagnostic groups (disease/ normal).

In my study the state of necrotizing fasciitis is assessed applying the LRINEC score as seen in fig 3.
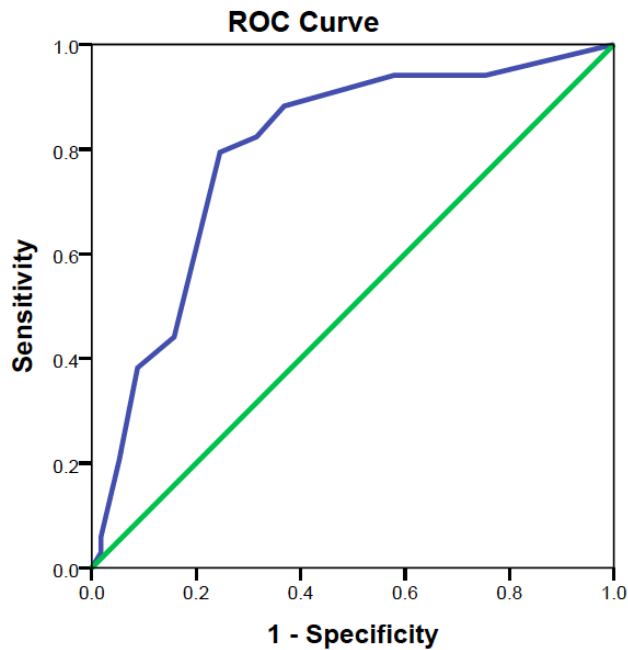

ROC Curve

Diagonal segments are produced by ties.

Fig 3ROC

Clinical variables	SOFT TISSUE INFECTION (n=57)	NECROTIZING FASCIITIS (n=34)	P value
Age in years			
<45 years	5 (14.7%)	13 (22.8%)	0.878
45-65 years	24 (70.5%)	25 (43.8%)	
>65 years	5 (14.7%)	19 (33.3%)	
Gender			
Male	31 (91.2%)	45 (78.9%)	0.452
Female	3 (8.8%)	12 (21.1%)	
Hemoglobin			
<11.0	14 (14.1%)	23 (40.3%)	0.265
11.0-13.5	18 (52.9%)	25 (43.8%)	
>13.5	2 (5.8%)	9 (15.7%)	
Total count			
<15000	16 (47%)	35 (61.4%)	0.047
15000-25000	13 (38.2%)	19 (33.3%)	
>25000	5 (14.7%)	3 (5.2%)	
RBS			
<=180	12 (35.2%)	15 (24.6%)	0.561
>180	22 (64.7%)	42 (75.4%)	

Serum creatinine			
<=1.4	24 (70.5%)	45 (78.9%)	0.902
>1.4	10 (29.5%)	12 (21.1%)	
Sodium			
<135	17 (50%)	17 (29.9%)	0.260
>135	17 (50%)	40 (70.1%)	
CRP			
<150	14 (41.1%)	49 (85.9%)	0.001
>150	20 (58.8%)	8 (14%)	
LRINEC SCORE			
>6	27(79.4%)	14 (24.55%)	0.001
<6	7 (20.5%)	43 (75.4%)	

Table 8 showing the consolidated values.

DISCUSSION

LRINEC score was applied on admission to the 91 patients presenting to ER with soft tissue infections and they were observed clinically after 48 hours to see if these patients progressed to necrotizing fasciitis. Validation of the score would help prognosticate patients (at admission) who are likely to progress to necrotizing fasciitis. A review of literature states that there is no age or gender prediction for necrotizing fasciitis. Most common age group was between 45-65 years, accounting for 70% of the necrotizing fasciitis group. While mean age group was 55.59±14.36 years in the present study, it was 51.5, 54 and 50.8±15.4 in David.et.al [5], Paulin.et.al [6], and N. Shahik.et.al [7], respectively. In our study, 91.2% of the patients were males whereas it was 27.4%, and 69% in David.et.al [5], and Paulin.et.al [6] respectively.In the necrotizing fasciitis group, the mean of CRP was 1.80mg/dl, where as in a similar study done by Wong.et.al [4] it was 2.54mg/dl. The mean CRP value in our study was significantly higher in the necrotising fasciitis group compared to that of soft tissue infection group.

In the necrotizing fasciitis group, the mean of white blood cell count was 16797.06cmm, where as in similar studies done by Wong.et.al [4] and N. Shaik.et.al [7] it was 16232.1cmm and 20720.7cmm respectively. The mean white blood cell count was higher in the necrotizing fasciitis group as compared to that of soft tissue infection group.

In the necrotizing fasciitis group, the mean of sodium was 134.74mmol/l, where as in similar studies done by Wong.et.al [4] and N. Shaik.et.al [7] it was 133.5mmol/l and 129.3mmol/l respectively. The mean sodium was higher in the necrotizing fasciitis group as compared to that of soft tissue infection group.

In the necrotizing fasciitis group, the mean of creatinine was 1.23mg/dl, where as in similar studies done by Wong.et.al [4] and N. Shaik.et.al [7] it was 1.09mg/dl and 1.5mg/dl respectively. The mean creatinine was higher in the necrotizing fasciitis group as compared to that of soft tissue infection group.

In the necrotizing fasciitis group, the mean of random blood sugar was 166.8mg/dl, where as in similar studies done by Wong.et.al [4] and N. Shaik.et.al [7] it was 225.18mg/dl and 281mg/dl respectively. The mean random blood sugar was higher in the necrotizing fasciitis group as compared to that of soft tissue infection group.

In our study, out of the total 91 patients, 34 patients (37.4%) progressed to necrotizing fasciitis. Out of the 34 patients, 27 (79.4%) of them had a LRINEC score of more than 6 and was statistically significant (P value < 0.001).

There was great variation in the results observed in various studies. In our study the sensitivity was 79.4% and specificity was 75.4% in

comparison with similar studies done by Liao.et.al [8] and Wong.et.al. [4] it was 59.2% and 83.8%, 89.9% and and 96.9% respectively.

The positive predictive value of LRINEC score > 6 was 65.9% as compared to 92% and 37.9% in similar studies done by Wong.et.al. [4] and Liao.et.al [8] respectively. The negative predictive value of LRINEC in our studies was 86.0% as compared to 96 % and 92.5% in studies done by Wong.et.al. [4] and Liao.et.al. [8] as seen in Fig 4
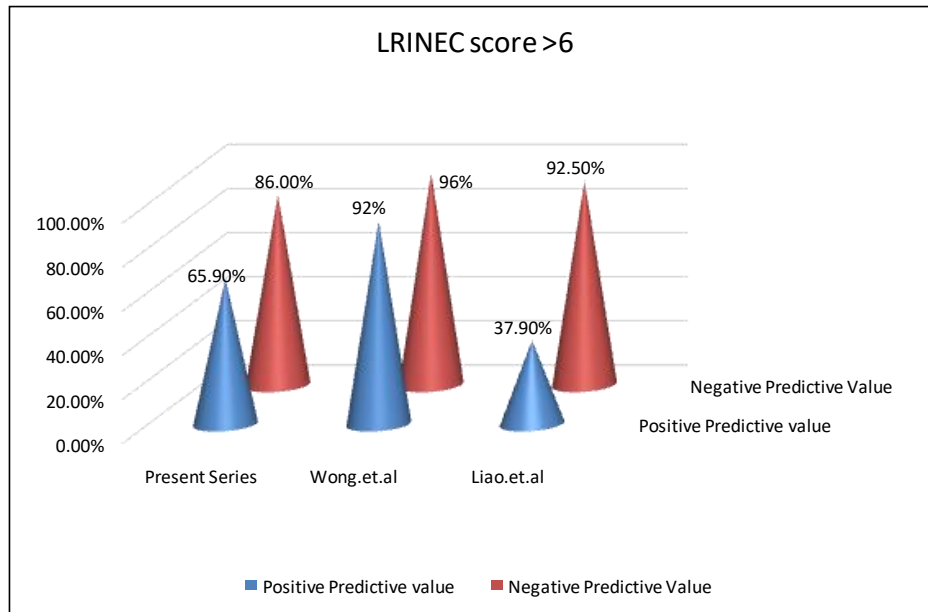

Fig 4: LRINEC SCORE in different studies.

The paucity of studies with LRINEC score remains a stumbling block for greater analysis. LRINEC is useful in distinguishing necrotizing fasciitis from other soft tissue infections. However the small sample size is one of the limitations of this prospective study. Meta analysis of data will be needed for a greater validation.

CONCLUSIONS

In our prospective study of 91 patients presenting with soft tissue infection, 34 patients (37.4%) progressed to necrotizing fasciitis whereas 57 patients (62.6%) did not.

Of the 41 patients who had a Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score of greater than 6, twenty seven patients progressed to necrotizing fasciitis and of 50 patients with score lesser than 6, seven patients progressed to necrotizing fasciitis.

Various variables of the LRINEC score such as C-Reactive protein, white blood cell count, hemoglobin, random blood sugar, creatinine and sodium were analyzed individually. Laboratory parameters such as C- Reactive protein and white blood cell count were also statistically significant with p-value of 0.001 and 0.047 respectively as seen in Table8.

We found that LRINEC had a sensitivity of 79.4% and positive predictive value of 65.5%.

LRINEC score is a useful tool to prognosticate patients at initial assessment and can serve as a predictor of patients who present with soft tissue infection and progress to necrotizing fasciitis

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