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TO STUDY EFFECTIVENESS OF LRINEC (LABORATORY RISK INDICATOR FOR NECROTIZING FASCIITIS) SCORING SYSTEM IN THE DIAGNOSIS OF NECROTIZING FASCIITIS AMONG PATIENTS PRESENTING WITH SOFT TISSUE INFECTIONS

Submitted by

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DISSERTATION SUBMITTED TO
B. L. D. E. (Deemed to be university)'s

SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL& RESEARCH CENTRE, VIJAYAPUR, KARNATAKA

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY

In

GENERAL SURGERY

UNDER THE GUIDANCE OF

Dr. M. B. PATIL

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation, " TO STUDY EFFECTIVENESS OF LRINEC (LABORATORY RISK INDICATOR FOR NECROTIZING FASCIITIS) SCORING SYSTEM IN THE DIAGNOSIS OF NECROTIZING FASCIITIS AMONG PATIENTS PRESENTING WITH SOFT TISSUE INFECTIONS**"** is a bonafide and genuine research work carried out by me under the guidance of **Dr.M.B.PATIL MS , FIAGES** Professor, Head of the Department of General Surgery at BLDE (Deemed to be university), Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapur.

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Dr. SEGGAM SINDHURA

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LIST OF ABBREVIATIONS:-

NSTI	NECROTIZING SOFT TISSUE INFECTIONS
LRINEC	Laboratory Risk Indicator for Necrotizing Fasciitis
Sps	Species
NF	Necrotizing Fasciitis
ROC	Receiver operator curve
CDC	Centers for Disease Control and Prevention
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
Yrs	Years

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ABSTRACT

AIMS & OBJECTIVES

To study effectiveness of LRINEC (Laboratory risk indicator for necrotizing fasciitis) scoring system in the diagnosis of Necrotizing Fasciitis among patients presenting with soft tissue infections.

MATERIALS AND METHODS:-

This is a prospective observational study of 180 patients presented with soft tissue infections in B.L.D.E (DU)'S Shri B.M.Patil Medical College and were divided into three risk groups – Low, Intermediate and High, based on LRINEC scores.

Results:-

Out of 180 patients, 60-69 years age group was predominant (20.6 %) in the present study. The male participants were almost three-fold higher than females. DM has major co morbid present among the patients. Patients were grouped into 115 (63.9%) Low risk, 39 (21.7%) Intermediate, 26(14.4%) High risk groups. Mann Whitney U test was used to compare treatment modalities and found statistical significance. The mean ±SD of surgical intervention was lower than conservative management. Conservative management in low risk group was predominant (96.5%). But, both moderate (69.2%) and high risk (86.2%) groups had surgical intervention as a predominant treatment strategies. However, conservative treatment has also been observed in these moderate (30.8%) and high risk (3.8%) groups. Using Spearman's correlation coefficient, Age of the total participants was compared with LRINEC

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Score and found insignificant. The high-risk group (LRINEC score ≥8) has higher sensitivity (95.83 %) and specificity (100 %) than the intermediate risk group (LRINEC score 6-7) has moderate sensitivity (74.07 %) & specificity of 100% and Low-risk group (LRINEC score ≤5) has lower sensitivity (20 %) & specificity of 100%. The LRINEC score more than i.e. two groups (6-7 & ≥8) showed significant diagnostics accuracy for Necrotizing Fasciitis.

Conclusion: - LRINEC Score is useful tool for clinical diagnosis of Necrotizing Fasciitis from other soft tissue infections.

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1) INTRODUCTION

Necrotizing fasciitis is a rapidly progressive infection primarily involving the fascia and subcutaneous tissue. It is perhaps the most severe form of soft tissue infection and is potentially limb and life threatening. It results from synergistic, polymicrobial infection; most commonly a streptococcal species (Group A beta – hemolytic) in combination with Staphylococcus, Escherichia coli, Pseudomonas, Proteus, Bacteroides or Clostridia. 80% have a history of previous trauma/infection and over 60% commence in lower extremities. Predisposing conditions include: diabetes mellitus, smoking, penetrating trauma, pressure sores, immunosuppression, intravenous drug abuse, perineal infection (perianal abscess, Bartholin's cysts) and skin damage/infection (abrasions, bites, boils).

Classical clinical signs include: Edema stretching beyond skin erythema, a woody hard texture to the subcutaneous tissues, an inability to distinguish fascial planes and muscle groups on palpation, disproportionate pain in relation to the affected area, with associated skin vesicles and soft tissue crepitus.

Early recognition and aggressive debridement of all the necrotic fascia and subcutaneous tissue are major prognostic determinants, and delay in operative debridement has been shown to increase mortality rate.

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The differentiation of necrotizing fasciitis from other soft tissue infections is therefore critically important. However, early clinical recognition of necrotizing fasciitis is difficult, as the disease is often indistinguishable from cellulitis or abscesses early in its evolution. Delayed recognition is one of the main reasons for the high mortality rate.

Clinical modalities like computed tomography (CT), magnetic resonance imaging (MRI), and frozen section biopsy have been shown to be useful in early recognition of necrotizing fasciitis; Routine application of these modalities in the evaluation of soft tissue infections has been limited by cost and availability.

A simple, objective scoring system, the LABORATORY RISK INDICATOR FOR NECROTIZING FASCIITIS (LRINEC) Score, based on clinical parameters and the routinely laboratory investigations can help in distinguish Necrotizing fasciitis from other soft tissue infections.

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2) AIM & OBJECTIVES OF THE STUDY:-

To study effectiveness of LRINEC (Laboratory risk indicator for necrotizing fasciitis) scoring system in the diagnosis of Necrotizing Fasciitis among patients presenting with soft tissue infections.

Parameter	Points
Serum CRP ≥150 mg/l	4
White blood cell count	
15,000–25,000	1
>25,000	2
Hemoglobin (g/dl)	
11.0–13.5	1
<11.0	2
Serum sodium: <135 mEq/l	2
Serum creatinine: >1.6 mEq/l	2
Serum glucose: >180 mg/dl	1
Total score: ≥6, raise suspicion for necrotizing fasciitis; ≥8, highly predictive for necrotizing fasciitis. CRP, C-reactive protein.	

Table No. 1:- Parameters used in LRINEC score.

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3) RESEARCH HYPOTHESIS:

The LRINEC score is useful in early diagnosis and differentiation of Necrotizing fasciitis from other Soft tissue infections.

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4) REVIEW OF LITERATURE:-

HISTORIGICAL ASPECTS:-

- In the 5th century BC, Hippocrates[1] first described NSTI as a complication of acute streptococcal infection, writing "[Many were attacked by the erysipelas all over the body when the exciting cause was a trivial accident or a very small wound ... Many even while undergoing treatment suffered from severe inflammations, and the erysipelas would quickly spread widely in all directions. Flesh, sinews and bones fell away in large quantities.... The bones were bared and fell away, and there were copious fluxes. Fever was sometimes present and sometimes absent... There were many deaths. The course of the disease was the same to whatever part of the body it spread. Many lost the arm and the entire forearm.... In some cases, the entire thigh was bared or the shin and the entire foot. But the most dangerous cases of all such cases were when the pubes and genital organs were attacked]".

- In the late 18th century, English descriptions similar to NSTIs were given by the Naval surgeon Leonard Gillespie and Naval physicians Gilbert Blaine and Thomas Trotter. NSTI was known as phagedenic ulcer, phagedaena gangrenous, gangrenous ulcer, malignant ulcer, putrid ulcer, or hospital gangrene[2].

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- In 1871, during US Civil War, Confederate Army surgeon Joseph Jones described this infection as "hospital gangrene" during which mortality rate 46% of the 2,642 soldiers afflicted died from its complications[3].

- "In 1883, Dr Jean-Alfred Fournier[4] described a necrotizing infection of the perineum and scrotum, and the term Fournier gangrene is still in common usage"
- In 1952, DR.B.Wilson coined the term necrotizing fasciitis, reminiscing the key feature is necrosis extending beyond fascia to muscles, skin and surrounding structures[5].

- Wong et al (2004)[6] has conducted a retrospective observational study at the Changi General Hospital for necrotizing fasciitis between January 1997 and August 2002 and developed a novel diagnostic scoring system for distinguishing necrotizing fasciitis from other soft tissue infections based on laboratory tests routinely performed for the evaluation of severe soft tissue infections: the Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score. And has concluded that "LRINEC score is a robust score capable of detecting even clinically early cases of necrotizing fasciitis".

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- In 2008, Yi-chun su et.al. Started Retrospective observational cohort study[7] of 209 patients in one tertiary academic centre and one community, university-affiliated hospital concluded that the LRINEC score is associated with the outcomes of patients with NSTI (Necrotizing soft tissue infection). Patients with a LRINEC score of > or = 6 have a higher rate of both mortality and amputation.

- In 2010, V Corbin et.al. Started a prospective study[8] for fifty patients at the Department of Infectious diseases and Dermatology of the Clermont-Ferrand University Hospital. The evaluation criteria were: time from initiation of antibiotics to regression of erythema, fever duration and complications (abscess, surgery, septic shock, necrotizing fasciitis, death, and transfer to intensive care). Other Potential variables were: LRINEC score>6 at admission, comorbidities, clinical presentation and soft tissue ultrasound results. Patients belonging to moderate and high risk on admissions should be carefully evaluated and LRINEC score is a useful tool for detection severe forms of soft tissue infections.

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- In 2017, J Bechar, S Sepehripour, J Hardwicke, G Filobbos did a systematic review of English-language literature[9] articles about use of LRINEC score and the incidence of Necrotizing fasciitis was performed from 2004 to 2014. Concluded that the LRINEC score is a useful tool in the diagnosis and surgical treatment of patients with Necrotizing fasciitis, with a statistically positive correlation observed.

- In 2019, Abdullah M, McWilliams B, U. Khan S performed a systemic review[10] of eighteen clinical studies published during 2004–2018. And concluded that there is Level 3 evidence that LRINEC score is reliable tool in risk stratification of patients with severe soft tissue infections.

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Surgical anatomy of skin and subcutaneous tissue

Skin is the largest organ of human body. It consists of three components – Epidermis, dermis and hypodermis.

The outer most layer of skin is the Epidermis and is made of keratinized stratified squamous variety. It is divided into four layers according to keratinocyte morphology and the degree of differentiation into cornified cells.
The Epidermal appendages which are ectodermal in origin are – sweat gland, sebaceous glands, hair and nails[11].
Beneath the epidermis which provides structural and nutrition support is the dermis. It consists mainly of collagen fibers together with some elastic tissue, blood vessels, lymphatics and nerve fibers.

The hypodermis or subcutaneous tissue composed of adipocytes separated by septa. Its acts as a reserve energy supply, protects the skin, and allows mobility by sliding over underlying structures.

Underlying the hypodermis, is the organized connective tissue called as fascia. It is of two types- Outer fatty superficial fascia and inner membranous fascia.

Beneath deep fascia are the muscles, the bones, the joints with synovial sheaths and the cavities (e.g.: peritoneal)

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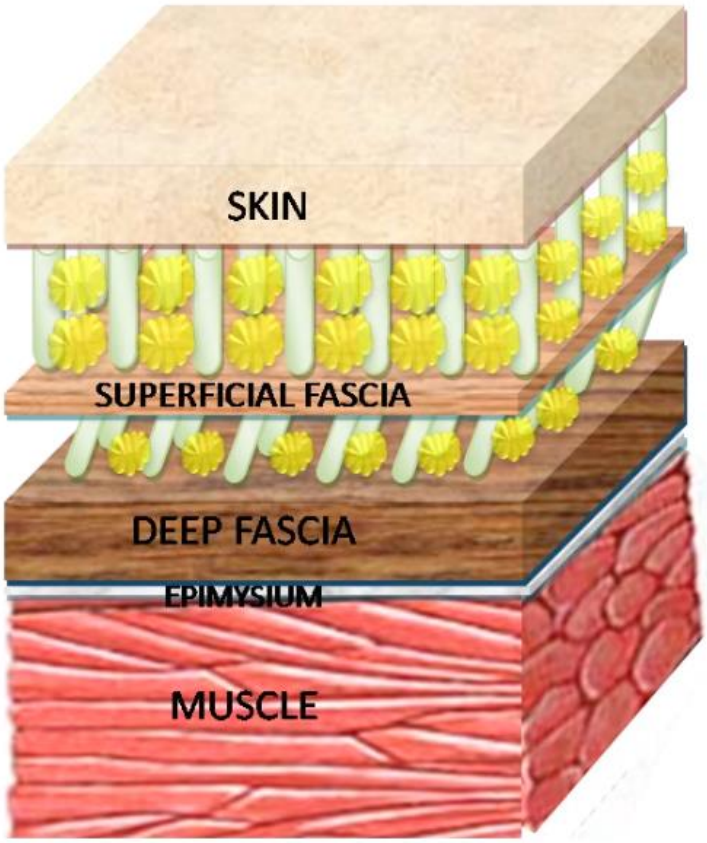

Figure No. 1: Anatomy of Skin and Subcutaneous tissue.

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CLASSIFICATION OF WOUND:-

Centers for Disease Control and Prevention (CDC) (2010)[12] has created a classification for surgical sounds which have risk of developing Surgical Site Infection (SSI). These include

Table 1

Surgical Wound Classification Grades (I–IV) as Defined by the CDC

CDC Surgical Wound Classification Definitions
Class I/Clean: An uninfected operative wound in which no inflammation is encountered, and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow no penetrating (blunt) trauma should be included in this category if they meet the criteria.
Class II/Clean-Contaminated: An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in a sterile technique is encountered.
Class III/Contaminated: Open, fresh, accidental wounds. In addition, operations with major breaks in a sterile technique (eg, open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute or no purulent inflammation is encountered are included in this category.
Class IV/Dirty-Infected: Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

CDC = Centers for Disease Control and Prevention.

Table No. 2:- CDC Classification of wounds

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WOUND HEALING

Surgeons should have a clear idea about wound healing.

Three phases of wound healing: -

1. Inflammatory phase
2. Proliferative phase
3. Remodeling phase.

- **Inflammatory phase** (lasts up to 72 hrs.): - After the injury to endothelium, it is immediately followed by coagulation, altered[12] vascularity, and inflammation, all of which modulate wound healing. Coagulation is mediated by platelets, and during thrombus formation, platelet factors that enhance fibroblast migration and proliferation are released.

  The normal inflammatory response soon follows as small blood vessels dilate, capillary permeability increases, and peripheral neutrophils and then monocytes migrate into the wound.

  As Monocytes ingest material, they are transformed into macrophages that phagocytize debris as well as enzymatically destroy bacteria. Macrophages also play a role in the induction of collagen synthesis. Prostaglandins also play a significant role in this process.

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- **Proliferative phase** (3rd day to 3rd week): - It consists mainly of fibroblast activity, production of collagen, growth of new blood vessels as capillary loops, and re-epithelization of the wound surface. Collagen provides strength and stability for all tissues of the body. The strength and integrity of all tissue repairs relies on the cross linking and deposition of collagen.

  It is not the collagen synthesis but the collagen cross linking that is the bottom line for the surgeon[13] because it is cross linking that provides strength and integrity to any repair.

  Collagen degradation, mediated by enzyme collagenase, is equally important as collagen synthesis in wound repair. In normal unwounded dermis collagen synthesis and degradation occur in[14-15] equilibrium. After wounding, however, the rates of collagen synthesis and degradation rise and fall in an ordered, sequential fashion, so that enough collagen is synthesized, cross linked, deposited, and removed to provide wound strength and integrity without excessive scarring.

- **Remodeling phase** (3rd week to 1 year or more): It is characterized by maturation of collagen type (type 1 replacing type 3). The myofibroblasts (a fibroblast-like cell with smooth muscle components) are the cells responsible for wound contraction.

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Types of wound healing:-

- Healing by Primary intention
- Healing by secondary intention
- Delayed primary closure

Skin and soft tissue infections can be localized or spreading, necrotizing or non-necrotizing.

“Necrotizing Soft Tissue Infections (NSTI) is defined as rapidly spreading inflammation and necrosis of skin, subcutaneous tissue and superficial fascia”.

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ETIOLOGY: -

Soft tissue infections evolve into a life threatening NSTI, if not treated immediately. NSTI occur when either soft tissue infections progress vertically towards the fascia or any trauma itself penetrating to the level of fascia[8].

The conditions which cause rapid spread of the infection: -

- Areas of skin with shallow subcutaneous tissue (olecranon or patellar surfaces)
- Infection at level of perifascial space
- h/o trauma or foreign body
- The avascularity of perifascial space and the low perfusion of overlying fat tissue and collagen barrier downwards cause spread of infection laterally.
- Toxin produced from virulent bacteria cause tissue necrosis and thrombosis of the microcirculation, which eventually leads to limb loss.
- They are most commonly seen in the extremities, perineum, and genitalia, with fewer arising on the chest or the abdomen. NSTI involving perineum or genitalia called as Fournier's gangrene.

  Causes include- trauma, IV drug abuse, subcutaneous injections, skin infections and ulcers, animal and insect bites, enterocutaneous fistulas, surgical complications, abscesses, and idiopathic.

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CLASSIFICATION

Necrotizing fasciitis is classified depending on type of organism's cultured[25-27]

TYPE	ASSOSCIATION
I	POLYMICROBIAL (aerobic and anaerobic bacteria such as Clostridium and Bacteroides species)
II	group A Streptococcus
III	Gram negative marine organisms (such as Vibrio vulnificus)
IV	Fungal species

Table no. 3:- Classification of NSTI

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PATHOPHYSIOLOGY: -

When injury violates the fascia, allows the initiation of infectious event occurs. Risk factors for NSTI are Older age, Diabetes, Immunocompromised state, Intravenous drug abuse, etc. which lead to progress of the infection. Toxin producing pathogens such as clostridium sps, streptococcal sps, etc are cytotoxic and result in necrosis of tissue, thrombosis of microcirculation.

Within 24-48hrs, infection of muscle fascia leads to poor blood supply which allows for progression of infection which results in Tachycardia and Hypotension. Dead tissue becomes nutrient source for further microbial growth, increase in toxin production and further necrosis. Thrombosis of the perforating nutrient blood vessels of overlying skin and subcutaneous tissues causes extension of infection above fascia.

After 72-96hrs of initial insult, proliferation of bacteria and production of toxins leads to activation of apoptosis[20] and proteolysis of host tissue and extra cellular matrix, which in turn leads to rapid onset tissue destruction causing increased Serum Lactate and Serum Creatinine Kinase. Pyogenic exotoxins activate T cells results in release of cytokines (increase WBC and Fever). It in turn, leads to increased Capillary permeability (Edema & Fluid filled Blisters).

Delayed treatment (more than 96hrs) leads to Tissue ischemia resulting to further progression of infection leads to SIRS, MODS and death.

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Type I NF – they are classically polymicrobial with various species of gram-positive cocci, gram-negative rods, and anaerobes including clostridial species. Most affected location is trunk and perineum[25]. Patients with type I NSTIs are typically older, with co morbidities such as diabetes, and often have no history of trauma.

A Relatively rare Clostridial infection, traditionally known as gas gangrene. Two primary lethal toxins are thought to be most responsible: α-toxin and θ-toxin[27]. Both the toxins cat synergistically and cause impairment in phagocyte function and interferes stages of inflammation. Thus, it leads to local ischemic conditions at the site of infection, which causes reduction in the tissue pH and establishes a favorable local environment for bacterial proliferation.

Type II NSTIs involve group A β-hemolytic streptococci (GAS), either alone or in combination with staphylococcal species. They have a significant potential for aggressive local spread, as well as systemic toxicity including toxic shock syndrome. Patients with type II infections tend to be younger, healthier, and more commonly give a history of trauma, surgery, or IV drug use. Streptococci produce superantigen activity M proteins. The M proteins causes Activation of this inflammatory cascade leads to the shock. GAS species also produce several potent exotoxins that damage neutrophils, prevent phagocytosis and bacterial clearance by fluid secretions, and break down hyaluronic acid in connective tissues[30-31].

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Type III NSTI are mostly seen in warm coastal regions. Infection can occur via exposure through an open wound or other break in the skin contaminated with salt water[32-33].

Type IV NSTI is the result of fungal infections, mainly Candida spp. and Zygomycetes. It is found mainly in the immunocompromised host. Infections often occur following trauma.

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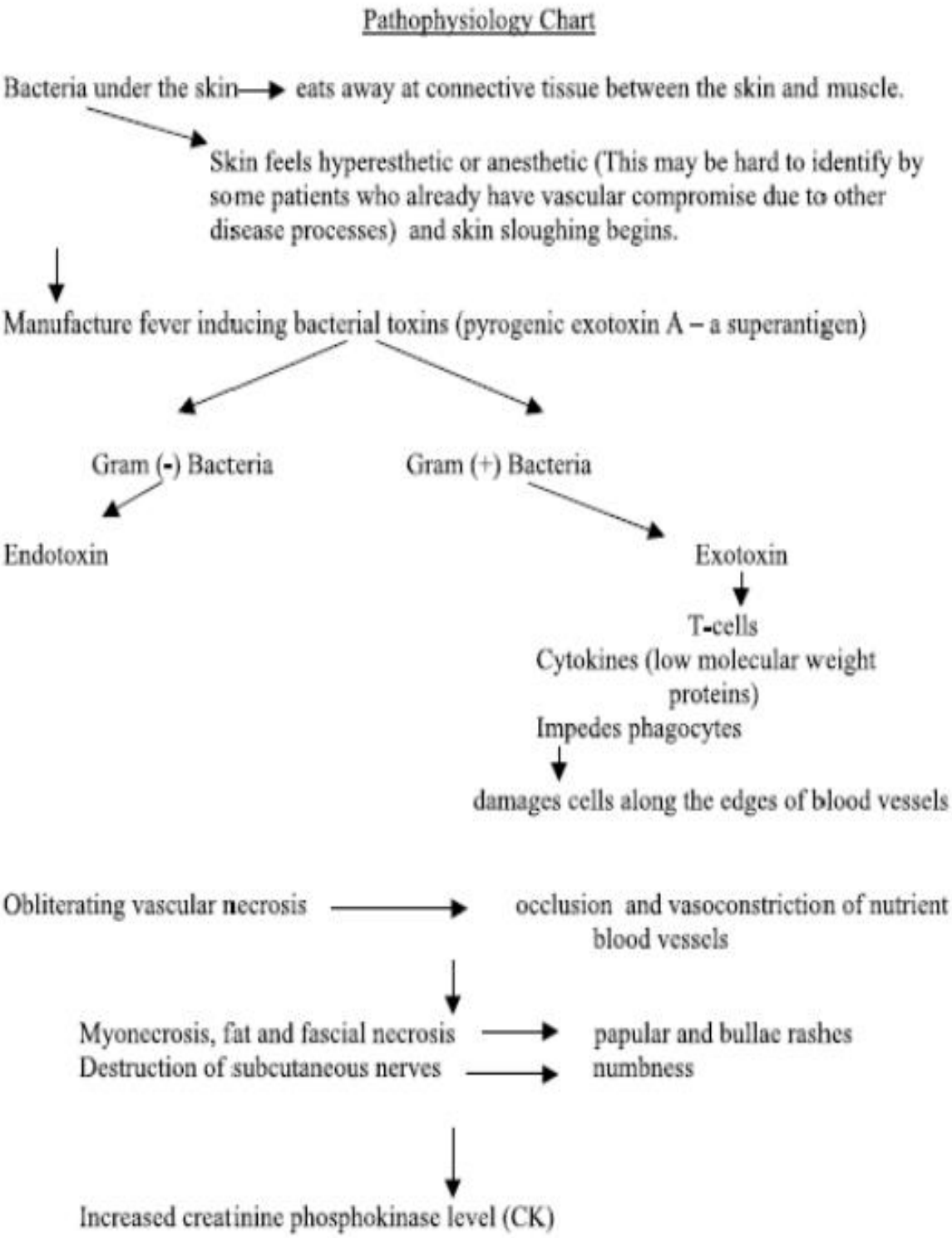

Figure No.2:- Flow chart showing Pathophysiology of NSTI

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CLINICAL FEATURES: -

Early signs and symptoms of NSTI are identical to those seen with cellulitis or abscesses potentially making the correct diagnosis difficult.
The clinical presentation will vary depending on the organism responsible, anatomical region involved and depth of infection.

Classical triads of symptoms seen are local pain disproportionate to examination, swelling, and erythema[34].
The early signs are erythema, local warmth, skin sclerosis, and edema.

Three forms of NSTI:

- Fulminant form: - critically ill patient with signs and symptoms of severe septic shock and multiple organ dysfunction[28] syndrome, along with extensive necrosis of soft tissue. In this case, the clinical picture deteriorates rapidly within a few hours; pain is severe and usually manifests before the cutaneous signs.
- Subacute form: - It has a relatively slow clinical course (days or weeks). Result of preexisting infection.
- Acute form

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Other late findings include –

1. Bullae
2. Ecchymosis of the skin followed by skin necrosis
3. Crepitus or gas underneath the tissues observed in x-ray
4. Cutaneous anesthesia (spread to local nerves)

These findings are strongly indicative of necrotizing infections and prompt immediate surgical exploration.

Systemic manifestations: - Tachycardia, Fever is the most common vital sign abnormalities, followed by Hypotension, Tachypnea, Altered mental state.
If the patient remains untreated or undiagnosed, it progresses to SIRS (Systemic Inflammatory Response Syndrome), MODS (Multiorgan Dysfunction Syndrome) and eventually death.

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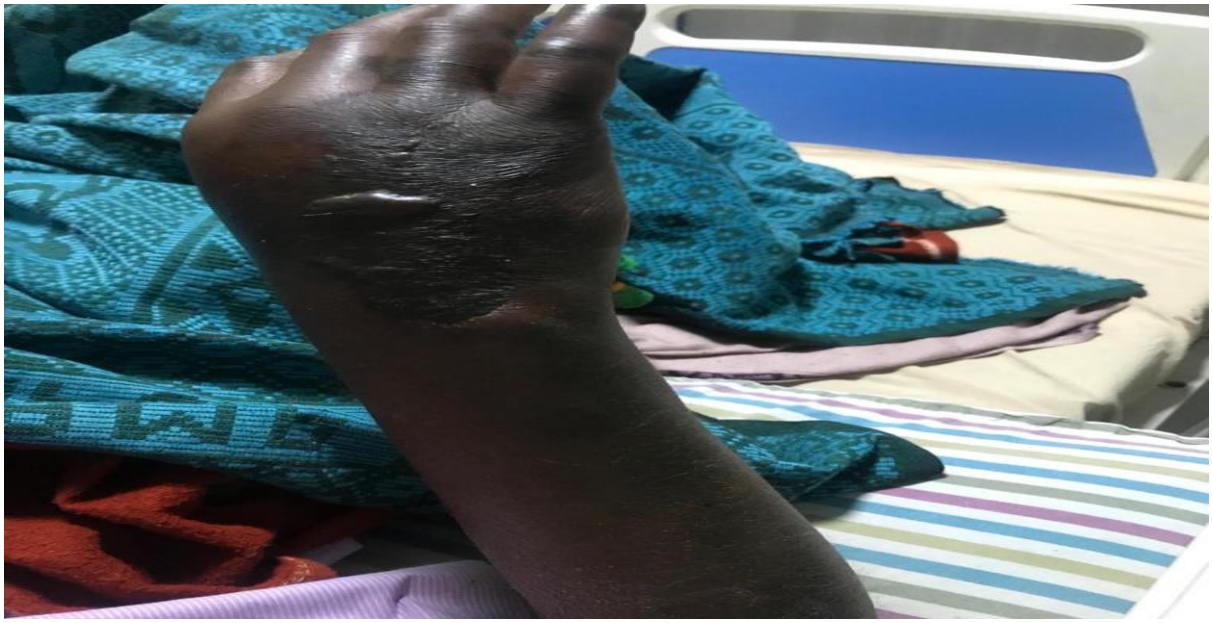

Figure No 3: Necrotizing fasciitis of Right forearm and hand

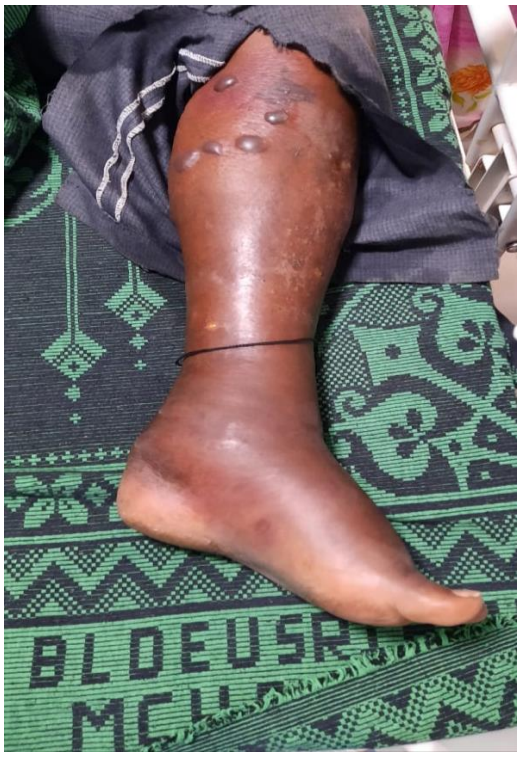

Figure No 4:- Necrotizing fasciitis of Left leg

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INVESTIGATIONS

1. Routine Blood Investigations[6] -

- Complete blood picture: - It is general investigation which gives us idea about anemia, raised total WBC count (indicator of sepsis),
- CRP – It's elevated in cases of infection.
- Bleeding time and clotting time – Abnormal levels do require correction when patient taken for surgery
- Random blood sugar – To find out whether patient is diabetic. HbA_1c is done in known case of Diabetes-Mellitus patients.
- Renal function test: - It is an indicator for acute kidney injury or renal failure.
- HIV 1 & 2 and HBsAg – diagnosis of Retroviral disease and Hepatitis B infection for taking universal precautions during surgery.
- Examination of the urine – It shows any urinary tract infection or diabetes-mellitus. Urine for ketone bodies is done in Diabetes-mellitus patients to rule out diabetic ketoacidosis.

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LRINEC[6] (Laboratory Risk Indicator of Necrotizing Fasciitis):

Early operative debridement is the gold standard treatment for necrotizing fasciitis. But early recognition of cellulitis progressing into necrotizing fasciitis is difficult. This scoring system is used based on laboratory tests[6].

The following parameters are

a) 1. Hemoglobin
b) 2. Total White Cell Count
c) 3. Serum Sodium
d) 4. Serum Creatinine
e) 5.Random Blood Sugar
f) 6. Serum C-reactive Protein

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2. IMAGING STUDIES: -

- Radiography:-

It includes soft-tissue opacity and thickening initially similar to cellulitis. The classical finding is the presence of gas along the fascial planes in case of gas forming organisms.

- Ultrasonography: -

In the workup of necrotizing fasciitis, role of ultrasound is limited, as there is lack of resolution of deeper structures. The presence of soft-tissue gas can be more apparent on ultrasound compared to X-ray films. Findings include an echogenic layer of gas above the deep fascia with posterior dirty acoustic shadowing. Hallmarks of NF include abnormal echogenicity and increased thickness of the dermis with indistinct "haziness" and increased echogenicity of the subcutaneous tissue and “COBBLE STONE Appearance” (due to subcutaneous edema. Color Doppler evaluation may not reveal hypervascularity.

Specific signs that are helpful to differentiate necrotizing fasciitis from cellulitis include irregularity of the fascia, abnormal fluid collection along fascial planes, and diffuse fascia thickening when compared to the contralateral unaffected side.

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- Computed Topography (CT) SCAN: -

  It is the one of the primary modality in the diagnosis of NF due to wider availability and higher spatial resolution as compared to X-RAY and Ultrasound. Gas within fascial planes is the characteristic of the NF as described previously.

  Thickening and nonenhancement of the fascia on contrast-enhanced CT may be helpful to distinguish from nonnecrotizing fasciitis. Other findings are increase soft tissue attenuation, fat stranding, etc. It is helpful in identifying potential complications like vessel injury.

- Magnetic Resonance Imaging (MRI): -

  It is the gold standard for soft tissue infections, as it shows excellent soft tissue resolution. Sequences include T_1 weighted imaging to assess anatomy, and T_2 weighted imaging to look for fascial thickening and edema. “Hyper intensity and thickness of the fascia greater than or equal to 3 mm on fat saturated T_2 weighted or short tauinversion-recovery images with involvement of three or more compartments is a sensitive finding to suggest necrotizing fasciitis.” MR imaging tends to overestimate the extent of deep fascial involvement because sensitivity exceeds its specificity, therefore, the therapeutic regimen should be based on a combination of clinical findings and MR imaging.

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3. **OTHER TESTS:-**

- Finger test: - It is the bedside procedure. Under local anesthesia, a 2-cm incision taken deep to fascia and gentle probing of index finger is applied. If characteristic dishwater pus with lack of bleeding and less tissue resistance observed indicative of NSTI.

- Incisional biopsy down to the fascial level with an immediate frozen section, culture, and Gram stain.

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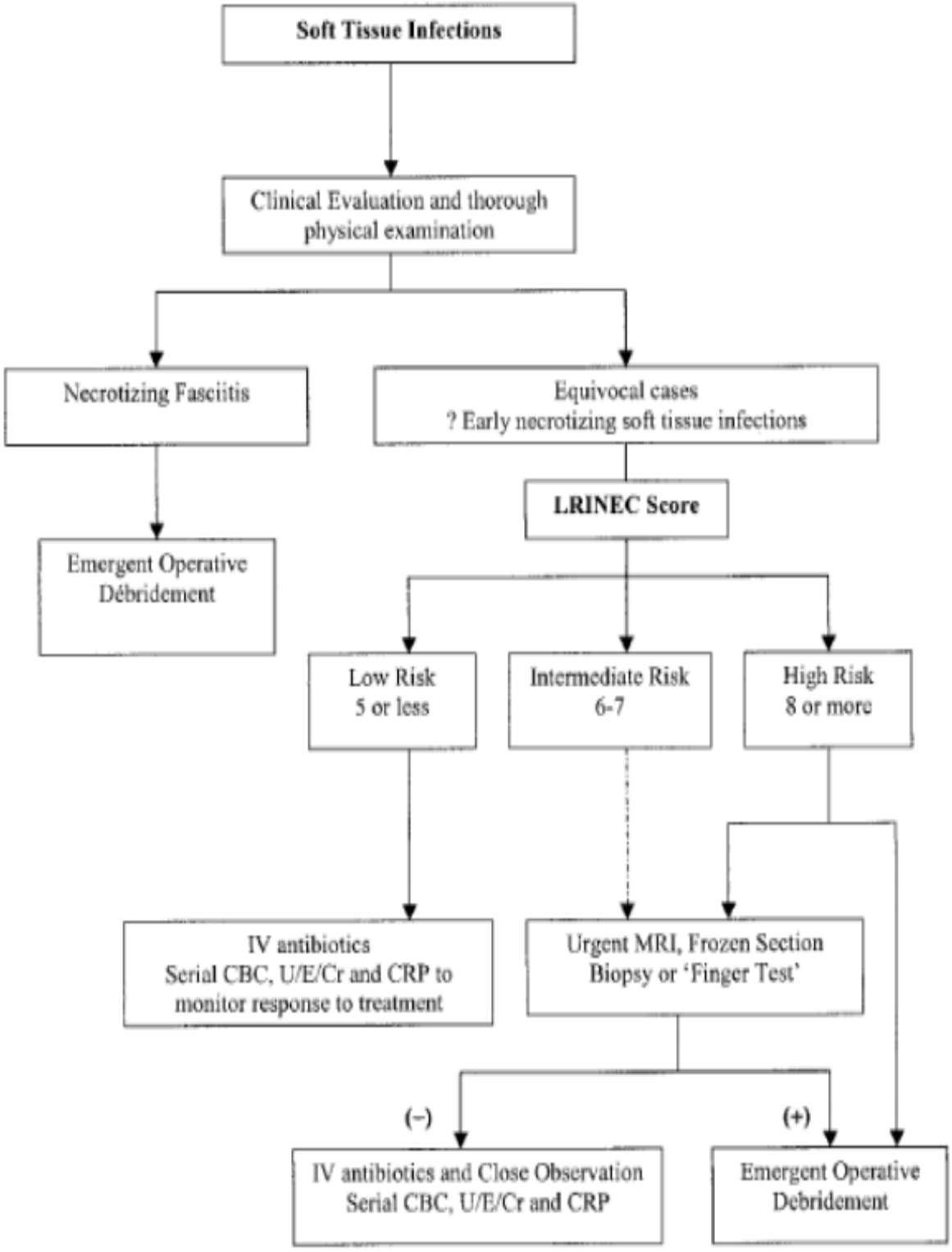
Figure 5:-Flow chart of Management of Soft tissue Infections



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MANAGEMENT

Early diagnosis of the soft tissue infections progression into necrotizing infections based on LRINEC score

Risk category	LRINEC score, points	Probability of NSTI, %
Low	≤ 5	< 50
Intermediate	6-7	50-75
High	≥ 8	> 75

LRINEC: Laboratory risk indicator for necrotizing fasciitis, NSTI: Necrotizing soft tissue infections

Table 4:- Risk Categorization based on LRINEC Score

Patients with high risk should undergo emergency debridement.

Patients with low and intermediate risk should be monitored both subjective and clinically.

The appropriate treatment modality for patients with NSTI is early and radical surgical debridement to remove infected and necrotic tissue.

The treatment modality for NSTI include coordination of surgical and intensive care team. It includes: -

- ➔ **Resuscitation,**
- ➔ **Early surgical debridement,**
- ➔ **Antimicrobial therapy.**

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➔ **Early Surgical intervention** is life-saving and delay in treatment beyond 12 h in fulminant forms of NF can prove fatal. Several studies showed that timing and the extent of the first debridement are the risk factors in terms of increased mortality rate. Mock et al.(2006)[32] have shown that the 7.5 times greater relative risk in cases of restricted first debridement.

Surgical management is indicated especially for patients displaying classical triad of symptoms and signs of SIRS, MODS.

➔ **Debridement: -**

It is the removal of necrotic tissue from the wound. The necrotic or dead tissue acts as a delaying factor in healing and preventing the formation of healthy granulation tissue and a good environment to harbor more bacteria, henceforth increasing the risk of sepsis.

Necrotic tissue is removed by autolytic debridement and this process may be helped by the application of a moist wound dressing[30] .

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Other types of debridement include

- Enzymatic (agent impregnated either on wound or dressing)
- Mechanical (physical removal of dead tissue either using dry gauze or DE sloughing solutions) and
- Sharp debridement. Debridement of totally dead or necrotic tissue using a scalpel or scissors and the more extensive removal of tissue under anesthesia (when a surgeon removes enough tissue until tissue with a good bleeding capillary base is found.

To prevent less scar and better wound healing, Incisions are performed parallel to Langer's[8] lines. And extend at least beyond the area of induration. The presence of induration indicates that dermal lymphatic's are blocked and post capillary venules are thrombosed, leading to tissue necrosis.

Excision should be extended till healthy; bleeding tissue at all margins are observed.

Second look of the wound is needed. Re-debridement, if needed to be done.

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➔ **Antibiotic therapy**:

Ischemia and hypoxia lead to inadequate delivery of antibiotic to the site of infection. So, immediately after surgical management of the NSTI, BROAD SPECTRUM ANTIBIOTICS to be started.

Initially, antibiotics such as Amoxicillin- Clavulanate acid, Ampicillin–Sulbactam[32] , Piperacillin– Tazobactam, Ticarcillin– Clavulanate acid, third or fourth generation Cephalosporins, Carbapenems are used. Later, changed according to microbiological culture sensitivity report.

Metronidazole, Clindamycin is effective for anaerobic coverage for type I infections.

Type II infections are treated with first or second generation of Cephalosporin's.

For Methicillin Resistant Staphylococcus aureus (MRSA) infections, Vancomycin is the Drug of choice. Daptomycin can also be used.

Linezolid is used in cases where Staphylococcus .aureus is resistant to Vancomycin.

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Other treatment modalities: -

- **Hyperbaric oxygen treatment—**

  It is a treatment modality in which patient is placed in a high-pressure chamber, resulting in delivery of 100% oxygen at 2-3 times typical atmospheric pressure absolute for 60- 90 minutes. Elevated levels of oxygen at tissue level reduces edemas and activates oxygen reactive species, which leads to cytotoxic effects on organisms.

  Some retrospective cohort studies, I.e., (Riseman 1990; Wilkinson 2004, Hollabaugh 1998)[33-36] report a significant reduction in mortality with adjunctive HBOT, whilst others report no change in mortality (Brown 1994; Shupak 1995). Most of studies showed mixed results, but can be considered in hemodynamically stable patient with no signs of progression of infection.

- **Intravenous immunoglobulin (IVIg)**—

  It involves the administration of pooled IVIg from human donors as it binds to exotoxins produced by type II infections and limits systemic inflammatory response. Studies suggest that consideration of IVIg therapy is limited to critically ill patients with TYPE II infections. A study by Anaya et al.[32] highlighted the role of IVIG in the treatment of type II NSTI.

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The authors concluded that the use of IVIG in patients with group A streptococcal infection who developed streptococcal toxic shock syndrome and in those with a high mortality risk (advanced age, hypotension, and bacteremia) proved beneficial. Most of the studies are non-randomized or underpowered; suggest weak evidence towards benefit of the patient.

Wound management:-

Moist environment has shown to facilitate healing process of wounds and bandage acts as a barrier.

Type of dressings varies upon factors such as depth, size, location, and the wound surface

Dressings:

It can be classified into films, composites, hydro gels, hydrocolloids, alginates, foam and other absorptive dressings including NPWT-Negative Pressure Wound Therapy. Saline soaked dressings and magnesium sulphate with glycerol dressings are used in soft tissue infections

Due to hygroscopic action and providing moisturizing effect to the skin, magnesium sulphate with glycerol is most commonly used in patients with cellulitis.

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Skin Grafting:-

It is the transfer of tissue from donor area to recipient area without its blood supply or nerve supply. It is indicated in clean granulated ulcer where defect cannot be opposed.

It can be divided into several categories based on composition of graft: -

- Split-thickness skin grafts [39](STSG): - It is also called as Thiersch graft. They are composed of the epidermis and a superficial part of the dermis.
- Full-thickness skin grafts (FTSG) contain both the full epidermis and dermis.
- Composite grafts contain skin and another type of tissue, usually cartilage.

AMPUTATION: -

It is defined as surgical removal of a limb or a body part. It is usually done in cases delayed presentation of patient with necrotizing soft tissue infections (I,e gangrene of limbs).

Types of Amputation are: -

- ♦ Ray's amputation
- ♦ Below knee amputation
- ♦ Above knee amputation
- ♦ Hip disarticulation
- ♦ Hind quarter amputation.

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In most the NSTI of Lower extremities, Below-Knee and Above -Knee Amputations are done.

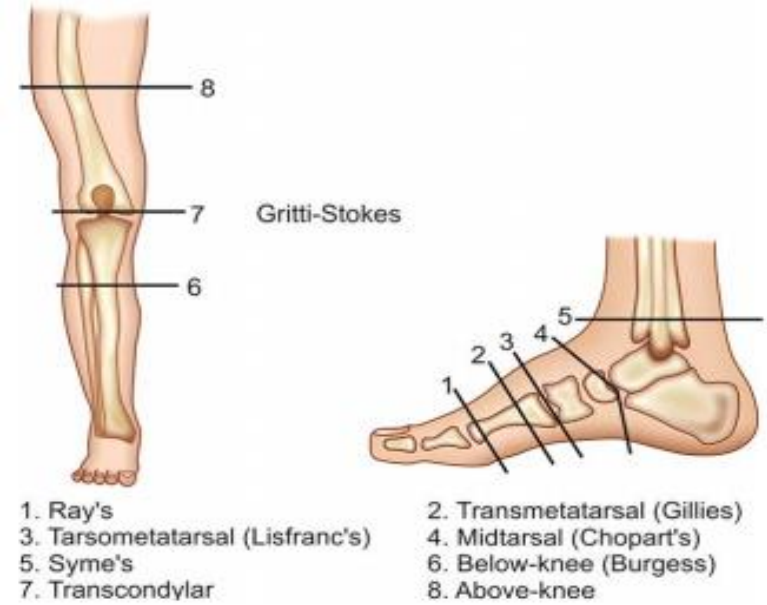

Figure No.6:- Types of Amputations of Lower limb

Chang et al 2018[38] has concluded patients with hemorrhagic bullae, comorbidity with peripheral vascular disease, presence of bacteremia, or LRINEC score > 8 should receive early and primary amputation in order to prevent mortality" in a retrospective cohort study in tertiary teaching hospital in Taiwan.

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Khamanuan et al 2015[37] has concluded that the patient with clinical predictors for amputation like diabetes mellitus, soft tissue swelling, skin necrosis, gangrene, and serum creatinine values of more than 1.6 mg/dL on admission should be monitored closely for progression and receive early aggressive treatment to avoid amputation.

- GLYCEMIC CONTROL: -

Increase in levels of blood sugars or Diabetes Mellitus patients show decreased wound healing and are more susceptible for infections. Insulin will often be required in those not previously receiving it, even if only temporary.

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PREVENTION: -

Centres for Disease Control (CDC) [10]has reported the following list of recommendations to prevent the disease:

- Patients with sore throats should consult a doctor.
- Patients with streptococcal throat infections should stay home until 24 hours after their last antibiotic dose.
- Proper hand wash does prevent the spread of Group A Streptococcus (GAS) infection, especially before preparing food or eating, after sneezing and coughing.
- Keeping the skin intact is essential.
- Patients with infected wounds and fever should seek early medical care.
- Wounds should be cleaned and monitored regularly for signs of infection (redness, swelling, drainage, pain).
- Elevation of affected area and treatment of predisposing conditions leads to decrease in recurrence.

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MATERIAL AND METHODS

SOURCE OF DATA:

All patients presenting to B.L.D.E.(D.U.)'s Shri B.M.Patil Medical College Hospital and Research Centre, Vijayapur and admitted patients in whom the diagnosis of SOFT TISSUE INFECTIONS is considered from NOVEMBER 2018 to JUNE 2020.

METHOD OF COLLECTION OF DATA:

- This is a prospective observational study in which patients presenting with Soft tissue infections in B.L.D.E.(D.U)'s Shri B.M. Patil Medical College Hospital will be taken up into study. Three groups are made based on LRINEC Score, i,e. Low (≤5), Intermediate (6-7) and High (≥8) Risk.
- Minimum permissible error of 1% in each group will be taken up for the study.
- The period of study is from NOVEMBER 2018 to JUNE 2020.
- Diagnosis of Necrotizing Fasciitis will be made on the basis of thorough clinical examination, appropriate laboratory investigations.
- A pretested structural Performa will be used to collect relevant information for each individual patient selected.
- Data will be entered on master chart for analysis.
- The data will be analyzed by using student t- test.

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- Cases will be selected consequently with following inclusion and exclusion criteria

INCLUSION CRITERIA:-

- Both sex
- Soft tissue infection

EXCLUSION CRITERIA:

- Non tissue infection/ necrotizing fasciitis.
- Transferred from other institutions.
- Patient with uncertain LRINEC score that we could not determine to be ≥ 6.
- For patients with multiple admissions due to necrotizing fasciitis, only the first admission was recorded.
- Patient on immunosuppressive drugs
- Known malignancies

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SAMPLING:

Study period from NOVEMBER 2018 to JUNE 2020. All the patients admitted during this period, who fulfill the inclusion criteria, will be included in this study.

ESTIMATION OF SAMPLE SIZE:

With anticipated Proportion of LRINEC Score (Intermediate and High Risk) , 81% (ref hospital statics January 2017- August 2018) , the minimum sample size is 90 patients per group with 5% level of significance and 10% relative error.

Formula used

$$\mathbf{n=\frac{z^2\ p*q}{d^2}}$$

Where Z= Z statistic at α level of significance

d^2= Absolute error

P= Proportion rate

q= 100-p

Statistical Analysis:

Data will be represented using Mean ±SD, percentages and diagrams.

Data will be analysed using

-ROC CURVE

-Sensitivity, Specificity, PPV and NPV

-Scores will be compared using independent t test

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RESULTS:-

180 patients with soft tissue infections were included in this study. All the patients were evaluated based on Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC). Based on their LRINEC score, the patients were classified as Low, Intermediate and High Risk for the onset of Necrotizing fasciitis.

- The study population has been categorized based on their age (Table 5).

- The 60-69 years age group was predominant (20.6 %) in the present study (Fig.7). 18.9 % of patients were young adults (30-39 years) and 17.8 % of patients belonged to 50-59 years. 15.6 % of the adults (40-49) population have been observed in the present study. In the total study population, 13.3% of patients were age group of 70-79 years. The remaining age groups were less than 10 % of the total study population.

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Table No. 5: Age categories of the study population

Age (Years)	No. of patients	Percentage (%)
< 20	01	0.6
20 - 29	10	5.6
30 - 39	34	18.9
40 - 49	28	15.6
50 - 59	32	17.8
60 - 69	37	20.6
70 - 79	24	13.3
80 - 89	12	6.7
>90	02	1.1
Total	180	100.0

Figure 7 :- **Age distribution of the study population**

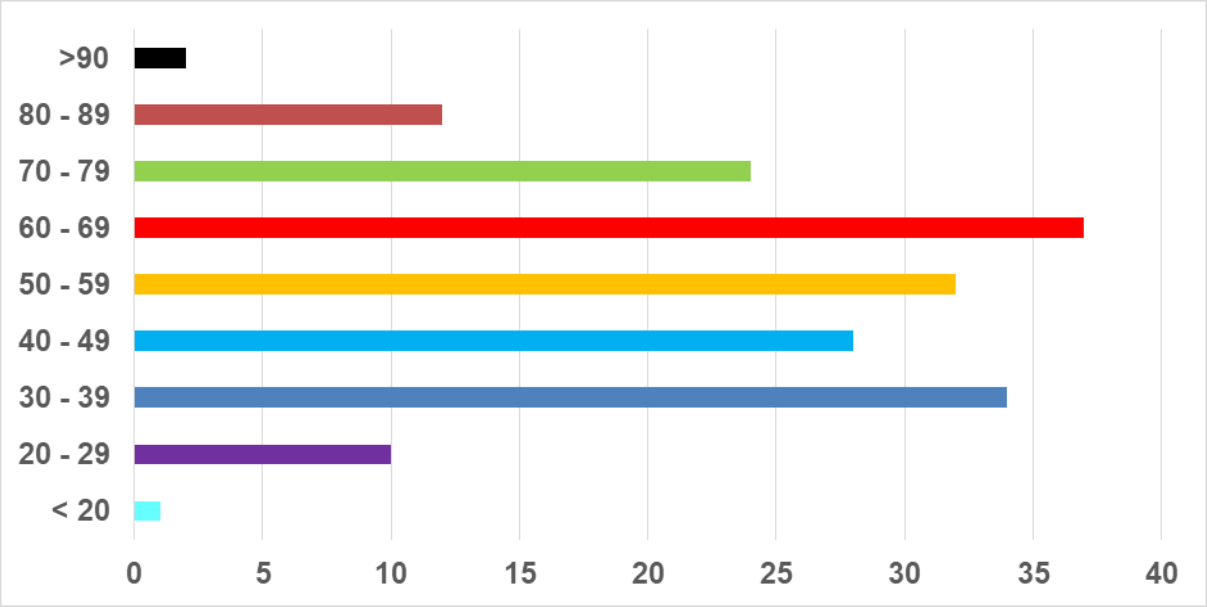

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Table No. 6: Distribution of patients according to gender

Gender	No. of patients	percentage
Female	48	26.7
Male	132	73.3
Total	180	100.0

The male patients (73.3%) were major participants in the study than female patients (26.7%) (Table 6). The male participants were almost three-fold higher than females (Fig.8).

Figure No. 8: Gender Distribution

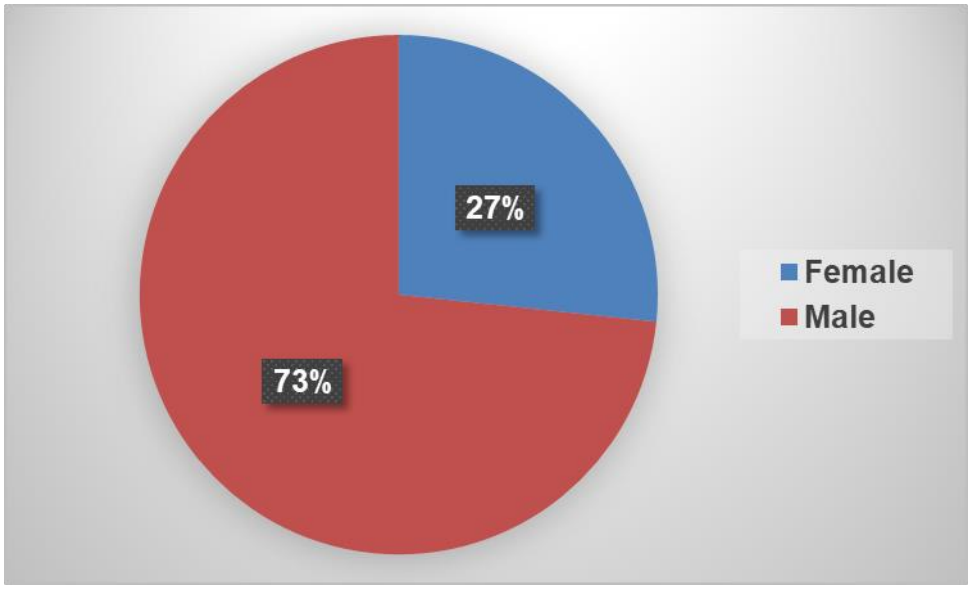

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Table 7: List of co morbid conditions in the study population

Co morbidities	Yes	No
Diabetes Mellitus	39 (21.66%)	141(78.33%)
Hypertension	24 (13.33%)	156 (86.66)

- In the present study, Diabetes mellitus (21.66 %) and Hypertension (13.33 %) were two co morbid conditions in the study patients (Table 7).

However, DM has major co morbid present among the patients (Fig.9).

Figure No.9: Co morbidity of the study population

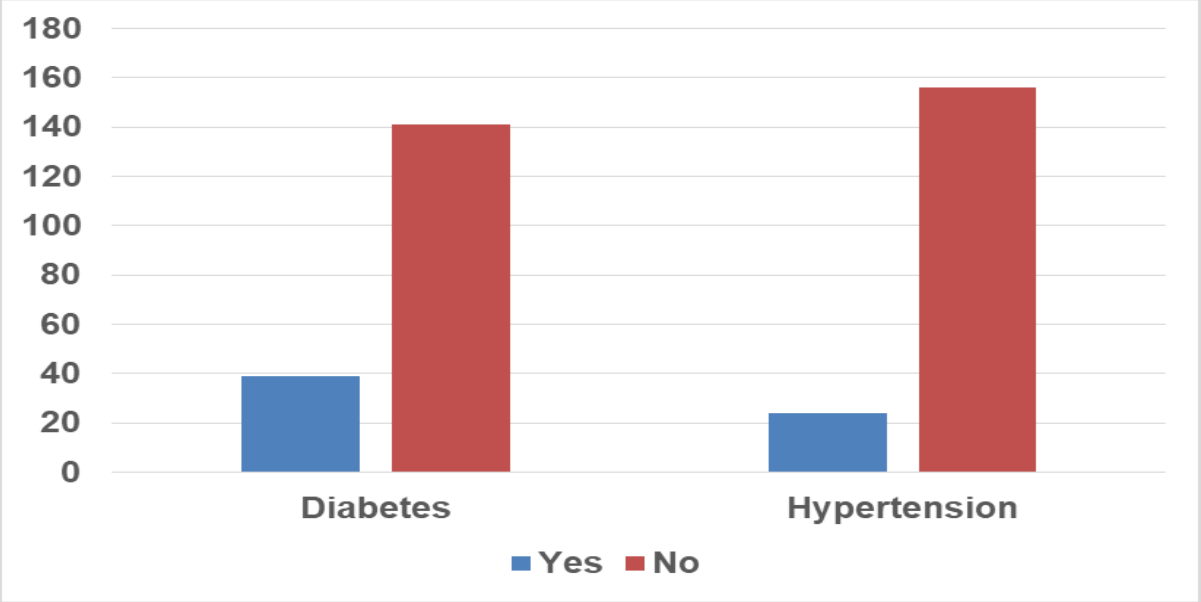

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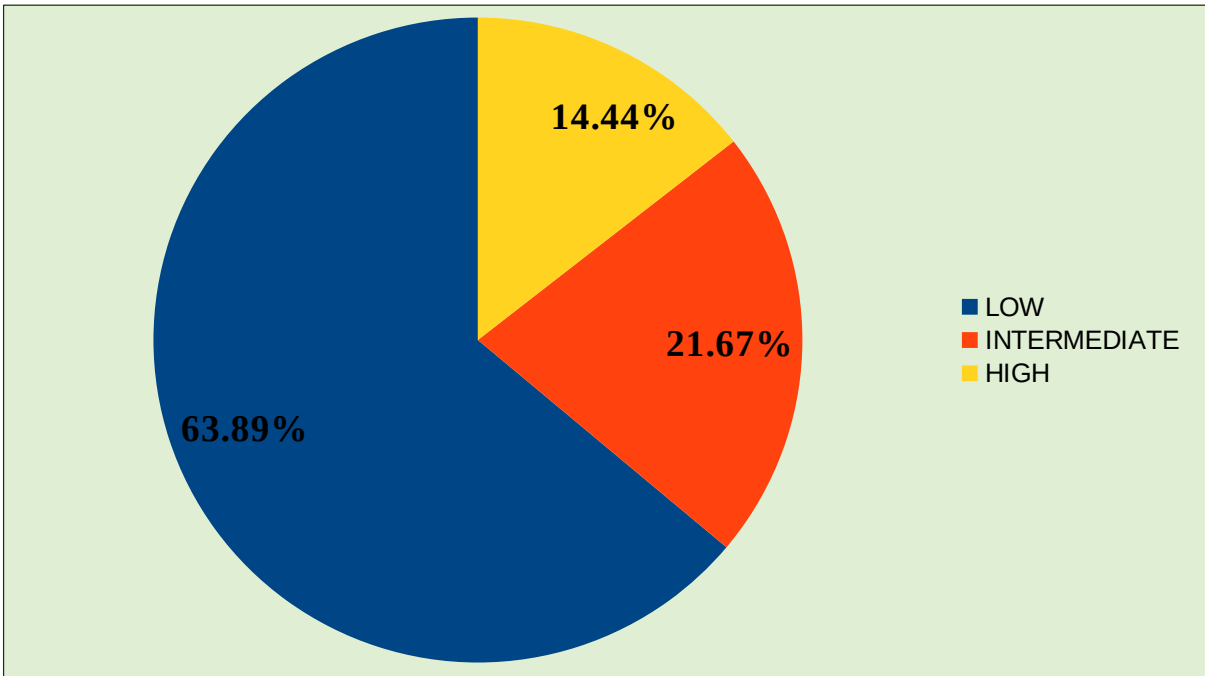
Table 8: Distribution of patients according to LRINEC Score

LRINEC Score	No. of patients	Percentage
≤5(Low Risk)	115	63.9
6-7 (Intermediate Risk)	39	21.7
≥8 (High Risk)	26	14.4
Total	180	100.

Figure No. 10: **Patient grouping based on LRINEC Score**



Based on the LRINEC score (Table 8), the study patients were categorized into three groups (Fig.10). The age was compared among each group and found there was no significant difference. Similarly, the LRINEC score showed a significant difference among the three groups. (Table 9).

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Table No.9: Comparison of age among three groups and LRINEC Score among three groups

	≤5(I) (N=115)	6-7 (II) (N=39)	≥8 (III) (N=26)	I Vs II *P*	I Vs III *P*	II Vs III *P*
Age	52.05±16.23	55.15 ±14.87	55.73±19.13	0.2944	0.3145	0.4001
LRINEC Score	2.89 ±1.29	6.52±0.50	8.61±0.69	<0.0001	<0.0001	<0.0001

In the study, most of the patients of 55-56 yrs. Age group are presented with soft tissue infections belong to Intermediate and High Risk groups. Age group of (52.05±16.23) years belong to Low risk Group.

Table 10: Distribution of patients according to Treatment

Treatment	**No. of patients**	**percentage**
Conservative management	123	68.3
Surgical intervention	57	31.7
Total	180	100.0

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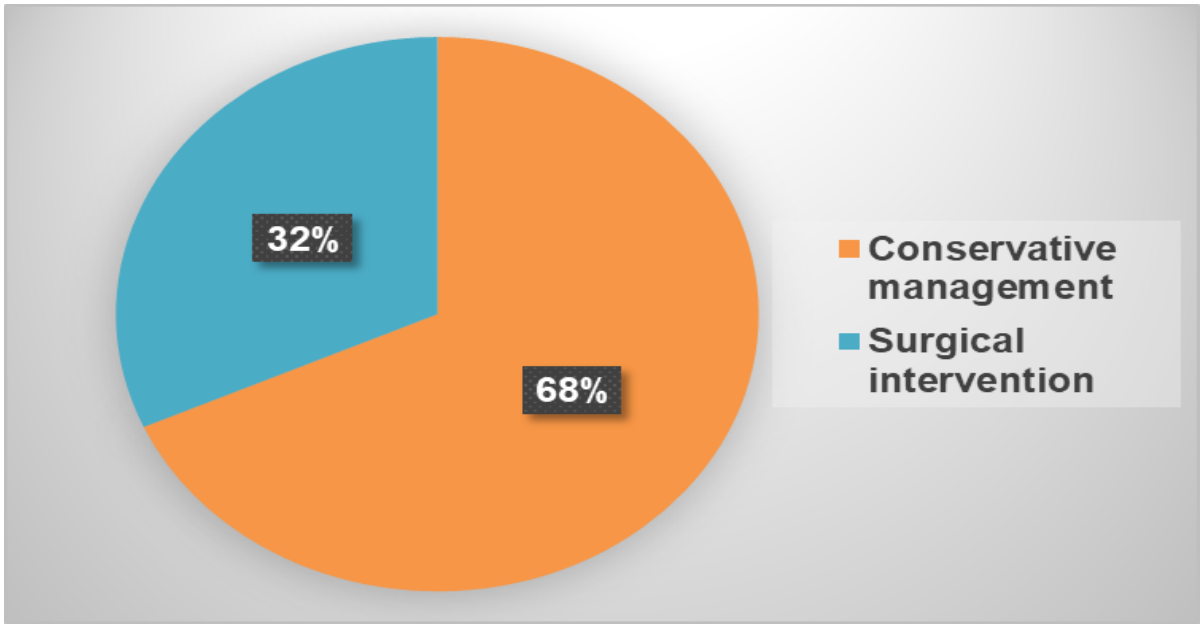
Figure 11: Treatment modalities



- The treatment modality of the present study was grouped into conservative and surgical management (Table 10). Among these, mainly conservative management (68.3%) has been done and surgical management was done in 31.7 % of the patients (Fig.11).

- **The Mann Whitney U test was used to compare the differences between two independent variables which is not normally distributed. Hence, the present study compared the two treatment modalities and found statistical significance (Table 8). The mean ±SD of surgical intervention was lower than conservative management.**

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Table No.11: Nonparametric comparison of treatment modalities

Management	**No. of patients**	**Mean±SD**	**Mann Whitney U test**	***P* Value**
Conservative Management	123	3.11±1.61	U=371.00	*P*<0.0001*
Surgical Intervention	57	7.09±1.14		

Table No. 12 : Treatment options among groups

Treatment Options	**≤5 (N=115)**	**6-7 (N=39)**	**≥8 (N=26)**
Conservative management	**111 (96.5%)**	**12 (30.8 %)**	**01 (3.8%)**
Surgical Intervention	**04 (3.5%)**	**27 (69.2 %)**	**25 (86.2%)**

Table 9 stated that the conservative management in low risk group was predominant (96.5%). But, both moderate (69.2%) and high risk (86.2%) groups had surgical intervention as a predominant treatment strategies. However, conservative treatment has also been observed in these moderate and high risk groups (Fig.12)

In Low risk (Score ≤5) category, most of them managed conservatively (96.5%).Only 4 (3.5%) patients underwent surgical intervention on 3 rd or 4 th day of treatment as the Serial LRINEC Score increased.

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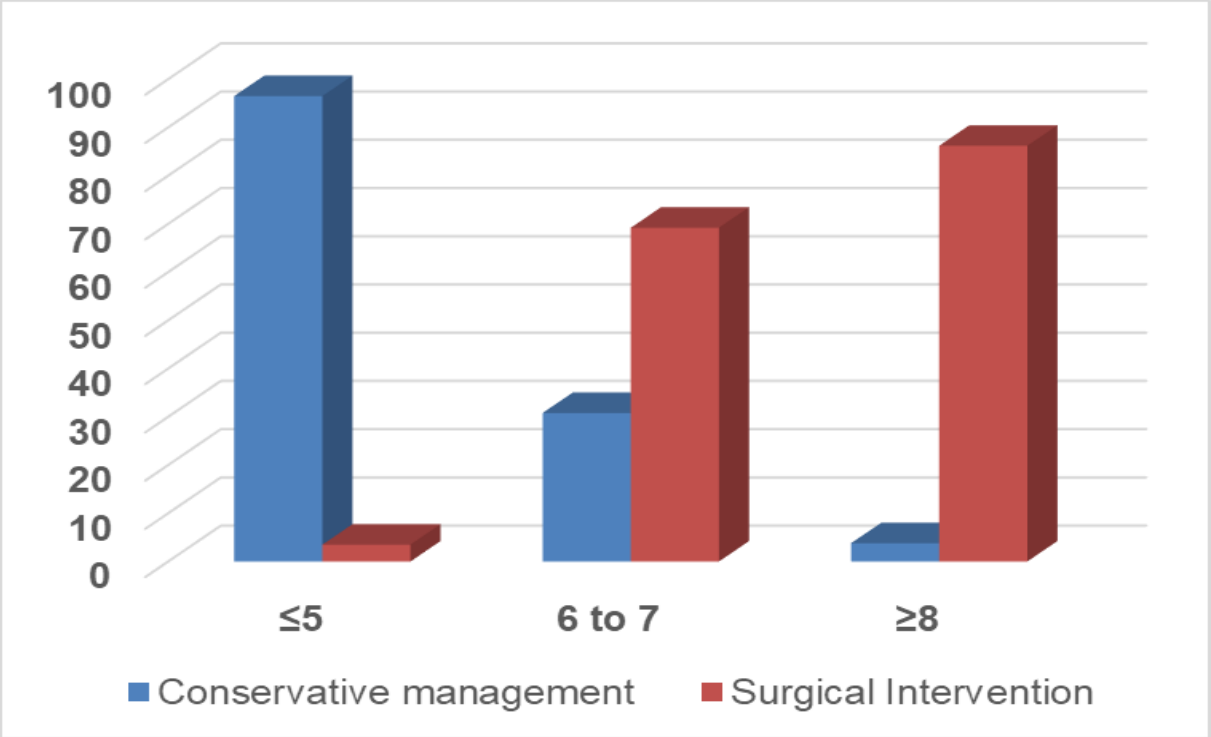
Figure 12: Treatment modalities among groups



- The age of the total participants were compared with LRINEC Score using Spearman's correlation coefficient and found non-significant (P=0.182) (Table 13).
- The regression analysis were also showed there was no significant (Fig.13).

Table No. 13: Correlation between Age of patients and LRINEC Score

	Spearman's Correlation coefficient	*P* value	Remark
Age (Years) and LRINEC Score	r =0.10	*P* = 0.182	Not significant

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Figure 13 : Regression Analysis of Age and LRINEC Score

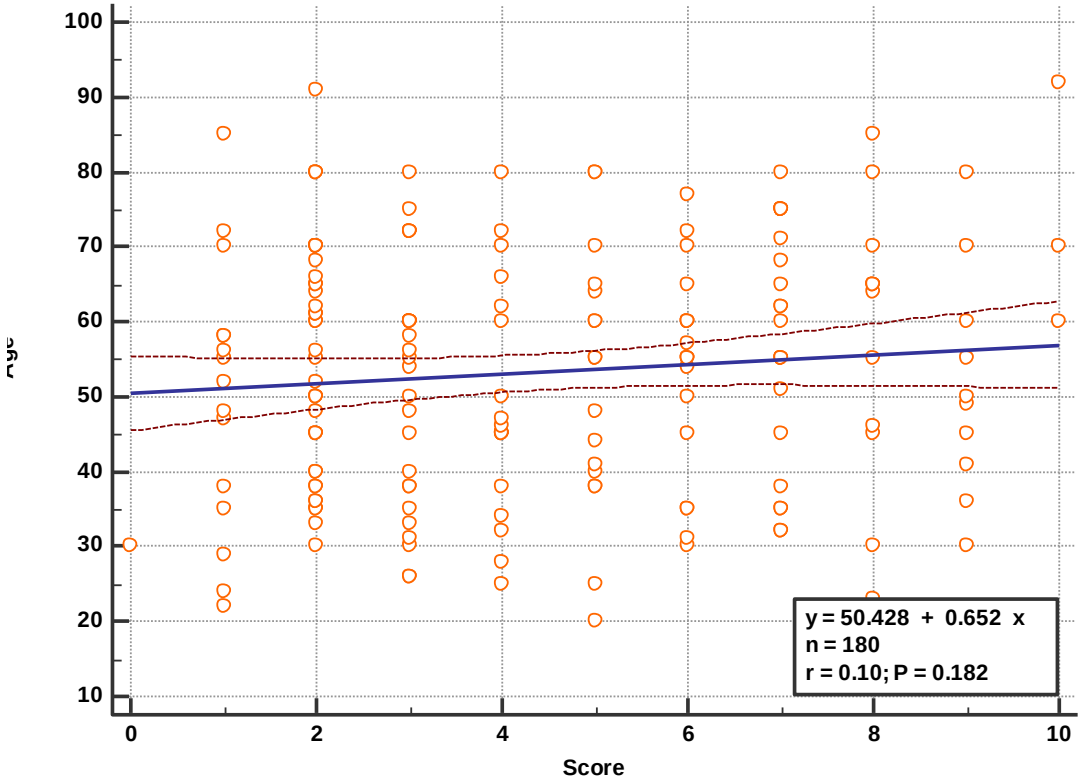

Table No.14: Diagnostic accuracy of LRINEC Score

Accuracy	**≤5**	**6-7**	**≥8**
Sensitivity %	20	74.07	95.83
Specificity %	100	100	100
Area Under the Curve	0.600	0.870	0.979
P Value	0.0293	<0.0001	<0.0001

The diagnostic accuracy of LRINEC score with three groups were compared with treatment modalities. The LRINEC score more than i.e. two groups (6-7 & ≥8) showed significant diagnostics accuracy for Necrotizing Fasciitis (Table 14).

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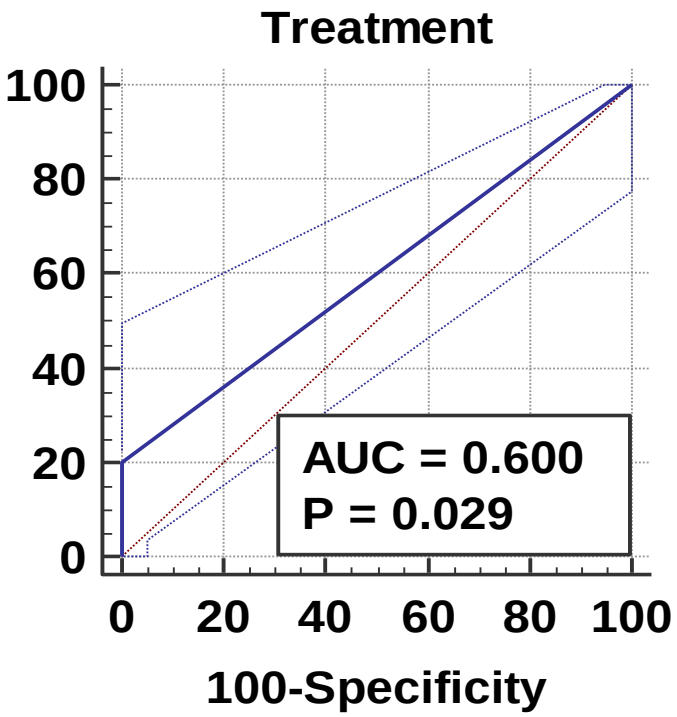
The high-risk group (LRINEC score ≥8) has higher sensitivity (95.83 %) and specificity (100 %) than the intermediate risk group (LRINEC score 6-7) has moderate sensitivity (74.07 %) & specificity of 100% and Low-risk group (LRINEC score ≤5) has lower sensitivity (20 %) & specificity of 100% (Fig.14).

Figure 14: Receiver Operating Curve Analysis of LRINEC scores :-

a) **LRINEC score ≤5**



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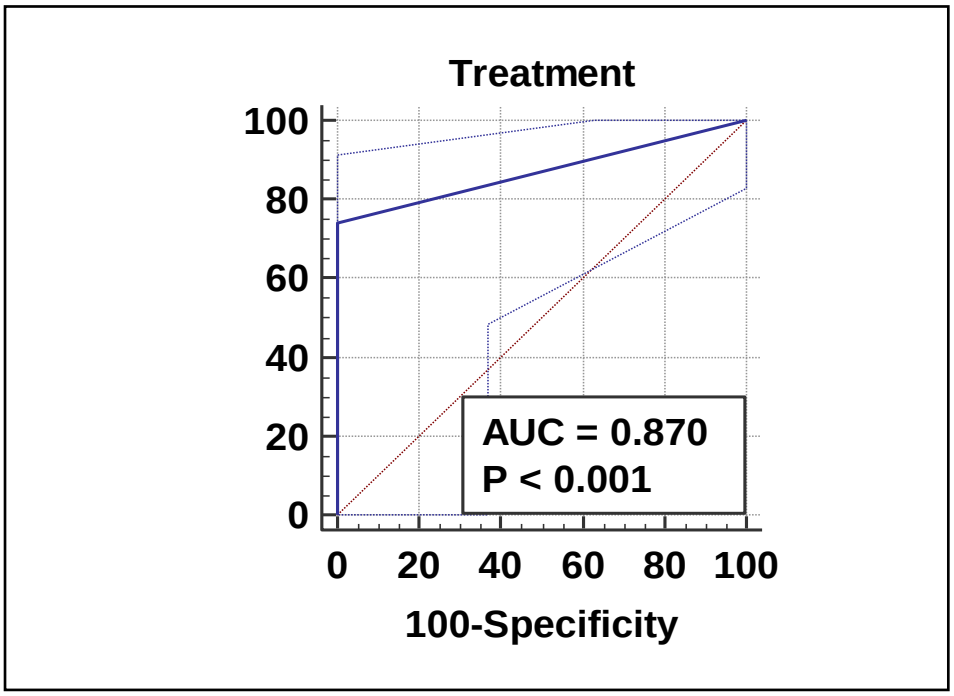
b) LRINEC score 6-7



c) LRINEC score ≥8

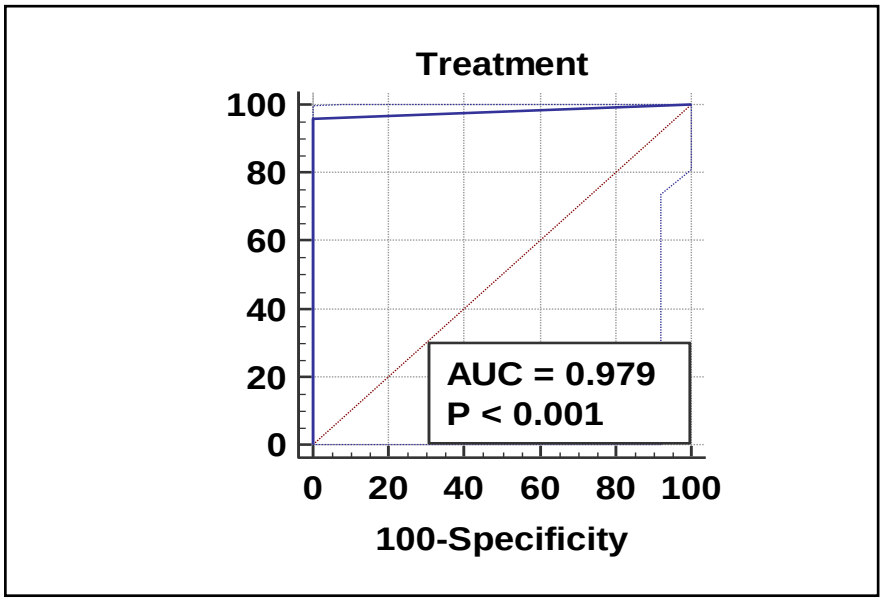


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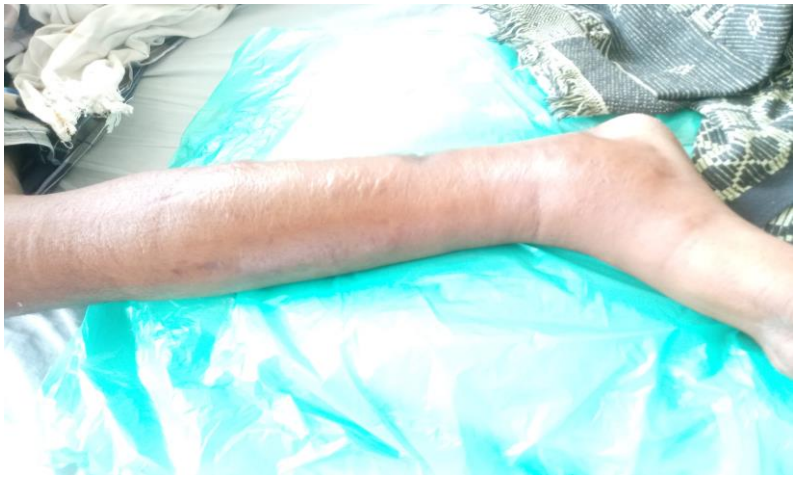
Figure No. 15:- Intermediate risk group patient with cellulitis of Right lower limb managed conservatively.



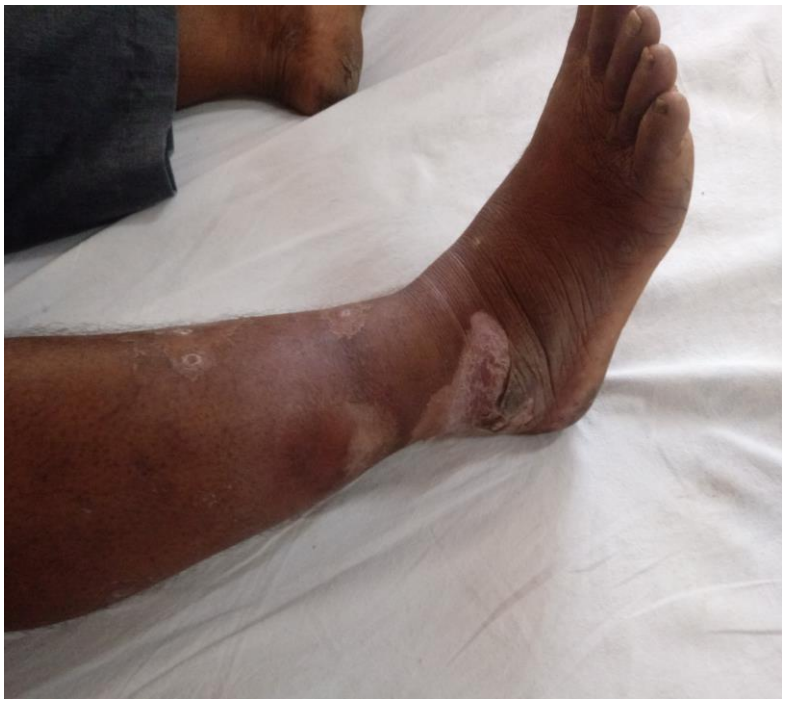


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Figure 16:- Patient with soft tissue infection underwent Fasciotomy over posterior aspect of Right thigh

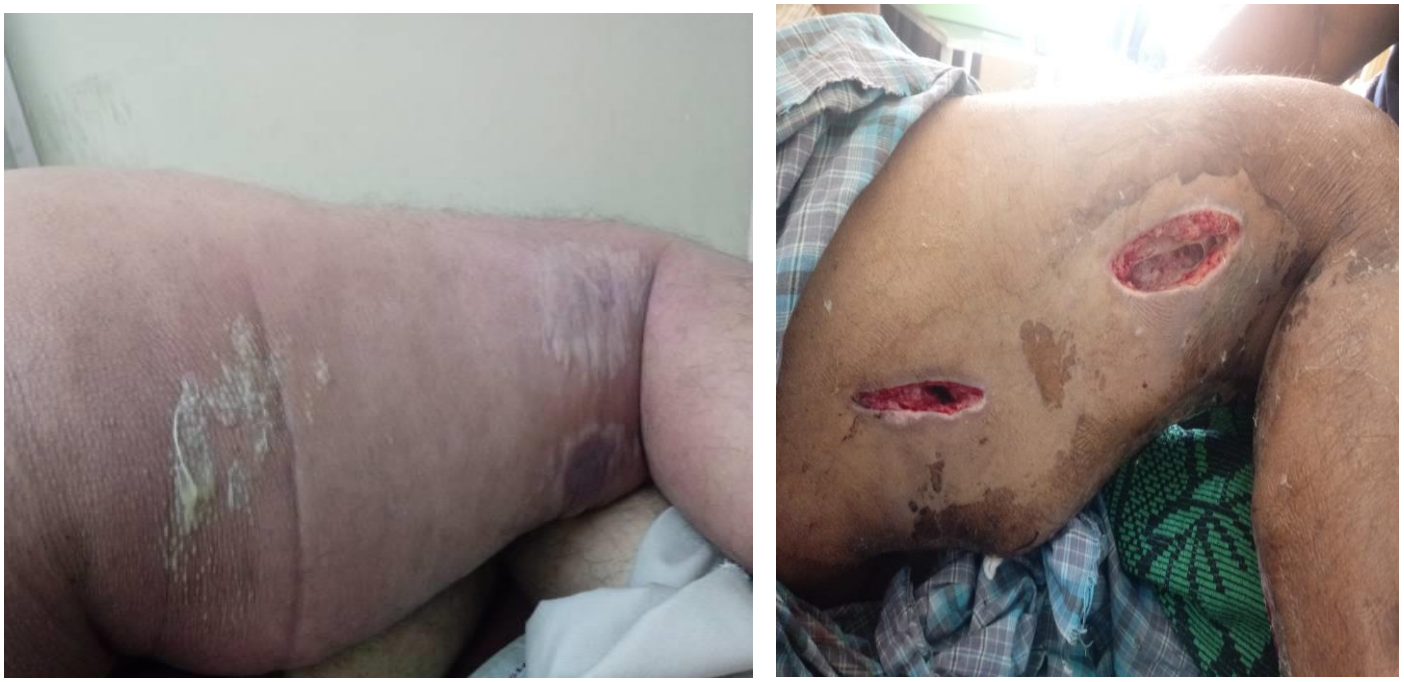

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Figure 17:- Cellulitis of Right leg managed conservatively.

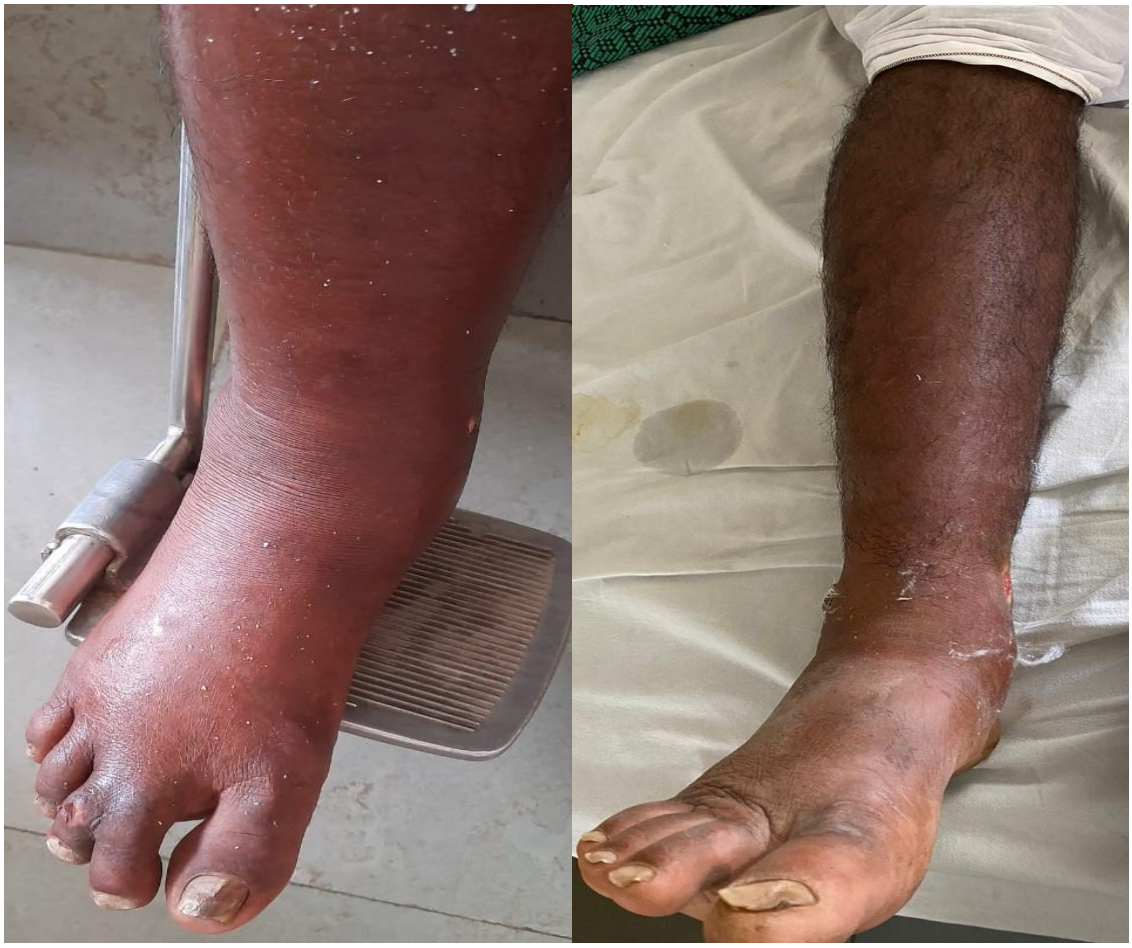

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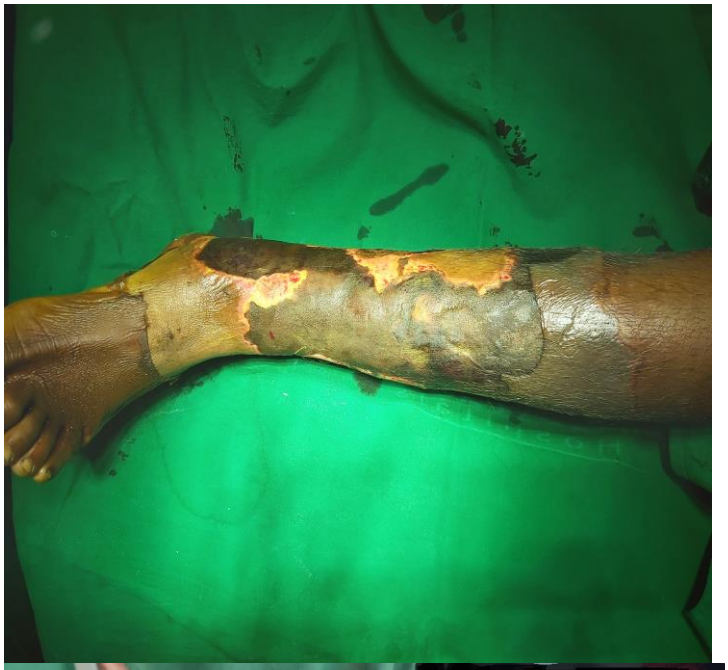
Figure 18:- NSTI OF LEFT LEG



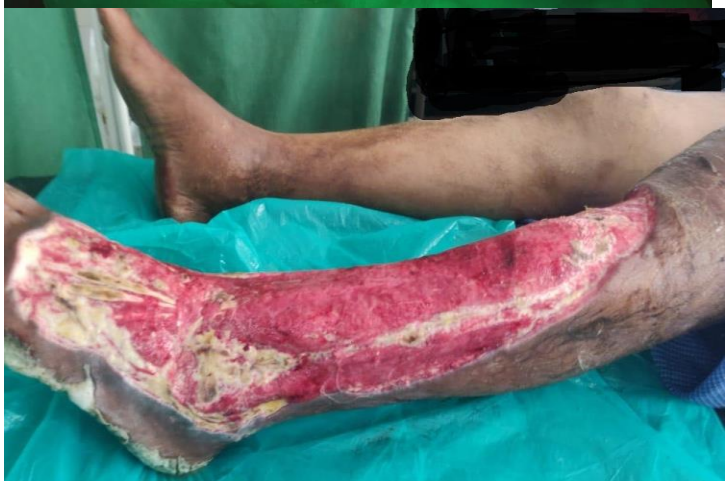


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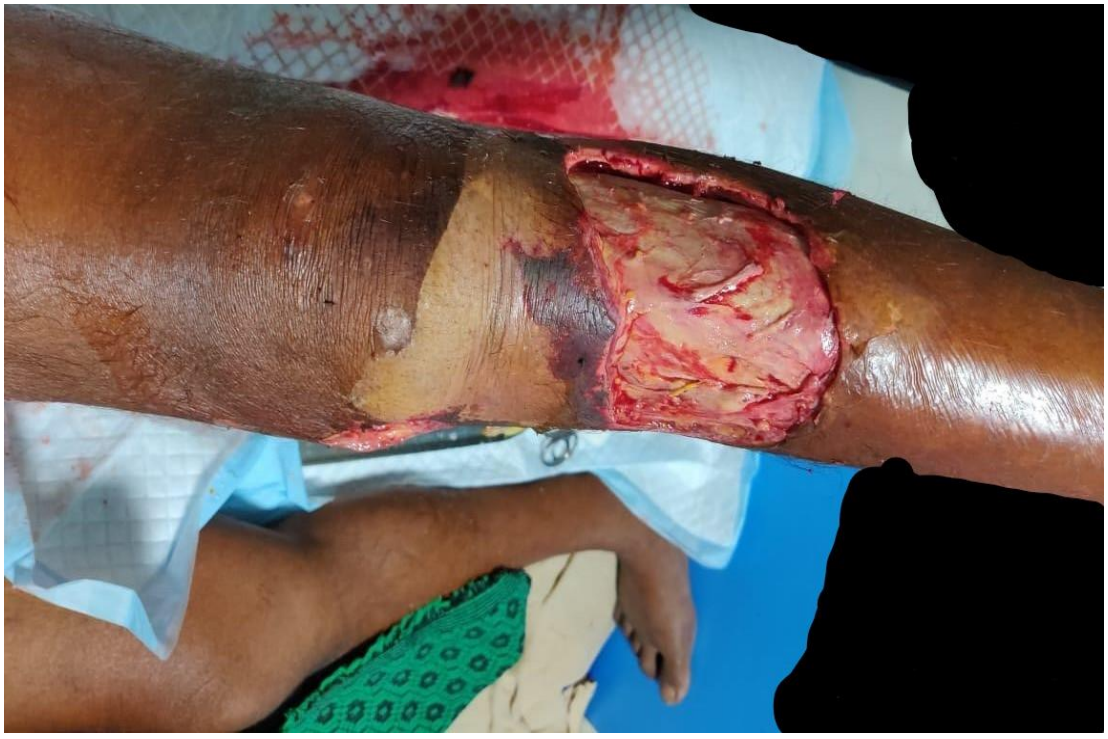
Figure 19:- NSTI of left leg



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5) DISCUSSION

Necrotizing Fasciitis are common life threatening soft tissue infection characterized by a fulminant course and a high mortality rate[41]. The early clinical recognition of Necrotizing fasciitis is difficult due to its indistinguishable features. The LRINEC can categorize patients with soft tissue infections into Necrotizing and Non-Necrotizing Soft Tissue Infections. Compared with Non-Necrotic soft tissue infection, the incidence of necrotic soft tissue infection and severe sepsis is higher. The LRINEC score can predict the presence of Necrotizing Fasciitis based on the severity of sepsis, and ultimately contribute to the early identification and treatment of Necrotizing Fasciitis. Few studies have been done correlating LRINEC score with the clinical features of Necrotizing Fasciitis and using it in the early surgical management of this lethal entity. Present study design was simple and results comparable with other studies conducted earlier.

Majority of the patients in present study were in the age group of 60 – 69 years (20.6%) with a mean age of 53.34 ± 16.40 years. The earlier study also reported the mean age of 56 years which was comparable to the present study. Another study reported that patients mean age was 56.8±15.7. The present study mean age was also almost near to the reported studies[42,43].

The male patients (73.3%) were predominant in the present study. The male: female ratio might be around 3:1. The current study outcome was similar to that reported by Wall et al(2000). Anaya et al(2005) concluded that male to female ratio

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was found to be 3:2. However, the two research conclusions are consistent with the results of this research. The reason for this advantage may be due to the increased prevalence of influencing factors such as smoking, drinking alcohol and lower limb trauma in men.[44,45]

The study by Yi-Chun Su et al,[43] stated in his study that diabetes mellitus was the commonest comorbidity among the study participants. The similar findings were observed in the present study also. In the present study, 21.66 % of patients had DM as their comorbidity.

It has been suggested that the LRINEC score is capable of detecting early cases of necrotizing fasciitis among patients with severe soft tissue infections. Wong *et al*.(2004) 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[6] . The similar observation has been made in the present study also. It is important to adopt evidence-based methods to diagnose necrotizing fasciitis, which may lead to early diagnosis, surgical intervention, and improvement of morbidity and mortality. The average LRINEC score reported in an earlier study[46] was 6.06, which exceeded the threshold of 6 reported by Wong et al[6] . However, in this study, the average score of LRINEC was 4.47.

Patients with a LRINEC score <6 respond well to the expected treatment and have a shorter hospital stay. A score between 6 and 10 requires active and continuous debridement and a longer hospital stay[47]. Similar results were observed in this study,

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that is, ≤5 responds well to conservative treatment, and LRINEC score ≥6 requires surgical intervention, as previously reported[47].

The retrospective validation and meta-analysis studies have shown conflicting results about the accuracy of the LRINEC score. Liao et al.[48] (2012) conducted largest retrospective study (NF group: 233, severe cellulitis group: 1394) showed that the Area under ROC curve of the NF LRINEC score was only moderately 0.779. Neeki et al.[49](2017) done a second largest retrospective (NF group: 47, severe cellulitis group: 948) indicated that the specificity of LRINEC score ≥ 6 was 89% and the sensitivity was 36%, which was lower than ours result (sensitivity ≥ 75%, specificity 100%). A recent meta-analysis also found that the sensitivity of LRINEC score ≥ 6 was 68.2%, and the specificity was 84.8%,[50] which is close to the results of this study.

However, some studies report that the LRINEC score is a useful clinical tool for the diagnosis of NF[51,52]. A report retrospectively verified the LRINEC score. The Area under ROC was 0.925, the specificity was 93.1% and the sensitivity was 76.3%. According to the LRINEC value ≥6, the positive and negative predictive values for distinguishing NF from severe cellulitis were respectively 95.5% and 88.1%[51]. The same outcome was also observed in this study. The conclusion is that LRINEC score is a useful and powerful scoring system, which can be used as an auxiliary means for early diagnosis of NF. A meta-analysis included 16 studies of 846 patients with an Area under ROC of 0.925[46]. This study showed that the LRINEC score is an effective clinical determinant of NF. Although these retrospective validation and meta-analysis

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studies have reached conflicting conclusions, our prospective validation results indicate that the accuracy of the LRINEC score is moderate, and LRINEC may be an accurate tool for NF risk stratification based on our research.

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SUMMARY:-

This is a Prospective Observational study of 180 patients presented to our hospital with soft tissue infections during the period November 2018 to June 2020. Patients were stratified into three groups – Low (≥5), Intermediate (6-7) & High risk (≤8) groups based on LRINEC Score.

In the present study, 60-69 years age group was predominant (20.6 %). Majority were the male patients (73.3%) in the study. Two factors, i.e. Diabetes Mellitus, Hypertension were considered co morbidity in the study. Out of which, Diabetes Mellitus is the major co morbidity observed in the patients (21.66 %). Age of the total patients were compared with LRINEC score using Spearman's correlation coefficient and found non-significant (P=0.182).

Based on LRINEC score, 115 (63.9%) patients are of ≤ 5 score, 39 (21.7%) patients of 6-7 score and 26 (14.4%) patients of ≥ 8 score. Treatment modality was grouped into conservative management and surgical management. The major treatment modality of the present study was conservative treatment (68.3%). Except low risk group, both intermediate and high risk group had surgical intervention predominantly.

Among patients grouped under ≤5 LRINEC score (115), 4 (3.5%) patients underwent surgery (debridement, fasciotomy), as these patients progressed to moderate risk upon serial recordings on Day 3 or 4. Patients grouped under 6-7 LRINEC score (i,e. 39), 12(30.8%) patients were managed conservatively.

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Mann Whitney U test was used to compare the treatment modalities and found statistical significance. The mean ±SD of surgical intervention was lower than conservative management in our study.

Diagnostic accuracy of LRINEC score and ROC analysis of three groups were compared. The LRINEC score of two groups (6-7 & ≥8) showed significant diagnostic accuracy. Moderate risk group (LRINEC score 6-7) has moderate sensitivity and 100% specificity. High risk group (LRINEC score ≥8) has higher sensitivity (95.83 %) and specificity (100 %). Low risk group has higher sensitivity (100%).

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CONCLUSION:-

Necrotizing Fasciitis is the common life threatening problem among patients with soft tissue infections. Early recognition of NSTI is difficult due to indistinguishable features. Most of the surgeons are in dilemma, whether to manage patient conservatively or debridement. Often leads to surgical intervention in cellulitis patients or delayed recognition of NSTI, which leads to higher mortality and economic burden to the patients. The LRINEC score is a simple useful tool for clinical diagnosis of Necrotizing Fasciitis from other soft tissue infections. The INTERMEDIATE Risk category group patients mostly come under this dilemma whether to manage conservatively or surgically. Our study showed that those patients can be managed conservatively too, avoiding surgical intervention. Our study has a statistically positive correlation and diagnostic accuracy specifically the LRINEC score ≥6. And more specificity for LRINEC score 6-7. Due to its availability, ease of use and cost effectiveness, it is recommended as part of an overall approach in early diagnosis of NSTI from other soft tissue infections.

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ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

B.L.D.E (Deemed to be University)
SHRI.B.M.PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE
VIJAYAPUR – 586103

IEC/No: 286/2018
17-11-2018

INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 13-11-2018 at 03-15 PM scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.

Title : The study effectiveness of LRINEC (Laboratory risk indicator for Necrotizing Fasciitis) scoring system in the early diagnosis of Necrotizing Fasciitis among patients presenting with soft tissue infections.

Name of P.G. Student : Dr Seggam Sindhura Department of General Surgery

Name of Guide/Co-investigator: Dr M B Patil, Professor of Surgery

DR RAGHAVENDRA KULKARNI
CHAIRMAN
Institutional Ethical Committee
BLDE(U)'s Shri B.M. Patil
Medical College, BIJAPUR-586103.

Following documents were placed before E.C. for Scrutinization:

1) Copy of Synopsis/Research Project
2) Copy of informed consent form.
3) Any other relevant documents.

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ANNEXURE II

SAMPLE INFORMED CONSENT FORM

B.L.D.E (D.U)'s SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE, VIJAYAPUR – 586103, KARNATAKA.

TITLE OF THE PROJECT:

To study effectiveness of Modified LRINEC (Laboratory risk indicator for necrotizing Fasciitis) scoring system in the diagnosis of Necrotizing Fasciitis among patients presenting with soft tissue infections.

PRINCIPAL INVESTEGATOR: **DR .SEGGAM SINDHURA**
Department of General Surgery
Email:- seggam.sindhura@gmail.com

PG GUIDE: **DR. M.B.PATIL MS**
Professor of Surgery
B.L.D.E. Deemed to be University's
Shri B.M. Patil Medical College & Research Centre, Sholapur Road, Vijayapur 586103

PURPOSE OF RESEARCH:

I have been informed that this study will analyze the Effectiveness of Modified LRINEC score system in diagnosis of Necrotizing Fasciitis from other Soft tisue infections.

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study

PROCEDURE:

I understand that relevant history will be taken. I will undergo detailed clinical examination after which necessary investigations will be done whenever required, which would help the investigator for appropriate management.

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RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain and discomfort during the examination or during my treatment. This is mainly the result of my condition and the procedure of this study is not expected to exaggerate these feelings which are associated with the usual course of treatment.

BENEFITS:

I understand that I/my wards participation in this study will help to analyse the effectiveness of Modified LRINEC scoring system in diagnosis of necrotizing Fasciitis from other Soft tissue infections.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this Hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. DR.SEGGAM SINDHURA is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form will be given to me for careful reading.

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REFUSAL OR WITHDRAWL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that DR SEGGAM SINDHURA will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate .**INJURY STATEMENT:**

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Dr. M.B.PATIL	Dr .SEGGAM SINDHURA
(Guide)	(Investigator)

DocuSign Envelope ID: B9BE6D33-194C-4AB4-91B8-9796BA1B02F1

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. SEGGAM SINDHURA has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

(Participant) Date

(Witness to above signature) Date

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ANNEXURE III

PROFORMA

CASE NO:

1. Name : IP No :
2. Age/sex: DOA:
3. Occupation:
4. Address: DOD:
5. CHIEF COMPLAINTS:

- Mode Of Onset
- Duration
- Number
- Site
- Size and Extent
- Associated Pain
- Discharge
- Others
- Any Associated Disease
- Past history of Similar Wound

PAST HISTORY:

- Diabetes Mellitus
- Hypertension
- HIV
- Any other chronic illness

PERSONAL HISTORY:

- Diet
- Sleep

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- Appetite
- Bowel & bladder
- Habits

FAMILY HISTORY :-

7. GENERAL PHYSICAL EXAMINATION:

- Mental Status
- Built
- Nourishment
- Pallor
- Icterus
- Cyanosis
- Clubbing
- Edema

VITAL SIGNS:-

- Pulse Rate
- Blood Pressure
- Respiration
- Temperature
- Any Obvious Deformity

A. LOCAL EXAMINATION :

INSPECTION-

- SITE
- NUMBER
- SIZE
- SHAPE
- DISCHARGE:

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- Amount
- Character
- Odour

- ADJACENT AREA:
  - Any Swelling
  - Any Skin Change
  - Any Secondary Changes
- LIMB EXMANINATION:
  - Peripheral Pulsations
  - Lymph nodes

PALPATION:

- TEMPERATURE
- TENDERNESS
- SIZE
- BLEEDING
- RELATION WITH DEEPER STRUCTURES
- SURROUNDING STRUCTURE

B. EXAMINATION OF LYMPH NODES

SYSTEMIC EXAMINATION:-

1. **ABDOMEN EXAMINATION -**
2. **RESPIRATORY SYSTEM-**
3. **CARDIOVASCULAR SYSTEM-**

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4. **CENTRAL NERVOUS SYSTEM-**

DIAGNOSIS:-

INVESTIGATIONS:

1. Hemoglobin (g/dl) : >13.5 11-13.5 <11
2. White Blood Cell Count (Cells/cmm) : <15,000 15,000-25,0000 >25,000
3. Blood Glucose (mg/dl) : <180 >180
4. Serum Creatinine (mg/dl) : <1.58 >1.58
5. Serum Sodium (mmol/l) : >135 <135
6. C-Reactive Protein (mg/l) : <150 >150

Total Score:-

0(MIN) - 13(MAX)

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Key to MASTER CHART:-

S no. – Serial Number

Ip no. – In Patient Number

M- Male, F- Female

DM- Diabetes Mellitus

HTN- Hypertension

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MASTER CHART

S no	name	age	sex	ip no	score	DM - II	HTN	TREATMENT	Column1
1.	SUDHARANI	29	F	29914	1			CONSERVATIVE	
2.	NANAGOUDA	55	M	30528	5	YES		CONSERVATIVE	
3.	BANDAWWA	80	F	30528	7	YES		SURGICAL	
4.	SAIFANASAB	75	M	30550	7	YES		CONSERVATIVE	
5.	SANGOUDAPPA	80	M	31372	5			CONSERVATIVE	
6.	SHANKREPPA	72	M	31578	1			CONSERVATIVE	
7.	GANAPATHI	62	M	33175	7	YES		SURGICAL	
8.	SADUSAB	55	M	33204	3			CONSERVATIVE	
9.	SHANTABAI	35	F	32854	1			CONSERVATIVE	
10.	MOULAALI	58	M	31386	3			CONSERVATIVE	
11.	MAHANANDI	22	F	32733	1			CONSERVATIVE	
12.	ASHOK	36	M	39800	9			CONSERVATIVE	
13.	MAYAPPA	48	M	42904	5			CONSERVATIVE	
14.	BASAPPA	35	M	37529	3			CONSERVATIVE	
15.	SHIVALINGAPPA	72	M	41378	6			SURGICAL	
16.	SAVITRI	20	F	3950	5			SURGICAL	
17.	BASAPPA	48	M	37529	3			CONSERVATIVE	
18.	SHRISHAIL	45	M	38447	4	YES		CONSERVATIVE	
19.	NINGAPPA	64	M	353	5			CONSERVATIVE	
20.	MALLESH	32	M	492	7			SURGICAL	
21.	NAGAPPA	38	M	11338	2			CONSERVATIVE	
22.	MALLANNA	45	M	12911	3			CONSERVATIVE	
23.	CHANDAMMA	80	F	10189	4			CONSERVATIVE	
24.	GANGADHAR	28	M	1122	4			CONSERVATIVE	
25.	BASAVRAJ	45	M	12901	4			CONSERVATIVE	
26.	KUMAR	38	M	16953	5	YES		CONSERVATIVE	DEBRIDEMENT
27.	ANUSHAYA	40	F	40437	5			CONSERVATIVE	
28.	AMARAPPA	30	M	32612	3			CONSERVATIVE	
29.	MADIVALAPPA	40	M	32368	2			CONSERVATIVE	
30.	CHANBASAWWA	80	F	14895	2			CONSERVATIVE	
31.	SUBHASH CHANDRA	46	M	17170	8			DEBRIDEMENT	
32.	KALAWATI	30	F	15658	2			CONSERVATIVE	
33.	UDAY	60	M	18765	3			CONSERVATIVE	
34.	UMESH	41	M	19439	9			DEBRIDEMENT	
35.	NANDABASU	60	M	15955	2			CONSERVATIVE	
36.	GANGAYYA	70	M	27167	8			DEBRIDEMENT	
37.	VALUBAI	45	F	30072	2		YES	CONSERVATIVE	
38.	SAYAWWA	92	F	30037	10		YES	DEBRIDEMENT	

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39.	DAYANAND SHIVAPPA	44	M	9873	5			CONSERVATIVE
40.	MALAPPA	45	M	17970	4			CONSERVATIVE
41.	TUKARAM	32	M	30870	4			CONSERVATIVE
42.	PRAKASH	62	M	18824	2			CONSERVATIVE
43.	SHANTABAI	60	F	26719	7	YES		DEBRIDEMENT
44.	JATEPPA	65	M	20425	2			CONSERVATIVE
45.	DHANASINGH	50	M	30235	3			CONSERVATIVE
46.	TUKARAM	55	M	28670	2			CONSERVATIVE
47.	DEVIBAI	85	F	26015	8	YES		DEBRIDEMENT
48.	CHANDRASHEKHAR	51	M	27337	7			DEBRIDEMENT
49.	MALAPPA	35	M	26399	6			DEBRIDEMENT
50.	UMESH	31	M	11585	3			CONSERVATIVE
51.	GURANNA	65	M	22521	6			DEBRIDEMENT
52.	KALAPPA	60	M	37889	2			CONSERVATIVE
53.	BAPU MANE	55	M	39981	6			FASCIOTOMY
54.	SHARANAYYA	55	M	39942	1			CONSERVATIVE
55.	BHIMANNA	66	M	33877	2			CONSERVATIVE
56.	SHANKREPPA KASAPPA	72	M	35216	3			CONSERVATIVE
57.	MALLAPPA SIDDAPPA	50	M	33797	2			CONSERVATIVE
58.	IRAMMA	40	F	39800	2			CONSERVATIVE
59.	RENUKA	38	F	2004	2			CONSERVATIVE
60.	NAGESH KALAL	45	M	17003	8			DEBRIDEMENT
61.	BASANAGOUDA	48	M	16326	2			CONSERVATIVE
62.	MALLAPA N	50	M	15267	2			CONSERVATIVE
63.	VIJAYSHANKAR	72	M	13438	3			CONSERVATIVE
64.	SHANKARAYYA	54	M	13322	3			CONSERVATIVE
65.	PUTALABAI	70	F	16738	2			CONSERVATIVE
66.	BASAPPA DHANAPPOL	60	M	36967	3	YES		CONSERVATIVE
67.	SIDDARAM SUTAR	55	M	40813	5	YES		CONSERVATIVE
68.	BASAVANTAPPA	64	M	14615	2			CONSERVATIVE
69.	VALUBAI PAWAR	45	F	30072	9			DEBRIDEMENT
70.	SHANTABAI RATHOD	60	F	26719	3			CONSERVATIVE
71.	LACHAPPA GUDIA	70	M	31762	10			FASCIOTOMY
72.	SHANTABAI BHAVI	85	F	1905	1			CONSERVATIVE
73.	PARVATI	56	F	1286	2			CONSERVATIVE

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	KONADI							
74.	RAGVENDRA MORE	38	M	7380	7	YES	YES	CONSERVATIVE
75.	PANDU RATHOD	68	M	30157	7			DEBRIDEMENT
76.	SHARANGOWDA	68	M	29744	2		YES	CONSERVATIVE
77.	GURULINGAPPA TALWAR	70	M	28837	5	YES		CONSERVATIVE
78.	ALLABASHA	35	M	27239	2			CONSERVATIVE
79.	YOUNUS PATEL	38	M	26275	5	YES		CONSERVATIVE
80.	SHANKARGOWDA	65	M	24277	8			DEBRIDEMENT
81.	RAJSHEKARWALI	38	M	796	1			CONSERVATIVE
82.	MASTANSAB	50	M	12985	2			CONSERVATIVE
83.	BALRAM DASAR	33	M	12662	2			CONSERVATIVE
84.	BAGAMMA BIRADAR	45	F	9536	2			CONSERVATIVE
85.	VIJAY BIRADAR	30	M	11187	6	YES		DEBRIDEMENT
86.	RAMCHANDRA	55	M	10757	8			DEBRIDEMENT
87.	SIDDU BHOSLE	35	M	9061	6		YES	DEBRIDEMENT
88.	RENUKA	30	F	15451	0			CONSERVATIVE
89.	MALLAPPA SINDAGI	45	M	15742	4		YES	CONSERVATIVE
90.	SHANKARAPPA	52	M	14939	1			CONSERVATIVE
91.	BIMANNNA BIRADAR	45	M	41678	7			FASCIOTOMY
92.	GOPAL TUGAR	32	M	40018	7	YES	YES	DEBRIDEMENT
93.	RAFIQ MULLA	56	M	3580	1			CONSERVATIVE
94.	SADASHIV MANE	47	M	3565	1			CONSERVATIVE
95.	BHIMANNA GUJJAR	58	M	1319	1			CONSERVATIVE
96.	GANGAWAR	70	F	32238	2			CONSERVATIVE
97.	JAIBUNBEE	55	F	42393	7		YES	DEBRIDEMENT
98.	LALSAB NODAY	61	M	33336	2			CONSERVATIVE
99.	IRANNA	60	M	39800	4	YES		CONSERVATIVE
100.	NORAHMED	52	M	12767	2	YES	YES	CONSERVATIVE
101.	HEMAYYA HIRRANATH	80	M	13096	3	YES		CONSERVATIVE
102.	VIJAYA CHAWAN	72	F	13438	4			CONSERVATIVE
103.	HANUMANTH MADAR	80	M	14363	5			CONSERVATIVE
104.	DANAPPA	70	M	37828	2			CONSERVATIVE

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	KAMBALE							
105.	KALAPPA BADIGER	60	M	37889	6	YES	YES	DEBRIDEMENT
106.	BASAYYA HIREMANTH	75	M	40633	3			CONSERVATIVE
107.	REBAWATI	65	F	11724	2			CONSERVATIVE
108.	SOPANNA SAGAR	58	M	40973	1			CONSERVATIVE
109.	SANDEEP MORE	40	M	43134	3	YES		CONSERVATIVE
110.	HANUMANTH PUJARI	62	M	43328	4	YES		CONSERVATIVE
111.	PARSHURAM	48	M	32607	1			CONSERVATIVE
112.	BAPPU GOWDA	65	M	10507	5	YES		CONSERVATIVE
113.	BHIMAJI CHAWAN	36	M	12617	2			CONSERVATIVE
114.	PARWATI	60	F	317	3		YES	CONSERVATIVE
115.	SHANKARAYYA	54	M	13322	6			FASCIOTOMY
116.	GURUBASAPPA	60	M	10566	3			CONSERVATIVE
117.	SIDDAMMA	71	F	5031	7	YES	YES	DEBRIDEMENT
118.	SANKALP UPPAR	18	M	43652	8			DEBRIDEMENT
119.	SHIWAPPA	61	M	40481	2			CONSERVATIVE
120.	CHAITRA	38	F	14435	3		YES	AMPUTATION
121.	BASAVARAJ	35	M	15656	2			SURGICAL
122.	SRIPAL	23	M	14069	8	YES		SURGICAL
123.	MAYURI	24	F	15771	1			CONSERVATIVE
124.	SANJEEVAPPA BEVORR	50	M	4141	4	YES		DEBRIDEMENT
125.	UMESH VATHAR	31	M	8896	6			DEBRIDEMENT
126.	DODAPPA HANGREDI	57	M	1938	6	YES	YES	DEBRIDEMENT
127.	UMESH VATHAR	36	M	8868	2			CONSERVATIVE
128.	CHNAYYA GARACHAN	70	M	8256	1			CONSERVATIVE
129.	NINGANAGOU DA PATIL	60	M	8054	6			DEBRIDEMENT
130.	RAJASHEKAR SAJJAN	45	M	131	2			CONSERVATIVE
131.	ROOPLABAI RATHOD	80	F	8970	9	YES	YES	DEBRIDEMENT
132.	SHANKREPPA GANIGER	55	M	3592	7		YES	DEBRIDEMENT
133.	BASALINGAM	45	F	23612	6	YES		CONSERVATIVE

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	MA YALLAWAR								
134.	BASAVANTAPPA KENGANAL	64	M	14615	8		YES	DEBRIDEMENT	DEBRIDEMENT
135.	MALLAPA MASALI	60	M	13051	5			CONSERVATIVE	
136.	SHAMRAO GADYAL	75	M	8989	7			CONSERVATIVE	
137.	RAGHAVENDRA MORE	38	M	7360	4			CONSERVATIVE	
138.	BANDENAMAZ	38	M	32324	3			CONSERVATIVE	
139.	KALPANA	25	F	32438	4			CONSERVATIVE	
140.	GADIGEPPA	41	M	32893	5	YES		CONSERVATIVE	
141.	ASHOK	80	M	34286	2			CONSERVATIVE	
142.	PURUSHOTTHAM	66	M	34294	4		YES	CONSERVATIVE	
143.	SHANTAYYA	56	M	34762	3			CONSERVATIVE	
144.	GANGABAI	70	F	37247	6			CONSERVATIVE	
145.	SHRIKANTH	55	M	37303	7			CONSERVATIVE	
146.	HANUMANTHRAYA	30	M	42301	8			DEBRIDEMENT	
147.	SUMEDHA	30	F	43117	9	YES		DEBRIDEMENT	
148.	KALLAPPA	77	M	3287	6		YES	CONSERVATIVE	
149.	BOURAMMA	26	F	5206	3			CONSERVATIVE	
150.	NAGAPPA	55	M	5839	9	YES	YES	DEBRIDEMENT	
151.	SHRIMANTH	60	M	7823	10	YES		DEBRIDEMENT	
152.	SURAKSHA	25	F	12342	5		YES	CONSERVATIVE	
153.	basappa dhareooagol	60	M	36937	6			CONSERVATIVE	
154.	RAMAPPA	35	M	36984	7			DEBRIDEMENT	
155.	SUVARNA TELI	46	F	37715	4			CONSERVATIVE	
156.	SHIVARAJ KARDE	26	M	40565	3			CONSERVATIVE	
157.	SUSHMA PATIL	34	F	40792	4	YES		CONSERVATIVE	
158.	SIDDARAM SUTAR	55	M	40813	6			CONSERVATIVE	
159.	NEELAVVA DINNI	75	F	27921	7			DEBRIDEMENT	
160.	BASAVARAJ MUDAGAL	62	M	27305	7		YES	DEBRIDEMENT	
161.	KONTEWWA WAGMORE	65	F	26948	8			DEBRIDEMENT	
162.	JAKKAWWA	70	F	26405	9			DEBRIDEMENT	
163.	CHANDRABHAGA AWAJI	91	F	25560	2		YES	CONSERVATIVE	
164.	REVABAI SHAPETI	70	F	25298	2			CONSERVATIVE	
165.	KASAVVA	80	F	25067	2			CONSERVATIVE	

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	BALAGANUR								
166.	SHIVAPPA MASHABINAL	60	M	25050	5	YES		CONSERVATIVE	
167.	MANAPPA CHAVAN	55	M	24907	6			DEBRIDEMENT	DEBRIDEMENT
168.	MALASIDDA ANSHETTI	72	M	24790	3			CONSERVATIVE	
169.	GURAPPA BALWANDGI	70	M	24242	4			CONSERVATIVE	
170.	CHANDRAMMA KALYANI	50	F	24073	6			DEBRIDEMENT	
171.	LAXMAN PAWAR	75	M	3655	7	YES		CONSERVATIVE	
172.	NEELAMMA CHOWDARI	80	F	22934	8			DEBRIDEMENT	DEBRIDEMENT
173.	GURANNA YALAGOND	65	M	22638	8			DEBRIDEMENT	
174.	FAKIRAPPA KUMBAR	49	M	22521	9	YES		DEBRIDEMENT	
175.	SHIVAMURTHY MATH	60	M	20654	9	YES	YES	DEBRIDEMENT	
176.	RAMJI CHAVAN	50	M	19771	9	YES		DEBRIDEMENT	
177.	SUBHASH AWATI	47	M	19574	4			CONSERVATIVE	
178.	MALAMMA HADIMANI	65	F	19475	7	YES		DEBRIDEMENT	
179.	GYANAPPA KANSERI	35	M	18163	7			CONSERVATIVE	
180.	MAHATESH BIDARAKUNDI	33	M	404	3			CONSERVATIVE	