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Original Article

Surgery Section

Clinical and Bacteriological Profile of Necrotising Fasciitis at a Tertiary Care Hospital, New Delhi: An Observational Study

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ABSTRACT

Introduction: Necrotising Soft Tissue Infection (NSTI) is a rapidly progressing infection characterised by extensive necrosis and widespread destruction of the soft tissues located anywhere from the superficial epidermis of the skin to the deep musculature.

Aim: To explore the clinical characteristics and identify the bacterial agents responsible for Necrotising Fasciitis (NF).

Materials and Methods: The present observational study was conducted in the Department of Surgery, University College of Medical Sciences and Guru Teg Bahadur (GTB) Hospital, New Delhi, India, from November 2017 to April 2019, involving 77 NF patients. The clinical characteristics and identification of bacterial agents were achieved by analysing clinical specimens from cases clinically diagnosed with NF. The antibiotic resistance patterns of these bacterial isolates were also determined. Data was recorded in an Excel worksheet, and statistical analysis was conducted using Statistical Package for Social Sciences (SPSS) software version 21.0.

Results: Total of 77 patients were included, among which 62 (80.5%) were males and 15 (19.4%) were females with the mean±Standard Deviation (SD) age 43.96±19.3 years. The most common bacteria isolated were *Escherichia coli*, 20 (25.3%). *Staphylococcus aureus* was isolated in nine patients, and of them, six were Methicillin-resistant *Staphylococcus Aureus* (MRSA).

Conclusion: Early detection of NF, a severe infectious condition, can significantly reduce morbidity and mortality. The findings underscore the critical need for early diagnosis and treatment due to significant mortality rates.

Keywords: Bacterial agents, Clinical pattern, Methicillin-resistant *Staphylococcus aureus*

INTRODUCTION

The Necrotising Soft Tissue Infection (NSTI) is a rapidly progressing infection characterised by extensive necrosis and widespread destruction of the soft tissues located anywhere from the superficial epidermis of the skin up to the deep musculature [1,2]. Despite timely complete debridement, broad-spectrum antibiotics and a multidisciplinary critical care approach, mortality in NSTI patients remains high [1-3]. The lack of adequately randomised studies has led to most of the current standard of care recommendations for the management of NSTI patients being based on retrospective studies [4].

Understanding NF disease's manifestation and progression is a significantly challenging task for the treating surgeon. The severity of the disease can vary, from minor skin necrosis to severe infections that can affect a limb or even a patient's life. The onset of symptoms can be rapid, and the progression of the disease is often erratic and difficult to predict [5-7].

The most reported risk factors associated with NSTI are Diabetes Mellitus (DM), peripheral vascular disease, chronic pulmonary diseases, chronic liver disease, chronic renal failure, heart failure, immunocompromised conditions like Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS), intravenous drug abuse, chronic alcoholism and malignancy [4-10]. Nevertheless, NF can also arise in healthy adults, typically triggered by some kind of injury or trauma [11,12].

The NSTI is categorised into various subtypes according to the specific types of microbes involved. Type I NSTI is an infection comprising both aerobic and anaerobic microorganisms [12]. Although certain studies indicate it as the predominant type, constituting nearly 80% of all NSTIs, other research suggests its occurrence is around 30-50% [13-16].

Early diagnosis, surgical intervention combined with the administration of appropriate antibiotics, is the cornerstone of this treatment. Prognosis depends on the initiation of appropriate antibiotic treatment. The present study aimed to explore the clinical characteristics and identify the bacterial agents responsible for NF.

MATERIAL AND METHODS

The present observational study was conducted in the Department of Surgery, University College of Medical Sciences and Guru Teg Bahadur (GTB) Hospital, New Delhi, India, from November 2017 to April 2019. Institutional Ethical Committee clearance (IEC/HR/017/32/58) and informed consent from patients were obtained. The study population included all consecutive patients who presented to units I and IV of the Department of Surgery and were diagnosed with NF.

Sample size calculation: Based on a previous study conducted by Chen IC et al., considering the most prevalent organism (21.4%)-gram positive cocci Methicillin susceptible *Staphylococcus aureus* (*S. aureus*), among single etiological agents from wound culture, the sample size was calculated to be around 67 at a 95% Confidence Interval (CI) with an absolute precision of 10%. The final sample size in the study was 77 [17]. Simple random sampling technique was used for the recruitment of participants.

Inclusion criteria: Patients of all ages, regardless of gender, admitted to the hospital with a clinical or surgical diagnosis of NF were include in the study. Patients or their guardians (in the case of minors or incapacitated individuals) who gave informed consent for participation and patients from whom clinical specimens (e.g., tissue samples, swabs) for bacteriological analysis can be obtained were also included in the study.

Exclusion criteria: Patients with conditions that mimic NF but are diagnosed with other diseases (e.g., cellulitis, gas gangrene) and patients who have received extensive antibiotic treatment before sample collection, as this might affect bacteriological findings were

excluded from the study. Patients who have had recent surgery at the site of infection, unless the study specifically aims to include postsurgical cases, were also excluded from the study.

Study Procedure

The patients were admitted and after obtaining informed consent, a detailed case proforma was completed, including various demographic and clinical features. Demographic parameters such as age, gender, occupation and Socio-economic Status (SES) were recorded. SES was assessed using the Modified Kuppuswamy classification [18]. History of various co-morbid conditions, history of smoking, alcoholism, intravenous or any other form of drug abuse, history of long-term steroid intake or any immunosuppressant drug intake were documented. At the time of presentation, height, weight, pulse, blood pressure, respiratory rate and temperature were recorded. Hypotension, if present, was defined by a Mean Arterial Pressure (MAP) <70 mm Hg. Tachycardia was defined as a pulse rate >100 beats/minute, and tachypnoea as a respiratory rate >20 breaths/minute. Clinical parameters such as pain, swelling, redness, discharge, skin discoloration, loss of sensation and duration of symptoms were noted during the local examination. Skin changes such as swelling, vesicles, blisters, bullae, haemorrhagic bullae, crepitus, anaesthesia, skin discolouration and gangrene were documented. A blood sample of approximately 10 mL was collected at the time of admission for the following investigations: C-reactive protein (CRP), complete blood count, serum electrolytes, serum creatinine, blood urea, serum total protein, serum albumin, serum bilirubin, random blood glucose, prothrombin time, International Normalised Ratio (INR), arterial blood gas analysis, blood cultures for sensitivity, antibiotic sensitivity and tissue cultures were sent.

Sample collection method for microbiological test:

- **Blood culture and sensitivity testing:**

A) **Timing:** Blood samples were taken before starting antibiotic treatment to ensure that any present bacteria or fungi could be accurately detected and not suppressed by the antibiotics.

B) **Procedure:** The collected blood samples were cultured to identify any pathogens present in the bloodstream. This process involves incubating the blood in special nutrient media to promote the growth of any microorganisms.

C) **Sensitivity testing:** Once pathogens were isolated, sensitivity testing was performed to determine the most effective antibiotics for treatment. This helps tailor antibiotic therapy to the specific bacteria or fungi causing the infection, improving treatment outcomes.

- **Tissue and wound swab analysis:**

A) **Sample collection:** Tissue samples or wound swabs were taken from the site of infection. This is particularly important in conditions like NF, where localised infection can rapidly spread.

B) **Microbiological examination:** These samples were cultured and examined to identify the causative organisms.

C) **Gram stain and Polymerase Chain Reaction (PCR):** Additional tests such as Gram staining and PCR have been used for rapid preliminary identification of the bacteria.

A diagnosis of NSTI was made based on the following criteria:

Pain, swelling, tenderness, erythema with any one of the following:

1. Vesicles, blister, or bulla formation/haemorrhagic bulla.
2. Crepitus.
3. Skin anaesthesia.
4. Skin necrosis with dusky discoloration or frank gangrene.

STATISTICAL ANALYSIS

Data was recorded in an Excel worksheet, and statistical analysis was conducted using SPSS software version 21.0. For the analysis, the level of significance was set at <0.05. Continuous variables were analysed using Student's t-test, while categorical variables were analysed using the Chi-square test. The test was considered statistically significant at <0.05 (2-tailed).

RESULTS

A total of 77 patients with NSTI admitted under the Surgery unit were included in the study. The demographic characteristics are summarised in [Table/Fig-1] for survivors and non survivors. There were 62 (80.5%) male patients and 15 (19.5%) female patients. The mean±SD age of the patients was 43.96±19.3 years. According to the Modified Kuppuswamy scale, 54 (70.1%) patients belonged to the upper-lower SES class IV.

Variables	All patients (n=77) n (%)	Survivors (n=67), n (%)	Non survivors (n=10), n (%)	p-value
Age (years)				
Mean±SD	43.96±19.3	42.5±19.4	53.6±16.1	0.088*
≤20	10 (13.0)	9 (13.4)	1 (10.0)	
21-60	45 (58.4)	40 (59.7)	5 (50.0)	
>60	22 (28.6)	18 (26.9)	4 (40.0)	
Sex				
Male	62 (80.5)	53 (79.1)	9 (90.0)	0.417≠
Female	15 (19.5)	14 (20.9)	1 (10.0)	

[Table/Fig-1]: Demographic characteristics of Necrotising Fasciitis (NF) patients (N=77). *Independent t-test was used; ≠: Chi-square test was used; The p-value <0.05 was considered statistically significant.

The most common co-morbid condition was DM, present in 7 (9.1%) patients. The next most common co-morbid condition was Chronic Obstructive Pulmonary Disease (COPD), seen in 6 (7.8%) patients. On analysis, the combination of two or more co-morbid diseases was more likely to be associated with death than other co-morbid conditions occurring individually (p-value=0.001) [Table/Fig-2].

Medical co-morbidities	All patients (n=77) n (%)	Survivors (n=67) n (%)	Non survivors (n=10) n (%)	p-value*
None	45 (58.4)	43 (64.2)	2 (20.0)	0.198
Diabetes Mellitus (DM)	7 (9.1)	5 (7.5)	2 (20.0)	
COPD	6 (7.8)	4 (6.0)	2 (20.0)	
Malignancy	2 (2.6)	2 (3.0)	0	
HIV/AIDS	2 (2.6)	2 (3.0)	0	
Coronary artery disease	2 (2.6)	2 (3.0)	0	
Peripheral vascular disease	1 (1.3)	1 (1.5)	0	
Others	4 (5.2)	4 (6.0)	0	-
Combination of 2 or more co-morbidities	8 (10.4)	4 (6.0)	4 (40.0)	0.001

[Table/Fig-2]: Co-morbidities of Necrotising Fasciitis (NF) patients. *Chi-square test

Trauma was the most common trigger factor for NSTI, present in 18 (23.4%) patients. Trauma secondary to accidental falls was the most common mode of trauma seen in six patients, with road traffic accidents and falls of heavy objects seen in three patients each. Other triggering factors included folliculitis/furuncles accounting for 10 (13.0%) cases, anorectal abscesses with 4 (5.2%) cases, insect bites with 6 (7.8%) cases, dog bites in 3 (3.9%) cases, and snake bites in 1 (1.3%) case. Neuropathic ulcers were observed in 5 (6.5%) cases, while 3 (3.9%) cases were due to intravenous injections. Urinary tract infections and other abscesses each accounted for 2 (2.6%) cases. Skin diseases like tinea and scabies were identified in 2 (2.6%) cases. Bed sores, epididymo-orchitis secondary to urinary tract infection, cystolitholapaxy (surgery), and scabies with furuncle each constituted 1 (1.3%) case. Interestingly, no trigger factor was identified in 17 cases, making up 22.1% of the reported conditions.

Histories of smoking, alcoholism, intravenous drug abuse and long-term steroid intake were present in 52 (67.5%), 37 (48.1%), 5 (6.5%) and 8 (10.4%) patients, respectively.

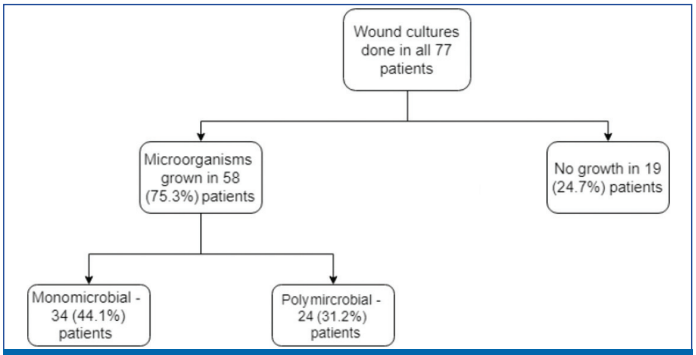
Ten patients died during the index admission giving a mortality rate of 13%. Early deaths (within 72 hours of admission) occurred in 2 (20%) patients. Both of these patients presented to the hospital with septic shock and deteriorated despite early debridement and other supportive measures. Late deaths (more than 72 hours of admission) occurred in eight patients.

The following clinical characteristics were observed: Pain, swelling, and redness were seen in 70 (90.9%) patients, 16 (20.8%) patients and 43 (55.8%) patients, respectively. Vesicles/bullae/haemorrhagic bullae were observed in 44 (57.1%) patients, skin anaesthesia was present in 63 (81.8%) patients, and crepitus was observed in only 4 (5.2%) patients. Forty-nine (63.6%) patients presented five days or more after the initial onset of symptoms, while the remaining 28 (36.4%) patients presented within four days of symptom onset. The average duration of symptoms at the time of presentation was 6.1 days (SD=3.1 days) [Table/Fig-3].

Clinical characteristics	n (%)
Pain	70 (90.9)
Swelling	6 (20.8)
Redness	43 (55.8)
Discharge	55 (71.4)
a) Purulent type	40 (52)
b) Serous toxic fluid type	15 (19.5)
Purplish/dark/black discolouration of the skin	69 (89.6)
Vesicles/bullae/haemorrhagic bullae	44 (57.1)
Anaesthesia of skin	63 (81.8)
Crepitus	4 (5.2)
Hypotension	9 (11.7)
Tachycardia	38 (49.3)
Tachypnoea	17 (22.1)
Altered level of consciousness	6 (7.8)
Mean±SD MAP (mmHg)	84.4±13.8
Mean±SD pulse rate (beats/minute)	102.4±17.4
Mean±SD respiratory rate (breaths/minute)	17.7±4

[Table/Fig-3]: Clinical characteristics.
MAP: Mean arterial pressure

Microbiological findings of the patients who succumbed to Necrotising Fasciitis (NF) revealed the following: Blood cultures were performed on all 77 patients, with only 11 (14.3%) patients showing positive results. *Staphylococcus aureus* was isolated in nine patients, six of which were MRSA. Tissue cultures were conducted for all patients at the time of primary debridement. Among them, 58 (75.3%) patients showed growth, while no growth was observed in the remaining 19 (24.7%) patients [Table/Fig-4]. Initial gram staining indicated the presence of pus cells in 68 out of 77 (88.3%) patients. A single organism was identified as the causative bacteria in 34 (44.1%) patients, making the monomicrobial type of NSTI the most common in the present study patient group. Polymicrobial growth (more than one microorganism) was found in (31.2%) patients. [Table/Fig-5a-c] presents microbiological findings and culture sensitivity patterns. Monomicrobial growth was observed in the majority of patients, specifically 34 (41.8%). Among the various isolated organisms, *Escherichia coli* was the predominant organism, isolated in 20 patients (25.3%).



[Table/Fig-4]: Wound cultures in NSTI.

Microorganisms	All patients (N=77), n (%)	Survivors (n=67), n (%)	Non survivors (n=10), n (%)	p-value*
Monomicrobial	34 (44.2)	28 (41.8)	6 (60.0)	0.5447
Polymicrobial	24 (31.2)	22 (32.8)	2 (20.0)	
No growth	19 (25.4)	17 (25.4)	2 (20.0)	
Total isolated organisms	79	67	12	-
Escherichia coli	20 (25.3)	18 (26.9)	2 (16.7)	0.644
Staphylococcus aureus	15 (19.0)	15 (19.0)	15 (19.0)	0.368
Acinetobacter baumanii	15 (19.0)	15 (19.0)	15 (19.0)	0.965
Pseudomonas aeruginosa	5 (6.3)	5 (6.3)	5 (6.3)	0.630
Enterococcus species	5 (6.3)	5 (6.3)	5 (6.3)	0.630
Proteus vulgaris	4 (5.1)	4 (5.1)	4 (5.1)	0.024*
Proteus mirabilis	2 (2.5)	2 (2.5)	2 (2.5)	0.115
Citrobacter koseri	4 (5.1)	4 (5.1)	4 (5.1)	-
Citrobacter freundii	1 (1.3)	1 (1.3)	1 (1.3)	-
Klebsiella pneumoniae	2 (2.5)	2 (2.5)	2 (2.5)	-
Enterobacter cloacae	2 (2.5)	2 (2.5)	2 (2.5)	-
Group A *Streptococcus*	1 (1.3)	1 (1.3)	1 (1.3)	-
More than 2 organisms grown	3 (3.8)	3 (3.8)	3 (3.8)	-

[Table/Fig-5a]: Microorganisms in tissue culture.
*Chi-square test applied to check growth of organisms between survivors and non survivors; The p-value <0.05 was considered statistically significant

Gram negative microorganisms cultured (number of times the organism was isolated)	Antibiotic	No. of times sensitive to the antibiotic
Escherichia coli (n=20)	Amikacin	11
	Gentamycin	13
	Piperacillin-Tazobactam	7
	Meropenem	10
	Imipenem	2
	Ertapenem	2
	Polymyxin B	10
	Cefotaxime*	3
Acinetobacter baumanii (n=15)	Polymyxin B	12
	Colistin	2
	Tigecyclin	1
	Netilmycin	1
Pseudomonas aeruginosa (n=5)	Piperacillin-Tazobactam	3
	Amikacin	3
	Meropenam	1
	Imipenam	2
	Cefotaxime*	1
Proteus vulgaris (n=4)	Piperacillin-Tazobactam	3
	Amikacin	3
	Meropenam	1
	Imipenam	2
	Cefotaxime*	1
Proteus mirabilis (n=2)	Piperacillin-Tazobactam	2

Citrobacter koserii (n=4)	Polymyxin B	4
	Gentamycin	2
Citrobacter freundii (n=1)	Piperacillin-Tazobactam	1
	Ciprofloxacin*	1
Klebsiella pneumoniae (n=2)	Piperacillin-Tazobactam	1
	Polymyxin B	1
	Cefotaxime*	1
Enterobacter cloacae (n=2)	Colistin	2
	Tetracycline	1

[Table/Fig-5b]: Antibiotic sensitivity pattern of gram-negative bacteria.
*Represents the antibiotic used after de-escalation

Gram positive microorganisms cultured (number of times the organism was isolated)	Antibiotic	No. of times sensitive to the antibiotic
Staphylococcus aureus (n=15)	Amikacin	5
	Gentamycin	4
	Piperacillin-Tazobactam	2
	Meropenam	2
	Polymyxin B	1
	Cefotaxime*	1
Enterococcus species (n=5)	Polymyxin B	2
	Tigecycline	2
	Netilmycin	1
Group A Streptococcus (n=1)	Piperacillin-Tazobactam	1

[Table/Fig-5c]: Culture sensitivity pattern of gram-positive bacteria.
*Represents the antibiotic used after de-escalation

DISCUSSION

The most common co-morbid condition observed was DM, seen in 9.1% of the present study patients, with COPD being the next most common at 7.8%. A combination of two or more co-morbid conditions was found in 10.4% of patients. Upon analysis, a combination of two or more co-morbid diseases was more likely to be associated with death than other individual co-morbid conditions (p-value=0.001). Most studies have reported a higher percentage of patients with co-morbidities. Tsai YH et al., reported DM as the most common co-morbid condition in 18.9% of their patients, with a combination of DM and other co-morbid conditions seen in 18.9%, and no co-morbidities were observed in 7.7% of their patients [5]. Faraklas I et al., in a study of 1392 patients, had an even higher number of patients with DM (49%), with COPD being the second most common at 9% [7]. Both Faraklas I et al., and Tiu A et al., concluded in their studies that DM was one of the factors associated with an increased risk of mortality [7,8].

In the present study, purplish/dark/black discoloration of the skin or necrosis of the skin was observed in 89.6% of the patients, and vesicles/bullae/haemorrhagic bullae were seen in 57.1% of the patients. In comparison with the present study findings, most available studies have reported fewer incidences (less than 50%) of hard signs of NSTI being present in their patients [18,19]. Elliott DC et al., in their study of 198 patients, reported skin discoloration in 18.4% of their patients, blistering in 23.7% and crepitus in 36.5% of their patients [9]. In a study of 472 patients by Huang KF et al., pus discharge was observed in 18.9% of their patients, skin discoloration in 16.1%, blistering in 13.3% and haemorrhagic bullae in 8.3% of their patients [20].

In the current study, blood cultures were conducted on all patients, with positive results observed in only 14.3% of patients. The most common organism isolated from blood cultures was *Staphylococcus aureus*. Similar observations were made by Tsai YH et al., from Taiwan, where in their study of 143 patients, blood cultures were positive in only 4.2% of patients. The most common organism grown in wound cultures in their study was Vibrio vulnificus [5]. In Nischal N et al.,'s study, findings revealed that 50% of cultures showed growth, with polymicrobial infections being the most prevalent [21]. Among the isolated organisms, *Pseudomonas aeruginosa* emerged as the most common, followed by *Staphylococcus aureus* and Klebsiella. Notably, beta-haemolytic Streptococcus and *Escherichia coli* were identified as significant contributors to monomicrobial infections. Similarly, in Halbhavi SN et al.,'s study, the culture and sensitivity reports of 150 patients showed that 90.66% had positive growth [22]. *Staphylococcus aureus* was the most prevalent gram positive bacterial isolate, found in 45.28% of cases, while *Pseudomonas aeruginosa* dominated as the most common gram negative isolate, appearing in 38.33% of cases. Treatment typically involved a combination of antibiotics such as Cefoperazone-sulbactam or Piperacillin-tazobactam for Gram negative coverage, supplemented with aminoglycosides. For Gram positive organism coverage, clindamycin or trimethoprim-sulfamethoxazole was used. Anaerobic coverage was provided by metronidazole or tinidazole.

In a study of 472 patients by Huang KF et al., from Taiwan, blood cultures were positive in 25.7% of their patients, and wound cultures were positive in 90.9% of their patients [20]. Similar to our study's results, monomicrobial growth in the wound was observed in 57.2%, and polymicrobial growth was observed in 33.7% of their patients. The most common microorganism isolated in their study was S. aureus, seen in 30.5% of their patients. The study had a prospective design that allowed for the collection of real-time data, providing more accurate and reliable information on the clinical and bacteriological profile of NF. Conducted in a tertiary care hospital, the research benefited from access to a diverse and complex patient population, offering valuable insights into the disease's presentation and specialised management. The inclusion of bacteriological profiles enhanced the study's comprehensiveness, facilitating a deeper understanding of the microbial agents responsible for NF and their antibiotic resistance patterns. Moreover, the study's setting in a tertiary care hospital suggested potential applicability of findings to similar settings and populations, allowing for broader generalisation.

Limitation(s)

The study had potential limitations in its sample size, which might have been relatively small, impacting the statistical power and ability to detect significant associations or differences. Furthermore, bacterial cultures might not have identified all causative organisms due to factors such as fastidious organisms or anaerobic culture was not performed.

CONCLUSION(S)

Despite being a severe infectious disease, early detection can reduce morbidity and mortality. It is crucial to focus on identified risk factors and complications to enhance treatment results for patients admitted with NF. Early and late mortality rates highlight the severity of NSTI, emphasising the need for prompt diagnosis and treatment.

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