

Original Research Article

DOI: <https://dx.doi.org/10.18203/2349-2902.ijssurgery20210364>

The study of the prognostic outcome of necrotizing fasciitis patients with and without diabetes mellitus

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Received: 07 January 2021

Revised: 17 January 2021

Accepted: 19 January 2021

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ABSTRACT

Background: Necrotizing fasciitis is highly lethal infection. It can be defined as infection of any layers within the soft tissue compartment (dermis, subcutaneous tissue, superficial fascia, deep fascia or muscle). Early diagnosis and management with identification of co morbidities and treating them brings down the morbidity and mortality rate. To make a full assessment of the cause, all patients require a detailed history, examination and, investigations.

Methods: This is a cross sectional comparative study of 50 patients having symptoms of necrotizing fasciitis to be divided into two groups of 25 patients each where one group is having diabetes mellitus and other group without diabetes mellitus.

Results: Diabetes mellitus patients have more morbidity and mortality in term of more days of hospital stay, rate of amputations and number of debridements. Early diagnosis and early aggressive debridement is the mainstay of management. Aggressive surgical debridement at initial stages of presentation can halt the clinical process and patient can have better prognosis. In neglected diabetic patient's debridement alone is not sufficient and amputation may be required in some cases.

Conclusions: Early diagnosis and aggressive debridement in necrotizing fasciitis patients results in better outcomes.

Keywords: Necrotizing fasciitis, Diabetes mellitus, Debridement, Amputation

INTRODUCTION

Necrotizing fasciitis (NF) is a rapidly progressive soft issue infection characterized by necrosis of the subcutaneous tissue and fascia.¹⁻³ It is a known cause of morbidity and mortality in all age group patients. It is recognized more than a century ago and has been referred to as hospital gangrene, acute infective gangrene, necrotizing erysipelas, hemolytic streptococcus gangrene and suppurative fasciitis.⁴⁻⁸ Necrotizing fasciitis of scrotum and perineum is known as fournier's gangrene. Necrotizing Fasciitis is more prevalent in males. The male to female ratio is 2.6:1.⁹ Necrotizing fasciitis can affect people of any age group but is more prevalent in middle to old age (44 to 68).¹⁰ The annual rate of

necrotizing fasciitis reported to be 0.4 cases per 1 lakh population. The incidence of this disease has increased about 5 folds during the last decade, which can be partly due to increase in the number of immune deficient patients.¹¹

The cause of necrotizing fasciitis can be spontaneous or can be due to several etiological factors like trauma, abrasions, cuts, bruises, IV drug abuse, boils, insect bite, fall, burns, perineal abscess, bartholin abscess, balanitis, intramuscular injections, foreign body injury or without any history of trauma. Post-surgical procedures that can lead to necrotizing fasciitis are appendectomy, inguinal herniorrhaphy, gastrectomy, aorto- iliac endarterectomy, hip nailing, muscle biopsy and exploratory laparotomy.¹²

Several comorbid conditions are associated with necrotizing fasciitis. These are Diabetes mellitus, cirrhosis, alcoholism, chronic disease, immunosuppressive drugs (e.g. prednisolone), malnutrition, age>60 years, peripheral vascular disease, renal failure, underlying malignancy, obesity, chronic obstructive pulmonary disease, upper gastrointestinal bleeding, cardiac disease, alcoholism, CVA, malignancy, acute pancreatitis, pemphigus disease.¹³

Necrotizing fasciitis can involve any part of the body. Lower extremity is the most common site. Other sites involved are upper extremity, perineum, chest, buttocks, abdomen and neck. Lower extremities are the most common sites involved.¹⁴

Necrotizing fasciitis is classified into 3 types. Type 1 is a poly-microbial infection with atleast one anaerobic species in combination with one or more facultative anaerobic species, such as non typable streptococci and members of enterobacteriaceae. It is typically located at the trunk, perineum and abdomen. Type 2 Necrotizing Fasciitis is a mono-microbial infection, most commonly caused by invasive group A streptococci (GAS)-pyogens, mostly in extremities. Type 3 NF is caused by marine vibrios and mostly on extremities.¹⁵

Several micro-organisms are isolated in patients with necrotizing fasciitis. In the anaerobic bacteria, clostridium species is the most commonly isolated.¹⁶

In necrotizing fasciitis anaerobic organism proliferate in an environment of local tissue hypoxia. So this is the reason necrotizing fasciitis is most commonly associated with diabetes mellitus. High blood sugar in necrotizing fasciitis patients provides a good medium for bacterial growth and predisposes to an environment of low oxygen tension. Diabetics also cause defective phagocytosis, decreased cellular immunity and micro- vascular disease with resultant ischemia. As the condition evolves, ischemic necrosis of the skin develops with gangrene of the subcutaneous fat, dermis and epidermis, manifests progressively as bullae formation, ulceration and skin necrosis.¹⁷

In diabetic patients there is sustained hyperglycemia, pro-inflammatory environment and peripheral neuropathy. These factors leads to altered immune cell function, ineffective inflammatory response, endothelial cell dysfunction and impaired neovascularization. These all responses lead to abnormal wound healing. This is the reason for morbidity and mortality in diabetic patients.¹⁸

METHODS

The cross sectional comparative study was conducted in the department of General Surgery of Sri Guru Ram Das Institute of Medical Sciences and Research Vallah, Sri Amritsar from April 2019 to August 2020. Fifty cases of necrotizing fasciitis were divided into two groups:

Group A (n=25)- necrotizing fasciitis patients with diabetes mellitus.

Group B (n=25)- comparative group—necrotizing fasciitis patients without diabetes mellitus.

Inclusion criteria

Both groups were having men and women in age group of 20-80 years with the signs and symptoms of necrotizing fasciitis.

Exclusion criteria

Exclusion criteria were 1) patients below 20 years of age 2) the patients who left the treatment against the medical advice 3) patients previously treated outside our hospital.

Ethical consideration

After taking informed consent patients were included in the study. Data was collected as per proforma sheet. ethical approval was taken from institutional ethical committee.

Study procedure

Signs and symptoms of necrotizing fasciitis includes intense pain and tenderness over the involved skin and underlying muscle. It is associated with fever, malaise and myalgias. Other findings include edema extending beyond the areas of erythema, skin vesicles and crepitus. In some cases subcutaneous tissue have a wooden, hardened feel.

Of those patients admitted with necrotizing fasciitis, 50 patients were selected for the study. Their clinical findings were recorded as per proforma case sheet. Necessary investigations done and analyzed. Depending on clinical findings and Routine investigations patients were divided into two groups, group A includes necrotizing fasciitis patients with diabetes mellitus & group B includes patients without diabetes mellitus. Medical management was done according to wound swab culture sensitivity report.

Investigations includes

Routine blood investigations: Hemoglobin, total leucocyte count, differential count, ESR, FBS, HbA1c and corresponding urine sugar on regular basis

Routine urinalysis: albumin, sugars, ketones and microscopy blood urea and serum creatinine. Wound discharge for culture and sensitivity. Arterial and venous doppler study (optional).

Statistical analysis

The data from the present study was systematically collected, compiled and statistically analysed with SPSS

Statistics-26 version to draw relevant conclusions. The observations were tabulated in the form of frequency, percentage and mean±standard deviation (SD). In parametric data, student's 't' test. Categorical variables were correlated using chi square test. The level of significance was determined as its 'p' value with $p>0.05$ as insignificant, $p<0.05$ as significant and $p<0.001$ as highly significant.

RESULTS

The present study of 50 patients in age group of 20-80 years having signs and symptoms of necrotizing fasciitis were observed after taking informed consent. Patients were divided into two groups of 25 each.

Group A: (n=25) necrotizing fasciitis patients with Diabetes mellitus.

Group B: (n=25) necrotizing fasciitis patients without diabetes mellitus.

Table 1 shows that out of 25 patients in group A, 1 (4%) was <30-year age, 1 was 31-40 (4%) years, 8 (32%) were in between 41-50 years, 15 (60%) were >50 years. Out of 25 patients in Group B, 8 (32%) were <30 years, 4 (16%) were in between 31-40 years, 6 (24%) patients were 41-50 years and 7 (28%) were >50 years age. The mean age is higher (56.6 ± 13.15) in group A than group B (51.56 ± 15.07) and data is statistically insignificant as $p>0.05$.

Table 1: Age distribution of subjects & mean age in both the study groups.

Age (years)	Group A		Group B	
	N	%	n	%
<30	1	4	8	32
31-40	1	4	4	16
41-50	8	32	6	24
>50	15	60	7	28
Total	25	100	25	100
	56.6 ± 13.15		51.56 ± 15.07	
P value	0.214			

Out of 25 patients in group A, 6 (24%) were female, 19 (76%) were males. Out of 25 patients in group B, 3 (12%) were female, 22 (88%) were males. From the above observation, male predominance is present in both the groups and data is statistically insignificant as $p>0.05$ as shown in Table 2.

Table 3 shows that out of 25 patients in group A, upper extremity was involved in one patient (4%), lower extremities were involved in 21 (84%) patients. Scrotum was involved in 2 (8%) patients, back was involved in one (4%) patient. Out of 25 patients in group B, upper extremity was involved in one (4%) patient, lower extremities were involved in 23 (92%), scrotum was

involved in one (4%) patient. From this observation most common site involved in both the groups is lower extremity and data is statistically insignificant as $p>0.05$.

Table 2: Gender distribution of subjects in both the study groups.

Gender	Group A		Group B	
	N	%	N	%
Female	6	24.00	3	12.00
Male	19	76.00	22	88.00
Total	25	100.00	25	100.00

X^2 (df: 1, n=50)=1.220, $p=0.269$

Table 3: Distribution of subjects on the basis of site involved in both the study groups.

	Group A		Group B	
	N	%	N	%
Upper Extremity	1	4.00	2	8.00
Lower Extremity	21	84.00	22	88.00
Scrotum	2	8.00	1	4.00
Back	1	4.00	0	0.00
Total	25	100.00	25	100.00

X^2 (df: 5, n=50)=3.805, $p=0.578$

Out of 25 patients in group A, electrocution was the etiological factor in one (4%) patient, insect bite was the etiological factor in 2 (8%) patients, intramuscular injection was the etiological factor in one (4%) patient, trauma was the etiological factor in 12 (48%) patients and no etiological factor was found in 9 (36%) patients. Out of 25 patients in group B, insect bite was etiological agent in one (4%) patient, thorn prick was etiological agent in one (4%), trauma was etiological agent in 11 (44%) patients, no etiological agent was identified in 12 (48%) patients. From the above observation most common etiological agent identified in group A was trauma and in group B was idiopathic and data is statistically insignificant as $p>0.05$ as depicted in Table 4.

Table 4: Distribution of subjects on the basis of etiological factors in both the study groups.

Etiological factors	Group A		Group B	
	N	%	N	%
Electrocution	1	4.00	0	0.00
Insect bite	2	8.00	1	4.00
Intramuscular Injection	1	4.00	0	0.00
Thorn Pick	-	0.00	1	4.00
Trauma	12	48.00	11	44.00
No	9	36.00	12	48.00
Total	25	100.00	25	100.00

X^2 (df: 5, n=50)=3.805, $p=0.578$

Table 5 depicted that out of 25 patients in group A, 22 (88%) undergone split skin grafting surgery, 2 (8%) undergone flap cover surgery and primary closure was done in 1 (4%) patient. Out of 25 patients in group B, 19

(76%) patients undergone split skin grafting, 2 (8%) patients undergone flap cover surgery and 4 (16%) patients undergone primary closure. In both the groups split skin surgery was the most common definitive surgery performed and data is statistically insignificant $p>0.05$.

Table 5: Distribution of subjects on the basis of definitive surgery in both the study groups.

Definitive Surgery	Group A		Group B	
	N	%	N	%
SSG	22	88.00	19	76.00
Flap cover	2	8.00	2	8.00
Primary closure	1	4.00	4	16.00
Total	25	100.00	25	100.00

χ^2 (df: 1, n=50)=1.087, p=0.297

Out of 25 patients in group A, amputation was performed in 3 (12%) patients and amputation was not required in 22 (88%) patients. Out of 25 patients in group B, amputation was performed in 1 (4%) patient and amputation was not required in 24 (96%) patients. From this observation, more number of amputations were performed in group A as compared to group B. The comparison of both the groups is statistically insignificant ($p>0.05$) as shown in Table 6.

Table 6: Distribution of subjects on the basis of requirement of amputation in both the study groups.

Amputation	Group A		Group B	
	N	%	N	%
No	22	88.00	24	96.00
Yes	3	12.00	1	4.00
Total	25	100.00	25	100.00

χ^2 (df: 1, n=50)=1.087, p=0.297

Table 7 shows that the mean hospital stay in days in group A was 26.24 ± 11.79 and mean hospital stay in days in group B was 18.68 ± 8 . The mean hospital stays in days found to be higher in group A as compared to group B. Comparison of both the groups was found to be statistically significant ($p<0.05$).

Table 7: Mean days of the hospital stay in both the study groups.

Hospital stay in days	Group A (n=25)	Group B (n=25)	P value
	26.24 ± 11.79	18.68 ± 8	0.011

Table 8 shows that out of 25 patients in group A, 17 (68%) patients underwent 1 debridement, 7 (28%) patients underwent 2 debridements and 1 (4%) patient underwent 3 debridements. Out of 25 patients in group B, 20 (80%) patients underwent 1 debridement, 5 (20%) patients underwent 2 debridement's. The number of debridements required was more in group A as compared

to group B. Comparison of both the groups was found to be statistically significant ($p<0.05$).

Table 8: Distribution of subjects on the basis of debridement in both the study groups.

Number of debridement	Group A		Group B	
	N	%	N	%
1	17	68.00	20	80.00
2	7	28.00	5	20.00
3	1	4.00	-	-
Mean±SD	1.36 ± 0.57		1.08 ± 0.28	
P value		0.032		

Table 9 shows that out of 25 patients in group A, swab culture sensitivity report of 6 (24%) patients had *E. coli* growth, 5 (20%) had *Klebsiella pneumonia* growth, 5 (20%) patients had *Pseudomonas aeruginosa* growth, 7 (28%) patients had *Staph aureus* growth, 1 (4%) patients had *Burkholderia cepacia* growth and 1 (4%) patients had no growth. Out of 25 patients in group B, swab culture sensitivity of 1 (4%) patient had *Acinobacter baumanii* growth, 3 (12%) had *E. coli* growth, 5 (20%) patients had *Klebsiella pneumonia* growth, 6 (24%) patients had *Pseudomonas aeruginosa* growth, 3 (12%) patients had *Staph aureus* growth and 7 (28%) patients had no growth. From this observation, most common organism isolated in group A is *Staph aureus* and most common organism isolated in group B is *Pseudomonas aeruginosa*. The data is statistically insignificant as $p>0.05$.

Table 9: Distribution of subjects on the basis of swab culture in both the study groups.

Swab C/S	Group A		Group B	
	N	%	N	%
<i>Acinobacter Baumanii</i>	-	-	1	4.00
<i>E. Coli</i>	6	24.00	3	12.00
<i>Klebsiella pneumoniae</i>	5	20.00	5	20.00
<i>Pseudomonas Aeruginosa</i>	5	20.00	6	24.00
<i>Staph Aureus</i>	7	28.00	3	12.00
<i>Burkholderia Cepacia</i>	1	4.00	-	-
No growth	1	4.00	7	28.00
	25	100.00	25	100.00

χ^2 (df: 6, n=50)=9.190, p=0.163

DISCUSSION

The cross sectional comparative study was conducted in the department of General Surgery of Sri Guru Ram Das Institute of Medical Sciences and Research Vallab, Sri Amritsar. Fifty cases of necrotizing fasciitis were divided into two groups:

Group A- cases-necrotizing fasciitis patients with diabetes mellitus.

Group B- comparative group-necrotizing fasciitis patients without diabetes mellitus.

Males are more commonly involved with necrotizing fasciitis. The reason could be males are more commonly involved in outdoor activities and work place hazards. Minor injuries are common at work place. Shiakh conducted a study on necrotizing fasciitis: A decade of surgical care experience. 94 patients with necrotizing fasciitis were included in their study. He concluded that disease is more prevalent in males (75.5%) than females (24.5%).¹ In another study by Jain et al. on surgical outcome of necrotizing fasciitis in diabetic lower limbs. They reported that male to female ratio is 3:1.12. Similarly in our study disease is more prevalent in males, 76% in group A and 88% in group B.

Necrotizing fasciitis can occur at any age group, but the most common age group involved is middle age to old age. This might be due to occurrence of risk factors in these age groups.

Korhan et al. conducted a study on idiopathic necrotizing fasciitis: risk factors and strategies for management. They concluded that necrotizing fasciitis is prevalent in patient age>55 years and median age is 60 years. In another study conducted by Rea et al. on necrotizing fasciitis, they reported that disease is more prevalent in 50-59-year age group patients. In our study necrotizing fasciitis is more prevalent in patients>50 years of age in group A, while in group B most patients affected are<30 years of age. The median age in group A is 56.6 ± 13.15 and in group B is 51.56 ± 15.07 .

Most common site involved in necrotizing fasciitis is lower limb. This might be due to lower limbs being commonly injured by trauma. Wang et al. conducted a study on necrotizing fasciitis: eight-year experience and literature review. They included 115 patients in their study. In their study most common site involved with necrotizing fasciitis was lower limb (61%), followed by upper limb (10%), trunk (13%), perineum & scrotum (10%) and head and neck in order (3%). In Rea et al conducted a study on necrotizing fasciitis. They reported that most common site of occurrence is lower extremity followed by upper extremity, abdomen, inguinal region. Back and buttocks and subcostal region. Another prospective study of cases with necrotizing fasciitis: experience at a tertiary care hospital by Mittal et al they included 50 patients in their study. They concluded that most common site involved in necrotizing fasciitis is lower extremity (34 patients), followed by scrotum (10 patients), upper extremity (4 patients) and face (2 patients). Similarly, in our study, most common site involved is lower extremity in both the groups (84% in group A and 92% in group B). Other sites involved are scrotum (8% in group A and 4% in group B), upper extremity (4% in both the groups) and back (4% in group A).

Swab culture is important for the management of necrotizing fasciitis. On the basis of swab culture sensitivity report patient can be managed by appropriate antibiotics. On swab culture sensitivity of patients with necrotizing fasciitis growth can be monomicrobial or polymicrobial. In study by Wang et al on necrotizing fasciitis: eight-year experience and literature review. They reported that most common microorganism isolated in patients with necrotizing fasciitis is *staph aureus*, followed by *streptococci*, *E. coli*, *klebsiella pneumonia*, *enterobacter* species and *proteus mirabilis*. In another study conducted by Legbo of necrotizing fasciitis. They concluded that the most common organism isolated on Swab culture sensitivity from infected area is *staph aureus* (60.7%), followed by *pseudomonas aeruginosa* (51.8%), *klebsiella* species (50%), *streptococcus pyogenes* (46.2%), *E. coli* (37.5%) in order. While no growth in 8.9% of cases. Similarly, in our study, most common organism isolated on swab culture sensitivity is *staph aureus* (28%). In group B, most common organism isolated on swab culture is *pseudomonas aeruginosa*.

Mittal conducted a prospective study of cases with necrotizing fasciitis: experience at a tertiary care hospital. They included 50 patients in their study over a period of 3 years. They reported that most common etiological factor in patients was trauma. More than two- thirds (78%) of the patients presented with history of trivial trauma. The other common cause was post insect bite.⁴⁴ Similarly, in our study most common etiological factors in both the groups is trauma (48% in group A and 44% in group B). Other etiological factors are insect bite, intramuscular injection, thorn prick and electrocution.

Ekka et al conducted a study on necrotizing fasciitis. They observed that debridement and fasciotomy were the main stay of management. They included 60 patients in the study. Out of 60 patients, 14 patients required amputation (23.33%). Diabetes mellitus was the only comorbidity that was significantly associated with limb loss ($p=0.02$). Cheng et al conducted a study on necrotizing fasciitis. They compare clinical characteristics of the non-diabetics and diabetic patients. They reported that amputation rate was more in diabetic patients (24%) as compared to non- diabetic patients (11%).¹⁹ Similarly in our study, amputation rate is more in group A patient (12%) as compared to group B patients (4%). Cheng et al also reported that mean hospital stay in days in diabetic patients was 39.1 ± 28.6 and non-diabetics was 41.1 ± 38.4 .¹⁹ In our study, mean hospital stay in days is 26.24 ± 11.79 in group A as compared to 18.68 ± 8 in group B. Necrotizing fasciitis involves skin and subcutaneous tissues. After debridement wound is closed by split skin grafting or by primary closure in small wounds. Rajappan K conducted a comparative study on the incidence of necrotizing fasciitis in diabetic and non- diabetic and its outcome. They included 50 patients in their study. They reported that most common surgery performed was split skin grafting in diabetic (52.9%) and non- diabetic (43.8%) patients.¹⁶ Similarly in our study, most common

surgery performed is split skin grafting, 88% in group A and 76% in group B.

Surgical debridement is a mandatory life saving step and should be performed as soon as possible. The most important determinants of mortality are the timing and adequacy of debridement. Surgical debridement must be done until brisk bleeding occurs from adjacent overlying subcutaneous tissues and underlying muscles, if involved. All necrotic tissues, including fascia must be removed to reduce the bacterial load, stimuli to inflammation and facilitate recovery. In addition, as it exposes tissues to oxygen, surgery may prove antagonistic to anaerobic bacteria. The wound should be bluntly probed in all directions, especially in highly suspected areas such as pockets or subcutaneous or submuscular extension of infection. Repeated debridements may be necessary (as dictated by the state of the wound) until the infections are adequately controlled. Tissues are often edematous and highly secreting, so wounds are usually left open after debridement. Second debridement is done only if needed.

Limitations

Further studies with large sample size are needed.

CONCLUSION

Necrotizing fasciitis is a potentially lethal infection of subcutaneous tissue and fascia. Diabetes mellitus patients have more morbidity and mortality in term of more days of hospital stay, rate of amputations and number of debridements. Early diagnosis and early aggressive debridement is the mainstay of management. Aggressive surgical debridement at initial stages of presentation can halt the clinical process and patient can have better prognosis. In neglected diabetic patient's debridement alone is not sufficient & amputation may be required in some cases.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kaur N, Mittal S, Kapoor S, Gupta A. The study of the prognostic outcome of necrotizing fasciitis patients with and without diabetes mellitus. Int Surg J 2021;8:563-8.