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Factors for In-Hospital Mortality in 145 Male Patients with Fournier's Gangrene: A 10-Year Observational Study from a Single Tertiary Referral Center in Indonesia

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Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
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Background: Fournier's gangrene (FG) is a potentially fatal necrotizing infection. Due to the rapid progression of the disease, the fatality rate remains high despite advances in therapy. This 10-year observational study from a single tertiary referral center in Indonesia aimed to identify the risk factors for in-hospital mortality from 145 male patients diagnosed with FG.

Material/Methods: This retrospective cohort study was conducted at one of Indonesia's largest tertiary referral hospitals. The risk factors of in-hospital mortality were analysed using data collected through hospital medical records. All patients diagnosed with FG from January 2012 until December 2021 were included. Outcome measured was sociodemographic factors, comorbidities, laboratory findings, length of stay, culture results, and disease outcome. The microbiological culture was performed on FG lesions isolates. The statistical analysis was conducted using SPSS version 26.0.

Results: The analysis included 145 male patients with a median age of 52 (IQR, 43-61) years. Of them, 38 (26.20%) patients died. There were more patients with diabetes mellitus (DM) in non-survivor groups compared to survivor groups (76.3% vs 57%, p=0.035). On multivariate analysis, DM and *Clostridium perfringens* infection were found to be independent factors of in-hospital mortality [adjusted odds ratio (aOR)2.583, 95% confidence interval (CI)=1.061-6.289, aOR 5.982,95% CI=1.241-28.828, respectively].

Conclusions: The mortality rate for FG was considerably high. DM and *Clostridium perfringens* infection were shown to be independent risk factors for mortality among men.

Keywords: Adolescent Health • Gangrene • Infectious Disease Medicine • Mortality • Risk Factors

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Background

Fournier's gangrene (FG) is a sporadic disease that rapidly spreads. It involves a potentially fatal necrotizing infection of soft tissues that most often affects the external genitalia and perineum but may also affect the abdominal wall and thighs [1]. Although the main etiology of FG remains unclear, the probable underlying causes are anorectal illnesses, urogenital anomalies, and trauma [1]. Infectious diseases potentially provoke high mortality among FG patients. Most bacteria identified as causes of FG are *Coliforms, Klebsiella, Streptococci, Staphylococci, Clostridia, bacteroids, and Corynebacteria* [2,3]. FG is more common in men compared to women, with a ratio of 10: 1, respectively [4].

The diagnosis of Fournier's gangrene can be assisted by a combination of blood and imaging studies, although the primary diagnosis is clinical. Clinicians should maintain a high suspicion for any inflammatory or infectious process involving the perineum or genitals, especially in older diabetic men and others at high risk [5]. Fournier's gangrene is managed with surgical intervention and medical resuscitation, as the patient is often septic and in shock [6].

Due to the rapid progression of the disease, the fatality rate remains high despite early surgical interventions, advances in critical care, and new medications [7,8]. In the latest review, the mortality in high-income countries rates between 20% and 40% (Sorensen and Krieger 2016). In developing countries, the mortality rate was between 17% and 28% [9,10]. Several variables have been identified as risk factors for mortality in patients with FG, including older age, congestive heart failure, renal failure, and coagulopathy [7]. Additionally, laboratory indicators such as hematocrit, serum sodium, and serum potassium are also significantly associated with mortality [11-13].

Considering that men are more likely to have FG and that the mortality rates of FG is high, we believe that it is necessary to evaluate the mortality rates and to explore the risk factors associated with in-hospital mortality among male FG patients. This 10-year observational study from a single tertiary referral center in Indonesia aimed to identify the risk factors for in-hospital mortality from 145 male patients diagnosed with FG.

Material and Methods

The study was conducted according to the Declaration of Helsinki and was approved by the ethical review board of Dr. Soetomo General Academic Hospital (Approval number: 0911/LOE/301.4.2/V/2022). The requirement of written informed consent was waived because this was a retrospective study. Details that might disclose the identity of the respondents were omitted.

We performed a retrospective observational study conducted at Dr. Soetomo General Academic Hospital, the largest tertiary referral hospital in the eastern part of Indonesia. The study was conducted on hospitalized FG patients during the 10-year period between January 2012 and December 2021. We included adult males with FG, and the exclusion criterion was patients with incomplete data.

Data Collection

Sociodemographic factors, comorbidities, laboratory findings, length of stay, culture results, and the outcome were collected from the patient medical record. Microbiological culture was performed on FG lesions isolates. FG severity index (FGSI) was manually scored based on the data from the medical records [14]. The diagnosis of FG was based on the presence of pain, erythema, ulcers, swelling, crepitus, necrosis, and purulent discharge found in the emergency room and confirmed by tissue inspection in the operating room. Mortality was defined as death during the hospital stay.

Statistical Analysis

The statistical analysis was conducted using the SPSS version 26.0 (IBM Corp., Armonk, N.Y., USA). Data normality was determined using one-sample Kolmogorov-Smirnov test. Data was presented as mean±standard deviation (SD) for normally distributed data, as median [interquartile range (IQR)] for skewed data, and as frequency (percentage) for nominal data. Independent t-test, Mann-Whitney test, chi-square test, and Fisher's exact test were used as appropriate. Two step logistic regression analyses were performed with in-hospital mortality as the outcome for the risk factor analysis. In the first step, univariate logistic regression analysis was performed for the clinical characteristics and the culture results. In this step, crude odds ratio (cOR) was obtained. In the second step, backward multivariate logistic regression analysis was performed, by including all variables with p-values <0.05 from the univariate analysis. In this step, an adjusted odds ratio (aOR) was obtained. Variables with a p-value <0.05 from the multivariate logistic regression analysis were considered the independent risk factor for in-hospital mortality.

Results

One hundred sixty-seven patients with FG were admitted to the hospital between January 2012 and December 2021. Of them, 145 were included in the analysis (**Figure 1**). The median age of the study population was 52 (43-61) years. Over half of the FG was in the scrotum. The prevalence rate for in-hospital mortality was 26.2%. The median length of stay in the hospital was 12 (5-23) days. The length of stay was longer

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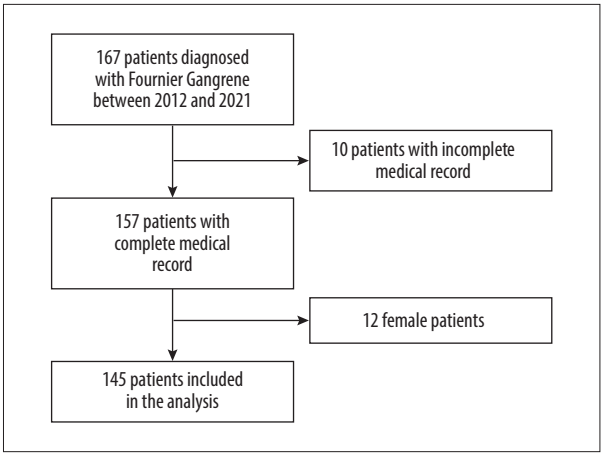

Figure 1. Patient inclusion and exclusion algorithm.

in survivor than in non-survivor patients (12 (7-23) days vs 8 (4-19) days, *P*=0.020). The prevalence of patients with diabetes mellitus (DM) as a comorbidity was significantly higher in non-survivors than in survivors (76.3% vs 57.0%, p=0.035). The median FGSI was similar between patients who died and patients who survived (7.5 (4.8-12.0) vs 8.0 (5.0-13.0), *P*=0.487) (**Table 1**). Among all bacteria that was cultured from the FG lesion, the most frequently encountered bacteria as the cause of FG was *Pseudomonas aeruginosa*, followed by *Klebsiella pneumoniae* (**Table 2**).

In the univariate regression analysis, patients with DM as comorbidity (cOR=2.430, 95% CI=1.049 to 5.629, p=0.038) and patients with *Clostridium perfringens* as the cause of FG were more likely to die (cOR=5.253, 95% CI=1.191 to 23.166, *P*=0.028), while patients with higher white blood cell counts on admission were less likely to die (cOR=0.946, 95% CI=0.897 to 0.997, *P*=0.040) (**Supplementary Table 1**). In the multivariate regression analysis, DM as comorbidity and *Clostridium perfringens* as the cause of FG were identified as the independent risk factors for mortality (**Table 3**).

Discussion

In this study, we analysed the risk factors of in-hospital mortality using data collected through hospital medical records. It was found that there were more patients with diabetes mellitus (DM) in non-survivor groups compared to survivor groups (76.3% vs 57%, *P*=0.035). DM and *Clostridium perfringens*

Table 1. Clinical characteristics of patients with Fournier's gangrene.

Variables	Total N=145	Non-survivors N=38	Survivors N=107	P value
Age in years, median [IQR0	52 [43-61]	55 [43-61]	52 [42-60]	0.257
Length of stay, median [IQR]	12 [5-23]	8 [4-19]	12 [7-23]	**0.020**
Location, n (%)				
Perineum	38 (26.2)	12 (31.6)	26 (24.3)	0.381
Scrotum	84 (57.9)	23 (60.5)	61 (57.0)	0.706
Penoscrotal	23 (15.9)	3 (7.9)	20 (18.7)	0.118
Diabetes mellitus, n (%)	90 (62.10)	29 (76.3)	61 (57)	**0.035**
Hypertension, n (%)	37 (25.5)	9 (23.7)	28 (26.2)	0.763
C-reactive protein, median (mg/dL) [IQR]	10.6 [4.3-21.9]	9.6 [4.2-26.3]	11.4 [4.2-18.6]	1.0
Hemoglobin (g/dL), mean±SD	11.4±2.1	11.2±2.4	11.46±2.0	0.551
White blood cells (10^3/µL), median [IQR]	16.6 [11.6-22.5]	14.2 [9.6-20.1]	17.2 [12.2-23.5]	**0.039**
Sodium level (mmol/L), median [IQR]	135 [132-139]	135 [133-140]	135 [131-138]	0.504
Serum creatinine (mg/dL), median [IQR]	1.10 [0.80-1.55]	0.95 [0.71-1.55]	1.10 [0.80-1.60]	0.361
Potassium level (mmol/L), median [IQR]	4.0 [3.6-4.5]	4.0 [3.7-4.9]	4.0 [3.5-4.5]	0.426
Hematocrit (%), median [IQR]	35.3 [31.2-38.4]	34.8 [31.2-38.3]	35.3 [31.1-38.4]	0.716
Neutrophile (10^3/µL), median [IQR]	11.3 [7.8-18.5]	10.3 [6.8-19.4]	12.9 [8.2-18.5]	0.226
Lymphocyte (10^3/µL), median [IQR]	1.54 [0.96-2.24]	1.47 [0.78-2.35]	1.66 [1.03-2.23]	0.475
FGSI, median [IQR]	8.0 [5.0-12.5]	7.5 [4.8-12.0]	8.0 [5.0-13.0]	0.487

IQR – inter-quartile range; SD – standard deviation. In bold, statistically significant results.

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Table 2. Bacterial culture results from the Fournier's gangrene patients.

Culture result	Total N=145	Non-survivors N=38	Survivors N=107	p value
Acinetobacter baumannii, n (%)	21 (14.5)	7 (18.4)	14 (13.1)	0.422
Candida sp., n (%)	6 (4.1)	3 (7.9)	3 (2.8)	0.185
Clostridium perfringens, n (%)	8 (5.5)	5 (13.2)	3 (2.8)	**0.029**
Escherichia coli, n (%)	21 (14.5)	5 (13.2)	16 (15)	0.787
Fusobacterium, n (%)	12 (8.3)	4 (10.5)	8 (7.5)	0.514
Gemella morbilorum, n (%)	1 (0.7)	0 (0.0)	1 (0.9)	1.0
Klebsiella pneumonia, n (%)	24 (16.6)	4 (10.5)	20 (18.7)	0.245
Pseudomonas aeruginosa, n (%)	31 (21.4)	7 (18.4)	24 (22.4)	0.605
Staphylococcus epidermidis, n (%)	3 (2.1)	0 (0.0)	3 (2.8)	0.567
Streptococcus beta haemoliticus, n (%)	5 (3.4)	1 (2.6)	4 (3.7)	1.0
Streptococcus bovis II, n (%)	1 (0.7)	0 (0.0)	1 (0.9)	1.0

In bold, statistically significant results.

Table 3. Independent risk factors for in-hospital mortality in patients with Fournier's gangrene.

Variables	aOR (95% CI)	p-value
Diabetes mellitus as comorbid	2.583 (1.061-6.289)	0.037
Clostridium perfringens as the cause of Fournier's gangrene	5.982 (1.241-28.828)	0.026

aOR – adjusted odds ratio; CI – confidence interval.

infection found to be independent factors of in-hospital mortality [adjusted odds ratio (aOR) 2.583, 95% confidence interval (CI)=1.061-6.289, aOR 5.982,95% CI=1.241-28.828, respectively].

We estimated that the in-hospital mortality rate of FG patients in our study population was 26.2%. In Indonesia, it has previously been identified that the mortality rate of FG ranged from 17 to 28% [9,10]. Ergo, our findings are in line with such previous findings. Further, we identified that DM and *Clostridium perfringens* were the independent risk factors for in-hospital mortality of male FG patients. We also found that non-survivors FG patients had a shorter length of stay and lowered white blood cells than the survivors.

In our study, the median age was 52 (43-61) years, which was in line with previous report [15]. While older age is a substantial and well-known independent predictor of death for patients with FG [4,16-18], we were unable to demonstrate the association between mortality and age. Similarly, previous study from another tertiary hospital in Indonesia also showed no significant difference in age between survivors and non-survivors [9]. It is questionable whether increasing age may increase the risk of mortality in individuals with FG. Age is an independent predictor of death in population-based studies when combined with other risk factors such as renal insufficiency or surgical delay [19]. In addition, it has been noted that despite advancements in treatment techniques, antimicrobial agents, and intensive care procedures, FG still has a mortality risk up to 50% in specific regions in Indonesia or globally [4,20,21].

One of the risk factors of FG is chronic diseases such as diabetes, substance abuse, and others [22]. In this study, 62.1% of the patients had DM as comorbidity. Patients with DM had a 2.5 times higher risk of in-hospital mortality than patients without DM. Previous studies have shown the correlation between DM and a poor prognosis in FG patients, aligned with our findings [23-25]. When blood sugars are not properly controlled, diabetes is known to harm the immune system, thus increasing mortality in FG patients [25,26].

Pseudomonas aeruginosa is the most frequently identified pathogen in our FG patients, followed by *Klebsiella, E. coli, and Acinetobacter*. Identified pathogens in this study were different from the previous study, where E.coli was the most frequent pathogen in FG patients while Pseudomonas species was rarely isolated [17]. Although culture results from different studies vary, it is acknowledged that the causative bacteria for FG are both aerobic and anaerobic gram-negative and positive species, with aerobic species being identified more often than anaerobic species [27]. Some of our patients had

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negative wound culture results. This is most likely due to the presence of anaerobic bacteria in the mix, as well as a fungal or viral cause that could not be isolated under the conditions that we employed to cultivate them [17].

In previous study, Tenório et al. developed a Simplified Fournier Gangrene Severe Index (SFGSI) scoring system that identified extension of the lesion to the abdomen, hematocrit, serum potassium levels, and creatinine levels as independent risk factors for mortality [28].

In our investigation, the prevalence of *Clostridium perfringens*-dominated cultures was significantly higher in non-surviving FG patients. Furthermore, *Clostridium perfringens*-dominated cultures were found to be an independent risk factor of in-hospital mortality in FG patients. *Clostridium perfringens* infection, according to the literature, is linked with a high mortality rate [29]. This is because *Clostridium perfringens* can cause gas gangrene due to its capability of producing neurotoxic exotoxins and histotoxins, in which causing necrotizing soft tissue infection that leads to death [30]. The toxin typically has lytic and vacuolating properties, responsible for rapid necrosis and disease progression in FG patients [9,31,32].

The most reliable clinical indicators for predicting a poor prognosis in persons with FG continue to be contested and vary across studies. Although the FGSI score system is often used to predict mortality in FG patients, it has a low sensitivity and specificity [9,33]. Throughout the last two decades, this score's validity was assessed in several case series in an effort to establish its predictive validity; nevertheless, the results were inconsistent [34,35]. According to a preliminary study, people with the higher FGSI score are more likely than the general population to have more surgical procedures, remain in the hospital longer, develop sepsis, develop complications, and die [12]. In our study, no statistically significant difference between FGSI scores of survivors and non-survivors was observed. There was no correlation with any of its constituting components except for white blood cells count. Thus, our finding supports the notion that FGSI is not a good predictor of mortality.

This study has certain limitations. Both the retrospective nature and single-center observation in this study reflect significant constraints. Despite these limits, we conducted the first epidemiological research on FG and its related mortality risk factor in Indonesia, using high sample numbers and lengthy study duration. We note that our work logically builds on and advances previous research on FG.

Conclusions

We found a considerable mortality rate for FG in male patients. DM as comorbidity and the presence of *Clostridium perfringens* in the culture were shown to be independent risk factors for mortality among men. A multicenter prospective study is necessary to corroborate the results further.

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Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

Supplementary Material

Supplementary Table 1. Univariate regression analysis for in-hospital mortality in patients with Fournier's gangrene.

Variables	Crude odds ratio (95% CI)	p-value
Age	1.017 (0.991 to 1.044)	0.203
Length of stay	0.992 (0.970 to 1.014)	0.477
Location of Fournier's gangrene		
Perineum	Ref	Ref
Scrotum	0.817 (0.354 to 1.884)	0.635
Penoscrotal	0.325 (0.081 to 1.309)	0.114
Diabetes mellitus as comorbid	2.430 (1.049 to 5.629)	**0.038**
Hypertension as comorbid	0.876 (0.369 to 2.076)	0.763
C-reactive protein level	0.995 (0.983 to 1.007)	0.379

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Supplementary Table 1 continued. Univariate regression analysis for in-hospital mortality in patients with Fournier's gangrene.

Variables	Crude odds ratio (95% CI)		p-value
Haemoglobin level	0.947	(0.793 to 1.131)	0.548
White blood cells level	0.946	(0.897 to 0.997)	**0.040**
Sodium level	1.016	(0.955 to 1.081)	0.618
Serum creatinine level	1.074	(0.813 to 1.419)	0.615
Kalium level	1.395	(0.834 to 2.331)	0.204
Hematocrit level	0.991	(0.939 to 1.046)	0.739
Neutrophil level	0.991	(0.966 to 1.017)	0.485
Lymphocyte level	1.050	(0.898 to 1.226)	0.542
FGSI score >9	0.934	(0.438 to 1.989)	0.859
Bacteria found in culture			
Acinetobacter baumannii	1.500	(0.555 to 4.054)	0.424
Candida sp.	2.971	(0.573 to 15.403)	0.195
Clostridium perfringens	5.354	(1.191 to 23.166)	0.028
Escherichia coli	0.862	(2.93 to 2.538)	0.787
Fusobacterium	1.456	(0.412 to 5.142)	0.560
Gemella morbilorum	0.0	(0.0 to 0.0)	1.0
Klebsiella pneumonia	0.512	(0.163 to 1.607)	0.251
Pseudomonas aeruginosa	0.781	(0.306 to 1.994)	0.605
Staphylococcus epidermidis	0.0	(0.0 to 0.0)	0.999
Streptococcus beta	0.696	(0.075 to 6.429)	0.749
Streptococcus bovis II	0.0	(0.0 to 0.0)	1.0

CI – Confidence Interval; FGSI – Fournier Gangrene Severity Index. In bold, statistically significant results.

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