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Use of Simplified Prognostic Scoring System to evaluate prognostic factors for the survival in patients with Fournier's gangrene (FG)

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ABSTRACT
Objectives*: to evaluate prognostic factors for the survival in patients with Fournier's gangrene (FG), and applying a prognostic scoring systems to assess the outcomes of survival.*
Aim of the study: To evaluate prognostic factors for the survival in patients with Fournier's gangrene (FG), and applying a prognostic scoring systems for to assess the outcomes of survival.
Settings and Design*: A prospective study was conducted in the department of Urology, Surgical Sub-Specialties Hospital, and Medical City Complex in Baghdad.*
Patients and Methods*: Starting from January 2015, till December 2016; a total of 40 male patients who were between age group of 40–70 years, who had clinical picture of Fournier's gangrene, were enrolled in a prospective study and they were classified according to age, body mass index, early detection, area involved and comorbidity. We apply simplified prognostic scoring system for evaluation of highest risk of mortality.*
Main outcomes and Measures: The primary endpoint was the disease-related death, and the secondary endpoint was risk factors of mortality.
Statistical Analysis*: all patient data entered using computerized statistical package for social sciences (SPSS),and the level of significance (p value) set at < 0.05, the Chi-square test was used for categorical variables.*
Results*: There were three grades according out simplified prognostic scoring system; grade I from 8-10 points, grade II from 11-14 points and grade III from 15-18 points.*
Patients with grade III carried a higher mortality rate than those with grade I and gradeII
Conclusion*: the simplified clinical scoring system is a reliable tool to predict severity of Fournier's gangrene to identify patients at highest risk of death or major complications.*

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I. Introduction

Fournier's gangrene (FG) is an acute progressive necrotizing fasciitis affecting mainly the perineal, perianal and external genital regions of men[(1)]. Fournier's gangrene was considered as an idiopathic syndrome but in the majority of cases, urogenital and perineal traumas, including pelvic and perineal injury or pelvic interventions, are incriminated [2]. Systemic comorbidities are also identified in patients with Fournier's gangrene such as diabetes mellitus (DM), malignancy and malnutrition [3]. The cornerstones of treating patients with Fournier's gangrene are urgent necrotic tissue debridement, proper doses of broad spectrum antibiotics and resuscitation with fluids[(1)].Despite advanced management policies, mortality from Fournier's gangrene is still high [1,4].

The mortality rate associated with Fournier's gangrene varies from 3 to 45 % depending on the series. Although is lower than others forms of necrotizing fasciitis, probably because the scrotal area allows a relatively more efficient surgical debridement [(7)].

In the initial Fournier's description, the illness was considered idiopathic, However, in 1764 Bauriene reported a case of scrotal gangrene witch is considered to be the first case published in medical literature,

although the origin of the case was not idiopathic but due to injury by ox horn [(5)]. In the past, some authors advocated that the eponym Fournier should be reserved for the idiophatic cases of perineal gangrene, and use the term secondary necrotizing fasciitis to the cases with a proven etiology, this classification is not used in the present [(6)]. The American surgeon Frank L. Meleney described in 1924 for the first time the importance of extensive debridement of the necrotic tissues to achieve better results, the term Meleney's gangrene is associated with a synergistic gangrene that affects the skin and subcutaneous tissues, but not the deep fascia except in advanced cases, and always stars as a necrotic ulcer [(7)]. Other historical terms applied to Fournier's Gangrene include periurethral phlegmon, phagedema or synergistic necrotizing cellulitis [(7)].

Fournier's Gangrene Severity Index. FGSI

In the FGSI score, nine parameters were calculated, temperature, heart rate, respiratory rate, serum sodium, potassium, Creatinine, bicarbonate levels, hematocrite and leukocyte.

The degree of derivation from normal is graded from 0 to 4. The individual values are summed to obtain the FGSI score. [(21)]. Results published in the articles shows that a score >9 has 75% of death and patients with a score <9 were associated with 78% of survival, other series of patients analyzed with the same score shows FGSI >10.5 is associated with 96% of death and <10.5 96% of survival. [(22)]

Other medical groups use Chalson Comorbidity Index. It was calculated using 17 weighted indicators of coexisting conditions. A high score in Chalson Comorbidity Index is associated with a high mortality. [(20)]

The simplified clinical prognostic scoring system

Here, use an eight clinical parameter-in prognostic scoring system with a maximum score of eighteen points denoting the highest risk of mortality and a minimum score of eight points carrying a relatively lower risk of mortality.[(23)]

Disease detection was considered early or delayed or late according to clinical presentation. Medical illness was traced as diabetes mellitus only or concomitant with other disease such as cardiovascular, renal disease, hepatic disease. Early patient presentation was considered when there were features of cellulitis like pain, hotness, redness, swelling, and crepitus but without obvious gangrene. Delayed presentation was noticed with fever above 38°C, tachycardia, offensive wound discharge and cutaneous gangrene. Late presentation was considered if patient toxic, with systemic manifestations of shock. [(23)]

Regarding the clinical prognostic scoring system, there were three grades; grade I from 8-10 points, grade II from 11-14 points and grade III from 15-18 points. Patients with score of 8-10 points [grade I] carried a lower mortality rate and less hospital stay than those with score of 11-14 points [grade II] and score of 15-18 points [grade III]. [(23)]

II. Patients And Methods

A total of 40 patients presented with manifestations of Fournier's gangrene were reviewed prospectively from January 2015 to September 2016.

Emergency department managements:

Patients first time seen in emergency department, most of them between 40-70 years old, with single or multiple medical comorbidies (DM, IHD, CRF) presented with history of perianal or scrotal pain, LUTS, new onset purulent discharge, and scrotal swelling and discoloration. The mean time interval between initial symptoms and arrival at the hospital was 2-4 days.

On examination, most of them were febrile, with tachycardia, and local examination reveal scrotal and perineal swelling, tenderness, crepitus, offensive discharge, and blackish discoloration.

In severely delayed cases systemic signs and symptoms are often associated to systemic inflammatory response syndrome (SIRS) like fever, tachycardia, tachypnea with spreading of disease to involve the whole scrotum, perianal area, and can spread up the anterior abdominal wall.

We consider severe sepsis if there is dysfunction of one organ, hypotension or hypoperfusion[(36)].

Urgent resuscitation with intravenous fluids and Empiric broad spectrum antibiotic therapy was instituted as soon as possible, vasopressors use in patients who present with shock to improve hemodynamics may be also needed. Basic laboratory analysis done in ER like Hb , WBC count, BUN, S. creatinine, ECG& CXR also done.

Inward management:

Admission to the ward done rapidly, preparation of blood if indicated, in most cases we take opinion of general surgery regarding perianal involvement and need for fecal diversion.

Radical surgical debridement was done in the theater, all-necrotic tissue excised until well perfused viable tissue is reached, testicles usually preserved except if there is questionable viability, orchiectomy was

done, Urinary or faecal diversion may be necessary depending upon extension of disease (perianal or urethral involvement).

After surgery patient return either to the ward or ICU according to patient condition.

In the ward, the patient was kept on close monitoring, frequent wound dressing, broad-spectrum antibiotics, controlling of hyperglycemia in association of department of medicine, daily laboratory monitoring of RFT, electrolyte, and hb.

Multiple surgical debridement required in extensively involved cases.

Once the infection is eradicated, granulation tissue develops where patient transferred to plastic surgery ward for further reconstruction.

Scoring system:

A questionnaire was applied to all patients that included in this study; and the patients were classified according to their age, weight (BMI), early detection, whether single or multiple area involved and other medical illness. According to this classification, we apply the simplified clinical prognostic scoring system for evaluation of mortality rate as shown in table (2) .

Table 2 simplified scoring system of Fournier gangrene [(23)]

1. Patient's age:
≤50 years=1 point. ≥ 50 years=2 points.
2. BMI:
BMI<25=1 point. BMI < 30 = 2 points BMI > 30 =3 points.
3. Temperature:
< 38°C= 1 point. >38°C= 2 points.
4. Pulse:
<100 beats/min = 1 point. > 100 beats/min =2 points.
5. Systolic blood pressure:
>90 mm Hg= 1 point. < 90 mm Hg= 2 points.
6. Presentation:
Early = 1 point. Delayed = 2 points. Late = 3 points
7. Area involved:
Single = 1 point. multiple = 2 points
8. Comorbidity:
DM = 1 point. multiple = 2 points.

Disease detection was considered early, delayed, or late according to clinical presentation. Medical illness was traced as diabetes mellitus only or concomitant with other disease such as cardiovascular, renal disease, hepatic disease. Early patient presentation was considered when there were features of cellulitis like pain, hotness, redness, swelling, and crepitus but without obvious gangrene. Delayed presentation was noticed with fever above 38°C, tachycardia, offensive wound discharge and cutaneous gangrene. Latepresentation was considered if patient toxic, with systemic manifestations of shock.

The maximum score of **eighteen points** denoting the highest risk of mortality and a minimum score of **eight points** carrying a relatively lower risk of mortality.

The patients were classified in to three grades; **grade I** from 8-10 points, **gradeII** from 11-14 points and **grade III** from 15-18 points.

Patients with score of 8-10 points [grade I] carried a lower mortality rate and less hospital stay than those with score of 11-14 points [grade II] and score of 15-18 points [grade III].

III. Statistical analysis:

All patient data entered using computerized statistical package for social sciences (SPSS), and Chi-square test was used for categorical variables, p value of < 0.05 was considered to be statistically significant.

IV. Results

Total 40 Patients were classified according to their ages, BMI, and incidence ofhyperglycemia. Most of patient age in this study above 50 years old, with BMI > 25 m2/kg, and with single or multiple medical comorbidities mainly hyperglycemia as shown in (Table 3).

Table 3: patients distribution regarding their ages, BMI, and hyperglycemia.

Age	> 50 yrs	31	77,5%
	< 50 yrs	9	22,5%
BMI	<25	2	5%
	25-30	21	52,5%
	>30	17	42,5%
hyperglycemia		26	65%

Regarding the time of presentation, 2 patients in our data with early presentation, 30 patients (75%) presented with delayed courses of the disease and only eight patients (20%) presented with late manifestations according to (figure 1)

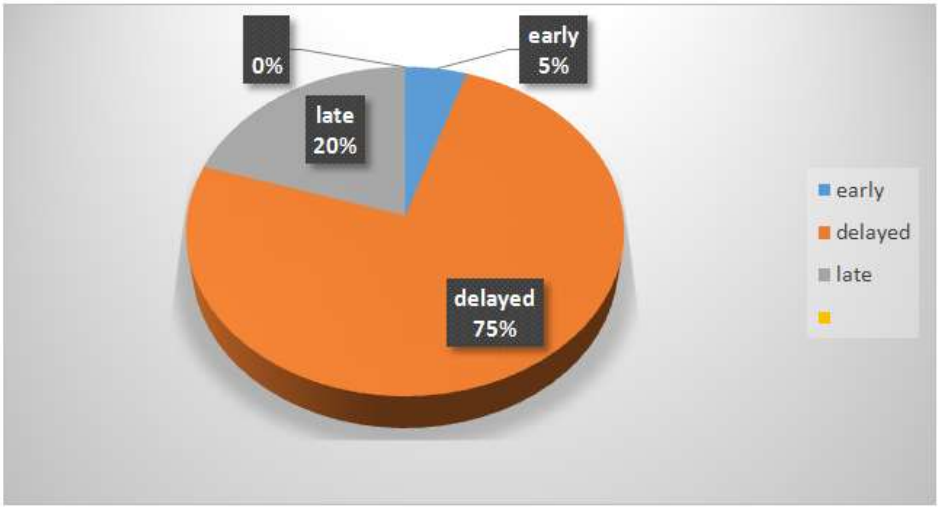

Figure 1: patient's distribution regarding time of their presentations.

The extension of disease was sub divided to either single primary site, or multiple sites that including the primary sites and disease extension sites. Genitalia were the most common primary site of the disease (55%), perianal and regions are 2nd most common primary site of the disease (45%) as shown in figure 2.

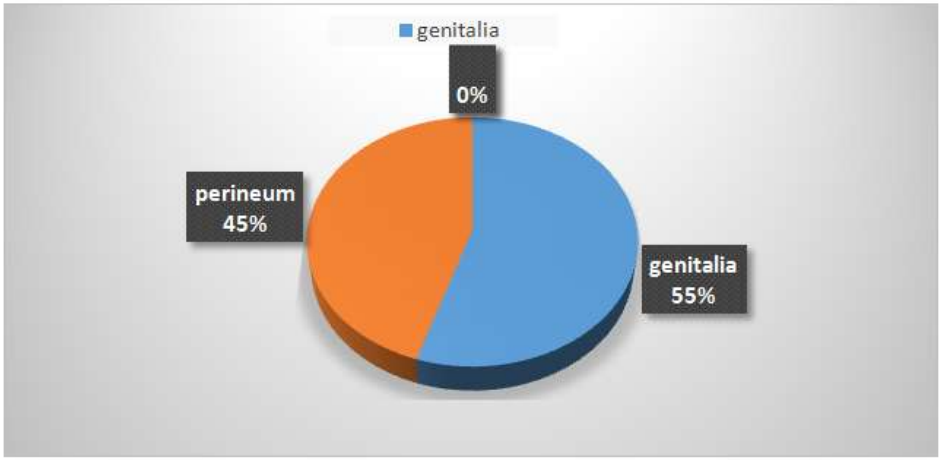

Figure 2patient's distribution regarding the primary site of the disease.

After finishing the questionnaire of scoring system, we calculate the total grade for each patient and classify data in to three grades:
Grade I from 8-10 points, **grade II** from 11-14 points and **grade III** from 15-18 points.
We found that 2 patients who presented with grade I while 30 patients presented with grade II and 8 patients with grade III scores, as shown in figure 3

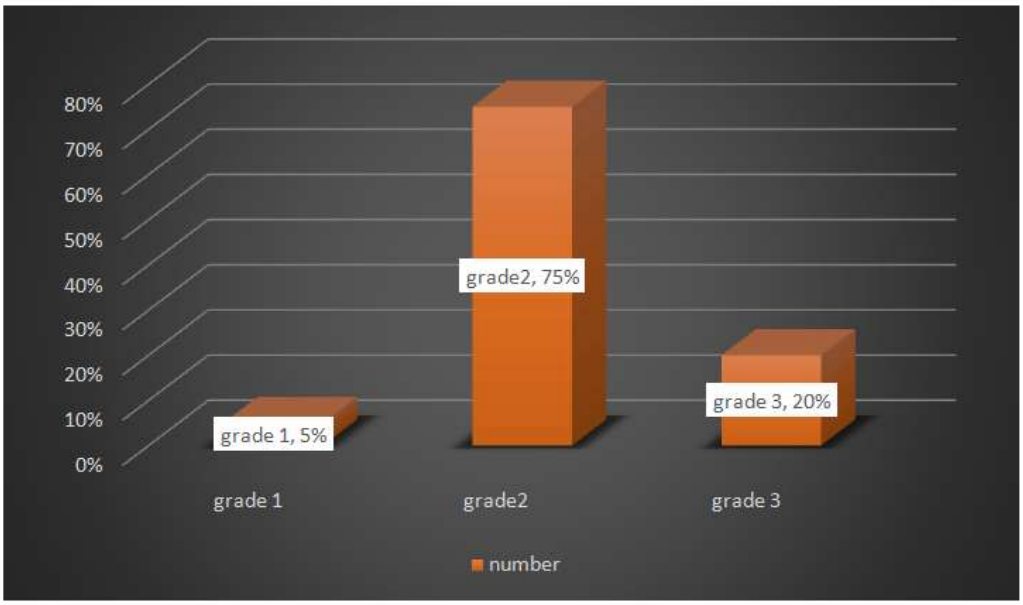

Figure 3 distribution of patient according to scoring grade

In this study, 8 patients died as a direct result of the disease, most of them with multiple risk factors like (age > 50 years, high body mass index, and late presentation, and with multiple comorbidity mainly DM) as shown in table 4. The mortality rate was significant in elderly patients (p- value <0,03), with BMI > 30 m2/kg (p- value <0,002), and highly significant in diabetic patients(p- value <0,001) , with late presentation (p- value <0,001) .

Table 4: mortality rate in relation to age, BMI , time of presentation and hyperglycemia.

age	< 50 yrs	1	12,5%	**p- value <0,03**
	>50 yrs	7	**87,5%**	
BMI(kg/m2)	<25	0		**p- value <0,002**
	25-30	0		
	>30	8	**100%**	
presentation	early	0		**p- value <0,001**
	delayed	0		
	late	8	**100%**	
hyperglycemia		6	**75%**	**p- value <0,001**

Regarding the mortality group, all of them with late presentations and grade III. The clinical prognostic scoring system was directly proportional to the mortality rate where patients with grades III score as shown in (figure 5).

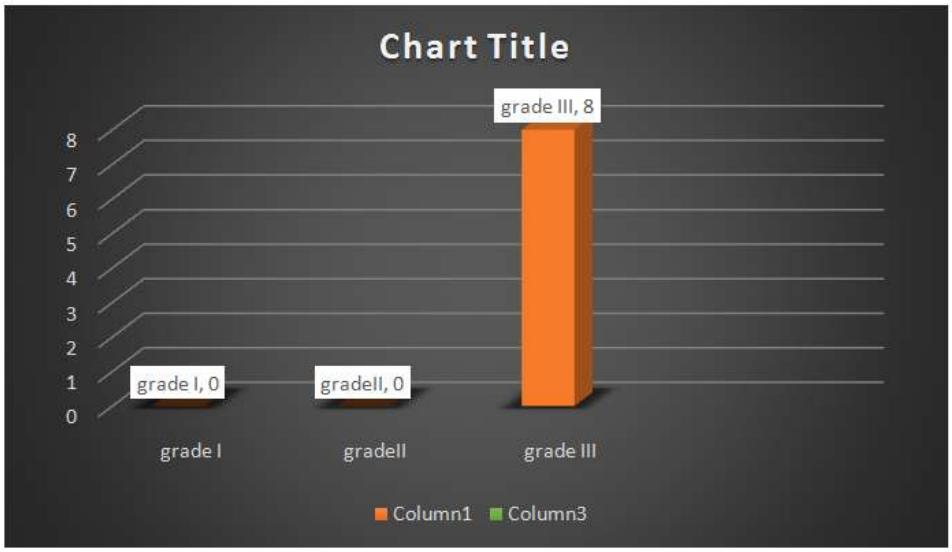

Figure 4 assessment of mortality group according to grade of scoring system

There is a strong correlation between high grade scoring system and mortality, this is may be due to that this scoring is highly precise in the explanation of most parameters which predict mortality.

V. Discussion

Fournier's gangrene is an acute, rapidly progressive, and potentially fatal, infective necrotizing fasciitis affecting the external genitalia, perianal or perineal regions, which commonly affects men, but can also occur in women and children [(1)].

Aly Saber et al use a simplified clinical prognostic scoring system with a maximum score of 18 points that refer to the highest risk of mortality and a minimum score of 8 points carrying a lower risk of mortality. This system contains patient's age, body mass index, temperature, pulse rate, systolic blood pressure, and time of presentation, the involved body region and comorbidity[(23)].

There are other systems can help clinicians for predicting the prognosis of FG patients like Fournier's Gangrene Severity Index (FGSI) and was described by Laor et al.[(37)] to This index includes nine metabolic and physiologic parameters. Laor et al.[(37)] found that a FGSI score greater than 9 indicated a 75% likelihood of mortality while a score of 9 or less was associated with a 78% likelihood of survival. However, this scoring systems lack the timing of patient presentation, (BMI), and medical comorbidity that has been included in simplified scoring system [(38-44)].

Increased age, BMI > 30 m2/kg, multiple co morbidities, late presentation with delayed time between the first symptom and surgical intervention , and extensive disease involving multiple area of body were major factors for mortality.[(1,3,45)].

In this study the age > 50 years is a major risk factors for morbidity and mortality and present in 77,5% of all patient and in 87,5% in mortality group. This result because increase age associated with impaired immunity, and increase incidence of medical comorbidity like DM , IHD, and CRF. This results came in agreement with Aly Saber et al., Mallikarjuna et al., and other studies of same interest. [(1,3,23, 45)].

In this study high BMI > 30 m2/kg found in all mortality patients.

This due to strong relationship of obesity with other medical comorbidity like DM, hyperlipidemia, and hypertension (metabolic syndrome) and is considered as a major risk factors for mortality [(46,47)].

This result came in agreement with Wang et al. and Kara et al. that consider obesity as important parameters for outcome prediction of FG [(46, 47)] .

In this study all mortality group presented with late presentation, with multiple area involvements.

The late time of presentation associated with significant mortality due to extensive spreading of disease to multiple area that lead to septicemia and death [(48,49)].

The relation between extension of the disease beyond the primary site and the mortality rate are controversial, Benjelloun et al. report that the spread of the disease is related to a higher mortality rate, while Vyas et al. reported that the extension of the disease does not relate to a poor outcome [(50)]. Aly Saber et al was found that the extension of the FG to the abdominal wall and thighs is a predictor of mortality [(23,50,51)]. The associated medical illnesses included diabetes mellitus, chronic renal failure, chronic liver disease, hypertension usually associated with higher mortality rates [(49)]. Other studies reported that various comorbidities are known to

be associated with Fournier gangrene, of which DM is the most common but its association with high mortality is controversial [52,53]. In this study the most common associated medical illnesses is diabetes mellitus (uncontrolled hyperglycemia present in 65% of all patient and 75% of mortality group). Hyperglycemia associated with detrimental effects on cellular immunity and increase in susceptibility to infections, and could be associated with more progressive fatal outcome, due to impairment of Chemotaxis, phagocytosis and neutrophil dysfunction [16]. In Aridogan et al. and other studies, the majority of the patients had DM [4,54] and the percentage varied from 54% to 70% [1, 48]. Unlap et al. found that existence of one or more co-morbidities as DM, chronic renal diseases, immunosuppression, and, liver diseases can affect morbidity and mortality rates in FG [53]. In this study the overall mortality rate was 20% which is depends on many related risk factors according the clinical scoring systems, all of them with grade III (15-18) points.

Jeong et al. and Eke et al., found the mortality rate was 25-30% and Morua et al. found that mortality rate may reach 20–50%.

VI. Conclusions

1- Fournier's gangrene is usually extensive disease with high mortality even with aggressive surgical treatment.
2- We use the simplified clinical scoring system as a reliable tool to predict severity of Fournier's gangrene to identify patients at highest risk of death or major complications.
3- Prompt early diagnosis and management of Fournier gangrene may improve the morbidity and mortality of this disease.

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