**Original** Article

# **Evaluation of Fournier Gangrene and Stoma Intervention**

Tyng Shuoh Hu<sup>1,2</sup> Yen Cheng Chen<sup>1,2</sup> Yu-Bing Lim<sup>1,2</sup> Chi Chou Huang<sup>1,2</sup> Bei-Hao Shiu<sup>1,2</sup> Wen-Chien Ting<sup>1,2</sup> <sup>1</sup>Division of Colorectal Surgery, Department of Surgery, Chung Shan Medical University Hospital, <sup>2</sup>Institute of Medicine, Chung Shan Medical University, Taichung, Taiwan

*Key Words* Fournier gangrene; Necrotizing fasciitis; Stoma; Colostomy **Purpose.** Fournier gangrene (FG) is a form of necrotizing fasciitis that occurs simultaneously in the perianal, perineal, or genital area; causes embolism of the subcutaneous small blood vessels; and develops into gangrene of the overlying skin. Its associated high mortality rate, prolonged hospitalization, and medical costs have been of concern for physicians. This study aimed to evaluate the effect of stoma creation on the mortality rate and duration of hospitalization of patients with FG.

*Methods.* We retrospectively enrolled 46 patients diagnosed with FG at our hospital between 1998 and 2018. The data collected included the patient characteristics, clinical parameters, operative factors, postoperative factors, length of hospital stay, and mortality rate. The patients were grouped into two for analysis based on the presence or absence of a stoma.

**Results.** The patients with a stoma had shorter hospitalization stays than those without (p = 0.044). Among the patients with postoperative wound diameters less than 20 cm, those with a stoma had longer hospitalization stays than those without (p = 0.001). However, for patients with postoperative wound diameters larger than 20 cm, those who had a stoma had significantly shorter hospital stays than those without (p = 0.039).

*Conclusion.* We inferred that a higher proportion of patients with stoma had hospital stays exceeding 30 days than those without. Patients with stomas showed a trend for increased mortality, which was not significant due to the low death count. Milder FG results in smaller wound diameter, a lower rate of stoma creation, and shorter hospitalization stays.

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**F**ournier gangrene (FG) is a type of necrotizing fasciitis that occurs simultaneously in the perianal, perineal, or genital area; causes embolism of the subcutaneous small blood vessels; and develops into gangrene of the overlying skin. Baurienne was the first venereologist to describe this disease in a document in 1764. In 1883, a clinical article described the symptoms and signs of five cases of the disease and named it "Fournier gangrene" after Jean Alfred Fournier1. At the time of diagnosis, 30-50% of the patients do not

have identifiable risk factors; however, predisposing factors reported for FG include age, diabetes mellitus, hypertension, immunosuppression, chronic renal failure, alcoholism, obesity, cachexia, pulmonary diseases, and systemic disorders 2-4. The complicated clinical course of FG, prolonged duration of hospitalization, and high morbidity and mortality rates are concerns for both physicians and patients. This study aimed to evaluate the effect of stoma creation on the mortality rate and duration of hospital stay of patients with FG.

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Correspondence to: Dr. Wen-Chien Ting, Division of Colorectal Surgery, Department of Surgery, Chung Shan Medical University Hospital, No. 110, Sec. 1, Jianguo N. Rd., South Dist., Taichung 40201, Taiwan. 886-4-2473-9595 ext. 34601; E-mail: tingwenchien@gmail.com

## Materials and Method

#### Patients

We retrospectively enrolled 46 patients diagnosed with FG between January 1998 and December 2018 at Chung Shan Medical University Hospital (Taichung, Taiwan). Patients who had undergone surgery for FG were included in this study, while those with incomplete surgical notes or laboratory data were excluded. The study protocol was approved by the institutional review board of the Chung Shan Medical University Hospital, and the study was conducted in accordance with the Declaration of Helsinki.

#### **Clinical data**

The patients with FG were divided into two groups: those with a stoma and those without. The characteristics and clinical parameters of the patients evaluated in this study included risk factors, sex, age, serum glucose concentration, C-reactive protein (CRP) concentration, white blood cell (WBC) count, neutrophillymphocyte ratio (NLR), Fournier gangrene severity index (FGSI), surgeries performed by various departments, postoperative wound diameter, number of debridement surgeries, duration of hospital stay, and frequency of wound dressing change.

#### Statistical analysis

Continuous variables are presented as mean  $\pm$  standard deviation (SD), and categorical variables are presented as percentages. The independent sample t-test and Pearson's chi-squared test were used to compare the continuous and categorical variables of the two groups, respectively. *p*-values of < 0.05 represented statistical significance. All statistical analyses were performed on a personal computer using the statistical package SPSS for Windows (Version 20, SPSS, IBM Inc., Chicago, Ill, United States).

## Results

A total of 46 patients was included in this study. Their demographic and clinical characteristics are described in Table 1. Of the 46 patients, 80% were older

Table 1. Patient characteristic and clinical data			
	n (%)	Min-Max	Mean $\pm$ SD
Patient	46 (100%)		
Sex	. ,		
Male	41 (89.13%)		
Female	5 (10.87%)		
Age		24-85	$54.04 \pm 15.66$
≤ 65	9 (19.57%)		
> 65	37 (80.43%)		
Fecal diversion with stoma			
Yes	15 (32.61%)		
No	31 (67.39%)		
Wound diameter	× ,		
$\leq 20 \text{ cm}$	35 (76.09%)		
> 20 cm	11 (23.91%)		
Department	× ,		
Colorectal surgery	21 (45.65%)		
Plastic surgery	5 (10.87%)		
Urology	20 (43.48%)		
Laboratory parameters			
CRP (mg/dl)		1.0-43.0	$17.20 \pm 9.61$
WBC		3370-60530	$18325 \pm 11668$
N-L ratio		0.29-85.00	$14.65 \pm 16.13$
HbA1c (%)		5.0-16.0	$7.75 \pm 2.45$
Times of operation		1-9	$3.24 \pm 1.78$
Days of hospital stay		3-98	$31.51 \pm 25.85$
$\leq 30 \text{ days}$	28 (60.87%)		
> 30  days	18 (39.13%)		
FGSI	16 (34.78%)	0-20	$9.63 \pm 6.02$
Mortality	6 (13.04%)		

N-L ratio: neutrophil-lymphocyte ratio.

than 65 years, and 89% were male. The number of surgeries underwent ranged from 1 to 9 (average:  $3.2 \pm$ 1.8), and 15 patients had fecal diversion (33%). Eleven patients (24%) had wound diameters larger than 20 cm after surgery. The duration of hospital stay ranged from 3 to 98 days, with an average of  $31.5 \pm 25.9$  days, and the mortality rate was 13%. The patients underwent treatment mainly in the departments of colorectal surgery (46%) and urology (43%). The mean CRP concentration, WBC count, and mean HbA1c concentration were  $7.20 \pm 9.61 \text{ mg/dL}$ ,  $18325 \pm 11668 \text{ per}$ µL, and  $7.75\% \pm 2.45\%$ , respectively. The average NLR was  $14.65 \pm 16.13$ . Only 16 patients had adequate data for FGSI, which ranged from 0 to 20, with a mean value of  $9.6 \pm 6.0$ .

The analysis results for the distribution of variables based on fecal diversion are provided in Table 2.

Table 2. Distribution of variables according to fecal diversion

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Patients without a stoma had significantly shorter hospital stays than those with a stoma (p = 0.044). There were no significant differences in sex, age, wound diameter, inpatient department, FGSI, mortality rate, number of surgeries, and laboratory parameters, including CRP, WBC, NLR, and HbA1c, between the two groups.

Based on the data presented in Table 2, we can analyze and discuss the relationship between mortality and fecal diversion (stoma). The table provides the distribution of variables stratified based on the presence or absence of fecal diversion, including sex, age, wound diameter, department, length of hospital stays in days, FGSI, mortality rate, times of operation, and laboratory parameters. The mortality rate was 13.04% (n = 6) for the 46 patients included in the study. Four of the patients (26.67%) who died had fe-

Variables	With stoma $(n = 15)$	Without stoma $(n = 31)$	р
Sex*			0.524
Male	14 (34.15%)	27 (65.85%)	
Female	1 (20.00%)	4 (80.00%)	
Age*			0.573
≤ 65	11 (30.56%)	25 (69.44%)	
> 65	4 (40.00%)	6 (60.00%)	
Wound diameter*			0.761
≤ 20 cm	11 (31.43%)	24 (68.57%)	
> 20 cm	4 (36.36%)	7 (63.64%)	
Department*			0.692
Colorectal surgery	8 (38.10%)	13 (61.90%)	
Plastic surgery	2 (40.00%)	3 (60.00%)	
Urology	5 (25.00%)	15 (75.00%)	
Days of hospital stay*			0.044
$\leq$ 30 days	6 (21.43%)	22 (78.57%)	
> 30 days	9 (50.00%)	9 (50.00%)	
FGSI $(n = 16)^*$			0.515
≤ 9	2 (28.57%)	5 (71.43%)	
> 9	4 (44.44%)	5 (55.55%)	
Mortality*	4 (26.67%)	2 (6.45%)	0.056
Times of operation <sup>†</sup>	$3.80 \pm 1.568$	$2.87 \pm 1.857$	0.102
Laboratory parameters <sup>†</sup>			
CRP	$19.071 \pm 10.8164$	$16.230\pm8.97$	0.376
WBC	$21797.33 \pm 13214.89$	$16451.6 \pm 10667.21$	0.163
N-L ratio	$18.25\pm16.55$	$12.91 \pm 15.95$	0.334
HbA1c	$6.89 \pm 1.69$	$8.27\pm2.74$	0.189

N-L ratio: neutrophil-lymphocyte ratio.

\* Data are shown as n (%) and compared by means of the Pearson Chi square test. <sup>†</sup> Data are shown as mean  $\pm$  standard deviation and compared by means of the T test.

cal diversion (with stoma), while 2 (6.45%) did not (without stoma). However, the difference in the mortality rates between the two groups was not significant (p = 0.056).

Analysis of the other variables related to fecal diversion revealed the following:

There were no significant differences in the distributions of sex (p = 0.524), age (p = 0.573), wound diameters ( $\leq 20$  cm and > 20 cm) (p = 0.761), patients across different departments (colorectal surgery, plastic surgery, and urology) (p = 0.692), and FGSI scores ( $\leq 9$  and > 9) (p = 0.515) between the two groups. The mean number of surgeries was slightly higher for the group with fecal diversion ( $3.80 \pm 1.568$ ) than for that without fecal diversion ( $2.87 \pm 1.857$ ), but the difference was not statistically significant (p = 0.102). The CRP concentrations, WBC, NLRs, and HbA1c concentrations of the two groups were also not significantly different. However, the distribution of patients in the two groups with hospital stays of  $\leq 30$  days and > 30 days were significantly different (p = 0.044).

The subgroup analysis results for the length of hospital stay are provided in Table 3. The sex distribution of those with longer and shorter hospital stays was not significantly different (p = 0.311). However, an age-based subgroup analysis revealed a significant association (p = 0.003) between age and hospital stay; a higher proportion of patients older than 65 years had stays exceeding 30 days than patients younger than 65 years. Further analysis of wound diameter demonstrated a significant correlation (p = 0.001) between larger wound diameters (> 20 cm) and prolonged hospital stays. However, the distribution of patients across different departments did not show a significant difference (p = 0.375). The presence of a stoma was found to be significantly associated (p = 0.044) with prolonged hospital stays, with a higher proportion of patients with stomas having longer stays. However, the FGSI score did not exhibit a significant difference (p = 0.696) between the two groups.

No significant difference in mortality rate (p = 0.755) was observed between the patients with hospital stays of  $\leq 30$  days and those with stays exceeding 30 days. Similarly, the number of surgeries did not show a significant difference (p = 0.102) between the

two groups. The CRP concentrations, WBC, NLR, and HbA1c concentration did not demonstrate statistically significant differences in the patients with varying lengths of hospital stay.

The subgroup analysis results for postoperative wound diameter are shown in Table 4. Among the patients with postoperative wound diameters less than 20 cm, those with a stoma had longer hospital stays than those without (p = 0.001). However, patients with postoperative wound diameters larger than 20 cm who had a stoma had a significantly shorter hospitalization than those without a stoma (p = 0.761). The sex distribution was also not significantly different (p = 0.372). However, an age-based subgroup analysis revealed a significant association (p = 0.002) between age and postoperative wound diameter; the patients younger than 65 years had smaller wounds. However, the distribution of patients across different departments did not show a significant difference (p = 0.852). The presence of a stoma was not significantly associated (p =0.761) with wound diameters, but a higher proportion

Table 3.	Subgroup	analysis	for pro	longed h	nospital	stav
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Variables	$\leq$ 30 days (n = 28)	> 30 days (n = 18)	р
Sex*			0.311
Male	26 (63.40%)	15 (36.60%)	
Female	2 (40.00%)	3 (60.00%)	
Age*			0.003
≤ 65	26 (72.20%)	10 (27.80%)	
> 65	2 (20.00%)	8 (80.00%)	
Wound diameter*			0.001
$\leq 20 \text{ cm}$	26 (74.30%)	9 (25.70%)	
> 20 cm	2 (18.20%)	9 (81.80%)	
Department*			0.375
Colorectal surgery	15 (71.40%)	6 (28.60%)	
Plastic surgery	2 (40.00%)	3 (60.00%)	
Urology	11 (57.90%)	8 (42.10%)	
Stoma*			0.044
With stoma	6 (40.00%)	9 (60.00%)	
Without stoma	22 (71.00%)	9 (29.00%)	
FGSI (n = 16)*			0.696
≤ 9	3 (42.90%)	4 (57.10%)	
> 9	3 (33.33%)	6 (66.67%)	
Mortality*	4 (66.67%)	2 (33.33%)	0.755

N-L ratio: neutrophil-lymphocyte ratio.

\* Data are shown as n (%) and compared by means of the Pearson Chi square test.

37 11	≤ 20 cm	> 20 cm	
Variables	(n = 35)	(n = 11)	р
Sex*			0.372
Male	32 (78.00%)	9 (22.00%)	
Female	3 (60.00%)	2 (40.00%)	
Age*			0.002
≤ 65	31 (86.10%)	5 (13.90%)	
> 65	4 (40.00%)	6 (60.00%)	
Department*			0.852
Colorectal surgery	17 (81.00%)	4 (19.00%)	
Plastic surgery	4 (80.00%)	1 (20.00%)	
Urology	14 (73.70%)	5 (26.30%)	
Stoma*			0.761
With stoma	11 (73.30%)	4 (26.70%)	
Without stoma	24 (77.40%)	7 (22.60%)	
Days of hospital stay*			0.001
$\leq$ 30 days	26 (92.90%)	2 (7.10%)	
> 30 days	9 (50.00%)	9 (50.00%)	
FGSI (n = 16)*			0.838
≤9	5 (71.40%)	2 (28.60%)	
> 9	6 (66.70%)	3 (33.30%)	
Mortality*	3 (50.00%)	3 (50.00%)	0.108

Table 4. Subgroup analysis for wound size

N-L ratio: neutrophil-lymphocyte ratio.

\* Data are shown as n (%) and compared by means of the Pearson Chi square test.

of patients with stomas had longer stays. The FGSI scores were not significantly different (p = 0.838) between the two groups.

No significant difference (p = 0.108) was observed in the mortality rates between the two groups.

#### Discussion

FG is a rapidly progressive infective disease that may induce a life-threatening condition and constitute a surgical emergency.<sup>5,6</sup> The backbone of therapy for FG is an emergency surgery for debridement combined with broad-spectrum antibiotic medication.<sup>7-9</sup>

A systemic review by Sarofim et al.<sup>10</sup> reported diversional stomas as predictors of poor outcomes in patients with FG. It showed that the mortality rate remained high, and fecal diversion did not reduce the rate of mortality. Furthermore, significantly high number of surgical procedures was performed for the group with stoma formation. These results are similar to those

of our study; the number of patients with diversional stomas hospitalized for more than 30 days were more than that of those without stoma (p = 0.044). There was no significant difference in the mortality rate between the two groups.

We hypothesized that the creation of a diversional stoma improves the prognosis of patients with FG. We divided the patients into two groups according to the postoperative wound diameter. Among the patients with postoperative wound diameters less than 20 cm, those with fecal diversion had longer hospital stays (> 30 days) than those without fecal diversion (p = 0.001). Among the patients with postoperative wound diameters larger than 20 cm, those with a stoma had shorter hospitalization stays than those without a stoma (p = 0.039). A higher proportion of patients with stoma had hospital stays exceeding 30 days than those without stoma.

These contradictory findings may be attributed to several factors. First, patients with larger postoperative wound diameters are likely to have a more severe disease, and it is possible that some of the patients may not have survived long enough for stoma creation. Second, the duration of case collection in this study was relatively long, ranging from the period when computed tomography (CT) imaging was not widely available to the current era where it is readily accessible for suspected cases. This advancement in diagnostic technology has improved the accuracy of diagnoses and allowed for earlier detection.

Therefore, if a wound has a diameter exceeding 20 cm and involves the perianal area, a diversional stoma should be created. The advantages of stoma formation include eliminating fecal contamination, facilitating wound healing, and minimizing the frequency of changing the dressing, which reduce patient discomfort and pain.

Despite advances in understanding the etiology and pathophysiology of FG, the reported mortality rate remains high at the range of 20-40%.<sup>4,7-9,11</sup> In our study, the mortality rate (13.04%) was lower than the average rate. Adequate resuscitation, broad-spectrum antibiotic therapy, and surgical debridement decrease systemic toxicity and halt the progression of infection. Six of our patients died, of whom four underwent fecal diversion. Of the four, two died of aspiration pneumonia, one died of hospital-acquired pneumonia, and the other one had extensive bleeding from esophageal varices due to long-term liver cirrhosis. The cause of death of the other two patients (without stoma) was refractory systemic infection related to FG.

Regarding the relationship between mortality and fecal diversion, patients with stomas showed a trend for increased mortality, but the difference was not significant due to the few deaths (6 cases).

Other factors such as patient characteristics, comorbidities, surgical techniques, and postoperative care that could influence mortality should also be considered. To further investigate the impact of fecal diversion on mortality, future studies with larger sample sizes and more comprehensive data collection are warranted. Additionally, considering the limitations of this study and the potential confounding factors, a multivariate analysis could be performed to adjust for these factors and assess their independent association with mortality.

The FGSI scores, which were determined based on the Acute Physiology and Chronic Health Evaluation score proposed by Laor et al. in 1995,<sup>12</sup> have been widely used for assessing the prognosis of patients with FG. According to the study, a FGSI score above 9 indicates a 75% probability of mortality, while a score below 9 indicates a 78% survival expectation. Studies support the efficacy of FGSI scores with similar prognostic outcomes.<sup>13-16</sup> However, the FGSI score could be calculated for only 16 patients (34.78%) in our study. Therefore, further analysis may have no clinical significance.

The difficulties in collecting FGSI scores can be attributed to the following. First: the study had a long duration (spanning more than 10 years), which increased the risk of missing medical record data. Second, FGSI is not a routine or commonly used index in the emergency department of our hospital. Typically, patients with FG are likely to be admitted through the emergency department. However, if the symptoms are mild, the required values for FGSI may not be collected, which posed challenges in retrospectively estimating FGSI in this study. Third, due to advancements in CT imaging technology and equipment in recent years, our emergency physicians and surgeons seem to rely more on combining blood analysis and CT imaging findings to assess the severity of FG. They consider both the results to evaluate the severity. In terms of stoma surgery selection, the approach at our hospital is to perform debridement during the first surgery and proceed with stoma creation and debridement during the second surgery. FGSI could not demonstrate a meaningful comparison due to the limited number of cases recorded.

Regarding the length of hospital stay, this study showed that more patients who stayed in the hospital for less than 30 days had wounds smaller than or equal to 20 cm in diameter. Additionally, number of patients with hospital stays of less than 30 days who required stoma creation was low. Therefore, we can reasonably infer milder FG results in smaller wounds, a lower rate of stoma creation, and shorter hospital stays. However, further research is necessary to validate these findings and investigate additional factors influencing the length of hospital stay.

Regarding wound size, this study had two main findings. First, the patients with wounds smaller than or equal to 20 cm in diameter were younger. Second, patients with wounds smaller than or equal to 20 cm in diameter had short hospital stays. In summary, smaller wounds were associated with younger ages and shorter hospital stays. Assessing wound size poses certain challenges; it is difficult to obtain accurate and objective measurements of the size (regardless of area or volume), decide on the timing of measurements, and establish the criteria for grouping. Further research is needed to address and understand these challenges.

This study has some limitations. First, it was a retrospective single-center study. Second, the sample size was small, although we analyzed cases diagnosed between January 1998 and December 2018. Finally, patient information for the assessment of the FGSI score was limited. Despite these limitations, the results of this study support stoma creation in patients with FG who have a postoperative wound larger than 20 cm in diameter, as there has not been any major advances in the medical or surgical treatment for FG.

## Conclusion

This study showed that a higher proportion of patients with stoma had hospital stays exceeding 30 days than those without stoma. Patients with stomas showed a trend for increased mortality, but this was not significant due to the low death count. Milder FG results in smaller wound diameter, a lower rate of stoma creation, and shorter hospital stays. The causal relationships require further in-depth analysis and study.

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#### <u>原 著</u>

## 佛尼爾氏壞疽與大腸造口介入之評估

胡庭碩<sup>1,2</sup> 陳彥誠<sup>1,2</sup> 林毓冰<sup>1,2</sup> 黃啟洲<sup>1,2</sup> 許倍豪<sup>1,2</sup> 丁文謙<sup>1,2</sup>

<sup>1</sup>中山醫學大學附設醫院 外科部 <sup>2</sup>中山醫學大學附設醫院 大腸直腸外科

**前言** 佛尼爾氏壞疽 (FG) 是一種壞死性筋膜炎,同時發生在肛周、會陰或生殖器區域, 導致皮下小血管栓塞,並發展為上覆皮膚的壞疽。幾十年來,高死亡率、延長住院時間 和與之相關的醫療費用一直困擾著醫生。本研究旨在評估造口對佛尼爾氏壞疽患者死亡 率和住院時間的影響。

方法 我們回顧性納入了 1998 年至 2018 年間在我院診斷為 FG 的 46 例患者。根據他 們是否接受造口進行分析,將患者分為兩組。

**結果** 有造口的患者的住院時間明顯短於沒有造口的患者 (*p* = 0.044)。兩組在性別、年齡、傷口直徑、住院科、Fournier 壞疽嚴重程度指數 (FGSI)、死亡率、手術次數和實驗室參數 (包括 C 反應蛋白、白細胞)等方面均無顯著差異計數、中性粒細胞-淋巴細胞比率和糖基化血紅蛋白。亞組分析顯示,術後傷口直徑小於 20 cm 的患者中,有造口的患者住院時間比沒有造口的患者長 (*p* = 0.001)。然而,在術後傷口直徑大於 20 cm 的患者中,有造口的患者

結論 我們推論患有造口的病患,其住院時間超過 30 天的比例較高,相較於沒有造口的病患。具有造口的患者呈現死亡率上升的趨勢,但由於死亡數量較低,這種趨勢並不具統計學意義。FG病情較輕會導致較小的傷口直徑,造口率較低,且住院天數較短。

關鍵詞 Fournier 壞疽、壞死性筋膜炎、腸造口、大腸造口。