Fournier's Gangrene: A Review and Outcome Comparison from 2009 to 2016

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Objective: The outcome of Fournier's gangrene (FG) may be affected by comorbidities, demographics, and choice of treatment modality. We sought to evaluate our institution's management protocol of FG measured by mortality rate (MR) and length of hospital stay (LHS) in a retrospective cohort study.

Approach: A database of 20 FG cases at our institution throughout the 2009–2016 study period was assembled by a retrospective review of medical records. A Fournier's Gangrene Severity Index Score (FGSIS) was calculated for each case. Data were analyzed for statistical significance using logistic regression.

Results: The most common presentation of FG at our institution was a hyperglycemic diabetic male in his fifth decade of life with a second risk factor such as recent surgery or active malignancy. The average FGSIS was 9 overall and 14 for the mortalities. An increased FGSIS was predictive of having an increased MR or hospital stay above the median (>25 days) ($p=0.0194$). The average LHS was 32 days overall, 22 days for patients treated with hyperbaric oxygen therapy and 40 days for patients treated with tangential hydrosurgery. Overall MR was 15%.

Innovation: This is the second known study to characterize usage of tangential hydrosurgery in the management of FG.

Conclusion: Treatment outcomes at our institution are comparable to those reported in recent literature, a significant decline from the historical MR of 50–60%.

Keywords: comorbidity, demographics, disease management, Fournier's gangrene, hyperbaric oxygenation, length of stay

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INTRODUCTION

FOURNIER'S GANGRENE IS a life-threatening urologic emergency that has challenged surgeons since it was first described by Baurienne in 1764.¹ The disease has historically been associated with a high rate of morbidity and mortality; however, modern mortality rates have been reported ranging from 4.7% to 10.1%.^{2–4} As described by Fournier in 1883, the typical patient was a young healthy male who developed an idiopathic, fulminant, necrotizing fasciitis of the male genitalia.² Since its first description, this classic

picture of the Fournier's gangrene patient has changed. Fournier's gangrene has been shown to be associated with several different comorbidities, have distinct etiologies, afflict both young and old, and affect female patients as well.³

Several studies have examined methodologies for predicting the severity of a case of Fournier's gangrene. A Fournier's Gangrene Severity Index Score (FGSIS) has been described by Laor *et al.*, consisting of nine separate metrics: serum creatinine, hematocrit, potassium, body temperature, heart

rate, respiratory rate, white blood cell count, serum sodium, and serum bicarbonate.^{5,6} Each variable is then ranked on a scale of 0–4 according to severity. This methodology has since been validated in the literature by several studies.^{6,7} Other studies have offered alternatives for measuring the severity and predicting mortality in Fournier's patients.^{3,7} Lin *et al.* proposed and validated a simplified scoring index based on the FGSIS to only include creatinine, hematocrit, and potassium.⁷

Traditionally, the mainstay of therapy for Fournier's gangrene has focused on early diagnosis, application of broad-spectrum intravenous antibiotics, and immediate surgical debridement.² In recent decades, negative pressure wound therapy (NPWT) and hyperbaric oxygen therapy (HBOT) were introduced as adjunctive treatment modalities. Rosser *et al.* were the first to report applying NPWT to a Fournier's gangrene patient and reported a positive outcome on hospital stay in a single case report.^{8,9} Several studies have examined the use of HBOT on Fournier's gangrene patients with mixed results. In a series of 11 patients, Pizzorno *et al.* attributed a 0% mortality rate to the adoption of HBOT.¹⁰ However, in a larger retrospective study, Mindrup *et al.* found no difference in length of stay or mortality with HBOT.¹¹ Mindrup *et al.* cautioned against routine HBOT adoption based on the cost associated with the therapy, \$600–\$1,300 per treatment at their center.¹¹ In contrast, most recently, Rosa and Guerreiro reported a mortality rate of 20.8% in a series of 34 patients treated with HBOT.¹²

Tangential hydrosurgery has been proposed as a possible tool in the management of FG. Tangential hydrosurgery has been utilized by plastic and burn surgeons for surgical debridement in various clinical situations, including burns, necrotizing fasciitis, venous stasis ulcers, pressure sores, and diabetic ulcerations.^{13,14} However, utilization of tangential hydrosurgery for debridement of Fournier's gangrene has only been reported in one case previously and was shown to effectively and safely debride the necrotic tissue in a timely manner.¹⁴

At the three hospitals affiliated with our residency program, the existing standard protocol for management of Fournier's gangrene patients consists of early diagnosis, initiation of the hospital's sepsis protocol, administration of broad-spectrum antibiotics, and prompt surgical debridement. At our primary hospital, we have recently adopted the use of HBOT; however, the other two hospitals affiliated with our residency program have not. NPWT has been available for use at all three hospitals during this period. One of the hospitals without hyperbaric wound therapy did utilize a tangential hydrosurgical

device to aid in debridement of select patients. Currently, the use of each therapy is made on a case-by-case basis according to surgeon judgment.

In an effort to improve the quality of patient care, our urology department is analyzing our performance with various urologic conditions and analyzing ways to improve our diagnosis and management of patients. Given the high mortality and morbidity associated with Fournier's gangrene, reviewing our current management protocols, examining our outcomes, and searching for ways to improve management is an important endeavor. This quality improvement study was conducted to improve our understanding of how we manage these patients.

CLINICAL PROBLEM ADDRESSED

Effective treatment of Fournier's gangrene requires timely surgical intervention and aggressive postoperative management to reduce the risk of mortality and morbidity of extended hospital stay. The use of advanced surgical debridement tools and new wound healing modalities may be useful in improving patient outcomes and decreasing duration of hospital stay. This retrospective analysis demonstrates that surgical debridement using tangential hydrosurgery appears to be a safe and feasible innovation that warrants further study.

MATERIALS AND METHODS

The study was reviewed and approved by the New York Medical College Institutional Review Board. Patient consent was waived because there was minimal risk to patients and no identifying information was collected. A retrospective chart review, from January 2009 to October 2016 was conducted by searching each hospital's electronic medical record system using Fournier's gangrene ICD-9 codes. Search results revealed 20 cases (Table 1) of Fournier's gangrene within the study period. Demographic, presentation, management, operative, and outcome data were recorded. Statistical analysis was performed with Microsoft Office Excel and MedCalc statistical software. Logistic regression was used for analysis of data. A *p*-value of less than 0.05 was considered statistically significant.

During the study period, HBOT was available for use at one hospital. At the other two hospitals, HBOT was not available, but a tangential hydrosurgical device, the Versajet, was available. NPWT was available at all three medical centers. Standard management at each hospital consisted of early diagnosis, initiation of sepsis protocol, administration of broad-spectrum antibiotics, and

Table 1. Patient characteristics

Patient	Year Treated	Age	Gender	Primary Site	Involvement			Comorbidities ^a										Presentation		FSBG (mg/dl)	Lactate (mmol/L)
					Abdominal	Rectal	Diabetes	Hepatitis	EtOH Abuse	Drug Abuse	Smoking History	Dementia	Recent Surgery/Trauma	Active Malignancy	Time (No. of Days)						
1	2010	54	M	Scrotum	Y		Y							Y	Y	1	19	35	120		
2	2011	63	M	Scrotum, Penis			Y									14	8	32	183	3.0	
3	2014	58	M	Perineum	Y		Y									4	9	53.5	504	7.9	
4	2012	57	M	Scrotum	Y		Y							Y		4	11	44	245	4.0	
5	2009	72	F	Perineum			Y		Y	Y					Y	2	2	31.1	286		
6	2014	74	M	Scrotum	Y		Y									1	14	31.5	219	8.9	
7	2016	74	M	Scrotum	Y								Y		Y	1	6	24	89	2.8	
8	2013	20	M	Perineum	Y											3	12	23	111	7.3	
9	2012	55	M	Perineum			Y									2	2	35	228	2.7	
10	2012	72	M	Scrotum	Y										Y	3	11	18	107	1.8	
11	2012	55	M	Perineum	Y				HCV+		Y					1	13	24	91		
12	2014	45	M	Scrotum, Perineum			Y					Y		Y	Y	14	12	37.1	107	1.1	
13	2014	53	M	Perineum			Y									10	4	26.1	124	1.2	
14	2014	54	M	Scrotum			Y									10	3	28	167		
15	2014	36	M	Scrotum			Y		HAV+							3	4	26.6	333		
16	2016	66	M	Perineum			Y								Y	2	6	37.4	134		
17	2011	63	M	Scrotum	Y				HCV+					Y		3	16	29	777	8.6	
18	2012	52	M	Penis			Y				Y		Y	Y		2	12	20.3	189	0.9	
19	2010	56	M	Scrotum	Y											0	8	26.9	110		
20	2012	50	M	Scrotum			Y							Y		3	2	34.2	103		

^aComorbidities-0/20 patients were HIV⁺.

BMI, body mass index; FSBG, finger stick blood glucose; FGSIS, Fournier's Gangrene Severity Index Score.

prompt surgical debridement. Tangential hydro-surgery, NPWT (or vacuum-assisted closure therapy, wound V.A.C.), and HBOT were utilized based on surgeon's discretion.

Data were collected from each chart by reviewing each patient's admission history and physical, operative reports, laboratory and radiological reports, progress notes and discharge summaries. Demographic data, including age and sex, were recorded for each patient. Length of hospital stay (LHS), time until first operation, delay before presentation, number and type of operative procedures were all recorded. Presenting characteristics, laboratory values, radiological findings, and culture results were all recorded. Charts were reviewed to determine management strategy, including types of antibiotics and utilization of new technologies. An FGSIS was calculated for each patient as described by Laor *et al.*³

RESULTS

Of the 20 patients treated for Fournier's gangrene over the study period of 2009–2016, the majority (19/20) were male. The average age at presentation was 56 (range: 19–74). The scrotum was the primary site of involvement in 60% (12/20) of patients. The perineum was the primary site in 40% (8/20) and penis the primary site in 5% (1/20) of patients. Fifty percent (10/20) of patients had abdominal wall involvement, and twenty-five percent (5/20) of patients

had documented rectal involvement. No patients had thorax involvement. The most common associated comorbidity was diabetes mellitus with an average finger stick blood glucose of 211.4 ± 167.9 mg/dL. Sixty-five percent (13/20) of patients were diabetics, 20% (4/20) had history of drug or alcohol abuse, 30% (6/20) had recent surgery/trauma, 20% (4/20) had a documented smoking history, 30% (6/20) had an active malignancy, 15% (3/20) had hepatitis, 15% (3/20) were paraplegics, and 10% (2/20) suffered from dementia.

Positive urine or blood bacterial cultures were identified in 85% (17/20) of patients. All patients with negative cultures had received broad-spectrum intravenous antibiotics before obtaining cultures. All patients with positive cultures (17/17) had multiple organisms identified. All patients (20/20) received combination broad-spectrum antibiotic therapy with the most frequently utilized agents being vancomycin ($n=10$), piperacillin–tazobactam ($n=9$), clindamycin ($n=6$), and ampicillin–sulbactam ($n=3$). Less frequently utilized agents included gentamicin, meropenem, trimethoprim–sulfamethoxazole, and fluconazole. NPWT was utilized in 40% (8/20) of patients, HBOT in 20% (4/20) of patients, and tangential hydrosurgery in 10% (2/20) of patients. Sixty percent (12/20) of patients required urinary diversion and thirty percent (6/20) required fecal diversion. None required orchiectomy. The median number of times patients were brought to the operating room was four (range: 1–10). The median

Table 2. Treatment and outcomes

Patient	Number of Surgical Interventions	Fecal Diversion		Urinary Diversion		Treatment			Length of Hospital stay (Days)	Deceased?
		Completed?	Type	Completed?	Type	Tangential HS	HBOT	NPWT		
1	7	Y	Colostomy	Y	Suprapubic cystostomy			Y	32	Y
2	7	Y	Colostomy	Y	Suprapubic cystostomy			Y	63	
3	1							Y	4	
4	6	Y	Colostomy	Y	Suprapubic cystostomy				48	
5	1			Y	Suprapubic cystostomy				19	
6	5			Y	Suprapubic cystostomy				69	
7	2							Y	6	Y
8	8			Y	Suprapubic cystostomy			Y	63	
9	1								24	
10	2								24	
11	10	Y	Colostomy					Y	61	
12	2			Y	Suprapubic cystostomy				27	
13	4			Y	Suprapubic cystostomy		Y	Y	23	
14	4	Y	Rectal tube				Y		32	
15	2						Y		12	
16	6						Y		19	
17	2								5	Y
18	6			Y	Bilateral nephrostomy	Y			36	
19	2	Y	Rectal tube						22	
20	4			Y	Suprapubic cystostomy	Y		Y	44	

HBOT, hyperbaric oxygen therapy; NPWT, negative pressure wound therapy.

number of days before operating on patients was 1 day, with most patients being brought immediately to the operating room. The median number of days before presentation was three (range: 0–14 days). Of those patients who presented in less than 3 days ($n=14$) compared to those who presented after 3 or more days ($n=6$), 42.9% (6/14) and 66.7% (4/6) had a hospital stay duration of greater than 25 days, respectively.

The average FGSIS was 9 (range: 0–19). The average FGSIS for the mortalities was 14. On logistic regression, increased FGSIS was predictive of LHS longer than median (>25 days) or mortality ($p=0.0194$). Among patients treated with HBOT, the average FGSIS was 4, the average hospital stay was 22 days, 25% (1/4) of patients required urinary diversion, and 25% (1/4) of patients required fecal diversion. Among patients not treated with HBOT, the average hospital stay was 34 days. For the two patients treated with tangential hydrosurgery, the average FGSIS was 7, the average hospital stay was 40 days, both patients required urinary diversion, and one required fecal diversion. Fifteen percent (3/20) of patients in this study died during their hospital stay. Treatment and outcomes are summarized in Table 2. Logistic regression analysis is summarized in Table 3.

DISCUSSION

Our data are consistent with recent data suggesting that Fournier's gangrene most commonly affects males aged between 50 and 60 years.^{2,15} Modern mortality rates have been reported from 4.7% to 10.1%.^{2–4} Kim *et al.* reviewing 650 Fournier's patients obtained from a large national database (the National Surgical Quality Improvement Program database) found the mortality rate to be 10.1% and suggested that this represented a more accurate description of contemporary mortality rates from the disease.⁴ The mortality rate of 15% (3/20) in this series falls within the range of mortality rates reported in the literature and is closer to the more contemporary rate published by Kim *et al.* All three patients who died in our cohort were transferred from other healthcare facilities, suggesting possible

pre-existing deconditioning on admission. Two of the three patients had received treatment with NPWT, while none was treated with HBOT or tangential hydrosurgery. Two of the patients died within the first week of admission (LHS <7), while the third patient had a prolonged hospital course (LHS >25) complicated by active pancreatic malignancy. The authors believe that utilization of these modalities within FG is more likely to affect wound healing time and LHS than mortality rates. Therefore, we believe it unlikely that the use of either tangential hydrosurgery or HBOT in these patients would have changed the hospital course for these patients.

The average FGSIS of the patients in our study was 9. This number also falls within ranges reported in the literature, suggesting that our cases were similar in severity to those reported in the literature.^{16,17} Our patients had a median hospital stay of 25 days and an average hospital stay of 32 days. This number falls within the range of data reported in the literature for average length of stay as well.^{3,16,17} On logistic regression, increased FGSIS was predictive of LHS greater than 25 days (above median) or mortality (odds ratio [OR] = 1.29, confidence interval [CI] = 1.0071–1.6671, $p=0.0194$). For every 1-point increase in a patient's FGSIS, this conferred a 32% increased chance of mortality or staying in the hospital for 25 days or longer.

The proposed benefits of HBOT are that increasing tissue oxygenation may improve wound healing through the direct antimicrobial properties of reactive oxygen species and through potentiation of angiogenesis.¹⁸ The patients treated with HBOT in our cohort had an average hospital stay lower than the median (22 days). However, the low (0%) mortality rate and lower than average FGSIS of 4 suggest that there may be a selection bias of utilizing HBOT for less severe cases of Fournier's gangrene.

Due to the low sample size in this study, we were not able to adequately compare different subgroups. We would like to have been able to compare those treated with HBOT, tangential hydrosurgery, or vacuum-assisted wound closure devices to patients who were not. This article represents only the second reported incidence of using tangential hydrosurgery in the management of Fournier's gangrene. Of the two patients treated with tangential hydrosurgery, one had several comorbidities and an FGSIS of 12, while the other had a relatively low FGSIS of 2. Both patients had an LHS greater than the median of 25 days. While this may suggest that the device may not be beneficial for improving LHS, our sample size is too small to determine this. Our experience with the device is consistent with Chammas *et al.*, in that the technology is safe and feasible for use in select

Table 3. Logistical regression for factors predictive of mortality or length of hospital stay >25 days

Factor	Odds Ratio	Confidence Interval	p
FGSIS	1.32	1.0071–1.667	0.0194
BMI	1.10	0.87–1.089	0.6567
FSBG	1.00	0.99–1.004	0.7085
Lactate	1.74	0.745–1.78	0.5095
Abdominal wall involvement	2.40	0.373–1.461	0.3593

patients.¹⁴ Further study of the device should determine whether any benefit is derived from its utilization in the management of Fournier's gangrene.

The time to presentation for the 20 patients in this cohort ranged from only a few days to two full weeks. This dramatic range contributed to extended hospital stays and highlights the need for protocols to be in place to assess and treat patients presenting with FG. When these patients finally seek medical attention, many are in critical condition. Thus, early involvement with necessary specialties is an important early step in the treatment plan following hemodynamic stabilization of the patient. These patients represent complicated cases with multiple disease processes occurring at once, and all members of the treatment team must function in unison from the beginning. Early administration of broad-spectrum antibiotics immediately after blood is drawn for culture is the second step in the treatment algorithm. Coverage for gram-positive, gram-negative, and anaerobic bacteria should be included with initial antibiotic selection. Antibiotics may then be adjusted according to culture and sensitivity results from wound, blood, and urine cultures.

Based on recommendations of existing literature and utilization of this methodology in our patient cohort, we would recommend early surgical intervention and consideration of early diversion, urinary or fecal, whenever appropriate. The primary procedure should be focused on aggressive surgical debridement of infected, ischemic, and necrotic tissue. Our experience with HBOT and tangential hydrosurgery is limited, but both modalities appear as safe and viable treatment methods for FG. These therapies were not involved with any mortality and the patients who were treated with these modalities had hospital stays comparable to the other patients in the study. These modalities were not predictive of decreased mortality or hospital stay less than 25 days ($p = 0.55$, $OR = 0.5556$, $CI = 0.0800-3.8585$) on logistic regression analysis. The observed power was 0.08 and a sample size of 217 patients would be needed to detect a difference. As our institution only saw 20 FG patients during our 7-year study period, this statistic highlights the need for collaboration between institutions to improve our understanding of this rare disease.

A major limitation of our study, as well as most studies involving Fournier's gangrene, is that they are retrospective in nature and typically lack sufficient power. Our study contributes to the

KEY FINDINGS

- Following a standard protocol of broad-spectrum antibiotics, initiation of sepsis protocol, and prompt surgical debridement, Fournier's gangrene is associated with a 15% mortality rate at our institution and patients had an average length of stay in the hospital of 32 days. These findings are comparable to the contemporary Fournier's gangrene mortality rate of 4.7–10.1%.^{2–4}
- Every 1-point increase in FGSIS conferred a 32% increased chance of prolonged hospital stay (>25 days) and risk of mortality.
- The tangential hydrosurgery device, HBOT, and NPWT are effective modern treatment modalities that are safe and feasible. Further studies with larger numbers of patients are warranted to determine if they confer any therapeutic benefit.

reservoir of knowledge that can be utilized in future epidemiologic investigations of Fournier's gangrene. To test whether any of the new technologies should be adopted on a routine basis, a large study involving many institutions over several years would need to be undertaken, given the low incidence of Fournier's gangrene in the U.S. population.

INNOVATION

The introduction of tangential hydrosurgery has the potential for improving FG outcomes by enhancing the surgical debridement stage of care. This novel technology may deliver faster debridement and higher surgical precision, enabling a greater percentage of healthy tissue to be salvaged compared to traditional debridement. In addition, tangential hydrosurgery may be associated with reduced operative blood loss and reduced risk of infection spread due to the localized vacuum aspiration of infectious particles. However, any supposed benefit of the technology would require further study.

AUTHOR DISCLOSURE AND GHOSTWRITING

No competing financial interests exist. No ghostwriter was utilized in the preparation of this article.

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Abbreviations and Acronyms

BMI	= body mass index
CI	= confidence interval
FG	= Fournier's gangrene
FGSIS	= Fournier's Gangrene Severity Index Score
FSBG	= finger stick blood glucose
HBOT	= hyperbaric oxygen therapy
LHS	= length of hospital stay
MR	= mortality rate
NPWT	= negative pressure wound therapy
OR	= odds ratio