# Enteric Fistula Treatment and Management: Results of an Institutional Inpatient Treatment Protocol

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## ABSTRACT

**Introduction:** Enterocutaneous fistulae (ECF) are abnormal communications between the gastrointestinal tract and skin that may occur following an abdominal operation and result in significant morbidity and even mortality. Standardized care of patients with ECF has not been implemented at the majority of tertiary hospitals. We sought to evaluate the benefits of a multidisciplinary team utilizing an evidence-based clinical treatment protocol for inpatient management of ECF.

**Methods:** We performed an Institutional Review Board-approved retrospective analysis of outcomes after the implementation of an evidence-based clinical treatment protocol for patients admitted with ECF to the acute care surgical service at a large academic medical facility. Patients managed prior to the established protocol were considered part of the pre-protocol cohort (pre) while patients managed following implementation were included in the postprotocol cohort (post). A review of all eligible patients' hospital and clinic medical records was performed.

**Results:** In the pre cohort (n=6), the average length of stay was 37 days, ranging from 16-67 days, with a 16% spontaneous closure rate and 60% requiring operative management for closure. A single patient was not offered surgery due to significant comorbidities. The post cohort (n=13) demonstrated an average length of stay of just 16 days, ranging from 4 to 28 days, with an 84% spontaneous closure rate and 16% requiring operative closure.

**Conclusion:** Utilization of a standardized treatment approach results in high spontaneous closure rates with a decreased hospital length of stay.

# INTRODUCTION

Enterocutaneous fistulae (ECF) are abnormal communications between the lumen of the gastrointestinal tract and skin that most often occur as a devastating complication following an abdominal operation. They occur due to disruption of the intestinal lining as a result of various processes, including spontaneous perforation or transmural necrosis, infection, surgical instrumentation, mechanical trauma, inflammatory bowel disease, or foreign body.1-4 ECF are classified based on their anatomic site of origin (eg, gastric, small bowel, colonic) and output volume.2,3,5 Management requires a complex, multidisciplinary approach focused on proper nutritional support, sepsis control, and supportive care to maximize spontaneous closure rates.3,6,7

While there has been a focused effort to improve many of the components of care for ECF patients, there has been little emphasis on a comprehensive protocol to aid in the management of these patients.

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We hypothesized formation of an evidence-based treatment protocol for ECF management would result in increased nonoperative closure rates.

The basis for many of the components incorporated within our protocol has been previously described and published.<sup>2,6,8-10</sup> Within our institution, an interprofessional committee formulated a standardized treatment protocol for the management of patients with ECF, utilizing an evidence-based approach. The protocol focuses on correcting intravascular volume deficits along with early and regular nutritional assessments. An emphasis on wound management, including fistula isolation and output control for prevention of wound-associated complications, is essential.

The aim of this study was to evaluate patient outcomes before and after implementation of this interprofessional treatment protocol.

## **METHODS**

An Institutional Review Board-approved retrospective chart review was performed on all patients with a diagnosis of ECF admitted to or receiving inpatient consultation from the Acute Care Surgery service (ACS) at an urban academic institution between November 1, 2011 and May 15, 2016. All patients with ECF were included, except those who chose to pursue immediate palliative care measures. Patients receiving care prior to implementation of the evidence-based treatment protocol on January 21, 2014 were classified as the pre-protocol (pre) cohort. Patients treated after January 21, 2014 were enrolled in the post-protocol (post) cohort. Patient data recorded and analyzed includes patient demographic information, cause of ECF, anatomic location of ECF (if known), complications of treatment, spontaneous closure of fistula, time to fistula closure, hospital length of stay, and discharge disposition. Unfortunately, due to the small sample size, nonparametric or parametric statistical testing could not to be used in this analysis to determine significance. Therefore, descriptive statistics were used to describe the differences in outcomes between the groups.

In the pre cohort, there was no standardized process for managing patients. Each patient was managed by different physicians and their care was dictated by the single physician. This created variability on choices in nutrition, wound care, and medication use. Therefore, some patients received some of the care provided in the later-developed protocol and some received none of it.

### **Inpatient ECF Treatment Protocol**

The protocol contains 8 key components within 4 algorithmic stages designed to optimize management of the hospitalized ECF patient. The protocol is designed for a target discharge of 14 to 21 days following ECF identification. The 8 components within each stage address wound management, infection control, social constructs, laboratory evaluation, patient mobility, nutritional support, fistula output management, and pain control. Each of the stages is defined below. (*For complete ECF protocol, see Appendix online at https://www.wisconsinmedicalsociety.org/\_WMS/publications/wmj/pdf/118/2/Appendix-Kugler.pdf.*)

Stage 1 (Days 1-3): Identification and source control of intraabdominal fluid collections is carried out with percutaneous drainage and/or antibiotics as clinically indicated. Patients undergo extensive laboratory evaluation, including electrolyte surveillance with a focus on basic metabolic panel, magnesium, phosphorus, and urine urea nitrogen. Intravascular volume deficits are corrected with attention to electrolyte and acid base status. A 1:1 replacement with half-normal saline is utilized when fistula outputs are greater than 1 liter per 24 hours. Attempts to define the ECF anatomy are made with a fistulagram, considered the gold standard test.<sup>11-13</sup> Fistula outputs are measured and controlled utilizing nasogastric suction and/or proton pump inhibitors when indicated. Baseline nutritional assessments are performed utilizing indirect calorimetry. Early parenteral nutrition (PN) is initiated following control of any underlying sepsis, regardless of the volume of their fistula output. Patients are evaluated by physical and occupational therapy services. Patient and family questions are addressed and an overview of each stage is discussed to help guide patient expectations.

Stage 2 (Days 4-7): Following stabilization and initial evaluation, each of the core components is readdressed continuously. Wound management with refined dressings aimed at fistula isolation is performed. Subcutaneous octreotide therapy is initiated at 200 mcg every 8 hours if outputs remain high and/or hinder isolation, with a goal output less than 1 liter daily, and discontinued if the outputs do not decrease by 100% after 48 hours. Source control should be achieved and antibiotics continued as deemed clinically necessary. Repeat lab evaluation, including nutritional assessment, continues. Total parenteral nutrition (TPN) is continued to optimize nutrition; however, enteral nutritional (EN) access is achieved with initiation of therapy, including oral intake, as able. EN initiation is determined by fistula output volume less than 1 liter and wound care stability. Continuous adjustments in parenteral nutrition should address each individual patient's metabolic needs.

Stage 3 (Days 8-10): Wound management efforts continue with an emphasis on dressing plans that last greater than 24 hours, as transition to outpatient management is the goal. Need for further source control and antibiotic therapy is continuously reevaluated. All unnecessary lines should be removed, including Foley catheter and central venous access unless required for TPN. In the event that TPN must be continued, nutrient adjustments and cycling of infusion over 18 hours provide movement toward an outpatient regimen. ECF output control to less than 1 liter daily is the goal in assisting with fistula isolation, along with nutrition and hydration. Finally, pain management should be transitioned towards maximization of nonnarcotic oral medications with supplemental oral narcotics as needed. Utilization of liquid formulations is typically implemented in the setting of ECF within 90 cm of the pylorus.

**Stage 4 (Days 11-14):** As wound management is in the final stages of adjustment, dressings commonly remain in place greater than 24 hours without interim need for attention. At this stage, source control has been achieved and antibiotics are stopped as soon as appropriate. All central venous access is transitioned to tunneled

lines, with dual lumen access used only when peripheral lab draws are not feasible. Patients continue to undergo continuous nutritional reassessment even at this late stage with minor adjustments as needed. If tolerated, enteral nutrition and oral intake are maximized to limit need for TPN. Any necessary TPN is now transitioned to 12-hour infusions to aid in potential home regimens. Pain management regimens are finalized with oral narcotic supplements limited as much as feasible.

#### **Negative Pressure Wound Therapy Application**

The dressing system utilized within these subjects was comprised of application of a fistula ring made from the VAC GranuFoam sponge covered in the standard drape and sized to incorporate the site of drainage. In circumstances where patients suffer from enteric adherence factor, a single base layer of Acticoat (Smith & Nephew) was placed over the exposed bowel/granulation tissue beneath the VAC GranuFoam sponge with negative pressure wound therapy (NPWT) set to 75 mmHg continuous suction or less. Use of NPWT was determined based on location of the fistula and concomitant abdominal wound rather than fistula output. If the fistula could not be isolated from the wound, a wound manger was used over the entire wound to protect intact skin.

#### Discharge

Determining discharge destination is at the forefront of patient management, as approval of home health resources or facility placement require planning. As a rule, long-term acute care facilities have been utilized for ECF patients when patients require complex wound care (eg, dressing changes > 30 minutes), with some demonstrating deconditioning and/or need for TPN administration. Inpatient rehabilitation traditionally has been the focus for patients who exhibit a deconditioned state with potential need for TPN but less complex wound care needs. While nursing homes tend to be ideal for deconditioned patients who may or may not require TPN, such facilities typically are not optimal for complex wound management. Finally, in that subset of patients who are capable of returning home, home nursing care is most often deemed necessary for management of TPN and wound care.

#### RESULTS

A total of 19 patients with ECF who met inclusion criteria were included for analysis. Patient demographics, comorbidities, and fistula characteristics are outlined in Table 1. Overall, the pre cohort was slightly older than the POST cohort (mean age 57 years vs 50 years), with small bowel injury the most common cause of ECF within both groups. Of note, the post cohort included 2 patients with comorbid malignancy, while the pre group had none. Protocol compliance in the post cohort was 100%.

ECF treatment protocol implementation resulted in a decrease in length of stay from 37 days (range: 16-67 days) to 16 days (range: 4-28 days). Additionally, protocol implementation resulted in improved rates of spontaneous closure at a shorter interval. The

|                         | Pre-Protocol<br>n = 6 | Post-Protoco<br>n = 13 |
|-------------------------|-----------------------|------------------------|
|                         |                       |                        |
| Age (years)             | 57 (38-77)            | 50 (26-81)             |
| Male, n (%)             | 4 (66.6%)             | 4 (30.7%)              |
| Comorbidities, n (%)    |                       |                        |
| Hypertension            | 4 (66.6%)             | 4 (30.7%)              |
| Diabetes                | 2 (33.3%)             | 5 (38.5%)              |
| Depression/Anxiety      | 2 (33.3%)             | 4 (30.7%)              |
| Malignancy              | 0 (0%)                | 2 (15.4%)              |
| Malnutrition            | 2 (33.3%)             | 2 (15.4%)              |
| Hyperlipidemia          | 1 (16.7%)             | 1 (7.7%)               |
| Other                   | 1 (16.7%)             | 1 (7.7%)               |
| Primary Cause, n (%)    |                       |                        |
| Small Bowel Injury      | 3 (50.0%)             | 4 (30.7%)              |
| Anastomotic Leak        | 0 (0%)                | 3 (23.1%)              |
| Pancreatitis            | 1 (16.6%)             | 2 (15.4%)              |
| Post Cesarean Section   | 0 (0%)                | 1 (7.6%)               |
| Unknown                 | 0 (0%)                | 1 (7.6%)               |
| VAC Dressing Injury     | 1 (16.6%)             | 0 (0%)                 |
| Fistula Location, n (%) |                       |                        |
| Small Bowel             | 4 (66.6%)             | 10 (76.9%)             |
| Colon                   | 2 (33.3%)             | 3 (23.1%)              |
| Fistula Output, n (%)   |                       |                        |
| Low (≤500 mL/day)       | 4 (66.6%)             | 5 (38.5%)              |
| High (> 500 mL/day)     | 2 (33.3%)             | 8 (61.5%)              |

Abbreviation: VAC, vacuum-assisted closure.

|                              | Pre-Protocol<br>n=6 | Post-Protocol<br>n=13 |
|------------------------------|---------------------|-----------------------|
| Length of stay (days)        | 37                  | 16                    |
| Spontaneous closure, n (%)   | 1 (16.7%)           | 11 (84.6%)            |
| Time to closure. n (%)       | 8 months            | 2.7 months            |
| 30-day mortality, n (%)      | 2 (33.3%)           | 1 (7.7%)              |
| Complications, n (%)         | 3 (50%)             | 3 (23.1%)             |
| MSSA infection               | 0 (0%)              | 1 (33.3%)             |
| Urinary tract infection      | 0 (0%)              | 1 (33.3%)             |
| Wound infection              | 1 (33.3%)           | 0 (0%)                |
| Enterocutaneous fistula      | 1 (33.3%)           | 0 (0%)                |
| Deep venous thrombosis       | 1 (33.3%)           | 0 (0%)                |
| Discharge disposition, n (%) |                     |                       |
| Home                         | 1 (16.7%)           | 10 (76.9%)            |
| Long-term acute care         | 4 (66.7%)           | 1 (7.7%)              |
| Inpatient rehabilitation     | 1 (16.7%)           | 1 (7.7%)              |
| Skilled nursing facility     | 0 (0%)              | 1 (7.7%)              |

pre cohort experienced a spontaneous closure rate of 16.7% with 4 of the remaining 5 requiring operative closure. One patient was not offered operative intervention due to extensive medical comorbidities. Patients managed following protocol implementation experienced a spontaneous closure rate near 85%, with the remaining 2 patients ultimately requiring operative closure. Secondary outcomes demonstrate a decrease in complication rates and improved 30-day mortality. Following implementation of the ECF protocol, a greater percentage of patients were discharged home (77% vs 17%) with less reliance on facility outpatient management. See Table 2 for complete outcomes.

## DISCUSSION

Management of patients with ECF is challenging, resulting in significant expenditure of time and resources within our health care system. Prior to implementing this standardized protocol within our institution, we found that few goals were outlined to ensure progressive care for these patients and that care was extremely disorganized, with little attention paid to ensuring a balanced approach. The majority of patients within the pre cohort did not have the expertise of each of the disciplines represented within the protocol, and much of their treatment was not focused on evidence-based approaches. This study demonstrates that an interprofessional approach with standardized treatment using evidencebased guidelines for ECF management may prove beneficial to patient outcomes. After implementation of our protocol, patients experienced a reduction in the length of inpatient hospital stay, an increase in spontaneous closure rate, and lower morbidity and mortality.

Initial management of ECF requires a comprehensive approach that focuses on the medical aspects of care. To maximize the likelihood of spontaneous fistula closure, factors such as etiology, fistula output, free distal flow, and comorbid disease must be identified, considered, and managed. Researchers and clinicians in the past have described the use of TPN, somatostatin, and NPWT to decrease output and facilitate spontaneous closure.<sup>14-17</sup>

This study describes our successfully implemented standardized approach to managing such complex patients. The majority of ECF in our patient population occurred after small-bowel injury. However, other common causes such as anastomotic leak, pancreatitis, gunshot wounds, and vacuum dressing injury were treated, improving the applicability of these findings to multiple patient populations. Interestingly, spontaneous closure of ECF was successful in the majority of patients after implementing the protocol, but was rare prior to implementation. We believe this is a result of the aggressive medical management of this patient group, particularly optimization of nutrition to facilitate healing.

ECF are classified according to output: high (>500 cc/24 hours), medium (200-500 cc/24 hours), and low (<200 cc/24 hours).<sup>5,18</sup> Often, anatomic location of the ECF has a direct relationship to its output. As high output fistulas are less likely to close spontaneously and are associated with a higher mortality, all attempts at decreasing output are critical to management. Proper nutrition in the setting of ECF is essential to successful management, with TPN utilization being key. TPN has been shown to decrease the enteric secretions and, thereby, fistula output.<sup>8,19-21</sup> Octreotide, a somatostatin analogue, has been widely recommended to help in ECF closure.<sup>22,23</sup> However, the success of octreotide in limiting fistula output and increasing spontaneous closure rates remains debated.<sup>24-27</sup> We chose to utilize octreotide 200 mg every 8 hours in patients with high-output fistula and those in whom dressings proved difficult due to fistula output. Output was monitored closely, and if no significant decrease in output occurred within 48 hours, the octreotide treatment was stopped. Of note, we observed decreased fistula output in nearly all of our post cohort following initiation of octreotide therapy; however, we were unable to isolate its benefit given the multifaceted approach presented in this study. The high spontaneous closure rates observed in our post cohort compare favorably with rates reported in the literature and likely exhibit the combined benefits of these adjunct therapies.

Prevention of wound complications is essential to successful management of an ECF. Patients with large open wounds are frequently treated with NPWT as a means of isolating the wound and protection from effluent spillage.<sup>28-30</sup> One of the feared complications of NPWT is formation of an ECF; however, utilization of NPWT within the post cohort demonstrated no subsequent fistula formation. We attributed this to the utilization of a protective Acticoat layer between the bowel and the sponge.

The relatively low mortality rate of 7.7% in the post cohort compared to 33.3% in pre cohort compares favorably with rates reported by other studies.<sup>3,8,21</sup> An improved mortality outcome is achieved with a focus on early sepsis control, electrolyte correction, and nutritional support. Prevention of organ failure through early identification and treatment of sepsis is essential as sepsis has been shown to be the main cause of death in ECF.<sup>7,9,31-33</sup>

One of the focuses of this study was reduction in length of stay, as inpatient hospitalizations following ECF formation are often long, translating to a significant expense. Length of stay for the purposes of this study was based solely on hospital days at our institution. This study demonstrates an impressive decrease in length of stay within the post cohort, which we postulate is the result of early identification of ECF patient needs, allowing early arrangements for home health care or long-term treatment when indicated. Decreasing length of stay can be challenging, as it requires substantial communication between the hospital care providers, community facilities, and home care agencies. Additionally, early identification of insurance needs provides adequate time for approval, preventing further delay. Finally, a great challenge in discharge is aligning family and patient expectations with those of health care providers. Prior to implementation of the protocol, discharge planning was a significant challenge given a lack of guidance and organized criteria. The post cohort demonstrates the benefits of this protocol, as discharge is achieved in a safe and timely manner by addressing a patients' clinical, social, and financial needs.

There are several limitations to this study, including its retrospective nature, small size of the study population, and the single institution setting. Utilization of a historical control cohort prior to formation of the treatment protocol provides opportunity for confounding variables in care that are not accounted for in this study. Unfortunately, due to the small sample size, we are unable to utilize nonparametric or parametric statistical testing to determine significance. Therefore, we chose to use descriptive statistics to describe the differences in outcomes between the groups. Furthermore, it should be noted that none of our patients had an underlying etiology of inflammatory bowel disease, which is also a common cause of ECF. These limitations should be considered when evaluating the generalizability of the data; however, given the success of the current approach, we believe that patients with ECF and the health care system benefit from a standardized approach to this complex problem.

#### CONCLUSION

Inpatient management plays a pivotal role in the treatment of ECF patients. An interprofessional team utilizing a standardized, evidence-based treatment protocol can lead to reduced inpatient length of stay and improved rates of spontaneous ECF closure, thereby reducing overall morbidity and mortality.

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