# Enterocutaneous fistula: Are treatments improving?

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**Background.** We studied the etiology, treatment, and outcome of enterocutaneous fistulas in 106 patients to evaluate our current practice and the impact of newer therapies—octreotide, wound vacuum-assisted closure (VAC), and fibrin glue—on clinical outcomes. Review of the literature and our own 1990 study indicate a mortality rate of 5% to 20% for enterocutaneous fistula, and a healing rate of 75% to 85% after definitive surgery.

**Methods.** We reviewed all cases of gastrointestinal-cutaneous fistula from 1997 to 2005 at 2 large teaching hospitals. We identified 106 patients with enterocutaneous fistula; patients with irritable bowel disease and anorectal fistulas were excluded.

**Results.** The origin of the fistula was the small bowel in 67 patients, colon in 26, stomach in 8, and duodenum in 5. The etiology of the fistula was previous operation in 81 patients, trauma in 15, hernia mesh erosion in 6, diverticulitis in 2, and radiation in 2. Of the 106 patients in the study, 31 had a high output fistula (greater than 200 mL/day), 44 had a low output fistula, and, in 31 patients, the fistula output was low but there was no record of volume. Initial treatment was nonoperative except for patients with an abscess who needed urgent drainage. In 24 patients, the effect of octreotide was monitored: in 8 patients, fistula output declined; in 16 patients, octreotide was of no benefit. Fibrin glue was used in 8 patients and was of benefit to 1. The wound VAC was used in 13 patients: 12 patients still required operative repair of the fistula, whereas the fistula was healed in 1 patient. The main benefit of the VAC system was improved wound care in all patients before definitive surgery. Total parenteral nutrition was used in most patients to provide nutritional support. Operative repair was performed in 77 patients and was successful in 69 (89%), failing in 6 patients with persistent cancer or infection. Nonoperative treatment was used in 29 patients and resulted in healing in 60%. Of 106 patients, 7 (7%) died of fistula complications. The cause of death was persistence or recurrence of cancer in 4 patients and persistent sepsis in 3.

**Conclusion.** Enterocutaneous fistula continues to be a serious surgical problem. The wound VAC and fibrin glue had anecdotal successes (n = 2), and one-third of patients responded to octreotide. We believe that octreotide should be tried in most patients and that the wound VAC has a role in selected patients. Although 7% overall mortality is lower than in previous studies, the number managed without operation (27%) remains the same. In addition to early control of sepsis, nutritional support, and wound care, a well-timed operation was the most effective treatment. (Surgery 2006;140:570-8.)

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THE TREATMENT OF ENTEROCUTANEOUS FISTULA (ECF) continues to be a challenging surgical problem. Hospital stays are long, patients are often malnourished and depleted, wound infection and sepsis

Presented at the 63rd Annual Meeting of the Central Surgical Association, Louisville, Kentucky, March 9-11, 2006.

Supported

Accepted for publication July 10, 2006.

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0039-6060/\$ - see front matter

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570 SURGERY

frequently coexist, the spontaneous closure rate of the fistula is less than 25%, and the 5% to 20% mortality rate is considerable. Most fistulas are caused by previous abdominal surgery, trauma, or Crohn's disease. Review of published series, in addition to our own study in 1990, indicate that the mortality rate of this condition is 5% to 20% , with a fistula-healing rate of 75% to 85% after definitive surgery.<sup>1-4</sup> In addition, the incidence of ECF is not decreasing.

The principles of ECF treatment have been clearly delineated and generally accepted. They include patient resuscitation, early recognition and treatment of sepsis, localization and study of the fistula, wound and skin care, nutritional support, a team approach, and a properly timed operation.<sup>4-6</sup> In the past 10 to 15 years, a number of new and

specific therapies have been developed to help with the management of ECF. These include biologic fibrin glue injection, wound vacuum-assisted closure (VAC), and the use of somatostatin analogs. It is also possible that the etiology of fistula formation today has changed due to the widespread use of laparoscopy. The purpose of this study was to evaluate our current experience with ECF and to analyze newer therapies— octreotide, wound VAC, and fibrin glue—on clinical outcomes in patients with ECFs.

## MATERIALS AND METHODS

We analyzed the charts of all patients with external gastrointestinal fistulas seen at the University of Louisville Hospital and Norton Hospital from 1997 to 2005. Patients with esophageal, tracheoesophageal, pancreatic, or anorectal fistulas were excluded from the study. Patients with inflammatory bowel disease also were excluded from the study because of the tendency of patients with Crohn's disease to spontaneously form internal and external fistulas and because these patients often are on medications such as steroids and antimetabolites that are unique and could confound interpretation of results. Each chart was reviewed for the following information:

(1) origin of the fistula, (2) volume of fistula output, (3) etiology. (4) length of hospital stay, (5) type of therapy selected (ie, nonoperative vs operative or both), (6) timing of therapy, (7) outcomes of nonsurgical and surgical treatments, and (8) mortality. In addition, specific observations were made regarding the use of octreotide, fibrin glue, and wound VAC. The characteristics of the fistula, the indications, and the results of the newer modalities of treatment were specifically evaluated. The results were compared with the results reported in an earlier study from this institution.<sup>1</sup> This study was approved by the University of Louisville Human Studies Committee.

### RESULTS

We reviewed the medical records of 193 patients who received treatment for an intestinal fistula by our faculty at these 2 hospitals between January 1997 and July 2005. Following chart review, we identified 106 patients who had an ECF originating from the stomach, small intestine, or colon and who met the criteria of this study. A total of 87 patients were excluded: 60 patients with inflammatory bowel disease, 9 patients with esophageal fistulas, 4 patients with tracheoesophageal fistulas, 6 patients with pancreatic fistulas, and 8 patients with anorectal fistulas. Of the 106 patients included in

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Location	No. of fistulas
Stomach	8
Duodenum	5
Small bowel	67
Colon	26
Total	106

this study, 58 were men and 48 were women. The median age was 52 years (range, 23 to 81 years). For most patients, the length of hospital stay was 2 to 4 weeks with a mean stay of 22 days (range, 1 to 71 days).

Initial management. Initial treatment consisted of an overall assessment of the patient, the nature of the fistula, and condition of the wound. We evaluated patients for infection and sepsis, corrected fluid and electrolyte abnormalities, imaged the fistula, and consulted our wound care/ostomy nurses. Patients were usually made NPO. Radiologic fistulograms and abdominal CT scans generally identified the source and anatomy of the fistulas, and indicated whether a distal bowel obstruction was present, keeping the fistula open. A nasogastric tube was placed for the higher, more proximal fistulas, and proton pump inhibitors were given to decrease gastric secretion. Sources of infection and sepsis were addressed early. Abdominal fluid collections and abscesses were drained either by CT-guided percutaneous drainage techniques or by operation in one-fourth of our patients. All patients received nutritional support via enteral feedings or total parenteral nutrition (TPN). In most cases, control of fistula drainage and protection of the skin was directed by the hospital's wound care/ ostomy nurses. The initial objective included a trial of medical, nonoperative therapy for each patient to allow for spontaneous fistula closure, unless conditions such as distal bowel obstruction or ongoing abdominal sepsis precluded this approach. Once stabilized, subcutaneous octreotide was used in some patients in an attempt to decrease fistula output.

**Fistula description and characteristics.** The anatomic sites of the fistulas are given in Table I. The small intestine was the origin of the fistula in 67 of the 106 patients, the colon in 26, the stomach in 8, and the duodenum in 5 patients. The most common cause of these fistulas was a recent abdominal operation in 81 patients. These operations consisted of procedures for cancer, small-bowel obstruction and lysis of adhesions, gynecologic tumors, and ventral hernia repairs. Two fistulas

Etiology	No.
Previous operation	81
Trauma	15
Hernia mesh erosion	6
Diverticulitis	2
Radiation	2
Total	106

**Table II.** Etiology of fistulas

were the result of a laparoscopic bowel injury. The second most common etiology was abdominal and pelvic trauma in 15 patients with injury to the viscera. Hernia mesh erosion (n = 6), previous bowel radiation (n = 2), and diverticular disease (n = 2) were infrequent causes of fistula (Table II).

We characterized fistulas as high output if the discharge of enteric contents over a 24-hour period exceeded 200 mL.<sup>1</sup> The fistulas are classified by output in Table III. A total of 31 patients had high output fistulas and a fluid loss of greater than 200 cubic mL per day. The majority of fistulas (75/106) were classified as low output. Forty-four patients had documented fistula outputs less than 200 ml per day; output was not recorded in 31. However, in each case, the discharge was managed with simple gauze dressings changed 2 or 3 times/day.

Octreotide. Octreotide was administered as therapy in 24 patients and as prophylaxis in 4 patients following definitive surgery for a fistula. Patients were started at doses of 100 mcg every 8 hours by subcutaneous or intravenous injection; subsequent doses were titrated based on the initial response. In 8 of the 24 patients, fistula output declined significantly (>50%), and octreotide was deemed beneficial (Table IV). Of these 8 patients, 4 (50%) healed the fistula without an operation versus 25% in the 16 nonresponders. In 16 patients, octreotide had no impact on output or obvious benefits on the fistula management. In the entire group of 24 patients, the fistula healed spontaneously in 30%, surgery was required in 50%, and the fistula had not healed or closed in 20%.

Wound vacuum-assisted closure (VAC) system. In 13 patients, the VAC system (KCI, San Antonio, Tex) was used (Table IV); the system is composed of an evacuation tube embedded in a polyurethane foam dressing. The VAC technique involves placing an open-cell foam sponge dressing into the wound cavity. A wound catheter with lateral perforations (the evacuation tube) is then laid on top of the foam. The wound is sealed by an adherent occlusive dressing, and the tube is attached to a vacuum unit that applies a controlled subatmospheric pres-

Table III. Fistula output

Classification	No.
High output	31
Low output: volume recorded	44
Low output: volume not recorded	31
Total	106

Table IV. Treatment outcomes

Regimen	No. of patients	No. benefited
Octreotide	24	8
VAC	13	1
Fibrin glue	8	1

VAC, Vacuum-assisted closure.

sure (typically 125 mm Hg below ambient pressure) to the wound. This device was applied to patients with deep, open wounds with omentum, fascia, or granulation tissue at the base without visible bowel and with a fistula tract tunneling through the granulation tissue. In all patients, the wound VAC protected the skin, improved the condition of the wound. In several patients, the VAC device promoted wound contracture and healing. There were no septic complications from the VAC, and fistula output did not increase. In 1 case, VAC treatment healed the fistula. In 12 patients, there was no improvement in the fistula; these patients required definitive operative repair of the fistula. The patient with a successful outcome was a 29year-old patient who had a high output small-bowel fistula that exited into the base of a large transverse upper abdominal wound. The wound VAC was applied for 2 months and changed twice a week. The fistula gradually closed, and a skin graft was applied to the wound.

Fibrin glue. Fibrin glue was used in 8 patients, 7 of whom had a low output fistula. In each patient, the wound edges were debrided and the tract was irrigated with sterile saline in preparation for the delivery of the fibrin. Five to ten milliliters of fibrin glue were injected into each fistula's tract via a double-barreled syringe, which mixes the right combination of fibrinogen and thrombin that in turn simulates the coagulation cascade in the fistula tract. At the surgeon's discretion, multiple sessions (2 to 5) of glue injection were performed in 3 of the 8 patients. There was a response in 1 patient who had a low output fistula following colon surgery for a colonic perforation. This fistula healed after 2 glue injections were given 3 weeks apart (Table IV).

**Sepsis.** One-fourth of these patients had abdominal wall or intraabdominal infections or abscesses that needed treatment as part of the initial resuscitation. If possible, the intraabdominal fluid collections were treated with a CT-guided drainage; otherwise exploratory laparotomy was performed.

**Operative treatment.** Definitive surgery was carried out in 77 of 106 patients and was successful in terms of fistula healing in 69 patients (89%). Timing of the operation after initial diagnosis ranged from 1 to 34 weeks, with an average time interval of 12 weeks in this series.

Of all the patients, 29 were selected for nonoperative treatment; the fistula healed in 18 (60%) during the hospital stay or the follow-up period. In the remaining 11 patients, the patients are either waiting definitive surgery or their medical conditions are too fragile to contemplate operative surgery and repair.

**Fistula output and operation.** In review of the entire 106 patients, 31 patients had a high output fistula and 21 (68%) required an operation. In the 75 patients with a low output fistula,

56 (74%) required an operation (Table IV). The rate of operation performed between these 2 groups was not significantly different.

**Morbidity and mortality.** Of the 106 patients, 7 died during the course of treatment for their intestinal fistulas. Three of the 7 deaths were caused by sepsis, and 4 patients died from complications of persistent cancer of the ovary, colon, or rectum.

## DISCUSSION

In this study, we have analyzed the results and overall management of patients with ECF by 1 group of surgeons over an 8-year period (1997 to 2005). The fistulas were most often a complication of previous operations or abdominal trauma and either blunt or penetrating. Despite concerns about the risk of bowel injury during laparoscopic surgery, there were only 2 such cases in this series of 106 patients.

A total of 29 patients were treated non-operatively, whereas 77 underwent planned operation on an elective basis for resection of the fistula. Spontaneous healing of fistulas without operation occurred in 18 patients (16%). The healing rate after definitive operation was 89%. For the entire group of 106 patients, the overall fistula-healing rate was 82% and the mortality rate was 7%.

The main objective of this study was to evaluate the role, the indications, and the effectiveness of the wound VAC system, biologic fibrin glue, and octreotide as new therapies for intestinal fistulas. To date, there have only been a few case reports that indicated successful healing with these techniques; there has not been an investigation of the role of these therapies as a strategy in the overall surgical management of ECFs.

**Octreotide.** Octreotide administration had a beneficial effect on the fistula output in one-third of the 24 patients to whom it was given. The somatostatin analog reduced fistula output about 50% in these 8 patients. The decision to use octreotide was made by the attending surgeon. Because a trial of octreotide was not a standing policy, only 24 patients received this therapy. When patients had a favorable response to octreotide, this effect was apparent within 3 days, as has been reported by others.<sup>3</sup> The octreotide response in these 8 patients seemed to be more effective in fistulas with a high output (>200 ml per day of fluid loss).

Sancho et al<sup>8</sup> reported inconclusive results for octreotide administration. In their prospective trial of octreotide plus TPN (14 patients) versus TPN plus placebo (17 patients), fistula closure within 20 days was observed in 8 of 14 fistulas in patients given octreotide, and in 6 of 17 in patients receiving placebo (P = 0.4). They did not find that the addition of octreotide had any advantage or improvement over TPN plus the usual supportive measures. These were all patients with postoperative fistulas, and treatment was started within 8 days of a diagnosis. The paper by Nubiola et al<sup>7</sup> is most frequently cited as evidence that somatostatin (octreotide) has a useful role in the treatment of smallbowel fistulas, especially once sepsis is under control. His group reported on 27 patients with 11 low output fistulas, 11 high output fistulas, and 5 fistulas arising from abdominal wall defects, in which octreotide (100 ug q.8 hours) decreased fistula output by an average of 55% within the first 24 hours. A 77% spontaneous closure rate was observed, using TPN and octreotide after an average of 6 days compared with 4 to 6 weeks of using TPN alone. This, of course, suggests that octreotide itself can substantially shorten the length of hospitalization and overall morbidity associated with ECF. It is interesting that they were not able to duplicate those findings in 1995.8 It is our recommendation that, once patients have been stabilized, a trial of octreotide is worthwhile. If there is a significant reduction in fistula output within 3 days, octreotide should be continued. We found a trend toward greater healing without operation (50% vs 25%) in the responders.

**Wound VAC.** Our institutional experience with wound VAC has increased considerably in the last 5 years. It is apparent that a variety of open wounds, including some burn wounds and skin grafts, re-

spond nicely to the wound VAC in terms of accelerated closure and rates of healing. It is tempting to assume that the VAC system would aid healing of abdominal wounds with an intestinal fistula as well. On the other hand, there is the possibility that increased negative pressure applied to a wound with an active fistula will actually keep the fistula open and increase fluid loss through the tract.

We used the wound VAC in 13 patients in this series, and there were no adverse effects from this therapy. In all patients, the wound VAC reduced the size of the abdominal wall defect and reduced skin irritation and erythema. However, we could attribute actual healing to the wound VAC in only 1 patient. The other 12 patients still required an operation to control and correct their fistulas. Although not specifically measured in this study, it is our impression that the wound VAC allowed most patients to be discharged several days sooner than usual from the hospital with continued wound VAC therapy at home.

Reports of successful outcomes with the wound VAC for ECF are anecdotal. To date, this system has not been approved for this use. In the literature, 2 groups have reported on their experience using the wound VAC in the management of enterocutaneous fistula in 4 patients.<sup>9,10</sup> The fistulas developed after complex surgery for a small-bowel obstruction in 2 patients, and after colon and pelvic operations for cancer in 2 other patients. In these articles, the authors report a decrease in fistula output and complete healing of small-bowel fistulas in 3 patients after 3 weeks, 5 weeks, and 8 weeks duration of VAC treatment. In the fourth patient, operation to resect the fistula and perform intestinal reanastomosis was performed with a good outcome. We also observed that use of the wound VAC did not increase fistula output in our series, dispelling one concern about this form of treatment. Our current position is that a trial of the wound VAC is in order if the wound is clean and starting to granulate. The type of wound most suited for this system would appear to be an open wound with some depth and no exposed bowel, and with soft tissue available at the edges to close in on the open defect.

**Fibrin glue.** Our experience with fibrin glue injection into fistula tracts was limited to 8 patients and was not encouraging. We got a successful response—closure of the fistula—in only 1 patient but only for 11 days. The other 7 patients had small-bowel fistulas with high outputs, and fibrin glue did not seem to help. Reports in the literature regarding use of fibrin glue for postoperative fistulas are few, and they describe endoscopic delivery

of the glue.<sup>11-13</sup> Rabago et al<sup>11</sup> treated 13 patients with an external fistula arising from either the stomach, esophagus, or the small bowel or colon.<sup>11</sup> This team was able to identify the source of the fistulas with endoscopy and injected 2 to 4 mL of the fibrin glue, with complete sealing of the fistula in 86% of cases. Only 1 of the sealed fistulas reopened. All were reachable with the endoscope. Truong et al<sup>12</sup> have described a technique of injecting pieces of vicryl mesh and sealed off with fibrin glue for anastomotic leaks in 9 patients with good results in 7 after 1 or 2 endoscopic treatments.<sup>12</sup> In our opinion, fibrin glue has a limited role, but it would seem the ideal fistula for such treatment would be a long fistula with a narrow tract. We have no experience with the endoscopic approach.

High output vs low output fistulas. In our experience there was little difference in the patients with high output versus low output fistulas in terms of spontaneous closure, length of hospital stay, or necessity for operative resection. We found that an operation was necessary in 68% of patients with a high output fistula versus 75% for patients with a low output fistula. This contradicts general statements in the literature, where the assumption is made that the rate of spontaneous closure for patients with high output fistulas is significantly less with conservative treatment than the rate of closure for patients with low output fistulas.<sup>6</sup> On the other hand, McIntyre et al<sup>4</sup> from St. Mark's Hospital reported results similar to ours. In a series of 132 patients with ECFs arising from both large- and small-bowel, they found the rate of spontaneous closure with high output and low output fistulas was 27.6% and 25% respectively. Overall, there was a 28% spontaneous closure rate of all small-bowel fistulas regardless of output, location, or cause. In our series, the rate of spontaneous closure was only 16%, and several patients had been treated and operated upon at other hospitals before transfer to us, which indicates that these patients had complex fistulas. We also excluded patients with inflammatory bowel disease, which may impact the results regarding spontaneous closure.

**Operative therapy.** Over the years, the results of operative treatment have improved (Table V). In our series, operative treatment was successful in terms of fistula closure in 89% of patients. Surgeons have come to recognize that resuscitation of patients with a fistula, wound care, and restoration of nutrition take initial priority, and that operation should be delayed for weeks to months to allow for decrease in the inflammatory response and the adhesions. Conter, Roof and Roslyn<sup>14</sup> were the first

Windsor  $(2004)^3$ 

Current study (2006)

mortanty rates		
Study	Mortality (%)	
Welch (1960) <sup>15</sup>	43	
Tountas (1975) <sup>17</sup>	23	
Dunphy (1978) <sup>16</sup>	22	
Fazio $(1983)^2$	30	
Cheadle $(1991)^1$	19	

11

7

**Table V.** Gastrointestinal enterocutaneous fistulamortality rates

to write about this concept, and McIntyre<sup>4</sup> has advocated waiting until the abdomen becomes "soft" before operating. We waited an average of 12 weeks but some have recommended waiting as long as 6 months.

Factors that were considered in choosing the time to reoperate in our series included the nutritional status of the patient, the softness and pliability of the abdomen, and the surgeon's preference. In one-half of our patients, the operations were performed 3 to 6 months after onset of the fistula.

Decrease in overall mortality. The overall mortality of ECF has gradually declined after Edmonds and Welch<sup>15</sup> drew attention to the enormity of the problem in their landmark paper on this subject in 1960 (Table V). They observed a mortality rate of 43%. Since then, surgeons have realized that corrective surgery should be performed later rather than sooner, reserving immediate early operation for patients with abdominal infections not amenable to other treatments or hemorrhage. Early treatment consists of patient resuscitation, correction of fluid and electrolyte deficiencies, controlling infection, nutritional support, and wound and skin care. The help of a stoma wound care nurse has been invaluable to this effort. In 1991, our mortality rate for 58 patients with an ECF was 19%. Fourteen years later that mortality is 7%. Then, as now, the most difficult patients are those with persistent cancer and infection.

#### SUMMARY

We found that the challenge of treating ECF continues to be considerable even though the overall mortality has declined in the last 40 years. In addition to following time-honored surgical principles for this complex condition, choosing a time for operative repair that is weeks to months after diagnosis represents good surgical judgment. With regard to the newer therapies for ECF, we believe that octreotide has a role in the management of these fistulas. Once the patient is stabilized, octreotide should be tried. A positive response is apparent within 3 days. Based on the results of this study, we also would encourage a greater use of the wound VAC in these patients. The wound VAC has a 2-fold therapeutic value: (1) it improves and simplifies wound care, and (2) in selected fistulas (ie, those associated with deep wounds and mobile soft tissue walls), the wound VAC promotes healing of the wound and potentially closure of the fistula. Fibrin glue injections were of minimal value in this study, although reports of success when given endoscopically can be found in the literature.

The mortality rate of 7% in this study is an improvement over the 19% mortality for ECF in our 1991 report. However, the number of patients managed non-operatively (27%) remains the same. This suggests that even though the newer therapies may have improved patient care, they still have not changed the number of patients who ultimately require an operation to repair the fistula.<sup>16</sup>

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## DISCUSSION

**Dr Merril Dayton** (Buffalo, NY): The authors conducted an 8-year retrospective chart review of gastrointestinal fistula with the specific purpose of looking at 3 new modalities to determine whether they had significant impact on fistula healing: octreotide injection, fibrin glue, and wound vacuum devices. Their interpretation of this study was that these 3 modalities have had very little real impact on the healing of fistula in the 20th century. In fact, 80% of their patients still had to have surgery with surgery being successful in almost 90% of these patients. It is frustrating that in 2006 we still have made so little progress in treating fistula other than with an operation.

The paper did provide a few surprises. One, for example, was that operation rates were as high for low volume fistulae as they were for as high volume. I would ask the authors why operation rates weren't higher in high volume patients.

Secondly, I saw no data about length of stay at a time when hospitals are placing so much emphasis on it. What was the average length of stay was in this series?

Third, one of the things that we have all learned about this condition is that if you operate on these patients too early, you really have a treacherous operation. In this series, the average length between the onset of fistula and surgical treatment was about 3 months, which is a little shorter interval than I normally would use. Would the authors tell us how they decide when to reoperate?

Fourth, why was octreotide utilized in only 20% of your patients? Your concluding statement mentions that it should be tried in most patients; and yet in the study, it was only tried in a minority of patients.

Finally, I am intrigued by the use of wound vacuum devices in the treatment of fistulae. Most payers will not pay for their use in these fistulae. I

wonder what your experience has been, particularly in high volume fistulae. Should it be tried only in low volume fistulae?

Particularly impressive is the lower mortality rate in this series. The fistula-specific mortality may be actually even lower than described because 4 of 7 patients who died had unresectable cancer.

**Dr Bruce A. Harms** (Madison, Wis): You report a positive response to octreotide, and it falls into the category of ancillary treatment options with definitive efficacy. But it is something that is only a treatment option to keep wounds clean, and it is not going to result in healing.

One thing that I would like to have you address is the overall management. You talked about what can be controlled, but what it really comes down to is the success in terms of our operative management.

I agree that the timing you report of an average of 11 weeks until surgery seems to me premature. The key word on fistula management should be patience.

What was the average number of operations these patients had? I believe you said they had 3 operations, but you didn't comment on the overall spectrum or average number of procedures.

The most difficult part of managing these patients sometimes is the wound closure. How did you manage them?

**Dr Michael S. Nussbaum** (Cincinnati, Ohio): The wound vacuum device has been a great help in the management of these patients. It may not close the fistula any sooner, but it certainly improves local wound care and allows patients to get out of the hospital sooner because they can be managed in a home-care setting. If more studies like this one establish that the wound vacuum devices are an important adjunct in the care of these patients, it becomes more likely that the insurers will allow payment for this device.

You conclude that octreotide should be used in more patients, yet your data does not support that conclusion. All that octreotide therapy did was decrease fistula output. It did not seem to provide an advantage in terms of fistulas closure. Only 4 out of 24 octreotide-treated patients had closure of the fistulas, which goes along with your statistics on spontaneous closure.

**Dr Harry M. Richter** (Chicago, Ill): Did the authors identify any patients who absolutely needed to be kept NPO during the waiting for either closure or operation? Or can we feed these patients regardless of fistula output?

**Dr Kimberly K. Nagy** (Chicago, Ill): My question relates specifically to the use of octreotide. You

mentioned that you started your patients at 100 micrograms TID. At what point did you decide to increase the dose? What was your maximum dose? And at what point did you discontinue it?

**Dr Palmer Q. Bessey** (New York, NY): I have 2 questions regarding the nutritional management of these patients. As you know, one of the benefits of TPN was demonstrated in the management of enterocutaneous fistulae almost 40 years ago. In your series you used both TPN and enteral feeding. Could you please tell us more about the criteria for using one versus the other? The second question regards the decision to proceed with reoperation. Did you make any assessment of the patient's nutritional status of the patient at the time, and, if so, what parameters did you use to decide to proceed with operation?

**Dr Mark A. Malangoni** (Cleveland, Ohio): Each of us has experience with patients in whom we are unable to control infection and usually can't wait 12 weeks for an operation. How many patients did you have to operate early for that particular reason, and how did that patient group fare compared to your overall group? Did they also have close to a 90% success rate with one operation?

Could you identify for us what type of prosthetic mesh caused fistulae? There was a paper from the University of Louisville in the early 1990s that pointed out that both absorbable and permanent mesh could result in the occurrence of enterocutaneous fistulas. I wonder if your experience with that has changed.

Tell us a little more about failures. I think we are all interested in the predictors of failure. Do you think you operated on some of these patients too early? Did you encounter some unexpected findings at operation that may have changed your therapy and perhaps led you to wait longer, and did that affect your results?

**Dr Katherine Jung-Mei Liu** (Chicago, Ill): Are high output patients more prone to have surgical failure? What is your strategy for patients that fail the operation?

**Dr John M. Draus:** Judging by the discussion generated by our presentation, I'd say that enterocutaneous fistula must be a common surgical problem.

In our comparison of patients with high output versus low output fistulas, we found that there was little difference in terms of spontaneous closure, length of stay, or need for operative resection in these 2 groups. Whether the output was high or low, 70% of patients required an operation. In 1984, McIntyre et al from St. Mark's Hospital described a series of 132 cases of intestinal fistulas. In their paper, they also noted that the rate of spontaneous closure of patients with high and low output fistulas was the same: 28% versus 25%. In our series, the rate of spontaneous closure was only 16%, and several patients had been treated at other hospitals before transfer to us, which indicates that our patients tended to have complex fistulas. These facts could partially explain why the operative rates were similar in both groups.

The average length of hospital stay for our patients was in the range of 2 to 4 weeks. The majority could be discharged at that time and then closely monitored in an outpatient setting. We believe that this is another benefit of the wound vacuum system. Once the patient is stable, you can place the vacuum dressing, send the patient home, and follow them along in clinic while you are planning the definitive surgical procedure.

With regard to timing of the operation, the early goals of management are resuscitation of the patient, good wound care, and restoration of nutritional status. Taken as a group, we waited an average of 12 weeks before proceeding to surgical resection of the fistula. However, about 50% of these patients were delayed three to six months. A lot of things should be taken into consideration when determining the appropriate time for the operation. We palpate the abdomen and wait until if feels soft. There should be fewer adhesions when this is found. We also want the patient to be in the best nutritional state possible and otherwise be a good physiologic candidate.

We believe that octreotide should be used in more patients. We suggest a 3-day trial of octreotide. If you do not see a dramatic decrease in the volume of fistula output, then it is probably not worth continuing beyond 3 days. Dr Harms commented about our overall management, and stated that 11 weeks seems somewhat premature for operative intervention. We would agree. In fact, in half of our patients, it was 3 to 6 months before we attempted resection of the fistula. You nicely stated that "patience" is the key word in the management of enterocutaneous fistulas. The average number of operations for patients in this study was 2.

Dr. Nussbaum, thank you for sharing your experience with the wound vacuum system in this patient population. We agree that it significantly helps with wound management. Further, if you can get the patient out of the hospital earlier, we believe that makes its use a little more cost effective.

The volume of fistula output had little bearing on our decision whether or not to use the vacuum system on a patient, as long as the patient's wound had the appropriate characteristics. We found that the system did not increase output from the fistula.

We found that about one-third of patients responded to the administration of octreotide. We started with 100 micrograms administered every 8 hours. Over the next 48 hours, the dosage was titrated based on effect. A few patients were increased to 200 or 300 micrograms every 8 hours. But again, we suggest a 3-day trial. If there is no response, the octreotide should be discontinued.

Somatostatin analog reduced fistula output about 50% in the 8 patients who responded to a trial. In this subset, only 4 patients still required an operation. We found a trend toward greater healing without operation.

We took a conservative approach towards feeding. If oral or G-tube feeds increased fistula output, then these patients were made NPO.

Almost every patient received either TPN or enteral feeds. We suggest using enteral feeds if the patient can tolerate them, and provided that the enteral feeds do not increase the volume of fistula output. Enteral feeds were given by mouth, gastric tube, or by feeding tube distal to the fistula. In some cases, it was given as a supplement to TPN. The parameters used to assess the patients' nutritional status were albumin, hemoglobin, and changes in weight.

Dr Malangoni asked about the need for very early operations in patients with uncontrolled infection. Twenty-five percent of our patients were septic at the time of admission to the hospital, and 60% of these patients required an early operation in addition to fluid resuscitation and antibiotics. Early operations were mainly to control infection, and most of those patients did require subsequent definitive operation for the fistula. The subsequent rate of healing for operations to repair the fistula was in line with the others. The healing rate was about 85%.

We had 6 patients with mesh erosions. These were trauma patients with complex, open abdominal wounds. Either vicryl or polypropylene mesh was used to restore abdominal closure. We did not specifically study if there was a propensity of one type of mesh over the other to cause fistulae, but that is a good idea.

The reasons for failure after definitive surgical resection were persistent cancer and sepsis. Therefore, we do not believe that intervening too early was a factor.

We found little difference between high output and low output fistulas in terms of their spontaneous closure, length of hospital stay, or need for operative resection.

For our patients who failed surgical repair, our long-term plan was to reoperate at an appropriate time. We had several patients who were transferred from outside hospitals after an attempted surgical repair of a fistula failed. Our approach to these patients was much like our approach toward other patients: resuscitation, control of sepsis, nutritional support, good wound care, and an appropriately timed definitive operation.