

Risk Factors for Recurrence After Repair of Enterocutaneous Fistula

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Objectives: To assess outcomes after repair of enterocutaneous fistulae (ECF) and identify factors that predict mortality and recurrence.

Design: Retrospective study.

Setting: University hospital.

Patients: One hundred thirty-five patients undergoing ECF repair between 1989 and 2005.

Main Outcome Measures: Mortality and recurrence of ECF.

Results: Definitive operation for ECF was attempted in 135 patients. Mortality was 8%, recurrence was 17%, and 84% of patients eventually survived with a closed fistula. The primary determinant of mortality was ECF recurrence (odds ratio [OR], 6.7; 95% confidence interval [CI], 1.9-23.4). Factors independently associated with ECF recurrence by multivariate logistic regression in-

cluded the presence of inflammatory bowel disease (OR, 4.9; 95% CI, 1.5-16.1), interval between diagnosis and operation of 36 weeks or longer (OR, 5.4; 95% CI, 1.8-16.4), location of fistulae in the small intestine (OR, 9.8; 95% CI, 1.7-57.6), and resection with stapled anastomosis (OR, 4.1; 95% CI, 1.3-13.2). Recurrence of ECF was 35% with resection and stapled anastomosis, 22% with simple oversew, and 11% with resection and hand-sewn anastomosis. Recurrence of ECF was 12% when operation was performed prior to 36 weeks from diagnosis, compared with 36% if performed at or beyond 36 weeks.

Conclusions: The primary determinant of mortality after ECF repair is a failed operation leading to recurrence of the fistula. Risk factors for ECF recurrence include inflammatory bowel disease, fistula located in the small intestine, an interval of 36 weeks or longer between diagnosis and operation, and resection with stapled anastomosis.

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ENTEROCUTANEOUS FISTULAE (ECF) are challenging surgical problems. The principles of management are well established and begin with resuscitation, sepsis control, nutritional support, anatomical characterization, and adequate drainage of fistula effluent.^{1,2} Fewer than 25% of ECF will close spontaneously,³ with the remainder requiring operative repair.

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Recent advances in nutritional support, interventional radiology, and wound management have greatly improved options for treatment of ECF, with a decline in overall mortality to 3% to 12%. Despite this decline, recurrence rates after

attempted definitive surgical repair vary between 9% and 33% and have not improved in recent years.^{1,4-6}

The present study was undertaken to analyze a current series of patients with ECF in a large university medical center and to identify variables affecting the outcome of operative repair. We hypothesized that nutritional repletion, delay of operative therapy for at least 3 months, resection of the intestinal segment containing the ECF, and restoration of intestinal continuity with a hand-sewn, 2-layer anastomosis would minimize recurrence and mortality.

METHODS

PATIENTS

We reviewed records of all patients who underwent an index definitive surgical proce-

cedure for the treatment of ECF originating from the stomach, duodenum, small bowel, or colon at University of California, Los Angeles (UCLA) Medical Center from January 1989 to December 2005. Enteroenteric, enterovesical, enterovaginal, and peristomal fistulae were excluded. Preoperative data selected for retrieval included age, sex, etiology, prior abdominal operations, comorbidities, serum analyte levels (albumin, prealbumin, creatinine), immunosuppression (corticosteroids, antirejection medications, or infection with human immunodeficiency virus), type of nutritional support, location of fistula, referral from outside institution, time from diagnosis to operation, and elective or emergent operation. Operative details included resection vs direct repair of the fistula, type of anastomosis (hand-sewn vs stapled), blood loss, and degree of adhesiolysis. Postoperative information included fistula recurrence and mortality. This study was approved by the institutional review board at UCLA.

STATISTICAL ANALYSES

Univariate and multivariate analyses were performed using Pearson χ^2 test, Fisher exact test for categorical variables, and analysis of variance for continuous variables. Unadjusted analyses were performed to assess whether any preoperative risk factors, comorbidities, operative technique, or postoperative complications were associated with recurrence and mortality. Multivariate logistic regression was performed to identify factors that independently predicted recurrence or death after definitive repair of ECF. The Hosmer-Lemeshow goodness-of-fit test was used to determine the percentage of variance accounted for by the final multivariate model.

RESULTS

We identified 135 patients who underwent definitive surgical repair of ECF at UCLA Medical Center from 1989 to 2005. The mean age was 54 years, and 53% were male. Sites of fistulae included small bowel in 90 patients (67%), colon in 44 patients (33%), duodenum in 3 patients (2%), and stomach in 2 patients (2%). Some patients had fistulae in more than one location. Comorbidities are shown in **Table 1**. Immunosuppression included patients receiving steroids (n=20) and/or antirejection medications following organ transplantation (n=4) or infection with human immunodeficiency virus (n=1). The majority of patients (52%) were referred from an outside institution.

PREOPERATIVE MANAGEMENT

Nutrition was maintained parenterally in 69% of patients and enterally in 30%, with 5 of the latter group receiving parenteral supplementation. Serum albumin level at the time of operation was lower than 3 g/dL (to convert to grams per liter, multiply by 10) in 64% of patients. Mean interval between diagnosis of the fistula and operative repair was 25 weeks (range, 1-208 weeks), as shown in **Table 2**.

OPERATIVE MANAGEMENT

Most procedures were elective. Emergency operations were performed in 14 patients (10%), 7 with intra-abdominal abscesses necessitating to the abdominal wall

Table 1. Comorbid Conditions in 135 Patients With Enterocutaneous Fistulae

Condition	No. (%)
Cancer	32 (24)
Inflammatory bowel disease	31 (23)
Immunosuppression	23 (17)
Diverticulitis	18 (13)
Diabetes mellitus	10 (7)
Hypertension	22 (16)
Chronic obstructive pulmonary disease	5 (4)
Congestive heart failure	3 (3)
Prior irradiation	8 (6)

Table 2. Rate of Enterocutaneous Fistula Recurrence by Interval From Diagnosis to Operation

Interval, wk	No. (%)	
	Patients	Recurrence
<2	7 (5)	0
2-6	12 (9)	1 (8)
7-12	15 (11)	2 (27)
13-36	70 (52)	7 (10)
>36	31 (23)	11 (36)

and 7 with anastomotic leak and peritonitis. Difficult adhesiolysis was described in 97 operations (72%). Operative techniques for repair of fistulae included resection and hand-sewn, 2-layer anastomosis in 91 patients (67%); resection and stapled anastomosis in 26 patients (19%); and direct repair by simple oversew techniques in 18 patients (13%). Abdominal wall defects required mesh closure in 19 patients (14%). Mean estimated blood loss was 483 mL (range, 0-2200 mL).

For the 18 patients in whom oversew techniques were used, adhesions were too dense or vascular to allow complete dissection of the involved intestine in 7 patients. In 3 patients, small-bowel fistulae were present that could have been treated with resection.

MORTALITY

Of 135 patients, 114 ultimately survived with a closed fistula (84%), 10 survived with a recurrent fistula (8%), and 11 died (8%). All deaths were due to sepsis and multiorgan failure (7 associated with a recurrent fistula; 2, with postoperative wound infection and dehiscence; 1, with gastric necrosis after embolization for bleeding; and 1, with aspiration pneumonia and adult respiratory distress syndrome after small-bowel obstruction). The only significant predictor for mortality in both univariate and multivariate analysis was postoperative recurrence of the ECF (odds ratio [OR], 6.69; 95% confidence interval [CI], 1.92-23.39; $P=.003$).

ECF RECURRENCE

Of the 135 patients undergoing definitive operation to repair ECF, 23 developed a recurrence of the fistula (17%). The recurrence rates for various intervals from diagno-

Table 3. Univariate Predictors of Enterocutaneous Fistula Recurrence

Predictor	No. (%)		Odds Ratio	P Value
	Recurrence	No Recurrence		
Serum albumin level, g/dL				
<3	14 (16)	72 (84)	0.99	.76
≥3	9 (18)	40 (82)	1.00	
Prealbumin level, g/dL, mean (SD)	15.7 (8.8)	16.3 (8.7)		.85
Preoperative alimentation				
Parenteral	19 (20)	75 (80)	3.21	.21
Enteral	4 (10)	37 (90)	1.00	
Comorbid conditions				
Inflammatory bowel disease	9 (29)	22 (71)	2.6	.04
Immunosuppression	4 (17)	19 (83)	1.03	.58
Hypertension	8 (36)	14 (64)	3.7	.01
Location of fistulae				
Small intestine	21 (23)	69 (77)	6.3	.007
Large intestine	2 (5)	42 (95)	1.00	
Interval from diagnosis to operation, wk				
<36	12 (12)	92 (88)	1.00	
≥36	11 (36)	20 (64)	4.21	.002
Type of fistula repair				
Stapled anastomosis	9 (35)	17 (65)	4.3	.01
Hand-sewn anastomosis	10 (11)	81 (89)	1.00	
Direct repair, oversew	4 (22)	14 (78)	2.3	.24
Mesh used in closure	5 (26)	14 (74)	2.08	.17
Death	7 (64)	4 (36)	6.2	.006

SI conversion factors: To convert serum albumin to grams per liter, multiply by 10; prealbumin to milligrams per liter, multiply by 10.

Table 4. Multivariate Predictors of Enterocutaneous Fistula Recurrence

Predictor	Adjusted Odds Ratio (95% Confidence Interval)	P Value
Type of fistula repair		
Hand-sewn anastomosis	1 [Reference]	
Stapled anastomosis	4.1 (1.3-13.2)	.02
Direct repair, oversew	3.3 (0.7-15.3)	.12
Inflammatory bowel disease		
No	1 [Reference]	
Yes	4.9 (1.5-16.1)	.008
Interval from diagnosis to operation, wk		
<36	1 [Reference]	
≥36	5.4 (1.8-16.4)	.003
Location of fistulae		
Large intestine	1 [Reference]	
Small intestine	9.8 (1.7-57.6)	.01

sis to operation are shown in Table 2. Since the recurrence rates were not significantly different for periods less than 36 weeks, these were combined to allow categorical variables for subsequent statistical analysis.

As shown by univariate analysis in **Table 3**, variables significantly associated with recurrence included location of the fistula in the small intestine, inflammatory bowel disease, interval from diagnosis to operation of 36 weeks or longer, hypertension, and resection with stapled anastomosis. Notable variables that were not significantly different between patients with and without recurrence included dependence on total parenteral nutrition (TPN); serum albumin, prealbumin, and creatinine

levels; emergency operation; prior radiation; extensive adhesiolysis; number of prior abdominal operations; preoperative comorbidities; immunosuppression; operative blood loss; oversew repair; and the use of mesh for abdominal closure.

Multivariate analysis of ECF recurrence is shown in **Table 4**. Variables included in the model were operative technique, presence of inflammatory bowel disease, interval from diagnosis to operation, and location of fistulae. The proportion of the variance explained by these variables is greater than 87% as determined by the Hosmer and Lemeshow goodness-of-fit test, indicating that a high percentage of the total variability between recurrence and non-recurrence is explained by this model. The model confirms location of the fistula in the small intestine, inflammatory bowel disease, interval from diagnosis to operation of 36 weeks or longer, and resection with stapled anastomosis as variables independently affecting ECF recurrence.

Since timing of operation was a major predictor of recurrence, we performed a univariate analysis for patients who underwent operation within (n=104) or at 36 weeks or longer (n=31) to identify potential covariates. Other than recurrence, the only variables that were statistically different between the 2 groups were preoperative TPN dependence, emergency operation, and sex. Nutrition was provided enterally in 55% of patients in the 36 weeks or longer group, compared with only 26% in the less than 36 weeks group (OR, 2.34; P=.04).

We evaluated the reasons for the long delay prior to operation in these 31 patients. Prolonged medical management was used in 20 patients with a low- to moderate-output fistula in the hope that it would eventually close

spontaneously, and 8 developed recurrence (40%). An additional 9 patients had a prolonged wait to achieve more favorable wound characteristics in large slow-healing wounds, and 3 developed recurrence (33%). It was not possible to determine the reason for the prolonged wait in the remaining 2 patients.

We also performed a univariate analysis for patients with resection and hand-sewn or stapled anastomosis to identify potential covariates. Recurrence was the only variable significantly different between the groups.

The subsequent course of the patients who developed postoperative recurrence of the ECF is shown in the **Figure**. Of the 23 patients, only 15 underwent a subsequent attempt at fistula closure. Two patients died, 1 in the early postoperative period of acute pulmonary and renal failure and another of aspiration associated with a small-bowel resection 1 year after successful reoperation. The fistula recurred a second time in 8 patients, and 2 of these patients died, both of complications associated with the fistula and wound. No attempt was made to repair the recurrent fistula in 8 patients. The fistula closed spontaneously in 1 patient, and 7 were left with a chronic fistula. Three of these 7 patients died, all of septic complications of the fistula and wound. In summary, of 23 patients with recurrence after index operative repair of ECF, only 26% ultimately had a successful outcome with a closed fistula, while 43% lived with a chronic fistula, and 30% died.

COMMENT

Advances in imaging, percutaneous drainage, and wound care technology have markedly improved the ability to identify and control septic foci prior to attempting definitive operative closure of ECF.² Comparing 6 early series prior to 1989 with 4 later ones (**Table 5**), mortality rates fell from 17% to 5%, while recurrence rates were relatively constant at 18% in the earlier era and 19% in the later. Our figures for mortality (8%) and recurrence (17%) are consistent with earlier reports.

Recurrence of ECF was the only variable significantly associated with mortality in our series, emphasizing the importance of an effort to define risk factors for this serious complication. Factors that independently increased the rate of fistula recurrence included inflammatory bowel disease, location of fistulae in the small intestine, interval from diagnosis to operation of 36 weeks or longer, and intestinal resection with stapled anastomosis. The first 2 are well-recognized causes of ECF recurrence, while the latter 2 are new observations from the present study.

Rates of ECF recurrence following operations at 36 weeks or later (36%) after diagnosis were significantly higher than for operations earlier than 36 weeks (12%). Moreover, after accounting for all other risk factors, the later group had a 5-fold increase in risk of ECF recurrence when compared with the earlier group. This observation suggests that prolonged preoperative management can increase recurrence rates after operative repair of ECF.

A single published study has addressed this possibility. Edmunds and colleagues³ reviewed ECF care at the

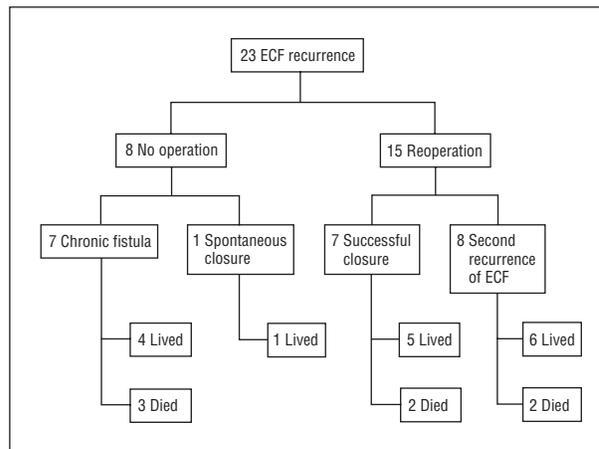


Figure. Schematic showing outcome of patients with recurrent enterocutaneous fistulae (ECF).

Massachusetts General Hospital in the era prior to use of TPN and concluded that an early operative attack on the fistula might avoid the complications associated with malnutrition and fluid and electrolyte problems. Subsequent series^{6-8,11,12} showed that the routine use of TPN all but eliminated mortality from these complications and allowed a delay for potential spontaneous closure of the fistula and, when closure did not occur, for the resolution of maximal inflammation¹³ and for complex wounds to soften¹⁴ prior to attempted repair. Many recent series report relatively long waiting periods with TPN support prior to operative attempts. As an example, Hollington et al⁹ reported a median preoperative interval of 9 months and fistula recurrence rate of 35% in patients undergoing definitive repair. We found a similar recurrence rate of 36% for patients with operation at 9 months or later after diagnosis, far higher than our 12% recurrence rate with operation within 9 months of diagnosis.

The reason for increased failure of fistula repair after 36 weeks is not obvious but may be related to other covariates. We found that patients with TPN dependence or requiring emergency operation were more likely to have operation within 36 weeks, while patients who underwent later operations were more likely to be fed enterally. Implicating enteral nutrition as a potential cause of recurrence is counterintuitive, as the enteral route should improve intestinal barrier function and immune competence. The most common reason for delay appeared to be prolonged nonoperative management at another institution with the hope that the fistula would eventually close or a reluctance to operate for undetermined reasons. Approximately one-third of the patients had a seemingly appropriate delay to await better wound characteristics. Given the limitations imposed by a lack of a specific protocol and variability introduced from patients transferred from other institutions, a prospective study with a protocol that specifies timing of operation according to specific criteria may be necessary to identify factors that increase risk for ECF recurrence when repair is delayed past 36 weeks.

Several studies have cautioned against early operation, when a dense peritoneal reaction makes dissection difficult and causes bleeding, enterotomies, and a high fistula

Table 5. Operative Repair of Enterocutaneous Fistula: Collected Series

Source	Period	No. (%)		
		Definitive Operation	Recurrence	Death
Edmunds et al, ³ 1960	1946-1959	67	8 (12)	10 (15)
Soeters et al, ⁷ 1979	1960-1970	76	13 (17)	11 (14)
Reber et al, ⁶ 1978	1968-1977	108	22 (20)	22 (20)
Aguirre et al, ⁸ 1974	1970-1973	38	8 (30)	6 (22)
Soeters et al, ⁷ 1979	1970-1975	88	19 (22)	18 (20)
Conter et al, ⁵ 1988	1978-1986	46	5 (11)	4 (9)
Hollington et al, ⁹ 2004	1992-2002	167	55 (33)	5 (3) ^a
Lynch et al, ⁴ 2004	1994-2001	203	42 (21)	6 (3)
Draus et al, ¹⁰ 2006	1997-2005	77	8 (11)	^b
Visschers et al, ¹ 2008	1990-2005	107	10 (9)	13 (12)
Current study	1989-2005	135	23 (17)	11 (8)

^aThese deaths were "fistula related within 30 days of surgery."

^bThe number of deaths in patients who were operated on could not be determined in this study.

recurrence rate.^{5,13} We found no recurrences in the few patients who underwent operation prior to 2 weeks and only 1 recurrence (8%) in patients who underwent operation between 2 and 6 weeks. The recurrence rate increased to 27% for patients with operation between 6 and 12 weeks, but this difference was not statistically significant. The overall recurrence rate of 19% in our patients with operation between 2 and 12 weeks is much lower than that reported by Lynch et al,⁴ who found that recurrence was 28% with reoperation between 2 and 12 weeks, compared with 15% with reoperation after 12 weeks. Patient selection is the likely principal reason for this observation. Patients in our early group accounted for 11 of the 14 emergency operations, and 41% had more favorable colonic fistulas; there were only 2 recurrences in the 44 patients with repair of colonic fistulae in our study. While most authors advocate waiting at least 12 weeks prior to definitive operative repair of ECF, Visschers and colleagues¹ recently reported a success rate of 90% in 107 patients with a median time to operation of 53 days. They reiterated the importance of awaiting the desired softness of the wound, a known principle of ECF management. While we do not advocate early operation, our data do suggest that carefully selected patients may have successful ECF closure within 12 weeks of diagnosis.

The second important finding in our study was that recurrence was influenced by the technique of fistula repair. The majority of patients (87%) had successful resection of the segment(s) of bowel containing the fistulae, followed by primary anastomosis. The anastomosis was hand sewn in 2 layers in 91 of these patients (78%) and stapled in 26 (22%). The recurrence rate was significantly higher in patients with stapled anastomosis (35%), compared with hand sewn (11%). Moreover, multivariate analysis found a 4-fold increase in recurrence for stapled compared with hand-sewn anastomosis when all other risk factors were controlled. While prior studies have reported the highest success rate for operative repair of ECF with resection and hand-sewn end-to-end anastomosis, ours is the first to our knowledge that compares results of stapled and hand-sewn anastomoses after resection of ECF.

Simple oversew of the fistula was used infrequently (13%) but was associated with a recurrence rate of 22%

($P = .12$), twice that seen with resection and hand-sewn anastomosis. Oversew was performed when highly vascular phlegmonous adhesions obscured discernible tissue planes or when operation was performed during the period of maximal inflammation between 2 and 12 weeks. While our numbers are small and did not reach statistical significance, we concur with other authors^{3,4,6} that oversew should be avoided as a definitive repair where possible and that resection may be feasible if operation can be delayed until more favorable wound characteristics are present. However, oversew remains an alternative if it is deemed unsafe to attempt the full dissection needed for segmental bowel resection and primary anastomosis.

In summary, mortality rates following ECF repair have declined, while recurrence remains common. Recurrence was the sole predictor of mortality in our series and was influenced by 4 variables, including inflammatory bowel disease, location of fistula in the small intestine, stapled anastomosis, and operative delay beyond 36 weeks. Our data are the first to our knowledge to suggest that resection with hand-sewn anastomosis and operation within 36 weeks of diagnosis may improve mortality by reducing recurrence. Future investigations should focus on operative technique and timing for repair of fistulae involving the small intestine.

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a series of 81 patients older than 65 years and 510 younger controls that postoperative complications were significantly increased among the elderly (40% vs 28%, $P=.01$). The elderly also tend to have more advanced and/or aggressive thyroid cancers, which in part might explain some of the disparity in outcomes observed based on age.

On a population level, there is published literature demonstrating that clinical and economic outcomes for patients aged 65 years or older undergoing thyroidectomy in the inpatient setting are considerably worse than for similar, younger patients. Based on a study of 4836 elderly thyroidectomy patients, those aged 80 years or older appear to have significantly longer lengths of stay, higher complication rates, and higher hospital costs than similar patients aged 65 to 79 years.⁴ In part, this might result from the observation that most thyroidectomies in aging Americans are performed by low-volume surgeons. If anything, this study underestimated the rates of adverse postoperative events, in that readmission was not captured by the data set.

It is known that surgery in the elderly entails an increased risk of rehospitalization, which is frequent and costly.⁵ In a recent study of 1.9 million patients enrolled in the Medicare fee-for-service program discharged from 4926 hospitals in 2003-2004, Jencks et al⁵ showed that 51.5% of those who had been discharged after select surgical procedures were rehospitalized or died within the first year after discharge. Among patients who were rehospitalized within 30 days of surgical discharge, 70.5% were readmitted for a medical condition.

In the end, it might be wise to put forward a more cautious conclusion from this interesting and important study by Seybt et al; that is, thyroid surgery in elderly patients can be safe when preoperative selection is appropriate, preparation is meticulous, and the procedures are performed by experienced thyroid surgeons, such as the authors of this study. More data are needed regarding indications for thyroidectomy in the elderly and the overall benefits, including long-term survival, quality of life, recurrence (for those with a diagnosis of thyroid cancer), and the effects of subsequent need for additional treatment of their thyroid disease.

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Correction

Error in Table. In the Original Article titled "Risk Factors for Recurrence After Repair of Enterocutaneous Fistula" by Brenner et al, published in the June issue of the *Archives* (2009;144[6]:500-505), an error occurred in Table 2. There were 4 recurrences (27%), not 2 (27%), at 7 to 12 weeks.