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Loop Ileostomy Vs. Total Colectomy As Surgical Treatment For Clostridium Difficile Associated Disease: An Eastern Association for the Surgery of Trauma Multicenter Trial

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PF conceived the study. PF and RC wrote the manuscript. RC performed all statistical analysis. All authors contributed with patients as well as participated in the critical review of the manuscript.

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- Dr. Haut is the primary investigator of a grant (1R01HS024547-01) from the Agency for Healthcare Research and Quality (AHRQ) titled “Individualized Performance Feedback on Venous Thromboembolism Prevention Practice.”
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Abstract

Objectives—The mortality of patients with Clostridum Dificile Associated Disease (CDAD) requiring surgery continues to be very high. Loop ileostomy (LI) was introduced as an alternative procedure to total colectomy (TC) for CDAD by a single center study. To date, no reproducible results have been published. The objective of this study is to compare these two procedures in a multicentric approach to help the surgeon decide what procedure is best suited for the patient in need.

Methods—This was a retrospective multicenter study conducted under the sponsorship of the Eastern Association for the Surgery of Trauma (EAST). Demographics, medical history, clinical presentation, APACHE score, and outcomes were collected. We used the Research Electronic Data Capture (REDCap) tool to store the data. Mann-Whitney (continuous data) and Fisher's Exact (categorical data) were utilized to compare TC with LI. Logistic regression was performed to determine predictors of mortality. A propensity score analysis was done to control for potential confounders and determine adjusted mortality rates by procedure type.

Results—We collected data from 10 centers of patients that presented with CDAD requiring surgery between July 1of 2010 to July 30 of 2014. Two patients died during the surgical procedure leaving 98 individuals in the study. The overall mortality was 32% and 75% suffered postoperative complications. Median age was 64.5 years, 59% were male. Concerning preoperative patient conditions 54% were on pressors, 47% had renal failure, and 36% suffered respiratory failure. When comparing TC and LI, there was no statistical difference regarding these conditions. Univariate pre-procedure predictors of mortality were age, lactate, timing of operation, vasopressor use, and acute renal failure. There was no statistical difference between the APACHE score of patients undergoing either procedure (TC=22 vs LI= 16). Adjusted mortality (controlled for pre-procedure confounders) was significantly lower in the LI group (17.2% vs. 39.7%, p=0.002).

Conclusions—This is the first multicenter study comparing TC with LI for the treatment of CDAD. In this study LI carried less mortality than TC. In patients without contraindications, LI should be considered for the surgical treatment of CDAD.

Level of evidence—prognostic retrospective multi-centric level III

Introduction

Diarrhea caused by infection with Clostridium difficile was first described nearly 40 years ago (1). However, it was only in the last few decades with the development of resistant Clostridium difficile infection that the United States has seen a disease less responsive to antibiotics (2–4).

As the resistance of Clostridium difficile infection increases, so does the severity of the disease (5). Clostridium difficile associated disease (CDAD) is a life threatening condition, defined as infection by the pathogen concomitant with organ failure, shock, hypotension, ileus or megacolon (5–8). Delay in surgical treatment in patients with CDAD is devastating (9).

The gold standard surgical treatment for CDAD is total abdominal colectomy (TC) (9). This procedure can be lengthy and associated with blood loss, both issues not desirable when treating a patient in a marginal physiological state (10). Furthermore, it leaves the patient in many cases with a permanent ileostomy that can lead to problems with dehydration and quality of life (11).

In 2011, Neal et al presented an alternative protocol for the treatment of CDAD with loop ileostomy, washout and high dose Vancomycin enemas (12). This protocol allowed for a relatively easy surgical re-anastomosis after the life threating disease had been treated. The protocol described decreased the operative time, and blood loss, and had a positive impact on the perioperative mortality of these critically ill patients (12).

Although promising, the initial success of this protocol, has yet to be replicated. Furthermore, there are findings in at least one small series which describes CDAD recurrence after re-anastomosis (13). Recently, Fashandi et al. published a case series showing no difference in mortality between LI and TC, but a higher recurrence rate of CDAD with colon preservation (14).

The objective of this study is to compare total colectomy (TC) with loop ileostomy (LI) for the surgical treatment of CDAD, in a wider range of hospitals to aid the surgeon in selecting what procedure is best suited for the patient in need. The hypothesis of the current study is that TC and LI carry a similar rate of mortality rate.

Methods

This was a retrospective multicenter study conducted under the sponsorship of the Eastern Association for the Surgery of Trauma.

We included all patients with CDAD undergoing surgery in between July, 1 of 2010 to July, 30 of 2014. Demographics, medical history, clinical presentation, APACHE II score, and outcomes were collected. Data were entered by each site into a Research Electronic Data Capture (REDCap) database. The study was approved by the institutional review board at each site that was enrolling patients. All statistical analysis was performed with STATA v14.

Pretreatment factors including demographics, vital signs, laboratory values, and antibiotic exposure during the hospitalization. Need for preoperative vasopressors, presence of acute renal failure or respiratory failure, and time from diagnosis to operation were compared between the TC and LI groups.

Outcomes including operative factors (estimated blood loss, transfusion volumes, and crystalloid volumes), post-operative complications (need for unplanned reoperation, organ

failure, infections, deep venous thrombosis/pulmonary embolism), length of stay (intensive care unit [ICU] length of stay [LOS], hospital LOS), ventilator days, and mortality were compared between groups.

Mann-Whitney (continuous data) and Fisher's Exact Test (categorical data) were used for group comparisons. Logistic regression was performed to determine predictors of mortality. An inverse probability of treatment weights (IPTW) propensity score analysis was done to control for potential pretreatment confounders including center effect and determine adjusted mortality rates by procedure type.

Overall adjusted mortality and adjusted mortality accounting for need for reoperation were compared between the TC and LI groups. The proportional increase in mortality associated with reoperation was determined for each procedure type ([adjusted mortality with reoperation – adjusted mortality overall]/adjusted mortality). For patients undergoing reoperation, procedures were categorized as planned if it was part of a two staged approach (i.e. abdomen left open at the first operation) or unplanned if the patient returned to the operating room for complication management. Statistical significance was determined at the $p<0.05$ level.

Results

We collected data from 10 centers for patients that presented with CDAD undergoing surgery during the study period. 100 patients undergoing operative intervention for CDAD were identified. Two patients were excluded since they died while in the operating room, leaving 98 patients for review. Median age was 64.5 years, 59% were male. The majority of these patients (95%) were initially admitted to medicine before undergoing surgical exploration.

Regarding perioperative factors in these patients, 54% were on pre-operative vasopressors, 47% had pre-operative renal failure, and 36% suffered pre-operative respiratory failure. There was no statistical difference regarding these conditions between the groups (Table 1).

Flagyl and Vancomycin were the most common pre-operative antibiotic treatments with 55% and 45% treated with each antibiotic, respectfully. Only 30% of the patients were receiving both Flagyl and Vancomycin.

The overall mortality was 32%. Of the entire group 75% suffered postoperative complications.

Loop ileostomy with washout (LI) was performed in 21% of the patients and the remainder underwent total colectomy (TC).

There were no statistically significant differences between the LI and TC groups in demographics, pre-operative vital signs, laboratory values, pre-operative organ failure, or exposure to pre-operative antibiotic therapy and type (Table 1).

Although not reaching statistical significance, LI patients had a lower APACHE II score (16 vs 22, p=0.219) and lower rate of pre-operative vasopressor use (38% vs 57%, p=0.144).

Patients with LI underwent operation later when compared with TC patients (25 hours vs. 12 hours after diagnosis, p=0.005).

Patients undergoing LI had decreased intraoperative resuscitative needs (Table 2) with the median estimated operative blood loss of 30 milliliters in the LI group compared with 250 milliliters in the total colectomy group (p<0.001).

There was no statistical difference in overall reoperation rates or unplanned reoperations by procedure type (Table 2). Ventilator days, ICU LOS, and hospital LOS were the same between groups. The rate of and type of complications were also similar between procedures (Table 3). The LI group had an overall complication rate of 81% compared with 73% in the TC group (p=0.58).

In the LI group, five patients required an unplanned reoperation. Of those five patients, three had a conversion to total colectomy. No patient in the LI group requiring an unplanned operation died.

For the LI group undergoing a planned reoperation (n=9), there was a 23% relative increase in adjusted mortality.

The TC group had a reoperation rate of 37.7% including 11.7% having an unplanned reoperation. For those undergoing unplanned reoperation, there was no change in mortality.

All statistical analysis were made based on the initial procedure to avoid bias if failure of LI would occur.

Unadjusted mortality was 23.8% in the LI group compared with 33.8% in the TC group (p=0.44). Pre-procedure predictors of mortality were age, lactate, timing of operation, vasopressor use, and acute renal failure (Table 4). Adjusted mortality (controlled for pre-procedure confounders) was significantly lower in the LI group (17.2% vs. 39.7%, p=0.002, Table 5).

Discussion

Incidence and mortality related to CDAD continues to be on the rise (15). Factors that predict the development of CDAD are hemodynamic instability with pressor requirement, old age, and anti-peristaltic medications (16). There have been multiple attempts to create early triggers for surgical intervention, yet these patients continue to present with high rates of morbidity and mortality (16).

Early surgical consultation, even if not resulting on a surgical procedure, has been shown to be beneficial for patients (16). Surgical intervention on patients with CDAD is life saving and should not be delayed (9). In our study the majority of the patients were admitted to the medicine service before a surgical intervention was offered. This emphasizes the need for continuous education and collaboration between disciplines to improve surgical access and outcomes in these patients.

Deciding in favor of an early surgical procedure in patients with CDAD has a degree of difficulty, since they often have many reasons to present in multi-organ system failure (17). Many of them are immunosuppressed and/or have concomitant infections (15). Since thus far the best option for surgery is an aggressive strategy such as a total abdominal colectomy, the decision becomes even more difficult for the clinician, to place these patients through a long procedure with secondary blood loss while they are in septic shock (9, 15).

Loop ileostomy and washout presents an attractive option since it signifies a lesser physiological toll for hypotensive patients (12). The challenge in choosing the right surgery for the patient has been to balance the degree of physiological compromise with the need to perform a definitive operation for treatment of their advanced colitis.

In the other hand, when a patient is in shock, the surgeon might have only one chance to impact survival, since the failure of a procedure can be translated into mortality.

Our data has confirmed that LI in this ill population leads to fewer intraoperative transfusions, and decreased blood loss. Though the reoperation rates and postoperative complication rates were statistically similar between the procedures, the LI has a survival advantage in this series. Adjusted mortality (controlled for pre-procedure confounders) was significantly lower in the Loop group (17.2% vs. 39.7%, p=0.002). This retrospective study is congruent with the previous publication by the Pittsburgh group (12). Loop ileostomy and washout represented less mortality for these patients.

Although not reaching statistical significance, there was a higher absolute reoperation rate and unplanned operation rate in the LI group. In order to understand this better, an adjusted analysis was performed to account for the additional mortality conferred if reoperation was required. For the LI group, if reoperation was needed there was a 23% relative increase in adjusted mortality. Importantly, the increased mortality was seen for patients with planned reoperations in LI group, no LI patient requiring an unplanned operation died.

In contrast, for the TC group, there was no additional risk of mortality associated with need for reoperation. Despite the higher need for reoperation, LI still has a persistent survival benefit and should be considered for patients needing surgical treatment for CDAD.

Limitations

The major limitations of this study was the retrospective design and the small sample size. The small sample size can be explained since we analyzed only patients that had CDAD and underwent surgery. Previously a prospective randomized control trial comparing LI and TC was closed since the lack of meaningful enrolment (ClinicalTrials.gov: NCT01441271). This is a statement of the paucity for this patient population.

Patients were not randomized to TC or LI, which may have introduced significant selection bias as there are likely residual confounders not captured in our dataset. We attempted to control for this selection bias by performing a propensity score analysis to account for confounders and attempt to reduce bias when evaluating the comparative effectiveness of the two treatments under consideration in this study. Bias in documentation could cause

misclassification and could have been introduced when determining complications and reasoning for reoperation. An adjusted mortality for unplanned operation could not be determined because there are no deaths in the Loop ileostomy group who underwent an unplanned operation.

Since this is a retrospective review of data, it does not provide with the surgeons critical reasoning for offering either procedure.

Since all these limitations we can only suggest, not recommend, the use of LI if no contraindications for the procedure exist.

A strong recommendation requires pooling of data from multiple studies as they become available, potentially as a future revision of the pervious guideline produced by EAST in this particular subject.

Conclusions

This is the first multicenter study comparing TC with LI for the treatment of CDAD. In this study LI carried less mortality than TC. In patients without contraindications, we suggest LI to be considered for the surgical treatment of CDAD.

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Table 1

Preoperative factors of those undergoing Total Colectomy (TC) and Loop Ileostomy (LI).

	n	Total Colectomy	Loop Ileostomy	Overall	p-value
Age (median)	98	65	60	64	0.553
Systolic BP (median)	94	110	117	112.5	0.440
Diastolic BP (median)	94	65	70	65	0.204
HR (median)	94	102	101	102	0.573
WBC (median)	98	13.6	19.2	16.5	0.074
Hemoglobin (median)	98	10.8	11.2	11.05	0.810
pH (median)	70	7.35	7.34	7.34	0.179
INR (median)	82	1.3	1.25	1.3	0.973
Lactate (median)	77	1.95	1.5	1.8	0.113
Base Deficit (median)	55	6	6	6	0.350
APACHE II (median)	55	22	16.5	22	0.219
Diagnosis to initial operation (mean)	96	12	25	22	**0.005**
% Male	98	59.7% (46/77)	61.9% (13/21)	60.2% (59/98)	1
Admitted from medicine	93	45.3% (34/75)	44.4% (8/18)	45.2% (42/93)	1
Vancomycin preop	98	45.4% (35/77)	38% (8/21)	43.9% (43/98)	0.625
Clindamycin preop	98	0%	0%	0%	n/a
Aminoglycoside preop	98	0%	0%	0%	n/a
Aztreonam preop	98	0%	0%	0%	n/a
Cephalosporin preop	98	15.6% (12/77)	23.8% (5/21)	17.3% (17/98)	0.515
Meropenem preop	98	3.9% (3/77)	4.8% (1/21)	4.1% (4/98)	1
Fluroquinolone preop	98	7.8% (6/77)	0%	6.1% (6/98)	0.336
Flagyl preop	98	54.5% (42/77)	57.1% (12/21)	55.1% (54/98)	1
Other antibiotic preop	98	42.9% (33/77)	47.6% (10/21)	43.9% (43/98)	0.805
Vancomycin + Flagyl preop	98	28.6% (22/77)	33.3% (7/21)	30% (29/98)	0.788
Preop Pressors	98	57.1% (44/77)	38% (8/21)	53.1% (52/98)	0.144
Preop Renal Failure	98	49.4% (38/77)	38% (8/21)	46.9% (46/98)	0.461
Preop Respiratory Failure	98	33.8% (26/77)	38% (8/21)	34.7% (34/98)	0.797

BP: blood pressure; HR: heart rate; WBC: white blood cell;

Table 2

Operative outcomes between the Total Colectomy (TC) and Loop Ileostomy (LI) groups.

		Total Colectomy	Loop Ileostomy	
	n	**n=77**	**n=21**	**p-value**
Any Reoperation	97	37.7% (29/77)	45.0% (9/21)	0.611
Unplanned operation	98	11.7% (9/77)	23.8% (5/21)	0.172
Any complication	98	72.7% (56/77)	81.0% (17/21)	0.577
LOS (median)	98	20	27	0.335
ICU LOS (median)	89	5	6	0.976
Ventilator days (median)	98	10	13	0.473
Intraop EBL (median mLs)	**93**	**250**	**30**	**<0.001**
Intraop crystalloid (median mLs)	**93**	**2400**	**1300**	**0.001**
Intraop PRBC volume (median mLs)	**90**	**300**	**0**	**0.001**
Intraop FFP volume (median mLs)	90	0	0	0.107
Intraop platelet volume (median mLs)	90	0	0	0.338
Fluid 1st 24 hrs after OR	87	4832	4424	0.304
OR vasopressors	91	70.1% (54/77)	66.7% (14/21)	0.393

LOS: length of stay; ICU: intensive care unit; Intraop: intraoperatively; EBL: estimated blood loss; mls: milliliters; PRBC: packed red blood cells; FFP: fresh frozen plasma; OR: operating room

Table 3

Postoperative complication comparison between Total Colectomy (TC) and Loop Ileostomy (LI).

		Total Colectomy	Loop Ileostomy	
	n	n=77	n=21	p-value
Any complication	98	72.7% (56/77)	81.0% (17/21)	0.577
Postop Pneumonia	98	11.7% (9/77)	14.3% (3/21)	0.716
Postop VAP	98	11.7% (9/77)	9.5% (2/21)	1
Postop Blood Stream Infection	98	20.8% (16/77)	14.3% (3/21)	0.756
Postop UTI	98	10.3% (8/77)	9.5% (2/21)	1
Postop Sepsis	98	42.9% (33/77)	42.9% (9/21)	1
Postop Thrombosis	98	6.5% (5/77)	0%	0.582
Postop Acute Renal Failure	98	37.7% (29/77)	57.1% (12/21)	0.137
Postop ALI/ARDS	98	27.3% (21/77)	28.6% (6/21)	1

VAP: ventilator associated pneumonia; UTI: urinary tract infection; ALI: acute lung injury; ARDS: acute respiratory distress syndrome

Table 4

Predictors of Overall Mortality

	OR	95% CI	p-value
Age	1.04	(1.01–1.08)	0.011
Lactate	1.33	(1.09–1.63)	0.005
APACHE II	1.13	(1.04–1.22)	0.004
Time from diagnosis to operation	1.03	(1.01–1.05)	0.008
Preop vasopressors	5.32	(1.93–14.67)	0.001
Preop Acute Renal Failure	4.62	(1.72–12.39)	0.002
OR vasopressors	7.43	(1.61–34.17)	0.010
Postop Sepsis	4.60	(1.86–11.36)	0.001
Postop Acute Renal Failure	5.28	(2.12–13.14)	0.000
Postop ALI/ARDS	5.29	(2.08–113.45)	<0.001

ALI: acute lung injury; ARDS: acute respiratory distress syndrome

Table 5

Mortality comparison between Total Colectomy (TC) and Loop Ileostomy (LI).

		Total Colectomy	**Loop Ileostomy**	
	n	**n=77**	**n=21**	**p-value**
Overall Mortality	98	33.8% (26/77)	23.8% (5/21)	0.440
Adjusted Overall Mortality	**75**	**39.7%**	**17.2%**	**0.002**
Mortality with Reoperation	38	37.9% (11/29)	22.2% (2/9)	0.456
Adjusted Mortality with Reoperation	**75**	**39.0%**	**21.2%**	**<0.05**
Mortality with Unplanned Operation	14	44.4% (4/9)	0% (0/5)	0.221