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Do Older Americans Undergo Stoma Reversal Following Low Anterior Resection for Rectal Cancer?

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Abstract

Objective—For low-lying rectal cancers, proximal diversion can reduce anastomotic leak after sphincter preserving surgery; however, evidence suggests that such temporary diversions are often not reversed. We aimed to evaluate non-reversal and delayed stoma reversal in elderly patients undergoing low anterior resection (LAR).

Design—SEER-Medicare linked analysis from 1991-2007.

Settings and Participants—1,179 primary stage I-III rectal cancer patients over age 66 who underwent LAR with synchronous diverting stoma.

Main Outcome Measures—1) Stoma creation and reversal rates. 2) Time to reversal. 3) Characteristics associated with reversal and shorter time to reversal.

Results—Within 18 months of LAR, 51% (603/1179) of patients underwent stoma reversal. Stoma reversal was associated with age < 80 years (p<0.0001), male gender (p=0.018), less comorbidities (p=0.017), higher income [quartile 4 vs. 1, (p=0.002)], early tumor stage [1 vs. 3; (p<0.001)], neoadjuvant radiation (p<0.0001), rectal tumor location [vs. rectosigmoid, (p=0.001)], more recent diagnosis (p=0.021), and shorter length of stay on LAR admission (p=0.021). Median

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Lipsitz – study design, analysis and interpretation of data, manuscript preparation.
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time to reversal was 126 days (IQR: 79-249). Longer time to reversal was associated with older age (p=0.031), presence of comorbidities (p=0.014), more advanced tumor stage (p=0.007), positive lymph nodes (p=0.009), receipt of adjuvant radiation therapy (p=0.008), more recent diagnosis (p=0.004) and longer LOS on LAR admission (p <0.0001).

Conclusions—Half of elderly rectal cancer patients who undergo LAR with temporary stoma have not undergone stoma reversal by 18 months. Identifiable risk factors predict both non-reversal and longer time to reversal. These results help inform pre-operative discussions and promote realistic expectations for elderly rectal cancer patients.

Introduction

Recent meta-analyses and a large randomized controlled trial have highlighted the important role that proximal diversion can have in decreasing rates of anastomotic leak and subsequent morbidity and mortality after rectal cancer resection.[1-4] As technology and surgical techniques are improving, a greater number of patients are undergoing sphincter sparing surgery,[5] many with temporary diversion. Given the low morbidity and potential advantages of diversion, it has been suggested that most rectal cancer patients should have a diverting stoma.[6]

Prior studies suggest that up to 32% of patients who undergo “temporary” diverting stoma during their resection for rectal cancer never undergo reversal.[5,7-10] Previously identified predictors of delay or failure in reversal include post-operative chemotherapy,[7,10] increasing age,[7] metastatic disease,[8] comorbidities[7] and perioperative complications[8,9,11,12], but only two studies have reported factors associated with ileostomy reversal failure after multivariable adjustment.[7,9] Additionally, while higher volume hospitals have been associated with decreased rates of permanent colostomy in rectal cancer patients,[13] little is known about the role of institution in reversal of temporary stoma patients. Given the association with age and comorbidities, we sought to evaluate institutional, patient and clinical characteristics that influence the likelihood of reversal or reversal delay for elderly rectal cancer patients undergoing LAR with diverting stoma. We hypothesized that many elderly patients are not undergoing reversal and that the timing of radiation and/or chemotherapy and patient demographics significantly influence reversal rates.

Methods

Data Sources

Data from the Surveillance, Epidemiology and End Results (SEER) registries and Medicare claims have been linked to allow for longitudinal analysis of cancer care. Additionally, these claims are linked to census tract and zip code level data to provide further demographic information.

Study Sample

Our study cohort included all Medicare beneficiaries age 66 and older diagnosed in SEER regions with primary rectal cancer from 1991 to 2005. We specifically selected for adenocarcinoma and American Joint Committee on Cancer (AJCC) stage I-III disease and excluded patients with stage IV and >N1 disease. Patients who were enrolled in healthcare management organizations (HMOs) or were not enrolled in both Medicare part A and part B continuously from 12 months prior to diagnosis to 18 months after LAR were excluded, as were patients with a diagnosis noted exclusively on death certificate or autopsy and those patients for whom the month of diagnosis was unknown. To minimize the influence of recurrence, we excluded those patients who had an International Classification of Diseases Clinical Modification (ICD-9-CM) code of 197.5 (secondary malignant neoplasm of large

intestine and rectum) or 196.2 (intra-abdominal lymph nodes) or a SEER 2nd rectal cancer diagnosis code within 3-18 months post-diagnosis.

We searched both part A and part B Medicare claims files for low anterior resections (LARs) (ICD-9-CM procedure code 48.6x, Current Procedural Terminology (CPT) codes 45111-13, 45119, 45397) performed from 30 days prior to 1 year post-diagnosis. Only patients who had a concurrent stoma creation were included in the final univariate and multivariable analyses. Stoma creation codes were adapted from those utilized in previous work by Hodgson et al.[13]: ileostomy (ICD-9 46.01, 46.02, 46.20, 46.21, 46.24, CPT 44187, 44310), colostomy (ICD-9 46.03, 46.04, 46.10, 46.11, 46.14, 48.62 CPT 44188, 44320, 45397). We excluded codes that indicate creation of a permanent stoma (ICD-9 46.13, 46.22, 46.23). Patients were eligible to undergo stoma reversal from 7 days post-LAR to 18 months post-LAR (ICD-9 45.90 – 45.95, 46.50 – 46.52, CPT 44130, 44227, 44620, 44625, 44626).

Covariates

Patient demographics, tumor-related variables (grade, tumor stage, lymph node status, and size), median household income and proportion of those with a college education (based on 2000 US census) were obtained from the SEER registry data. Comorbidities were identified in the year prior to diagnosis from the outpatient, inpatient and carrier claims using the Deyo implementation[14] of the Charlson comorbidity score[15], modified as described by Klabunde to include outpatient claims[16]. Variables were categorized as in Table 1 for univariate analysis but race (white, black, other), age (65-79, >=80), and comorbidity score (0,>=1) were collapsed for multivariable analysis. Hospital characteristics were obtained from the Medicare hospital file. The CMS region of the treating hospital was used to examine geographic variation.

Statistical Analysis

Stoma creation rates were calculated for all patients undergoing LAR who met our selection criteria (n=6,408). Stoma reversal rates were calculated for only those patients who had a synchronous stoma creation (n=1,179). Yearly rates of stoma creation and reversal were calculated and temporal relationships in procedure-specific rates were analyzed using Mantel-Haenszel chi-square test for trend. To allow for a more stable estimation, the distributions of stoma creation and reversal rates across hospitals were calculated for those performing at least 5 respective procedures in our cohort.

Rao-Scott chi-square statistics for categorical variables (such as tumor stage) and generalized estimating equations (GEE) for continuous variables (such as patient age), were used to evaluate the bivariate associations between the dichotomous variable stoma reversal (yes, no) and *a priori* specified patient and hospital characteristics, accounting for within-hospital clustering. Multivariable analyses for stoma reversal were performed using logistic regression, estimated via GEE to account for within-hospital clustering. All 1,179 patients who underwent LAR with synchronous stoma creation were included in these analyses.

We were also interested in analyzing the time to reversal, defined as the time from stoma creation to reversal, and the factors influencing time to reversal for those patients who were reversed. Since the majority of patients with temporary stomas undergo reversal by 18 months,[7,8,10,12,17,18] all patients who did not undergo reversal by 18 months after LAR were excluded from this analysis. Patients who died before reversal or were lost to follow up were included in the analysis and censored. This left an analytic cohort of 841 patients. Kaplan-Meier curves were used to estimate the unadjusted median time to reversal. The log-rank test was used to evaluate the bivariate association between adjuvant therapy and time to reversal.

A multivariable Cox proportional hazard model was used to identify all variables associated with shorter time to reversal.[19]

The multivariable logistic and Cox patient-level models included *a priori* potential explanatory patient and hospital characteristics and all tumor variables. Additionally, all other clinical, demographic and hospital variables with a p value <0.10 on univariate analysis were considered for inclusion. The length of stay (LOS) of the patient's hospitalization associated with their LAR was included as a proxy for postoperative complications. Odds ratios (from logistic regression) or Hazard ratios (from Cox regression) and 95% confidence intervals (CI) were calculated to evaluate the influence of included variables on stoma reversal and time to reversal respectively. Clustering by hospital was accounted for in all univariate and multivariable analyses.

The Dana-Farber/Harvard Cancer Center Office for Human Research Studies approved our study protocol. All statistical analyses were performed with SAS Version 9.2 (SAS Institute, Cary, NC). All p-values were two-sided, and were considered statistically significant if $p < 0.05$.

Results

Characteristics of Cohort

From 1991-2005, a total of 6,408 patients were diagnosed with stage I-III rectal cancer and underwent LAR; and 1,179 of these patients (18.4%) underwent synchronous stoma creation. The majority of our patients who had stomas created were Caucasian (90%), non-Hispanic (94%), with no co-morbidities (66%). Additional characteristics of our cohort and their associated hospitals are shown in Table 1.

Rate and Predictors of Stoma Reversal

Of the 1,179 patients who underwent stoma creation, 51% (603) underwent stoma reversal within 18 months of their LAR (Figure 1). Twenty percent (238) had incomplete claims, disenrolled or died within 18 months of LAR. Using the product-limit approach,[20] which takes these 238 censored patients into account, the reversal rate within 18 months was estimated to be 57% (95%CI 54.2%-60.3%). Significant factors associated with stoma reversal on univariate analysis are listed in Table 1 ($p<0.05$). In multivariable analysis (Table 2), patients were more likely to have their stoma reversed if they were <80 years old [OR 2.3 (95% CI 1.7, 3.1)], were male [OR 1.4 (95% CI 1.1, 1.9)], had higher income [quartile 4 vs. 1, OR 1.9 (95% CI 1.2, 2.8)], earlier tumor stage [1 vs. 3; OR 2.0 (95% CI 1.4, 3.0)], received neoadjuvant radiation [OR 2.7 (95% CI 1.9, 3.7)], had a rectal tumor location [vs. rectosigmoid, OR 1.7 (95% CI 1.2, 2.3)], had a shorter length of stay (LOS) on LAR admission [OR 1.06/day (95% CI 1.04, 1.08)] and were diagnosed more recently [OR 1.04/year (95% CI 1.01, 1.08)]. No hospital characteristics reported in Table 1 were significant on multivariable analysis.

Time to Reversal

The overall median time to reversal for patients who were reversed within 18 months of LAR was 126 days [95% CI 115,140 (IQR 79-249)] (Figure 2). Those who received adjuvant therapy had a significantly increased median time to reversal compared to those who did not receive adjuvant therapy [165 vs. 112 days ($p=0.008$)] (Figure 3). Age, marital status, comorbidity score, all tumor characteristics (stage, size, grade), nodal stage, receipt of neoadjuvant XRT, receipt of any adjuvant therapy, LOS on initial operative admission and year of diagnosis significantly influenced the timing of stoma reversal on univariate analysis. No hospital characteristics were significant.

On multivariable analysis (Table 3), shorter time to reversal (represented by a hazard ratio greater than 1) was associated with younger age [<80 yo; OR 1.3 (95% CI 1.02, 1.6) (p=0.031)], fewer comorbidities [HR 1.2 (95% CI 1.05, 1.5) (p=0.014)], earlier tumor stage [1 vs. 3; OR 1.4 (95% CI 1.1, 1.8) (p=0.007)], no nodal disease [N0, OR 1.3 (95% CI 1.1, 1.6) (p=0.009)], no adjuvant XRT [OR 1.3 (95% CI 1.1, 1.6) (p=0.008)], less recent diagnosis [HR 1.04/year (95% CI 1.01, 1.06) (p=0.004)] and shorter LOS on LAR admission [HR 1.05/day (95% CI 1.03, 1.07) (p <.0001)].

Time Trend

Time trends were calculated for both stoma creation and reversal from 1991 to 2005 (years of diagnosis for patients included in the study). Figure 4 illustrates the significant increase in both stoma creation 14% to 25% (p<0.0001) among rectal cancer patients who underwent LAR and stoma reversal 35% to 54% (p<0.001) among those receiving a stoma at the time of LAR.

Hospital Variability

Hospital rates of both stoma creation and reversal were calculated among those hospitals performing at least 5 procedures on our cohort. The median hospital created stomas on 15% of their LAR patients (IQR 6-25%, Range 0-80%). The median hospital reversed 60% (IQR 50-76%) of their patients who had an LAR with stoma.

Discussion

Nearly half of rectal cancer patients over 66 years old who underwent LAR with synchronous stoma did not undergo reversal within 18 months of their initial operation over this 16 year period. This is lower than previously reported for other populations and suggests that management may be different for patients in this age group. Our data suggests several trends over this time period including greater likelihood of stoma creation, as well as reversal rates, and longer time to reversal suggesting evolution of our treatment of rectal cancer in these patients.

Temporary stomas have been shown to be protective[1-4], and temporary diversion adds little to the overall morbidity of an operation.[21] However, proximal diversion is not benign. A meta-analysis in 2009 concluded that stoma closure results in additional morbidity for 17% of patients, a 3.7% reoperation rate and 0.4% mortality rate.[22] Furthermore, prior to reversal, stomas have been associated with complications like dermatitis, parastomal hernia, stenosis, hemorrhage, prolapse, retraction and dehydration in up to 60% of patients,[12,23-25] and the incidence increases with the duration of the stoma.[12] Therefore, we sought to further characterize factors associated with non-reversal and delayed reversal among elderly patients, those most at risk for non-reversal, to aid in pre-operative counseling and realistic expectation setting.[7,26,27]

While our 18.4% rate of stoma creation is within the wide range of other reported rates (17-71%)[3] and comparable with other multi-institutional evaluations of stomas in the treatment of rectal cancer,[7,28] our rate of 51% for stoma reversal, is significantly lower than 68-92% previously reported by single institution and multi-institution studies of reversal among rectal cancer patients of all ages.[8,10] This reflects, in part, patients who did not survive long enough to have their stoma reversed. However, after correcting for those patients who died or were lost to follow-up before reversal, the 57% rate of stoma reversal remains below the range previously reported. These previous evaluations of stoma reversal have found that receipt of post-operative chemotherapy,[7,10] increasing age,[7] metastatic disease,[8] comorbidities,[7] and perioperative complications,[8,9,11] were associated with non-

reversal. Our multivariable results corroborated the influence of older age and greater comorbidity on non-reversal, but we also found male gender (similar to diverticulitis[26]) and higher income increased a patient's chance of reversal. Additionally, unlike previous studies which did not incorporate tumor characteristics and staging information in their analyses, we found that lower tumor stage, rectal tumor location and receipt of neoadjuvant therapy improved a patient's chance of reversal. It is likely that both lower tumor stage and receipt of neoadjuvant therapy would increase the likelihood of a smaller tumor that lends itself to an increased margin without compromising sphincter function. The significance of rectal tumor location may represent a different decision; patients who undergo temporary diversion with rectal tumor location are more likely prophylactic, whereas those with rectosigmoid location may be diverted secondary to complications – decreasing chance of reversal.

We used LOS during LAR admission as a proxy for post-operative complications, given a previously documented high correlation.[29] While this may miss those patients who go on to have additional complications after the immediate post-operative period, our results suggest that LOS could influence the patient's interest in an additional operation or the provider's willingness to subject the patient to another elective operation for reversal.

Our low reversal rates may also reflect a higher rate of planned permanent stoma creation. We limited this influence by excluding procedure codes that explicitly refer to permanent stoma creation. However, it is not possible to determine the intent of less specific codes.

Recent studies of surgical procedures have suggested there may be large variations in surgical procedure rates and outcomes depending on hospital factors.[30-35] A study by David et al. found that permanent stoma rates may be decreased at higher volume institutions[7] which has been suggested to be an indicator variable for unmeasured institutional influence.[36] However, while we did find some institutional variability in our sample in both creation and reversal rates, we did not identify any measurable hospital characteristics to explain this variation. This variability may reflect different institutional beliefs and experiences or individual provider characteristics which are difficult to quantify and currently unmeasured, especially in administrative data.

While it is generally acceptable to wait 8-12 weeks after stoma creation to attempt reversal,[21] in rectal cancer patients, this often falls within the 1st cycle of post-resection chemotherapy.[24] Prior studies have shown that performing closure during adjuvant treatment periods increases the rate of complications[24] and may influence time to reversal.[7,9,10] Our results identified a temporal trend toward longer time to reversal suggesting that providers often delay reversal until after administration of adjuvant therapy. Additionally, we found that lower stage disease (N0 and/or T1), younger age, no comorbidities and shorter length of stay on LAR admission may shorten the overall time to reversal. These results suggest that the decision of stoma reversal is individualized and that providers tailor care by risk stratification.

Our study has several limitations. It is retrospective and relies on claims data. The results may not be generalizable to a younger population, but our goal was to investigate the elderly. We were unable to specifically control for recurrent disease, but we attempted to limit the influence of recurrence by excluding any patients with secondary malignancy codes within 18 months post-LAR as well as those at highest risk of recurrence (>N1 disease). While this limited the number of patients available for analysis, we felt this limitation was outweighed by the necessity to exclude those patients who are not reversed due to a recurrence. And while we used initial length of stay as a surrogate for immediate post-operative complications, we were unable to identify or adjust for those patients with anastomotic leak or stricture which could significantly influence reversal rates.[11] Finally, we

could not reliably distinguish between loop or end stomas based on billing codes, which may significantly influence rates of reversal.

Elderly patients are at risk for non-reversal and delayed reversal after temporary diversion following LAR for rectal cancer. Given the decreased quality of life associated with diverting stoma[37-39] and reported associated complication rates,[24] preoperative discussions should include this information in order to set realistic expectations for patients and aid in informed, individualized decision making.

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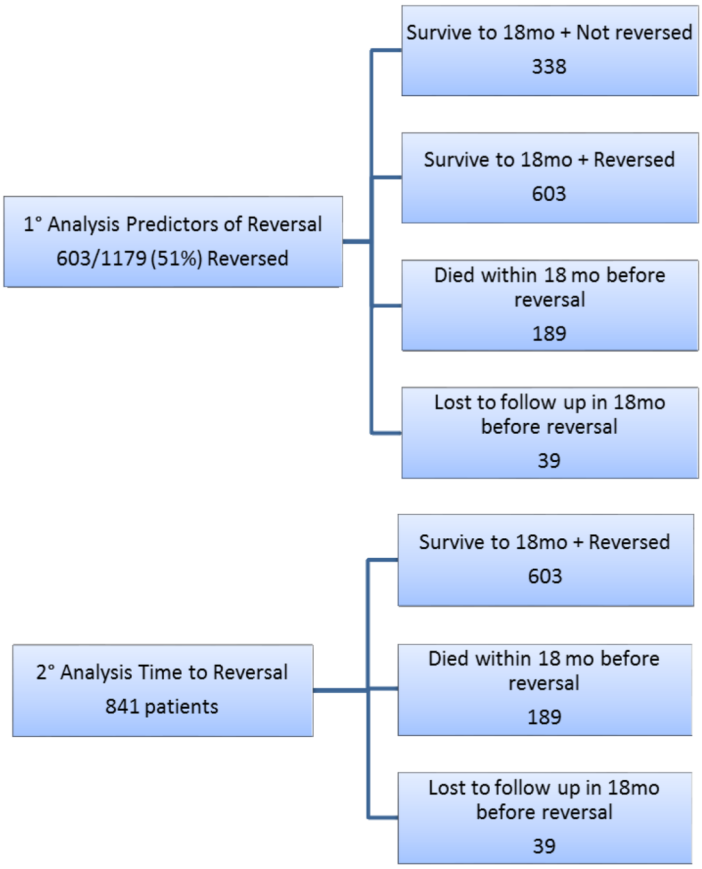
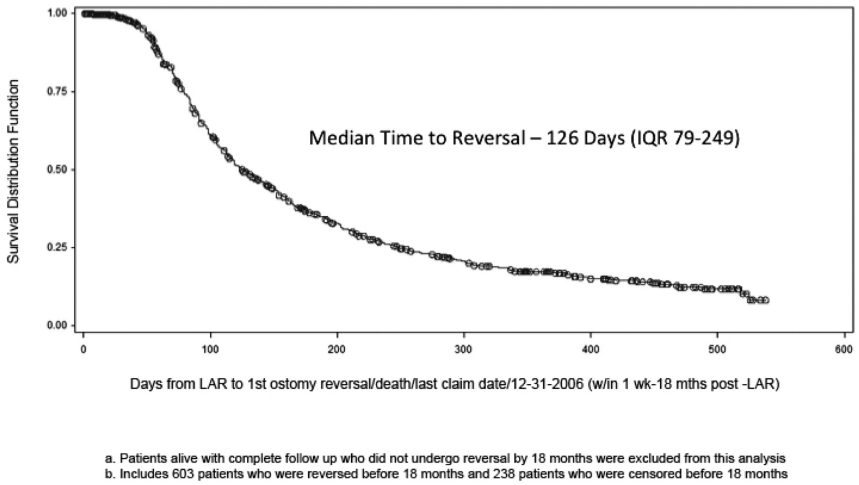
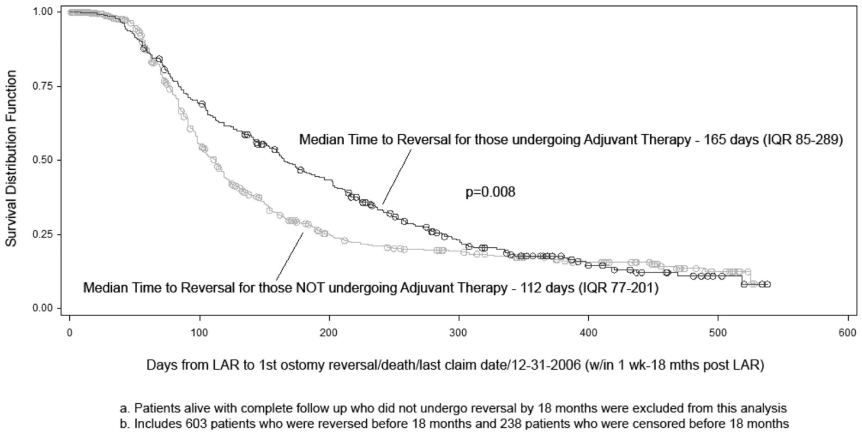


Figure 1. Analytic Cohort Flow Chart



a. Patients alive with complete follow up who did not undergo reversal by 18 months were excluded from this analysis
b. Includes 603 patients who were reversed before 18 months and 238 patients who were censored before 18 months

Figure 2. Days to Reversal for Rectal Cancer Patients with Diverting Stomas**



a. Patients alive with complete follow up who did not undergo reversal by 18 months were excluded from this analysis
b. Includes 603 patients who were reversed before 18 months and 238 patients who were censored before 18 months

Figure 3. Days to Reversal for Rectal Cancer Patients with Diverting Stomas
Stratified by Receipt of Adjuvant Therapy**

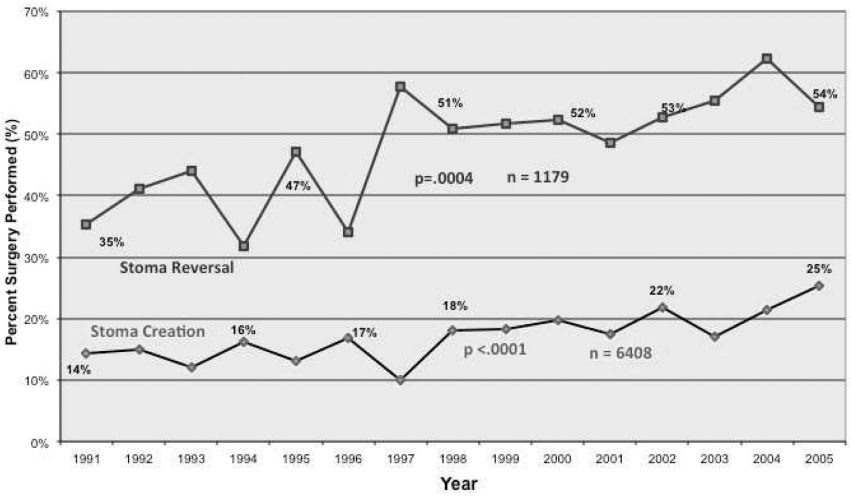


Figure 4. Stoma Procedure Time Trend from 1991 to 2005
Lines depict yearly rate of stoma reversal or stoma creation

Table 1
Characteristics of Rectal Cancer Patients Undergoing LAR with Diverting Stoma

Patient Characteristics	Not Reversed[a] n = 576 (49%)	Reversed[b] n = 603 (51%)	p value[c]
Age at Diagnosis, median, y	**77.8**	**73.4**	**<.0001**
Female	**283 (49%)**	**219 (36%)**	**<.0001**
Race/Ethnicity			
Caucasian	510 (89%)	549 (91%)	0.40
Black	35 (6%)	31 (5%)	
Asian/Pacific Islander/Other	31 (5%)	23 (4%)	
Hispanic	38 (7%)	27 (4%)	0.11
Married	**267 (46%)**	**386 (64%)**	**<.0001**
Median Percent Some College	27.3%	27.1%	0.96
Household Median Income	**$37,947**	**$41,278**	**<.001**
Charlson Comorbidity Score			
0	**355 (62%)**	**428 (71%)**	**<.0001**
1	132 (23%)	128 (21%)	
2+	89 (16%)	47 (8%)	
AJCC Stage			
0	**14 (2%)**	**31 (5%)**	**0.0016**
I	168 (29%)	215 (36%)	
II	243 42%)	202 (34%)	
III	131 (23%)	125 (21%)	
Unknown	20 (3%)	30 (5%)	
Tumor Grade			
Well Differentiated	53 (9%)	51 (9%)	0.49
Moderately Differentiated	402 (70%)	419 (70%)	
Poorly Differentiated/Anaplastic	81 (14%)	78 (13%)	
Not Determined	40 (7%)	55 (9%)	
Adjuvant Chemotherapy	**164 (29%)**	**226 (38%)**	**<.001**
Adjuvant Radiation Therapy	111 (19%)	116 (19%)	0.99
Neoadjuvant Chemotherapy	**66 (12%)**	**164 (27%)**	**<.0001**
Neoadjuvant Radiation Therapy	**86 (15%)**	**235 (39%)**	**<.0001**
Rectal Tumor Location	**343 (60%)**	**457 (76%)**	**<.0001**
Median LOS of 1° resection	**11d**	**8d**	**<.0001**
Hospital Characteristics			
Urban	526 (93%)	566 (94%)	0.26
NCI Center (Comprehensive)	19 (3%)	39 (7%)	0.05
Oncology Group	**409 (71%)**	**485 (80%)**	**<.001**
Teaching hospital	339 (60%)	384 (65%)	0.16
Med School Affiliation			
Major/Limited/Graduate	275 (48%)	325 (54%)	0.05

Patient Characteristics	Not Reversed[a] n = 576 (49%)	Reversed[b] n = 603 (51%)	p value[c]
None	298 (52%)	278 (46%)	
Control			
Nonprofit	474 (83%)	503 (83%)	0.45
Proprietary	43 (8%)	55 (9%)	
Governmental	54 (10%)	45 (8%)	
CMS Region			
Northeast	136 (24%)	178 (30%)	0.17
Midwest	145 (25%)	122 (20%)	
South	105 (18%)	121 (20%)	
West	187 (33%)	182 (30%)	

[a] Patients who lived at least 18 months without undergoing stoma reversal.

[b] Patients reversed within 18 months.

[c] Adjusted for clustering within hospital

Table 2

Predictors of Stoma Reversal for Patients Who Underwent LAR With Synchronous Diverting Stoma - Multivariable Logistic Regression

Variable	Odds Ratio	95% CI
More Recent Diagnosis (per year)	1.04	1.01-1.08
Shorter LOS on LAR Admission (per day)	1.06	1.04-1.08
Male Gender	1.4	1.1-1.9
No Comorbidities	1.4	1.1-18
Rectal Tumor Location[a] (vs. Rectosigmoid)	1.7	1.2-2.3
Higher Income Quartile (4 vs. 1)	1.9	1.2-2.8
Lower Tumor Stage (1 vs. 3)	2.0	1.4-3.0
Younger Age (<80 years old)	2.3	1.7-3.1
Receipt of Neoadjuvant XRT	2.7	1.9-3.7

[a]Based on SEER site code.

Table 3

Predictors of Shorter Time to Stoma Reversal for Patients Who Underwent LAR With Synchronous Diverting Stoma - Multivariable Cox Regression*

Variable	Hazard Ratio†	95% CI
Less Recent Diagnosis (per year)	1.04	1.01-1.06
Shorter LOS on LAR Admission (per day)	1.05	1.03-1.06
No Comorbidities	1.2	1.05-1.5
Younger Age (<80 years old)	1.3	1.02-1.6
No Nodal Disease (N0)	1.3	1.1-1.6
No Receipt of Adjuvant XRT	1.3	1.1-1.6
Lower Tumor Stage (1 vs. 3)	1.4	1.1-1.8

*Patients alive with complete follow up who did not undergo reversal by 18 months were excluded from this analysis

†Hazard Ratio >1 represents shorter time to stoma reversal