Patients With Temporary Ostomies

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Veterans Administration Hospitals Multi-institutional Retrospective Study

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ABSTRACT

PURPOSE: The purpose of this study was to describe clinical outcomes of patients with temporary ostomies in 3 Veterans Health Administration hospitals.

DESIGN: Retrospective descriptive study, secondary analysis.

SAMPLE AND SETTING: Veterans with temporary ostomies from 3 Veterans Health Administration hospitals who were enrolled in a previous study. The sample comprised 36 participants all were male. Their mean age was 67.05 ± 9.8 years (mean \pm standard deviation). Twenty patients (55.6%) had ileostomies and 16 patients (44.4%) had colostomies.

METHODS: This was a secondary analysis of data collected using medical record data. Variables examined included etiology for creation and type of ostomy, health-related quality of life, time to reversal, reasons for nonreversal, postoperative complications after reversal, and mortality in the follow-up period.

RESULTS: Colorectal cancer and diverticular disease were the main reasons for temporary stoma formation. The reversal rate was 50%; the median time to reversal was 9 months in our sample; temporary ileostomies were reversed more often than temporary colostomies (P = .18). Comorbid conditions were identified as the main reason for nonreversal. Mortality was not significantly different between the reversal and nonreversal groups. No significant differences were reported with health-related quality-of-life parameters between reversal and nonreversal groups.

CONCLUSIONS: This study identified that the proportion of temporary ostomies was limited to 50%. Complications during the index operation, medical comorbidities, and progression of cancer are the main reasons for nonreversal of temporary stomas. Study findings should be included in the counseling of patients who are likely to get intestinal stomas with temporary intention, and during consideration for later reversal of a stoma.

KEY WORDS: Anastomotic leak, Colorectal cancer, Colostomy, Diverticular disease, lleostomy, Inflammatory bowel disease, Quality of life, Stoma closure, Stoma reversal, Temporary stoma.

INTRODUCTION

Intestinal ostomies are designed to temporarily or permanently divert the fecal stream to an opening of the abdominal wall (stoma); they commonly incorporate the ileum or colon. Temporary ostomies may be constructed in a loop or end configuration. From 725,000 to 1 million ostomy patients reside in the United States, and approximately 100,000 new ostomy surgical procedures occur annually. In a recent study of 4000 participants from 11 countries, about 60% of those living with

an ostomy were older than 60 years, approximately 43% were colostomies, 37% were ileostomies, 18% were urostomies, and 1% were jejunostomies.⁴

Temporary ostomies are created when restoration of intestinal continuity is contraindicated or not feasible. They also may be created with the intention of protecting a distal anastomosis, as part of a salvage surgery, or as a palliative measure. They are constructed with the intention of stoma reversal (closure), requiring reconstruction of gastrointestinal continuity when the acute clinical issues are resolved, the patient's physiology

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and clinical status are improved, or adequate time has been allowed for the anastomosis to heal.

A retrospective review of data from the National Inpatient Database between 2008 and 2012 showed an average temporary stoma creation rate of 76,551 per year (46% colostomies and 54% ileostomies), with an annual reversal rate of 65.5% (50,155 patients per year). The reversal rate was lower among black patients, the uninsured, and those with low-income status.5 A review of the California Office of Statewide Health Planning and Development patient database between 1995 and 2010 showed reversal of nearly 72% of temporary stomas created in trauma patients by 5 years from the date of index operation.⁶ Postoperative complications such as anastomotic leakage or fistula formation following the index operation, advanced primary disease, local recurrence of tumor, and other associated comorbidities have been identified as risk factors associated with nonreversal of temporary ileostomy in patients who underwent sphincter-preserving surgery for rectal cancer.7

Ostomy reversal procedures may be associated with significant morbidity. Reversal of colostomy has been shown to be associated with surgical site infections (32%), anastomotic leak (12%), and unsuccessful reversal (10%).8 Ileostomy reversal is associated with an overall complication rate of 17.3%; complications include small bowel obstruction (7.2%), wound sepsis (5.0%), need for an exploratory laparotomy to complete the reversal (3.7%), and mortality (0.4%).9 Consideration of potential postoperative complications influences the decision to reverse a stoma constructed with temporary intention.

The purpose of this retrospective study was to describe the clinical outcomes of patients with temporary ostomies in 3 Veterans Health Administration hospitals. Our primary aim was to identify the proportion of patients who had their temporary stoma reversed. The secondary aim was to examine type of ostomy formed, etiology for stoma formation, time between formation and reversal of stoma, reasons for nonreversal of stoma if any, postoperative complications after reversal of stoma, and mortality in the follow-up period.

METHODS

This study is a secondary analysis using data from a previous study, "Health Related Quality of Life in Patients with Intestinal Stomas" (VA HSRD IIR 02-221, 2003-2005).² The original study was conducted at 3 academically affiliated Veterans Administration (VA) medical center sites: (1) Southern Arizona VA Health Care System, Tucson, Arizona; (2) VA Greater Los Angeles Healthcare System, California; and (3) Richard L. Roudebush VA Medical Center, Indianapolis, Indiana. These sites were chosen to ensure ethnic, geographic, and racial diversity. The study was approved by the human subjects protection committees at each of the aforementioned sites and written informed consent was obtained from all participants.

Patients with an ostomy were identified using International Classification of Diseases, Ninth Revision (ICD-9) procedure codes from the VA Patient Treatment File with ICD-9 codes for attention to or status of an ostomy ("V codes") from VA Outpatient Encounter File, dispensing of ostomy equipment from the VA pharmacy file, and ostomy nurse patient lists. The use of multiple VA databases ensured inclusion of all possible patients over the study period. Patients were eligible if they had been seen for VA care within 1 year prior to the initiation of the

study and at least 2 months had elapsed since index surgery. Participants were administered a mailed questionnaire that included the City of Hope Quality of Life (mCOH-QOL)-Ostomy and 36-Item Short-Form Health Survey for Veterans (SF-36V) questionnaires. The COH-QOL-Ostomy¹⁰ is based upon a 4-dimensional framework consisting of ostomy health-related quality of life (HRQOL); they are physical, psychological, social, and spiritual well-being. A score for total HRQOL, as well as these 4 domains, is calculated as the average of nonmissing items, with responses on a scale from 0 to 10 and coded as 10 being the best response. The SF-36V¹¹ is a modified SF-36¹² adapted for use with US veterans that closely resembles the current SF-36 version 2, one of the most commonly used health status measures for measuring HRQOL; it yields an 8-scale health profile as well as physical and mental health summary measures.

Subjects who identified their ostomies as temporary with plans for reversal were included in the present study. The mailed questionnaire queried whether the respondent's ostomy constructed during the index operation was permanent or temporary (created with intention or plans for reversal in future). Medical records (electronic and paper charts) of individual patients, including their operative reports, were reviewed to ensure that subjects had an ostomy constructed with temporary intention. Patients with incomplete or conflicting data were excluded from the study. Patients who were undergoing further treatment for cancer at the time of data collection (chemotherapy or radiation therapy) were excluded from the survey, as this could alter their health status and impact outcomes.

Follow-up data collection was completed between January 2012 and October 2015. The primary end point evaluated for this study was the number of patients who had their stoma reversed. Secondary variables were type of ostomy formed, etiology for stoma formation, time between formation and reversal of stoma, and reasons for nonreversal of stoma. Postoperative complications after reversal of stoma and mortality in the follow-up period, including death, were also evaluated. The follow-up period extended from date of index surgery wherein the temporary stoma was created until the date of data collection at each of the 3 sites or until death.

DATA ANALYSIS

Survival differences between the 2 groups of patients (reversed vs nonreversed and cancer vs non-cancer) were evaluated using a Kaplan-Meier analysis. We report the estimated mortality percentage from the survival function at selected years elapsed; these percentages do not necessarily correspond to an integer number of subjects, but we have provided the rounded approximate count as illustration. Crude mortality proportions (not accounting for censoring) were reported without statistical comparisons for illustrative purposes but not for inference. Median time to death was compared between groups using the Wilcoxon rank sum test. Proportions of subjects reversed, stoma characteristics, complications, reasons for formation of index stoma, and failure to reverse an ostomy are presented descriptively. Mean subscales from COH-QOL-Ostomy and SF-36V were compared between reversal and nonreversal groups with 2 sample *t* tests. The time to reversal and duration of follow-up are summarized by median, range, and interquartile range (IQR, the 25th to 75th percentiles).

RESULTS

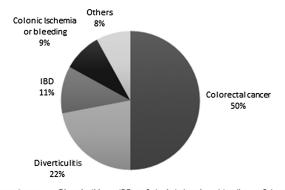
Thirty-eight patients were identified who had a temporary ostomy formed after bowel resection; 2 patients were excluded from the study due to incomplete data. Therefore, analysis was performed using the remaining 36 patients. All were male and their stomas were created between January 1980 and October 2004. Their follow-up period ranged between 58 and 430 months (mean 128 months). The median follow-up time was longer in patients without reversal compared to those with reversal (136 months vs 99 months, P = .047).

Colorectal cancer was the reason for stoma formation in 50% (n=18) of cases, followed by diverticular disease and inflammatory bowel disease, responsible for 22.2% (n=8) and 11.1% (n=4), respectively. Colonic ischemia or bleeding led to 3 temporary ostomies (8.4%). Other reasons accounted for 8.3% (n=3); they were nonmalignant bowel obstruction, cecal perforation, and unknown causes (Figure 1).

More than half of temporary stomas were ileostomies (56%; n=20, Figure 2). Ileostomies were formed more often (60%; n=12) to protect a distal anastomosis after surgery for cancer. More than a third of temporary colostomies (36.5%; n=6) were formed during surgery for diverticulitis or related complications.

During the follow-up period, 50.0% (n = 18) of patients had their stomas reversed, with a median duration between the formation and reversal of stoma of 9 months (IQR 5-14 months, range 2-23 months). Significant variation in the rates of stoma reversal was observed between the 3 centers (25%, n = 3/12; 33.3%, n = 3/9; 80%, n = 12/15; P = .008), with a median duration to reversal ranging from 8.5 to 13 months. Although not statistically significant, more ileostomies were reversed than were colostomies (60%; n = 12% vs 37.5%; n = 6; P = .18) (Table 1). Two patients in the colostomy reversal group experienced complications after reversal, necessitating formation of a second stoma in one and inability to complete the reversal in the other due to locally advanced cancer.

Major early complications after reversal operations were noted in 33.3% (n = 6) patients; they were anastomotic leak, abdominal abscess formation, enterocutaneous fistula, and wound-related complications. Delayed complications included tumor recurrence at the site of ileostomy takedown and incisional hernia formation during the follow-up period. Comorbid conditions, predominantly cardiac and/or respiratory, were cited as reasons for nonreversal of stoma in 33.3% (n = 6) of patients. These conditions were either present at



■Colorectal cancer ■ Diverticulitis ■ IBD ■ Colonic Ischemia or bleeding ■ Others

Figure 1. Reasons for temporary ostomy.

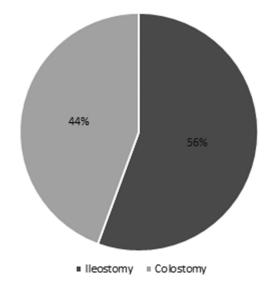


Figure 2. Types of temporary ostomy.

the time of the index operation leading to stoma formation with temporary intention or developed in the postoperative follow-up period. Progression of colorectal cancer and postoperative complications after the index operation, including anastomotic leak and fistula formation, were the other major reasons for nonreversal of temporary stomas (Table 2).

During the follow-up period, the crude mortality rate was 36.1% (n = 13), with a higher mortality rate in the nonreversal group (50.0%, n = 9/18). Progression of colorectal cancer was the principal cause of death (61.5%, n = 8 of total deaths). Crude mortality, which does not account for censoring, appeared to be considerably lower among patients who had stomas reversed during the follow-up period compared to those who did not undergo reversal (22.2%, n = 4/18, vs 50.0%, n = 9/18). However, accounting for follow-up time and censoring with the Kaplan-Meier analysis showed that the mortality did not significantly differ between the reversed and nonreversed groups (P = .65). At 10 years, mortality was 15% (approximately n = 3) in the reversal group versus 22% (approximately n = 4) in the nonreversal group; at 15 years, mortality was 58% (approximately n = 10) in the reversal group versus 72% (approximately n = 13) in the nonreversal group. The 10- and 15-year mortality rates were obtained from a survival function curve, enabling calculation of the approximate values provided for the 10- and 15 -year mortality rates.

When temporary stomas formed during surgical resections for colorectal cancers were evaluated alone, the reversal rate was somewhat higher than the full sample (61.1%, n =11/18), but the crude mortality rate during the follow-up period appeared to be higher in cancer subjects compared to those with stomas made for nonmalignant causes (44.4%, n = 8/18, vs 27.7%, n = 5/18, respectively). The Kaplan-Meier analysis showed that mortality was significantly higher in the cancer group (P = .04). At 10 years, the mortality rate was 32% (approximately n = 6) in the cancer group versus 10% (approximately n = 2) in the noncancer group; at 13 years, the mortality rate was 70% (approximately n = 13) in the cancer group versus 28% (approximately n = 5) in the noncancer group. Although not statistically significant, death during the follow-up period occurred earlier in cancer patients compared to noncancer patients (median 116 vs 156 months, respectively, P = .06). This difference does not account for censoring.

TABLE 1. Patient Characteristics by Ostomy Type

Type of Stoma	lleostomy	Colostomy	Total
	(n = 20)	(n = 16)	(n = 36)
Age, mean (SD); range, y ^a	68.8 (11.2);	65.3 (8.4);	67.05 (9.8);
	50-84	49-79	49-84
Time to reversal, median (IQR); range, mo	9 (7.5-15);	7.5 (3-14);	9 (5-14);
	3-23	2-21	2-23
Ostomy reversal, n (%)	12 (60.0)	6 (37.5)	18 (50)
Length of follow-up period, median (IQR); range, mo	99 (94-136);	135 (101-154);	111 (95-140);
	58-228	77-430	58-430

Abbreviations: IQR, interquartile range; SD, standard deviation.

No significant differences were observed for subscales from the COH-QOL-Ostomy and the SF-36V between reversal and nonreversal groups preoperatively. The cumulative HRQOL score (mean \pm standard deviation, reversal vs nonreversal) was (6.0 \pm 2.0 vs 6.1 \pm 2.0, P = .90), the SF-36V Physical Component scores were 35.4 \pm 10.3 versus 31.7 \pm 13.5 (P = .40), the SF-36V Mental Component scores were 46.0 \pm 11.4 versus 48.4 \pm 10.4 (P = .57, Table 3).

DISCUSSION

Temporary ostomies are formed with the intention of reversal in the future. Multiple studies have evaluated the reversal rate and reasons for nonreversal of stomas.^{6,7,9,13-16} To our knowledge, long-term follow-up and outcomes after temporary stoma formation among veterans have not been reported in the literature. The main finding of this study is difference in reversal rate, mean time for reversal, and mortality rates in veterans versus other populations. The reversal rate of temporary stomas was lower (50%; n = 18/36) among the cohort of veterans included in this study when compared to previous studies involving the general population (68%-91.5%). 9,14-21 This finding could be partially attributed to the likelihood that veterans have more comorbid conditions.²² Time for reversal of ostomies was also longer among veterans (mean 8.3 months, median 9 months) when compared to studies evaluating other populations (5.6-6.9 months).¹⁵⁻¹⁷

Reasons for nonreversal of stomas in the current study mirrored prior studies and included medical comorbidities and progression of colorectal cancer in the follow-up period. Anastomotic leaks during the index operation leading to distal stricture (anal/rectal stricture) have also been shown to be a factor against reversal of temporary stomas. 9,10,14-16 The National Bowel Cancer Audit Project (NBOCAAP) 2013 report

TABLE 2.Reasons for Nonreversal of Temporary Stomas

Conditions	Patients, n (%)
Medical comorbidities—cardiac, pulmonary	6 (33.3)
Progress of colon/rectal cancer	5 (27.8)
Complications from first surgery	3 (16.7)
Diagnosis of other visceral cancers	1 (5.6)
Incontinence	1 (5.6)
Unknown reasons	2 (11.1)

TABLE 3.
HRQOL and Function, by Reversal Status

	Reversal		
	(n = 18)	(n = 18)	P Value
COH-QOL-Ostomy			
Total QOL	6.0 (2.0)	6.1 (2.0)	.90
Physical well-being	6.1 (1.8)	6.3 (2.5)	.81
Psychological well-being	6.4 (2.2)	6.2 (1.8)	.75
Social well-being	5.5 (2.0)	5.9 (3.0)	.58
Spiritual well-being	6.5 (2.8)	6.0 (1.8)	.49
SF-36V			
Component summary scores			
Physical component score	35.4 (10.3)	31.7 (13.5)	.40
Mental component score	46.0 (11.4)	48.4 (10.4)	.57
Health domain scale			
Physical function	46.8 (25.8)	40.5 (33.8)	.53
Role physical	45.2 (29.8)	44.1 (33.5)	.92
Body pain	50.2 (33.1)	43.2 (28.0)	.50
General health	54.6 (24.2)	44.8 (20.3)	.21
Vitality	38.3 (19.6)	38.8 (27.8)	.96
Social function	62.5 (27.8)	57.6 (28.8)	.61
Mental health	64.3 (23.5)	67.5 (21.4)	.68
Role emotional	61.3 (31.0)	57.2 (28.4)	.69

Abbreviations: COH-QOL, City of Hope Quality of Life; HRQOL, health-related quality of life; SF-36V, 36-Item Short-Form Health Survey for Veterans.

recommended counseling patients undergoing anterior resection by including the following information: nonclosure rate of temporary ostomy of 40% at 18 months, a median closure delay of 7 months, and an approximately 10% chance of death with a nonreversed stoma state at 18 months.²¹ Our findings support these recommendations, although the nonclosure rates may be higher in the VA population. This could be attributed to the differences in disease recurrence, comorbidities, demographics, and/or socioeconomic status between veterans and the general patient population.²² These differences should be considered during construction of temporary stomas for veterans, and the information should be provided to veterans at the time of formation of temporary stomas and during patient education thereafter.

Our study also showed clinically relevant rates of postoperative complications after reversal operations among veterans (27.8%, n = 5) were consistent with previous studies (26%-31%).^{17,18} The risk of postoperative complications after reversal has been shown to be a significant factor in the decision whether to reverse a stoma by both surgeons and patients.¹⁸ Our analysis also provides important information about the long-term mortality rate among patients with temporary stomas. The difference in mortality rates between individuals with an ostomy with neoplastic and nonneoplastic causes (70% vs 28% at 13 years) underscores the relationship between the etiology leading to formation of stoma and long-term outcomes.

We did not demonstrate any significant differences in HRQOL between the 2 groups preoperatively, a factor that could potentially influence patient decisions and advice from surgeons whether to reverse stomas.²³ However, our ability to

^aAll subjects included in the study are males.

observe relationships between reversal and HRQOL was limited by our lack of longitudinal data regarding HRQOL after surgery.²³ This could explain differences between results from our study with others. 24-26 We observed a difference between the reversal and nonreversal groups in General Health from the SF-36 of nearly 10 points. Additional research with greater power to detect differences is needed to determine whether stoma reversal results in a difference in how veterans perceive their overall health and other issues related to temporary ostomy creation, stoma reversal, and other domains related to HRQOL. While reports may be contradictory concerning the effect of loop colostomy versus loop ileostomy on HRQOL, 24,27 both clearly impact these outcomes. Self-efficacy is likely also impacted,²⁴ which also influences HRQOL. Rectal cancer survivors with temporary stoma may have worse bowel function issues after takedown.²⁸ There is also evidence that overall HRQOL is not impaired prior to temporary stoma and after takedown, while issues such as physical functioning and sexual interest do improve.²⁹ Another issue that must be considered is that there may be delays in reversal for multiple reasons, such as chemotherapy for cancer survivors.^{29,30} These issues may be ignored for these ostomy patients, as the assumption is that they will have their life restored to normal. These studies provide further evidence that life will not be normal for extended periods of time with an ostomy, and may never return to prior levels.

STRENGTHS AND LIMITATIONS

To our knowledge, this is the first study to evaluate the longterm morbidity and mortality of patients after stoma formation, extending over a mean period of more than 10 years. Although our study included a small sample size and may have lacked adequate power to detect mortality and HRQOL differences by reversal status, another strength of the study was a robust mean follow-up period of 128 months. The longitudinal follow-up extending from 6 to 36 years was longer than any of the previously published studies and helps us understand the long-term clinical outcomes of these temporary stomas. While the differences noted between the 3 sites could be considered as an asset to the study that led to greater generalizability than a single-site study, it highlights that there is significant variation in outcomes and is still limited to veterans and predominantly males. The findings cannot be generalized to the nonveteran population. Finally, the retrospective and descriptive nature of this study limits the ability to infer causation.

CONCLUSIONS

Study findings provide additional knowledge about temporary ostomies. Reversal of temporary stomas may be delayed due to various reasons or may never be reversed. Complications during the index operation, medical comorbidities, and progression of cancer are the main reasons for nonreversal of temporary stomas. This information should be included in the counseling of patients who are likely to get intestinal stomas with temporary intention, and during consideration for later reversal of a stoma.

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 pass, you can print your certificate of earned contact
 hours and access the answer key. If you fail, you have
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 For questions, contact Lippincott Professional Development: 1-800-787-8985.

Registration Deadline: December 4, 2020

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Call for Authors: Ostomy Care

- Original research reports comparing surgical outcomes for patients who undergo preoperative stoma site marking by a WOC nurse compared to patients who do not.
- Case studies, case series or original research reports focusing on stomal or peristomal complications.
- Case studies, case series or original research reports focusing on other potential sequelae of ostomy surgery including physical manifestations such as low back pain or psychosocial manifestations such as depression, altered sexual function or embarrassment.
- Original research reports confirming or challenging the assertions of the ongoing WOCN Ostomy Consensus Session including ostomy pouch wear time and minimum standards for immediate postoperative education of patient and family.