Wound Concerns and Healthcare Consumption of Resources after Colorectal Surgery: An Opportunity for Innovation?

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Abstract

Background: Significant portions of patients undergoing colorectal surgical procedures have minor incision disturbances, yet very few meet definitions for surgical site infection (SSI). We sought to investigate the natural history of incision disturbances with a focus on the patient experience and resource utilization. We hypothesize that patients who have an incision disturbance consume frequent healthcare resources in the post-operative period despite the fact that most never receive a diagnosis of SSI.

Methods: A 24-month prospective observational study was undertaken at an academic institution. Patients undergoing elective colorectal operation by two board-certified colorectal surgeons were followed prospectively for 90 days. Incisions were photographed serially and clinically characterized beginning as early as post-operative day two and at follow-up visits. The primary outcome was patient concern for an incision disturbance. Three surgeons reviewed clinical data and photographs to determine the presence of an incisional surgical infection, and diagnosis required agreement from two of three surgeons.

Results: There were 171 patients included; 31 (15%) sought evaluation from a healthcare provider for concerns related to their incision including 46 telephone calls, six emergency department visits, seven primary care visits, 10 home health and 40 surgical clinic visits. Incision erythema and drainage were the most common sources of patient concern. Mean body mass index was higher in patients with concern for incision disturbances (34 vs. 28 kg/m², $p < 0.0001$). Ultimately, 8% (14/171) received a diagnosis of SSI by study criteria while only 2% (4/171) were captured as having an SSI by the institutional National Surgical Quality Improvement Program database ($p < 0.0001$).

Conclusions: Patients undergoing colorectal surgical procedures commonly are concerned with post-operative incision disturbance, yet few are associated with a diagnosis of SSI, and in-person evaluation yields frequent utilization of healthcare resources. This presents an opportunity for secure electronic communication with the surgical team and the patient to potentially reduce consumption of healthcare resources.

Keywords: colorectal/anal neoplasia; surgical site infection; wound photography

C OLORECTAL SURGICAL PROCEDURES are associated with high rates of surgical site infection (SSI), ranging from 9% to 25% [1,2]. Many additional patients experience minor incision disturbances that are non-infectious in etiology, such as erythema, serous discharge, and pain. Traditionally, colorectal surgical patients were hospitalized for extended periods post-operatively and thus had constant access to healthcare providers for assessment. In the current era

of minimally invasive surgery and enhanced recovery protocols, many surgical site complications occur in the outpatient setting because of shortened length of stay [3,4].

Surgical site symptoms may cause distress to the patient who cannot determine whether these are signs of normal healing or cause for concern [5,6]. Previous studies have shown that while patient evaluation of an incision has high negative predictive value, positive predictive value (PPV) for

patient assessment of an incision for infection is fairly low [7]. The patient's SSI concerns may lead to further healthcare evaluation, which impacts healthcare costs, antibiotic prescribing patterns, and resource utilization associated with evaluation and treatment [3]. These excess expenditures may be preventable, particularly if the patient ultimately does not receive a diagnosis of SSI.

Because of the high rate of post-discharge incision infections and the poor PPV of patient wound assessment, we sought to further investigate the natural history of these minor incision disturbances with a specific focus on the patient experience. We hypothesize that patients who have a surgical site disturbance consume frequent healthcare resources in the post-operative period despite the fact that most never receive a diagnosis of SSI.

Methods

Study design

Approval from the Institutional Review Board at the University of Virginia was obtained before study initiation. A 24-month prospective observational study was undertaken at the University of Virginia between November 29, 2012 and November 30, 2014. Adult patients (≥ 18 years) undergoing elective colorectal operation had consent obtained and were enrolled in the prospective study. All operations were performed by one of two board certified colorectal surgeons. Patients were excluded if they were younger than 18 years, pregnant, prisoners, or undergoing emergent surgery.

Post-operatively, patients were followed by a clinical research coordinator (CRC). The patients' wound was photographed every other day as early as post-operative day (POD) two during their inpatient stay, and at any surgery clinic visits up to 30 days or until incision healing in the case of an incision disturbance. Digital photographs and additional clinical data, such as whether the incision was opened, use of antibiotic agents, and presence of incision drainage, were documented and maintained separately from the patient's medical chart in a prospective database. After the completion of photography incision follow-up, patients were followed up additionally at 90 days either in person in the surgery clinic or via telephone call. The patient was asked specifically about his or her wound and if there were any healthcare encounters since they were last seen by the surgeon.

Retrospective chart review was undertaken separately to collect additional information not gathered prospectively, or from the telephone follow-up, such as antibiotic agents prescribed by a provider other than the primary surgeons. The type of evaluation was also abstracted from patient chart review, defined as a clinic visit, emergency department (ED) visit, inpatient admission, primary care evaluation, home health/rehabilitation, or other similar healthcare providers.

Surgical site analysis

Three board-certified surgeons (TLH, CMF, RGS), including a surgical infectious disease specialist (RGS), independently evaluated blinded incision photographs and clinical incision data. The three surgeons classified each surgical site based on the Centers for Disease Control and Prevention (CDC) definitions of SSI [8]. The CDC classifies SSI as an infection occurring within 30 days of an opera-

tion—superficial incisional, deep incisional, or organ/space infection. Diagnosis also requires purulent drainage, isolation of an organism, or diagnosis by a surgeon or attending physician. For this study, definition of an SSI required agreement from two of the three surgeon reviewers.

The institutional American College of Surgeons National Surgical Quality Improvement Project (ACS-NSQIP) database was also reviewed to document any SSI diagnosis recorded by NSQIP methodology, which has been described previously [9]. Surgical clinical reviewers abstract all procedures included in the colectomy and proctectomy modules in the targeted procedure program. Trained surgical clinical reviewers abstract data from the medical record and follow-up patient telephone calls to obtain 30-day outcomes. ACS-NSQIP uses CDC definitions for the diagnosis of SSI [9].

Outcome measures

The primary outcome measure for the current study is "SSI evaluation process" defined as a patient who sought additional evaluation (telephone call, clinic visit, ED visit, home health visit) outside of routine post-operative follow-up over concern for an incision infection within 90 days of operation. Patients were grouped into two categories: Those who did or did not undergo an SSI evaluation process. Secondary outcomes included differences in surgical site management, operative time, clinical incision characteristics, return to operating room, death, morbidity, and re-admission for patients who did or did not undergo the SSI evaluation process. An additional secondary outcome included the development of SSI as defined by: (1) Agreement from two of three surgeon reviewers or (2) ACS-NSQIP.

Total costs (including the total index hospitalization cost plus costs of all follow-up visits after discharge for 60 days from the operation date) were compared between the two groups. Observed financial data were provided by our institutional University HealthSystem Consortium clinical database.

Statistical analysis

Continuous variables were analyzed using Wilcoxon rank sum, and categorical variables were analyzed using chi-square or Fisher exact test, as appropriate. All statistical analysis was performed using SAS 9.4 (SAS Institute, Inc. Cary, NC). Significance was set at $p \leq 0.05$.

Results

Demographic and clinical comparisons

Consent was received from 192 patients during the study period. Twenty-one patients were excluded, leaving 171 patients in the final analysis: One patient was lost to follow-up, one died in the immediate post-operative period, two withdrew consent, six consented but did not undergo a surgical procedure, and 11 were not captured by NSQIP. An additional 28 patients were seen at 30 days but could not be reached again by 90 days. Thirty-one (15%) patients underwent an SSI evaluation process, whereas 140 did not. Baseline demographic comparisons can be found in Table 1. Those undergoing an SSI evaluation process did not differ in regard to age, gender, race, or insurance status. Similarly, there are no differences in regard to rates of diabetes mellitus, smoking status,

TABLE 1. DEMOGRAPHIC AND CLINICAL COMPARISONS BETWEEN GROUPS UNDERGOING A SURGICAL SITE INFECTION EVALUATION PROCESS

Variable	SSI process (n = 31)	No process (n = 140)	p
<i>Patient demographics</i>			
Race			0.30
White	26 (84%)	127 (91%)	
Black	5 (16%)	8 (6%)	
Other	0	5 (3%)	
Insurance			0.59
Private	17 (55%)	65 (46%)	
Medicare	9 (29%)	49 (35%)	
Medicaid	4 (13%)	13 (9%)	
Other	1 (3%)	13 (9%)	
Male	16 (52%)	66 (47%)	0.65
BMI (mean, SEM)	33.9 (1.7)	27.9 (0.55)	<0.0001*
Neoplasm	21 (68%)	79 (56%)	0.25
Diabetes mellitus	5 (16%)	16 (11%)	0.58
Smoker	5 (16%)	23 (16%)	1
Steroids	4 (13%)	17 (12%)	1
<i>Operative characteristics</i>			
Pre-operative stoma	6 (20%)	19 (13%)	0.58
ER protocol	12 (39%)	87 (62%)	0.02
ASA classification ≥ 3	14/31 (45%)	76 (54%)	0.95
Clean/contaminated	29 (93%)	119 (86%)	0.46
Stapled closure	22 (71%)	82 (59%)	0.20
Ostomy creation	10 (32%)	58 (42%)	0.63
Operative time (min)	183 (160, 243)	211 (152, 280)	0.62
<i>Clinical Outcomes</i>			
Length of stay, d	5 (3.8)	4 (3.7)	0.23
Re-admission	5 (16%)	11 (8%)	0.16
Re-operation	4 (13%)	6 (4%)	0.13

*Significant at $p < 0.05$.

SSI=surgical site infection; BMI=body mass index; SEM=standard error of the mean; ER=enhanced recovery; ASA=American Society of Anesthesiologists.

pre-operative steroid use, other co-morbidities, laparoscopic approach, or American Society of Anesthesiologists classification. The group undergoing an SSI evaluation process had a statistically significant association with higher body mass index (BMI); mean of 33.95 compared with 27.91 for patients with no incision concerns ($p < 0.0001$).

The group enrolled in an enhanced recovery protocol (ERP) had a lower association with surgical site concern. The majority of the patients who underwent the SSI evaluation process (61%, 19/31) were before implementation of the ER protocol ($p = 0.02$). Only 12% (12/99) of ERP patients sought evaluation over concern for an SSI, whereas 26% of pre-ERP patients (19/72) underwent the evaluation process ($p < 0.001$). There were no differences in regard to wound classification (clean/contaminated, dirty/contaminated), operative time, use of staples as primary incision management, or rates of ileostomy or colostomy creation. No incisions were left open at the index operation, because only elective cases were used in this analysis. There were no statistically significant differences in rates of return to the operating room, length of stay, death, morbidity or re-admission (Table 1). Overall, 71 (42%) patients had laparoscopic operations—42% in the SSI process group versus 41% in the no process group ($p = \text{NS}$).

Surgical site disturbances

Taken together, 63 of 171 patients (37%) experienced some type of surgical site disturbance including serous drainage, erythema, purulent drainage, or separation of tissue (Table 2). Nineteen had more than one of the aforementioned signs/symptoms. Surgical site disturbances were stratified based on patients undergoing an SSI process compared with those who did not (Table 2). Thirty-seven of the 63 patients had either erythema (15), serous drainage (17), or both (5) discovered incidentally at routine follow-up but were not associated with an SSI evaluation process initiated by the patient. None of these patients met criteria for an SSI. Patients who underwent the SSI evaluation process reported erythema, serous exudate, and separation of tissue at significantly higher rates than patients who did not undergo the SSI evaluation process ($p < 0.0001$). Fewer than half of patients undergoing an SSI evaluation process, however, ultimately received a diagnosis of SSI, based on independent, blinded, surgeon review, with confirmation from two of three attending surgeons ($p < 0.0001$); only 13% (4/31) of patients undergoing an SSI evaluation process were captured by NSQIP as actually having an SSI ($p = 0.0009$). Ultimately, 8% of the entire population met study criteria for an SSI while

TABLE 2. INCISION COMPLICATIONS FOR GROUPS UNDERGOING SURGICAL SITE INFECTION EVALUATIONS COMPARED WITH PATIENTS WITHOUT A SURGICAL SITE INFECTION EVALUATION

Variable	SSI process (n=31)	No process (n=140)	p
Erythema	16 (52%)	22 (16%)	<0.0001*
Serous exudate	16 (52%)	20 (14%)	<0.0001
Separation of tissue	8 (26%)	0	<0.0001
Purulent exudate	9 (29%)	0	<0.0001
Incision and drainage/debridement	8 (26%)	0	<0.0001
Surgeon SSI diagnosis	14 (45%)	0	<0.0001
NSQIP SSI diagnosis	4 (13%)	0	0.0009

*Significant at $p < 0.05$.

SSI=surgical site infection; NSQIP=National Surgical Quality Improvement Project.

only 2% were captured as having an SSI by the institutional NSQIP database ($p < 0.0001$).

SSI evaluation process

SSI evaluation took place in the form of 46 total telephone calls, 7 primary care physician (PCP) visits, 40 surgery clinic visits, 10 home health/rehabilitation visits, and six ED visits (Fig. 1). These evaluations were prompted specifically by patient SSI concerns. Two patients were admitted from the ED; however they did not have a diagnosis of SSI and were admitted for unrelated reasons. Last, 11 patients underwent more than one form of evaluation. There were no differences in 60-day total costs between patients who did and did not undergo the SSI evaluation process ($21,663 \pm 12,870$ vs. $21,904 \pm 16,078$, respectively, $p > 0.05$).

FIG. 1. Graphic depiction of the types of the surgical site infection evaluation process. ED=emergency department; surg=surgical; PCP=primary care physician.

Of the 31 patients undergoing an SSI evaluation process, only 14 received a diagnosis of SSI using study criteria (2/3 attending agreement). Resource utilization for the patients who sought evaluation but did not meet study criteria for SSI was further investigated (Table 3): 22 telephone calls, two ED visits, four PCP visits, two home health visits, and 14 surgery clinic visits were made by patients without an SSI. Six patients without an SSI had antibiotic agents prescribed for treatment of SSI. Five of these patients received antibiotic agents from the surgery clinic while one patient received them from a PCP. Two patients did necessitate intervention for their incision although did not meet criteria for an SSI: One patient underwent drainage of a seroma and one patient underwent drainage of a hematoma.

Discussion

Principal findings

We sought to evaluate the impact of patient surgical site concerns on healthcare consumption after elective colorectal operation. These results demonstrate that while concern for SSI that leads to additional surgical site evaluation occurs in a significant portion of colorectal operation patients, fewer than half of patients with a surgical site concern ultimately receive a diagnosis of SSI. Erythema, serous drainage, and incision separation were the most common reasons for concern. Most of these patients were seen in a physician's clinic for further evaluation. The SSI evaluation process was not associated with increased costs likely given that these evaluations occurred within the global period.

Comparison with similar studies

Our findings are similar to findings from other studies, which demonstrate that patients have poor positive predictive value in identifying SSIs [10,11]. Whitby et al. [10] reported a PPV of 28.7% in patients identifying SSI. The same study demonstrated poor correlation of patient recognition of clinical signs and symptoms of SSI to recognition by a nurse trained in clinical infections. Although patients were able to reliably discuss their symptoms, this did not correlate with an accurate assessment of the clinical picture [10,11]. Similarly, our results demonstrate that fewer than half of patients with concern for a wound disturbance ultimately received a diagnosis of SSI.

This was true particularly for obese patients in the current study, given that a high BMI was associated significantly

TABLE 3. TYPE OF EVALUATION PROCESS AND NUMBER PER PATIENT

Variable	SSI (n = 14)	No SSI (n = 17)	p
Number of phone calls	24	22	–
Patients making phone calls	8 (57%)	13 (76%)	0.44
Number of ED visits	4 (29%)	2 (12%)	0.37
Number of PCP visits	3	4	–
Number of home health visits	8 (57%)	2 (12%)	0.02*
Number of surgery clinic visits	30	10	–
Patients visiting surgery clinic	14 (100%)	8 (47%)	0.001
Patients receiving antibiotic agents	8 (57%)	6 (35%)	0.22
Patients undergoing incision and drainage or debridement	6 (43%)	2 (12%) ^a	0.10

*Significant at $p < 0.05$.

^a1 seroma, 1 hematoma.

SSI=surgical site infection; ED=emergency department; PCP=primary care physician.

with wound concern, leading patients to seek further SSI evaluation. While other studies have demonstrated high BMI to be a significant risk factor for development of SSI, few studies analyze BMI in relation to the SSI evaluation process. [1,12] Intuitively, obese patients are more likely to have seromas develop and associated serous drainage, which can potentially be mistaken for an SSI. It is interesting to also note that participation in an ERP was associated also with lower surgical site problems leading to further evaluation and the development of an SSI. Previous studies have shown a statistically significant decrease in the SSI rate for patients enrolled in an ERP [13,14]. This may be attributable to the reduction in intravenous fluid resuscitation and subsequent peripheral edema, reducing the amount of serous drainage through the incision, which is often mistaken as an SSI.

Clinical implications

The findings in this study have clinical significance, particularly in regard to resource utilization. Surgical patients frequently seek further medical evaluation of wounds because of uncertainty about the healing process. Patients think they are not adequately educated about incision appearance or infectious concerns at the time of discharge or during their inpatient stay. Heightening this disadvantage is the mental fatigue felt by the patient, brought on by pain medication and a recent major operation [6].

One approach would be to provide the patient with the ability to capture a surgical site through photography post-discharge and describe symptoms to a physician. This would allow a provider to determine whether further evaluation is necessary without a face-to-face visit. Patients often are distressed because of these irregularities in recovery; re-assurance by the provider can diminish this anxiety [6]. This system would decrease time and energy on behalf of the patient and would free up valuable clinic time for the provider, particularly if there are no infectious concerns. Patients have reported in other studies that the addition of surgical site photography would help them “feel peace of mind” and help them take ownership of the healing process [15]. More than 80% of patients find it a useful method to help them track their wounds.

Certainly this technology would not obviate completely the need for in-person evaluation for certain patients. It would provide, however, more granular information to providers than a phone conversation alone; and as men-

tioned previously, patient surgical site tracking does not necessarily correlate with accurate interpretation of the clinical site status [15].

Combining smartphone technology and the use of a surgical site photography app sent to a trained healthcare provider may not only increase patient ownership of the healing process but may also decrease unnecessary healthcare utilization. Given that the average ED visit is approximately \$1,200, the economic benefits could be sizeable if ED visits could be prevented [16]. A previous study [6] has demonstrated that patients show openness and comfort to a mobile health technology solution for surgical site monitoring with decreased barriers to post-operative care currently experienced in the post-discharge phase of recovery. Implementation of such a system, however, faces the challenge of competing post-discharge information needs for patients and providers [17]. While patients desire more immediate multi-media communication and feedback on surgical site photographs, providers struggle with how to incorporate patient-generated data streams from smartphones, activity monitors, and other wearable devices into existing care processes [17].

Next, several studies have demonstrated that an active SSI surveillance program lends itself to a reduction in SSI rates. Marchi et al. [18] have shown that a large majority of SSI was detected after discharge by post-operative day 22. The implementation of a national surveillance protocol, however, led to a 29% reduction in SSI. Similarly, a 6-year surveillance program in France reduced SSI rates by 55% [19], while a German national nosocomial infection protocol reduced SSI by 28% [20]. Based on these findings, patient generated data in an active surveillance program may also lead to a reduction in SSI, although this remains to be seen.

A discrepancy between the NSQIP and surgeon SSI capture rate is evident. Previously, we found poor inter-rater reliability among surgeons and NSQIP in identifying SSI according to CDC criteria [21,22]. In the majority of cases, omissions by NSQIP were because of lack of clear documentation leading to a very low rate of SSI in the NSQIP database. We also found, however, discordance between surgeons when looking at the surgical site photography, suggesting that surgeons, despite looking at the same site, could not agree reliably on the presence of an SSI. This is also reflected by the finding that five patients received antibiotic agents for SSI in the colorectal surgery clinic despite not meeting study criteria for SSI.

In the current study, 37% of patients had some type of surgical site disturbance. Given that there is a significant subjective component to the CDC definition, one must question whether the CDC criteria relying on the expert opinion of the attending surgeon is, in fact, valid. This is particularly true in an era when SSI is being tracked closely, and surgeons may have an inherent conflict of interest in identifying SSI. It is also possible that, because the CDC definitions only allow for a binary outcome (infected or not infected), surgeons can have a legitimate disagreement on the threshold to call a surgical site infected.

There have been studies now demonstrating discordant rates of institutional SSI between the various different quality databases such as ACS-NSQIP and the National Healthcare Safety Network (NHSN). Typically, ACS-NSQIP rates are higher than NHSN [23]. This is thought to be because of differences in surveillance strategies and documentation in the medical records. The current data reiterate that prospective surveillance with blinded review result in significantly higher rates of SSI than institutional surveillance. This has significant implications regarding the use of institutional SSI as an institutional quality measure and our ability to study SSI given the inherent difficulty in defining it accurately.

Strengths

This is one of the few studies to identify specifically the evaluation process patients seek when experiencing a post-discharge surgical site concern and compare this with percentage of SSI diagnosis. This enabled us to provide an accurate snapshot of the consumption of healthcare resources utilized by each of the patients related to concern of their incision. This will assist with developing technologies to provide easier communication between patient and provider.

Limitations

This study has important limitations. First, this is a single institution study. Although it occurred at a large, tertiary care center, our findings may not be generalizable to colorectal patients served in different care environments. Second, we acknowledge that the implementation of an ERP during the study period may have influenced the post-discharge process of care and led to a different threshold for patient-initiated contact with providers. Third, in some cases, there were overlapping reasons for telephone calls and clinic visits. For instance, some patients had a surgical site concern and nausea and vomiting. Therefore, it was at times difficult to tease out the surgical site complaint from another complaint as the initiating symptom of concern. Last, we may have missed encounters for patients who were seen by a physician or healthcare provider outside of the principal institution not confirmed by patients because of recall bias. Future studies using innovative patient generated data methods that do not rely on institutional electronic medical records may improve our ability to validate the current surveillance methods used widely by US hospitals.

Suggestions for future study

Patients undergoing colorectal operation are commonly concerned with post-operative surgical site disturbances, leading to frequent in-person evaluations and consumption of healthcare resources. This presents an opportunity for using

mobile technology to improve electronic communication between patient and provider, with the hope that this may improve patient satisfaction, reduce consumption of healthcare resources and inappropriate antibiotic prescription, and potentially reduce the rate of SSI.

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Author Disclosure Statement

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