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Multi-Institutional Assessment of Sphincter Preservation for Rectal Cancer

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Abstract

BACKGROUND—Sphincter preserving surgery (SPS) has been proposed as a quality measure for rectal cancer (RC) surgery. However, previous studies on SPS-rates lack critical clinical characteristics, rendering it unclear if variation in SPS-rates is due to unmeasured case-mix differences or surgeons' selection criteria. In this context, we investigate the variation in SPS-rates at various practice settings.

METHODS—Ten hospitals in the Michigan Surgical Quality Collaborative collected RC-specific data including tumor location and reasons for non-SPS of patients who underwent RC surgery from 2007–2012. Hospitals were divided into terciles of SPS-rates (frequent, average and infrequent). Patients were categorized as “definitely SPS-eligible” *a priori* if they did not have any of the following: sphincter involvement, tumor <6cm from the anal verge, fecal incontinence, stoma preference or metastatic disease. Fixed-effects logistic regression was used to evaluate for factors associated with SPS.

RESULTS—In total, 329 patients underwent RC surgery at 10 hospitals (5/10 higher-volume and 6/10 major teaching). Overall, 72% had SPS (range by hospital 47%–91%). Patient and tumor characteristic were similar between hospital terciles. On multivariable analysis, only hospital ID, younger age, and tumor location were associated with SPS, but not sex, race, BMI, AJCC stage, preoperative radiation, or ASA class. Analysis of the 181 (55%) “definitely-eligible” patients revealed a SPS-rate of 90% (65–100%).

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CONCLUSIONS—SPS-rates vary by hospital, even after accounting for clinical characteristics using detailed chart-review. These data suggest missed opportunities for SPS, and refute the general hypothesis that hospital variation in previous studies is due to unmeasured case-mix differences.

INTRODUCTION

Total mesorectal excision and advances in chemoradiation have significantly improved oncologic outcomes and long-term survival following rectal cancer surgery.¹ Modern techniques and stapling technology frequently permit sphincter preserving surgery (SPS) and the avoidance of a permanent stoma, even for low-lying tumors.^{2–5} Accordingly, SPS-rates have been proposed as a quality measure for rectal cancer surgery and multiple reports have shown wide variations in its utilization.^{6,7}

Population-based rates of SPS in Europe and Australia vary between 75–84% while rates in the US are anywhere between 48–77%.^{4,5} Moreover, previous studies using national registry data and hospital discharge data have shown that SPS rates vary based on patient demographics, education, geography and surgeon volume.^{4,8–12} However, these data lack critical clinical details, such as tumor location or sphincter involvement, which are necessary to determine if patients are candidates for SPS. This makes it difficult to discern whether the variation in SPS utilization is due to unmeasured case-mix differences or variable selection criteria across centers.

In this context, we studied SPS-rates at 10 community and academic hospitals participating in the Michigan Surgical Quality Collaborative. We sought to identify whether variation in SPS-rates can be explained by patient, tumor or treatment-related factors across hospitals. To our knowledge, this is the largest report addressing SPS-rates in the US from diverse practice settings based on clinical data.

METHODS

Study Setting

This study is based on a special project aimed at improving the quality of rectal cancer care within the Michigan Surgical Quality Collaborative (MSQC). The MSQC is a 52-hospital consortium representing diverse practice settings in Michigan. MSQC data abstraction and data quality assurance details have been described elsewhere.^{13,14} In brief, specially trained data abstractors prospectively collect data for patients undergoing specified surgical operations utilizing sampling algorithms that minimizes selection bias in accordance with established policies and procedures.

For the current study, 10 community and academic hospitals volunteered to retrospectively collect an additional set of rectal cancer-specific data, for their rectal cancer cases identified from the MSQC database. Data collection for MSQC is Institutional Review Board (IRB) exempt, and the current study was deemed “non-regulated” by the University of Michigan’s IRB.

Patient Population

Patients aged 18 years and older, who had undergone surgery for primary rectal cancer based on International Classification of Disease (ICD-9 code 154.1) were identified from 7/1/2007 to 6/24/2012. Detailed chart-review excluded patients who: had cancers other than primary adenocarcinoma (e.g. squamous cell carcinoma, carcinoid tumor), or underwent local excisions (e.g. trans-anal excision), total colectomies or pelvic exenterations.

Independent Variables

Tumor location was abstracted in one of two ways: (A) Exact distance measurement from anal verge, dentate line or anorectal ring (in centimeters) to the lowest extent of the tumor on *rigid* proctoscopy or digital rectal exam (DRE) from the surgeon's note prior to any therapy. If the distance from the anal verge to the lowest extent of the tumor was reported as a range estimate (e.g., lowest extent is 5–6 cm from anal verge) then the midpoint of this distance was used (i.e., 5.5 cm). Measurements that referenced the anorectal ring or dentate line were converted to anal verge measurements by adding 4 or 2 cm, respectively. If an actual measurement (in cm) was not found in the patient's record, the alternative method (B) was to abstract the tumor location in relation to the upper 1/3rd (>12cm), middle 1/3rd (6–12 cm) or lower 1/3rd (<6 cm) of the rectum based on the surgeon's proctoscopy report. These 2 methods were used to create the following categories for tumor location: > 12 cm (upper); 6–12cm (mid); and < 6 cm (lower). In 7 cases (2%) a tumor location was not found in the record, these cases were not used in the regression analyses.

Sphincter involvement was identified from the preoperative note(s), MRI reports, or the endo-rectal ultrasound report. Poor sphincter control was defined as having a documented history of fecal incontinence/seepage and/or poor sphincter function/tone. Patient preference for an ostomy was recorded when documented. Clinical stage designations were in accordance with AJCC 7th edition. Other collected clinical and demographic data included age, race, sex, ASA class, and body mass index (BMI).

Hospital-level data such as teaching status and bed size were obtained from the publically available American Hospital Association data file. Due to the small numbers in this sample population, hospital caseload was calculated using data from the Medicare dataset, averaging the number of colon and rectal cancer resections between 2008–2011. Hospitals were categorized as “higher volume” if they had an annual average of >40 colon and rectal cancer resections/year. Surgeon-level data were not available for this study.

Main Outcome Measure and Statistical Analysis

The use of SPS was the main outcome measure and was defined based on Current Procedural Terminology (CPT) codes representing a low anterior resection (LAR; 44140, 44145-44147, 44204, 44207-44208, 45111, 45112, 45114, 45119 or 45397). Non-sphincter preserving surgery included abdominoperineal resections (APR; 45110 or 45395) or Hartmann's-type procedures (44141, 44143, 44144, 44206).

Patients were defined as “**eligible for SPS**” *a priori* if they did **NOT** have any of the following: 1) sphincter involvement, 2) stoma preference, 3) poor sphincter control/fecal

incontinence, or 4) metastatic disease. Patients were further classified as “**definitely eligible**” if they met the above criteria and their tumor was >6 cm from the anal verge.

Hospitals were divided into terciles based on their overall crude SPS-rates into frequent, average, and infrequent terciles. Clinical and demographic variables for patients were compared using chi-square tests for categorical and analysis of variance (ANOVA) for continuous variables as indicated, with significance set at a p-value <0.05. Spearman's correlation statistics were used to compare hospital rankings before and after accounting for SPS-eligibility. A Spearman's correlation coefficient (ρ) of 1 indicates a perfect association of ranks, and a ρ of zero indicates no correlation.

A fixed-effects logistic regression model, which included a separate hospital identifier for each hospital, was constructed to determine which factors were associated with receiving SPS among SPS-eligible patients with significance set at $p < 0.05$.¹⁵ A fixed-effects models results in an unbiased estimate of the hospital effect when correlated with observable patient risk factors. The model was evaluated for discrimination using the c-statistic.

The fitted fixed-effects logistic regression model was then used to calculate the predicted probability of SPS for each eligible patient as if (contrary to fact) they had been treated at each of the 10 hospitals. Then the predicted SPS-rate for every hospital is calculated by averaging the appropriate patient predicted probabilities. The observed-to-expected ratio (O:E) compares the overall population rate to the expected (predicted) SPS-rate at each hospital. Multiplying the O:E ratio by the outcome's mean yields the risk-adjusted rates.¹⁵

All statistical analyses were conducted using STATA special edition (version 13, StataCorp, College Station, TX).

RESULTS

Characteristics of Participating Hospitals

The hospitals participating in this study represented various practice settings with 9/10 located in an urban location, 5/10 had higher colorectal cancer caseloads, 6/10 were major teaching centers, and 3/10 had more than 750 beds. However, none of these hospital characteristics were significantly associated with SPS on univariable analyses (all $p > 0.1$; data not shown).

Patient Characteristics

Of the identified 329 patients who underwent surgery for rectal cancer in the 5-year period, 237 (72%) had SPS. Clinical and demographic patient characteristics are summarized in Table 1 between the hospitals with “frequent”, “average” or “infrequent” SPS-rates. The patients in this study represent a fairly typical mix of upper and lower rectal cancers, as there were 60 cases with upper rectal cancer, 139 cases with mid rectal cancer, and 123 cases with low rectal cancer. These patients were treated with a total of 237 LAR's, 80 APR's and 12 Hartmann's Type resections. As shown in Table 1, patient and tumor characteristics were similar across terciles. Average age was 64 years, and over 50% of patients were male. The only statistical differences were noted for tumor stage and receipt of neo-adjuvant radiation

therapy; however, these differences were not linear across terciles. Importantly, the proportion of “definitely eligible” patients across terciles was similar.

Crude Hospital Performance versus Performance Based on Eligible Patients

As illustrated in Figure 1a, crude SPS-rates varied by hospital, with a mean rate of 72% (range by hospital: 47–91%). This rate improves to 90% (65–100%) after only including “definitely-eligible” patients as shown in Figure 1b. Hospital rankings before and after only including “definitely-eligible” patients were highly correlated (Spearman’s $\rho=0.9$).

The interaction between tumor location and SPS-rates among “eligible” patients is shown in Figure 2. The greatest variability in SPS-rates occurred for tumors <6 cm from the anal verge with a three-fold difference between the frequent and infrequent terciles. In general, hospitals in the infrequent tercile were less likely to perform SPS at all tumor locations.

Analysis of Hospital Variation

On multivariable analysis, only younger age, tumor location, and the unique hospital identifier were independently associated with SPS, but not race, sex, BMI, receipt of radiation therapy, AJCC stage, or ASA class as shown in Table 2. The most pronounced associations were with the unique hospital identifier. Thus, hospitals vary significantly in their SPS-rates, even with adjustment for clinical characteristics. Risk-adjusted O:E ratios for SPS at each hospital are shown in Figure 3. Of all 10 hospitals, hospitals “H” and “J” performed significantly more SPS than expected, while hospitals “A, B, C” performed significantly less SPS than expected. The risk-adjusted SPS-rate of at hospital “J” was more than two-fold that at hospital “A” independent of other factors ($p<0.001$).

Sensitivity analyses

In a sensitivity analysis, we regarded patients with BMI>40 or age >80 years as ineligible for SPS. The results were similar, thus not shown. Additionally, in a post-hoc analysis utilizing the hospital terciles in the multivariable model, the frequent hospital tercile was independently associated with SPS ($p<0.001$) meaning that apparently similar patients are significantly more likely to receive SPS if they have surgery at a SPS-frequent hospital versus SPS-infrequent hospitals.

DISCUSSION

In this study of 329 patients undergoing rectal cancer surgery at 10 community and academic hospitals, we demonstrate that (1) patient and tumor characteristics did not vary significantly between hospitals that frequently performed SPS and those that did not; (2) hospitals’ SPS rates varied widely, even after accounting for clinical features such as tumor location or sphincter involvement, and (3) hospitals’ crude SPS rankings correlate well with clinically adjusted rankings. These results suggest differing selection criteria for SPS surgery between institutions, and missed opportunities for SPS among potentially eligible patients.

The overall SPS-rate of 72% in the present report is better than previously published population-based US reports in the literature and is comparable to rates at specialty cancer centers.^{2,4} However, the range of SPS-rates from 65% to 100% for eligible cases suggests room for improvement at some hospitals. Moreover, there was over a two-fold risk-adjusted probability of receiving SPS between the most and least frequent SPS hospital. The implication of this study is that different surgeons at various hospitals have different selection criteria for SPS, which may be related to technical training and/or experience. This is most evident for low rectal cancer, as the largest variations were noted in tumors <6 cm from the anal verge, with a three-fold difference in SPS-rates between the SPS-frequent and SPS-infrequent hospital terciles, despite similar other patient characteristics.

How might one address this variation? Regional surgeon peer mentoring, workshops and/or training opportunities might be a logical strategy to disseminate SPS techniques to every hospital. In the Netherlands, there was a 32% nationwide decrease in the rates of APR's during and following the Dutch TME trial, where teaching sessions, tutor-assisted surgery and quality control formed an integral and important component for sharing surgical technique.¹⁶ Similarly in Sweden, SPS-rates improved from less than 50% before the TME project to more than 70%. The Swedish TME project comprised three workshops, including 11 video-based live surgery sessions and two histopathology sessions to colorectal surgeons.¹⁷ The effects of these interventions are potentially reproducible in the US within regional collaboratives.

Multiple studies have examined the associations between sphincter preservation and patient-, tumor- or treatment-related factors. For example, previous research has suggested that female gender, lower stages and lower BMI, are associated with SPS.^{4,5} In the present analysis, these associations are eliminated after adjusting for tumor location and the incorporation of a unique hospital identifier in the multivariable model. One can conclude that even among strictly defined eligibility criteria, some institutions have different practice patterns.

While several other studies have previously reported variations in SPS-rates in rectal cancer patients, the present study is unique in several aspects. First, the majority of contemporary studies from the US are based on administrative or billing data, which lack important clinical features. Although such methodology allows for a population-based analysis with large sample sizes, detailed patient and tumor data such as tumor location are not available. The inability to account for these factors is a significant limitation of previous reports, as clinically relevant confounders are not available. In the present study, we overcame this by collecting specific clinical details using comprehensive chart reviews. Other research, such as that by Temple and colleagues², is from specialty cancer centers, which limits the generalizability of the findings.

We also highlight the limitation of benchmarking hospitals using administrative data without accounting for critical clinical features. In the present study, SPS-rates improved to 90% after excluding cases that were deemed not eligible for SPS based on detailed chart review. In other words, previous reports from administrative data, such as that by Ricciardi and colleagues⁴ may underestimate true practice and inaccurately benchmark hospitals.

Nevertheless, hospitals having a low *crude* rate of SPS also consistently had a low rate of SPS in eligible cases in this study. Thus, crude rates based on administrative data using ICD-9 and CPT codes may serve as a reasonable proxy for identifying low-performance hospitals for quality improvement efforts.

Our study has several limitations. First, even though we had a detailed comprehensive chart review process, our data is highly dependent on provider documentation. It is possible that some patients met eligibility criteria in our analyses based on the absence of such documentation. However, this emphasizes provider diligence in documentation if SPS-rates are to be used as a quality measure. Second, this study is limited by the absence of surgeon-level data, such as surgeon volume or experience. However, hospitals are the appropriate target for quality improvement as they have the leverage to affect surgeon's practices. Furthermore, previous research has shown that provider practices are more similar within hospitals than between hospitals, and hospitals have been the unit of measure for similar studies.² Lastly, it is limited by the sample size. Nevertheless, to our knowledge this study represents the largest, multi-institutional report on SPS in the United States with clinical data at various practice settings, community and academic.

In conclusion, this multi-institutional study demonstrates significant variation in the use of sphincter preserving surgery between hospitals despite seemingly similar patient and tumor characteristics. These data refute the general hypothesis that hospital variation in SPS-rates in previous studies is due to unmeasured case-mix differences, highlighting the potential for quality improvement.

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Figure 1.

Sphincter preserving surgery (SPS) rates: (A) crude rates based on CPT codes in the entire sample (n=329) at hospitals (A-J); (B) rates after only including “definitely-eligible” patients (n=181), the horizontal line represents the mean SPS rate (72% and 90%, respectively). Note that hospitals maintained similar overall rankings (Spearman’s $\rho = 0.9$), but at some hospitals there were up to 35% missed opportunities for SPS.

Figure 2.
Sphincter preserving surgery (SPS) rates at different tumor locations stratified by hospital SPS-frequency tertile.

Figure 3.

Risk-adjusted observed-to-expected (O:E) ratios for SPS at hospitals (A-J). An O:E ratio of 1.0 indicates that the number of observed events equals the number of expected events. Since the outcome is favorable, an observed-to-expected ratios <1.0 indicate worse than expected outcomes; ratios >1.0 indicate better than expected outcomes. If the 95% confidence interval of the O:E ratio for each outcome did not include 1.0, then the hospital was designated as an “outlier” and highlighted in bold.

Table 1

Patient and tumor characteristics at tertiles of hospital SPS rates for the overall patient population. (Percentages may not add up to 100% due to rounding).

Characteristics	Tertiles of Hospital SPS-Rates						p Value
	Infrequent Tertile		Average Tertile		Frequent Tertile		
	No.	Col %	No.	Col %	No.	Col %	
Sample size	64		147		118		
Age, mean ± SD	63.8 ± 13.3		64.1 ± 13.6		64 ± 12.2		0.417
BMI, mean ± SD	29.5 ± 6.7		27.2 ± 5.9		27.8 ± 5.9		0.431
Gender; Male	36	56%	90	61%	73	62%	0.655
Race; White	57	89%	128	87%	101	86%	0.801
ASA Class >2	29	45%	66	45%	60	51%	0.597
AJCC Stage							0.003
I	13	20%	31	21%	39	33%	
II	27	42%	34	23%	32	27%	
III	18	28%	67	46%	41	35%	
VI	6	9%	15	10%	6	5%	
Preoperative XRT	39	61%	98	67%	59	50%	0.022
Tumor Location							0.104
<6 cm	20	31%	61	41%	42	36%	
6–12 cm	27	42%	64	44%	48	41%	
>12 cm	13	20%	21	14%	26	22%	
Unknown	4	6%	1	1%	2	2%	
Definitely Eligible	38	59%	73	50%	70	59%	0.214

Table 2

Multivariable analysis to determine factors associated with receiving SPS.

Characteristic	Adjusted Odds Ratio	[95% Conf. Interval]	p Value
Age	0.96	[0.93 – 0.99]	0.037
Race; White	1.36	[0.42 – 4.39]	0.552
Male Gender	0.71	[0.29 – 1.73]	0.613
BMI			
Normal	1	[ref]	
Underweight	0.35	[0.04 – 3.12]	0.345
Overweight	2.10	[0.70 – 6.24]	0.183
Obese	0.61	[0.23 – 1.58]	0.305
ASA Class >II	1.59	[0.67 – 3.77]	0.298
AJCC Stage			
I	1	[ref]	
II	0.92	[0.3 – 2.78]	0.878
III	1.72	[0.59 – 5.05]	0.322
Neoadjuvant XRT	0.43	[0.14 – 1.27]	0.129
Tumor Location			
< 6 cm	1	[ref]	
6–12 cm	7.94	[2.07 – 21.21]	< 0.001
> 12 cm	9.49	[2.10 – 42.86]	0.003