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Uptake of Total Mesorectal Excision and Total Mesorectal Excision Grading for Rectal Cancer: A Statewide Study

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Abstract

BACKGROUND: Total mesorectal excision is associated with decreased local recurrence and improved disease-free survival following rectal cancer resection. The extent to which total mesorectal excision has been adopted in the United States is unknown.

OBJECTIVE: We sought to assess trends in total mesorectal excision performance and grading in Michigan hospitals.

DESIGN: This is a retrospective cohort study from the Michigan Surgical Quality Collaborative. Trends in total mesorectal excision performance and grade assignment were analyzed using chi-square tests and linear regression.

SETTINGS: Participating hospitals (initially 14 hospitals, now 38) abstracted medical records data for rectal cancer cases from 2007–2016.

PATIENTS: Patients who underwent rectal cancer resection.

MAIN OUTCOME MEASURE: The main outcome measures were surgeon-documented total mesorectal excision performance and pathologist-reported total mesorectal excision grade.

RESULTS: Of 510 rectal cancer cases, 367 (72.0%) had surgeon-reported total mesorectal excision performance and 78 (15.3%) had pathologist-reported total mesorectal excision grade. Between-hospital variability in total mesorectal excision performance ranged from 0 to 97% and

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total mesorectal excision grading ranged from 0 to 90%. Total mesorectal excision grading was associated with a higher likelihood of also having adequate lymph node assessment (88.5% versus 71.9%, $p=0.002$). There has been a statistically-significant trend towards an increase in total mesorectal excision grading in the original 14 hospitals ($p=0.001$), but not in the complete cohort of all hospitals ($p=0.057$).

LIMITATIONS: Retrospective cohort design with sampled rectal cancer cases. Additionally, there is insufficient granularity to capture all factors associated with total mesorectal excision performance or grade assignment.

CONCLUSIONS: Rates of total mesorectal excision performance and grade assignment are widely variable throughout the state of Michigan. Overall, grade assignment remains very low. This suggests an opportunity for quality improvement projects to increase total mesorectal excision performance and grading, involving both the surgeons and pathologists for effective implementation. See **Video Abstract** at <http://links.lww.com/DCR/Axxx>.

Abstract

La escisión mesorrectal total se asocia con una menor recurrencia local y una mejor supervivencia libre de enfermedad después de la resección del cáncer rectal. Se desconoce hasta que punto se ha adoptado la escisión mesorrectal total en los Estados Unidos.

Se intentó evaluar las tendencias en el rendimiento y la clasificación de la escisión mesorrectal total en los hospitales de Michigan.

Este es un estudio de cohorte retrospectivo de la “Michigan Surgical Quality Collaborative”. Las tendencias en el rendimiento de la escisión mesorrectal total y la asignación de grado se analizaron mediante pruebas de chi-cuadrada y regresión lineal.

Los hospitales participantes (inicialmente 14 hospitales, ahora 38) extrajeron datos de registros médicos de los casos de cáncer rectal desde 2007 hasta 2016.

Pacientes que se sometieron a resección de cáncer rectal.

Las principales medidas de resultado fueron el rendimiento de la escisión mesorrectal total documentado por el cirujano y el grado de escisión mesorrectal total informada por el patólogo.

De 510 casos de cáncer rectal, 367 (72.0%) tenían un rendimiento de escisión mesorrectal total reportado por el cirujano y 78 (15.3%) tenían un grado de escisión mesorrectal total reportado por el patólogo. La variabilidad entre hospitales en el rendimiento de la escisión mesorrectal total varió del 0 al 97% y la clasificación de la escisión mesorrectal total varió del 0 al 90%. La clasificación de la escisión mesorrectal total se asoció con una mayor probabilidad de tener también una evaluación adecuada de los ganglios linfáticos (88.5% versus 71.9%, $p = 0.002$). Ha habido una tendencia estadísticamente significativa hacia un aumento en la clasificación de la escisión mesorrectal total en los 14 hospitales originales ($p = 0.001$), pero no en la cohorte completa de todos los hospitales ($p = 0.057$).

Diseño de cohorte retrospectivo con casos de cáncer rectal muestreados. Además, no hay suficiente granularidad para capturar todos los factores asociados con el rendimiento de la escisión mesorrectal total o la asignación de grados.

Las tasas de rendimiento de escisión mesorrectal total y asignación de grado son muy variables en todo el estado de Michigan. En general, la asignación de calificaciones sigue siendo muy baja. Esto sugiere una oportunidad para que los proyectos de mejora de la calidad aumenten el rendimiento y la clasificación de la escisión mesorrectal total, involucrando tanto a los cirujanos como a los patólogos para una implementación efectiva. Vea el resumen del video en <http://links.lww.com/DCR/Axxx>.

Keywords

Cancer care guidelines; Rectal cancer; Rectal cancer pathology; Rectal specimen grade; Total mesorectal excision

INTRODUCTION

The surgical technique of total mesorectal excision (TME) is considered standard of care for mid/low rectal cancer (RC) treatment. Multiple studies have shown that TME is associated with decreased local recurrence and improved disease-free survival following RC resection.¹⁻⁴ However, these findings are from randomized controlled trials conducted in specialty centers and may not be generalizable.⁵ In fact, limited data exist examining general adoption of TME performance across hospitals in the United States.

Following resection, pathologist-performed macroscopic evaluation of the quality of the surgical specimen ("TME grading") is also recommended as a part of high-quality rectal cancer care. A poor TME grade is an independent risk factor for local recurrence and cancer mortality and can function as a tool in determining prognosis and guiding therapy.^{6,7} The quality of surgical specimens has been shown to improve over time in response to the feedback provided by pathologists through TME grading, and may therefore provide essential feedback to surgeons.^[8] Because of these benefits, the TME specimen grade has been suggested as a possible surgical quality metric.⁶

Within the Michigan Surgical Quality Collaborative (MSQC), a quality assessment project for colorectal cancer (CRC) surgery has been developed to audit hospitals and surgeons and provide feedback regarding CRC quality of care.⁸ Thirty-eight community and academic hospitals now participate in this project. TME performance and TME grading were chosen as quality measures for mid- and low-rectal cancer surgery, and have been monitored over time. These metrics are especially relevant to surgeons yet rates of TME performance and grading are currently unknown in the United States.

The goal of this study was to assess trends in TME performance and grading in a broader spectrum of hospitals than the specialty hospitals typically represented in randomized trials. We hypothesized that these measures would vary markedly between hospitals, and that slow improvement in TME grading rates would be demonstrated over time.

METHODS

Study Setting

This was a retrospective cohort study of prospectively-collected data from the Michigan Surgical Quality Collaborative (MSQC). The MSQC is a statewide quality improvement initiative with 70 participating hospitals, funded by Blue Cross and Blue Shield of Michigan. These sites represent community and academic hospitals that perform major surgery. The data abstraction and quality assurance processes used by MSQC have been described in prior studies.⁹ In brief, trained nurses collect patient level data in addition to intraoperative and perioperative quality measures for selectively abstracted cases at participating hospitals. These cases are sampled in a way that accurately reflects the case types and patient outcomes for the individual hospital though it does not include every case performed.¹⁰ For this study, we focused on the MSQC Colorectal Cancer Project hospitals. These are self-selected hospitals that abstract additional, cancer-specific data for colorectal cancer resections, including surgeon documentation of TME performance and pathology-assigned TME grade for rectal cancer cases.¹¹ This group initially included only 14 hospitals (from 2007–2013), and now includes 38 hospitals with each additional hospital volunteering to participate after 2013. These hospitals are a mix of small and large hospitals, as well as both academic and community practices. Data is available from January 2007 to January 2016. Data collection and review for MSQC are institutional review board (IRB) exempt, and this research study of de-identified data is IRB approved. Per the MSQC data use agreement, all analyses are performed at the hospital level (we are not permitted surgeon-level data).

Patient Population

This study included rectal cancer cases abstracted into the MSQC registry from hospitals participating in the “colorectal cancer project”, with case eligibility defined by Current Procedural Terminology (CPT) procedure and International Classification of Disease (ICD) diagnosis codes. Sites with fewer than 5 RC cases were excluded from analysis. All cases are adult surgical patients who had rectal cancer resections for primary colorectal adenocarcinoma. Tumors in the proximal 1/3 of the rectum (above 12 centimeters from the anal verge) and tumors removed by a local transanal approach (non-TME) were excluded.

Outcomes

The primary outcomes of interest included the following rectal cancer-specific quality measures: (1) surgeon-reported TME performance (abstracted from operative reports) and (2) pathologist-reported TME grade (abstracted from pathology reports). The surgeons and pathologists involved in the cases analyzed did not receive standardized training on TME performance or grading for the purpose of this study. TME performance was defined as the use of any relevant language in the operative report, such as the terms “mesorectal”, “mesorectum”, and/or “fascia propria”. Other variables included: surgical approach (open versus minimally invasive), tumor location, cancer stage, number of examined lymph nodes, and margin positivity (both distal and circumferential resection margins). Time-trends in TME performance and TME grading were analyzed.

Statistical Analysis

Descriptive statistics were used to characterize the previously listed variables. Outcomes were summarized at the hospital level. Relationships between variables were analyzed using chi-square tests. Time trends in surgeon-reported TME performance and pathologist-reported TME grade were analyzed using linear regression modeling. All statistical analyses were performed using Stata IC version 14.2 (StataCorp, College Station, Texas).

RESULTS

Patient Characteristics

There were a total of 510 RC resection cases from 28 hospitals. This excluded all local excisions, tumors in the proximal 1/3 of the rectum, and hospitals with fewer than 5 cases. Patient and tumor characteristics are presented in Table 1.

TME Performance and Grade Assignment

Of the 510 RC cases, 367 (72.0%) had surgeon-reported TME performance and 78 (15.3%) had pathologist-reported TME grade. Between-hospital variability in TME performance ranged from 0 to 97%, and TME grading ranged from 0 to 90% (Figure 1). Of those with assigned TME grades, 55 (70.5%) cases received a “*Grade 3*”, 14 (17.9%) cases received a “*Grade 2*”, 9 (11.5%) received a “*Grade 1*” (Figure 2).

Other measures associated with TME performance and grading

On linear regression there was no association between hospitals with a high rate of surgeon-reported TME completion and likelihood of having an assigned TME grade ($p=0.171$). Seventy-five percent of MIS cases reported TME performance and 23.6% an assigned TME grade, compared to 69.9% ($p=0.229$) and 11.3% ($p<0.001$) for open cases, respectively. Reported TME grading had no association with margin status (12.8% positive with assigned grade versus 10.1% positive without a grade, $p=0.473$). However, reported TME grading was associated with a higher rate of adequate lymph node assessment (88.5% with assigned grade versus 71.9% without a grade, $p=0.002$).

Time-Trends in TME Performance and Grading

Over time, there was no significant change in rates of TME performance ($p=0.639$). Refuting our hypothesis that TME grading would be found to increase over time, there was not a statistically-significant increase ($p=0.057$) (Figure 3). However, a secondary analysis of the original 14 hospitals revealed that there was a significant increase in TME grading rate in this subset of hospitals ($p=.001$).

DISCUSSION

This study demonstrates that rates of surgeon-reported TME performance and pathologist-reported TME grade are widely variable between hospitals, and that TME performance and grade assignment as a quality measure remain underutilized. In addition, time trend analysis showed that rates did not significantly improve between 2007 to 2016. This study of community and academic hospitals is one of the largest and most generalizable studies on

the quality of rectal cancer surgery in the United States. It reveals considerable gaps in quality of care and opportunities for significant improvement.

TME performance and grade assignment are widely recognized as best practices for rectal cancer resections. Given the association with improved survival and the potential use of TME grade as a prognostic tool, the expectation is that this procedure should be performed and graded for all mid- and low- rectal cancer patients who undergo radical surgery.^{1,2,12} To our knowledge, this is the first study to evaluate widespread adoption of TME performance and grading in the United States, as these factors are not currently measured in available tumor registries.

This study is particularly relevant at the present time. The National Accreditation Program for Rectal Cancer (NAPRC) has recently been established by the American College of Surgeons' Commission on Cancer. NAPRC accreditation standards include use of synoptic operative and pathology reports, and routine evaluation of TME specimen photographs for quality. Our study shows that few hospitals would currently meet NAPRC TME documentation standards.^{13,14} It is possible that as hospitals begin applying for this program, we will see a national trend towards improved adherence in this quality measure, however this study helps identify the baseline across a diverse group of hospitals. We expect that these findings reflect that national trend in TME.

Not only is TME an important component of rectal cancer clinical practice, it may also serve as a quality measure. The American cancer care system has been described as a "system in crisis" by the Institute of Medicine, and they argue that improvement will be facilitated by more complete quality of care measurements.¹⁵ Current colorectal cancer quality measures (adjuvant chemotherapy and lymph node examination) focus on medical oncology and pathology practice more than surgical practice, which is equally important for rectal cancer.^{11,16} Despite the longstanding recommendation for TME performance and grading, our study demonstrates that there has been no significant increase in adherence over a 10-year time span, suggesting the current incentives are inadequate. Importantly, adoption of TME performance and grade assignment as quality measures would encourage high-quality multidisciplinary care by the surgeon/pathologist team, and may also demonstrate hospital-level adherence to CRC quality of care.^{6,17} Our study demonstrates that there is an association between TME grade assignment and assessment of 12 lymph nodes in the rectal cancer specimen. This suggests that, like lymph node evaluation, TME grading may serve as an indicator of institutional commitment to multidisciplinary rectal cancer care.

Our study is subject to several limitations. First, data abstracted to the MSQC database are reliant on provider documentation which, when incomplete, could underreport the actual number of TMEs performed by this cohort. It is less likely that this influenced TME grade assignment as this value was pulled directly from pathology reports. Second, due to our data use agreement, all analyses must be performed on the hospital level rather than surgeon level which limits our ability to dissect trends across individual surgeons. Additionally, all observational studies may be influenced by unmeasured confounding factors. There is insufficient granularity in any available dataset to capture all factors associated with TME performance or grade assignment. That said, the purpose of this study was to document the

current rates of TME in eligible patients, and even in the event of confounding factors, rates of adherence should not be adjusted to account for these influences.

Even with an upward trend in TME grading across the original cohort, rates remain very low. This suggests an opportunity for multidisciplinary quality improvement projects to increase surgeon-reported TME performance and pathologist-reported TME grading. TME performance and TME grading has been demonstrated to be standardizable and easily taught.^{18–20} Concerted efforts to further standardize TME documentation and grading across other hospitals and specialties will likely result in improvement in these quality measures.^{17,21,22} A single-institution study by Garcia-Granero, et al. evaluated formal implementation of a macroscopic TME evaluation protocol and found that rates of TME assessment improved from 55% to 99% over a 10-year span.²³ Similarly, in an evaluation of the Norwegian Rectal Cancer Project, a national intervention to standardize rectal resection technique, investigators found an improvement from 78% of eligible patients receiving a TME to 92% in only four years.²⁴ Such studies demonstrating successful implementation of TME protocols are encouraging and suggest similar efforts could be adopted regionally within the United States to improve adherence to TME performance and grading.

We believe that the findings in our study reflect that national adherence rates for TME documentation and grading, and demonstrate the need for directed intervention aimed at improvement. As such, we are in the early stages of an educational intervention designed to instruct and encourage TME grading in Michigan. This intervention involves multidisciplinary participation from all individuals involved in TME performance and evaluation – surgeons, pathologists and pathology assistants. Twelve volunteer hospitals from the MSQC are currently enrolled. The study consists of a web based training session, written materials for pathologists and surgeons, and visits to each hospital. The materials emphasize the importance of TME performance and grading, provide a systematic approach to TME grade assignment, and encourage surgeons and pathologists to document TME grade assignment. Data collection will continue for a 4-year timespan, after which we look forward to sharing our findings.

CONCLUSION

In conclusion, our study demonstrates that rates of surgeon-reported TME performance and pathologist-assigned TME grade are highly variable, and overall suboptimal. Efforts directed at surgeons and pathologists to increase TME performance and grading are warranted. These measures will help ensure that we provide the best possible care for rectal cancer patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Cumulative rates of surgeon-documented TME and pathologist-assigned TME grade for each Michigan hospital from 2007 to 2016 (28 hospital cohort).

Figure 2.
Number of TME specimens assigned a grade.

Figure 3.
Rates of surgeon-documented TME and pathologist-assigned TME grade for Michigan hospitals from 2007 to 2016 (28 hospital cohort).

Table 1.

Patient characteristics (unadjusted, n=510)

Characteristics	Number of Rectal Cancer Cases (n=510)
Age (mean) – 63.4 years	---
Sex, male , n (%)	290 (56.9%)
Preoperative Local Staging Imaging	
Transrectal or endorectal ultrasound (ERUS), n (%)	210 (41.2%)
MRI, n (%)	50 (9.8%)
Both ultrasound and MRI, n (%)	22 (4.3%)
Documentation of result but modality not specified, n (%)	21 (4.1%)
No ERUS/MRI documented in chart, n (%)	207 (40.6%)
Tumor Location	
Mid 1/3 rectum (6–12 cm from anal verge), n (%)	239 (46.9%)
Low 1/3 rectum (0–6 cm from anal verge), n (%)	264 (51.8%)
Surgical Approach	
Minimally Invasive, n (%)	164 (32.2%)
Open, n (%)	351 (68.8%)
Stage	
0, n (%)	5 (1.0%)
I, n (%)	91 (17.8%)
II, n (%)	168 (32.9%)
III, n (%)	201 (39.4%)
V, n (%)	45 (8.8%)
12 Lymph Nodes Examined, n (%) (LN yield range 0–58)	383 (75.1%)
Positive Margin (distal or circumferential), n (%)	54 (10.6%)
Operation Performed, n (%)	
Low Anterior Resection (LAR)	316 (62.0%)
Abdominoperineal Resection (APR)	161 (31.6%)
Other (e.g. total proctocolectomy)	33 (6.5%)