

Preliminary Normative Standards of the Mayo Clinic Esophagectomy CONDUIT Tool

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Abstract

Objective: To collect patient-reported outcomes after esophagectomy to establish a set of preliminary normative standards to aid in symptom-score interpretation.

Patients and Methods: Patients undergoing esophagectomy often have little understanding about postoperative symptom management. The Mayo Clinic esophageal CONDUIT tool is a validated questionnaire comprising 5 multi-item symptom-assessment domains and 2 health-assessment domains. A prospective nonrandomized cohort study was conducted on adult patients who have had esophagectomies using the CONDUIT tool from August 17, 2015, to July 30, 2018 (NCT02530983). The Statistical Analysis System v9.4 (SAS Institute Inc., Cary, NC) was used to calculate and analyze the scores.

Results: Over the study period, 569 patients were assessed for eligibility, and 241 patients consented and were offered the tool. Of these, 188 patients (median age: 65 years; range: 24 to 87 years; 80% male patients) had calculable scores. Of the 188 patients, 50 (26.6%) patients were identified as potential beneficiaries for educational intervention to improve symptoms (received moderate scores for a domain), and 131 (69.7%) patients were identified as needing further testing or provider intervention (received poor scores for a domain) based on the tool.

Conclusion: The CONDUIT tool scores, when compared with standardized scales with established preliminary normative scores, could be used to identify and triage patients who need targeted education, further testing, or provider interventions. These score ranges will serve as the first set of normative standards to aid in the interpretation of conduit performance among providers and patients.

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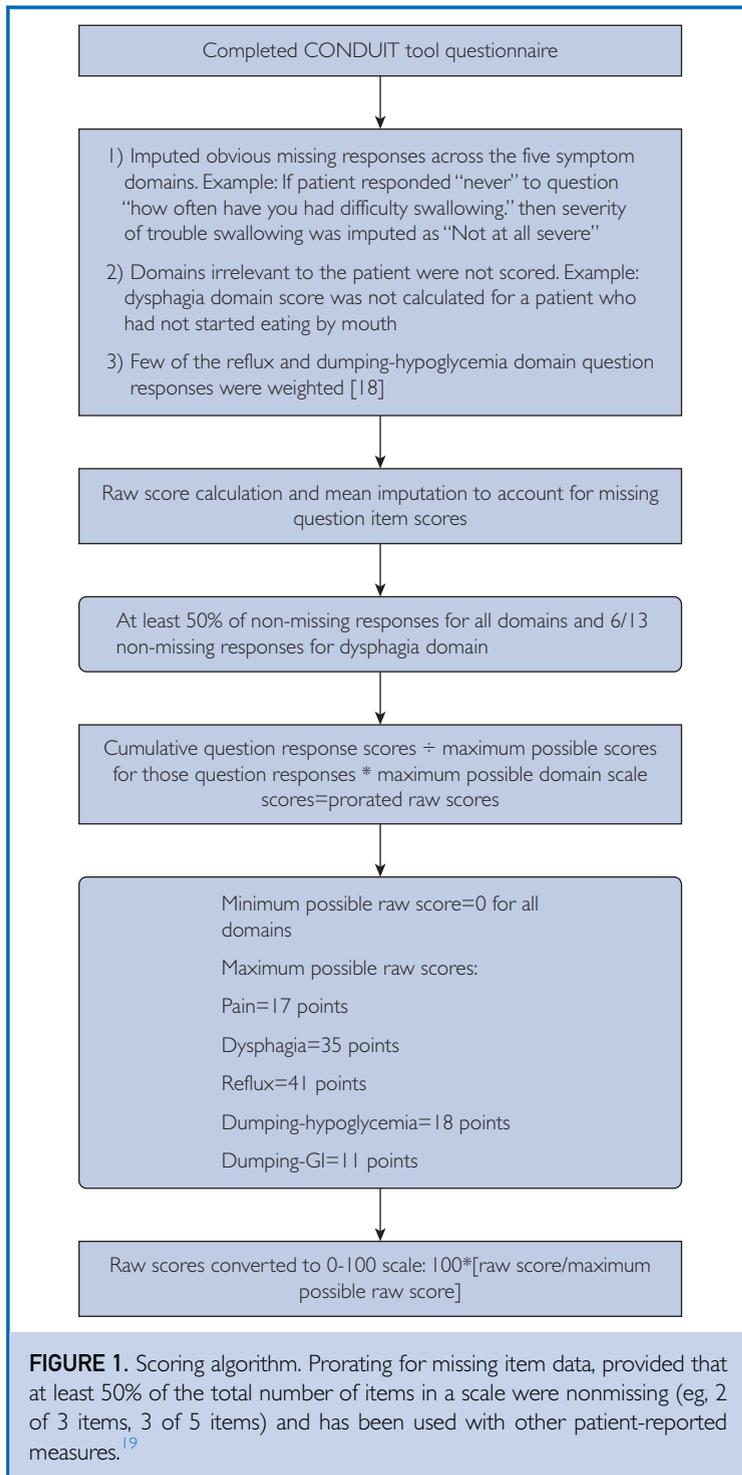
In 2019, we expect approximately 17,650 new esophageal cancer cases and 16,080 deaths from esophageal cancer in the United States.¹⁻³ Over the last 3 decades, there has been a 7-fold increase in the incidence of esophageal adenocarcinoma, with a 2:1 male-to-female incidence in the United States.^{2,3} In the 1960s and 1970s, only 5% of patients with esophageal cancer survived at least 5 years after diagnosis. Today, the overall 5-year survival rate has increased to approximately 20% and is higher for early-stage esophageal cancers.³ Immediate postoperative morbidity, mortality, and cost have had impact

on patients' quality of life.⁴ Patients surviving past the first few months after esophagectomy remain concerned about their long-term quality of life.^{5,6} However, there are no current standards for comprehensive tracking, triaging, and managing postoperative symptoms of patients who have had esophagectomies. Providers have little information to guide longitudinal management of these patients, and, as a consequence, the care is fragmented, and many patients endure suboptimal survival.^{7,8}

Patient-reported outcome measures (PROMs) are the focus of many quality improvement cancer programs, and tools



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such as Functional Assessment of Cancer Therapy-Esophageal Cancer (FACT-E) and European Organization for Research and Treatment of Cancer (EORTC, QLQ-OES18), and many others are used to

measure PROMs for patients with esophageal cancer and esophagectomies.⁹⁻¹⁵ Unfortunately, these tools were developed to assess quality of life during active cancer treatment and may not adequately address the patient's most pressing concerns in the months and years after esophagectomy.^{12,16} The Mayo Clinic esophageal CONDUIT tool was designed based on the data from patient focus groups with multidisciplinary expert panel consensus reviews to measure patient-reported outcomes after esophagectomy.^{16,17} The CONDUIT tool's content validity and psychometric properties have previously been established.^{16,17} The objectives of this study were to collect PROMs after esophagectomy to establish initial normative standards, based on the early results from the CONDUIT tool, and present them in the setting of standardized score scales that would set a context for remote and real-time monitoring of patients. This tool could assist providers to understand the patient experience after esophagectomy and help provide longitudinal postoperative care to patients who have had esophagectomies.

PATIENTS AND METHODS

A prospective nonrandomized cohort trial was conducted on patients with esophagectomies (≥ 18 years of age), using the CONDUIT tool from August 17, 2015, to July 30, 2018. This study was registered in clinicaltrials.gov as NCT02530983 and was approved by the Mayo Clinic Institutional Review Board. The Mayo Clinic esophageal CONDUIT tool is a novel and validated 67-item questionnaire composed of 5 multi-item symptom-assessment domains (dysphagia, reflux, dumping-hypoglycemia, dumping-gastrointestinal symptoms, and pain) and 2 patient-reported outcomes measurement information system (PROMIS) health-assessment domains (physical health and mental health). This tool was originally developed using the data from a series of patient focus groups that were conducted from a survivorship program at the Houston Methodist Hospital (Houston, TX). This included 432 patient encounters, with both qualitative and quantitative data that were used to develop the content of the tool.¹⁶ A modified Angoff methodology was used to establish the standards and cut points of the

domains in which patients would be placed into either a “good,” “moderate,” or “poor” category, based on their scores.¹⁷ The cutoff scores are set independent of the patient-reported average score and are color coded according to the score category (green = good, yellow = moderate, red = poor), based on where experts determine patients should be triaged for targeted education, further testing and/or provider intervention.¹⁷ A detailed description on how the domains and their score cutoffs were established—based on the data and feedback from patient focus groups, patient advocates, multidisciplinary expert panel discussions, and psychometric evaluations—have been detailed in the previous 3 publications.¹⁶⁻¹⁸

Esophagectomy patients were identified prospectively through a formal screening review of all Mayo Clinic thoracic surgery clinic patients on a daily basis and were approached for consent. If the research team was unable to meet with patients in the clinic, these eligible patients were contacted by mail for consent. The patients enrolled in this study first completed the 67-item CONDUIT tool questionnaire at their 1-month postoperative visit after esophagectomy and then were offered the questionnaire tool every 3 months for 1 year after esophagectomy. After this, patients were offered the CONDUIT tool at each surveillance clinic visit or at a minimum of once per year for their lifetime. During their first postoperative clinic visit, the patients also completed baseline questionnaires to capture their health histories and any related diagnoses from the time between their surgeries and their first CONDUIT tool questionnaires. The patients had the flexibility of completing the questionnaire either at their clinic visits, over the telephone, or by mail. During the trial, providers were blinded to the questionnaire scores. Concurrently, a separate study was conducted to determine differences between provider scores and CONDUIT tool scores. Although 2 separate hospitals (Houston Methodist Hospital and Mayo Clinic Rochester) were involved in earlier forms of the questionnaires, only those patients seen at Mayo Clinic were enrolled into the current trial. A prospective database was maintained using the Medidata Rave (Medidata, New

TABLE 1. Patient Demographics

Demographic variables	n (%)
Age, years	188
Range	24.2–87.1
Mean ± SD	64.6 ± 9.62
Median (IQR)	65.2 (58.5, 71.3)
Sex	
Male	150 (79.8)
Female	38 (20.2)
BMI	
Range	15.5 - 40.0
Mean ± SD	25.2 ± 4.58
Median (IQR)	24.8 (22.2, 28.3)
Comorbidities	
Hypertension	106 (56.4)
Diabetes	33 (17.6)
Cardiac (CAD/CHF)	21 (12.8)
Chronic obstructive pulmonary disease	16 (8.5)
Cerebrovascular disease	7 (3.7)
Pulmonary hypertension	2 (1.1)
Previous cardiothoracic surgery	34 (18.1)
Smoking	
Never	58 (30.9)
Former	124 (66)
Current	6 (3.2)
Esophageal disease type	
Malignant	172 (91.5)
Benign	16 (8.5)
Year of surgery	
Range	2001–2018
Median (IQR)	2016 (2014, 2017)
Type of esophagectomy	
Open	163 (86.7)
Minimally invasive or hybrid	25 (13.3)
Anastomotic site	
Cervical	57 (30.3)
Thoracic	123 (65.4)
Low thoracic	8 (4.3)
Type of pyloric drainage procedure or anatomy/gastrectomy	
Botox	29 (15.4)
Pyloromyotomy	118 (62.8)
Pyloroplasty	17 (9.0)
Gastrectomy	24 (12.8)
Type of conduit	
Gastric	167 (88.8)
Jejunal	21 (11.2)
Perioperative chemoradiation therapy	
Yes	140 (74.5)
No	48 (25.5)

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TABLE 1. Continued

Demographic variables	n (%)
Postoperative complications ^a	
Prolonged air leak ^b	2 (1.1)
Pulmonary embolism	3 (1.6)
Pneumonia	30 (16.0)
Anastomotic leak	20 (10.6)
Chyle leak	19 (10.1)
Ileus	49 (26.1)
Anastomotic stricture	56 (29.8)
Pyloric obstruction	3 (1.6)
Paraconduit hernia ^c	19 (10.1)

^a≤90 days after surgery.

^b≥ 6 days postoperatively.

^c≥90 days after surgery.

BMI = body mass index; CAD = coronary artery disease; CHF = congestive heart failure; IOR = interquartile range; SD = standard deviation.

York, NY) clinical data management system. Electronic medical records were reviewed to collect supplemental data.

Each domain of the CONDUIT tool questionnaire was scored separately. The CONDUIT tool questionnaire was modified over time, based on the data from patient focus groups and psychometric evaluation of the questionnaire content. The completed questionnaires from previous forms were scored for this study. The variations in these earlier forms were taken into account while developing a standardized scoring method for each domain. The scoring algorithm is illustrated in Figure 1.¹⁹

Descriptive statistics were used to summarize baseline variables and postoperative complications. These included median and interquartile range (IQR) for continuous variables and counts and percentages for discrete variables. As patients could contribute multiple questionnaires, and as their conditions varied over time, the data summaries were derived from the total number of questionnaires rather than the total number of subjects. The graphs were created using a scatterplot of scores over time and fit to a Loess curve, with 95% confidence intervals. The analyses were performed using Statistical Analysis System v9.4 (SAS Institute Inc, Cary, NC), and graphs were made using R v3.4.2.

RESULTS

Over the study period, 569 patients were assessed for eligibility, and 241 patients were consented and offered the tool. Patients were excluded from the study if they did not meet the eligibility criteria (n=27), declined to participate (n= 7), did not undergo surgery (n=149) or if patients left the hospital or the clinic before the research team could approach them to get consent (n=85). The initially screened and missed 85 patients who could not be approached in the hospital or the clinic for consent were later contacted via mail to consent, if deemed to be eligible. A total of 241 patients completed the questionnaires, and 188 patients had a calculable score for at least 1 domain. In some cases, all domain items were incomplete for accurate scoring, and thus some score reports had less than 7 domains. Age at the time of the surgery for these 188 patients ranged from 24.2 to 87.1 years (median of 65 years, with 80% male patients). Of the 188 patients, 172 (91.5%) had cancer, and 140 of 172 (81.4%) patients received chemoradiation therapy (neoadjuvant = 106, adjuvant = 3, both = 31). Patient characteristics are noted in Table 1. The majority of patients (81 of 188, 43.1%) were offered the opportunity to complete the questionnaires immediately following recovery (≤3 months) from esophagectomy. The remaining patients were offered the questionnaires when they returned to the clinic either to be evaluated for a complaint including outside hospital referrals (n=57 of 188, 30.3%) or for surveillance (n=50 of 188, 26.6%). A total of 360 questionnaires were scored, of which the majority (242, 67.2%) were completed within 1 years' time from esophagectomy. Most of the patients (n=78) completed the questionnaires only once, but an almost equal number (n=68) of patients completed the questionnaires twice, despite no score reports being provided to them in return.

Of the 188 patients, 50 (26.6%) patients received moderate scores for conduit function for at least 1 domain during the study period and were therefore identified as potential beneficiaries for educational intervention to improve symptoms. An additional 131 (69.7%) patients received poor scores for

TABLE 2. Score Statistics From the 360 Questionnaires From 188 Patients who Completed the CONDUIT Tool Questionnaire

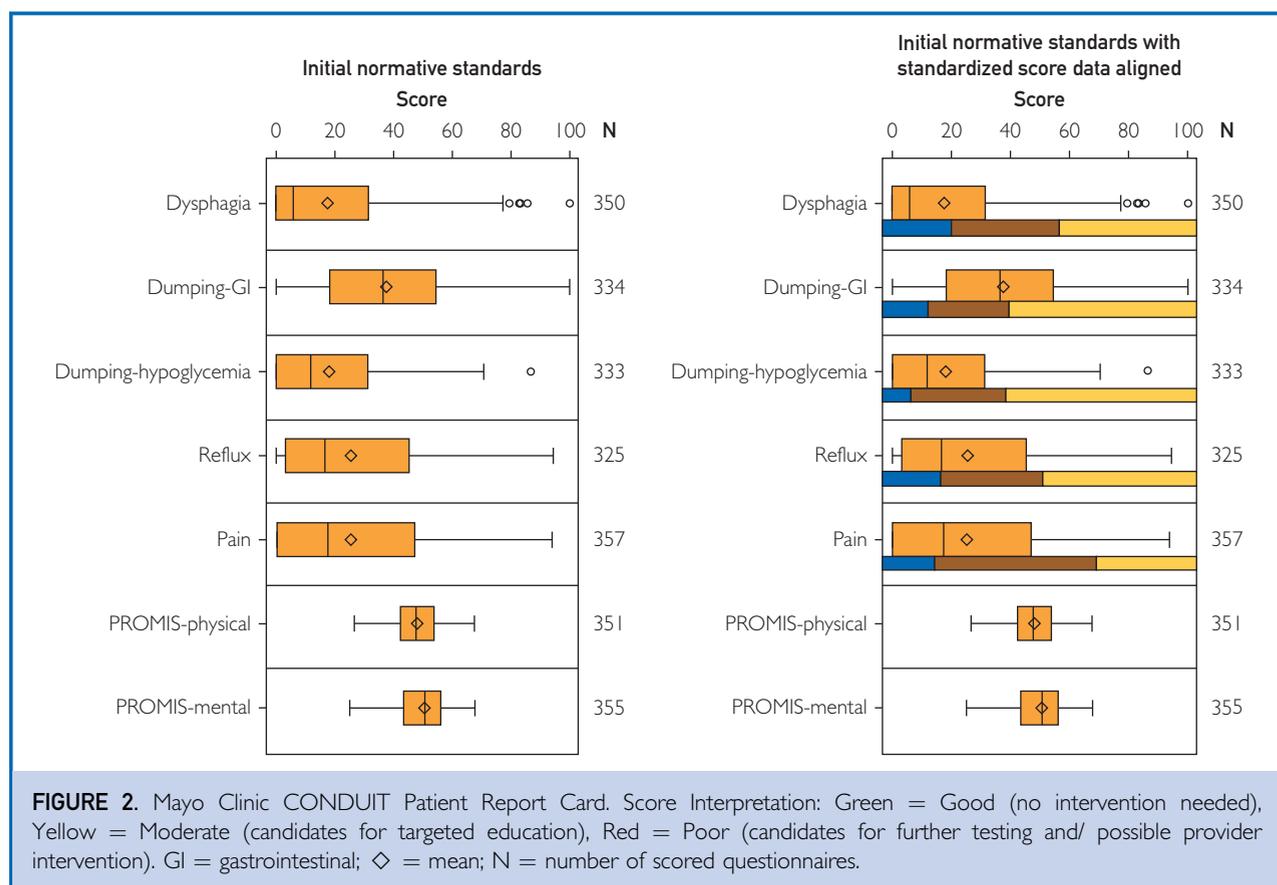
Domains	N (n)	Mean	Median	Interquartile range	Score interpretation
PROMIS-physical health (T. score)	351 (183)	48.0	47.7	42.3–54.1	In general population, mean score = 50 ± 10. Higher the score, better the quality of life
PROMIS-mental health (T. score)	355 (185)	50.4	50.8	43.5–56.0	In general population, mean score = 50 ± 10. Higher the score, better the quality of life
Pain	357 (186)	25.5	17.7	0–47.1	Good = 0–20.8 Moderate = 20.9–64.3 Poor = 64.4–100
Dysphagia	350 (186)	17.6	5.9	0–31.4	Good = 0–20.1 Moderate = 20.2–62.9 Poor = 63.0–100
Reflux	325 (175)	25.4	16.0	2.9–45.2	Good = 0–17.0 Moderate = 17.1–50.1 Poor = 50.2–100
Dumping hypoglycemia	333 (175)	18.0	11.8	0–31.3	Good = 0–7.2 Moderate = 7.3–37.9 Poor = 38.0–100
Dumping GI	334 (175)	37.4	36.4	18.2–54.6	Good = 0–12.0 Moderate = 12.1–42.8 Poor = 42.9–100

GI = gastrointestinal; N = number of scored questionnaires; n = number of individual patients who completed the questionnaire.

conduit function for at least 1 domain during the study period and were identified as in need of further testing or provider intervention. Over the study period, only 7 (3.7%) patients scored in the good category across all domains and at all assessments. [Table 2](#) shows the distribution of the observed scores computed from the 360 CONDUIT tool questionnaires completed by the 188 patients with esophagectomies and the score interpretation for each domain. The percent of good, moderate, and poor category scores across all CONDUIT tool questionnaire draft versions is detailed in [Supplemental Table 1](#) (available online at <http://mcpiqjournal.org>). [Figure 2](#) demonstrates the preliminary normative standards alongside standardized scores. [Figure 3](#) demonstrates how the CONDUIT tool with the early results of normative standards could be used in the clinical setting, through the phenotypic profile of a patient with a twisted conduit who was told by his original surgeon that his symptoms were typical after esophagectomy. His CONDUIT tool scores after the conduit was untwisted are also demonstrated in [Figure 3](#).

DISCUSSION

This study found that a majority of patients scored in the “poor” category for at least 1 domain after esophagectomy, suggesting that they might be candidates for improvement with provider intervention. Dumping-gastrointestinal domain was the most common domain for which patients were classified in the “poor” category. Although most patients receive information about dumping syndrome and are advised to watch for respective symptoms after esophagectomy, there is no standardized management for patients who complain of dumping syndrome after esophagectomy. Having a standardized way to measure, detect, and track improvement with intervention can facilitate the development of effective treatment. The CONDUIT tool score ranges will serve as the preliminary normative standards to aid in the interpretation of conduit performance among providers and patients. Presenting the scores from the tool to create a novel report card shows for the first time how calculation of scores can be used to simplify patient-reported outcomes data to

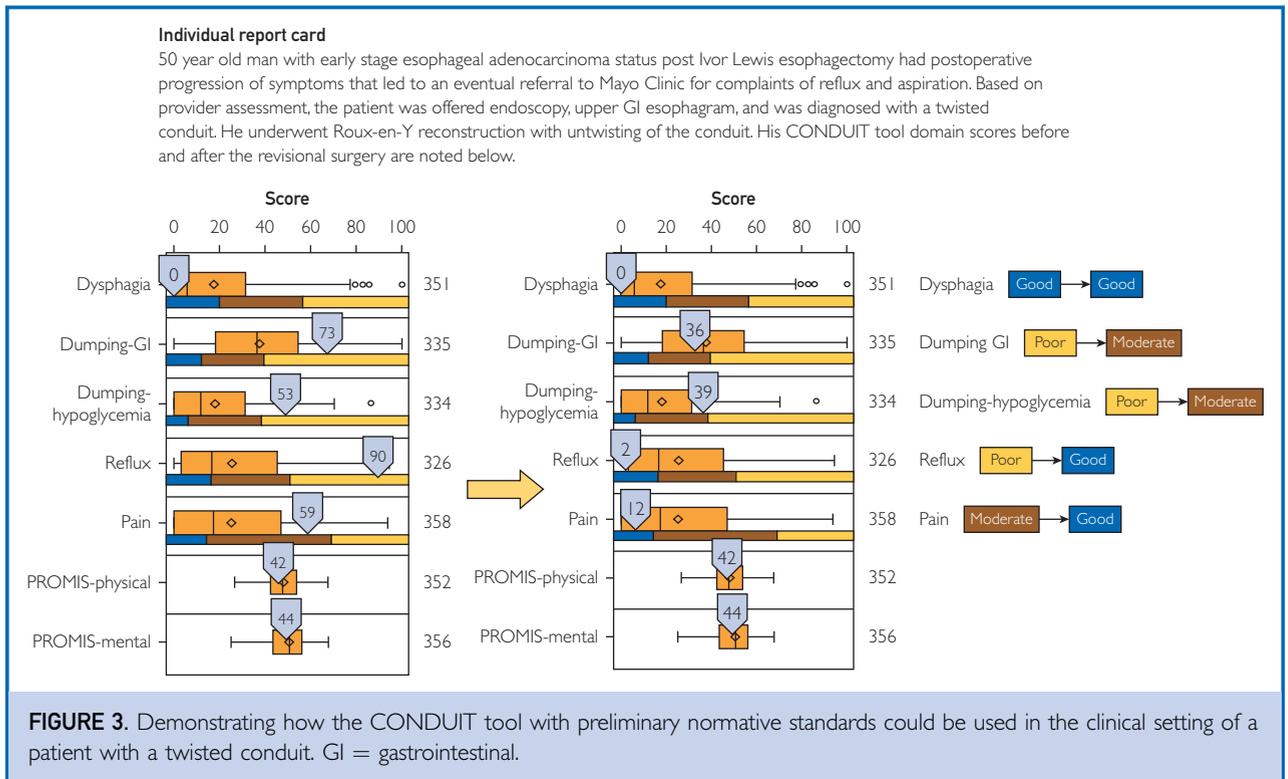


guide interventions through augmented human intelligence, to engage patients to report their symptoms, generate computerized algorithmic score reports to track outcomes, and eventually perform phenotypic analyses to recommend treatment. Presenting the scores in context with expectations and other patients' scores is the first step to set the stage for remote and real-time monitoring of patients.

Although the (EORTC) QLQ-OES18 questionnaire is a clinically and psychometrically validated tool for patients with esophageal cancer undergoing surgical or medical treatment, the major weakness of the EORTC questionnaire is the limited content validity due to lack of direct patient involvement in the item generation phase and the lack of independent subscale validation outside of the core instrument.^{13,20} The CONDUIT tool was developed, based on patient focus groups and panel discussions with expert multidisciplinary care

teams from high-volume esophagectomy centers, and the content of this tool underwent a formal psychometric validation process. This tool addresses the 2 major challenges of PROMs: expert tool validation and continued patient participation,^{16,20,21}

During this prospective cohort trial, the questionnaires were not scored in real time, and patient scores were not shared with their providers; hence, guided interventions were not performed using the CONDUIT tool. Rather, the intent was to generate preliminary results and develop initial normative standards before launching the tool into clinical practice. These preliminary standards provide an indication of the proportion of patients who may benefit from education or more intensive intervention so that providers and patients can anticipate the average postsurgical experience in various domains, and providers can effectively dedicate resources needed for optimal patient follow-up.



Further prospective studies will assess provider vs tool validation to measure how the scores from the tool compare with 30-minute patient visits with expert providers. Additional ongoing funded studies include assessing the effective use of the CONDUIT tool in clinical practice regarding cost, outcomes, and patient satisfaction in a randomized trial.

Limitations

The limitations of our study include relatively small patient numbers, a lack of long-term patient data, and lack of validation outside of the 2 institutions where it has been piloted. We plan to continue enhancing normative standards reports on a yearly basis with additional institutions and future patients within our own institution as more data are accumulated and collected in a similar manner and through an app that we have developed. Although this may not represent all practices across the globe, it is certainly considered a reasonable collection of prospectively enrolled patient data. In addition, patients coming into the clinic were offered the questionnaire, but no patients who remained in their community

and failed to follow up were offered the questionnaire. Only those patients who recently underwent esophagectomies were followed prospectively, and the rest were captured as they presented to clinics, sometimes specifically for problems. This means these results could be falsely negatively skewed. There may also be selection bias; however, the number of patients that were captured prospectively lessens this chance. Patients were also not offered to view their results, owing to a concurrent trial testing the provider score vs the domain score from the tool. An inability to view responses and scores might have prevented patients from finding personal value in answering the questionnaires completely or repeatedly as they returned for survivorship care.

Future planned studies include training machine-learning computer systems to recognize phenotypic patterns that reliably predict where problems may occur: for example, to recognize the pattern or cut-score for an anastomotic stricture that requires dilation, for a patient with dumping syndrome who has poor eating habits and requires targeted

education, or for patients with paraconduit hernias that require surgical repair. Also, it might be helpful to recognize the type of patient education needed—such as speech therapy, dietary coaching, or behavior modification—and when specific interventions—such as dilation, conduit revision, or medical therapy—would be appropriate. Eventually, this tool could help to establish a validated comparative effectiveness analysis for determining the best standardized method of creating an esophageal conduit that performs best for patients such as whether or not to drain the pylorus, how long to make the conduit, and to determine the best suitable types and methods of creating esophageal anastomoses. This could allow for a more standardized comparison among groups rather than subjective assessment of a variety of providers who care for these patients with varied clinical expertise. As more patients accrue, and more health care providers participate, this standardized survivorship care pathway, using the CONDUIT tool, can become more specific and robust. Hence, it could facilitate shared decision making for preoperative patients, increase engagement in patient-led apps, and even enhance informed consent.

CONCLUSION

This study demonstrated the heterogeneity of early implementation and grading of postoperative symptom domain scores among patients who have had esophagectomies and how many of these patients have manageable postoperative symptoms. The CONDUIT tool scores could help providers detect, triage, and manage patients who have had esophagectomies, who need targeted education, further testing, or provider intervention. Patients and providers can now evaluate the CONDUIT tool scores set against standardized scales alongside the established preliminary normative scores.

SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at: <http://mcpiqjournal.org>. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviations and Acronyms: **CONDUIT** = Conduit Outcomes Noting Dysphagia/Dumping and Unknown outcomes with Intermittent symptoms over Time after esophageal reconstruction; **EORTC** = European Organization for Research and Treatment of Cancer; **FACT-E** = Functional Assessment of Cancer Therapy-Esophageal cancer; **PROMs** = Patient-Reported Outcomes Measures; **PROMIS** = Patient-Reported Outcomes Measurement Information System

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Potential Competing Interests: Dr Blackmon has co-developed an esophageal anastomotic device with Boston Scientific and is a nonpaid consultant for Covidien, Medtronic, and Olympus. The other authors report no competing interests.

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