

Monitoring outcomes in colorectal cancer surgery Warps, A.K.

Citation

Warps, A. K. (2022, June 8). *Monitoring outcomes in colorectal cancer surgery*. Retrieved from https://hdl.handle.net/1887/3308382

Version: Publisher's Version

Licence agreement concerning inclusion of doctoral

License: thesis in the Institutional Repository of the University

of Leiden

Downloaded from: https://hdl.handle.net/1887/3308382

Note: To cite this publication please use the final published version (if applicable).

CHAPTER THREE

Textbook Outcome After Rectal Cancer Surgery As A Composite Measure For Quality Of Care: A Population-Based Study

A.K. Warps, MD^{A,B}; R. Detering, MD PhD^c; R.A.E.M. Tollenaar, MD PhD^{A,B}; P.J. Tanis, MD PhD^D; J.W.T. Dekker, MD PhD^E; on behalf of the Dutch ColoRectal Audit group

European Journal of Surgical Oncology. 2021;47(11):2821-2829. doi:10.1016/j.ejso.2021.05.045

Affiliations:

- ^ALeiden University Medical Centre, Department of Surgery, Albinusdreef 2, 2333 ZA Leiden, the Netherlands
- ^B Dutch Institute for Clinical Auditing, Rijnsburgerweg 10, 2333 AA Leiden, the Netherlands
- ^c Amsterdam University Medical Centers, University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands
- ^D Amsterdam University Medical Centers, Department of Surgery, University of Amsterdam, Cancer Center Amsterdam, De Boelelaan 1117, 1081 HV Amsterdam, the Netherlands
- ^E Reinier de Graaf Groep, Department of Surgery, Reinier de Graafweg 5, 2625 AD Delft, the Netherlands

ABSTRACT

Background: Textbook outcome is a composite measure of combined outcome indicators, which has been suggested to be of additional value over single outcome parameters in clinical auditing of surgical treatment. This study aimed to assess textbook outcome after rectal cancer surgery as short-term marker for quality of care.

Methods: Patients who underwent elective rectal cancer surgery between 2012 and 2019 and registered in the Dutch ColoRectal Audit were included. Textbook outcome was achieved when the following criteria were met: 30-day and primary hospital admission survival, no reintervention, tumor-free margins, no postoperative complications, a hospital stay of less than 14 days and no readmission. Hospital variation was evaluated in case-mix corrected funnel-plots. A multilevel logistic regression analysis was performed to identify associated factors with textbook outcome

Results: The study population consisted of 20,521 patients who underwent primary rectal cancer surgery, of whom 56.3% achieved textbook outcome. Postoperative complications were the main contributor to not achieving textbook outcome. Case-mix corrected funnel plots demonstrated that underperforming hospitals in 2012-2015 were no underperformers in 2016-2019 anymore. Female sex, laparoscopic surgery, and rectal resection without defunctioning stoma creation were positively associated with textbook outcome.

Conclusion: Textbook outcome after rectal cancer resection is mainly driven by postoperative complications. Although textbook outcome showed some discriminating value for identifying underperforming hospitals, it does not fit the plan-do-check-act cycle of clinical auditing. In our opinion, textbook outcome has little added value to the current outcome indicators for rectal cancer surgery.

INTRODUCTION

To ensure the best quality of care for every patient, it is essential to continuously assess, improve, and provide transparency of the quality of care. ^{1,2} Measuring quality of care has been described by the model of Donabedian in which three aspects are highlighted; the process, the structure, and the outcome. ^{3,4} These aspects are implemented in nationwide clinical audits, which were initiated to meet both the professional need to evaluate and benchmark quality of disease-specific care. Simultaneously, audits provide reliable data that gives substance to the public demand for transparency on quality of care. ⁴⁻⁶

Patients have indicated to prefer summarizing measures on quality of care over more detailed measures for selecting a hospital for treatment.⁷ One of those summarizing measures is textbook outcome. This is a composite measure of preferable outcomes that is suggested to improve patient satisfaction after surgical treatment.⁸ Furthermore, it might also be a valuable measure for health care providers, insurance companies, and healthcare inspectorate. Previous studies have reported several advantages of textbook outcome over single outcome parameters, as it has the ability to summarize hospital performance, to prevent indicator-driven practice, to show the multidimensional surgical procedure, and to identify hospital variation due to statistical advantages.^{9–17}

Since 2009, the Dutch ColoRectal Audit collects information on all patients with primary colorectal cancer who underwent resection. The audit provides short-term information on primarily single parameters, for example, resection margin and 90-day mortality. In a previous study of the DCRA, it was found that textbook outcome after colon cancer surgery was achieved in 49% of the patients. Analysis of hospital variation identified eight hospitals as negative outliers, indicating that textbook outcome could identify underperformers.¹³

It would be very interesting to evaluate textbook outcome for its' added value as an outcome indicator after primary rectal cancer surgery. Furthermore, in the colon cancer study, ¹³ the construction of a stoma was one of the included parameters and considered no textbook outcome. In rectal cancer, creating a stoma can be an expression of excellent, sensible care after careful counselling the patient within a shared decision-making process. The aim of the present study is to evaluate textbook outcome, which represents the proportion of patients with a desired short-term outcome after elective rectal cancer surgery, as outcome indicator for quality of care.

METHODS

This study is a national observational cohort study with data from the Dutch Colorectal Cancer Audit (DCRA). The DCRA is a nationwide registry in which all patients undergoing surgery for colorectal cancer are registered. No ethical approval was needed for this study under Dutch law. 18,19

Patient selection

All patients who underwent elective surgery for a first primary rectal carcinoma between 2012 and 2019 were potentially eligible. From the start of the DCRA in 2009, rectal cancer diagnosis was mainly based on a distance between the lower edge of the tumor and the anal verge of less than 15 cm. Since January 1, 2017, until the end of the study period, MRI based definitions of rectosigmoid and rectal cancers were used: the rectum was considered to be the distal part of the bowel from the peritoneal fold on the ventral side, and hence total extraperitoneally located; the rectosigmoid was considered to be the part of the bowel between peritoneal fold on the ventral side and the mesorectum on the dorsal side until the level of the promontory. Patients with multiple tumors or patients who underwent local excision were excluded. Besides, cases with missing/unknown data on textbook outcome were excluded.

Data extraction and outcome parameters

Patient and tumor characteristics, treatment characteristics, and short-term outcomes were extracted from the DCRA. Until 2017, the 30-day postoperative outcomes were registered in the DCRA, and since January 1, 2018, the 90-day postoperative outcomes were registered. The primary outcome in this study was the percentage of patients with textbook outcome after rectal cancer surgery. Secondary outcomes were the time-trend in textbook outcome rate, hospital performance by identifying underperforming and best performing hospitals and factors associated with textbook outcome.

Parameters and definitions

A selection of relevant outcome parameters reflecting an uneventful postoperative course was determined by expert opinion of the DCRA scientific committee members, who reviewed the included parameters in the previous study regarding textbook outcome study after colon cancer surgery.¹³ The ostomy parameter was not included in the textbook outcome measure after rectal cancer surgery because constructing a stoma can be good care after careful counselling the patient within a shared decision-making process. The 30-day readmissions are registered in the DCRA since 2012 and were not included in the study of Kolfschoten et al.¹³ However,

the 30-day readmission rate has been included in the textbook outcome parameter by several studies and was therefore, also included in this study.8-10,15-17 The selected parameters were placed in chronological order based on severity and sequence: 30-day and primary hospital admission survival, no reintervention, tumor-free margins, no postoperative complications, a hospital stay of less than 14 days (LOS <14 days) and no readmission. Reinterventions included endoscopic, image-guided and surgical procedures. Postoperative complications included cardiac, pulmonary, infectious, neurologic and thromboembolic complications, as well as anastomotic leakage, abscess, ileus, fascial dehiscence, wound infection, hemorrhage, bowel perforation, or bladder/ureter injury. A tumor-free margin was defined as a tumor-free bowel resection margin, as well as a tumor-free retroperitoneal resection margin and negative circumferential resection margin for rectal cancer (>1 mm). If one of both criteria was not met, the resection was defined as incomplete tumor-free margins. Textbook outcome was achieved if all parameters were met. For evaluating surgical procedure, four categories were identified: rectal resection with a defunctioning stoma (including total mesorectal excision (TME) and partial mesorectal excision (PME) with defunctioning stoma creation), rectal resection without a defunctioning stoma, low Hartmann's procedure and abdominoperineal excision (APE).

Statistical analysis

Baseline characteristics were reported for patients without textbook outcome and those with textbook outcome after rectal cancer surgery. Categorical or dichotomous outcomes were represented as absolute numbers of cases and percentages. A Pearson Chi-square test was used to assess significant differences.

The overall proportion of rectal cancer patients who had textbook outcome as well as the percentages of cases fulfilling each of the separate criteria of the composite textbook outcome measure were calculated. In addition, the cumulative (i.e., conditional) percentages of patients in whom each consecutive outcome was achieved under the condition that all previous conditions were met, were reported.

The percentage of patients with textbook outcome was calculated for each year to analyze a potential time trend. The association between year of registration and textbook outcome was assessed using univariate logistic regression analysis.

Hospital variation in textbook outcome and the identification of best performing and underperforming hospitals were assessed by observed and expected outcomes, corrected for risk factors. Hospital performance is shown in case-mix corrected funnel-plots for two different time-periods (2012-2015 and 2016-2019). Case-mix factors used were sex, age, body

mass index (BMI), American Society of Anesthesiology (ASA) score, Charlson Comorbidity Index (CCI), clinical tumor stage, preoperative tumor-related complications (e.g., anemia, perforation, obstruction/ileus or peri-tumoral abscess), additional resection for metastasis, multivisceral resection for local ingrowth, M stage, neoadjuvant (chemo)radiotherapy, surgical approach.

Multilevel logistic regression analyses were performed to assess predictive factors for textbook outcome. Multilevel analyses provide a more accurate estimate when dealing with hierarchically/nested structured data than traditional logistic regression analyses since it accounts for a dependency of patients within hospitals. 20,21 Multicollinearity was assessed with the variance of inflation factor (VIF), and a VIF of >2.5 was considered multicollinear, resulting in the exclusion of one of the variables. Results are reported in adjusted odds ratio (AOR) with 95% confidence intervals (95% CI). A p value of <0.05 was considered significant. The analysis was performed in Rstudio version 1.3.959 (2020).

RESULTS

A total of 23,996 patients underwent elective surgery for a first primary rectal carcinoma between January 1, 2012, and December 31, 2019. Patients with synchronous colorectal cancer (N= 527), another surgical procedure than an oncological rectal resection (N=2,215), or missing/unknown data on one of the textbook outcome parameters (N=733) were excluded, resulting in a total of 20,521 patients included in this study.

Patient, tumor, and treatment characteristics

Of the 20,521 patients who underwent rectal cancer surgery, 11,556 patients (56.3%) achieved textbook outcome (Table 1). Patients who did not achieve textbook outcome compared to patients who did were more frequently 75 years or older (27.9% to 24.5%, p<0.001) and male (68.3% - 58.5%, p<0.001), and had more often ASA score of III+ (22.8% - 15.1%, p<0.001), CCI II+ (26.4% - 19.8%, p<0.001), and preoperative tumor-related complications (21.3% - 16.8%, p<0.001). In addition, both the clinical and pathological TNM stage was higher for patients not achieving textbook outcome.

The non-textbook outcome study population received more often neoadjuvant radiotherapy (69.2% - 59.2%, p<0.001), underwent more frequently an open resection (24.2% - 14.4% p<0.001), a multivisceral resections for local ingrowth and additional resection for metastasis (respectively 10.1% - 4.4% p<0.001 and 3.8% - 2.0% p<0.001). In secondary hospitals, patients

achieved significantly more often textbook outcome compared to patients in tertiary hospitals (58.0% - 45.1%, p < 0.001).

TABLE 1: Baseline Characteristics Of The Total Rectal Cancer Study Population Stratified For Textbook Outcome

		Textbook outcome (N=11,556)	No textbook outcome (N=8,965)	<i>P</i> value
	_	N (%)	N (%)	
PREOPERATIVE C	HARACTERISTICS			
Age (years)	≥75	2827 (24.5)	2,497 (27.9)	< 0.001
	Missing	2	2	
Sex	Male	6,760 (58.5)	6,124 (68.3)	< 0.001
	Missing	4	2	
BMI (kg/m²)	<18.5	168 (1.5)	135 (1.5)	< 0.001
	18.5-30.0	9,357 (82.5)	6,983 (78.9)	
	≥30	1,809 (16.0)	1,722 (19.5)	
	Missing	4	5	
ASA score	III+	1,745 (15.1)	2,040 (22.8)	<0.001
	Missing	2	0	
CCI	II+	2,285 (19.8)	2,367 (26.4)	<0.001
Neoadjuvant	No	4,683 (40.5)	2,758 (30.8)	<0.001
radiotherapy	SCRT	3,090 (26.7)	2,892 (32.3)	
	CRT	3,629 (31.4)	3,161 (35.3)	
	Other RTx scheme	126 (1.1)	146 (1.6)	
	Missing	8	28	
Hospital type	Secondary	10,168 (88.0)	7,272 (80.1)	<0.001
	Tertiary	1,388 (12.0)	1,693 (18.9)	
Tumor		1,942 (16.8)	1,911 (21.3)	<0.001
complications	Missing	9	15	
cT stage	cT1-2	3,529 (30.5)	2,159 (24.1)	<0.001
	cT3	6,677 (57.8)	5,359 (59.8)	
	cT4	906 (7.8)	1,127 (12.6)	
	Missing	444	320	
cN stage	cN0	5,326 (46.1)	3,566 (39.8)	<0.001
Ü	cN1-2	5,845 (50.6)	5,104 (56.9)	
	Missing	385	295	
SURGICAL CHARA				
Technique ^A	Open	1,662 (14.4)	2,166 (24.2)	<0.001
-	Laparoscopic	9,772 (84.6)	6,729 (75.1)	
	Missing	122	70	
Procedure	APE	2,721 (23.5)	2,674 (29.8)	<0.001
	Low Hartmann	1,538 (13.3)	1,368 (15.3)	
Rectal resection with def. stoma		3,015 (26.1)	2,962 (33.0)	
Rectal resection, no def. stoma		4,282 (37.1)	1,961 (21.9)	

TABLE 1 continued: Baseline Characteristics Of The Total Rectal Cancer Study Population Stratified For Textbook Outcome

		Textbook outcome (N=11,556)	No textbook outcome (N=8,965)	<i>P</i> value
	_	N (%)	N (%)	
Multivisceral		508 (4.4)	903 (10.1)	<0.001
resection	Missing	134	181	
Add. resection		233 (2.0)	341 (3.8)	<0.001
for metastasis	Missing	10	6	
TUMOR CHARACTER	ISTICS			
(y)pT stage	(y)pT0-1	2,302 (19.9)	1,390 (15.5)	<0.001
	(y)pT2	3,785 (32.8)	2,625 (29.3)	
	(y)pT3	4,996 (43.2)	4,328 (48.3)	
	(y)pT4	354 (3.1)	545 (6.1)	
	Missing	119	77	
(y)pN stage	(y)pN0	7,642 (66.1)	5,645 (63.0)	<0.001
	(y)pN1-2	3,821 (33.1)	3,227 (36.0)	
	Missing	93	93	
M stage	M1	804 (7.0)	824 (9.2)	<0.001

Table 1: baseline table. Missing values of less than 10% are reported as numbers in this table. A: Laparoscopic approach includes all conventional and robot-assisted laparoscopic procedures as well as all transanal TME procedures. The *p* value is calculated by a Chi-square test. SCRT: short-course radiotherapy, CRT: chemoradiotherapy, other RTx scheme: unspecified radiotherapy scheme. Def. stoma: defunctioning stoma. APE: abdominoperineal excision.

Contributors to textbook outcome and time trend

Table 2 shows the percentages of the individual textbook outcome parameters and the cumulative percentages, which are also visualized in Figure 1. After rectal cancer resection, 56.0% suffered from any type of postoperative complication. Based on the cumulative rates, postoperative complications had the most negative impact on textbook outcome of all individual parameters (decrease of 20.3%). Assessing textbook outcome over time showed an increase from 52.4% in 2012 to 58.4% in 2019 (OR 1.038, 95% CI 1.025-1.051, p<0.001) (Figure 2).

TABLE 2: Percentages And Conditional Percentages On Textbook Outcome

	Population (N, %)	Conditional (N, %)
Total	20,521	
Survival	20,303 (98.9)	20,303 (98.9)
No reintervention	17,762 (86.6)	17,652 (86.0)
Tumor-free margin	16,375 (94.3)	16,651 (81.1)
No complications	13,125 (64.0)	12,478 (60.8)
LOS < 14 days	17,316 (84.4)	12,001 (58.5)
No readmissions	17,662 (85.9)	11,556 (56.3)
Textbook outcome		11,556 (56.3)

 $Table \ 2 \ shows \ the \ rates \ of \ the \ individual \ parameters \ included \ in \ textbook \ outcome \ and \ the \ conditional \ percentages \ after \ adding \ one \ of \ the \ parameters \ after \ each \ other \ for \ textbook \ outcome.$

100%
80%
60%
40%
20%
0%
Total population
30 tay strivial
No reintertentation
Turnout free markin
No complication's LOS 2 14 tay's Readingsion Textbook outcome
Textbook outcome

FIGURE 1: Textbook Outcome After Rectal Cancer Surgery Per Individual Parameter

Figure 1 shows the rates of the individual parameters (bars) included in textbook outcome and the conditional percentages (line) after adding one of the parameters after each other for textbook outcome.

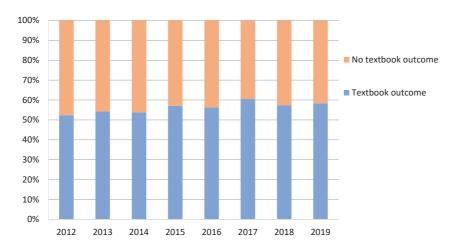


FIGURE 2: Time Trend Of Textbook Outcome After Rectal Cancer Surgery

Figure 2: Time trend (2012-2019) of textbook outcome for rectal cancer surgery. Chi-square test was used to calculate the p value for textbook outcome in 2012 vs 2019 showing p<0.001. Univariate logistic regression analyses for the year of surgery showed an OR of 1.038, 95% CI 1.025-1.051, p<0.001.

Hospital performance

The mean adjusted textbook outcome ranged from 8.9% to 73.9% among the 76 Dutch Hospitals during 2012-2019. Hospital variation in textbook outcome is demonstrated in case-mix corrected funnel plots by the expected and observed/expected ratio for 2012-2015 and 2016-2019 (Figure 3). Between 2012-2015, three hospitals were identified as underperforming hospitals, with two high-volume hospitals performing outside the 99% CI. Four hospitals were identified as best performers, with three above the 95% CI and one above the 99% CI. However, the same under and best performing hospitals based on the period 2012-2015 subsequently had textbook outcome within the 95% CI during 2016-2019. Three different high-volume hospitals were identified as underperforming hospitals. During the second period, more hospitals with a lower and a higher expected number of textbook outcome cases were seen.

Associated factors with textbook outcome

Factors independently associated with textbook outcome as identified by multilevel logistic regression analyses are shown in Table 3. A total of eleven factors were found to be negatively associated with textbook outcome: age \geq 75 years (AOR 0.912, 95%CI 0.846-0.984), BMI \geq 30 kg/m2 (AOR 0.747, 95% CI 0.689-0.810), ASA score III+ (AOR 0.676, 95% CI 0.621-0.736), CCI II+ (AOR 0.809, 95% CI 0.749-0.873), preoperative tumor-related complications (AOR 0.893, 95% CI 0.822-0.971), neoadjuvant (chemo)radiotherapy (SCRT: AOR 0.761, 95% CI 0.695-0.834, CRT: AOR 0.888, 95% CI 0.801-0.984), other radiotherapy scheme: AOR 0.724, 95% CI 0.555-0.944, multivisceral resection for local ingrowth (AOR 0.617, 95% CI 0.533-0.715), (y)pT3 and (y)pT4 stage (AOR 0.787, 95% CI 0.718-0.863 and AOR 0.575 95% CI 0.478-0.692, resp.), and surgery in a tertiary hospital (AOR 0.775, 95% CI 0.646-0.929). A positive independent association with textbook outcome was demonstrated for female sex (AOR 1.599, 95% CI 1.499-1.706) and laparoscopic surgery (AOR 1.323, 95% CI 1.201-1.458). Furthermore, the type of procedure showed a positive association with textbook outcome, with the highest AOR for rectal resection without defunctioning stoma (AOR 1.934, 95% CI 1.773-2.109), low Hartmann procedure (AOR 1.328, 95% CI 1.196-1.474) and APE (AOR 1.105, 95% CI 1.021-1.208).

FIGURE 3: Case-Mix Corrected Funnel Plot Of Textbook Outcome After Rectal Cancer Surgery

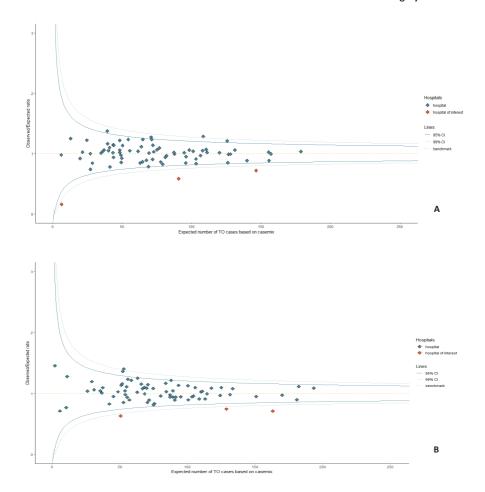


Figure 3: Case-mix corrected funnel plots for textbook outcome after elective rectal cancer surgery for 2012-2015 (Figure 3A) and 2016-2019 (Figure 3B). Case-mix factors used for risk adjustment are sex, age, BMI, ASA, CCI, preoperative tumor complications, cT-stage, neoadjuvant (chemo)radiotherapy, multivisceral resection for local ingrowth, additional resection for metastases, surgical procedure, and M stage.

TABLE 3: Multilevel Analyses To Determine Factors Predictive For Textbook Outcome

		AOR	95% CI	P value
Age	<75	1.00 (Ref.)		
	≥75	0.912	0.846-0.984	0.017
Sex	Male	1.00 (Ref.)		
	Female	1.599	1.499-1.706	< 0.001
ВМІ	18.5-30	1.00 (Ref.)		
	<18.5	0.977	0.760-1.257	0.857
	≥30	0.747	0.689-0.810	< 0.001
ASA score	I-II	1.00 (Ref.)		
	III+	0.676	0.621-0.736	< 0.001
CCI	0-1	1.00 (Ref.)		
	II+	0.809	0.749-0.873	< 0.001
Tumor	No	1.00 (Ref.)		
complications	Yes	0.893	0.822-0.971	< 0.001
Neoadjuvant	No	1.00 (Ref.)		
adiotherapy	SCRT	0.761	0.695-0.834	< 0.001
	CRT	0.888	0.801-0.984	0.024
	Other RTx	0.724	0.555-0.944	0.017
T stage	cT1-2	1.00 (Ref.)		
	cT3	0.962	0.888-1.042	0.341
	cT4	0.921	0.802-1.059	0.247
:N stage	cN0	1.00 (Ref.)		
	cN1-2	1.006	0.930-1.089	0.882
Technique ^A	Open	1.00 (Ref.)		
-	Laparoscopic	1.323	1.201-1.458	< 0.001
Surgical procedure	Rectal resection with def.	1.00 (ref.)		
	stoma			
	Low Hartmann	1.328	1.196-1.474	< 0.001
	Rectal resection, no def. stoma	1.934	1.773-2.109	< 0.001
	APE	1.105	1.021-1.208	0.014
Multivisceral	No	1.00 (Ref.)		
resection	Yes	0.617	0.533-0.715	< 0.001
Add. resection for	No	1.00 (Ref.)		
netastases	Yes	0.906	0.732-1.121	0.365
y)pT stage	(y)pT0-1	1.00 (Ref.)		
	(y)pT2	0.917	0.836-1.005	0.065
	(y)pT3	0.787	0.718-0.863	< 0.001
	(y)pT4	0.575	0.478-0.692	< 0.001
y)pN stage	(y)pN0	1.00 (Ref.)		
	(y)pN1-2	0.969	0.904-1.038	0.365
VI stage	M-	1.00 (Ref.)		
-	M1	1.061	0.933-1.206	0.366
Hospital type	Secondary	1.00 (Ref.)		
	, Tertiary	0.775	0.646-0.929	0.006
Year of surgery	- /	0.985	0.970-1.001	0.062

Table 3: Multilevel logistic regression analyses to determine factors predictive for textbook outcome. A: laparoscopic surgery includes conventional laparoscopy, robot-assisted laparoscopy, and trans anal total mesorectal excisions. SCRT: short-course radiotherapy, CRT: chemoradiotherapy, RTx another scheme: unspecified radiotherapy scheme. Add. Additional. The adjusted odds ratio, 95% confidence interval, and p value are shown. A p value <0.05 was considered as statistically significant.

DISCUSSION

This population-based study evaluated textbook outcome as a composite quality measure in rectal cancer surgery. We found that textbook outcome was achieved in 56.3% of the patients after rectal cancer surgery, mainly caused by the relatively high postoperative complication rate. The impact of margin status on achieving textbook outcome was minimal. Besides, textbook outcome was predominantly associated with patient and tumor characteristics, indicating that these factors mainly determine if textbook outcome can be achieved or not. After risk adjustment, the textbook outcome rate ranged from 8.9% to 73.9% among Dutch hospitals. Risk-adjusted funnel plots showed that just three hospitals performed below the 99% CI during 2012-2015 and 2016-2019. However, the underperforming hospitals were different for the two time periods. This might indicate that the provided benchmarked information contributed to quality improvement over time. Furthermore, continuous feedback is necessary to keep the quality of care at a certain level and to identify hospitals with decreasing performance over time.

The Committee on Quality of Health Care of the Institute of Medicine in the US states that health care needs to ensure all patients receive care that is safe, effective, patient-centered, timely, efficient, and equitable.²² Most of these conditions are commonly included in the textbook outcome measure and textbook outcome is therefore suggested to provide essential information regarding the overall quality of health care.^{10,14,15} In our textbook outcome parameter, safety is reflected by the absence of adverse events during the treatment course. Efficiency is incorporated in textbook outcome based on reintervention, readmission, and prolonged stay in hospital. Lastly, tumor-free resection margin refers to effective care.

We found that a larger proportion of patients who underwent rectal cancer surgery achieved a textbook outcome than patients who underwent colon cancer resection (49.0%), as seen by Kolfschoten et al. However, Kolfschoten et al. also included "no ostomy" as an outcome parameter, which was not included in the textbook outcome for rectal cancer surgery in the present study. Aside from APEs in patients in whom this is the only curative surgical option, constructing a stoma as part of Hartmann's procedure or to protect a low anastomosis can express excellent care. After all, personal preferences regarding risk and anticipated functional outcome are essential for good shared decision-making. Furthermore, Codd et al. showed that the permanent stoma rate is a misleading marker for the quality of rectal cancer care due to its association with multiple patient, tumor, and surgical characteristics. 23

The Dutch Cancer Society concluded that variation in provided care between hospitals points towards a potential area for further quality improvement.²⁴ However, comparing hospital

performance requires correction for complexity of care and random variation, known as casemix correction. A,8,10,15,17,25 Our case-mix corrected funnel-plots showed that during 2012-2015 three hospitals were performing below the 99% CI of the Dutch Benchmark. A previous study stated that an increase in observed-expected ratio for high-volume hospitals is more likely due to healthcare improvement than just change. Patients who underwent surgery in a tertiary hospital less often achieved textbook outcome than patients treated in secondary hospitals. The difference between secondary and tertiary hospitals remained significant after adjusting for risk factors, but residual confounding is likely present. Literature reveals controversial results about these associations. S, 25, 27–29 In the Netherlands, complex rectal cancer cases are commonly referred to tertiary centers, and different outcomes in these centers are considered acceptable based on complexity of care that is sometimes difficult to measure.

Our results demonstrated that rectal resection without defunctioning stoma creation was the surgical procedure with the strongest association with textbook outcome. Similar results were found by other studies, which showed a significantly lower postoperative morbidity rate, reintervention rate, readmission rate, and shorter stay in hospital after the construction of a primary anastomosis without defunctioning stoma. Sneijders et al. found that a defunctioning stoma in rectal cancer surgery did not result in a lower overall anastomotic leakage rate nor a lower mortality rate and suggested that preferable outcomes can be achieved by selecting the right patient for stoma construction. In addition, stoma reversal is associated with a substantial overall morbidity, major complication rate, and reoperation rate. Considering these results, one might suggest that patient selection for the type of resection and the construction of a stoma play a role in achieving textbook outcome after rectal cancer surgery.

Studies have shown that composite outcome measures, such as textbook outcome, have a statistical advantage over single outcome parameters for assessing hospital performance and variation. R10,13-15,35 Two high-volume hospitals were identified in the first period as underperformers. The fact that textbook outcome has never been provided as an outcome indicator by the DCRA suggests that these hospitals have improved their postoperative outcomes by reviewing their results based on the individual outcome parameters. This indicates that there is probably little added value of the textbook outcome measure compared to the separate measures for identifying hospital outliers in highly prevalent diseases such as rectal cancer, in contrast to low-volume surgical procedures, such as esophagogastric cancer resection. Postoperative complications frequently occur after rectal cancer surgery, whereas tumor positive resection margins occur less often. The high postoperative complication rate

dominates the textbook outcome parameter, for which reason the statistical advantage of combining surgical and pathologic outcomes in rectal cancer is little.

Long-term outcome is not captured in the DCRA, therefore the association between long-term survival and textbook outcome could not be assessed. However, it has been demonstrated that a good result on the textbook outcome parameter also results in better long-term survival after surgery for gastro-esophageal cancer, 35,37,38 pancreatic cancer, 39 and hepatocellular cancer. 46 Yang et al. found that colon cancer patients achieving a textbook outcome after surgery had a better 5-year disease-free survival. 40 In contrast. Bos et al. showed that hospitals performing more than 20 rectal cancer resections per year had a lower conversion rate and a lower postoperative mortality rate but found no differences in overall survival. 41 This questions whether variability in textbook outcome will translate into survival differences after rectal cancer surgery.

The impact of clinical auditing is typically based on the continuous plan-do-check-act cycle, in which the results are reviewed against benchmarked criteria.⁶ Previous research concluded that composite measures suffer from significant limitations, such as providing no detailed information which might result in masking substantial variation and areas of improvement in quality of care. Furthermore, composite measures do not reflect the difference in personal preference and the importance of the individual indicators. In addition, combining indicators in a composite measure might be challenging for case-mix correction because case-mix factors might vary between individual indicators. 42,43 Besides, ranking hospitals based on textbook outcome might be misleading because hospitals might have a similar textbook outcome rate but based on a different single outcome parameter with a different severity (for example, mortality versus prolonged length of hospital stay). Although weighting the individual measures might solve the problem of under-identification of hospitals with more severe events, the methodology for weighting is not straightforward.^{43–46} Besides, the composite character of textbook outcome provided hospitals with no specific information regarding the area of underperformance. For evaluating and improving care, the results of the single parameters are needed. This indicates that textbook outcome is not a short-term indicator that fits in the plan-do-check-act cycle.

Several limitations of this study need to be addressed. The use of the DCRA has limited the choice of parameters for textbook outcome. Although the selection of the included variables for the textbook outcome parameter was performed by the scientific committee, which reviewed the variables included in the textbook outcome parameter for colon cancer surgery,

there might be a risk of availability bias. In addition, the desired outcome might differ between patients and physicians. Patient-related outcomes measures were insufficiently registered in the DCRA for this study. Due to the continuous development of the DCRA, definitions of parameters have been changed. Until 2017 the 30-day complication rate, reintervention rate, readmission rate was registered, and since 2018 the 90-day outcome rates were registered. This resulted in a slightly lower textbook outcome (a 30-day postoperative outcome) for 2018 and 2019. This might be why the year of surgery was not significant in the multilevel logistic regression analyses.

CONCLUSION

Textbook outcome after rectal cancer surgery seems mostly associated with patient and tumor characteristics, and for this reason, the measure probably not accurately reflects surgical performance. Furthermore, achieving a textbook outcome was determined mainly by postoperative complications, with a minimal role of the resection margin. Textbook outcome had limited discriminating value to identify underperforming hospitals, and these hospitals casually performed within the confidence intervals later on. Textbook outcome has minimal statistical advantages in rectal cancer surgery. Besides, underperforming hospitals cannot use textbook outcome for improving care without assessing individual outcome measures. Thus, textbook outcome does not fit in the plan-do-check-act cycle.

3

Funding: No financial support was received for this research project.

Ethics approval and consent to participate: The National Audit from the healthcare inspector required no informed consent of patients to collect data. Data analyses were performed on a pseudonymized dataset and did not need ethical approval according to Dutch law.

Consent for publication: Not applicable

Availability of data and material: The data supporting the results of the present study are available from the Dutch Institute for Clinical Auditing (DICA) but are not publicly available. Data are, however, available from the authors upon reasonable request and with permission of the Dutch Institute for Clinical Auditing and the Dutch ColoRectal Audit Board.

Code availability: Statistical codes that are used for this study is available from the authors upon reasonable request and with permission of the Dutch Institute for Clinical Auditing and the Dutch ColoRectal Audit Board.

Credit authorship contribution statement: A.K. Warps: Conceptualization, Study concepts & design, Data curation, Data acquisition, Formal analysis, Statistical analysis, Data interpretation, Writing original draft, Drafting the manuscript, Writing - review & editing. R. Detering: Conceptualization, Study concepts & design, Data interpretation, Writing -review & editing, Critical review and feedback on the manuscript. R.A.E.M. Tollenaar: Conceptualization, Study concepts & design, Data interpretation, Writing - review & editing, Critical review and feedback on the manuscript. P.J. Tanis: Conceptualization, Study concepts & design, Data interpretation, Writing - review & editing, Critical review and feedback on the manuscript. J.W.T. Dekker: Conceptualization, Study concepts & design, Data interpretation, Supervision, of manuscript, Writing – review & editing, Critical review and feedback on the manuscript.

Declaration of competing interest: The authors declare no competing interests.

Acknowledgement: The author would like to thank all surgeons, data managers, physician assistants, administrative nurses who registered all patients in the DCRA.

REFERENCES

- Singh AA, Boyle JR. Evaluating quality in clinical care. Surgery (United Kingdom). 2020;38(10):632-636. doi:10.1016/j.mpsur.2020.07.010
- Karltun A, Sanne JM, Aase K, et al. Knowledge management infrastructure to support quality improvement: A qualitative study of maternity services in four European hospitals. *Health Policy*. 2020;124(2):205-215. doi:10.1016/j.healthpol.2019.11.005
- Donabedian A. Evaluating the quality of medical care. Milbank Quarterly. 2005;83(4):691-729. doi:10.1111/j.1468-0009.2005.00397.x
- 4. Van Leersum NJ, Snijders HS, Henneman D, et al. The dutch surgical colorectal audit. *European Journal of Surgical Oncology*. 2013;39(10):1063-1070. doi:10.1016/j.ejso.2013.05.008
- 5. Blomgren M. The drive for transparency: Organizational field transformations in Swedish healthcare. *Public Administration*. 2007;85(1):67-82. doi:10.1111/j.1467-9299.2007.00634.x
- Radcliffe Medical Press Ltd. National Institute of Health and Care Excellence: Principles of Best Practice in Clinical Audit 2002.; 2002.
- Dijs-Elsinga J, Otten W, Versluijs MM, et al. Choosing a hospital for surgery: the importance of information on quality of care. Medical decision making: an international journal of the Society for Medical Decision Making. 2010;30(5):544-555. doi:10.1177/0272989X09357474
- Mehta R, Tsilimigras DI, Paredes AZ, et al. Is Patient Satisfaction Dictated by Quality of Care Among Patients Undergoing Complex Surgical Procedures for a Malignant Indication? *Annals of Surgical Oncology*. 2020;27(9):3126-3135. doi:10.1245/s10434-020-08788-w
- Austin PC, Ceyisakar IE, Steyerberg EW, Lingsma HF, Marang-Van De Mheen PJ. Ranking hospital performance based on individual indicators: Can we increase reliability by creating composite indicators? BMC Medical Research Methodology. 2019;19(1). doi:10.1186/s12874-019-0769-x
- Mehta R, Tsilimigras DI, Paredes AZ, et al. Comparing textbook outcomes among patients undergoing surgery for cancer at U. S. News & World Report ranked hospitals. *Journal of Surgical Oncology*. 2020;121(6):927-935. doi:10.1002/jso.25833
- 11. Nolan T, Berwick DM. All-or-none measurement raises the bar on performance. *Journal of the American Medical Association*. 2006;295(10):1168-1170. doi:10.1001/jama.295.10.1168
- Reeves D, Campbell SM, Adams J, Shekelle PG, Kontopantelis E, Roland MO. Combining multiple indicators of clinical quality: An evaluation of different analytic approaches. *Medical Care*. 2007;45(6):489-496. doi:10.1097/MLR.0b013e31803bb479
- Kolfschoten NE, Kievit J, Gooiker GA, et al. Focusing on desired outcomes of care after colon cancer resections; Hospital variations in "textbook outcome." European Journal of Surgical Oncology. 2013;39(2):156-163. doi:10.1016/j.ejso.2012.10.007
- Busweiler LAD, Schouwenburg MG, van Berge Henegouwen MI, et al. Textbook outcome as a composite measure in oesophagogastric cancer surgery. *British Journal of Surgery*. 2017;104(6):742-750. doi:10.1002/bjs.10486
- Merath K, Chen Q, Bagante F, et al. Textbook outcomes among medicare patients undergoing hepatopancreatic surgery. Annals of Surgery. 2020;271(6):1116-1123. doi:10.1097/ SLA.0000000000003105
- Tsilimigras DI, Mehta R, Merath K, et al. Hospital variation in Textbook Outcomes following curativeintent resection of hepatocellular carcinoma: an international multi-institutional analysis. *Hpb*. 2020;22(9):1305-1313. doi:10.1016/j.hpb.2019.12.005

- Ten Berge MG, Beck N, Steup WH, et al. Textbook outcome as a composite outcome measure in non-small-cell lung cancer surgery. European Journal of Cardio-thoracic Surgery. 2021;59(1):92-99. doi:10.1093/ejcts/ezaa265
- CCMO. https://www.ccmo.nl. uw-onderzoek-wmo-plichtig-of-niet. https://www.ccmo.nl/ onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek/uw-onderzoek-wmoplichtig-of-niet. Accessed March 20, 2021.
- Marja van Bon-Martens T, Evert-Ben van Veen M. Handreiking ontsluiten patiëntgegevens voor onderzoek: werken volgens de regels uit AVG, UAVG en WGBO. https://www.zonmw.nl/fileadmin/ zonmw/documenten/GGz/AVG/Projecten/Handreiking_ontsluiten_patientgegevens_def__002_. pdf. Published 2019. Accessed March 21, 2021.
- Austin PC, Tu J V., Alter DA. Comparing hierarchical modeling with traditional logistic regression analysis among patients hospitalized with acute myocardial infarction: Should we be analyzing cardiovascular outcomes data differently? *American Heart Journal*. 2003;145(1):27-35. doi:10.1067/ mhj.2003.23
- Twisk JWR. Applied Multilevel Analysis: A Practical Guide. Cambridge: Cambridge University Press.;
 2006. doi:10.1017/CBO9780511610806
- 22. Committee on Quality of Health Care in America (Institute of Medicine). *Crossing the Quality Chasm:* A New Health System for the 21st Century.; 2001.
- 23. Codd RJ, Evans MD, Davies M, et al. Permanent stoma rates: A misleading marker of quality in rectal cancer surgery. *Colorectal Disease*. 2014;16(4):276-280. doi:10.1111/codi.12509
- 24. Wouters MWJM, Jansen-Landheer MLEA, Van De Velde CJH. The quality of cancer care initiative in the Netherlands. *European Journal of Surgical Oncology*. 2010;36(SUPPL. 1). doi:10.1016/j. ejso.2010.06.004
- 25. Kolfschoten NE, Marang Van De Mheen PJ, Gooiker GA, et al. Variation in case-mix between hospitals treating colorectal cancer patients in the Netherlands. *European Journal of Surgical Oncology*. 2011;37(11):956-963. doi:10.1016/j.ejso.2011.08.137
- Kolfschoten NE, Marang-van De Mheen PJ, Wouters MWJM, et al. A combined measure of procedural volume and outcome to assess hospital quality of colorectal cancer surgery, a secondary analysis of clinical audit data. *PLoS ONE*. 2014;9(2). doi:10.1371/journal.pone.0088737
- Friese CR, Earle CC, Silber JH, Aiken LH. Hospital characteristics, clinical severity, and outcomes for surgical oncology patients. Surgery. 2010;147(5):602-609. doi:10.1016/j.surg.2009.03.014
- Borowski DW, Kelly SB, Bradburn DM, et al. Impact of surgeon volume and specialization on short-term outcomes in colorectal cancer surgery. *British Journal of Surgery*. 2007;94(7):880-889. doi:10.1002/bjs.5721
- Zhang W, Ayanian JZ, Zaslavsky AM. Patient characteristics and hospital quality for colorectal cancer surgery. *International Journal for Quality in Health Care*. 2007;19(1):11-20. doi:10.1093/intqhc/ mzl047
- Ihnát P, Guňková P, Peteja M, Vávra P, Pelikán A, Zonča P. Diverting ileostomy in laparoscopic rectal cancer surgery: high price of protection. Surgical Endoscopy. 2016;30(11):4809-4816. doi:10.1007/ s00464-016-4811-3
- 31. Blok RD, Stam R, Westerduin E, et al. Impact of an institutional change from routine to highly selective diversion of a low anastomosis after TME for rectal cancer. *European Journal of Surgical Oncology*. 2018;44(8):1220-1225. doi:10.1016/j.ejso.2018.03.033

- 32. Snijders HS, van Leersum NJ, Henneman D, et al. Optimal Treatment Strategy in Rectal Cancer Surgery: Should We Be Cowboys or Chickens? *Annals of Surgical Oncology*. 2015;22(11):3582-3589. doi:10.1245/s10434-015-4385-7
- Holmgren K, Kverneng Hultberg D, Haapamäki MM, Matthiessen P, Rutegård J, Rutegård M. High stoma prevalence and stoma reversal complications following anterior resection for rectal cancer: a population-based multicentre study. *Colorectal Disease*. 2017;19(12):1067-1075. doi:10.1111/ codi.13771
- Van Westreenen HL, Visser A, Tanis PJ, Bemelman WA. Morbidity related to defunctioning ileostomy closure after ileal pouch-anal anastomosis and low colonic anastomosis. *International Journal of Colorectal Disease*. 2012;27(1):49-54. doi:10.1007/s00384-011-1276-7
- Van Der Werf LR, Wijnhoven BPL, Fransen LFC, et al. A National Cohort Study Evaluating the Association between Short-term Outcomes and Long-term Survival after Esophageal and Gastric Cancer Surgery. Annals of Surgery. 2019;270(5):868-876. doi:10.1097/SLA.00000000000003520
- de Neree tot Babberich MPM, Detering R, Dekker JWT, et al. Achievements in colorectal cancer care during 8 years of auditing in The Netherlands. European Journal of Surgical Oncology. 2018;44(9):1361-1370. doi:10.1016/j.ejso.2018.06.001
- Kulshrestha S, Bunn C, Patel PM, et al. Textbook oncologic outcome is associated with increased overall survival after esophagectomy. In: Surgery (United States). Vol 168.; 2020:953-961. doi:10.1016/j.surg.2020.05.038
- 38. van der Kaaij RT, de Rooij M V., van Coevorden F, et al. Using textbook outcome as a measure of quality of care in oesophagogastric cancer surgery. *British Journal of Surgery*. 2018;105(5):561-569. doi:10.1002/bjs.10729
- Sweigert PJ, Eguia E, Baker MS, et al. Assessment of textbook oncologic outcomes following pancreaticoduodenectomy for pancreatic adenocarcinoma. *Journal of Surgical Oncology*. 2020;121(6):936-944. doi:10.1002/jso.25861
- Yang CC, Tian YF, Liu WS, et al. The association between the composite quality measure "textbook outcome" and long term survival in operated colon cancer. *Medicine*. 2020;99(40):e22447. doi:10.1097/MD.000000000022447
- 41. Bos ACRK, Van Erning FN, Elferink MAG, et al. No Difference in Overall Survival between Hospital Volumes for Patients with Colorectal Cancer in the Netherlands. *Diseases of the Colon and Rectum*. 2016;59(10):943-952. doi:10.1097/DCR.0000000000000660
- 42. Friebel R, Steventon A. Composite measures of healthcare quality: Sensible in theory, problematic in practice. *BMJ Quality and Safety*. 2019;28(2):85-88. doi:10.1136/bmjqs-2018-008280
- Barclay M, Dixon-Woods M, Lyratzopoulos G. The problem with composite indicators. BMJ Quality and Safety. 2019;28(4):338-344. doi:10.1136/bmjqs-2018-007798
- Shwartz M, Restuccia JD, Rosen AK. Composite Measures of Health Care Provider Performance: A Description of Approaches. *Milbank Quarterly*. 2015;93(4):788-825. doi:10.1111/1468-0009.12165
- 45. Seth S, McGillivray M. Composite indices, alternative weights, and comparison robustness. *Social Choice and Welfare*. 2018;51(4):657-679. doi:10.1007/s00355-018-1132-6
- 46. Greco S, Ishizaka A, Tasiou M, Torrisi G. On the Methodological Framework of Composite Indices: A Review of the Issues of Weighting, Aggregation, and Robustness. *Social Indicators Research*. 2019;141(1):61-94. doi:10.1007/s11205-017-1832-9

