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ORIGINAL ARTICLE

Association of certification, improved quality and better oncological outcomes for rectal cancer in a specialized colorectal unit

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Abstract

Purpose Centralization of cancer care is expected to yield superior results. In Germany, the national strategy is based on a voluntary certification process. The effect of centre certification is difficult to prove because quality data are rarely available prior to certification. This observational study aims to assess outcomes for rectal cancer patients before and after implementation of a certified cancer centre.

Patients and methods All consecutive patients treated for rectal cancer in our certified centre from 2009 to 2017 were retrieved from a prospective database. The dataset was analyzed according to a predefined set of 19 quality indicators comprising 36 quality goals. The results were compared to an identical cohort of patients, treated from 2000 to 2008 just before centre implementation.

Results In total, 1059 patients were included, 481 in the 2009–2017 interval and 578 in the 2000–2008 interval. From 2009 to 2017, 25 of 36 quality goals were achieved (vs. 19/36). The proportion of anastomotic leaks in low anastomoses was improved (13.5% vs. 22.1%, $p = 0.018$), as was the local 5-year recurrence rate for stage (y)pIII rectal cancers (7.7% vs. 17.8%, $p = 0.085$), and quality of mesorectal excision (0.3% incomplete resections vs. 5.5%, $p = 0.002$). Furthermore, a decrease of abdominoperineal excisions was noted (47.1% vs. 60.0%, $p = 0.037$). For the 2009–2017 interval, local 5-year recurrence rate in stages (y)p0-III was 4.6% and 5-year overall survival was 80.2%.

Conclusions Certification as specialized centre and regular audits were associated with an improvement of various quality parameters. The formal certification process has the potential to enhance quality of care for rectal cancer patients.

Keywords Rectal cancer · Quality indicators · Certified Colorectal Cancer Centre · Anastomotic leak · Local recurrence rate

Introduction

In 2007, a German expert group published a set of quality indicators for the diagnosis and treatment of rectal cancer [1]. The group also proposed benchmarks for each indicator with a clear definition of the numerator and denominator. Thus, a set of 36 quality goals was defined. The feasibility of these quality indicators could be proven by several groups specializing in rectal cancer care [2, 3]. We were also able to give positive proof of the practicability of the quality goals for a consecutive series of patients treated for rectal cancer from 2000 to 2008 [4].

In 2008, the German Ministry of Health together with two German cancer societies and the working group of German tumour centres agreed on a national cancer plan including the strategy that patients with common cancer entities such as colorectal cancer should be treated in certified centres to ensure a high standard of care [5]. Following the instructions of this strategy, our unit was certified in May 2008 by the German Society of General and Visceral Surgery and by the German Cancer Society in 2011. Preconditions for certification were several measures of quality assurance, implementation of structured workflows, and annual external audits [6, 7].

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Certification of the German Cancer Society mandated the nomination of at least two specialized colorectal cancer surgeons with a minimum of 10 rectal resections per year [7].

However, the impact of establishing certified centres for colorectal cancer on patient outcomes is difficult to assess and data that prove the benefit is scarce [8]. We hypothesized that implementation of a certified centre improves predefined quality parameters. In order to assess this, we compared the group of rectal cancer patients treated within the structure of a certified colorectal unit with a patient group treated before and documented in an identical manner [4]. The comparison was done using the detailed quality indicators of the German working group [1]. The primary endpoint of the study was the number of achieved quality goals. The secondary endpoint was the comparison of the two groups with respect to every single quality goal.

Patients and methods

Prospective tumour documentation for colorectal cancer patients was established as early as 1981 in our unit by means of a coloproctologic database. It is based on international standards [9, 10] and has been continuously improved over the years taking into account developments in diagnostics, treatment, and refinements in classification. Tumour, node, and metastasis (TNM) classification was done according to the valid edition of the International Union against Cancer (UICC) classification [11–13]. Follow-up is organized in a coloproctologic clinic were patients are seen annually for 5 years and biannually thereafter up to 10 years. Written informed consent for follow-up and inquiries is obtained at the outset of treatment. Further details of follow-up have been published previously [14]. According to national regulations, no formal approval of the responsible institutional review board is necessary for this kind of study.

All rectal cancer patients treated from January 2009 until December 2017 were retrieved from the database. Patients with a histologically proven primary adenocarcinoma of the rectum (≤ 16 cm from the anal verge as measured by rigid rectoscopy) were included. Carcinoma in situ was the only exclusion criterion. To provide an overview of potential confounders, we performed a comprehensive comparison of the baseline demographic, clinical, treatment, and pathological parameters. Data was analyzed according to the definitions of the German Working Group and are detailed in the respective tables [1]. Missing data are indicated with the results; the denominator was decreased accordingly. Proportions for the quality indicators are given as percentages with 95% confidence intervals (CI). Local recurrence and overall survival rates were calculated with the Kaplan–Meier method. The starting point for the estimation of local recurrences was the date of operation. However, the starting point for survival analysis was the date of diagnosis to include the time of neoadjuvant therapy. In both calculations, postoperative mortality was excluded. Postoperative mortality was defined as in-hospital death independent of the length of stay, according to the definition of the Working Group [1]. The calculation of cumulative local recurrence rates is not influenced by postoperative mortality [15]. In overall survival, exclusion of postoperative mortality reflects the tumour-related prognosis that can be achieved for the patient according to the chosen treatment [16]. The last follow-up for calculation of recurrence rates and survival analysis was set on 26 March 2019. Patients without known local recurrence or death at 5 years were censored accordingly.

This was in accordance with our previous analysis conducted for patients treated from 2000 until 2008 [4] to ensure a high comparability between the groups. Subsequently, the two groups were compared applying either the χ^2 test or the Fisher exact test for categorical variables. To illustrate trends over time, we displayed annual proportions of indicators that showed a statistically significant difference with a linear regression graph fitted for each time period. The log-rank test was applied to local recurrence and survival rates. A p value of < 0.05 was considered significant. For statistical analysis, SPSS V 25 (IBM Corp., Armonk, NY) was used.

If the result for each quality goal was within the range of the predefined benchmark, the goal was counted as achieved. For indicator 5b (tumour removal clinical stages I–II), the benchmark was interpreted as ≥ 90% without upper limit, because the rationale for an upper limit was not clear. Indicator 7b (neoadjuvant treatment depending on MR-assessed infiltration of potential CRM) describes a peculiar situation and applied in our series only to patients treated within the OCUM trial [17, 18]. It was summarized in indicator 7a. If only the 95% CI comprised the benchmark, the goal was counted as nearly achieved [2]. Indicators with six or fewer patients in the denominator were not assessed for the achievement of the benchmark.

The study, although retrospective in nature, is based on prospective data and has a longitudinal character regarding the implementation of a certified centre.

Results

For the time period from 2009 until 2017, we identified 481 patients with histologically proven adenocarcinoma of the rectum (334 males, 147 females) from the database. The median age of the study population was 68 (range 36–93) years. Median follow-up was 53.0 (range 1–128) months with 23 (4.8%) patients lost to follow-up. In comparison with the 2000–2008 group, there were significantly more patients with an elevated CEA level (39.1% vs. 28.4%, $p < 0.001$) and with clinical stages III (53.3% vs. 34.7%, $p < 0.001$) and IV (26.9%

vs. 16.8%, $p < 0.001$). The proportion of patients who did not undergo tumour resection remained stable (13.5% vs. 13.8%, $p = 0.877$) as did the proportion of sphincter preserving radical operations (62.1% vs. 57.3%, $p = 0.169$). The proportion of intersphincteric resections, however, increased significantly (6.0% vs. 2.1%, $p = 0.001$), while the proportion of abdominoperineal excisions (APE) decreased (13.7% vs. 17.3%, $p = 0.070$). Neoadjuvant therapy was administered in 57.8% vs. 43.3% ($p < 0.001$). Adjuvant radio(chemo)therapy almost disappeared (1.7% vs. 12.0%, $p < 0.001$) owing to the shift towards neoadjuvant therapy in the 2004 guidelines [19]. Pathologic parameters, especially TNM classification, were difficult to compare because of the different proportions of neoadjuvant therapy in the two time intervals. However, we observed a significant decrease of the pUICC stage I (16.1% vs. 25.5%, $p = 0.001$). The proportion of poorly differentiated carcinomas was significantly lower in the 2009–2017 group (15.5% vs. 23.4%, $p = 0.003$). In neoadjuvantly treated patients, the proportion of complete tumour regression according to Dworak [20] did not change significantly (14.2% vs. 17.2%, $p = 0.389$). Further patient and tumour characteristics are given in Tables 1, 2 and 3.

Overall, 25 of the 36 quality goals could be achieved in the 2009–2017 period. The set of achieved goals comprised as important goals as postoperative mortality in elective (0.8%) and emergency (14.3%) operations, pathologic CRM (only 2.5% positive), cumulative local recurrence rate at 5 years for stages (y)p0–III (4.6%) and almost all survival parameters (Tables 4, 5, 6 and 7). The 5-year overall survival for stages (y)p0–III was 80.2%.

In the 2009–2017 group, 6 more quality goals could be achieved than in the 2000–2008 group. Amongst the improved quality indicators are the proportion of anastomotic leaks in anastomoses up to 7 cm from the anal verge (13.5% vs. 22.1%, $p = 0.018$) and the local recurrence rate of stage (y)pIII rectal cancers (7.7% vs. 17.8%, $p = 0.085$; Fig. 1).

Table 1 Pretreatment characteristics

	2000–2008 $n = 578$	2009–2017 $n = 481$	Total $n = 1059$	p
Age (median (range)) in years	67 (37–95)	68 (36–93)	67 (36–95)	0.370
Sex				0.388
Male	387 (67.0)	334 (69.4)	721 (68.1)	
Female	191 (33.0)	147 (30.6)	339 (31.9)	
Lost to follow-up[a]	13 (2.2)[b]	23 (4.8)[c]	36 (3.4)	0.024
Follow-up (median (range)) in months	54.4 (1–116)	53.0 (1–128)	54.0 (1–128)	0.121
Lower tumour border (median (range)) in cm	8 (0–16)[d]	8 (0–16)[e]	8 (0–16)	0.498
Pretherapeutic CEA				< 0.001
Normal	391 (71.6)[f]	273 (60.9)[g]	664 (66.8)	
Elevated	155 (28.4)	175 (39.1)	330 (33.2)	
Clinical UICC stage				
0[h]	13 (2.3)[i]	5 (1.1)[j]	18 (1.7)	
I	115 (20.1)	55 (11.6)	170 (16.2)	
II	150 (26.2)	34 (7.2)	184 (17.6)	
III	199 (34.7)	253 (53.3)	452 (43.1)	< 0.001[k]
IV	96 (16.8)	128 (26.9)	224 (21.4)	< 0.001[l]

Values in brackets are percentages if not otherwise specified

CEA carcinoembryonic antigen, *UICC* Union for International Cancer Control [11–13, 21]

[a] Denominator: patients alive at the respective close of study

[b] $n = 369$

[c] $n = 312$

[d] Missing for 14 patients

[e] Missing for 14 patients

[f] Missing for 32 patients

[g] Missing for 33 patients

[h] Staging performed, but with cross-sectional imaging/endoultrasound no tumour detected

[i] Missing for 5 patients

[j] Missing for 6 patients

[k] Stage III compared with stages 0–II

[l] Stage IV compared with stages 0–III

Table 2 Treatment characteristics

	2000–2008 $n = 578$	2009–2017 $n = 481$	Total $n = 1059$	p
Neoadjuvant therapy[a]	466	339	805	< 0.001[b]
None	264 (56.7)	143 (42.2)	407 (50.6)	
Radio(chemo)therapy	194 (41.6)	176 (51.9)	370 (46.0)	
Short course radiotherapy	5 (1.1)	16 (4.7)	21 (2.6)	
others	3 (0.6)	4 (1.2)	7 (0.9)	
Operative procedures				
No operation	41 (7.1)	34 (7.1)	75 (7.1)[c]	0.877[d]
Stoma only	39 (6.7)	31 (6.4)	70 (6.6)	
Local excision	31 (5.4)	19 (4.0)	50 (4.7)	
PME	108 (18.7)	64 (13.3)	172 (16.2)	0.169[e]
TME	211 (36.5)	206 (42.8)	417 (39.4)	
Intersphincteric resection	12 (2.1)	29 (6.0)	41 (3.9)	0.001[f]
APE	88 (15.2)	16 (3.3)	104 (9.8)	
ELAPE	12 (2.1)	50 (10.4)	62 (5.9)	0.070[g]
HARTMANN	33 (5.7)	31 (6.4)	64 (6.0)	
others	3 (0.5)	1 (0.2)	4 (0.4)	
Adjuvant therapy[h]	437	339	776	< 0.001[i]
None	296 (67.7)	227 (67.0)	523 (67.4)	
Radio(chemo)therapy	59 (13.5)	7 (2.1)	66 (8.5)	
Chemotherapy	82 (18.8)	105 (31.0)	187 (24.1)	

Values in brackets are percentages if not otherwise specified

PME partial mesorectal excision, *TME* total mesorectal excision, *APE* abdominoperineal excision, *ELAPE* extra-levator APE

[a] Patients with metastases in pretherapeutic diagnostics or previous pelvic irradiation excluded

[b] Any form of neoadjuvant therapy vs. none

[c] Including 6 patients with wait and watch policy in 2000–2008 and 2 patients with wait and watch policy in 2009–2017

[d] No operation and stoma only combined vs. all others

[e] Sphincter preserving operations (PME, TME, intersphincteric resection) vs. APE, ELAPE, HARTMANN

[f] Intersphincteric resection vs. all other radical resections

[g] APE and ELAPE vs. all other radical resections

[h] Resected patients only, patients with metastases and postoperative mortality excluded

[i] For radio(chemo)therapy vs. all others

Furthermore, the quality of mesorectal excision improved significantly (0.3% incomplete resections vs. 5.5%, $p = 0.002$). For the proportion of APE in rectal cancers of the lower third, no benchmark was defined, but we could show a significant decrease from 60.0% to 47.1%, $p = 0.037$. Trends over time are displayed for proportions of both anastomotic leaks and APE in Figs. 2 and 3.

Another 5 quality goals were nearly achieved and only 4 quality goals were missed in 2009–2017. Missed goals included the proportion of specimens with ≥ 12 retrieved lymph nodes. Whereas the proportion remained stable for patients without neoadjuvant radio(chemo)therapy (76.6% vs. 76.4% in 2000–2008), it improved for patients after neoadjuvant therapy (58.2% vs. 45.7%, $p = 0.120$). We could not detect differences in overall survival, neither in the 2009–2017 group (73.3% for < 12 lymph nodes vs. 78.2% for ≥ 12 lymph nodes, $p = 0.306$), nor in the 2000–2008 group (69.6% for < 12 lymph nodes vs. 73.8% for ≥ 12 lymph nodes, $p = 0.581$).

Overall, the quality of documentation increased with the quality of mesorectal excision and pathologic CRM completely documented and urinary catheter newly documented in the 2009–2017 period. In the 2000–2008 group, three goals could not be evaluated; in the current group, this applied to two goals.

Discussion

Our study shows that despite starting from a high level, further improvements in the quality of rectal cancer treatment are possible with the implementation of a certified centre.

Table 3 Pathologic characteristics*

	2000–2008 *n* = 498	2009–2017 *n* = 416	Total n=914	p[a]
pT category				
1	75 (15.1)	33 (7.9)	108 (11.8)	
2	78 (15.7)	43 (10.3)	121 (13.2)	
3	121 (24.3)	76 (18.3)	197 (21.6)	
4	5 (1.0)	8 (1.9)	13 (1.4)	
ypT category				
0	36 (7.2)	32 (7.7)	68 (7.4)	
1	14 (2.8)	18 (4.3)	32 (3.5)	
2	62 (12.4)	73 (17.5)	135 (14.8)	
3	94 (18.9)	116 (27.9)	210 (23.0)	
4	12 (2.4)	17 (4.1)	29 (3.2)	
X	1 (0.2)		1 (0.1)	
pUICC stage				0.001[b]
I	127 (25.5)	67 (16.1)	194 (21.2)	
II	63 (12.7)	33 (7.9)	96 (10.5)	
III	72 (14.5)	40 (9.6)	112 (12.3)	
IV	17 (3.4)	20 (4.8)	37 (4.0)	
ypUICC stage				
0	33 (6.6)	30 (7.2)	63 (6.9)	
I	59 (11.8)	57 (13.7)	116 (12.7)	
II	47 (9.4)	56 (13.5)	103 (11.3)	
III	39 (7.8)	58 (13.9)	97 (10.6)	
IV	41 (8.2)	55 (13.2)	96 (10.5)	
N category				
N[c]				
NX[d]	30 (6.0)	19 (4.6)	49 (5.4)	
pN1	1[e](0.2)	0	1 (0.1)	
pN				
0	164 (32.9)	84 (20.2)	248 (27.1)	
1	55 (11.0)	39 (9.4)	94 (10.3)	
2	32 (6.4)	18 (4.3)	50 (5.5)	
ypN				
0	149 (29.9)	164 (39.4)	313 (34.2)	
1	43 (8.6)	59 (14.2)	102 (11.2)	
2	24 (4.8)	33 (7.9)	57 (6.2)	
Grading				0.003[h]
Well	34[f] (6.9)	17[g] (4.1)	51 (5.6)	
Moderate	345 (69.7)	333 (80.4)	678 (74.6)	
Poor	116 (23.4)	64 (15.5)	180 (19.8)	
Tumour regression grade[i] (Dworak [20])				0.273[l]
0	2[j] (1.0)	6[k] (2.5)	8 (1.9)	
1	35 (18.2)	34 (14.2)	69 (16.0)	
2	42 (21.9)	41 (17.2)	83 (19.3)	
3	80 (41.7)	126 (52.7)	205 (47.8)	
4	33 (17.2)	32 (13.4)	64 (15.1)	

Values in brackets are percentages

UICC Union for International Cancer Control [11–13, 21]

[*] Resected patients only

[a] Selected comparisons only

[b] pUICC stage I vs. all others

[c] Local excision

[d] N0 in clinical staging

[e] One patient with local lymph node excision

[f] Missing in 3 patients

[g] Missing in 2 patients

[h] Poorly differentiated vs. all others

[i] Primary tumour only

[j] Missing in 27 (9.3%) of 219 patients with yp staging

[k] Missing in 17 (6.3%) of 256 patients with yp staging

[l] Regression grade 4 (histopathologically complete response) vs. all others

Table 4 Quality indicators for diagnostics of rectal carcinoma

Definition of the Working Group Workflow Rectal Carcinoma II [1]				Results Dresden-Friedrichstadt		
No. AS	Quality indicator	Reference group	Quality goal	n/reference group % (95% CI)		
				2000–2008	2009–2017	*p*
A. Clinical diagnostics						
1 AA	Determination of pretherapeutic clinical T, N, and M category	All patients	95%	573/578 [a] 99.1 (98.4–99.9)	475/481 [a] 98.8 (97.8–99.8)	0.541
2 B A	Proportion pT1 carcinomas	All patients with removal of an infiltrative carcinoma	5–15%	75/498 15.1 (11.9–18.2)	33/416 7.9 (5.3–10.5)	0.001
B. Pathologic diagnostics						
3 C C	Number of histologically examined lymph nodes	All patients with radical tumour removal	(a) Without prior long-term radiotherapy or long-term radiochemotherapy: in 95% at least 12 lymph nodes	(a) 204/267 76.4 (71.3–81.5)	(a) 144/188 76.6 (70.5–82.7)	(a) 0.962
C C			(b) After prior long-term radiotherapy or long-term radiochemotherapy: in 75% at least 12 lymph nodes	(b) 90/197 45.7 (38.7–52.7)	(b) 121/208 58.2 (51.5–64.9)	(b) 0.120
4 B A	Proportion of lymph node-positive patients	All patients with radical tumour removal without prior long-course radiotherapy or long-course radiochemotherapy	40–45%	96/267 36.0 (30.2–41.7)	78/188 41.5 (34.4–48.6)	0.232

AS—achievement status: A—target value achieved, B—target value nearly achieved, C—target value not achieved

[a] Except pTis

Table 5 Indicators of process quality of therapy

Definition of the Working Group Workflow Rectal Carcinoma II [1]				Results Dresden-Friedrichstadt		
No. AS	Quality indicator	Reference group	Quality goal	n/reference group % (95% CI)		
				2000–2008	2009–2017	*p*
5 A A	Tumour removal (surgical or endoscopic)	All patients with infiltrative carcinoma	(a) All patients, all clinical stages: 85–95%	(a) 498/578 86.2 (83.3–89.0)	(a) 416/481 86.5 (83.4–89.6)	(a) 0.877
A A			(b) Clinical stages I–II: 90–95%	(b) 252/265 95.1 (92.5–97.7)	(b) 86/89 96.6 (92.8–100)	(b) 0.546
6 C C	Definitive complete tumour removal (R0) line break; by local (surgical or endoscopic) procedures	Patients with R0 tumour resection	(a) pT1, G1–2, L0: > 75%	(a) 26/63 41.3 (28.8–53.8)	(a) 17/30 56.7 (38.7–74.7)	(a) 0.125
A A			(b) pT2, G1–2, L0: < 10%	(b) 0/43 0	(b) 0/38 0	(b) n.a.
B X			(c) G3–4 or L1: ~ 0	(c) 2/45 4.4 (0–10.7)	(c) 1/6 16.7 (0–49.3)	(c) 0.319
`7 B B	Neoadjuvant long-course radiochemotherapy in cT3 and/or cN1–2 M0 carcinoma of the middle and lower third	(a) In institutions without modern high-resolution MRI: patients with cT3 and/or cN1–2 carcinoma	(a) > 90 %	(a) 66/78[a] 84.6 (76.4–92.8)	(a) 179/209 (80.9–90.4)	(a) 0.826
		(b) In institutions with modern high-resolution MRI: patients with MRI-positive CRM	(b) > 90%		(b) 6/6 100	(b) n.a.
8 C C	Adjuvant therapy in patients without neoadjuvant therapy	R0 patients without neoadjuvant therapy	(a) Stage III: > 80%	(a) 44/70 [b] 62.9 (51.2–74.5)	(a) 21/40 [b] 52.5 (36.8–68.2)	(a) 0.288
X X			(b) Stage I or II with intraoperative tumour cell dissemination: > 80%	(b) 1/6 -	(b) 0	(b) n.a.
9 A A	Total/partial mesorectal excision (TME/PME)	Patients with radical R0-tumour resection	(a) Tumours of the middle and lower third: TME in > 90%	(a) 320/320 100	(a) 285/285 100	(a) n.a.
A A			(b) Tumours of the upper third: PME in > 90%	(b) 103/104 99.0 (97.1–100)	(b) 82/82 100	(b) 1.000
10 B B	Abdomino-perineal rectal excision	Patients with radical tumour resection	(a) Upper third: ~ 0	(a) 1/118 0.8 (0–2.5)	(a) 2/90 2.2 (0–5.3)	(a) 0.580
A A			(b) Middle third: ≤ 20%	(b) 15/209 7.2 (3.6–10.7)	(b) 7/186 3.8 (1.1–6.5)	(b) 0.140
n.a.			(c) Lower third: ?[c]	(c) 84/140 60.0 (51.8–68.2)	(c) 57/121 47.1 (38.2–56.0)	(c) 0.037

Table 5 (continued)

Definition of the Working Group Workflow Rectal Carcinoma II [1]				Results Dresden-Friedrichstadt		
11 A A	Postoperative mortality	Patients with radical tumour resection	(a) Elective procedures: < 5%	(a) 4/465 0.9 (0–1.7)	(a) 3/390 0.8 (0–0.9)	(a) 1.000
X A			(b) Emergency procedures: 10–15 %	(b) 1/2 -	(b) 1/7 14.3 (0–42.3)	(b) 0.417
12 B A	Clinically relevant anastomotic leakage[d]	Patients with (high or low) rectal resection	(a) Anastomosis ≤ 7 cm from anal verge: < 20%	(a) 49/222[e] 22.1 (16.6–27.6)	(a) 30/222[e] 13.5 (9.0–18.0)	(a) 0.018
B B			(b) Anastomosis > 7 cm from anal verge: < 10%	(b) 15/112[f] 13.4 (7.0–19.8)	(b) 10/79[f] 12.7 (5.3–20.1)	(b) 0.882
13 X A	So-called neurogenic bladder (urinary catheter at time of discharge from hospital necessary)	Patients with radical tumour resection	< 10%	Not documented	27/396 6.8 (4.5…9.3)	n.a.

AS—achievement status: A—target value achieved, B—target value nearly achieved, C—target value not achieved, X—not relevant

CRM circumferential resection margin, *TME* total mesorectal excision, *PME* partial mesorectal excision

[a] 2006 to 2008, excluding patients with prior radiotherapy of the pelvis

[b] Excluding postoperative mortality

[c] For this quality goal no consensus was reached; benchmarks of ≤ 60% and ≤ 40% were discussed

[d] Corresponding to severity grades B and C of the international classification [22]

[e] For tumours of the middle and lower third

[f] For tumours of the upper third

Table 6 Indicators for the outcome quality of therapy: surrogate indicators

Definition of the Working Group Workflow Rectal Carcinoma II [1]				Results Dresden-Friedrichstadt		
No. AS	Quality indicator	Reference group	Quality goal	n/reference group % (95% CI) 2000–2008	2009–2017	*p*
14 A A	Intraoperative local tumour perforation	All patients with primary radical tumour removal and R0 (without neoadjuvant long-course RT/RCT)	(a) Anterior resection (high, low): < 5%	(a) 4/181 2.2 (0–4.4)	(a) 2/139 1.4 (0–3.4)	(a) 0.701
A A			(b) Abdomino-perineal excision: < 10%	(b) 4/47 8.5 (0.2–16.8)	(b) 0/18 0	(b) 0.569
15 A A	R1, 2 resection	All M0 patients with radical tumour removal	< 20%	8/410 R1 = 4 R2 = 4 2.0 (0.6–3.3)	2/320 R1 = 2 R2 = 0 0.6 (0.2–1.8)	0.124
16 A A	Pathohistologic CRM–positive tumour removal	All patients with radical tumour removal in curative intention	< 10%	6/115[a] 5.2 (1.1–9.3)	10/394 2.5 (0.9–4.1)	0.147
17 A A	Quality of mesorectal excision: proportion of incomplete mesorectal excision	All R0 tumour removal with TME or PME	≤ 10% incomplete mesorectal excisions	5/91[b] 5.5 (0.7–10.3)	1/353[c] 0.3 (0–0.6)	0.002

AS—achievement status: A—target value achieved, B—target value nearly achieved, C—target value not achieved

RT radiotherapy, *RCT* radiochemotherapy, *CRM* circumferential resection margin, *TME* total mesorectal excision, *PME* partial mesorectal excision

[a] For 2006 to 2008 only, documentation complete for 115/126 patients

[b] For 2006 to 2008 only, documentation complete for 91/117 patients

[c] Documentation complete for 353/367 patients

Improved key indicators were the local recurrence rate for stage (y)pIII tumours and the anastomotic leak rate in low anastomoses. Furthermore, we could decrease the proportion of abdominoperineal excisions.

The reasons for improvement are complex and multifactorial, with causal factors for singular developments difficult to specify. However, certification as a centre necessitates the implementation of a whole bundle of measures aimed at improving the structure, process and outcome quality. These measures include the regular discussion of all rectal cancer patients in the multidisciplinary team (MDT), quality meetings at a regular base and annual audits [7, 23–25]. Furthermore, every elective operation must be done or supervised by a specialized surgeon, and a certain percentage of patients must be included in registered clinical studies.

Local recurrence

Local recurrence is the key quality indicator of rectal cancer treatment with major improvements within the last decades. The most important step towards an overall local recurrence rate of below 10% was the embryology-based surgical technique with the introduction of total mesorectal excision [26, 27]. This approach was supplemented by extralevator abdominoperineal excision (ELAPE) for very low-lying tumours [28–30]. Both steps were flanked by a critical pathological work-up of the specimens resulting in measurements of the CRM and specimen grading [31–33]. Additionally, the assessment of the tumour in relation to the potential CRM became available with improved MRI techniques [34–36]. These diagnostic measures gave a stimulating feedback to the surgeon. The nomination of specialized surgeons very likely accelerated the improvement of surgical quality [37–39]. Furthermore, multidisciplinary management with (neoadjuvant) radio(chemo)therapy was able to further halve local recurrence rates [40, 41].

The low local recurrence rate for all tumours in our series reflects the implementation of these developments. In particular, the improvement of local recurrences in stage (y)pIII tumours might be a result of regular discussion at our MDT with a tailored approach to these advanced tumours [42]. In the high-risk group, however, this positive trend was offset by a rather high local recurrence rate in stage (y)pII. Local recurrence in the latter stage depends heavily on the proportion of (y)pT4N0 to (y)pT3N0 tumours. In our series, the percentage of (y)pT4N0 tumours was double as high (7.9%) in 2009–2017 than in 2000–2008 (3.8%).

Overall, our recurrence rates compare favourably with the literature (cumulative 5-year local recurrence rate for stages (y)p0–III 4.6% (2009–2017 period) in our series compared with 3.5–10.6% [2, 3, 43]).

Table 7 Indicators for the outcome quality of therapy: definitive indicators

Definition of the Working Group Workflow Rectal Carcinoma II [1]				Results Dresden-Friedrichstadt		
No. AS	Quality indicator	Reference group	Quality goal	n/reference group % (95% CI)		
				2000–2008	2009–2017	*p*
18 A A	5-year local recurrence rate	Radical R0-tumour removal, stages I to III	(a) Overall ≤ 10%	(a) 19[a]/398 5.9[b] (3.2–8.6)	(a) 11[a]/317 4.6[b] (1.7–7.5)	(a) 0.337
A A			(b) Stages y0 and (y)I: ≤ 5%	(b) 5/188 2.9 (0.2–5.6)	(b) 1/133 0.8 (0–1.6)	(b) 0.274
A A			(c) Stages (y)II: ≤ 10%	(c) 2/104 1.0 (0–3.0)	(c) 4/89 8.3 (0.3–16.3)	(c) 0.123
B A			(d) Stages (y)III : ≤ 15%	(d) 12/106 17.8 (8.2–27.4)	(d) 6/96 7.7 (0.8–16.3)	(d) 0.085
B B			(e) So-called high-risk carcinoma (< 12 cm from anal verge, stages (y)II and (y)III) ≤ 10%	(e) 13/149 11.5 (5.0–18.0)	(e) 10/136 10.9 (3.8–18.0)	(e) 0.566
19 B B	5-year overall survival rate	Patients with radical R0-tumour removal Carcinomas ≤ 16 cm from anal verge	(a) Stages y0 und (y)I > 90%	(a) *n* = 188 86.8[c] (81.3–92.3)	(a) *n* = 133 87.9[c] (81.6–94.2)	(a) 0.678
A A			(b) Stages (y)II ≥ 75%	(b) *n* = 104 79.9 (70.1–89.7)	(b) *n* = 89 79.5 (69.1–89.9)	(b) 0.810
A A			(c) Stages (y)III ≥ 55%	(c) *n* = 106 60.7 (49.5–71.9)	(c) *n* = 96 69.4 (58.6–80.2)	(c) 0.207
A A			(d) So-called high-risk carcinoma (< 12 cm from anal verge, stages (y)II and (y)III) ≥ 60%	(d) *n* = 149 70.2 (61.6–78.8)	(d) *n* = 136 73.5 (64.5–82.5)	(d) 0.356

AS—achievement status: A—target value achieved, B—target value nearly achieved, C—target value not achieved

[a] All observed recurrences (including those beyond 5 years; true for both columns)

[b] All percentages represent cumulative recurrence rates, postoperative mortality excluded (true for both columns)

[c] Kaplan–Meier, postoperative mortality excluded, time interval from diagnosis until death or last follow-up (true for both columns)

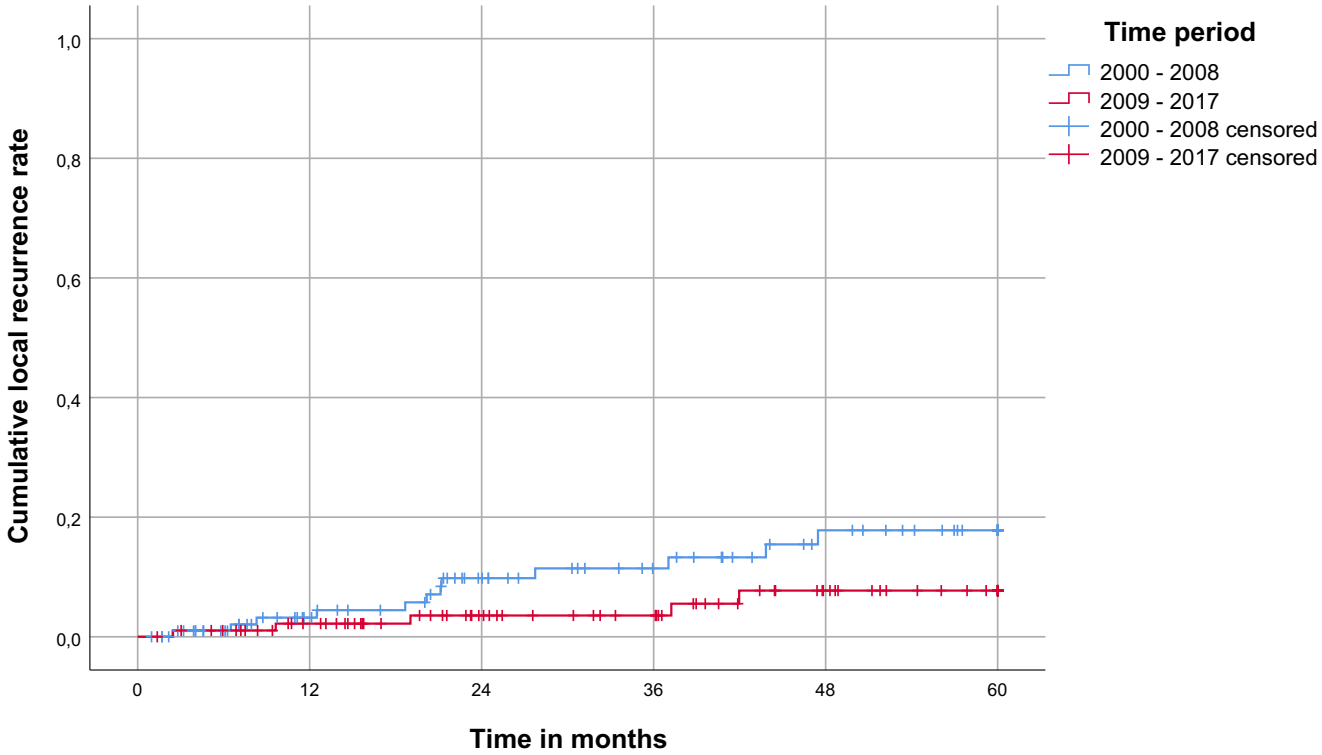

Fig. 1 Cumulative local recurrence rates for UICC stages (y)pIII. Five-year local recurrence rate for time period 2000–2008 (n = 106) = 17.8% and for time period 2009–2017 (n = 96) = 7.7% (p = 0.085). R0-resected patients only, postoperative mortality excluded

Anastomotic leak

The rather high anastomotic leak rate in our previous study induced a permanent discussion at the quality meetings with the successive implementation of measures that lead to stepwise improvement of the leak rate. Amongst these measures were the training of junior surgeons in the handling of stapling devices and the introduction of oral antibiotics in preoperative bowel preparation. Again, the increased case load of the specialized surgeons may also have contributed

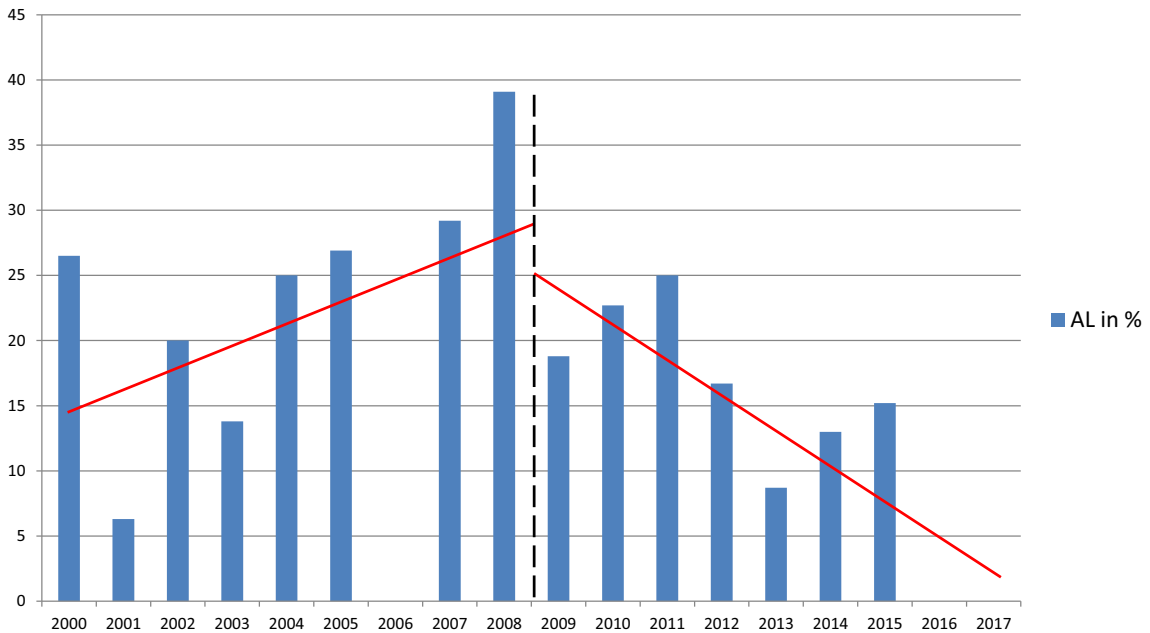

Fig. 2 Annual proportions of anastomotic leaks (AL). The dotted line marks the implementation of the certified centre. The red lines represent linear regression curves for each time period. Note: In 2006, 2017 and 2018, the proportion of AL was zero

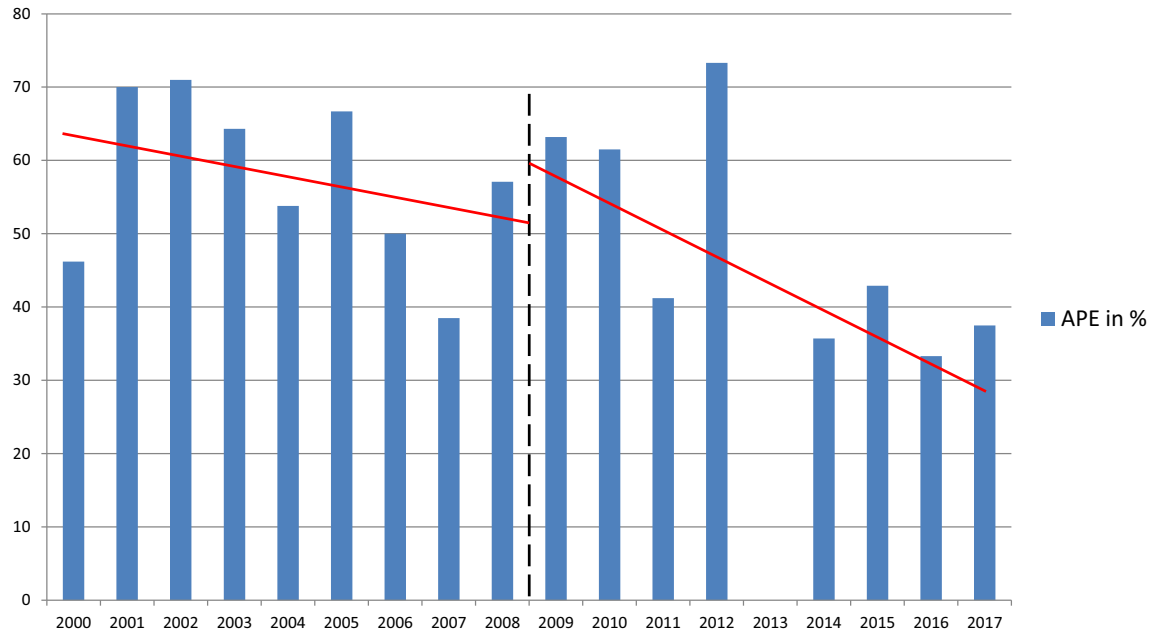

Fig. 3 Annual proportions of abdomino-perineal excisions (APE) for rectal cancers of the lower third. The dotted line marks the implementation of the certified centre. The red lines represent linear regression curves for each time period. Note: In 2013, the proportion of APE was zero

to the success. Reduction of anastomotic leak rates has been reported by various groups that analyzed the benefit of surgical specialization [44, 45].

Proportion APE

A further observation of our study is that the proportion of APE for tumours of the lower third of the rectum could significantly be reduced from 60.0 to 47.1%. Many factors have contributed to this development as the better MRI assessment of tumours of the lower third with high-resolution MRI and criteria according to the Low Rectal Cancer (MERCURYII) study [36] and surgical specialization [38, 46, 47]. Apart from surgical improvements and the oncologic feasibility, there are nowadays functional scores at hand that allow a proper counselling of patients in the decision-making process if an ultralow anterior/intersphincteric resection is discussed against an APE [48]. In our patient cohort, only very few patients declared that a permanent stoma would have been the better choice indicating an appropriate patient selection [49].

Pathologic CRM

The most important surrogate prognostic parameter is the free pathologic CRM [32]. It reflects various parameters of process quality such as exact MRI assessment of the primary tumour (and its lymph nodes) in relation to the mesorectal fascia, the correct decision-making of the MDT with respect to neoadjuvant therapy, the quality of re-assessment after neoadjuvant therapy and the quality of surgery including strategies to extend the operation in areas where the mesorectal fascia is infiltrated [50–53]. It strongly correlates to local recurrence and was chosen as the study endpoint in many important studies [36, 54–56]. Recent studies have reported a pathologic CRM involvement in 5.4 to 10% [51, 57, 58]. In our series, it improved from 5.2 to 2.5% and was in both time periods well below the target value of < 10%.

Survival

Survival data also improved favourably. Especially in stages (y)pIII, overall survival at 5 years improved from 60.7 to 69.4% and was well beyond the benchmark of 55%. The reasons for this development are similar to those given for the improvement of local recurrence rates [59, 60]. Furthermore, trends as advanced liver surgery, peritoneal surface surgery with hyperthermic intraperitoneal chemotherapy (HIPEC), the availability of targeted therapy, radiofrequency ablation (RFA) and selective intracorporal radiotherapy (SIRT) have contributed to improved survival in those patients who develop metachronous metastases. The benchmark was only nearly achieved for stages (y)p0–I. The cause for the latter is not quite clear; only 3 of the 13 events in the 2009–2017 group (n = 133) were tumour-related.

Urinary function

The newly documented quality indicator was urinary function. Data that would allow a reasonable benchmark are rare in the

literature. We noticed that 6.8% of patients were discharged with a permanent urinary catheter (suprapubic and urethral combined), which is well below 10%. Merkel et al. reported a proportion of 5.8% in the most recent patient group of their study [2]. Therefore, the proposed target value seems to be reasonable; however, it does not take T4 tumours with the possible need to remove the pelvic side wall compartment and the ensuing inevitable damage to autonomic nerves into account.

Retrieved lymph nodes

The number of retrieved lymph nodes was amongst the quality goals that were not achieved. While the proportion of patients with ≥ 12 investigated lymph nodes improved considerably in patients after neoadjuvant radio(chemo)therapy, it remained stable for patients without neoadjuvant treatment. Lymph node detection is an indicator of both surgical and pathological quality. As a direct effect of external auditing and measures taken to enhance the number of retrieved lymph nodes, we could indeed detect a continuous improvement in the last few years; however, for the entire 2009–2017 period, it was not sufficient for an achievement or near achievement of the goal.

A number of studies indicate that lymph node retrieval is a prognostic factor with respect to survival [61–64]. There is, however, some controversy in the literature as to the threshold of examined lymph nodes, which was given at a range of 8–9 in some studies [65–67]. The impact of lymph node yield after neoadjuvant CRT is also not yet clear, because preoperative treatment may well result in complete disappearance of lymph nodes [68–70]. For ypN0 cancers, no correlation of survival with number of retrieved lymph nodes was found [67, 71, 72]. We could not detect a significant difference in survival for patients with less than 12 examined lymph nodes compared to the group with ≥ 12 nodes in our series. It may well be that a stable surgical quality can compensate the drawbacks that might result from a limited lymph node retrieval [73–75].

The strength of our study is the completeness and quality of our database, which enabled us to analyze our quality parameters shortly after the set of quality indicators was published in 2007. The availability of a level 3 guideline and its full implementation in daily clinical practice [19] coincided with the certification of our unit as a coloproctologic/bowel cancer centre. Thus, phase 2 of the study reflects the adherence to guidelines and the results achievable with this strategy. The implementation of a certified centre in 2008 can be seen as an "intervention," and the following time period mirrors the effect of it. There are only minor changes in the two patient groups as reflected by the demographic data and a number of quality indicators that characterize the composition of the groups. A direct comparison of the two groups which comprise more than 1000 patients with rectal cancer is therefore warranted and shows an improvement in four quality goals (11.1%) that could now be achieved. Another two quality goals that were not documented before or not applicable were now additionally achieved. This observation adds to the growing body of evidence that treatment of patients within centres improves quality of care [76–78].

The German Cancer Society implemented its own set of quality indicators and benchmarks for annual reporting at the external audits. Likewise, quality indicators were defined within the German Guidelines Colorectal Cancer [79]. Both sets of quality indicators underwent a process of refining over the years with changing items and target values. The 31 quality indicators defined by the German Cancer Society in 2018 reflected only five indicators as defined by the Working Group and used herein. The local recurrence rate at 5 years is not reported. The most recent version of the German Guidelines (released in 2019) defines only 12 quality indicators without target values. There are several reasons for these differences including the coverage of quality indicators that only apply to colon cancer, the definition of more general goals and the function of quality indicators as control instruments. To provide a comprehensive report on rectal carcinoma treatment outcome, we esteem the quality indicators as published by the working group as the most detailed set of parameters available so far. Nevertheless, some quality indicators may need to be reconsidered, such as the R1,2 rate of < 20% or the inclusion of the distance of the tumour to the mesorectal fascia in pretherapeutic MRI. It is, however, beyond the scope of this study to provide suggestions for change, because for that a formal consensus process based on a meta-analysis for each item would be needed.

While the German approach to higher specialization is via voluntary certification, there are some European countries that implemented centralization by administration and auditing on a national/regional level. Reports from these countries, namely Sweden, Norway, Netherlands and Spain (Catalonia), show a permanent improvement in a number of quality indicators, especially regarding survival, local recurrence, negative CRM, use of neoadjuvant treatment, discussion at MDTs and mortality [78, 80–83]. For local recurrence, a decrease at 5 years on a national level from 8.7 to 5.0% was recently reported from Sweden [80] and from 14.5 to 5.0% from Norway [83]. A voluntary training program in Spain also resulted in a 5-year local recurrence rate of 4.7% [84].

While these data underline the benefit of centralization, it has recently been questioned with respect to German cancer centres. Vogel did not find factors associated with anastomotic leak reflected in the subset of structure and process parameters of the data entry form [85]. Likewise, Ghadban et al. could not detect improvements in several aspects of morbidity on a national level despite the annual numeric increase of certified bowel cancer centres [86]. However, they used administrative data which were not based on a dedicated cancer

registry or structured audit. The quality of these data is therefore questionable [87].

Our study reveals some limitations that need to be discussed. First, although based on prospectively collected data, the study is retrospective in nature. However, the inclusion of all consecutive patients, the high follow-up rate and the assessment by means of predefined quality indicators render the results valid for general conclusions. Second, during the study period, four editions of the TNM classification were in operation. Apart from a number of subclassifications which were of no relevance for our study, there were changes regarding the classification of small perirectal tumour deposits. Whereas these deposits were classified as T3 if smaller than 3 mm (5th ed.) or if irregular in shape (6th ed.), they were classified as lymph nodes (N1c) in the 7th and 8th editions [11–13, 21]. Therefore, some patients were classified N positive in the recent group with the resulting stage migration. The magnitude of affected patients, however, is only in the range of 1% (2 patients out of 317 resected patients without distant metastases). Third, the complexity of the analyses and the long time period make the study liable for confounding. Whereas we displayed patient, treatment and pathological characteristics of the two cohorts and used the predefined numerators and denominators to maximize comparability, additional potential confounders may bias the results. These includes more detailed characteristics that were not included in the database like performance status or co-morbidities, as well as diagnostic and treatment measures that evolved over time independently of the centralization of patient care. The latter include a more comprehensive staging by high-resolution MRI, refined surgical techniques as ELAPE, the introduction of new strategies in the management of metachronous metastases and the start of a screening colonoscopy program in 2002. However, the implementation of these new developments is likely to be accelerated by the multidisciplinary teamwork of a certified centre.

Conclusion

Implementation of clinical pathways within a certified centre is associated with an improvement in the quality of care for rectal cancer patients. Using a set of 36 predefined quality goals, six more quality goals could be achieved as compared with a previous study period. Improvement was detected in complex indicators such as the local recurrence rate in stage (y)pIII patients, anastomotic leak rate in low anastomoses and the APE rate for low rectal cancers. Certification as a specialized centre therefore signals high standard of care.

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