CHAPTER 4

Benchmarking clinical outcomes in elective colorectal cancer surgery: the interplay between institutional reoperation- and mortality rates

D.Henneman
J.W.T. Dekker
M.W.J.M. Wouters
M.Fiocco
R.A.E.M. Tollenaar

European Journal of Surgical Oncology 2014;40(11):1429-35.

ABSTRACT

Background: "Unplanned reoperations" has been advocated as a quality measure in colorectal cancer surgery as it is correlated with complications and postoperative mortality at a patient level. However, little is known about the relation between reoperation rates and postoperative mortality rates at a hospital level.

Methods: Data were derived from the Dutch Surgical Colorectal Audit 2009-2012 database. Hospitals with significantly higher and lower reoperation rates than average were identified and grouped accordingly. Postoperative mortality rates were compared between the groups.

Results: Some 28,667 patients who underwent elective colorectal cancer resections in 92 hospitals were analyzed. Fourteen hospitals had significantly higher (mean 14.6%) adjusted reoperation rates than average (10%), 20 had lower (5.3%) rates than average. Adjusted mortality rates were similar in groups with high reoperation rates and the majority cohort (3,5-3,2%) and significantly lower in hospitals with low reoperation rates (2,3%). However, individual hospitals with relatively high reoperation rates had low mortality rates and vice versa.

Conclusions: Reoperation rates after elective colorectal cancer resections varied. Hospitals with significantly higher reoperation rates than average did not have higher mortality rates. The group with lowest reoperation rates also had lower postoperative mortality rates; however, this did not apply to all hospitals in the group. In conclusion, 'reoperations' seems suitable as benchmark information to hospitals but less suitable to detect poor performers. Best practices should be identified as hospitals with both low reoperation- and mortality rates.

INTRODUCTION

There is an increasing demand for transparency of information that aids in rating hospitals' performance, both from policy makers and patients. At the same time, clinical outcome registries are becoming more widespread, helping caregivers to improve by generating benchmark information[1]. As a result, measuring and comparing quality of surgical care has become increasingly important in the last decades, and in several quality improvement projects, quality indicators have been defined[2]. Quality indicators measure a certain aspect (structure, process, or outcome[3]) of care and are compared against a standard or average. They may be used for internal purposes (feedback and quality improvement) as well as external purposes (making public of information on hospital performance).

Colorectal surgery is associated with relatively high surgical postoperative morbidity rates[4] and accounts for a disproportionate share of reoperations within the spectrum of general surgery[5]. "Unplanned reoperation" is a well-accepted quality measure for colorectal surgery. In the Netherlands, it is a compulsory quality indicator collected by the Dutch Healthcare Inspectorate. Many publications have concluded that the measure is suitable as a quality measure because it is a factor independently associated with other adverse outcomes such as prolonged hospital stay and postoperative mortality[5-7]. Obviously, this is because of the close relationship between reoperations and surgical complications such as anastomotic leak or haemorrhage. An advantage over postoperative mortality as an outcome indicator would be that in elective surgery, postoperative mortality is less frequent and may therefore not discriminate worse performing hospitals from better performing hospitals. On the other hand, timely reoperations in case of complications may save the patients' life and higher reoperation rates may in fact be associated with lower

postoperative mortality rates[8]. Although on a patient level the association between reoperations and postoperative mortality is well established, little is known about the relation between reoperation rate and postoperative mortality rate at a hospital level.

This study aims to investigate the value of reoperation rates as a marker for quality of care in elective colorectal cancer surgery by exploring hospital variation, the presence of hospitals with significantly lower or higher reoperation rates than average (low and high outliers) and the association with postoperative mortality rates.

MATERIALS AND METHODS

Data

Data was derived from the Dutch Surgical Colorectal Audit (DSCA), a nationwide clinical registry and continuous quality improvement project in which a wide range of variables concerning patient and disease-specific details, diagnostics, treatment, and outcomes are collected prospectively. The dataset is disease-specific for colorectal cancer and shows a case ascertainment of >95% and high accuracy level on comparison against the Netherlands Cancer Registry (NCR) dataset[9,10].

Patients

For this study, no ethical approval or informed consent was required under Dutch law. All patients undergoing a surgical resection for primary colorectal cancer between the 1st of January 2009 and 31st of December 2012, and registered in the DSCA before March 15th 2013, were evaluated. Minimal data requirements to consider a patient eligible for analyses were information on tumor location, date of surgery, and mortality. In total, 35,749 patients were eligible.

Patients undergoing non-elective surgery (n=5546), local tumor excisions (n=393), and surgery for multiple synchronous colorectal tumors (n=1122) were excluded from analysis. The total number of patients diagnosed with stage I-IV colorectal cancer in the Netherlands during the study period was 52,046; increasing from 12,423 in 2009 to 13,408 in 2012[11].

Outcomes

Primary outcomes

Reoperations were defined as unplanned operations within 30 days from the primary operation. Postoperative mortality was defined as death within 30 days from the primary operation and/or during the index admission.

Statistical analysis

Categorical variables were compared using a chi-square test, and continuous variables using the independent samples t-test. A 2-sided $p \leq 0.05$ was considered statistically significant.

Potential, clinically relevant risk factors for adverse events were selected from the dataset and logistic regression models were employed to estimate expected outcomes. The variables age, gender, ASA score, Charlson comorbidity index, BMI, TNM stage, neoadjuvant therapy, type of index procedure and extended resections were incorporated in the model. Data were aggregated at a hospital level and observed-to-expected rates were multiplied with the average outcome in the study population in order to obtain casemix-adjusted outcomes for each hospital.

Hospital variation in adjusted reoperation rates is illustrated in a funnel plot, showing the overall average reoperation rate with its 95% confidence limits, based on a Poisson distribution, varying in

relation to the population size. The funnel plot was used to identify hospitals with reoperation rates that were significantly higher or lower than the national average (high and low outliers, hospitals that are outside the 95% confidence limits). Hospitals were grouped accordingly (higher reoperation rate than average; lower reoperation rate than average; and the majority cohort with reoperation rates within the 95% confidence limits). Outcomes were compared between these groups.

Also after aggregating the data on a hospital level, comparison of outcomes between the three hospital groups was performed. This was done by applying the analysis of variance (ANOVA). Pairwise comparisons between the hospitals groups were carried out by using one-way multiple comparisons with Bonferroni correction. All statistical analyses were performed in PASW Statistics, version 20 (Chicago, IL, USA).

RESULTS

Some 28,667 patients undergoing elective colorectal cancer resections were included in the analysis. Patient characteristics are displayed in table 1. The average reoperation rate was 9.7%, ranging from 0.7% to 20.9% among the 92 hospitals.

Outlier hospitals concerning reoperation rates

Adjusted reoperation rates for all hospitals are shown in figure 1. Fourteen hospitals had adjusted reoperation rates that were higher than average (two hospitals had similar caseloads and reoperation rates and cannot be distinguished from each other in this figure). Twenty hospitals had adjusted reoperation rates that were lower

Table 1. Patient-, tumor- and treatment characteristics.

characteristic		**n**	**%**
gender	male	15,839	55.3%
Age	mean, SD	70	11
BMI	mean, SD	26	4.4
Charlson comorbidity index	0	15,584	54.4%
	1	6,295	22.0%
	2	3,954	13.8%
	3 or higher	2,834	9.9%
ASA score	I - II	22,314	77.8%
	III	5,687	19.8%
	IV - V	314	1.1%
	unknown	352	1.2%
TNM stage	X/missing	1,049	3.7%
	1	6,738	23.5%
	2	9,566	33.4%
	3	8,629	30.1%
	4	2,685	9.4%
tumor location	right colon	8,912	31.1%
	transverse/left colon	2,889	10.1%
	sigmoid colon	7,481	26.1%
	rectum	9,385	32.7%
neoadjuvant therapy	none	20,655	72.1%
	short course RT	4,390	15.3%
	CRT	3,014	10.5%
	other	608	2.1%
procedure	ileocecal resection	233	0.8%
	right hemicolectomy	8,937	31.2%
	transverse colectomy	574	2.0%
	left hemicolectomy	1,791	6.2%
	LAR/sigmoid colectomy	13,212	46.1%
	subtotal colectomy	396	1.4%

Table 1. Patient-, tumor- and treatment characteristics. (continued)

characteristic		n	%
	APR	2,923	10.2%
	panproctocolectomy	163	0.6%
	other	438	1.5%
extended resection	locally advanced tumor	2,419	8.4%
	metastasectomy	849	3.1%

BMI: body mass index; SD: standard deviation; ASA: American Society of Anesthesiologists; TNM: tumor, node metastasis classification (5th edition); RT : radiotherapy; CRT: chemoradiotherapy; LAR: low anterior resection; APE: abdominoperineal resection

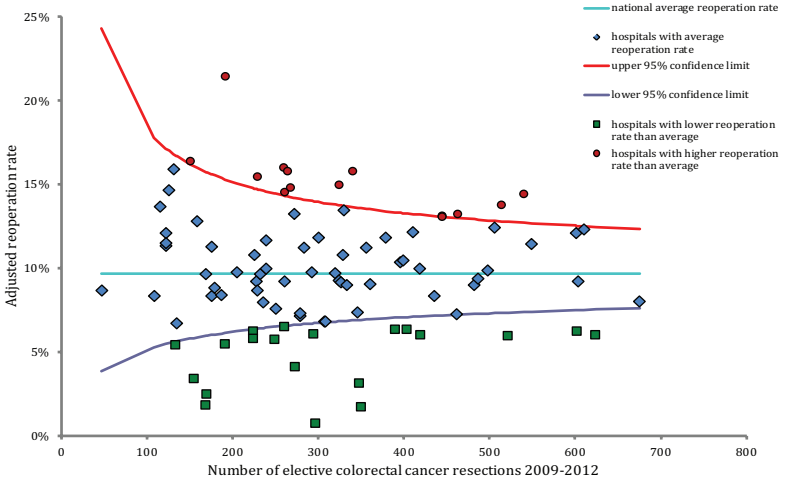

Figure 1: Funnel plot of risk-adjusted reoperation rates in 92 hospitals in the Netherlands

Table 2. stoma rates and outcomes for patients operated in hospitals with high, average and low reoperation rates (as identified in figure 1). * percentage in relation to all patients in the group ** percentage in relation to all re-interventions (reoperations and percutaneous re-interventions)

		High reoperation rates	Average reoperation rates	Low reoperation rates	p
patients		4691	17410	6566	
anastomosis	without fecal diversion	3012 (65.4%)	11298 (67.2%)	4321 (66.8%)	0.094
	with fecal diversion	678 (14.7%)	2232 (13.3%)	899 (13.9%)	
	no anastomosis	914 (19.9%)	3279 (19.5%)	1246 (19.3%)	
reoperations	any	685 (14.6%)	1743 (10%)	350 (5.30%)	<0.001
anastomotic leak		325 (6.9%)	831 (4.8%)	158 (2.4%)	<0.001
bleeding		35 (0.7%)	98 (0.6%)	25 (0.4%)	0.034
ileus		75 (1.6%)	164 (0.9%)	37 (0.6%)	<0.001
fascial dehiscence		82 (1.7%)	194 (1.1%)	42 (0.6%)	<0.001
iatrogenic bowel injury		23 (0.5%)	62 (0.4%)	9 (0.1%)	0.003
bladder/urethral injury		6 (0.1%)	17 (0.1%)	2 (0%)	0.171
other		98 (2.1%)	291 (1.7%)	62 (0.9%)	<0.001
negative relaparotomy		12 (0.3%)	14 (0.1%)	3 (0.0%)	<0.001
postoperative mortality		160 (3.4%)	559 (3.2%)	155 (2.4%)	0.001
percutaneous reinterventions *		92 (2.0%)	206 (1.2%)	74 (1.1%)	<0.001
proportion of percutaneous reinterventions**		92/777 (11.8%)	206/1945 (10.6%)	74/424 (17.6%)	<0.001
blood transfusion postoperatively		658 (14.8%)	2540 (15.8%)	684 (11.5%)	<0.001
length of stay	> 14 days	981 (21.2%)	3430 (20.1%)	1023 (15.8%)	<0.001

than average. The remaining hospitals had reoperation rates that were within the 95% confidence limits (the 'majority cohort').

Table 2 compares outcomes between the groups (high and low rates and the majority cohort as identified in the funnel plot in figure 1). As reoperation rates may be influenced by the construction of a an anastomosis and/or a defunctioning stoma, anastomosis- and stoma rates are displayed as well. The proportion of patients receiving an unprotected primary anastomosis, an anastomosis with a diverting stoma, or an end-colostomy did not differ significantly between the groups. The majority cohort had slightly but significantly lower rates of laparoscopically completed procedures.

Most reoperations were performed for anastomotic leaks. For all indications except bladder- or urethral injury, reoperation rates were different between the groups. The number of registered negative reoperations was very small, but did differ between the groups and was highest in the group with high reoperation rates.

Postoperative mortality

Unadjusted postoperative mortality rates were 3,4% in hospitals with high reoperation rates, 3,2% in the majority cohort and lower (2,4%) in hospitals with lowest reoperation rates. Figure 2 displays postoperative mortality rates, adjusted for case-mix, for the three hospital groups, based on the aggregated data on a hospital level. The group of hospitals with high reoperation rates had an adjusted mortality rate of 3,5%. The majority cohort had an adjusted postoperative mortality rate of 3,2% and the group with low reoperation rates had an adjusted postoperative mortality rate of 2,3%. The ANOVA showed a significant difference between the groups ($p=0.009$). The group with low reoperation rates had significantly lower mortality rates than the group with high reoperations ($p=0.022$), and also than the majority cohort ($p=0.019$). Mortality rates were not significantly

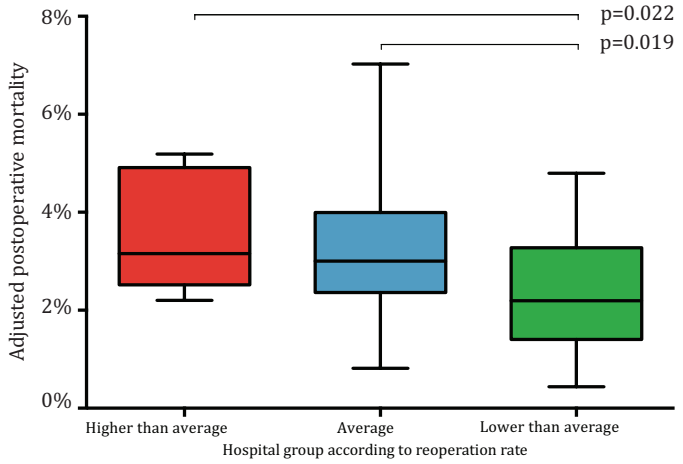

Figure 2: Risk-adjusted postoperative mortality in hospitals grouped according to reoperation rates (higher than average, average and lower than average). P values are derived from one-way multiple comparisons with Bonferroni correction.

different when comparing hospitals with high reoperation rates and the majority cohort.

Postoperative mortality: individual hospitals

The funnel plot in figure 3 displays postoperative mortality rates, adjusted for casemix, for all 92 hospitals marked with different colours corresponding with high or low reoperation rates or the majority cohort. It shows a variation between 0,5% and 7% postoperative mortality around the average of 3%. Figure 2 showed that the hospitals with low reoperation rates have lowest mortality rates when compared as groups of hospitals, figure 3 shows that individual hospitals with low reoperation rates had mortality rates that were higher than some hospitals with high reoperation rates. Also, some hospitals with high reoperation rates had postoperative mortality rates that

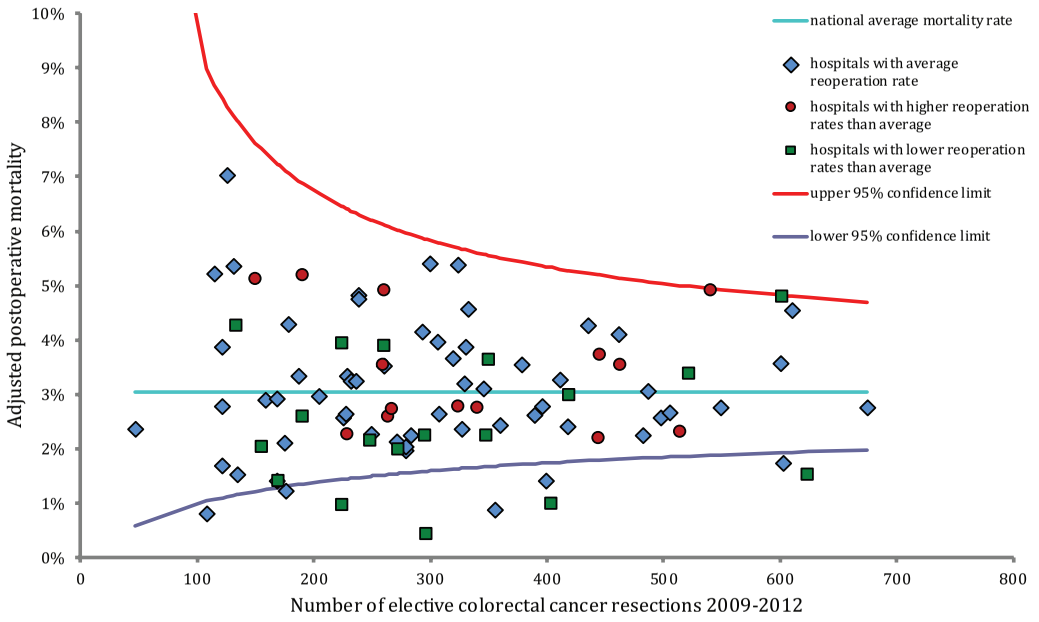

Figure 3: Funnel plot for risk-adjusted postoperative mortality rates. Hospitals are marked according to reoperation rates (higher than average, average and lower than average).

were as low as 2%. Nine hospitals had postoperative mortality rates that were significantly lower than average, 5 of which were hospitals with reoperation rates within the 95% confidence limits.

The low reoperation group also had significantly lower rates of percutaneous re-interventions than the other groups (table 2). However, the ratio between percutaneous re-interventions and all re-interventions (reoperations and percutaneous procedures altogether) was significanlty higher in the low reoperation group, with 17.6% of all re-interventions being a percutaneous procedure.

The high reoperation group had a relatively high percentage of laparoscopy in case of a reoperation (10.7% of all reoperations, vs. 6.0 and 6.6% in the majority cohort and the low reoperation rate groups).

DISCUSSION

This study evaluated the value of reoperation rates as a marker of surgical quality of care in colorectal cancer surgery. A large hospital variation was found, with many hospitals having significantly higher or lower reoperation rates than the national average. The group of hospitals with high reoperation rates had similar outcomes as the majority cohort with reoperation rates within the 95% confidence limits. The group of hospitals with low reoperation rates had a lower rate of postoperative mortality. However, when comparing all hospitals on an individual basis, lower reoperation rates than average could go together with relatively high mortality rates, although no hospitals had mortality rates that were significantly higher than average. Merkow et al., analyzing over 20,000 elective colorectal surgery cases from the American College of Surgeons NSQIP dataset, found a large hospital-by-hospital variation (ranging from 0% to

38%) in reoperation rates with the presence of many high and low outlier institutions[12]. Because of this hospital variation, the authors conclude that reoperation rates are valuable as mirror information for institutions participating in a quality improvement project. Burns et al. report national reoperation rates after colorectal resections in England derived from the Hospital Episode Statistics database[7]. These authors found a large variation in reoperation rates between hospitals/trusts, using a database with various pathologies and indications for colorectal resections, both emergent and elective. One study demonstrated the correlation between reoperation- and mortality rates after colorectal resections on a hospital level[13]. This study found a weak correlation between reoperation rate and mortality rate on the whole. Importantly, for individual hospitals the performance on reoperation rate could be the exact opposite of the performance on postoperative mortality: one high mortality outlier trust had a lower reoperation rate than average and one low mortality unit had a reoperation rate above the 2 standard deviation limit.

Our study builds on these publications, confirming the large hospital variation and the presence of outlier institutions. We showed that lower reoperation rates than average are, on the whole, associated with a lower postoperative mortality. However, hospitals with higher reoperation rates than the national average perform similarly to the institutions with average reoperation rates when it concerns postoperative mortality. We confirm the findings of Almoudaris et al[13] that group outcome patterns do not apply to all individual hospitals in the group (in this case, reoperation rate outlier status).

The 30-day reoperation rate we found in this study is relatively high when compared to the rates in the abovementioned American and English cohorts. Differences in patient populations may prohibit direct comparison, however the reoperation rate of 5.9% in the subset of elective colorectal cancer resections that Burns et al. describe

still compares favourably to the 9.7% we found. The single-centre series of van Westereenen et al., reporting a 12.5% reoperation rate, is the only publication from the Netherlands we can use as a reference, but this study included benign indications as well[14]. Perhaps the differences between our findings and the English publication reflect differences between a clinical registry and administrative data.

The present study focused on elective surgery. We also did a sub analysis on the patients undergoing urgent/emergency resections (n=5546). In this group, the reoperation rate was slightly higher than in the elective group (12.2% vs 9.8%), but postoperative mortality was three times higher in this group (9.3% vs 3%). Although hospital variation in reoperation rates and mortality rates proved wide (reoperations: range 0-27%; mortality: range 0-29%), it is hard to draw conclusions concerning individual hospital performance and correlation between each other, as numbers break down quickly and confidence intervals become extremely wide in this relatively small cohort. Future research on a larger (international) database may focus on this subject.

There are some limitations to this study. The data is self-reported, so selection bias cannot be completely excluded. However, the dataset is highly detailed and validated against data from the Netherlands Cancer registry. Moreover, the relatively high registered reoperation rates do not suggest under-reporting of this outcome. Unfortunately, our database only contains information concerning patients who underwent surgical resection of colorectal cancer. The percentage of patients selected for surgery may vary per region or hospital. In future research, requiring linkage of Cancer Registry data to Audit data, it would be interesting to study whether differences in the preoperative selection process are related to the found variation in outcomes.

Another limitation concerns the risk adjustment. The DSCA dataset was designed with the objective of performing adjustment for differences in casemix between hospitals, and relevant risk factors were included in the dataset at an early stage of development of the dataset based on a Delphi method by an expert panel[15,16]. The included variables are therefore mainly risk factors for mortality which may or may not be the same as risk factors for reoperations- although from a clinical point of view they seem relevant for this outcome, too, and compare with the confounders adjusted for in other publications[6,7,12,17]. Although adjustment was made for many variables, a large variation in outcomes between hospitals remains after adjustment; which may be due to true differences in performance as well as possible limitations of the adjustment model. Thirdly, we conclude that high outliers have mortality rates similar to hospitals with reoperation rates within the 95% confidence limits. This only concerns 30-day and/or in-hospital mortality, whereas reoperations may be associated with a higher risk of 1-year mortality[14]. It is unknown to what extent hospital reoperation rates correlate with longer-term mortality rates.

Hospitals with lowest reoperation rates had a relatively high rate of percutaneous reinterventions compared to the two other groups. This may be due to less severe complications or due to other factors such as improved radiological support or a better selection for percutaneous solutions for surgical complications in these hospitals.

"Reoperation" is a measure that reflects many factors in the postoperative process. There are, however, no guidelines concerning return to the operating room. Decisions regarding postoperative management remain at the surgeon's discretion and surgeons may differ in their threshold for performing a reoperation on a patient with a suspected surgical complication. As a timely reoperation may be an effective measure to rescue a patient with a postoperative complica-

tion, a low threshold for a reoperation is not necessarily a reflection of a low quality of surgical care. A problem that may be associated with this outcome, is that the threshold for reoperation may rise when it is being used as an outcome indicator. For the individual patient, it may have dramatic results when the surgeon does not re-operate or waits too long, as a timely intervention may result in better outcomes[18]. Our study shows that some individual hospitals with high reoperation rates have relatively low postoperative mortality rates, well below the national average. Some majority cohort hospitals even had mortality rates that were significantly lower than average. Apparently, the surgical teams in these hospitals have a good ability to rescue patients with a surgical complication. On the other hand, a high reoperation rate puts a low mortality rate in perspective: clearly the low mortality comes at a high cost. Conversely, some hospitals with significantly lower reoperation rates than the national average had quite high postoperative mortality rates. Best practice should be sought in hospitals with both low reoperation and mortality rates. Another valuable outcome indicator relating to both complications and postoperative mortality is "failure to rescue (FTR)", defined as the mortality rate among patients with a serious complication[19]. Almoudaris et al. introduced the outcome measure "failure to rescue-surgical (FTR-S)" : the mortality among patients that underwent a reoperation[20], reflecting the ability of a surgical team to effectively manage surgical complications. They found that high-mortality hospitals were characterized by high FTR-S rates rather than high reoperation rates. For the DSCA, FTR is defined as the mortality rate among patients with a serious complication (leading to a reintervention or a prolonged in-hospital stay)[21]. Regardless of the definition, such a FTR measure takes away possible hesitations to intervene in case of a surgical complication, as a successful intervention will merely lower

FTR rates. In our opinion, this is an important outcome measure to consider alongside the outcome indicator reoperation rate.

In conclusion, the results of this study show a wide hospital variation in reoperation rates after colorectal cancer resections in the Netherlands. Although several high outlier institutions could be identified, this could not be linked to worse mortality rates. Conversely, hospitals with low reoperation rates did perform better on other outcomes and it can be concluded that the outcome is suitable as feedback information to hospitals in quality improvement projects but not to stigmatize hospitals with high reoperation rates as poor performers. Best practices with regard to clinical outcomes should be identified as hospitals with both low reoperation rates and low mortality rates.

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