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Learning from best performers in colorectal cancer surgery

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Learning from best performers in colorectal cancer surgery

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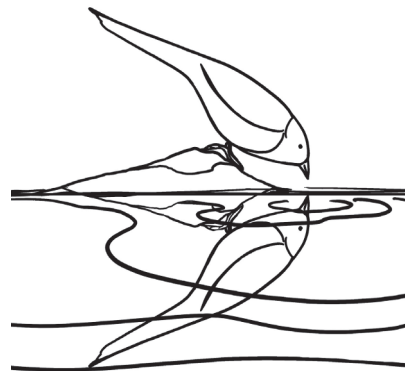
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Chapter 1

Introduction and outline of thesis



Colorectal cancer is one of the most common diagnosed cancers worldwide; in 2016 the incidence in the Netherlands was 15,121 patients.^{1,2} The cornerstone of treatment of colorectal cancer is a surgical resection, completely removing the tumor, the major vascular pedicle and the lymphatic drainage basin of the affected segment. Colorectal surgery has high rates of postoperative morbidity, a risk of mortality and reduced quality of life. In most patients restoring the bowel continuity can be accomplished by making an anastomosis. However, a (temporary) colostomy or diverting ileostomy can be necessary.³⁻⁵

In 2007 the Dutch Cancer Society formed a 'Quality of Cancer Care' taskforce, with the aim to evaluate and improve quality of cancer care. This taskforce advised that complex or high-risk cancer procedures should be provided in a specialized setting, with the right infrastructure, sufficient volume and adequate expertise. Furthermore, outcomes should be monitored and fed back to caregivers. This led to the introduction of a minimum volume standard of 50 colorectal and 20 rectal resections per year, and norms for the degree of specialization and certification of surgical oncologists and gastro-intestinal surgeons. In addition, a nationwide clinical audit including all patients undergoing a resection for primary colorectal cancer in the Netherlands was initiated by the Association of Surgeons in the Netherlands.⁶ The data collection for the Dutch Surgical Colorectal Audit (DSCA) started in 2009. Within two years all hospitals in the Netherlands participated. Gradually, due to the multidisciplinary facets of colorectal cancer care the DSCA expanded, involving not only surgeons, but also radiotherapists, oncologists and pathologists. In 2017 the DSCA changed its name into the multidisciplinary Dutch Colorectal Audit (DCRA).^{5,7} The objective of this clinical audit is to improve colorectal cancer care by:

- 1) feeding back benchmarked process and outcome information to clinicians,
- 2) nationwide insight and evaluation of quality of care, and
- 3) learning from 'best practice'.

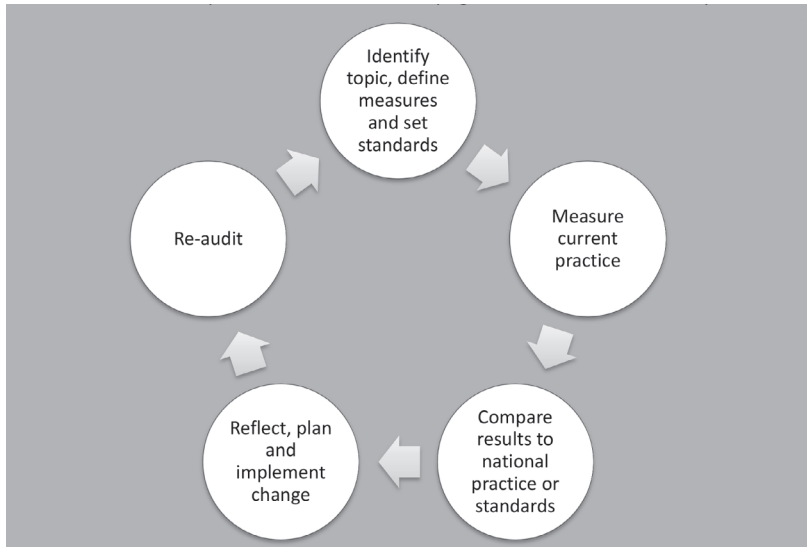
The focus of this thesis will be on reflection and planning change, by trying to find determinants for best performance.

Feedback information

The first aim of a clinical audit is feeding back data to clinicians. At this moment the DCRA provides disease specific feedback information on a set of process and outcome measures. A scientific committee, in which all disciplines involved in colorectal cancer care are represented, develops the set of quality indicators, which is updated on a yearly basis. Participation in the audit is one of the quality standards of the Association of Surgeons in the Netherlands and subsequently all Dutch colorectal surgeons are obliged to register all their patients undergoing surgery for primary colorectal cancer in the DCRA. The DCRA is shown to be very complete, with high accuracy of data items.^{5,8} The surgical teams receive weekly updated feedback on their performance, which is presented online, accessible through a secured website for each hospital. The feedback information includes process and outcome indicators and is compared to the national average, corrected for differences in patient and tumor characteristics (case-mix) between hospitals. This gives surgical teams the possibility to monitor their performance in comparison to other hospitals and improve where necessary.^{5,9-12} However, the first issue with reaching an effective audit cycle (Figure 1) is that timely feedback is dependent on timely registration and completeness of data. Not every hospital is able to provide adequate data-management to ensure an effective audit cycle for their clinicians. The second problem with reaching an effective audit cycle is that the step in which the teams in the hospitals reflect on the data and plan the implementation of change is left to the hospitals themselves, and the determinants of better performing hospitals are not well known. In addition to self-reflection, the Association of Surgeons of the Netherlands (ASN), initiated an 'audit board', a team of experts visiting hospitals with unfavorable results, to give advice and help them start improvement projects. The audit board uses a checklist with quality aspects, but could use more specific variables as input for this checklist. Hospitals eager to improve are often in the dark about the aspects of care that could be improved and whether these are likely to be effective.

Figure 1.

A typical clinical audit cycle consists of: defining relevant measures and set standards where possible, measure current practice, compare results of practice to national practice or standards, reflect, plan and implement change and re-audit.¹³ Disease specific clinical audits have been introduced over the last years in several countries trying to reach an effective audit cycle.^{5,9-12}



Nationwide insight and evaluation

The second aim of the audit is nationwide evaluation of processes and outcomes. This national evaluation is done by outcomes research using the audit data. Outcomes research focuses on variations in care processes and outcomes between providers to identify targets for improvement. Yearly the results are published in the annual report of the DCRA and throughout the year in (inter)national peer-reviewed journals. These publications showed variation in processes (e.g. guideline-adherence)^{14,15}, outcomes (e.g. mortality)¹⁶ and determinants for this variation (hospital and patient characteristics).^{16,17} By showing variation between hospitals in structure, care processes and outcomes, the disease specific clinical audit facilitated a shift from volume based to quality driven discussions on how to improve colorectal cancer care.¹⁸ The nationwide quality information of the DCRA has caught interest of, among others, the Dutch Health Care Inspectorate, patient organizations and

health insurance companies. In an era of increased accountability¹⁹, all these organizations are demanding transparency of hospital-specific process and outcome information. In 2011 the Association of Surgeons in the Netherlands agreed on a process in which outcomes of the surgical departments in the DCRA became publicly available in a stepwise fashion, which was realized in 2014.⁷ This transparency of outcomes could make it possible for policymakers to monitor quality of care²⁰, and for health insurers to 'pay for performance'. In the future it might guide patients to choose in which hospital they prefer to be treated. Although patients have reported to use hospital reputation, previous hospital experience or waiting time as most important in choosing which hospital they want to be treated,²¹ Marang-van de Mheen et al showed in a 'hospital choice experiment' that patients would in fact use quality information on outcomes in a hospital, when available.²² However, transparency of data also has its risks. It could lead to avoiding high-risk surgery and collection of inaccurate data (gaming).²⁰ In the Netherlands, since the start of the audit, no signs of risk averse behavior were found.⁷ Furthermore, external data verification showed that national data are accurate.⁸

Learning from best practice

Finally, the third aim of the audit is improving care by learning from 'best practice'. The term 'best practice' shows 10682 hits on pubmed, of which 1151 articles were published in 2017. The term 'best practice' is used in different ways; it can describe just one process, or combination of processes leading to good results on one outcome or a combination of outcomes. In this thesis 'best practice' is defined as the combination of processes leading to best overall outcomes. In literature, several 'best practices' have been proposed, for example the 'central line bundle' leading to less bloodstream infections²³ and the 'colorectal care bundle' reducing surgical site infections²⁴. A more comprehensive approach is the 'Enhanced recovery after surgery (ERAS)' protocol defining a combination of processes leading to best outcomes in colorectal surgery. At the start of the DCRA (then DSCA), ERAS was implemented in most of the Dutch hospitals and showing high compliance rates²⁵. Though still substantial variation in outcomes was observed between hospitals with an implemented ERAS protocol.⁵ However, it has been shown

complicated to get the same effect of implementing these combinations of processes in different hospitals, suggesting that difference in adherence and context may play an important role.²⁶ This context (a combination of teamwork, communication and attitude) is also suggested to be of importance in the effect of another example of a 'best practice' checklist, the surgical safety checklist (SURPASS). SURPASS is associated with reductions in complications and mortality in general surgery.²⁷ So, although these different projects in combination with scientific research show us several steps to 'best practice', a combination of processes essential to achieve overall best performance in colorectal cancer care is not found yet.

To learn about 'best practice' from best performing hospitals, the aim of this thesis was to first identify best performing hospitals and then investigate which structural, procedural and contextual factors are correlated with best performance in these hospitals.

WHAT IS BEST PERFORMANCE?

Identifying best performance

One of the great challenges in identifying best performing hospitals is that it requires the question on what is considered 'best performance' to be answered. In previous literature more than 766 different definitions of outcome measures are described for colorectal cancer²⁸ which may all be the quality indicators for a certain aspect of care. One hospital could perform well on the outcome '30-day mortality', while at the same time performing badly on the outcome 'radical resection'. To measure the quality of the whole chain of processes, a combination of outcomes might be more suitable. 'Textbook outcome' is suggested as a composite measure combining several outcomes in one comprehensive indicator: in-hospital and 30-day survival, negative resection margins, no need for reintervention, no ostomy, no adverse outcomes and a hospital stay of less than 14 days.²⁹ This combination was chosen to optimize both short-term as well as long-term outcomes. However, a composite measure has some disadvantages.^{30,31} First of all, which combination of outcomes defines best performance is not clear, there still is an ongoing search for a definition of a core outcome set in colorectal cancer care.³² Second, combining

a core outcome set in one composite measure gives the same importance to every single outcome, while for example in textbook outcome, from a patients' perspective, mortality is probably more important to avoid than a hospital stay of more than 14 days. Third, outcomes could be related to each other on patient level.³³ E.g., in TO, if a patient does not have an adverse outcome, there is no need for reintervention. Furthermore Hofstede et al show that it is very important to account for the difference in association on patient and hospital level.³³ So, in this search for a core outcome set it is important to take into account how the outcomes differ in importance and how they are related to each other on patient level. Is it possible to find a combination of indicators defining best performance?

Besides these questions regarding the concept of 'best performance', there are also methodological challenges in identifying best performance. Reliability of the data is very important. Internal and external verification showed the DCRA to be very accurate and complete.^{5,8} Furthermore, previous studies demonstrated the importance of the adjustment for case-mix in the comparison of outcomes between hospitals.^{17,34} Last, comparison of some outcomes may to a large extent be depending on chance.³⁴⁻³⁶ Is it thus possible to reliably identify a hospital performing better than the other? To find an answer to this question this thesis explores which (combination of) measure(s) can reliably identify 'best performance' of a hospital in colorectal cancer surgery (**chapter 2**). The pros and cons to use (combinations of) measure(s) will be investigated. Furthermore, this study examines whether hospitals consistently perform well on several outcomes, i.e. that high performance across different outcomes is related.

Specific outcomes

In contrast to overall 'best performance' of a hospital it might be more interesting for the start of improvement projects to feedback very specific performance aspects, showing specific starting points for improvement. An outcome measure focusing on a specific aspect of the care process is 'failure to rescue' (FTR). FTR, introduced by Silber et al. is the percentage of patients dying after a serious complication.³⁷ High postoperative mortality was shown

not to correlate with a higher rate of serious complications but with relatively more fatal complications.³⁸ To reduce a high mortality rate, providers might not know where to start improvements, whereas, to reduce a high FTR rate suggests a specific improvement for healthcare providers in the care of patients with a serious complication, to prevent these from becoming fatal (and thereby reducing mortality). Close monitoring of patients' recovery, timely recognition of symptoms and adequate treatment of complications are all actions within the reach of surgical teams that may contribute to a decrease in FTR rates.

Another example of a specific outcome as well as a serious and frequently encountered complication in colorectal cancer surgery, with a large contribution to postoperative mortality, is anastomotic leakage (AL).³⁹ Improving the AL rate is challenging, and surgical teams often do not know where to start improvement projects. It has been shown that case-mix is not of much influence on AL rates on a hospital level.⁴⁰ However, in **chapter 3** we search for more specific risk factors, by separating AL depending on the timing at which these occur. The hypothesis is that in early AL the technical skills of the surgeon might be more influential and that for late AL patient characteristics are more important. This could lead to different starting points for improvement of care.

DETERMINANTS OF BEST PERFORMANCE

After having identified best performance, this thesis will look for best practice. What determinants make best performance in a hospital? The determinants for best performance can be divided into roughly two categories. Structural factors define the setting of the hospital, usually cannot be influenced by doctors, but could be influenced by national or local policy makers. Process factors, are the actual activities that take place in a hospital, and can be influenced by health care providers.

Which structural factors are 'best practice'?

Identifying which structural factors may lead to best outcomes brings us back to the 'hospital volume' discussion. One of the most described structural factors associated with good performance is a high hospital volume of the specific patient group or procedure. Centralization seems effective in patients

with stroke⁴¹, and high risk, low volume surgery.^{42–45} However, the effect in colorectal cancer is small and high hospital volume may just be a proxy for underlying processes that are ‘best practice’. Is high hospital volume the key to reach best performance, or are we able to find these underlying processes?

Another structural factor frequently mentioned to be correlated with best performance is hospital teaching type.^{46–52} In the Netherlands, three hospital teaching types are distinguished, each of these having their own characteristics and hospital volume. Academic hospitals function as tertiary referral centers for a selected group of patients and are aligned with Dutch universities for medical education. These hospitals lead the way in innovation and research and typically provide high-complex low-volume care. Teaching hospitals are aligned with an academic hospital in their region and collaborate in facilitating training of surgical residents. These hospitals are mostly high volume hospitals. Non-teaching hospitals, or general hospitals provide accessible care with the possibility to refer to teaching or academic hospitals when necessary. These are usually low volume hospitals. If further centralization would be the solution to reach better performance in the Netherlands, mostly general hospitals would have to stop performing colorectal surgery. This could have the consequence that patients have to travel further to reach a hospital performing this surgery. This could mean a delay in treatment, especially important in patients that need emergency surgery, an already frail population.^{53,54} The aim of **chapter 4** of this thesis is to evaluate the short-term outcomes of patients surgically treated for colon cancer in hospitals with different ‘hospital teaching status’, gaining insight in whether best performance is depending on hospital teaching status.

In this age where technology is everywhere, the options for IT systems in health care are not always optimally used. The electronical system has followed the paper system in type of information. However, the electronical system has the benefit that information is available at any time, from any computer. Our hypothesis is that the right digital system, supporting care processes, could be a very helpful tool to make health care more efficient and improve performance.⁵⁵ Could digitalization be one of the structural determinants for best performance? The hypothesis in **chapter 5** of this thesis is that patients have a more efficient

hospitalization in a hospital where digitalization is implemented on the ward. Efficient communication could make it possible to transfer patients from an intensive care unit (ICU) to a general ward or discharge patients from the ward without delay, but also prevent medical or organizational mistakes and with that improve performance. In **chapter 5** this hypotheses is tested by comparing length of stay in hospitals with digitalization or no digitalization on the ward.

Which combination of process factors and what context is 'best practice'?

Traditionally, as in many countries, most process measures in the clinical audit are evaluating guideline adherence, with the idea that adherence to evidence-based guidelines will result in better outcomes.^{5,9-12,56} However, guideline adherence might not be 'best practice' in every patient. For some indications it might even be 'best practice' not to adhere to the guidelines. Before judging guideline non-adherence it is thus important to know the reasons behind non-adherence. In **chapter 6** we aim to evaluate national guideline adherence on performing a completion TME after local excision of rectal cancer. Rectal preserving surgery (local excision) can be performed as an alternative to the total mesorectal excision (TME) in patients with low risk rectal cancer, defined as pT1, cN0M0 rectal cancer, with favorable histopathology. According to Dutch guidelines, patients with locally excised rectal cancer with higher T stages or unfavorable features should undergo a completion TME. Because the determinants for guideline (non)adherence in these patients are currently unknown, we investigate these in **chapter 6** of this thesis.

In **chapter 7 and 8** we present an in-depth investigation aiming to uncover clinical processes and context associated with better performance on serious complications, failure to rescue (FTR) and mortality. The first step in unraveling the process of care in better performing hospitals was to identify which factors gastrointestinal surgeons (experts) perceive as most important to explain hospital differences in outcomes. (**Chapter 7**) The next step was visiting the hospitals with better and worse performance to review patient records (processes) and conduct in-depth semi-structured interviews with the

healthcare providers (context) in those hospitals, to assess whether hospitals with better versus worse performance differ on those factors. (**Chapter 8**)

The overall aim of this thesis thus is to contribute to how we can learn from 'best practice'. By identifying best performance and best performing hospitals, and subsequently, trying to find both structural and process factors associated with best performance, we hope to find starting points to further improve the quality of colorectal cancer care.

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Chapter 2

Identifying best performing hospitals in colorectal cancer care; is it possible?

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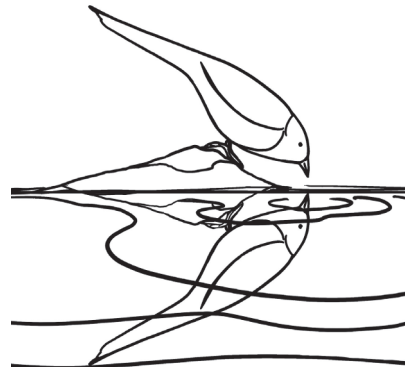
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Submitted



ABSTRACT

Background

Comparing outcomes across hospitals to learn from best performing hospitals can be valuable. However, identifying best performance is challenging. This study assesses reliability to distinguish, and consistency of best performance on different outcomes.

Methods

Data from the Dutch ColoRectal Audit between 2013-2015 were used. Outcomes considered were textbook outcome (colon), (circumferential) resection margins, (serious) complications, mortality, and 'failure to rescue'. To include uncertainty in rankings, random effect logistic regression models were used calculating expected ranks (ERs), for each hospital and outcome. Rankability was calculated for each outcome, as measure of reliability of ranking. Furthermore, correlation between ERs on different outcomes was assessed.

Results

The study included 32143 patients; 11373 were treated in 2015 across 84 hospitals, 8181 colon and 3192 rectal cancer patients. In 2015 'Postoperative complications' had highest rankability for colon (57%) and rectal (41%) surgery. No (group of) hospital(s) had highest ER(s) on all outcomes. Correlation of outcomes was moderate (0.40-0.59) in 2 and strong (>0.60) in 4 of 25 combinations. Rankability of colorectal mortality increased from 14% in 2015 to 35% in 2013-2015.

Conclusion

Highest reliability of identifying best performance on an outcome was 57%. No (group of) hospital(s) could be identified as best performer on all outcomes. Performance was not consistent on outcomes.

INTRODUCTION

In several countries, disease specific, nationwide clinical audits have gradually been introduced for internal and external quality improvement purposes.¹⁻³ Comparing outcomes across hospitals and learning from processes in best performing hospitals can be a valuable asset as a starting point to improve quality of care both in individual hospitals and nationwide. Transparency of outcomes can be useful for monitoring the quality of care by policy makers and, possibly in the future, to guide patients' choices in which hospital they want to be treated.⁴

In 2009, the Dutch Surgical Colorectal Audit (DSCA) started to measure structural, process and outcome indicators in the Netherlands. In 2017 this audit changed into the multidisciplinary Dutch ColoRectal Audit (DCRA). Colorectal cancer surgery is frequently performed and has relatively high post-operative morbidity and even mortality. Since the introduction of the DSCA, short-term outcomes have improved.¹ However, variation across hospitals on these outcomes still exists and the question on what makes a best performing hospital is increasingly important.^{5,6}

To reliably distinguish hospitals performing better on outcomes than other hospitals is challenging. Multiple studies demonstrated the importance of the adjustment for hospital case-mix in the comparison of outcomes.⁷ Furthermore, random variation should be taken into account to adjust for chance.^{7,8} Comparison of clinically relevant outcomes, may be relatively unreliable and less suitable for direct hospital comparison in case of low event rates, such as in-hospital mortality.⁹⁻¹¹ Expected ranks and rankability, measures that express the reliability of ranking hospitals based on performance, have been suggested as a suitable method to incorporate chance variation in hospital comparisons and rankings.^{10,11}

An additional problem in identifying best performing hospitals, may be that it depends on the outcome considered to indicate 'best performance'. Previous studies describe more than 766 different definitions of outcome measures for colorectal cancer.¹² Each individual outcome might be an indicator of the

quality of a certain aspect of colorectal cancer care and thereby very helpful for quality improvement, for example by facilitating the evaluation of targeted improvement projects. However, policy makers and patients might be more interested in one comprehensive measure of the overall performance of a hospital in treating a certain condition. A promising composite outcome measure to assess overall quality of care in colorectal cancer surgery was recently described by Kolfshoten et al., the so called 'textbook outcome' (TO).⁶

The present study aims to assess how reliable high performing hospitals can be identified for individual outcomes of colorectal cancer care. Further, we investigate whether hospitals consistently perform well on several outcomes, i.e. that high performance across different outcomes is related.

METHODS

Data

Data were derived from the Dutch ColoRectal Audit (DCRA, previously DSCA), a nationwide audit containing a wide range of variables regarding diagnostic, treatment and outcome variables in colorectal cancer surgery. To adjust for case-mix factors the audit also contains patient and tumor characteristics. Data are collected prospectively. Details of the dataset, regarding data collection and methodology have been published previously.^{1,7}

Patients

All patients undergoing surgical resection for primary colorectal cancer between January 1, 2013, and December 31, 2015, and registered in the DCRA before March 31, 2016, were evaluated in this study. Minimal data requirements to consider a patient eligible for analyses were information on: tumor location, date of surgery, and mortality. Patients undergoing a local excision and patients with synchronous tumors were excluded given well-known differences in outcomes.^{13,14}

Outcomes

Outcomes considered for this study were: textbook outcome (TO, colon), positive resection margin (colon), Circumferential Resection Margin (CRM)

involvement (rectum), postoperative complications, serious complications, mortality and failure to rescue (FTR). Definitions of all outcomes are in accordance with definitions in previous studies using DCRA data:

Colon only:

- Textbook outcome (TO): Hospital and 30-day survival, negative resection margins, no need for reintervention, no ostomy, no adverse outcome and a hospital stay of <14days.⁶
- Positive resection margin: Microscopic resection margin $\leq 1\text{mm}$ (R1 or R2) ¹

Rectum only:

- Circumferential resection margin involvement: CRM was considered positive if tumor cells were in a distance $\leq 1\text{ mm}$ from the resection margin according to the definition of the Royal college of Pathologists.¹⁵

Both colon and rectum:

- Postoperative complication: Any adverse event within 30 days after surgery.^{1,5}
- Serious complication: Patients with a postoperative complication after surgery leading to an in-hospital stay of more than 14 days, a surgical, endoscopic or radiological reintervention, or to death. ^{1,5}
- Mortality: Patients that died within 30 days after surgery or during the first hospital admission.^{1,5}
- Failure to rescue (FTR): Patients that died within 30 days after surgery or during the first hospital admission after a serious complication (e.g. the denominator is all patients with a serious complication).⁵

Statistical analyses

Descriptive statistics were used to show patient-, tumor- and treatment characteristics of all patients. Random effect logistic regression models were used to calculate the expected rank of each hospital for each outcome. This method was used to account for uncertainty in rankings. The expected rank of a certain hospitals can be interpreted as the number of hospitals (out of the total number) that is expected to perform better. E.g. an Expected Rank of 4 implies that at most 4 out of the total number of hospitals in the sample are expected to do better than this hospital. Subsequently, rankability was calculated for each outcome. Rankability can be interpreted as the percentage

of between-hospital variation in outcome that cannot be ascribed to chance variation. Hence, it may reflect the percentage of hospital variation that is due to actual differences between hospitals and possibly in quality of care. This is computed by relating heterogeneity between hospitals to the uncertainty of the individual hospital. This measure was used to show the reliability of ranking hospitals on the specific outcome. Further details on the calculation of the expected rank and rankability are described in previous papers.^{9–11,16} We considered rankability of <50% as poor, 50-70% as moderate and >70% as high.¹⁰ All outcomes were adjusted for case-mix which included gender, age, BMI, ASA score, Charlson comorbidity index, preoperative complications, location of the tumor (colon), neo-adjuvant therapy (rectum) urgency (e.g. emergency or elective resection) and TNM stage. Details concerning case-mix models have been described elsewhere.⁷

Data of 2015 were used to calculate rankability for different outcomes in the basic analyses. Additionally, data of 2013-2015 were used to calculate rankability for some outcomes on 2 (TO, postoperative complications, serious complications and mortality) and 3 (mortality) years to see if the rankability increases with a higher event rate as for instance the 1-year mortality rate is known to be rather low. Furthermore, we assessed whether expected ranks (in 2015) across different outcomes were correlated in specific hospitals by calculating correlation coefficients for the expected rank of the hospitals on different outcomes. We considered correlation below 0.40 as weak, 0.40-0.59 as moderate, and above 0.60 as (very) strong.¹⁷

All statistical analyses were performed using R version 3.2.4.

RESULTS

All 32143 patients that underwent surgery for primary colorectal cancer in the Netherlands between 2013 and 2015 were evaluated. After exclusion of patients with transanal local excision of rectal cancer (n=421), multiple synchronous tumors (n=1048) and patients with missing values in the outcomes (n=585), 30 689 patients were included in our study. These patients were treated in 84 hospitals. Most of the analyses were performed on 11373 patients that

underwent surgery in 2015. Of these patients 8181 underwent surgery for colon cancer and 3192 underwent surgery for rectal cancer. Patient, tumor and treatment characteristics of all patients are shown in Table 1.

Table 2 shows the percentage, range and rankability of all outcomes in 2015. Of the patients with colon cancer, 5113 (63%) had textbook outcome (TO) and 1227 (15%) had a serious complication. In 188 (15%) of these 1227 patients, failure to rescue (FTR) occurred. Of the rectal cancer patients, 155 (5%) patients had CRM involvement. The serious complication rate was 20%. In 6% of these 633 patients, FTR occurred. Mortality was 2% in colon cancer and 1% in rectal cancer patients.

Rankability of TO after colon cancer surgery was 54.1%. This rankability of 54% means that around half of the observed differences is due to chance and the other half might be due to quality of care. Compared to the other outcomes, postoperative complications had the highest rankability for both colon (57%) and rectal (41%) cancer surgery. Rankability of mortality was 17% after colon and 0% after rectal cancer surgery, indicating that much of the between hospital differences is due to chance. Despite considerable between-hospital variation, rankability for FTR was lowest for both groups (13% colon, 0% rectum), due to its small number of events.

In Figure 1a and b, each line represents a hospital with their expected ranks on all outcomes. These figures illustrate that no hospital is a best performer on all outcome parameters. This is confirmed by the relatively low correlations between different outcomes after colon and rectal cancer surgery, as shown in table 3. Correlation in colon cancer surgery between TO and postoperative complications was strong (-0.77 , $p < 0.001$), while correlation between TO and in-hospital or 30 day mortality was weak (-0.01 , $p = 0.761$). In rectal cancer, correlation between CRM involvement and postoperative complications was weak (-0.19 , $p = 0.081$), as well as correlation between CRM involvement and mortality (-0.07 , $p = 0.873$). Overall correlation is only high when outcomes incorporate partly the same information. For example, as expected, mortality and FTR (correlation 0.86 ($p < 0.001$) in colon and 0.79 ($p < 0.001$) in rectum) are

related since FTR is mortality in patients with a serious complication. Also as expected, postoperative complications and serious complications (correlation 0.59 ($p<0.001$) in colon and 0.64 ($p<0.001$) in rectum) are related, since a postoperative complication is a criterion for a serious complication.

Rankability of colorectal mortality increased from 14% in 2015, to 23% in 2014-2015 and to 35% when data over the period of 2013-2015 were combined. This is a direct result of the increased sample size and number of events, and can also be seen in Figure 2. The expected ranks diverge, meaning that hospitals with good and bad performance can be more reliably identified based on more years of data. Figure 2 also illustrates that the ranking of individual hospitals can change considerably when previous years are taken into account. If two years are included, rankability of TO of colon increases to 69%. Rankability of postoperative complications and serious complications increases to respectively 72% and 39% for colon and 56% and 30% for rectum if two years data are taken into account.

DISCUSSION

In this study we aimed to assess whether best performing hospitals can be identified on individual outcomes and whether performance on different indicators is consistent within hospitals in colorectal cancer care. We found that the reliability of identifying best performance based on separate outcomes was low. The outcome 'postoperative complications' has the highest rankability, while between-hospital variation on mortality and FTR is mostly based on chance. Rankability increases significantly when data of a longer time period are used. The low to moderate correlation across independent outcomes indicates that high performance on several outcomes is not consistent within hospitals. Furthermore, the difference in expected ranks of specific hospitals between the different outcomes shows that no single hospital stands out as best performer on all outcomes.

This is the first study to test rankability and correlation for several outcomes in colorectal cancer surgery. It shows that outcomes with a large in between hospital variation and with a high number of events are the most reliable

outcomes for hospital rankings. It confirms the unreliability of ranking hospitals based on outcomes with few events. Like Henneman et al., we found postoperative mortality to have low rankability.⁹ Furthermore we showed that FTR also has a low rankability, despite the large variation.⁵ These results suggest that rarely occurring outcomes like mortality and FTR, not to be suitable or relevant for reliable hospital comparison and that the attention these outcomes get might be misguided for external evaluation. However, individual feedback information on mortality or FTR could still be very useful as internal information as it serves as a warning signal for individual hospitals and could initiate improvement projects. Especially FTR could be suitable, as it gives specific feedback information on the areas that need improvement.⁵

To overcome the shortcomings of single outcome measures, Kolfshoten et al developed TO as a composite measure indicating overall hospital quality. Composite outcomes, like TO, have the advantage of occurring more frequently, which results in higher rankability (54% over 1 year and 69% over 2 years). However, a composite measure also comes with limitations. First of all, there is a loss of specificity of information it generates. Furthermore, we showed that the correlation between TO and Mortality is low, which means that a hospital can perform well on TO while having a high mortality rate. To overcome this, one may consider adding weighing factors to composite measures. This however, makes the interpretation of the outcome even more complicated¹⁸ and therefore could be less suitable to inform policymakers and patients about quality of care. By showing both composite outcomes and detailed outcomes, improvement projects are easier to lead in the right direction.¹⁹

To determine if it is possible to identify a best performing (group of) hospital(s) it is important to define which outcome(s) is/are most important for both experts in the field and for patients. This definition of best performance could very well differ for each patient. For example TO is not reached if a ostomy has been performed, whereas in some high risk patients, placement of an ostomy could very well be a better choice than making an unsafe anastomosis, prone for leakage. In literature, there is an ongoing search for definition of a core outcome set.²⁰ Moreover, the definition of 'best performance' is also dependent

on the component of time. If outcomes are measured over a longer period of time, the rankability increases. This was also shown by a study of Verburg et al, which demonstrated that rankability of mortality in ICU patients increased from 73% to 89% if the period measured increased from 1 to 3 years.²¹ However, because outcomes vary over time, one could argue that capability to improve continuously is just as important as 'best performance' during a certain period. Moreover, a longer feedback loop, due to combining data of more years, reduces the potential for timely improvement based on this feedback.

Some limitations of this study should be taken into account. First, DCRA was initiated as an improvement instrument and it has been shown to reduce variation, so rankability could have decreased over the last years. However, rankability of mortality as tested in 2009-2011 by Henneman et al. (38%)⁹ did not change much compared to rankability of mortality in our study (35%). Second, although we tested multiple outcomes, there might be other (combinations) of outcomes that are better measures of performance. Still, we tested outcomes that are nationally and internationally well-accepted and frequently used for comparison of hospitals. Also, up until now DCRA only contains clinical outcomes so we could not test the rankability of Patient Reported Outcome Measures (PROMS) or costs. Third, even with high rankability one should always be careful judging hospitals' performance based on these rankings, for we could not account for unobserved confounders and quality indicators are a simplification of overall quality. Furthermore, despite internal and external validation, hospitals could differ in data registration and quality. Finally, the correlation coefficients between the ranks of the hospitals on different outcomes assume independency of these outcomes, which is not the case (e.g. a patient with FTR will also count for the outcome mortality). However, we were interested in the correlation between the different indicators as they are currently used.

Despite these limitations we believe that our study has implications on the future direction for measurement of quality of care. Our study adds to the increasing amount of literature showing that interpretation of outcomes, as a measure of quality of care, is very complicated and might even be

impossible.^{22,23} Transparency of outcomes that are not well rankable could be risky for a less methodologically informed public, while hospitals could be unjustly stigmatized due to outcomes mostly based on chance. Therefore, focus of publically available quality indicators should be on reliable and rankable outcome measures to monitor overall quality of care. While focus of feedback information for healthcare providers should be more on valuable information for optimizing internal improvement projects. Health care providers should be stimulated to improve, without fear of wrong conclusions when data become publicly available. With this difference in suitable information for public and health care providers it is important to leave the era of ravenous inspection and control and to change beliefs to enter a new era towards appropriate trust in health care providers.²⁴

Still, also for feedback information, reliability of a difference is important. Reliability of ranking increases when more years of data are combined or when more outcomes are combined, e.g. in TO over 2 years, but at the cost of relevance and actionability. Thus, there is a vulnerable balance between rankability and valuable information when measuring quality of colorectal cancer care based on outcomes. For an effective audit cycle, feedback information should contain information about a recent situation to make sure to measure quality of care at that point in time and that changes in quality of care are not discounted.²¹ Also, while best performance might be reached by continuous improvement, it might be interesting not to measure a period of time, but to measure improvement.²⁵ Measuring improvement is statistically even more challenging, among others because of regression to the mean.²⁶

For public information it is more important to have very reliable information. Still, also then the question remains on the definition of 'best outcome' for the patient. In this era of increasing personalized medicine, there might never be a core outcome set that is fully applicable for every patient. The current development of Patient Reported Outcome Measures (PROMS) could probably help us to tailor the best outcomes for patients. However, PROMs are likely to have the same (or even more) rankability problems for comparison between hospitals.

Conclusion

Our study shows the vulnerable balance between reliability of an outcome and actionability of this outcome. No (group of) hospital(s) could be identified as best performer on all outcomes. The overall rankability of outcomes was low. Composite measures, or a longer period of time could increase rankability but with the disadvantage of losing information. These findings highlight the need to make a clear distinction between valuable information for public transparency and valuable information for health care providers to improve.

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Conflict of interest

None of the authors have anything to disclose.

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TABLES AND FIGURES

Table 1. Patient, tumor and treatment characteristics

	Colon 2015		Rectum 2015		Colorectal 2013-2015	
	N	%	N	%	N	%
Gender						
Male	4427	54.1%	2046	64.1%	16929	56.3%
Female	3754	45.9%	1146	35.9%	13143	43.7%
BMI						
unknown	293	3.6%	70	2.2%	991	3.3%
<18.5	130	1.6%	46	1.4%	487	1.6%
18.5-25	3019	36.9%	1216	38.1%	11626	38.6%
25-30	3161	38.6%	1325	41.5%	11802	39.2%
30+	1578	19.3%	538	16.8%	5184	17.2%
Age						
<=60	1071	13.1%	655	20.5%	5079	16.9%
61 - 70	3466	42.4%	1381	43.3%	10877	36.2%
71 - 80	2419	29.6%	869	27.2%	9671	32.1%
>=81	1222	14.9%	288	9.0%	4454	14.8%
Charlson-score						
0	4013	49.1%	1797	56.2%	15255	50.7%
1	1867	22.8%	642	20.1%	6763	22.5%
2+	2301	28.1%	756	23.7%	8071	26.8%
ASA						
I - II	6161	75.3%	2680	83.9%	23237	77.3%
III	1882	23.0%	494	15.5%	6428	21.4%
IV - V	136	1.7%	20	0.6%	413	1.4%
Localization tumor						
Caecum	1414	17.3%			3973	13.2%
Appendix	60	0.7%			169	0.6%
Ascending colon	1377	16.8%			3817	12.7%
Hepatic flexure	515	6.3%			1330	4.4%
Transverse colon	598	7.3%			1613	5.4%

Table 1. Continued

	Colon 2015		Rectum 2015		Colorectal 2013-2015	
	N	%	N	%	N	%
Splenic flexure	277	3.4%			716	2.4%
Descending colon	600	7.3%			1423	4.7%
Sigmoid colon	3340	40.8%			8608	28.6%
Rectum			3192	100.0%	8440	28.1%
Pathological T stage						
missing	10	0.1%	6	0.2%	63	0.2%
pT0/1	1043	12.8%	633	19.9%	3702	12.4%
pT2	1399	17.1%	985	30.9%	6153	20.5%
pT3	4325	53.0%	1439	45.1%	16037	53.5%
pT4	1381	16.9%	125	3.9%	4019	13.4%
Metastasis						
No	7258	88.7%	2988	93.5%	26948	89.6%
Yes	923	11.3%	207	6.5%	3141	10.4%
Preoperative complications						
No	5583	68.2%	2635	82.5%	19539	64.9%
Yes	2598	31.8%	560	17.5%	10550	35.1%
Urgency						
Elective	7068	86.4%	3165	99.1%	26514	88.1%
Urgent/Emergency	1111	13.6%	30	0.9%	3570	11.9%
Additional resections						
because of metastasis	312	3.8%	118	3.7%	1089	3.6%
because of extensive tumor growth	290	3.5%	117	3.7%	1144	3.8%
because of limited tumor growth	428	5.2%	127	4.0%	1527	5.1%

Table 2. Outcome, range and rankability

	Outcome n (%)	Range between hospitals (min-max)	Rankability
Colon (n=8181)			
Textbook outcome	5113 (62.9%)	62.9% (22.2%-85.1%)	54.1%
Positive resection margin	164 (2.0%)	11.4% (0.0%-11.4%)	20.3%
Postoperative complications	2274 (27.8%)	50.9% (6.9%-57.8%)	56.7%
Serious complications	1227 (15.0%)	33.3% (0.0%-33.3%)	24.9%
Mortality	188 (2.3%)	9.0% (0.0%-9.0%)	16.9%
FTR (denominator n=1227)	188 (15.3%)	60.0% (0.0%-60.0%)	13.1%
Rectum (n=3192)			
CRM involvement	155 (5.0%)	17.4% (0.0%-17.4%)	8.5%
Postoperative complications	1186 (37.1%)	63.6% (0.0%-63.6%)	40.9%
Serious complications	635 (19.8%)	45.5% (0.0%-45.5%)	19.9%
Mortality	39 (1.2%)	14.3% (0.0%-14.3%)	0.0%
FTR (denominator n=633)	39 (6.2%)	50.0% (0.0%-50.0%)	0.0%
Colorectal mortality			
2015 (denominator n=11.376)	227 (2.0%)	6.3% (0.0%-6.3%)	13.8%
2014-2015 (denominator n=21.097)	404 (1.9%)	5.9% (0.0%-5.9%)	23.1%
2013-2015 (denominator n=30.689)	580 (1.9%)	5.8% (0.0%-5.8%)	34.7%

Table 3. Correlation of expected ranks on different outcomes, a Spearman correlation test

<i>Colon</i>	TO	Positive resection margin	Postoperative complications	Serious complications	Mortality	FTR
TO	1.00					
Positive resection margin	-0.04 p=0.578	1.00				
Postoperative complications	-0.77 p<0.001	-0.11 p=0.334	1.00			
Serious complications	-0.56 p<0.001	-0.02 p=0.881	0.59 <0.001	1.00		
Mortality	-0.01 p=0.761	-0.03 p=0.759	0.02 p=0.731	0.29 p=0.001	1.00	
FTR	0.15 0.169	0.02 p=0.864	-0.24 p=0.026	-0.07 p=0.522	0.86 p<0.001	1.00
<i>Rectum</i>		CRM involvement	Postoperative complications	Serious complications	Mortality	FTR
CRM involvement		1.00				
Postoperative complications		-0.19 p=0.081	1.00			
Serious complications		-0.24 p=0.038	0.64 <0.001	1.00		
Mortality		-0.07 p=0.873	0.08 p=270	0.31 p=0.004	1.00	
FTR		0.05 p=0.668	-0.18 p=0.089	-0.09 p=0.263	0.79 <0.001	1.00

Figure 1.

a. Expected ranks of hospitals on all outcomes after colon cancer surgery in 2015, each line representing a hospital

b. Expected ranks of hospitals on all outcomes after rectal cancer surgery in 2015, each line representing a hospital

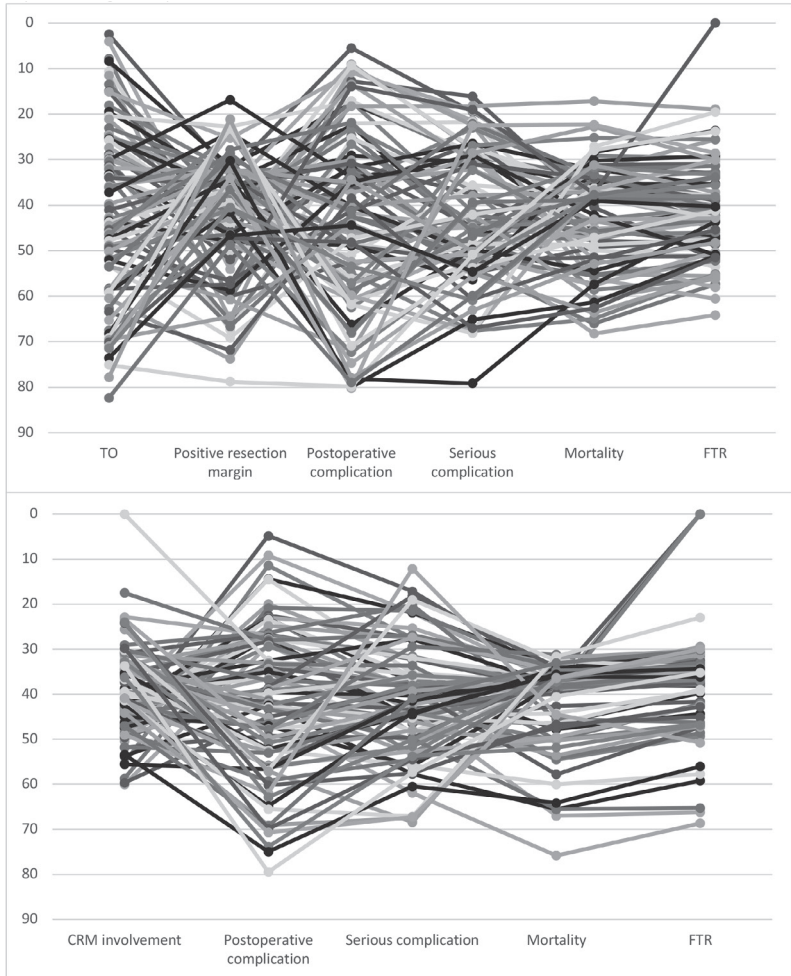
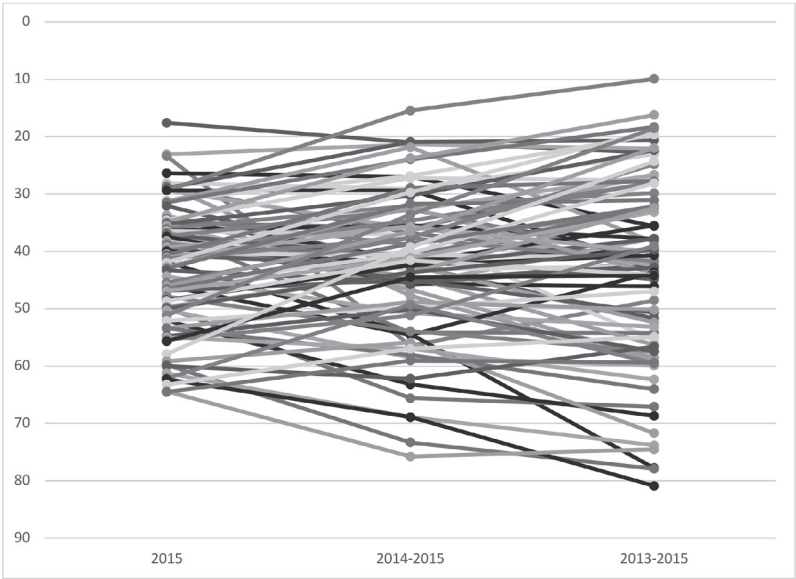


Figure 2.
Expected ranks for each hospital on mortality after colorectal cancer surgery in 2015, 2014-2015 and 2013-2015, each line representing a hospital



Chapter 3

Different risk factors for early and late colorectal anastomotic leakage in a nation-wide audit

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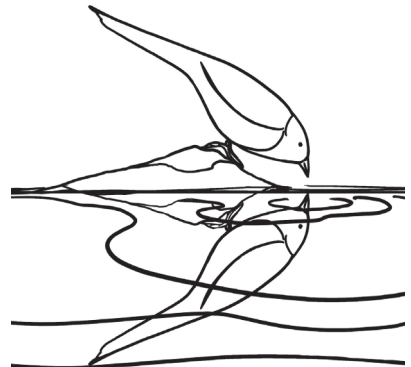
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ABSTRACT

Background

Anastomotic leakage remains a major complication after surgery for colorectal carcinoma but its origin is still unknown. Our hypothesis was that early anastomotic leakage is mostly related to technical failure of the anastomosis and late anastomotic leakage to healing deficiencies.

Objective

The aim of this study was to assess differences in risk factors for early and late anastomotic leakage.

Design

This was a retrospective cohort study.

Settings

The Dutch Surgical Colorectal Audit is a nationwide project, which collects information on all Dutch patients undergoing surgery for colorectal cancer.

Patients

All patients undergoing surgical resection for colorectal cancer in the Netherlands between 2011-2015.

Main Outcome Measures

Late anastomotic leakage was defined as anastomotic leakage leading to re-intervention later than 6 days postoperatively.

Results

In total 36,929 patients were included, early anastomotic leakage occurred in 863(2.3%) patients and late anastomotic leakage occurred in 674(1.8%) patients. From a multivariable multinomial logistic regression model, independent predictors of early anastomotic leakage relative to no anastomotic leakage and late anastomotic leakage relative to no anastomotic leakage included male gender (OR 1.8 $p<0.001$ and OR 1.2 $p=0.013$) and rectal cancer (OR 2.1 $p<0.001$ and OR 1.6 $p=0.046$). Additional independent predictors of

early anastomotic leakage relative to no anastomotic leakage included BMI (OR 1.1 $p=0.001$), laparoscopy (OR 1.2 $p=0.019$), emergency surgery (OR 1.8 $p<0.001$) and no diverting ileostomy (OR 0.3 $p<0.001$). Independent predictors of late anastomotic leakage relative to no anastomotic leakage were Charlson Comorbidity Index of $\geq$ II (OR 1.3 $p=0.003$), ASA score III-V (OR 1.2 $p=0.030$), preoperative tumor complications (OR 1.1 $p=0.048$), extensive additional resection because of tumor growth (OR 1.7 $p=0.003$), preoperative radiation (OR 2.0 $p=0.010$).

Limitations

This was an observational cohort study.

Conclusions

Most risk factors for early anastomotic leakage were surgery related factors, representing surgical difficulty, which might lead to technical failure of the anastomosis. Most risk factors for late anastomotic leakage were patient related factors, representing frailty of patients and tissues, which might imply healing deficiencies.

INTRODUCTION

Surgical resection is the gold standard for curative treatment of colorectal cancer. Unfortunately anastomotic leakage (AL) remains a major complication after resection, but its origin is still mainly unknown. The incidence of AL in literature varies from 3% to 28% and one third of all postoperative mortality is related to AL.¹ Delay in diagnosing AL results in increased postoperative mortality.²

In general, AL is diagnosed within the first two weeks after surgery.³⁻⁵ In previous studies late AL has been defined as AL diagnosed 21 or 30 days after surgery or as AL diagnosed after hospital discharge.⁶⁻¹¹ However, a recent study advocated that redefinition of early and late AL with a proper cut-off point of a specific day is necessary for precise discrimination and they determined the cut-off at postoperative day 6.¹² This demonstrates that there is no consensus in literature regarding the definition of late AL.

Most previous studies suggested that early and late AL are different entities although based on relatively small sample sizes.⁶⁻¹¹ These previous studies have shown that the postoperative course differs for patients with early AL and late AL. Patients with early AL are more likely to undergo re-laparotomy as intervention.^{10, 12} However, the long-term stoma retention rate in patients with late AL is higher than in patients with early AL.¹¹ These differences in postoperative course emphasize that in clinical practice, more attention should be paid to the distinction between early AL and late AL. In addition, better insight in the nature of AL could also contribute to early detection of AL, especially of late AL since one third of AL is diagnosed after 30 days after surgery.¹³

A technically not well-constructed anastomosis might result in immediate anastomotic dehiscence with subsequent clinical symptoms, while a well-constructed anastomosis will develop anastomotic dehiscence more slowly in case wound healing is impaired. The aim of this study was to assess differences in risk factors for early and late AL in order to demonstrate whether early AL is related to technical failure of the anastomosis and late AL to healing deficiencies.

MATERIALS & METHODS

DCRA

Data were derived from the Dutch ColoRectal Audit (DCRA), a nationwide quality improvement project, which collects information on all Dutch patients undergoing surgical resection for primary colorectal cancer. Data registered were patients', tumor and treatment characteristics as well as patient outcomes. For this study no ethical approval or informed consent was required under Dutch law. Further details of this dataset regarding collection and methodology have been published previously.¹⁴

Inclusion and exclusion criteria

All patients undergoing surgical resection for primary colorectal cancer in the Netherlands between January 2011 and December 2015, and registered in the DCRA before March 31st 2016 were included in this study. Patients without a primary anastomosis, and patients of whom the day of diagnosis of AL was unknown were excluded from analysis. Patients in whom AL occurred later than 90 days after surgery were excluded. Data are usually registered at 30 days after surgery unless the initial hospital stay takes longer. Therefore, we considered data registered about AL later than 90 days after surgery as unreliable. We excluded patients with multiple synchronous tumors due to differences in prognosis.¹⁵

Early versus late AL

AL was defined as clinically relevant AL that requires radiological or surgical re-intervention.¹⁶ We defined early AL as AL leading to re-intervention until day 6 postoperatively and late AL as AL leading to re-intervention after day 6 postoperatively. In previous literature, there is no consensus on the definition of late AL. To test our hypothesis, it was not sufficient to base our definition on the day of discharge, which is highly sensitive to institutes and other postoperative complications. Although it might be a fluent transition for early to late AL, for precise discrimination we think it is important to use a definition based on a specific day. Besides, the transition in origin of AL from technical failure to healing deficiencies should be captured during the first postoperative days.

Outcomes

Early and late AL were primary outcome measures. Potential risk factors for early and late AL were retrieved from the DCRA database including patients characteristics (gender, age, Body Mass Index (BMI), Charlson Comorbidity Index^{17,18}, American Society of Anesthesiologists score (ASA)¹⁹, previous abdominal surgery), tumor characteristics (tumor location, tumor stage, metastasis, preoperative tumor complication), and treatment characteristics (surgical technique, urgency of surgery, diverting ileostomy, additional resection of adjacent organs because of tumor growth or because of metastasis and preoperative radiotherapy). In the DCRA database preoperative tumor characteristics are specified as anemia, ileus, abscess, and perforation.

Statistical analysis

Multiple imputation was performed to deal with missing values assuming data were missing at random.²⁰ Five imputed datasets have been created based on AL, hospital, gender, Charlson Comorbidity Index, diverting ileostomy, metastasis and preoperative tumor complication. Multivariate multinomial logistic regression analyses were performed to test independent associations between patient, tumor and treatment characteristics and the occurrence of no, early and late AL. A multinomial logistic regression model is applicable when an outcome variable has more than 2 categories, but no ordering in these categories can be assumed. All clinically relevant variables were added to the model as independent variables (full model). Covariate selection was driven by available knowledge and biological plausibility of potential confounders. Tests for interactions between covariates were not implemented. More details concerning the relevant predictors of AL were described elsewhere.^{21,22} Results were reported as odds ratios with 95 percent confidence intervals. Significance was considered as a p-value <0.05. All statistical analyses were performed in SPSS version 22.

RESULTS

A total of 49941 patients underwent surgery for primary colorectal cancer in the Netherlands between 2011 and 2015. After exclusion of patients without a primary anastomosis (n=11246), 38695 patients were eligible for inclusion.

Patients in whom AL occurred later than 90 days after surgery, and patients of whom the day of diagnosis of AL was unknown (n=558) were excluded from analysis. Due to differences in prognosis we excluded patients with multiple synchronous tumors (n=1208). In total, 36929 patients were included.

Of these 36929 patients, 80.9% of these patients underwent surgery a colon tumor and 63.1% of these patients underwent laparoscopic surgery (Table 1).

AL leading to re-intervention occurred in 1537 (4.2%) patients. Early AL occurred in 863 (2.3%) patients and late AL occurred in 674 (1.8%) patients. The median interval between colorectal resection and intervention for AL was 6 days. The median interval between colorectal resection and intervention for early AL was 4 days and for late AL 10 days. In 18% AL was diagnosed after hospital discharge. In patients with early AL 3.1%, and in patients with late AL 37.4% was diagnosed after hospital discharge. The incidence of early AL in patients with a colon tumor was 2.3% and 2.4% in patients with a rectum tumor while the incidence of late AL was 1.6% in patients with a colon tumor and 3.0% in patients with a rectum tumor.

From a multivariable multinomial logistic regression model, independent predictors of early AL relative to no AL and late AL relative to no AL included male gender (OR 1.8 95% CI 1.6 – 2.1 $p<0.001$ and OR 1.2 95% CI 1.0 - 1.4 $p=0.013$) and rectal cancer (OR 2.1 95% CI 1.6 -2.8 $p<0.001$ and OR 1.6 95% CI 1.0 – 2.4 $p=0.046$). Additional independent predictors of early AL relative to no AL included BMI (OR 1.1 95% CI 1.0 – 1.2 $p=0.001$), laparoscopic surgery (OR 1.2 95% CI 1.0 - 1.4 $p=0.019$), emergency surgery (OR 1.8 95%CI 1.4 - 2.2 $p<0.001$) and no diverting ileostomy (OR 0.3 95% CI 0.2 – 0.4 $p<0.001$). Independent predictors of late AL relative to no AL were Charlson Comorbidity Index of $\geq$ II (OR 1.3 95% CI 1.1 – 1.6 $p=0.003$), ASA score III-V (OR 1.2 95% CI 1.0 – 1.5 $p=0.030$), preoperative tumor complications (OR 1.1 95% CI 1.0 – 1.4 $p=0.048$), extensive additional resection because of tumor growth (OR 1.7 95%CI 1.2 – 2.5 $p=0.003$), preoperative radiation (OR 2.0 95%CI 1.2 - 3.4 $p=0.010$) (Table 2).

Independent predictors for early AL relative to late AL were male gender (OR 1.5; 95% CI 1.2 – 1.9), laparoscopic surgery (OR 1.3; 95% CI 1.0 – 1.6), emergency surgery (OR 1.9; 95% CI 1.3 – 2.7), no diverting ileostomy (OR 0.4; 95% CI 0.2 – 0.6), and no preoperative radiotherapy (OR 0.4; 95% CI 0.2 – 0.8). These variables had a different effect on the occurrence of early AL compared to late AL (Table 2).

In addition, stratification for colon and rectum showed that diverting ileostomy and preoperative radiotherapy were independent risk factors for late AL in rectum tumors but not for colon tumors. Furthermore, in the stratified analysis open surgery was an independent risk factor for early AL in colon tumors while laparoscopic surgery was an independent risk factor for early AL in rectum tumors.

DISCUSSION AND CONCLUSION

This study showed that male gender and rectal cancer were independent risk factors for both early and late AL. Younger age, increased BMI, laparoscopic surgery, emergency surgery, and no a diverting ileostomy were independent risk factors for early AL. In addition, high Charlson Comorbidity Index, high ASA score, preoperative complications, additional resection because of tumor growth, and preoperative radiotherapy were independent risk factors for late AL. Male gender, laparoscopic surgery, emergency surgery, construction of diverting ileostomy and preoperative radiotherapy, had a different effect on the occurrence of early, compared to late AL. Our results demonstrated that most risk factors for early AL were surgery related factors, representing surgical difficulty, which might lead to technical failure of the anastomosis. Most risk factors for late AL were patient related factors, representing frailty of patients and tissues that influences the healing capacity of bowel tissue.

The results of this study are in accordance to previous literature. A previous study has shown that prolonged duration of surgery and blood loss during surgery, both representing surgical difficulty, were related to early AL.⁶ Another study indicated that preoperative radiotherapy or chemoradiation was a risk factor for late AL.^{7,10,11} Although, it has been demonstrated that advanced tumor

stage (AJCC stage III-IV) and a histological finding of poorly differentiated or mucinous adenocarcinoma were independent risk factors for early AL, this study did not find this.¹¹ One study found a low incidence of late AL (0.04%) and the authors attributed this to the extended period of pelvic drainage, which may shortened the interval of diagnosis.⁸ On the contrary, another study reported an incidence of AL after 30 days postoperatively of 31.6%.²³ It should be taken into account that these previous studies applied different definitions for late AL. Besides, these previous studies were based on relatively small sample sizes.

Male gender was an independent risk factor for both early AL and late AL and thus for AL in general. However, male gender seemed to be a greater risk factor for early AL when compared to late AL. This could be attributable to the smaller pelvis and stronger muscular wall in males, which impedes surgery. Furthermore, rectal cancer was an independent risk factor for both early and late AL which can be explained by the fact the risk of AL in general is increased for anastomoses situated closer to the anal verge.²⁴

Younger age and increased BMI were independent risk factors for early AL, possibly because younger patients are less prone for healing deficiencies. Also, increased BMI is associated with AL in colorectal surgery.²⁵ The increased mesocolon thickness and abdominal pressure in obese patients may complicate the construction of the anastomosis. On the other hand, increased BMI is related to impaired microcirculation, considered to decrease the healing capacity at the anastomotic site, may also play a role for late AL, although this study did not demonstrate this.

Furthermore, we found that laparoscopic surgery was an independent risk factor only for early AL. The COLOR study indicated that the incidence of AL does not differ between laparoscopic and open surgery.^{26,27} Nevertheless, recently it has been shown that risk factors for AL are different between laparoscopic and open surgery. Risk factors for AL after laparoscopic surgery were related to surgical difficulty.²⁸ This is in accordance to our findings and hypothesis. Furthermore, in the early years of laparoscopic surgery some comorbidities were considered as contraindications for laparoscopic surgery.

Therefore, in this observational study, we should take into consideration that selection bias might have affected our results even though we have adjusted for comorbidities in the multivariate analysis.

Emergency surgery was also identified as an independent risk factor for early AL. Emergency surgery is often performed during evening and night shifts because of acute indications. Surgery at these hours is associated with worse postoperative outcomes.^{29,30} Colorectal surgery performed during evening and night shift is related to AL.³¹ Surgery at these times might be performed by less specialized surgeons implying surgical difficulty due to less experience highly suggestive for technical failure of the anastomosis.

Preoperative tumor complications were heterogeneous in influencing our hypothesis, because these did not only represent surgical difficulty but also frailty of patients' tissue at the anastomotic site. Nevertheless, our results proposed that preoperative tumor complications were an independent risk factor for late AL. Table 1 showed that almost 20% of the preoperative tumor complications was anemia which may lead to reduced healing capacity at the anastomotic site. Furthermore, ileus could also strongly affect the quality of bowel tissue, but this also represents surgical difficulties constructing the anastomosis.

No diverting ileostomy was an independent risk factor for early AL. From DCRA it was previously shown that stoma construction in rectal surgery does not affect the incidence of AL or mortality rates.³² In addition, it was recently shown that when AL occurred in patients with a diverting ileostomy that less re-interventions were required which could be suggestive for less severe clinical presentation of AL.³³ It might be possible that a diverting ileostomy delays the diagnosis of AL because of less severe presentation of AL.

Also, additional resection because of tumor growth was an independent risk factor for late AL. These major surgical procedures are demanding for patients, among others because of blood loss and hypotension during surgery. Hypotension compromises local tissue perfusion and leads to reduced tissue oxygenation causing healing deficiencies. Surgery with additional resections

because of tumor growth is also technically demanding but might not specifically complicate the construction of the anastomosis.

Preoperative radiotherapy is indicated in most cases of rectal cancer.³⁴ Preoperative radiotherapy reduces the incidence of local recurrence but is also related to higher postoperative morbidity.³⁵ Our results showed that preoperative radiotherapy was an independent risk factor for late AL. Preoperative radiotherapy not only affects tumor tissue but also the surrounding healthy tissue including the adjacent bowel wall and its vascularization. This could imply decreased healing capacity at the anastomotic site and therefore be related to late AL.

In addition, stratification for colon and rectum showed comparable results. As expected, diverting ileostomy and preoperative radiotherapy were not a risk factor for late AL in colon resections possibly due to the small numbers because these strategies are usually not applied in the treatment of colon tumors. Furthermore, in the stratified analysis open surgery was an independent risk factor for early AL in colon tumors while laparoscopic surgery was an independent risk factor for early AL in rectum tumors. However, laparoscopic approach reflects a technical challenging procedure, it is possible that in colon surgery, open approach was used more often for difficult cases resulting in selection bias.

In this study, the cut-off between early and late AL was set on 6 days based on the median. However, the transition from early AL, hypothesized to be related to surgical difficulty, to late AL, hypothesized to be related to frailty of tissue and patients, might not be captured at this exact day but the transition might very well be a more fluent process. Therefore, we could not state that there are two separate populations of AL but our findings indicate that within the group of AL there might be different entities.

This distinction in origin between early and late AL also has implications for fair comparison of quality of hospitals. In early AL the technical skills of the surgeon

are more of influence and hence the surgeon could be more accountable, while for late AL patient characteristics might be of more influence.

There were some limitations in our study. First, the definition of late AL was arbitrary. This study only evaluated clinically relevant AL that required re-intervention and therefore the definition of late AL was based on the day of re-intervention. For this retrospective study, registration of day of intervention was more reliable than day of clinical symptoms. In previous studies, late AL was defined as AL diagnosed after hospital discharge, after 6, 21 or 30 days postoperatively. Most previous studies aimed to determine whether there are two entities of colorectal AL. However, we hypothesized that the time of occurrence of AL reflects the origin of leakage. Therefore, we defined late AL as AL leading to re-intervention after day 6 postoperatively, which was the median (postoperative day 6). Since data were available, we have also performed the analysis with the cut-off point of late AL at first quartile of discharge (day 5) and third quartile of discharge (day 10). These analyses did not fundamentally change the results presented in our study and the conclusion was similar.

Second, the DCRA data are usually registered until 30 days after surgery unless the initial hospital stay is longer. Therefore, extreme late AL is not included. Besides under registration of AL in general might be a problem in nation-wide databases. Lastly, the analysis of observational data could be affected by confounding and this might lead to bias. Although we performed a multivariate analysis to adjust for patient, tumor and treatment characteristics, still unknown confounding factors could be present that were not registered in the DCRA such as medication use, smoking, criteria for diverting ileostomy, mobilization of splenic flexure, blood loss and operative time.

However, the strength of this study was that results were based on a nationwide cohort representing a large sample size that induces statistical power to detect differences between risk factors for early and late AL. Furthermore, previous studies only concerned AL of the sigmoid and rectum, we have now shown that our hypothesis may be applicable to AL of all colorectal cancers.

In conclusion, this study demonstrated that early and late AL have different risk factors. Our findings suggest that risk factors for early AL are related to surgical difficulty that may lead to technical failure of the anastomosis resulting in immediate anastomotic dehiscence while risk factors for late AL are related to frailty of patients and tissues, which may imply healing deficiencies at the anastomotic site leading to delayed anastomotic dehiscence in a possibly technically well-constructed anastomosis. In our opinion, especially in patients with high risk for late AL, it is important for surgeons to inform patients about possible occurrence of AL in the late postoperative period especially since 18% of AL occurred after hospital discharge. Furthermore, in early AL, quality of the surgery seems more of influence than in late AL, so hospital comparison should consider the different entities separately, with different case-mix adjustments.

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TABLES AND FIGURES

Table 1. Patient, tumor and treatment characteristics. Values in parentheses are percentages. SD indicates standard deviations; BMI, body mass index; ASA, American Society of Anesthesiologists.

	No anastomotic leakage n = 35392	Early anastomotic leakage n = 863	Late anastomotic leakage n = 674
Patient characteristics			
Gender			
Female	16373 (46.3%)	276 (32.0%)	273 (40.5%)
Male	19008 (53.7%)	587 (68.0%)	401 (59.5%)
Missing	11 (0.0%)	0	0
Age, mean $\pm$ SD, yr			
	69.3 ($\pm$ 10.67)	68.6 ($\pm$ 10.55)	69.0 ($\pm$ 9.83)
Missing	16	0	0
BMI, mean $\pm$ SD, kg/m³			
	26.3 ($\pm$ 4.71)	27.0 ($\pm$ 6.54)	26.4 ($\pm$ 4.81)
Missing	1332	21	13
Charlson Comorbidity Index			
0	18401 (52.0%)	428 (49.6%)	311 (46.1%)
I	8025 (22.7%)	197 (22.8%)	159 (23.6%)
$\geq$ II	8966 (25.3%)	238 (27.6%)	204 (30.3%)
ASA score			
I-II	27872 (78.8%)	650 (75.3%)	503 (74.6%)
III-V	7471 (21.1%)	213 (24.7%)	171 (25.4%)
Missing	49 (0.1%)	0 (0.0%)	0 (0.0%)
Previous abdominal surgery			
No	23332 (65.9%)	603 (69.9%)	435 (64.5%)
Yes	12006 (33.9%)	257 (29.8%)	238 (35.3%)
Missing	54 (0.2%)	3 (0.3%)	1 (0.1%)
Tumor characteristics			
Tumor location			
Colon	28723 (81.2%)	697 (80.8%)	463 (68.7%)
Rectum	6669 (18.8%)	166 (19.2%)	211 (31.3%)
Tumor stage			
T1	3867 (11.0%)	84 (9.7%)	76 (11.3%)
T2	7026 (20.0%)	140 (16.3%)	117 (17.4%)
T3	19604 (55.4%)	524 (60.7%)	385 (57.1%)
T4	4503 (12.8%)	112 (13.0%)	95 (14.1%)
Missing	392 (0.8%)	3 (0.3%)	1 (0.1%)

Table 1. Continued

	No anastomotic leakage n = 35392	Early anastomotic leakage n = 863	Late anastomotic leakage n = 674
Metastasis			
No	32023 (90.5%)	770 (89.2%)	600 (89.0%)
Yes	3369 (9.5%)	93 (10.8%)	74 (11.0%)
Preoperative tumor complication			
No/missing	23378 (66.1%)	551 (63.8%)	423 (62.8%)
Yes	12014 (33.9%)	312 (36.2%)	251 (37.2%)
Perforation	253 (0.7%)	3 (0.3%)	5 (0.7%)
Abscess	253 (0.7%)	3 (0.3%)	8 (1.2%)
Anemia	6774 (19.1%)	147 (17.0%)	138 (20.5%)
Ileus	3257 (9.2%)	116 (13.4%)	61 (9.1%)
Treatment characteristics			
Surgical technique			
Open	12864 (36.3%)	292 (33.8%)	261 (38.7%)
Laparoscopic	22343 (63.1%)	566 (65.7%)	410 (60.8%)
Other/missing	185 (0.6%)	5 (0.5%)	3 (0.5%)
Urgency of surgery			
Elective	31860 (90.0%)	738 (85.5%)	610 (90.5%)
Urgent/Emergency	3519 (9.9%)	125 (14.5%)	64 (9.5%)
Missing	13 (0.0%)	0 (0.0%)	0 (0.0%)
Diverting ileostomy			
No	29962 (84.7%)	796 (92.2%)	519 (77.0%)
Yes	5430 (15.3%)	67 (7.8%)	155 (23.0%)
Additional resection because of tumor growth			
No	31519 (89.1%)	797 (92.4%)	598 (88.7%)
Limited	1727 (4.9%)	31 (3.6%)	38 (5.6%)
Extensive	1121 (3.2%)	35 (4.1%)	38 (5.6%)
Missing	1025 (2.9%)	0 (0.0%)	0 (0.0%)
Additional resection because of metastasis			
No	34140 (96.5%)	836 (96.9%)	642 (95.3%)
Yes	1179 (3.3%)	26 (3.0%)	31 (4.6%)
Missing	73 (0.2%)	1 (0.1%)	1 (0.1%)
Preoperative radiotherapy			
No	28768 (81.3%)	694 (80.4%)	463 (68.7%)
Radiation	2716 (7.7%)	52 (6.0%)	104 (15.4%)
Chemo radiation	1994 (5.6%)	37 (4.3%)	56 (8.3%)
Missing	1914 (5.4%)	37 (4.3%)	51 (7.6%)

Table 2. Multivariate multinomial logistic regression model representing independent risk factors for early and late anastomotic leakage. OR indicates odds ratio; CI, confidence interval; BMI, body mass index; ASA, American Society of Anesthesiologists.

	Early vs no anastomotic leakage		Late vs no anastomotic leakage		Early vs late anastomotic leakage	
	OR (95% CI)	P value	OR (95% CI)	P value	OR (95% CI)	P value
Patient characteristics						
Gender						
Female	1.0		1.0		1.0	
Male	1.8 (1.6 - 2.1)	<0.001	1.2 (1.0 - 1.4)	0.013	1.5 (1.2 - 1.9)	<0.001
Age, per 10 year increase						
	0.9 (0.9 - 1.0)	0.015	1.0 (0.9 - 1.1)	0.413	1.0 (0.9 - 1.0)	0.322
BMI, per 5 kg/m² increase						
	1.1 (1.0 - 1.2)	<0.001	1.0 (0.9 - 1.1)	0.881	1.0 (1.0 - 1.2)	0.079
Charlson Comorbidity Index						
0	1.0		1.0		1.0	
I	1.0 (0.9 - 1.2)	0.707	1.2 (1.0 - 1.5)	0.078	0.9 (0.7 - 1.1)	0.279
≥ II	1.1 (0.9 - 1.3)	0.206	1.3 (1.1 - 1.6)	0.003	0.8 (0.6 - 1.1)	0.169
ASA score						
I-II	1.0		1.0		1.0	
III-V	1.2 (1.0 - 1.4)	0.091	1.2 (1.0 - 1.5)	0.030	0.9 (0.7 - 1.2)	0.618
Previous abdominal surgery						
No	1.0		1.0		1.0	
Yes	1.0 (0.8 - 1.1)	0.566	1.1 (0.9 - 1.3)	0.262	0.9 (0.7 - 1.0)	0.220

Table 2. Continued

	Early vs no anastomotic leakage OR (95% CI) P value	Late vs no anastomotic leakage OR (95% CI) P value	Early vs late anastomotic leakage OR (95% CI) P value
Tumor characteristics			
Tumor location			
Colon	1.0	1.0	1.0
Rectum	2.1 (1.6 - 2.8)	1.6 (1.0 - 2.4)	1.4 (0.8 - 2.3)
Tumor stage			
T1	1.0	1.0	1.0
T2	1.0 (0.7 - 1.3)	0.8 (0.6 - 1.1)	1.2 (0.8 - 1.8)
T3	1.3 (1.0 - 1.6)	1.0 (0.8 - 1.3)	1.2 (0.9 - 1.7)
T4	1.2 (0.9 - 1.6)	1.1 (0.8 - 1.5)	1.1 (0.7 - 1.7)
Metastasis			
No	1.0	1.0	1.0
Yes	1.1 (0.8 - 1.4)	1.1 (0.8 - 1.4)	1.0 (0.7 - 1.4)
Preoperative tumor complication			
No	1.0	1.0	1.0
Yes	1.0 (0.8 - 1.1)	1.1 (1.0 - 1.4)	0.8 (0.7 - 1.0)
Treatment characteristics			
Surgical technique			
Open	1.0	1.0	1.0
Laparoscopic	1.2 (1.0 - 1.4)	0.019	1.3 (1.0 - 1.5)
		0.619	0.048

Table 2. Continued

	Early vs no anastomotic leakage		Late vs no anastomotic leakage		Early vs late anastomotic leakage	
	OR (95% CI)	P value	OR (95% CI)	P value	OR (95% CI)	P value
Urgency of surgery						
Elective	1.0		1.0		1.0	
Emergency	1.8 (1.4 - 2.2)	<0.001	0.9 (0.7 - 1.3)	0.711	1.9 (1.3 - 2.7)	<0.001
Diverting ileostomy						
No	1.0		1.0		1.0	
Yes	0.3 (0.2 - 0.4)	<0.001	0.8 (0.6 - 1.1)	0.207	0.4 (0.2 - 0.6)	<0.001
Additional resection because of tumor growth						
No	1.0		1.0		1.0	
Limited	0.8 (0.6 - 1.2)	0.364	1.2 (0.9 - 1.7)	0.259	0.7 (0.4 - 1.1)	0.146
Extensive	1.3 (0.9 - 2.0)	0.136	1.7 (1.2 - 2.5)	0.003	0.8 (0.5 - 1.3)	0.330
Additional resection because of metastasis						
No	1.0		1.0		1.0	
Yes	0.9 (0.6 - 1.3)	0.544	1.2 (0.8 - 1.8)	0.478	0.8 (0.4 - 1.4)	0.347
Preoperative radiotherapy						
No	1.0		1.0		1.0	
Radiation	0.8 (0.6 - 1.2)	0.265	2.0 (1.2 - 3.4)	0.010	0.4 (0.2 - 0.8)	0.005
Chemo radiation	0.9 (0.6 - 1.5)	0.684	1.4 (0.8 - 2.8)	0.256	0.6 (0.2 - 1.6)	0.310

Chapter 4

Hospital teaching status and patients' outcomes after colon cancer surgery

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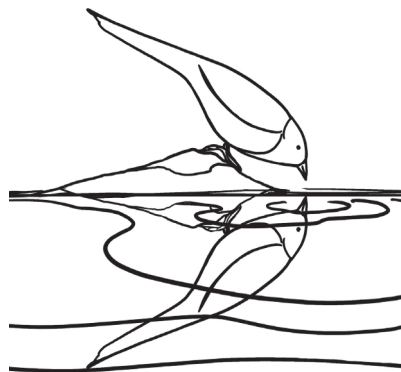
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ABSTRACT

Background and objectives

It is increasingly accepted that quality of colon cancer surgery might be secured by combining volume standards with audit implementation. However, debate remains about other structural factors also influencing this quality, such as hospital teaching status. This study evaluates short-term outcomes after colon cancer surgery of patients treated in general, teaching or academic hospitals.

Methods

All patients (n=23593) registered in the Dutch Colorectal Audit (DCRA) undergoing colon cancer surgery between 2011 and 2014, were included. Patients were divided into groups based on teaching status of their hospital. Main outcome measures were serious complications, failure to rescue and 30-day or in-hospital mortality. Multivariate logistic regression models on these outcome measures and with hospital teaching status as primary determinant were used, adjusted for case-mix, year of surgery and hospital volume.

Results

Patients treated in teaching and academic hospitals showed higher adjusted serious complication rates, compared to patients treated in general hospitals (Odds ratio 1.25 95%CI[1.11-1.39], and OR 1.23[1.05-1.46]. However, patients treated in teaching hospitals had lower adjusted failure to rescue (FTR) rates than patients treated in general hospitals (OR 0.63[0.44-0.89]). However, for all outcomes there was considerable between-hospital variation within each type of teaching status

Conclusion

On average, patients treated in general hospitals had lower serious complication rates, but patients treated in teaching hospitals had more favorable FTR rates. Given the hospital variation within each hospital teaching type, it is possible to deliver excellent care regardless of the hospital teaching type.

INTRODUCTION

Colon cancer is one of the most common malignancies in the world. It is the third leading cause of diagnosed cancer in males and the second in females. In the Netherlands 10 646 new patients were diagnosed in 2014.^{1,2} Surgery still remains the cornerstone of treatment; a surgical resection is the only curative treatment modality for localized colon cancer. The goal of resection is complete removal of the colonic tumor, the major vascular pedicles, and the lymphatic drainage basin of the affected colonic segment.

In the Netherlands, colon cancer surgery is performed in 87 hospitals. All hospitals provide general surgical care, both elective and urgent, for patients in their catchment area. Three different 'hospital teaching types' are distinguished. Academic hospitals (n=8) are all associated with Dutch universities and thus are responsible for education and surgical training. Also, these hospitals function as tertiary referral centers for a selected group of patients with colon cancer. These hospitals provide high-complex and lower volume care. Second, teaching hospitals (n=48), are associated with one specific academic hospital in their region. These hospitals also facilitate training of surgical residents and usually are high volume hospitals, thereby increasing possibilities for residents to gain sufficient surgical experience. And third, nonteaching or general hospitals (n=31), these hospitals do not facilitate surgical training. The general hospitals are usually lower volume hospitals considered to provide accessible care with the possibility to refer to teaching or academic hospitals when necessary.^{3,4} These different 'hospital teaching types' differ in organization of the peri-operative processes, personal concerned with the ward and short or long lines of communication, all factors that are described to influence outcomes in colon cancer surgery.

In 2009, members of the Association of Surgeons of the Netherlands (ASN) initiated the Dutch Surgical Colorectal Audit (DSCA). In 2017 this audit changed into the multidisciplinary Dutch ColoRectal Audit (DCRA). The DCRA is a nationwide audit, used to monitor, evaluate and improve quality of primary colorectal cancer care. It provides periodic feedback with a nationwide benchmark to all hospitals in the Netherlands on a set of quality measures

and indicators. Already in the first years after initiation of the DCRA, a decrease in variation between hospitals and overall improvement of results on several process and outcome indicators was observed.⁵⁻⁷

Until recently, hospital volume was frequently considered a surrogate for quality of care and more specifically a proxy for the experience of the team with the surgical procedure and perioperative care.^{5,6} From this perspective, the ASN in 2011 introduced a minimum annual hospital volume of 50 colorectal resections, regardless of the distribution between colon and rectal surgeries.^{5,7,8} In addition, indicators derived from the DCRA became obligatory and are nowadays used by the Dutch Health Care Inspectorate, patient organizations and insurance companies for annual monitoring and transparency. Combining minimum hospital volume standards with the implementation of this audit has gradually become accepted as an effective way to secure quality of colon cancer care.⁷ However, there still remains debate about the relation between other structural hospital factors, such as 'hospital teaching status', and patient outcomes after colon cancer surgery.^{7,9-12}

The objective of this study was to evaluate the short-term outcomes of patients surgically treated for colon cancer in hospitals with different "hospital teaching status", using the detailed quality indicators from the DCRA.

METHODS

Data were derived from the DCRA, a nationwide audit system containing a wide range of variables concerning diagnostics, treatments and outcomes in colorectal surgery. The dataset is based on evidence-based guidelines. To adjust for case-mix factors, the audit also contains patient and tumor characteristics. Data are collected prospectively. All 87 hospitals performing colon surgery register their patients in the DCRA. The approximate completeness in 2012 was 97% based on comparison with the Netherlands Cancer Registry. Details of the dataset, regarding data collection and methodology have been published previously.^{4,5}

Patients

No ethical approval or informed consent was required under Dutch law. For the present analysis all patients (n=27 118) registered in the DCRA undergoing surgery for primary colon cancer between January 1st 2011 and December 31st 2014 in 87 hospitals, were evaluated. Minimal data requirements to consider a patient eligible for analyses were: date of surgery, 30-day or in-hospital mortality and primary location of the tumor. A total of 108 patients were excluded due to missing data on these variables, evenly divided over different hospitals and hospital types. Patients with additional resections for locally advanced tumors or metastases were also excluded (n=3417) as these procedures are mostly performed in academic or specific teaching hospitals suitable for these high complex procedures and this could introduce treatment by indication bias. This resulted in 23 593 included patients for the present analysis.

Hospital teaching status and hospital volume

For this study the hospitals were divided into three groups based on their hospital teaching status: general, teaching or academic hospital. Hospital volume was defined as the mean annual number of procedures between 2011 and 2014. Hospital volume can be seen as a proxy for experience with this procedure and it differs considerably per hospital teaching type. We used tertiles of hospital volume in the analyses to distinguish between hospitals with relatively high versus relatively low volumes. All calculations for hospital volume were performed before exclusion of patients with additional surgery, while these surgeries also add to the experience hospitals have with the procedure.

Outcome measures

We examined the following short-term outcome measures after colon cancer surgery: serious complications, postoperative mortality and failure to rescue. The definitions of these outcome measures are displayed in Table 1 and are based on previous studies using DCRA data.^{5,6}

Statistical analysis

First, patients treated in different hospital teaching types were compared on baseline characteristics and differences between these variables were analyzed

using Chi-square tests. Relevant case-mix factors that were considered are: age, gender, Body Mass Index (BMI), ASA score, Charlson comorbidity index, preoperative complications, location of the tumor, urgency and TNM stage, as described elsewhere.^{4,13} Significance was considered when the p-value was <0.05 . A p-value <0.10 was defined as a trend towards significance, but caution is required and no definite conclusions can be drawn based on trends.

Second, a multivariate logistic regression analyses was used to determine whether outcome differed between patients treated in different hospital teaching types when adjusted for differences in case-mix. Risk adjustment was done for all case-mix factors that showed significant differences in the univariate analyses, and year of surgery, to account for possible trends over time in outcomes. Thirdly, the multivariate logistic regression analyses was repeated, adjusting for case-mix, year of surgery, and tertiles of hospital volume (as a categorical variable). This was done to test whether a relatively high hospital volume in some hospital types could (partly) explain the difference in outcomes between different hospital teaching types.

To show the magnitude of hospital variation by hospital volume within each hospital teaching type, funnelplots for all outcome measures were created. In these funnelplots each dot represents an individual hospital, with the hospital volume (in 2011-2014) plotted on the x-axis and case-mix adjusted percentage of the outcome measure on the y-axis. Hospitals are displayed in different colors according to their 'hospital teaching status'. The average percentage of the outcome for all patients is shown by the horizontal dotted line. The 95% and 99% confidence intervals are based on a Poisson distribution varying in relation to the population size of each hospital.

Statistical analyses were performed in IBM SPSS Statistic version 22.

RESULTS

Patients and treatment characteristics

A total of 23 593 patients, registered by 8 academic, 48 teaching and 31 general hospitals were included in this study. Table 2 shows that patients treated

in academic hospitals were younger and more often had a high Charlson comorbidity score compared to patients in teaching and general hospitals. Patients treated in teaching hospitals were comparable to patients in general hospitals, although in general hospitals patients more often underwent surgery in an urgent setting.

In addition it is shown that hospital volume was higher in teaching hospitals compared to general and academic hospitals (Table 2). Hospital volumes of each group increased over the last 4 years. In 2011 general hospitals had a median hospital volume of 53 patients (IQR 42-62), increasing to 57 (IQR 41-69) in 2014. The same trend is observed in both teaching and academic hospitals ranging from 85 (IQR 68-112) and 44 patients (IQR 32-52) respectively in 2011, to 111(IQR 85-138) and 68 (IQR 38-84) patients in 2014.

OUTCOMES

Serious complications

Table 3 shows the difference in serious complication rates of patients treated in general hospitals (15.6%), and patients treated in teaching (17.6%) and academic hospitals (18.3%). After adjusting for case-mix and year of surgery, patients treated in teaching and academic hospitals had significantly higher serious complication rates than patients treated in general hospitals, with Odds ratio of 1.22 [95%CI 1.13-1.33] and 1.23[1.05-1.45]. After also adjusting for hospital volume the effect did not change much (OR 1.25 [1.12-1.39] and 1.23 [1.05-1.46], indicating that volume does not explain this difference in serious complication rates. Teaching and academic hospitals showed no significant difference (data not shown).

Figure 1 shows the variation of adjusted serious complication rates among the Dutch hospitals. The funnelplot demonstrates serious complication rates and hospital volume within general, teaching and academic hospitals. It demonstrates that within each category of teaching status, variation in hospital volume and risk of complications was observed. In addition, all negative outliers were teaching hospitals, while positive outliers were general and teaching

hospitals. It also showed that the results from of the regression model are not due to these few outliers.

Failure to rescue

Patients treated in teaching hospitals showed a trend towards lower failure to rescue rates as compared to general hospitals after adjusting for case-mix and year of surgery, however, this effect was not significant (table 3). After additional adjustment for hospital volume the failure to rescue rate of patients treated in teaching hospitals compared to general hospitals was significantly lower (OR 0.63 [0.44-0.89]). Academic hospitals showed an effect in the same direction, but this was not significant. Teaching and academic hospitals showed no significant difference (data not shown).

Figure 2 shows the considerable variation between hospitals in failure to rescue rates within different hospital teaching types. Nine hospitals had significantly lower failure to rescue rates than the Dutch average of 12.2%, both general and teaching hospitals were represented in these positive outliers. Two general hospitals and one teaching hospital had a significantly higher failure to rescue rate than the Dutch average.

Postoperative mortality

Patients treated in different hospitals types showed no difference in 30 day or in-hospital postoperative mortality after colon cancer surgery (Table 3). Variation in postoperative mortality between hospitals showed a similar pattern to that of failure to rescue (data not shown).

DISCUSSION

The present study showed that patients treated in teaching hospitals and academic hospitals on average had higher serious complication rates than patients treated in general hospitals after primary colon cancer surgery when adjusted for case-mix and year of surgery. Hospital volume could not explain these differences. However, patients treated in teaching hospitals had lower adjusted failure to rescue rates than patients treated in general hospitals. Postoperative mortality did not differ between patients treated in different

hospital types. For all these outcomes considerable hospital variation was shown within all hospital teaching types and hospitals with best outcomes are found in all hospital teaching types.

The results of this study contribute to the discussion whether certain structural factors, such as teaching status, are related to good outcomes after colon cancer surgery. Previous studies have suggested that hospital teaching status is associated with outcomes for patients treated for several medical conditions and after several surgical procedures. In most studies, outcomes were favorable for patients treated in teaching and academic hospitals.^{6,10,14-18} However, (the size of) the association between teaching status or hospital volume and postoperative mortality seems to differ considerably per procedure and condition.^{6,8,10,14-21} In colorectal cancer surgery, previous studies in the Netherlands and Canada showed no or a small effect of hospital teaching status on post-operative mortality of patients.^{21,22} However, Frieze et al. showed no effect of hospital teaching status on failure to rescue and postoperative mortality in surgical oncology, after risk adjustment.²⁰ Furthermore, Elferink et al. found that patients treated in general hospitals had a lower odds on ≥ 10 lymph nodes adequately investigated and a higher odds for receiving adjuvant therapy. The postoperative mortality did not differ with different structural factors. However, survival was suggested to be better for patients treated in university hospitals.¹¹

The present study adds to this literature by showing the association on several short-term outcome indicators. It confirms the absence of an association between teaching status and postoperative mortality after colon cancer surgery but adds that patients treated in different hospital types on average seem to differ in risk of serious complication and failure to rescue. However, we also showed considerable hospital variation within each hospital teaching status. Part of this hospital variation in outcomes might be explained by differences in process indicators as shown by Elferink et al within each teaching group.¹¹ This might also explain that best performers are found in all hospital teaching types, suggesting that all hospitals can achieve good outcomes after colon

cancer surgery, regardless of their difference in hospital teaching status (and hospital volume).

The question remains whether it is the effect of the hospital teaching status on short-term outcomes or rather a combination of processes more prevalent in certain hospital types that lead to better outcomes. If it is indeed this combination of processes, identifying these processes might be more effective than using indirect factors that are not amenable for change. Suggested factors accounting for variation are for instance: difference in advanced technology and nurse staffing.^{6,7,9,11} Possible explanations could also be surgeon specific, such as degree of specialization, availability during on-call hours and, efficient escalation of care from nurses to specialized-surgeons. All of these factors might contribute to preventing that a patient develops a serious complication or even death.^{3,23-25} Further research, measuring these potentially explanatory factors, might be relevant to improve quality of all hospitals, independent of their hospital teaching type.

Some limitations should be noted. First, selection bias cannot be completely excluded, as doctors report the data themselves. However, as is shown in previous publications, the dataset is detailed and frequently validated both internal and against other external sources.^{4-6,12,13} Furthermore, although we adjusted for a variety of most relevant case-mix factors, unknown confounding case-mix factors may possibly play a role such as medication or smoking habits.^{4,13} Last, we used data derived from the Dutch population so it is not known if our results can be generalized to other countries. Factors that may influence this generalization are: the minimum volume standard that is in place, whether a clinical audit system is performed, but also density of the population and thus access to hospitals and distribution of hospitals over the country.

So, even though we have shown that on patient-level hospital teaching status was significantly related to lower risk of serious complication in general hospitals and lower failure to rescue rates in teaching hospitals, considerable between hospital variation was shown regardless of teaching status. Best performers are found in all hospital teaching types, which suggests that is

it possible to deliver excellent care in each hospital teaching type. This study shows that to learn from best performers further research should start looking for other factors than structural factors to improve our outcomes in colon cancer surgery.

Conflict of interest

None of the authors have anything to disclose.

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TABLES AND FIGURES

Table 1. Definitions of outcome measures

Serious complications	Percentage of patients with a serious complication leading to an in-hospital stay of more than 14 days, a surgical, endoscopic or radiological reintervention, or to death
Postoperative mortality	Percentage of patients that died within 30 days after surgery or during the first hospital admission
Failure to rescue	The percentage patients with a serious complication that died in-hospital or within 30 days after surgery

Table 2. Patient and tumor characteristics per hospital teaching type.

	General		Teaching		Academic		p
Number of hospitals	31		48		8		
Median hospital volume (before exclusion of patients with additional resections)	43 (IQR 43-61)		95 (IQR 76-124)		49 (IQR 40-63)		
Number of patients	6095		16250		1248		
Gender							
Male	Count	%	Count	%	Count	%	0.367
	3266	53.60%	8533	52.50%	658	52.70%	
BMI categories							<0.001
<18.5	78	1.30%	254	1.60%	30	2.40%	
18.5-25	2222	36.50%	6432	39.60%	494	39.60%	
25-30	2331	38.20%	6244	38.40%	482	38.60%	
30+	982	16.10%	2603	16.00%	210	16.80%	
Unknown	482	7.90%	717	4.40%	32	2.60%	
Age							<0.001
<=60	955	15.70%	2512	15.50%	242	19.40%	
61 - 70	1740	28.60%	4819	29.70%	391	31.30%	
71 - 80	2195	36.00%	5759	35.50%	426	34.10%	
>=81	1203	19.70%	3152	19.40%	189	15.10%	
Charlson score							<0.001
Charlson score 0	2956	48.50%	7969	49.00%	512	41.00%	
Charlson score 1	1478	24.20%	3833	23.60%	257	20.60%	
Charlson score 2+	1661	27.30%	4448	27.40%	479	38.40%	

Table 2. Continued.

	General		Teaching		Academic	p
ASA score						0.003
I - II	4453	73.40%	12092	74.50%	880	70.50%
III	1485	24.50%	3852	23.70%	336	26.90%
IV - V	131	2.20%	281	1.70%	32	2.60%
Location primary tumor						<0.001
Caecum	1211	19.90%	2983	18.40%	248	19.90%
Appendix	49	0.80%	84	0.50%	18	1.40%
Ascending colon	1146	18.80%	3052	18.80%	206	16.50%
Hepatic flexure	386	6.30%	1010	6.20%	80	6.40%
Transverse colon	391	6.40%	1201	7.40%	112	9.00%
Splenic flexure	198	3.20%	503	3.10%	42	3.40%
Descending colon	365	6.00%	972	6.00%	68	5.40%
Sigmoid colon	2349	38.50%	6445	39.70%	474	38.00%
Pathological T stage						<0.001
T1 and ypT0	497	8.15%	1368	8.41%	163	13.06%
T2	1047	17.18%	2801	17.24%	212	17.00%
T3	3697	60.66%	9954	61.26%	737	59.05%
T4	793	13.01%	1972	12.14%	130	10.42%
Missing	61	1.00%	73	5.85%	25	2.00%

Table 2. Continued.

	General	Teaching	Academic	p
Pathological N stage				0.011
N0	3612	9634	767	61.50%
N1	1487	3987	291	23.30%
N2	935	2500	168	13.50%
Unknown	57	124	21	1.70 %
Metastasis (without additional surgery)				<0.001
	620	1495	117	9.40%
Preoperative tumor complication				<0.001
	2709	6657	536	42.90%
Urgent setting				0.001
	1176	2783	217	17.40%
Type of surgery				0.001
Laparotomy	2709	7075	581	47.20%
Laparoscopy	3383	9163	651	52.80%

Table 3. Unadjusted percentage and multivariate regressions of the outcome measures: serious complications, postoperative mortality and failure to rescue.

Outcome	Unadjusted percentage (n/N)	Multivariate regression** 95% C.I. for EXP(B)			Multivariate regression (incl. volume)*** 95% C.I. for EXP(B)		
		Odds	Lower	Upper	Odds	Lower	Upper
Serious complications							
General (ref.)	15.6% (948/6095)	1			1		
Teaching	17.6% (2856/16250)	1.22	1.13	1.33	1.25	1.12	1.39
Academic	18.3% (228/1248)	1.23	1.05	1.45	1.23	1.05	1.46
Postoperative mortality							
General (ref.)	3.3% (201/6095)	1			1		
Teaching	3.0% (492/16250)	1.04	0.87	1.24	1.05	0.84	1.33
Academic	3.4% (41/1248)	1.14	0.80	1.63	1.14	0.80	1.63
Failure to rescue*							
General (ref.)	18.3% (119/649)	1			1		
Teaching	14.7% (304/2073)	0.78	0.60	1.00	0.62	0.44	0.88
Academic	7.9% (23/164)	0.77	0.46	1.29	0.74	0.44	1.24

*Denominator: patients with a serious complication that underwent elective surgery

**Adjusted for: case-mix and year of surgery

***Adjusted for: case-mix, year of surgery and hospital volume in tertiles

Figure 1. Percentage of serious complications after colon cancer surgery according to hospital type and hospital volume in 2011-2014. Percentage of each hospital was adjusted for case-mix and year of surgery.

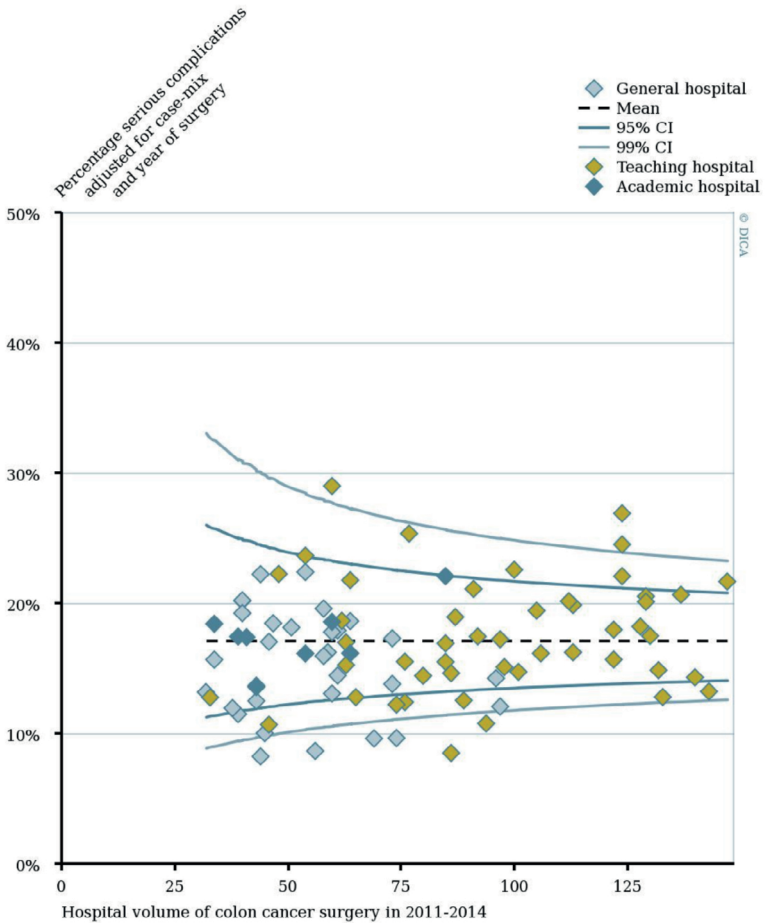
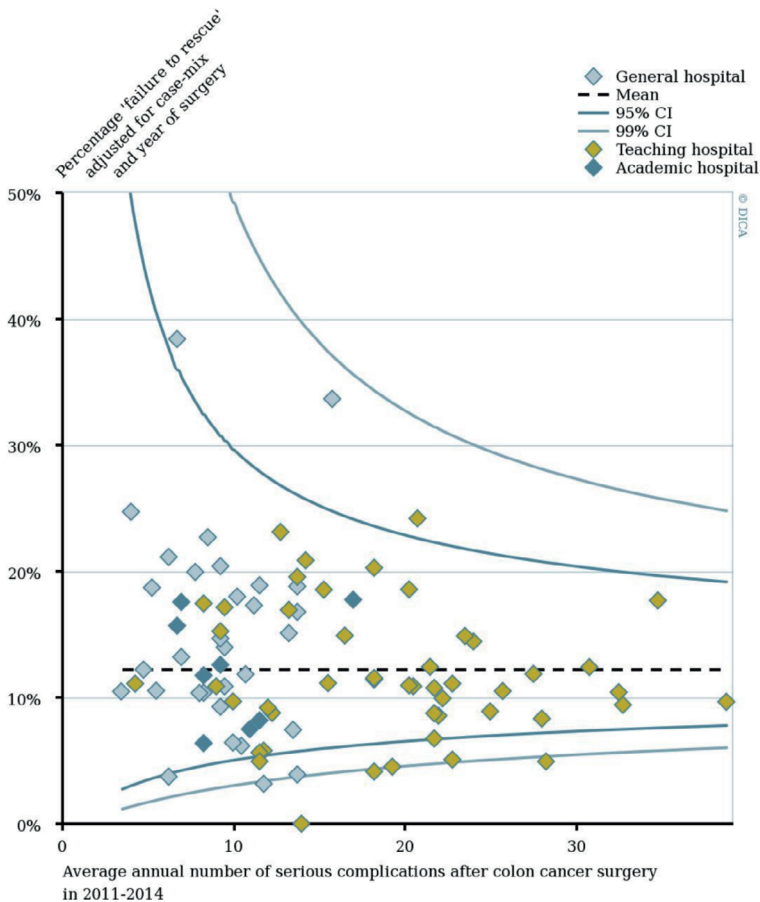


Figure 2. Percentage of failure to rescue after colon cancer surgery according to hospital type and hospital volume of serious complications in 2011-2014. Percentage of each hospital was adjusted for case-mix and year of surgery.



Chapter 5

Level of digitization in Dutch hospitals and the lengths of stay of patients with colorectal cancer

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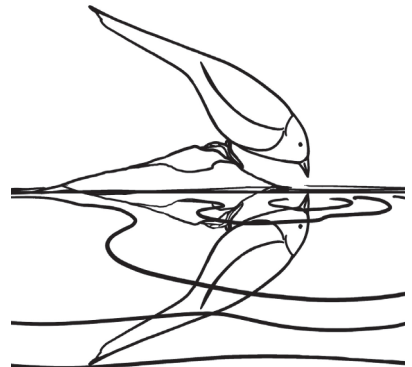
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ABSTRACT

Background

A substantial amount of research has been published on the association between the use of electronic medical records (EMRs) and quality outcomes in U.S. hospitals, while limited research has focused on the Western European experience. The purpose of this study is to explore the association between the use of EMR technologies in Dutch hospitals and length of stay after colorectal cancer surgery.

Methods

Two data sets were leveraged for this study; the HIMSS Analytics Electronic Medical Record Adoption Model (EMRAMSM) and the Dutch surgical colorectal audit (DSCA). The HIMSS Analytics EMRAM score was used to define a Dutch hospital's electronic medical records (EMR) capabilities while the DSCA was used to profile colorectal surgery quality outcomes (specifically total length of stay (LOS) in the hospital and the LOS in ICU). A total of 73 hospitals with a valid EMRAM score and associated DSCA patients (n=30.358) during the study period (2012 – 2014) were included in the comparative set. A multivariate regression method was used to test differences adjusted for case mix, year of surgery, surgical technique and for complications, as well as stratifying for academic affiliated hospitals and general hospitals.

Results

A significant negative association was observed to exist between the total LOS (relative median LOS 0,974, CI 95% 0.959-0,989) of patients treated in advanced EMR hospitals (high EMRAM score cohort) versus patients treated at less advanced EMR care settings, once the data was adjusted for the case mix, year of surgery and type of surgery (laparoscopy or laparotomy). Adjusting for complications in a subgroup of general hospitals (n=39) yielded essentially the same results (relative median LOS 0,934, CI 95% 0,915 - 0,954). No consistent significant associations were found with respect to LOS on the ICU.

Conclusions

The findings of this study suggest advanced EMR capabilities support a healthcare provider's efforts to achieve desired quality outcomes and efficiency in Western European hospitals.

INTRODUCTION

Implementations of potentially transformative eHealth technologies throughout the world frequently have a significant impact on national health expenditures. Such large-scale efforts and investments have been justified on the grounds that the EMR, picture archiving and communication systems (PACS), electronic prescribing (ePrescribing) and associated computerized provider (or physician) order entry systems (CPOE), and computerized decision support systems (CDSS) are supposed to help to address the problems of variable quality and safety in modern health care¹⁻⁶. However, the scientific basis of such claims, which are repeatedly made and seemingly uncritically accepted, remains to be firmly established.

For the measurement of the level of implementation of information systems a concept of maturity of these systems has been developed. There is a large number of methods or models available to measure the level of implementation of information technology.⁷ One of these methods is the so-called Electronic Medical Record Adoption Model (EMRAM) scoring approach developed by Healthcare Information and Management Systems Society (HIMSS) Analytics.⁸ EMRAM is an eight stage maturation model reflecting the EMR capabilities in hospitals, ranging from a completely paper-based environment (Stage 0) to a highly advanced paperless and digital patient record environment (Stage 7). The scoring process is done by identifying the software used in the different functional areas of the hospital. At least 150 questions per hospital are included about demographics, software functionalities, processes, integration standards, usage in percentage by physician and nurses, depending on the available software in the hospital. Previous studies on this model in the Netherlands show that EMRAM stage 3, the first stage in which clinical functionalities (nursing) become available, presents as the first notable challenge to Dutch hospitals; 37.5% of the hospitals in this study have yet to satisfy the requirements of this stage. The basic and more advanced clinical capabilities should help to increase the quality, safety and efficiency of the treatment of patients in the hospital.⁹

The Dutch surgical colorectal audit (DSCA), started in 2009, is a nationwide audit used to monitor, evaluate and improve quality of care of primary colorectal cancer surgery. It provides feedback to all hospitals in the Netherlands on a set of quality measures and indicators. While EMRs may lead to better hospital performance and outcomes, hospitals may use EMRs to improve the quality of care. This paper has the objective to contribute to the scientific discourse on the relationship between the digitalization of hospital data and the effect on quality of care, with colorectal cancer as a guiding example.^{10,11}

Our thesis behind this study is that when basic clinical functionalities (EMRAM $\geq$ 3) are available in a hospital, the patients will have a more efficient hospitalization. Efficient communication could prevent medical or organizational mistakes and make it possible to transfer patients from an intensive care unit (ICU) to a general ward and transfer patients from the ward to home without undue delay. We used the post-operative length of stay (LOS) in this study because that is where the presumed effect is expected. Preoperative patients are usually admitted to the hospital the same day or the day before the surgery.

University and top teaching hospitals provide a great deal of specialized care and medical research, as well as the training and education of many of the nation's health care providers. Former studies^{12,13} indicate that academic affiliated hospitals may more easily adapt to changes than general hospitals. According to Retchin and Wenzel¹³, university health centers, as well as top teaching hospitals, can easily adapt to the use of EMRs because they, "have the expertise to resolve remaining software issues, the components necessary for the integrated delivery, a culture for innovation in clinical practice, and a generation of future providers that can be acclimated to the requisites for computerized records"(p.493 of Retchin and Wenzel¹³). Another reason for this increased likelihood is that medical training occurs in these hospitals, and younger medical trainees tend to be more comfortable with computers as they have recently used them in school.¹⁴ Because of this, the staff resistance to EMR use may not be as great as in other hospitals.¹³ Based upon these properties we expect that in academic affiliated hospitals the above mentioned

effect is even stronger. From this model (Figure 1) we deducted the following hypotheses.

Hypothesis 1: In hospitals with more advanced EMR capabilities the likelihood of a shorter LOS on average of colorectal cancer surgery patients in the hospital increases.

Hypothesis 2: In hospitals with more advanced EMR capabilities the likelihood of a shorter LOS on average in the ICU of colorectal cancer surgery patients increases.

Hypothesis 3: The likelihood of a shorter LOS on average of colorectal cancer surgery patients increases in academic affiliated hospitals with more advanced EMR capabilities.

Hypothesis 4: The likelihood of a shorter LOS on average in the ICU of colorectal cancer surgery patients increases in academic affiliated hospitals with more advanced EMR capabilities.

METHODS

Data were collected from the DSCA. This disease specific registry contains information on patient, tumor, treatment and short-term outcome characteristics. All hospitals in the Netherlands register their primary colorectal cancer patients that undergo a resection in this database. Details of this dataset regarding collection and methodology have been published previously.^{15,16}

Patients

All patients undergoing surgical resection for primary colorectal cancer between January 1, 2012, and December 31, 2014, and registered in the DSCA before March 30, 2015, were evaluated in this study. For this study no ethical approval or informed consent was required under Dutch law. Minimal data requirements to consider a patient eligible for analyses were information on tumor location, date of surgery, and mortality. Patients with local excisions were excluded (n=393) Patients with LOS of 0 or less, or LOS that was missing were excluded (n=358), because the origin of this outcome is possibly grounded on registration mistakes.

Hospitals

Every hospital in the NL (N=93) was invited to participate in the EMRAM study. In 2014, 73 hospitals (80%) joined the EMRAM program. Of this group of hospitals (N=34) are considered academic affiliated (university and top teaching hospitals) for the purpose of this study. These hospitals provide high-complex care, lead the way in innovation and research and train (surgical) residents. For the primary objective of this study, the EMRAM scores of the hospitals present in both databases (EMRAM and DCSA) were dichotomized into hospitals with clinical functionalities (EMRAM $\geq$ 3) and hospitals without clinical functionalities (EMRAM $<$ 3).

Outcomes

Length of stay is shown in days, calculated by subtracting the date of surgery from the date of dismissal from the hospital. Length of stay on the ICU is registered directly into the registry.

Statistical analysis

The primary analysis is a multivariate regression analysis on the logarithmically transformed LOS, adjusted for patient and tumor characteristics, year of surgery, hospital type and type of surgery (laparoscopy of laparotomy). Patient and tumor characteristics adjusted for are: gender, BMI-index, age, ASA classification, primary location of the tumor, pathological T stage, metastasis, perioperative tumor complications, urgency, additional resections for tumor growth and metastasis. Details concerning the use of relevant case-mix factors have been described elsewhere.^{16,17} We repeated the multivariate regression, by additionally adjusting for surgical complications in three stages: a single complication, a complication combined with reoperation and a complication leading to death. The analyses are repeated for the total group of hospitals (N=73), the group of academic affiliated hospitals (N=34) and the group of general hospitals (N=39). Significance was considered for the primary research question, with a p-value $<$ 0.05.

RESULTS

Patients and hospitals

In total 73 hospitals, including 30.358 patients were included in this study. In table 1 the distribution of patients' characteristics among the EMRAM low group and the EMRAM high group are shown. A significant effect (relative median LOS=0,974, CI 95% 0.959 - 0,989) is found between patients in the EMRAM low group and the LOS in the EMRAM high hospital group when corrected for the case mix, year of operation and type of surgery (laparoscopy or laparotomy). Additional adjustment for patients with complications confirms the association (relative median LOS 0,969, CI 95% 0,956 – 0,981). For LOS in the ICU the multivariate regression does not show a significant association of higher EMRAM score with smaller LOS (relative median LOS 0,995, CI 95% 0,942 – 1,050). After adjustment for patients with complications there is also no significant association (relative median LOS 1,010 CI 95% 0,962 – 1,060).

Looking at the subgroup of academic affiliated hospitals (N=34) (Table 3) the significance of the change of the LOS in the hospital when corrected for the case mix, year of operation and type of surgery (laparoscopy or laparotomy) disappears. Still, when corrected for complications there is a significant decreasing effect.

Looking at the subgroup of general hospitals (n=39) (Table 4) a significant negative association (relative median LOS 0,934, CI 95% 0,915 - 0,954) is found when corrected for the case mix. This means an estimated decrease of the median LOS of 6,6% and 6,1% when also corrected for complications (eB1=0,939). For LOS in de ICU the multivariate regression shows a significant (relative median LOS 1,104, CI 95% 1,036 – 1,177) increase for hospitals with higher EMRAM scores. When additionally adjusted for complications, there are no significant associations.

Results of tests regarding the hypotheses.

Hypothesis 1 (in hospitals with more advanced EMR capabilities the likelihood of a shorter LOS on average of colorectal cancer surgery patients in the hospital increases) is supported by our findings. Hypothesis 2 (in hospitals with more

advanced EMR capabilities the likelihood of a shorter LOS on average in the ICU of colorectal cancer surgery patients increases) is not supported by our findings. On the contrary a not significant increase of the LOS in the ICU is found. Hypothesis 3 (the likelihood of a shorter LOS on average of colorectal cancer surgery patients increases in academic affiliated hospitals with more advanced EMR capabilities) is not supported by our findings. On the contrary a stronger effect is measured by general hospitals instead by academic affiliated hospitals. Hypothesis 4 (the likelihood of a shorter LOS on average in the ICU of colorectal cancer surgery patients increases in academic affiliated hospitals with more advanced EMR capabilities) is also not supported by our findings.

DISCUSSION

For this study we tested the relation between the availability of clinical software in the hospital (EMRAM stage 3 and higher) and the LOS. For the total group of hospitals, we found a significant association as expected; LOS is shorter in hospitals with more advanced clinical software. Looking in more detail at the group of hospitals we found that the correlation is stronger in general hospitals than in academic affiliated hospitals, even when corrected for their different case mix.¹¹ A possible reason behind this difference might be that the academic affiliated hospitals have had EMRs longer, thus they have already made some macro adjustments that affect LOS and general hospitals are not yet as mature in EMR use and thus are still deriving the initial benefits. In addition, it is shown¹⁸ that resident involvement may increase LOS in advanced laparoscopic surgery. This could mask the effect of the EMR.

Not clear is the slightly larger LOS in the ICU of EMRAM stage 3 or higher hospitals, especially in general hospitals (significant after case-mix correction). The difference could lie in the different levels of ICU; the least advanced ICU level is in the Netherlands frequently used for extended recovery. After repeating the analyses of general hospitals with exclusion of the lowest ICU level we see the correlation changes to a decreasing ratio, but after correction for complications also this is not significant anymore (data not shown). During our EMRAM investigation of the hospitals we found out that the software used in the ICU and the operating room, the so called Patient Data Management

System (PDMS), is most of the time not integrated with the EMR system of the entire hospital. So the management of the LOS in the ICU may differ from the management of the LOS in the hospital. Only at EMRAM stage 6 and 7 the integration of the EMR system with the PDMS system is mandatory. It may also be a side effect of the diversity of hospitals in the EMRAM high group. In this group, hospitals with basic clinical facilities are present, but also hospitals with more advanced digital processes and evidence based intelligence. In future more hospitals will reach the highest, full digital, stage 7 level a third group (EMRAM $\geq$ 6) can be added to look for the association with more advanced (outcome) indicators in the DSCA database. Further research is suggested to look for this relationship.

Limitations of the study and suggestions for further research

There are limitations to our study. First, although we achieved a 77% response rate, the hospitals that did not respond to our survey were somewhat different from those that did respond. Small hospitals and hospitals located in the northern part of the Netherlands were underrepresented in the study. The 72 hospitals that did participate provided a fairly good representation of the total population of the Netherlands 93 hospitals. Given that non-responding hospitals were more likely to have characteristics associated with lower levels of adoption of electronic health records, residual bias may have led us to overestimate adoption levels. Furthermore, although we adjusted for an extensive number of patient and tumor factors, unknown confounding factors could still be present.

Conclusion

We found a significant association between the level of digitalization of hospitals and the length of stay after colorectal cancer surgery, consistent with shorter length of stay in hospitals with higher levels of digitization.

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Conflict of interest statement

All authors declare no conflict of interest.

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TABLES AND FIGURES

Table 1. Patient and hospital characteristic per EMRAM Group

Patient and hospital characteristics	EMRAM <3		EMRAM ≥3	
	Count	%	Count	%
Sex				
Male	4462	55,8%	9341	55,1%
Female	3540	44,2%	7627	44,9%
BMI in categories				
Unknown	199	2,50%	451	2,7%
<18.5	170	2,1%	276	1,6%
18.5-25	3195	39,9%	6758	39,8%
25-30	3110	38,8%	6732	39,7%
30+	1334	16,7%	2759	16,3%
Age				
≤60	1528	19,1%	2972	17,5%
61 – 70	2538	31,7%	5341	31,5%
71 – 80	2674	33,4%	5903	34,8%
≥81	1268	15,8%	2747	16,2%
Charlson score				
Charlson score 0	3967	49,5%	8586	50,6%
Charlson score 1	1813	22,6%	3877	22,8%
Charlson score 2+	2228	27,8%	4513	26,6%
ASA score				
I – II	6157	77,0%	13099	77,2%
III	1732	21,6%	3620	21,3%
IV – V	112	1,4%	254	1,5%
Location of tumor				
Caecum	1126	14,1%	2321	13,7%
Appendix	40	0,5%	89	0,5%
Ascending colon	1043	13,0%	2221	13,1%
Hepatic flexure	315	3,9%	751	4,4%
Transverse colon	413	5,2%	1013	6,0%
Splenic flexure	195	2,4%	403	2,4%
Descending colon	368	4,6%	773	4,6%
Sigmoidal colon	2307	28,8%	4617	27,2%
Rectum	2201	27,5%	4788	28,2%
Pathological T stage				
Tx/T0	23	0,3%	35	0,2%
T1	812	10,2%	1693	10,1%
T2	1564	19,7%	3390	20,2%

Table 1. Continued

Patient and hospital characteristics	EMRAM <3		EMRAM ≥3	
	Count	%	Count	%
T3	4544	57,1%	9442	56,2%
T4	1012	12,7%	2255	13,4%
Distant metastasis				
No/missing	7092	88,6%	15190	89,5%
Yes	916	11,4%	1786	10,5%
Pre-operative tumor complications				
No/missing	5330	66,6%	9619	56,7%
Yes	2678	33,4%	7357	43,3%
Urgency				
Elective (incl. after stent)	6864	85,8%	14741	86,9%
Urgent/Emergency	1140	14,2%	2227	13,1%
Additional resection because of metastasis				
No	7643	95,4%	16470	97,0%
Yes	365	4,6%	506	3,0%
Additional resection because of extensive tumor growth				
No	7209	90,0%	15489	91,2%
Extensive	353	4,4%	682	4,0%
Limited	446	5,6%	805	4,7%
Surgical technique				
Laparotomy	3424	43,0%	6864	40,6%
Laparoscopy	4546	57,0%	10039	59,4%
Complications				
No complications	5570	69,8%	11362	67,1%
Complication	1431	17,9%	3400	20,1%
Complications and reintervention	770	9,6%	1777	10,5%
Complications and death	214	2,7%	403	2,4%
Size of hospital admitted				
Small	1489	18,6%	2006	11,8%
Medium	3711	46,3%	5789	34,1%
Large	2808	35,1%	9181	54,1%
Type of hospital admitted				
General hospitals	4446	55,5%	5965	35,1%
Academic (affiliated) hospitals	3562	44,5%	11011	64,9%
Region of hospital admitted				
East	1271	15,9%	3438	20,3%
North	1517	18,9%	1728	10,2%
South	1727	21,6%	5547	32,7%
West	3493	43,6%	6263	36,9%

Table 2. Length of stay of patient in total hospital group

	Univariate regression		Multivariate regression***		Multivariate regression****	
	B	Lower Upper	B	Lower Upper	B	Lower Upper
Logarithm of LOS in the hospital						
median LOS >=3 /median LOS <3	0,998	0,981 1,016	0,974 0,959 0,989	0,969	0,956	0,981
Logarithm of LOS in the ICU						
median LOS >=3 /median LOS <3	1,106	1,047 1,169	0,995 0,942 1,050	1,010	0,962	1,060

*** adjusted for: case-mix, year of registration, hospital type and technique of treatment (laparoscopic/laparotomy)
**** adjusted for: as before plus complications

Table 3. Length of stay (LOS) for patients in academic affiliated hospitals

	Univariate regression		Multivariate regression***		Multivariate regression****	
	B	Lower Upper	B	Lower Upper	B	Lower Upper
Logarithm of LOS in the hospital						
median LOS >=3 /median LOS <3	0,987	0,963 1,011	0,991 0,971 1,011	0,967	0,950	0,982
Logarithm of LOS in the ICU						
median LOS >=3 /median LOS <3	1,093	1,002 1,192	1,011 0,939 1,089	1,017	0,952	1,086

*** adjusted for: case-mix, year of registration, hospital type and technique of treatment (laparoscopic/laparotomy)
**** adjusted for: as before plus complications

Table 4. Length of stay (LOS) for patients in general hospitals

	Univariate regression			Multivariate regression***			Multivariate regression****		
	B	Lower	Upper	B	Lower	Upper	B	Lower	Upper
Logarithm of LOS in the hospital									
median LOS >=3 /median LOS <3	0,973	0,948	0,998	0,934	0,915	0,954	0,939	0,922	0,956
Logarithm of LOS in the ICU									
median LOS >=3 /median LOS <3	1,077	1,000	1,161	1,104	1,036	1,177	1,056	0,998	1,115

*** adjusted for: case-mix, year of registration, hospital type and technique of treatment (laparoscopic/laparotomy)
**** adjusted for: as before plus complications

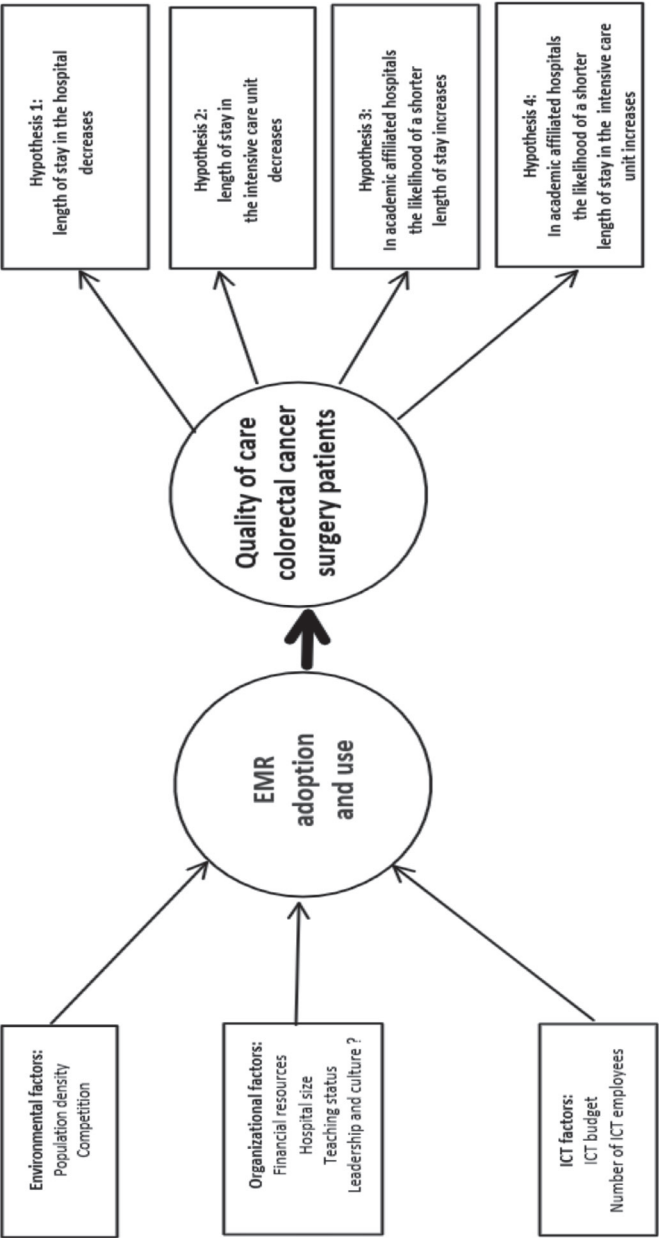


Figure 1. The theoretical model

Chapter 6

Evaluation of a completion total mesorectal excision (cTME) in patients after local excision of rectal cancer; a word of caution

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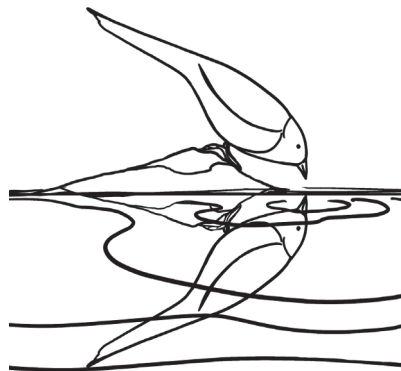
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ABSTRACT

Background

According to Dutch guidelines, locally excised low-risk pT1 or ypT0-1 rectal cancer should not necessarily be followed by completion total mesorectal excision (cTME) in contrast to higher T stages or unfavorable features. The aim of this study is to evaluate cTME after local excision at a national level with possible determinants for decision-making.

Methods

All patients in the Dutch Colorectal Audit (DCRA) that underwent local excision of rectal cancer between 2012 and 2015 were included. Guideline adherence for performing cTME was determined with uni- and multivariate analyses to identify factors related to non-compliance.

Results

According to the guidelines, of 530 included patients, cTME was indicated in 283 of them (53%) and performed in 82 of the 283 mentioned (29%). Guideline adherence for cTME improved significantly ($p < 0.001$) from 10% in 2012 to 44% in 2015. Lower Charlson scores in patients with high-risk pT1 and younger patients with pT $\geq$ 2 were associated with more performance of a cTME (Odds ratio (OR) 13.50 [95%CI 1.39-131.32] and OR 6.25 [1.83-21.31]).

Discussion

In this population-based study from the Netherlands only a minority of patients underwent cTME after local excision of rectal cancer with pathological features indicating the need for further treatment, according to the guideline. Although over time the percentage of patients undergoing cTME increases, the study indicates a tendency towards rectal preserving treatment with potential oncological risks.

BACKGROUND

Total mesorectal excision (TME) is the gold standard for curative treatment of non-locally advanced rectal cancer. Together with preoperative radiotherapy, TME as a standardized surgical technique has significantly improved local control of rectal cancer over the last decades. The downside of TME is a high rate of postoperative morbidity, a risk of mortality, and reduced quality of life.¹⁻⁴ Rectal preserving surgery can be performed as an alternative in selected patients, thereby reducing postoperative morbidity and mortality and improving quality of life.^{5,6} Introduction of nationwide screening programs and neo-adjuvant (chemo)radiotherapy have led to an increase in patients eligible for rectal saving surgery with curative intent.⁷

Local excision only is considered an alternative to TME for early low risk rectal cancer, defined as pT1, cN0M0 rectal cancer, with favorable histopathology (diameter <3cm, good to moderate differentiation, no lymphovascular invasion, and negative resection margins), because recurrence rates of locally excised low risk T1 rectal cancers have been reported to be less than 5% and morbidity, mortality, and hospital stay is significantly lower compared to TME.^{8,9} If the pathology of the local excision specimen shows a high risk T1 rectal cancer or if the tumor is T2 or more invasive, the patient is left with unacceptable high recurrence rates (above 15%) and possibly reduced survival without further treatment compared to (c)TME.¹⁰ To enable rectal preserving treatment in these higher risk early rectal cancers, neo-adjuvant therapy followed by local excision in patients with (near) complete response (ypT0-1) has recently been introduced.¹¹⁻¹³ Similarly, more advanced rectal cancers with a routine indication for neo-adjuvant radiotherapy and a favorable response have been approached with local excision of the residual lesion or even a 'watch and wait' strategy.¹⁴ In moderate to non-responders to the neo-adjuvant therapy (ypT2 or more invasive), recurrence rates are high and cTME is advised.¹⁵ For early rectal cancers that have already been locally excised, adjuvant chemo radiotherapy has been suggested as an alternative, but lacks conclusive evidence.¹⁶ Long term outcomes of (neo-)adjuvant therapy and local excision need to be confirmed by large prospective randomized trials. Currently, the Dutch national guidelines consider these treatments experimental and state

that these should only be offered within a trial setting. A cTME is advised in stages higher than ypT0-1 if treatment is intentionally curative.¹⁷

Since 2009, the Dutch Colorectal Audit (DCRA), formerly known as the Dutch Surgical Colorectal Audit (DSCA), a nationwide quality-improvement project, has prospectively collected patient and tumor characteristics, diagnostics, treatments, and outcomes of all patients undergoing colorectal cancer surgery. It has proven its use in monitoring trends and making recommendations considering treatment protocol.¹⁸ Since 2012, details on rectal saving surgery have been registered.

The aim of this study is to evaluate guideline adherence to cTME after local excision of rectal cancer in the Netherlands and its development over time. Furthermore, we investigate possible determinants for performing cTME.

METHODS

Data

Data from the Dutch Colorectal Audit (DCRA), formerly known as the Dutch Surgical Colorectal Audit (DSCA) were used. The DCRA is a nationwide quality-improvement project which prospectively collects patient and tumor characteristics, diagnostics, treatments and outcomes for all patients undergoing colorectal cancer surgery. All Dutch hospitals performing these resections have to participate. Internal and external verification was performed. In 2011 more than 94% of patients with surgical treatment of colorectal cancer were registered in the DCRA (then DSCA). Further details of this dataset regarding methodology have been described in previous publications.¹⁹

Patients

For the present study, no ethical approval or informed consent is required under Dutch law. All patients who underwent local excision of primary rectal cancer between January 2012 and December 2015 and were registered in the DCRA were evaluated (n=691). Data requirements to consider a patient eligible for analysis were: information on tumor location, date of surgery, and 30-day mortality. Patients with an unknown pathological T stage (n=77) or

pT0 stage without having received neo-adjuvant therapy (n=34) were excluded because the indication for cTME cannot be determined. Patients with a positive clinical nodal stage (n=49) and patients with distant metastases (n=1) were also excluded. Eventually, 530 patients were included for the purpose of the present study. These patients were allocated to 5 groups, based on (y)pT stage, histopathological characteristics and neo-adjuvant treatment. (Figure 1)

Definitions

Local excision was defined as any surgical local excision including transanal open surgery, transanal endoscopic microsurgery (TEM) and transanal minimal invasive surgery (TAMIS). Low risk pT1 was defined in the Dutch guidelines as (having a) diameter <3cm, good to moderate differentiation, no lymphovascular invasion, and negative resection margins (>1mm). Patients with pT1 and positive (≤ 1 mm) or unknown resection margins, poor or unknown differentiation, and/or known lymphovascular invasion were considered high-risk pT1. In the DCRA, diameter of the tumor was not registered. Consequently, diameter was not taken into account when classifying tumors as low or high risk. Information on lymphovascular invasion was only available in patients that underwent a cTME. Absence of the margin and/or the differentiation scores were also considered as high risk criteria, and absence of the lymphovascular invasiveness was not a high-risk criteria on its own.

Statistical analysis

The number of patients treated with local excision only and local excision with cTME in each histopathological group was determined for each year. Significance of time trend of cTME was analyzed using a Chi2 for trend test. For the purpose of determining guideline adherence in a group of patients that was likely to be eligible for cTME, the proportion of cTME was calculated for patients with an indication for (c)TME and an ASA-score of 1-2, a normal BMI (20-25) and an age of <70. Potential determinants for receiving a cTME that were available in the DCRA data set were defined as: gender, age, Body Mass Index (BMI), Charlson Comorbidity Index, American Society of Anesthesiologists score (ASA), and tumor associated complications. Patients receiving a cTME were compared to patients not receiving a cTME in the high-risk pT1 or $\geq$ pT2

group, and the $\geq$ ypT2 group based on these potential determinants for clinical decision-making. Only variables that showed significance ($p < 0.05$) in univariate analysis were included in a multivariate logistic regression model. A p -value of < 0.05 was considered statistically significant and < 0.1 was considered as a trend to significance. Statistical analysis were performed in IBM statistics, version 22 (SPSS inc., Chicago, IL)

RESULTS

A total of 530 patients from 50 hospitals was included in this study. Figure 1 shows the in- and exclusion of the patients and the number of patients in the 5 different groups based on predefined histopathological characteristics: low-risk pT1, high-risk pT1, pT $\geq$ 2, ypT $\geq$ 2, and ypT0-1. Specification of the division between pT1 low-risk and high-risk is shown in Table 1.

Local excision without neo-adjuvant therapy was performed in 448 patients, of whom 47% ($n=209$) had pT1 low risk. Of the remaining 239 patients, 148 (62%) had pT2 or more invasive rectal cancer. Of the 91 patients with pT1 high-risk (38%), 15 (17%) had positive or unknown resection margins after local excision, 77 (85%) had a poor or unknown differentiation grade and two (2%) had known lymphovascular invasion (Table 1). Local excision after neo-adjuvant therapy was performed in 82 patients, of whom 47% ($n=38$) had a (near) pathological complete response (ypT0/1). Neo-adjuvant therapy consisted of short course radiotherapy with delayed surgery in 34 patients (41%), chemo radiotherapy in 40 patients (49%), chemotherapy only in 1 patient (1%) and other neo-adjuvant therapy in 7(9%). Patient and tumor characteristics of the 5 histopathological groups are summarized in Table 2.

Of all 530 included patients, 53% ($n=283$) had an indication for cTME according to the guideline based on histopathological characteristics (Figure 1), while this was performed in 29% ($n=82$) of these 283 patients. The proportion of cTME was 13% in pT1 high-risk, 38% in $\geq$ pT2, and 32% in patients with $\geq$ ypT2 after neo-adjuvant therapy. Figure 2 shows the number of patients that received local excision only and local excision with cTME in each histopathological category in each year. The percentage of patients with an indication for cTME (pT1 high-

risk, $\geq pT2$ or $ypT2$) that also underwent cTME increased significantly ($p < 0.001$) from 10% in 2012 to 44% in 2015. In patients under 70 years of age, with a normal BMI and ASA 1-2, guideline adherence to cTME was 36% (23/64). Table 3 shows that patients with high-risk $pT1$ that did undergo cTME have lower Charlson scores than patients that did not undergo a cTME. Patients with $\geq pT2$ that did undergo cTME are younger and have lower ASA scores than patients that did not undergo a cTME. In the group with $\geq ypT2$ the patients with cTME had lower ASA-scores than patients without cTME.

The multivariate analysis (table 4) revealed that in patients with high-risk $pT1$ a lower Charlson score was an independent determinant for performing a cTME, with an odds ratio (OR) of 13.5 [95% CI 1.39-131.32] for patients with a Charlson score of 1 compared to 2+. For patients with $\geq pT2$ a lower age was an independent determinant for performing a cTME, OR 6.25 [1.83-21.31] 61-70 versus ≥ 81 and OR 3.24 [0.96-10.95] 71-80 versus ≥ 81 (trend to significance).

DISCUSSION

Over fifty percent of all patients who underwent a local excision of rectal cancer had an indication for cTME according to the national guideline. Surprisingly, this cTME was performed in only 29% of these patients. Even considering only $pT \geq 2$ stage after local excision, 62% of patients did not undergo a cTME. This non-adherence to the guidelines with significant oncological risk could not be explained by patient characteristics. In the high-risk $pT1$ patients a lower Charlson score and in $\geq pT2$ patients a younger age appeared to be an independent determinant for performing a cTME. However, the effects are small and in the group with an indication for cTME that were relatively healthy, the majority of patients still seem to be undertreated, leaving them with a significant risk of local recurrence.

This is the first study to address this specific question. A treatment proposal for a patient with rectal cancer is multifactorial, it depends on patient characteristics and patients' choice. Next to good oncological outcome, sustaining quality of life is becoming a primary goal of treatment more and more. However, guidelines are still focusing on effectively controlling the

disease.^{3,20} Although Schiphorst et al. show that guideline adherence for patients with rectal cancer overall declines significantly with increasing age, this study shows only some association of age with performing a cTME in patients after neo-adjuvant therapy. When discussing treatment options with an individual patient after local excision, shared decision-making may lead to refraining from cTME. Several factors may contribute to this: first of all patient's choice, as some older studies show that cTME after local excision is associated with high colostomy rates, and still has a substantial risk of local recurrence.²¹ Although the technique of TME has improved, this may influence the patient's choice, even after precise counseling of possible negative side effects. Furthermore, patients could choose to refrain from cTME because some studies show promising results on disease free survival after neo-adjuvant therapy and local excision of T2 rectal cancer in very selective patients.^{12,13} On the other hand, it may be a doctor's preference to not perform a cTME. This may be based on underestimation of possible risks of this rectal saving treatment strategy. Either way, improving preoperative staging could possibly lower the number of patients in whom local excision is performed while a TME is indicated. This indicates an extra challenge since information on relevant parameters like lymphovascular invasion and submucosal infiltration in biopsies is marginal. Informing the patient before first treatment that the local excision can be curative, but could also turn out to be a diagnostic procedure that should be followed by cTME in case of unfavorable histology. This could help change patients' and doctors' preferential treatment.

The study has some limitations. First of all, the DCRA is a self-reported database by surgeons. The risk of under registration exists. In some patients that have had the cTME, it might not be sufficiently registered. Still, the DCRA is a large obligatory nationwide database and under-registration might only explain some of the discrepancy. Furthermore, the dataset was not built specifically for this study, but to activate an audit cycle in colorectal cancer care. This is, for example, why important information on diameter of the tumor was not available. This study caused the DRCA to improve their database and to work on improving standardized reporting of pathology after local excision. The discussion on high-risk criteria in pT1 rectal cancer is ongoing. Several

studies have addressed this issue, but definite conclusions are hard to draw. Therefore, although national guidelines have implemented high-risk criteria, it is questionable whether all assumed high-risk pT1 rectal cancers have had an indication for cTME. In this study, information on high-risk criteria was lacking in a large portion of patients, which makes the allocation to low or high risk insecure. However, even after exclusion of all pT1 cancers, the analyses show similar results. Last, although non-adherence could be the choice of the patients, information on this is lacking in the study.

Despite these limitations, this study has some implications for the future: First of all, while clinical understaging might be an explanation for the large number of patients that needed a cTME, this study suggests a discrepancy in clinical and pathological staging of early rectal cancer. If there was no discrepancy between clinical and pathological staging of early rectal cancers, cTME would not be needed, for all patients would receive the appropriate treatment directly. This finding suggests the need for quality improvement in radiological staging of rectal cancer, e.g. by MRI or endorectal ultrasound (ERS). Also, the lack of information on high-risk criteria implicates the need for quality improvement of the clinical audit database, but possibly also in pathologists evaluating these criteria. This becomes especially important with the increasing population of early stages of rectal cancer and the increasing interest of rectal saving surgery. Preoperative staging by a specialized multidisciplinary team is of the utmost importance for selecting patients suitable for a local excision. For some patients, non-adherence to a guideline could very well be the best choice. However, it is very important to reveal and explain the risks of recurrence to the patient in a way that the patient can form a well-informed decision. Last, for an optimal balance between treatment-related morbidity and oncological control, also another focus of research is needed, searching for alternatives to this cTME. In the Netherlands, a large multi-centered randomized trial is conducted to compare oncological safety of adjuvant chemo radiotherapy to a cTME.²² In our study adjuvant therapy was only given to 6 patients that did not receive a cTME while it was indicated (data not shown), so the start of this trial did not influence our study.

In conclusion, a large group of patients seems to receive insufficient treatment of their rectal cancer, leading to possible compromised oncological outcomes. This inadequacy cannot only be explained by frailty of the patients. These results expose a need for quality improvement in pre-operative staging and additional treatment after local excision of rectal cancer in the Netherlands.

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TABLES AND FIGURES

Table 1. pT1 and histopathological risk criteria.

pT1	n	%
Low-risk	209	100
Negative margins, good to moderate differentiation, no lymphovascular invasion	7	3.3
Negative margins, good to moderate differentiation, lymphovascular invasion unknown	202	96.7
High-risk	91	100
Positive margins , good differentiation, lymphovascular invasion unknown	9	9.9
Positive margins , differentiation unknown , lymphovascular invasion unknown	2	2.2
Negative margins, differentiation poor , lymphovascular invasion unknown	4	4.4
Negative margins, differentiation unknown , lymphovascular invasion unknown	70	76.9
Negative margins, good/moderate differentiation, lymphovascular invasion present	2	2.2
Margins unknown , differentiation unknown , lymphovascular invasion unknown	1	1.1
Margins unknown , good differentiation, lymphovascular invasion unknown	3	3.3

Table 2. Patient- and tumor characteristics of included patients.

	Pathological T1-stage low-risk		Pathological T1-stage high-risk		Pathological ≥pT2- stage		Pathological ≥ypT2- stage		Pathological ypT0-1- stage	
	Count	%	Count	%	Count	%	Count	%	Count	%
Sex										
Male	134	64.4%	53	58.2%	89	60.1%	26	59.1%	23	60.5%
Female	74	35.6%	38	41.8%	59	39.9%	18	40.9%	15	39.5%
BMI										
Missing	3	1.4%	2	2.1%	0	0%	0	0%	0	0%
<25	77	36.8%	28	30.8%	67	45.3%	21	47.7%	8	21.1%
25-30	90	43.1%	44	48.4%	65	43.9%	14	31.8%	23	60.5%
30+	39	18.7%	17	18.7%	16	10.8%	9	20.5%	7	18.4%
Age										
≤60	38	18.2%	16	17.6%	23	15.5%	9	20.5%	5	13.2%
61 - 70	80	38.3%	39	42.9%	47	31.8%	14	31.8%	16	42.1%
71 - 80	74	35.4%	33	36.3%	50	33.8%	9	20.5%	13	34.2%
≥81	17	8.1%	3	3.3%	28	18.9%	12	27.3%	4	10.5%
Charlson comorbidity score										
0	103	49.3%	58	63.7%	74	50.0%	19	43.2%	23	60.5%
1	55	26.3%	14	15.4%	32	21.6%	10	22.7%	5	13.2%
2+	51	24.4%	19	20.9%	42	28.4%	15	34.1%	10	26.3%

Table 2. Continued

Pathological T1-stage low-risk		Pathological T1-stage high-risk		Pathological $\geq$ T2- stage		Pathological $\geq$ ypT2- stage		Pathological ypT0-1- stage	
Count	%	Count	%	Count	%	Count	%	Count	%
ASA-score									
I - II	83.3%	85	93.4%	110	74.3%	28	63.6%	31	81.6%
III-V	16.8%	6	6.6%	38	25.7%	16	36.4%	7	18.4%
Pathological T stage									
pT0/pT1	100.0%	91	100.0%	0	0.0%	0	0.0%	38	100.0%
pT2	0.0%	0	0.0%	121	81.8%	35	79.5%	0	0.0%
pT3-4	0.0%	0	0.0%	27	18.2%	9	20.5%	0	0.0%

Table 3. Univariate analyses of patient- and tumor characteristics of patients with and without completion TME for patients with high-risk pT1 or ≥pT2 and patients with ≥pT2 after neo-adjuvant therapy

	High-risk pT1					≥pT2					≥ypT2				
	Local excision		Local excision with cTME		Chi2 p-value	Local excision only		Local excision with cTME		Chi2 p-value	Local excision only		Local excision with cTME		Chi2 p-value
	N	%	N	%		N	%	N	%		N	%	N	%	
Sex					0.206					0.647					0.402
Male	44	83.0%	9	17.0%		54	60.7%	35	39.3%		19	73.1%	7	26.9%	
Female	35	92.1%	3	7.9%		38	64.4%	21	35.6%		11	61.1%	7	38.9%	
BMI					0.120					0.528					0.035*
missing	2	100%	0	0.0%											
<25	27	96.4%	1	3.6%		41	61.2%	26	38.8%		11	52.4%	10	47.6%	
25-30	35	79.5%	9	20.5%		39	60.0%	26	40.0%		10	71.4%	4	28.6%	
30+	15	88.2%	2	11.8%		12	75.0%	4	25.0%		9	100%	0	0.0%	
Age					0.731					0.004*					0.252
≤60	13	81.3%	3	18.8%		16	69.6%	7	30.4%		4	44.4%	5	55.6%	
61 - 70	35	89.7%	4	10.3%		21	44.7%	26	55.3%		9	64.3%	5	35.7%	
71 - 80	28	84.8%	5	15.2%		31	62.0%	19	38.0%		7	77.8%	2	22.2%	
≥81	3	100%	0	0.0%		24	85.7%	4	14.3%		10	83.3%	2	16.7%	
Charlson comorbidity score					0.002*					0.209					0.811
0	53	91.4%	5	8.6%		41	55.4%	33	44.6%		12	63.2%	7	36.8%	
1	8	57.1%	6	42.9%		21	65.6%	11	34.4%		7	70.0%	3	30.0%	
2+	18	94.7%	1	5.3%		30	71.4%	12	28.6%		11	73.3%	4	26.7%	
ASA-score					0.131					0.037*					0.006*

Table 3. Continued

	High-risk pT1						≥pT2						≥pT2					
	Local excision only			Local excision with cTME			Local excision only			Local excision with cTME			Local excision only			Local excision with cTME		
	N	%		N	%	p-value	N	%		N	%	p-value	N	%		N	%	p-value
I-II	75	88.2%	10	11.8%			63	57.3%	47	42.7%			15	53.6%	13	46.4%		
III-V	4	66.7%	2	33.3%			29	76.3%	9	23.7%			15	93.8%	1	6.3%		
Pathological T stage						0.000*						0.000*						0.362
pT0-1	79	86.8%	12	13.2%			0	0.0%	0	0.0%			0	0.0%	0	0.0%		
pT2	0	0.0%	0	0.0%			84	69.4%	37	30.6%			25	71.4%	10	28.6%		
pT3-4	0	0.0%	0	0.0%			8	29.6%	19	70.4%			5	55.6%	4	44.4%		

Table 4. Multivariate logistic regression analyses for patients with high-risk pT1 or ≥pT2 with and without neo-adjuvant therapy. with the outcome: performance of a completion TME.

	High-risk pT1 n=91 OR [95%CI]	≥pT2 n=148 OR [95%CI]	≥ypT2 n=44 OR [95%CI]
Charlson comorbidity score			
0	1.70 [0.19-15.52]		
1	13.50 [1.39-131.32]*		
2+	1		
Age			
≤60		2.13 [0.52-8.74]	
61 - 70		6.25 [1.83-21.31]*	
71 - 80		3.24 [0.96-10.95]**	
≥81		1	
ASA-score			
I - II		1.89 [0.78-4.61]	5.66 [0.59-54.14]
III - V		1	1
BMI			
<25			1.76 [0.39-8.05]
25-30			1
30+			.

Figure 1. In- and exclusion

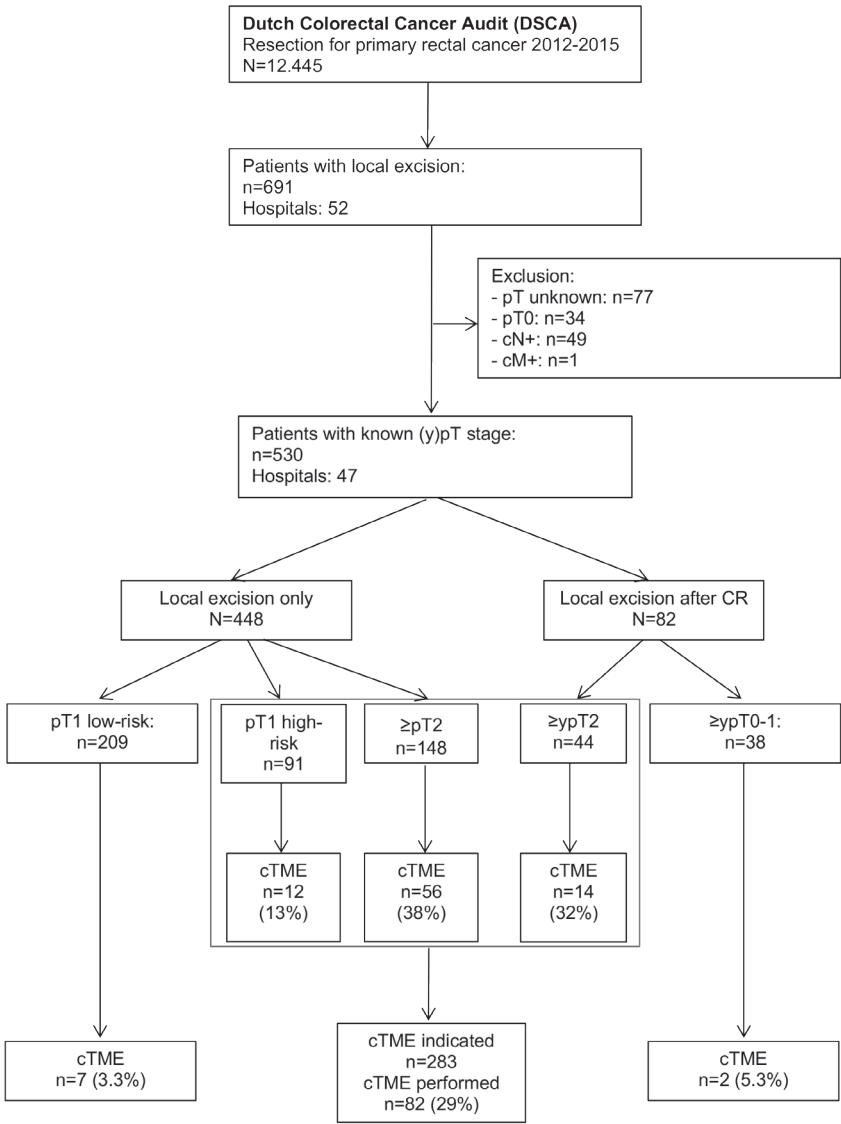
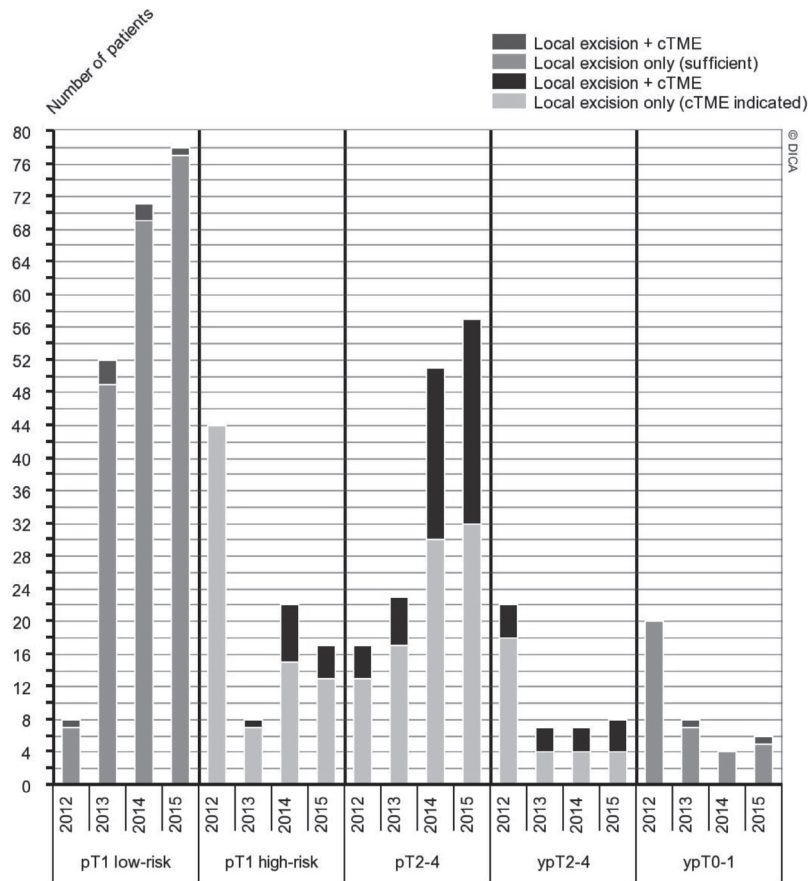


Figure 2. Number of patients with local exclusion of their rectal cancer with or without cTME per histopathological group per year.



Chapter 7

Surgeon perceived most important factors to achieve the best hospital performance on colorectal cancer surgery

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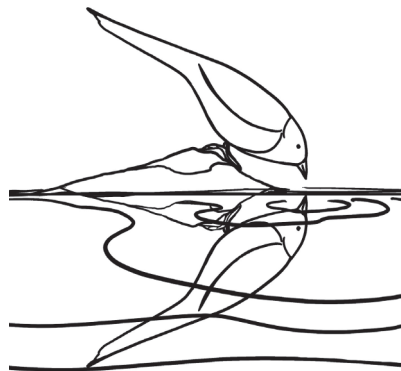
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ABSTRACT

Objectives

Hospital variation in risk-adjusted outcomes after colorectal cancer surgery has been shown. However, explanatory factors are not sufficiently clear. The objective of this study was to identify factors perceived by gastrointestinal surgeons as important to achieve excellent case-mix adjusted outcomes after colorectal cancer surgery.

Design

Based on literature and experts' opinion, 86 factors associated with serious complications, failure to rescue and mortality were listed. These were presented to gastrointestinal surgeons through two web-based surveys and an expert-meeting. Participants were asked to choose their top 10 of most important factors.

Participants

Dutch gastrointestinal surgeons (n=52) of different hospitals and different hospital types (general/teaching/academic).

Results

Of 31 invited experts for the first survey and meeting, 71% responded. Of 130 invited surgeons, 34 responded to the second survey. Factors deemed important were: procedural hospital volume (46% in top 10), specialized surgeons performing surgery, (elective 87%, emergency 60%, and re-operations 62% in top 10), accessibility of, and daily ward rounds by specialized surgeons (41% and 38% in top 10), pre-operative screening for malnutrition (57% in top 10), a protocol for recognition of anastomotic leakage and rapid re-intervention (54% and 49% in top 10).

Conclusion

Procedural hospital volume, specialization of surgeons, screening for malnutrition, early recognition of complications followed by rapid action were perceived as most important factors to achieve good outcomes by gastrointestinal surgeons.

Strengths and limitations of this study

- This study was designed find consensus among gastrointestinal surgeons about important factors leading to best performance in colorectal cancer surgery, an important first step in targeting quality improvement initiatives.
- Strengths of this study are the extensive questioning, in different rounds and in different manners, increasing the reliability of the identified most important factors.
- Extensive questioning also creates a risk of low response rates.

Data sharing statement

Additional individual participant data (after deidentification) are available to researchers with a methodologically sound proposal, upon reasonable request between 3 months and ending 3 years following article publication.

INTRODUCTION

Hospital variation in surgical outcomes is receiving increasing attention. Nowadays, in many countries, quality of surgical care is assured by concentration of care, minimum care standards, increasing specialization of surgeons, and clinical audit projects. Still, variation in case-mix adjusted outcomes between hospitals remains and mechanisms behind this are not completely understood.¹⁻³

Traditionally, in high-complex and low-volume procedures, variation in postoperative mortality was approached by centralization of care; reducing complications by increasing hospital procedural volumes. This volume-outcome relationship proved to be less strong in more commonly performed colorectal cancer surgery.^{4,5} Literature shows associations between outcomes and some structural factors, e.g. level of intensive care unit, nurse staffing or hospital procedural volume. However, best performing hospitals differ in their structural characteristics, and structural factors alone do not explain hospital variation in outcomes.⁶⁻⁹

Simultaneous to centralization efforts, many countries initiated clinical audits. Their aim was stimulating quality improvement projects in individual hospitals by benchmarking outcomes. In the Netherlands, the Dutch Surgical Colorectal Audit (DSCA) measures and feeds back processes and case-mix adjusted outcomes to all hospitals performing colorectal cancer surgery.¹⁰ Furthermore an expert team visits hospitals with significantly more serious complications or mortality than average, aiming to initiate an improvement cycle. Over the last years, the Dutch serious complication, 'failure to rescue' (FTR) and mortality rates improved, although variation between hospitals remains.^{2,3}

In addition to structural factors, many procedural factors could explain variation in outcomes, such as differences in postoperative monitoring and time to recognition.^{1,11-13} Furthermore, different health care professionals are involved in perioperative patient care: nurses, paramedical personnel, and different medical specialists. Hence, teamwork, culture and communication between these professionals may be important.¹¹ Another important factor could be

the increasing role of specialized gastrointestinal surgeons rather than the general surgeon, in surgery, but also in postoperative management and daily ward rounds.¹⁴

Which factors are most important in relation to the observed variation in outcomes is not sufficiently clear. In unraveling this process of care in good performing hospitals the first step is identifying factors related to differences in outcomes in a structured fashion.¹⁵⁻¹⁷ This study aims to identify factors that could be related to better or worse outcomes in colorectal cancer surgery and to identify those factors that gastrointestinal surgeons perceive as most important to explain hospital differences in outcomes.

METHODS

A modified Delphi method was conducted to collect opinions of Dutch surgeons participating in the DSCA (Figure 1). The outcomes of interest were: serious complications, FTR and postoperative mortality. Serious complications were defined as complications leading to, prolonged in-hospital stay (>14 days), a re-intervention or mortality. FTR was defined as the percentage of patients dying after a serious complication.¹⁸ Two web-based surveys¹⁹ and one expert-meeting were held between August 2014 and June 2015. After a literature search for potential influencing factors, a comprehensive list was composed. The first web-based survey (round 1) and the expert-meeting (round 2) were used to shorten the initial list of factors. The second web-based survey (round 3) was used to test perceived importance of selected factors among a larger group of gastrointestinal surgeons. The respondents were invited by email, one reminder sent in case of non-response. Both web-based surveys were open for 3 months.

Literature search

First, literature was searched for factors related to short-term outcomes after colorectal cancer surgery. The search was done in Pubmed and Embase. Search terms used were: (morbidity OR mortality OR postoperative complications OR Failure to rescue) AND (Colorectal Surgery OR ((surgery OR surgical OR operative OR operation) AND (colon OR colonic OR rectal OR

rectum OR colorectal)). Additional literature searches were done for factors derived from clinical experience. After this initial step, the list contained 86 factors, which were grouped into 9 categories.

Round 1: Web-based survey 1

The 86 factors were presented to a selected group (n=31) of (mandated) clinical experts in colorectal cancer care through a web-based survey. The respondents were first asked to select their top 10 of most important factors, and to divide 100 points between the factors mentioned in the top 10. Second, they were asked to rank the factors within 9 categories on the extent to which factors would vary between hospitals and would be relevant for the outcomes: serious complications, FTR, and postoperative mortality. The 9 categories covered preoperative, intra-operative and postoperative processes, the process of diagnosis and treatment of complications, structural hospital factors and factors involving the health care providers, including their accessibility outside working hours, communication, and level of education. One was defined as the highest rank; the lowest rank was dependent on the number of factors present in each category (varying from 8 to 10). Last, the respondents were asked to select their top 10 again, as seeing all factors in detail might have changed their assessment.

Round 2: Expert-meeting

Results of the first web-based survey were presented during the expert-meeting. Of the 31 invited experts, 14 were present at this meeting. Every category was presented and factors were ordered based on a combination of the perceived extent of variation between hospitals and perceived importance for outcomes. Mean rankings within a category, for each factor were shown, if this was higher than the median in that category, or if a factor was mentioned in a top 10, it was considered relevant for the next round. The experts had the possibility to switch factors from relevant to irrelevant or vice versa and the possibility to change the categories to which the factors were assigned. If new factors were mentioned during the meeting, consensus was found to decide if these were added to a suitable category.

After the expert-meeting the list consisted of 47 factors, divided into 9 (new) categories: preoperative, intra-operative (elective and emergency setting) and postoperative processes, communication, the team of health care providers and their accessibility during, and outside working hours, and structural hospital factors.

Round 3: Web-based survey 2

The second web-based survey was distributed to all surgeons (n=130) participating in the DSCA. This survey questioned the importance of the 47 factors explaining the hospital variation in outcomes. We specifically asked to select factors explaining variation between hospitals, so respondents would not chose factors that are embedded in all Dutch hospitals (e.g. enhanced recovery protocols). Again, respondents were asked to select a top 10. Additionally, respondents had the option to divide 100 points among the factors in their top 10 and to rank the factors within their 9 categories.

Analyses

We calculated the percentage of respondents selecting a factor in their top 10. We ordered the factors based on this percentage from high to low and we selected the ten factors with the highest percentage in the top 10 as most important factors. Potential differences assigned by surgeons working in general hospitals and in academic (affiliated) hospitals were tested using a chi-square test.

The additional questions were used to calculate a sum of points assigned to a factor and the mean rank (MR) within its category and to order the factors again based on these outcomes. Statistical analyses were performed in IBM SPSS Statistic version 22.

RESULTS

A total of 52 (40%) gastrointestinal surgeons participated in one or more rounds of the modified Delphi method (Table 1). Of these respondents, 13 were working in academic, 31 in teaching and 11 in general hospitals. In the first two rounds

the response rate was 71%, in the last round the response rate was 26% (Table 1).

Round 1 and 2: composing a list of factors

All new mentioned factors in the first web-based survey were included in our analyses. From the 86 factors initially selected by the project group and 15 new factors, 47 were selected for the next round based on consensus among the experts. Some factors were deleted and some were adapted or merged with another factor. The resulting list of 47 factors across 9 categories was used in the second web-based survey and is presented in table 2.

Round 3: Identifying most important factors

Forty-four surgeons started the second web-based survey, 34 surgeons selected their top 10. (Figure 1). Table 2 shows the percentage of surgeons that selected the factor in the top 10, sorted from highest to lowest importance within their category (10 most important factors marked with *). Our consensus shows 1 to 3 important factors in 7 of the 9 categories. In the categories 'communication' and 'health care providers' no factor was selected.

Only one factor differed significantly between surgeons working in general hospitals and surgeons working in academic (affiliated) hospitals. The accessibility of a specialized surgeon to also examine a patient during business hours was mentioned in the top 10 by more surgeons in general hospitals (67%) compared to surgeons in academic (affiliated) hospitals (28%, $p=0.025$). Other factors did not differ significantly, indicating broad consensus on most important factors regardless of work setting.

Additionally, 31 surgeons assigned points to the factors in their top 10 (Total 3100 points) and, 24 surgeons ranked the factors in all categories. The sum of assigned points and MRs (incl. standard deviation) are shown in Table 2. The main analyses and these sub analyses resulted in the same ten most important factors (marked with * in Table 2 and shown in Box 1).

Figure 2 shows the strong association between percentage of respondents selecting a factor in their top 10 and MR assigned to this factor. It shows all most important factors in the top right part of the figure, indicating a combination of high ranks (highest=1) and high percentages mentioning the factor in the top 10.

DISCUSSION

This modified Delphi method identified 10 factors deemed as most important by Dutch gastrointestinal surgeons in explaining variation in case-mix adjusted outcomes after colorectal cancer surgery. Procedural hospital volume was selected as an important structural factor. In 6 of the most important factors, the specialized surgeon has an important role. In the pre-operative phase, screening for malnutrition was considered important; in the postoperative phase, fast recognition of a complication followed by a rapid re-intervention and a protocol for early recognition of anastomotic leakage. In total 10 factors were selected as most important.

Comparing our results to the literature, it is striking that surgeons perceive procedural hospital volume as one of the most important factors. While procedural hospital volume has often been considered a proxy for high quality of care in high-complex and low-volume procedures, the evidence in colorectal surgery is less convincing. Several systematic reviews show a volume-outcome relationship in colorectal cancer surgery. However, the effect sizes are small, it is a non-linear effect and the definition of high hospital volume is heterogenic between different studies. This makes it hard to define a clear threshold for minimum annual number of colorectal cancer surgeries per hospital.²⁰⁻²⁴ Also, a difference between US and non-US data suggest that hospital level variability was less of a problem outside the US than in the US.^{20,24} Furthermore, Dutch studies show that volume is no guarantee for optimal outcomes in colorectal cancer care in the Netherlands.^{25,26} More importantly, investigating structural hospital factors only will not reveal differences in patterns of care that lead to good outcomes.^{25,26}

In addition to procedural hospital volume, the effect of individual surgeon volume and specialization of the surgeons seems more important.^{20,21} Respondents in our study strongly expressed that specialization of the surgeons performing colorectal cancer resections is associated with better outcomes. This was in accordance with studies reporting better survival, but also a better adherence to guidelines and a better use of appropriate surgical techniques.^{27,28} The postoperative presence and accessibility of specialized surgeons and daily presence at ward rounds is considered important by our respondents, although there is little evidence substantiating this.¹⁴ The surgeons perceive that specialization helps in installing preventive measures, and early recognition and better treatment of complications. Literature shows that for fast recognition and fast treatment, teamwork, communication and culture is important, and that the role of nurses and doctors of the ward is pivotal.^{11,29,30} Interestingly, in our study respondents did not chose the factors on 'communication' or 'experience of health care providers' as most important. However, respondents found adherence to postoperative protocols important, which could be an other way to regulate preventive measures, early recognition and better treatment of complications. These postoperative protocols for recognition of anastomotic leakage as well as standardized care programs are developed to improve patient safety and surgical outcomes.^{31,32} Adherence to these protocols is not well known and can very well differ between hospitals. Better adoption of programs and protocols that have shown to improve postoperative outcomes could lead to an improvement of colorectal cancer care.^{33,34}

With an increasing population of elderly patients and a high prevalence of malnutrition in colorectal cancer patients, risk-assessment and personalized preparation is increasingly important. Risk-assessment is mostly done with the American Society of Anesthesiologist (ASA) classification, but also specific scores for screening on malnutrition are used, e.g. malnutrition universal screening tool (MUST) or short nutritional assessment questionnaire (SNAQ). Our respondents perceive screening on malnutrition as highly important. Future data collection on these factors should show the extent to which this explains the observed variation in outcomes between hospitals.

There are limitations to this study. First, 40% of the invited surgeons participated in one or more rounds of this study, but 26% participated in the last round. Although these percentages are common in surveys among professionals, this could imply selection bias.^{35,36} However, the respondents were distributed across different types of hospitals (general and academic (affiliated) hospitals) in the same way this is distributed in the non-responders. This makes it plausible that our responders could reflect the beliefs of their (non-responding) colleagues. Second, we have no information on the experience of the surgeons. Still, because the invited surgeons were participating in the DSCA, interest is expected, and specialization in colorectal cancer surgery is likely. In this study, surgeons were invited and no nurses or doctors of the wards, which might be reflected in the answers given. Perspectives of other health care providers and even patients could result in selection of other factors than the ones listed in this study. However, because surgeons make most perioperative decisions and are up to date on available evidence regarding colorectal surgery, they were thought to have the best expertise to judge which factors might explain the observed variation in outcomes between hospitals. Certainly this study did not address all factors possibly influencing outcomes in colorectal cancer care (e.g. discharge follow-up or innovative technologies being offered). However the surgeons had the possibility to add new factors, which they thought to be important, in the expert meeting and those factors were included in the study. Furthermore, we investigated the opinion of Dutch gastrointestinal surgeons. Still, we feel that this study could be applicable to other countries with comparable processes already implemented nationwide. Last, we decided to select ten most important factors. This cutoff point is arbitrary.

Conclusion

According to Dutch surgeons, important factors to achieve low morbidity and mortality, and to explain hospital variation in case-mix adjusted short-term postoperative outcomes after colorectal cancer surgery are: procedural hospital volume, specialization of surgeons, screening for malnutrition and early recognition of complications followed by rapid action. More research is needed to determine to what extent the hospital variation in outcomes of colorectal cancer surgery in the Netherlands is explained by these factors. The

consensus present on these factors could form the basis for further in-depth research on possible differences between hospitals with better and worse outcomes.

Acknowledgement

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Ethical approval

No ethical approval was required under Dutch law.

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Conflict of interest

None of the authors have anything to disclose.

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TABLES AND FIGURES

Table 1. Number of respondents in all rounds

	Invited	Total response	Academic	Teaching	General
Composing list of items total	31	22 (71%)	9	13	0
Websurvey 1 only (round 1)		8			
Expert-meeting only (round 2)		2			
Both round 1 and 2		12			
Selecting most important items total	130	34 (26%)	5	18	11
Total participants	130	52 (40%)	13	28	11

Table 2. Percentage of respondents reporting a factor in their top 10, sum of points assigned and mean rank within category. Ten most important factors are marked with *

Factors leading to good outcomes in colorectal cancer surgery	Percentage in top 10 n= 34	Assigned points (min-max) n= 31	Mean Rank (standard deviation) n= 27 thru 24
Preoperative			n=27
<i>Preoperative screening of patients for malnutrition, followed by dietary measures*</i>	57%	150 (2-20)	3.07 (sd 1.639)
Preoperative screening of elderly by a geriatrician	35%	61 (3-10)	4.7 (sd 2.072)
Preoperative visit of the patient to an anesthesiologists	32%	63 (3-15)	4.33 (sd 2.572)
Preoperative opportunity to discuss a complex patient in a preoperative discussion with an intensivist or anesthesiologist	29%	93 (5-20)	4.59 (sd 3.067)
Preoperative counseling patients to quit smoking	19%	55 (5-20)	5.19 (sd 2.760)
Preoperative pulmonary training	19%	53 (0-20)	4.37 (sd 1.757)
The surgeon visits the patient the day before the surgery, or has seen the patient at the preoperative consultation	8%	20 (10-10)	5.63 (sd 2.871)
Preoperative visit of patients to a multidisciplinary outpatient clinic	3%	7 (7-7)	6.52 (sd 2.190)
The anesthesiologist that performs the anesthesia visits the patient the day before the surgery, or sees the patient at the preoperative consultation	3%	0	6.59 (sd 2.258)
Intra-operative, elective			n=26
<i>Elective surgery is performed by surgeons with a specialization in gastrointestinal oncology*</i>	87%	358 (5-50)	1.42 (sd 0.987)
A hypovolemic situation during the surgery is actively avoided	32%	90 (5-20)	3.73 (sd 1.756)
The ratio between laparoscopy and laparotomy in an elective setting	16%	37 (2-20)	4.69 (sd 2.035)
The percentage of patients with elective surgery that receive a definite ostomy	14%	35 (5-15)	4.04 (sd 1.708)

Table 2. Continued

Factors leading to good outcomes in colorectal cancer surgery	Percentage in top 10 n= 34	Assigned points (min-max) n= 31	Mean Rank (standard deviation) n= 27 thru 24
The percentage of patients with elective surgery that receive a diverting ostomy in addition to the anastomosis	8%	25 (5-20)	3.77 (sd 1.751)
The percentage of patients with laparoscopic surgery that has to be converted to laparotomy	5%	0	4.85 (sd 1.515)
The percentage of patients that receive epidural anesthetics	5%	0	5.5 (sd 1.421)
Intra-operative, emergency/urgent			n=26
<i>Emergency or urgent surgery is performed by surgeons with specialization in gastrointestinal oncology*</i>	60%	235 (5-20)	1.31 (sd 0.549)
The percentage of patient that receive an anastomosis in emergency or urgent surgery	22%	65 (5-20)	1.88 (sd 0.516)
De ratio between laparoscopy and laparotomy surgery in emergency or urgent setting	5%	10 (5-5)	2.81 (sd 0.567)
Postoperative			n=24
<i>Presence of a protocol for early recognition of anastomotic leakage*</i>	54%	175 (5-20)	2.96 (sd 1.628)
<i>Accessibility of a surgeon specialized in gastrointestinal oncology to also review a patient, during business hours (beyond ward rounds) *</i>	41%	108 (5-15)	2.79 (sd 1.062)
<i>Daily ward rounds by the surgeon that performed the surgery or an other surgeon specialized in gastrointestinal oncology*</i>	38%	123 (5-20)	2.08 (sd 1.472)
Patients are postoperative admitted on a ward specialized on gastrointestinal and oncological surgery	32%	90 (5-20)	3.71 (sd 1.517)
Presence of a protocol for testing CRP and consequences according to outcomes	22%	80 (5-20)	4.21 (sd 1.414)

Table 2. Continued

Factors leading to good outcomes in colorectal cancer surgery	Percentage in top 10 n= 34	Assigned points (min-max) n= 31	Mean Rank (standard deviation) n= 27 thru 24
Presence of a case manager who contacts the patient after hospitalization	3%	0	5.25 (sd 1.152)
Complications/re-interventions			n=24
<i>Reoperation is performed by surgeons with a specialization in gastrointestinal oncology*</i>	62%	185 (2-20)	1.71 (sd 0.999)
<i>Time elapsed between first symptoms of a complication and a re-intervention*</i>	49%	210 (5-25)	1.62 (sd 0.576)
Number of re-interventions per patient with a serious complication	5%	10 (10-10)	3.08 (sd 0.776)
The ratio between radiologic and surgical re-intervention	3%	10 (10-10)	3.58 (sd 0.504)
Evening, night and weekend shifts			n=24
<i>24/7 a surgeon specialized in gastrointestinal oncology is 'on call' (he/she does not have to be in the hospital, though is available for consultation)*</i>	65%	170 (5-15)	1.83 (sd 1.167)
A surgeon specialized in gastrointestinal oncology is present at ward rounds in weekends	14%	18 (0-8)	2.96 (sd 1.628)
Surgeon 'on call' is present at the evening report	11%	20 (10-10)	3.58 (sd 1.558)
The emergency room is 24/7 accessible	8%	10 (10-10)	3.08 (sd 1.283)
Presence of a surgeon in the hospital 24/7	3%	10 (10-10)	4.92 (sd 1.349)
Presence of a resident in the hospital 24/7	0%	0	4.63 (sd 1.245)
Communication			n=24
Communication between nurses and interns, residents or surgeons	30%	63 (3-12)	1.54 (sd 0.779)
Communication between surgeons	24%	45 (5-10)	2.13 (sd 0.741)
At least monthly discussion of outcomes (including discussion of complications)	19%	55 (5-15)	3.46 (sd 0.932)

Table 2. Continued

Factors leading to good outcomes in colorectal cancer surgery	Percentage in top 10 n= 34	Assigned points (min-max) n= 31	Mean Rank (standard deviation) n= 27 thru 24
Communication between surgeon and anesthesiologist	8%	15 (5-10)	2.88 (sd 0.992)
Health care providers			n=24
Average experience of nurses on the wards	30%	70 (2-20)	1.75 (sd 0.737)
Average experience of interns and residents responsible for the wards	11%	18 (8-10)	2.63 (sd 1.173)
The hospital is a referral center for colorectal surgery	5%	5 (5-5)	2.75 (sd 1.073)
Number of nurses per patient (nurse/patient ratio)	5%	5 (5-5)	2.88 (sd 1.154)
Number of surgeons specialized in gastrointestinal oncology in a hospital	5%	10 (10-10)	4.29 (sd 1.628)
Hospital structure			n=24
<i>Number of colorectal surgeries (both benign and malignant) performed in the hospital annually*</i>	46%	103 (2-20)	2.42 (sd 1.586)
Presence of Emergency intervention team (EIT)	24%	53 (2-15)	2.54 (sd 1.668)
Accessibility of an intervention radiologist	19%	35 (5-10)	4.17 (sd 1.633)
The ICU-level of the hospital	11%	30 (5-20)	4.08 (sd 1.381)
The operating team also performs other high-complex surgeries	8%	17 (2-10)	3.5 (sd 1.445)

Box 1. Surgeons perceived 10 most important factors to achieve the best hospital performance on colorectal cancer surgery

Elective surgery is performed by surgeons with a specialization in gastrointestinal oncology

24/7 a surgeon specialized in gastrointestinal oncology is 'on call' (he/she does not have to be in the hospital, though is available for consultation)

Reoperation is performed by surgeons with a specialization in gastrointestinal oncology

Emergency or urgent surgery is performed by surgeons with specialization in gastrointestinal oncology

Preoperative screening of patients for malnutrition, followed by dietary measures

Presence of a protocol for early recognition of anastomotic leakage

Time elapsed between first symptoms of a complication and a re-intervention

Number of colorectal surgeries (both benign and malignant) performed in the hospital annually

Accessibility of a surgeon specialized in gastrointestinal oncology to also review a patient, during business hours (beyond ward rounds)

Daily ward rounds by the surgeon that performed the surgery or an other surgeon specialized in gastrointestinal oncology

Figure 1. Modified Delphi method

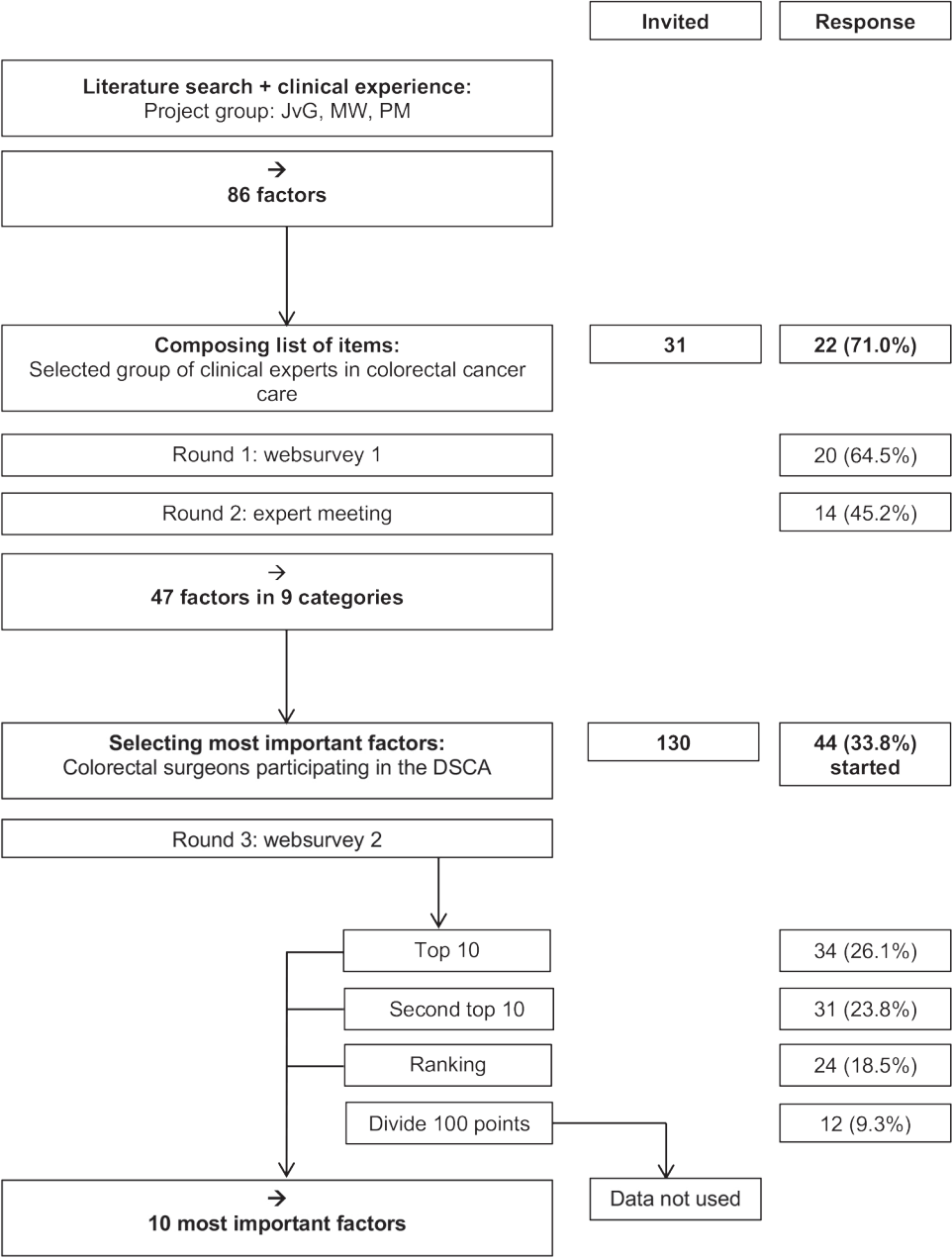
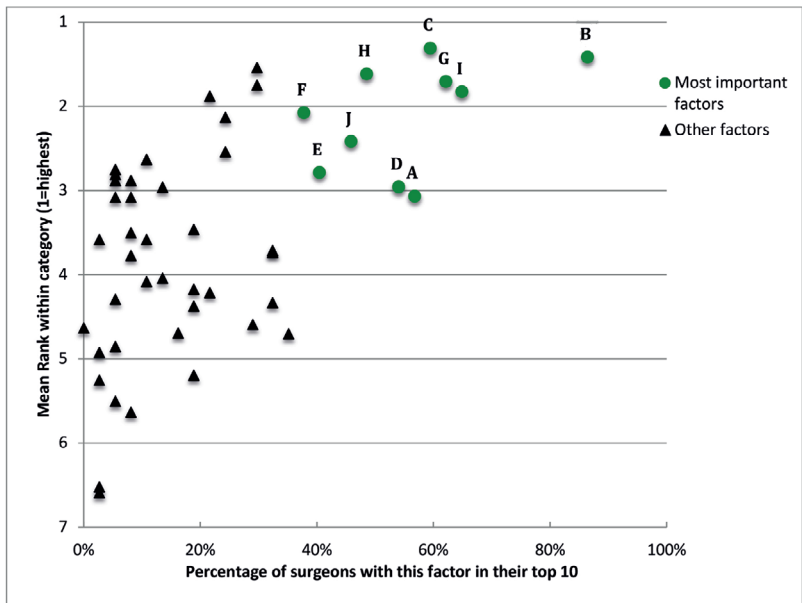


Figure 2. MR within category by percentage of surgeons selecting this factor in their top 10. Most important factors are: A) Preoperative screening of patients for malnutrition, followed by dietary measures; B) Elective surgery is performed by surgeons with a specialization in gastrointestinal oncology; C) Emergency or urgent surgery is performed by surgeons with specialization in gastrointestinal oncology; D) Presence of a protocol for early recognition of anastomotic leakage; E) Accessibility of a surgeon specialized in gastrointestinal oncology to also review a patient, during business hours (beyond ward rounds); F) Daily ward rounds by the surgeon that performed the surgery or an other surgeon specialized in gastrointestinal oncology G) Reoperation is performed by surgeons with a specialization in gastrointestinal oncology; H) Time elapsed between first symptoms of a complication and a re-intervention; I) 24/7 a surgeon specialized in gastrointestinal oncology is 'on call' (he/she does not have to be in the hospital, though is available for consultation) J) Number of colorectal surgeries (both benign and malignant) performed in the hospital annually.



Chapter 8

Which practice is associated with best performance on serious complications and 'failure to rescue' after colon cancer surgery? Record reviews and interviews to identify 'best practice'

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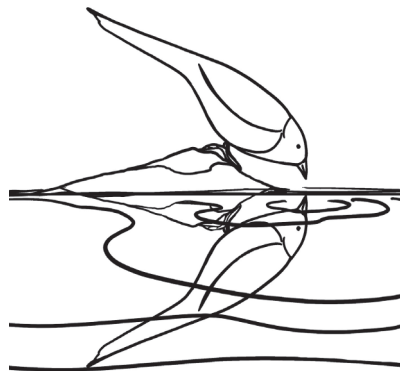
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Submitted



ABSTRACT

Background

The factors resulting in best performance after colon cancer surgery remain unknown. This study compares hospitals with better and worse serious complication- and 'failure to rescue'(FTR)-rates on potential explanatory factors.

Methods

From a total of 88, 9 better performing hospitals (BPHs) and 10 worse performing hospitals (WPHs) were selected based on case-mix adjusted serious complication- and FTR-rates. In the responding BPHs (n=4) and WPHs (n=5), semi-structured interviews were carried out with surgeons, doctors, and nurses to identify possible hospital-level factors. Records of patients with a serious complication were reviewed to identify possible patient-level factors explaining performance differences.

Results

Of 819 patients treated in participating hospitals in 2013, 168(20.5%) experienced serious complications. BPHs had significantly fewer serious complications compared to WPHs (odds ratio (OR) 0.44 [95%CI 0.36-0.55]), but did not differ in FTR (OR 0.75[0.43-1.30]). In BPHs, interviewees reported: striving to make 'every step perfect', using protocols as a tool to reach goals, and having specialized surgeons present at ward rounds (reported by surgeons and nurses). BPHs reported having a team dedicated to striving for continuous improvement. Patients treated in BPHs were significantly more often admitted to a specialized ward (OR 6.95[1.57-30.70]) and if they had a serious complication, more often had a reintervention within a day after symptoms started (OR 9.99[1.54-64.91]).

Conclusion

Practices associated with best performance on serious complications and FTR after colon cancer surgery include an open culture, a team dedicated to continuous improvement, a patient's postoperative stay on a specialized ward, and specialized personnel present at that ward.

BACKGROUND

Colon cancer is an important health care problem with a high incidence in Western countries. In the Netherlands, 11004 patients were newly diagnosed in 2016.¹ Surgical resection remains the cornerstone of curative treatment but is associated with considerable adverse outcomes. Between-hospital variation of these outcomes after colon cancer surgery has increasingly received attention.²⁻⁵ As a result, quality assurance and quality improvement initiatives have gained popularity, for example, by the implementation of minimum hospital volume standards, specialization and certification of providers, and initiation of clinical audits.⁵⁻¹⁰

In 2009, Dutch colorectal surgeons initiated the Dutch Surgical Colorectal Audit (DSCA), which became the multidisciplinary Dutch ColoRectal Audit (DCRA) in 2017.⁵ This audit generates feedback and benchmark information on care processes and case-mix adjusted outcomes¹¹ for all Dutch hospitals performing colorectal cancer surgery. Ultimately, the audit intends to stimulate quality improvement projects in the participating hospitals. Since the introduction of the DCRA (then DSCA), overall short-term outcome rates have improved, although there remains variation on certain outcomes.^{4,5} This variation can be a useful starting point for improving care by learning from hospitals with better performance.

If we want to learn from best performing hospitals, improvement is most likely achieved on indicators that are 'actionable'. Failure to rescue (FTR), defined as the proportion of deceased patients among those experiencing a serious complication, seems to be an actionable quality indicator. It has already been shown that hospitals differ considerably in case-mix adjusted FTR-rates, but the processes that are responsible for this variation are unknown.⁴ Reliably identifying best performing hospitals is methodologically challenging, but could be more reliable in colon cancer surgery due to large between-hospital variations and the large volume of patients per hospital.¹²

In the literature, some structural factors are suggested to contribute to good performance of hospitals on FTR, for example, capacity of intensive care units

available, nurse staffing, and hospital volume.^{13–16} However, good and worse performance on FTR is found in hospitals with all different structural factors.^{2,17} Furthermore, such factors are considered proxies for standards of care, and the actual explanatory factors in daily practice that enable some hospitals to achieve excellent outcomes remain to be clarified.

When asked, Dutch colorectal surgeons perceived procedural hospital volume as important, but were more focused on the level of involvement of colorectal surgeons.¹⁸ Additionally, screening for malnutrition and the early recognition of complications followed by rapid action were mentioned as important factors to achieve better short-term outcomes.¹⁸ Not mentioned as most important by these surgeons, but increasingly suggested in the literature, are teamwork, communication, and culture.¹⁹

This study aimed to identify the explanatory factors for the differences between better performing hospitals (BPHs) and worse performing hospitals (WPHs) on serious complication and FTR-rates after colon cancer surgery. Hospitals with the best and worst serious complication and FTR-rates were compared on a number of potential factors identified from the literature or expert opinion, using in-depth semi-structured interviews and record reviews of all patients with serious complications treated in those hospitals.

METHODS

Study design

This study was designed as an observational study to compare BPHs and WPHs on FTR. Mixed-methods were used to obtain insight into differences on both the hospital and patient level. To investigate hospital differences in communication, teamwork, and culture, in-depth interviews were conducted. To investigate hospital differences in processes prior to succeeding or failing to rescue a patient in case of a serious complication, records were reviewed of all patients with a serious complication treated in those hospitals. A schematic description of the design is shown in Figure 1. Ethical approval for this type of study was not required under Dutch national law.

Hospital selection

Data for the selection of hospitals were derived from the DCRA. All hospitals performing colon cancer surgery (n=92) participate in this nationwide audit system with a wide range of variables concerning diagnostics, treatments, and outcomes. Details of this dataset regarding methodology have been described previously.⁵ To identify BPHs and WPHs, outcomes of all patients undergoing surgical resection for primary colon carcinoma between January 1, 2011, and December 31, 2013, were evaluated (n=20301). Minimal data requirements to consider a patient eligible for analysis were: tumor location, date of surgery, and in-hospital or 30-day mortality (exclusion: n=103). Patients with synchronous colorectal tumors were excluded (n=709) due to differences in outcomes.²⁰ Four hospitals stopped performing colon cancer surgery during the study period and were excluded (n=438 patients). A total of 19051 patients in 88 hospitals were included for the selection of BPHs and WPHs.

Subsequently, case-mix adjusted serious complication- and FTR-rates were calculated for each hospital in each year. Serious complications was defined as the percentage of patients with a complication leading to an in-hospital stay of more than 14 days, a surgical, endoscopic, or radiological reintervention, or death. Failure to rescue was defined as the percentage of patients with a serious complication who died in-hospital or within 30 days after surgery. Details concerning the use of relevant case-mix factors have been described elsewhere (and are shown in Figure 1).^{11,21} Hospitals were divided into quintiles based on each adjusted outcome in each year. These quintiles were ranked from best (1) to worst (5) outcomes. Then a weighted score was calculated for each hospital by summing the squared quintiles in each year for both outcomes, so that being in the worst quintile was weighted heavier than being in the middle quintile. BPHs were defined as the hospitals with the lowest weighted scores, while WPHs were defined as the hospitals with the highest weighted scores (Figure 2). These hospitals are referred to as better and worse performing hospitals, even though we acknowledge that this is a relative ordering and that worse performing does not necessarily indicate bad quality of care. Nine BPHs and 10 WPHs were invited to participate by an email explaining the aim and design of the study without mentioning whether they were in the group of

hospitals with better or worse performance. Four (44%) BPHs and five (50%) WPHs agreed to participate. All of the responding hospitals were visited.

Semi-structured interviews – Hospital-level factors

In each hospital, 2-3 semi-structured interviews were conducted. Using purposive sampling, a colorectal surgeon, a surgical ward doctor, and a surgical ward nurse were invited. This approach was chosen to investigate the potential different perceptions of these professionals on teamwork, communication, and culture. Interviews were audiotaped and transcribed in full with the permission of the participants. Transcripts were anonymized and coded according to BPHs or WPHs and the individual hospital. This way, the BPHs and WPHs could be compared, but also interviews with different professionals within one hospital could be linked. Interviews were analyzed using thematic content analyses. The approach was data driven and involved open coding and subsequently bundling codes into themes.^{22,23} Coding was performed using ATLAS.ti software (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany). The researcher who conducted the interviews also coded them. She has a MD degree and experience on two surgical wards. She was not involved in clinical work at the time of the interviews. The interviewer knew the performance of the hospitals, but both groups were approached the same way and the same questions and prompts (Appendix A) were used, so all of the participants had an equal opportunity to share information. Interviewees were not told whether they were selected as better or worse performers, but could know their performance from the available DCRA feedback information. Interviewees' awareness of their outcomes was included in the results. Data saturation was reached at interview 18; nonetheless, all 26 interviews were conducted and coded as planned.

Medical record review – Patient-level factors

Given the interest in factors associated with FTR, all 168 patients with a serious complication in participating hospitals, from a total of 818 patients treated in 2013, were included in the record reviews. One researcher reviewed the patient records according to a predefined list of variables. The variables were chosen based on a previous study investigating expert opinions on factors possibly leading to better performance (Table 1). This study first identified factors from

the literature, followed by 2 consensus-based rounds, during which factors could be added or removed and in which factors were ranked in importance.

Statistical analyses

Differences in outcomes between selected BPHs and WPHs in the period 2011-2013 were tested with a chi-squared test and adjusted for case-mix factors using multivariate logistic regression analyses. In addition, the same analyses were done comparing the responding BPHs and WPHs.

To test for differences in patient-level explanatory factors or processes from medical record reviews, first each individual factor was tested between patients treated in BPHs versus WPHs using a chi-squared test. Consequently, a multivariable logistic regression was performed with being treated in a BPH or WPH as the dependent variable and including all factors significant in the univariable analyses as independent variables to assess which factors or processes independently influenced the likelihood of being treated in a BPH or WPH. Statistical analyses were performed using SPSS (IBM SPSS Statistics for Macintosh, Version 23.0).

RESULTS

Selected hospitals

Figure 2 shows the selected BPHs and WPHs sorted by their weighted scores. None of the hospitals performed best (Q1) or worst (Q5) on both outcomes in each year. Only one hospital had all outcomes in the best two quintiles.

The serious complication-rate between 2011 and 2013 was significantly lower for patients treated in selected BPHs (14%) compared to patients treated in WPHs (25%) ($p < 0.001$). After adjusting for case-mix, this difference remained (odds ratio (OR) 0.45 [95%CI 0.38-0.53]). Also, the FTR-rate in selected BPHs was significantly lower (15%) compared to WPHs (22%) ($p < 0.05$). After adjusting for case-mix, this difference remained (OR 0.46[0.29-0.72]).

Responding hospitals

Four BPHs and five WPHs responded and were visited. The serious complication rates of patients treated in BPHs and WPHs in 2013 were respectively 14% (n=53/386) and 27% (n=114/432). After adjustment for case-mix, the serious complication-rate of patients treated in the responding BPHs was significantly lower than patients treated in WPHs (OR 0.44[0.36-0.55]). FTR-rates of patients treated in the responding BPHs (15%, n=8/53) and WPHs (17%, n=19/114) did not differ after adjustment for case-mix (OR 0.75[0.43-1.30]).

Table 2 shows that different hospital teaching types and procedural hospital volumes were found in the responding BPHs and WPHs. However, none of the responding BPHs had the lowest level of ICU facilities. Furthermore, the BMI and age of patients treated in BPHs are lower compared to WPHs, indicating lower-risk patients. On the other hand, ASA-scores, preoperative tumor complications, and additional resections due to tumor growth of patients treated in BPHs were higher, suggesting higher-risk patients.

Interviews – Hospital-level factors

In the 26 in-depth interviews, a total of 45 factors influencing the hospital's outcomes after colon cancer surgery were reported. These were grouped into 8 major themes and a ninth theme in which suggestions of the interviewees were collected ("tips and tricks"). All of the factors were reported in more than 3 interviews. The most mentioned was "accessibility of the colorectal surgeons." Table 3 shows a selection of these themes, with underlying factors and illustrative quotes on how these differed in BPHs versus WPHs (Appendix B shows all of the quotes). Even though BPHs and WPHs mentioned similar factors and themes, their answers on how they dealt with certain issues were quite different.

Interviews – Preoperative

Interviewees in BPHs and WPHs seemed to be aware of the frailty of patients with colon cancer. However, surgeons in BPHs mentioned 'trying to make every step perfect' in the preoperative preparation, even if there was no proof yet (Table 3, B1.1 and B1.2), whereas surgeons in WPHs mentioned waiting for

evidence or guidelines, and even if these were available they did not always seem to believe in the effect of these measures (Table 3, W5.2).

Interviews – Intraoperative

In general, ward nurses and doctors were not informed much about the intra-operative process. A colorectal surgeon was reported to be part of the operating team during surgery (not just a general surgeon or resident) in both BPHs and WPHs. However, surgeons in BPHs reported that the reason for the presence of a colorectal surgeon during surgery was continuous learning from each other (Table 3, B5.1). In WPHs on the other hand, the presence of at least one colorectal surgeon was reported as a goal in itself (Table 3, W2.2)

Interviews – Postoperative

Almost all of the interviewees stated that, for early recognition of a possible complication, it is important to ascertain adequate postoperative monitoring. Important for this monitoring are the presence of experienced nurses, well-instructed and experienced ward doctors, and the active involvement of colorectal surgeons. The frequency at which a colorectal surgeon was present during ward rounds differed between both groups: one of the colorectal surgeons was scheduled for nothing else in the morning in BPHs (Table 3, B3.3) versus hoping that a colorectal surgeon would be present during ward rounds in WPHs (Table 3, W3.3). Moreover, in BPHs' statements on ward rounds of the surgeon, ward nurse, and doctor were in accordance with each other, while sometimes in WPHs, the surgeons stressed the goal of daily ward rounds but ward nurses or doctors reported that in reality, this goal was not often realized (Table 3, W3.2). Protocols were mentioned as a way to create a safety net when not enough experience is present on the wards in both BPHs and WPHs. However, in BPHs, these protocols were mentioned as being used as an instrument to create awareness about the symptoms of possible complications (Table 3, B3.4). In WPHs on the other hand, protocols sometimes seem to be interpreted as the goal itself (Table 3, W3.4)

Interviews – Communication

Communication and culture were not always mentioned explicitly in the interviews, but were subtly seen in many reported factors. Nurses in BPHs were mentioned to be experienced and capable of some clinical reasoning (Table 3, B4.3), while in WPHs, nurses reported not to be trained in clinical reasoning (Table 3, W4.3). Furthermore, in BPHs, ward nurses and doctors reported less hesitation to escalate care to a higher level in case of doubt (e.g., calling a colorectal surgeon) (Table 3, B4.2). In WPHs, ward nurses and doctors reported being more hesitant to do this, caused by a bad experience or the feeling of not to be taken seriously (Table 3, W4.2). Another difference was found in short lines of communication in the organization in BPHs (Table 3, B4.1) compared to communication via many people in WPHs (Table 3, W4.1).

Interviews – Dedication

Differences between the extent of dedication of the teams in BPHs and WPHs were seen in quotes throughout the different themes. Dedication is specifically illustrated by quotes such as: *“On the day of surgery, we always visit the patient on the recovery ward... ... And in 9 out of 10 times I’ll see the patient again the next day...”* (Table 3, B7.2) versus *“The downside of... ...We do not see all our own patients.”* (Table 3, W7.2). Dedication is also seen in the degree of specialization of the wards in BPHs (Table 3, B7.5) and WPHs. (Table 3, W7.5)

Interviews – Auditing and improvement cycles

Overall, surgeons were aware of the outcomes of their patients and how these compared to the Dutch population. A difference was found in the sense of urgency to change their practice and improve. In BPHs, surgeons were actively attempting to improve every step in the care process, even though performance sometimes only tended to go in the wrong direction but no significant worsening was present yet (Table 3, B5.1) However, in WPHs, surgeons tended to suggest reasons outside their own control to explain bad performance, for example, methodological flaws in the audit system so that they do not have to take action (yet) (Table 3, W5.1). Moreover, nurses in BPHs reported to actively measure outcomes and be involved in improvement cycles (Table 3, B5.3),

whereas nurses in WPHs reported that they were not involved as this was the responsibility of the doctors (Table 3, W5.3).

Interviews – Structural hospital factors

In BPHs, high procedural volume was reported to stimulate improvement because it creates awareness of all aspects of the procedure and its possible complications (Table 3, B6.3). In WPHs, centralization was mentioned as a solution in itself (Table 3, W6.2).

Interviews – Role of the patient

Both groups of hospitals appreciated the role of the patient in his/her own colon cancer treatment. BPHs reported actively involving patients in the whole process (Table 3, B8.1), while in WPHs, interviewees reported plans to involve patients in the future, but also reported barriers to doing so (Table 3, W8.1).

Record review – Patient-level factors

Table 4 shows differences between BPHs and WPHs in preoperative, intraoperative, and postoperative processes completed, not completed, and unknown in all patients with a serious complication. Unfortunately, substantial information could not be found in the records reviewed, resulting in much unknown or missing data (which may also be a proxy for quality). In multivariable analysis, only a few processes remained significantly different between patients treated in BPHs and WPHs. Patients with a serious complication treated in BPHs were significantly more often admitted to a specialized ward compared to patients treated in WPHs (OR 6.95[1.57-30.70]). A preoperative visit to the outpatient clinic of an anesthesiologist and a colorectal surgeon was significantly less often missing in patients treated in BPHs compared to WPHs (OR 0.02[0.001-0.28] and OR 0.14[0.03-0.71]), which could be indicators of good quality medical record keeping. However, whether the anesthesiologist performing the anesthesia had seen the patient preoperatively was significantly more often missing in BPHs (OR 16.40[3.83-70.23]). Finally, even though serious complications were less likely to occur in BPHs, these patients more often had a reintervention within a day after first symptoms compared to having no reintervention when they were treated in BPHs (OR 9.99[1.54-64.91]).

DISCUSSION

This study selected BPHs and WPHs on serious complications- and FTR-rates to assess which factors could be identified as “best practice.” From semi-structured interviews, differences were identified in approach to preoperative, intraoperative, and postoperative care and in involvement of patients in their own care process. In BPHs, the interviewees reported to strive for “making every step perfect,” used protocols as tools to reach a goal (for example, learning from each other or creating a low threshold in communication), and had a colorectal surgeon present at ward rounds (confirmed by ward nurses). BPHs were reported to have an open culture and a specialized team (surgeons, doctors, and nurses) completely dedicated to striving for continuous improvement. Procedural volume was suggested as an instrument to provide better care instead of as a goal itself. The record review found that patients with serious complications treated in BPHs were more often admitted to a specialized ward and reinterventions were more likely performed within a day after the first symptoms of a complication.

Although data on hospital performance is increasingly available to the health care providers of that hospital, very few tools are described to improve the quality indicators. To the best of our knowledge, this study is the first to investigate which practice is leading to best performance in colon cancer surgery using mixed methods and thereby able to investigate both quantitative and qualitative aspects. The different structural characteristics of the selected BPHs confirmed the results shown in previous literature that it is possible to reach better performance with different structural characteristics.¹⁷ However, having a specialized ward with a colorectal surgeon present at ward rounds was shown to be important for better outcomes in colon cancer care in the present study. Furthermore, the procedural volume of the surgeon or the team was reported to increase experience of the team with recognizing complications and finding starting points for improvement. A low threshold to escalate care, short lines of communication, and a sense of urgency to perform continuous improvement cycles were suggested to be created more easily on a specialized ward, with the commitment of all medical personnel to this specific care.

One of the first studies to describe a checklist for best combination of processes, “best practice,” was performed by Pronovost et al.²⁴ The authors described a checklist for decreasing catheter-related bloodstream infections in the ICU. They found a large decrease in these infections due to the implementation of a checklist. However, when repeating this study in other hospitals, the effect was smaller. In subsequent studies explaining this effect, the culture and dedicated team around the checklist seemed to be at least as important as the checklist itself.^{25–29} This is in accordance with our study suggesting that it may not be the combination of processes but mostly how health care providers handle these processes that differ between BPHs and WPHs. Protocols or checklists are best used to reach a certain goal, for example, to make the threshold low for escalation of care. Previous studies on “best practice” in colon cancer surgery described certain protocols or standardized processes to result in better outcomes. Several studies also described nationwide implementation and increasing adherence to these standardized processes and protocols.^{30–33} In the Netherlands, the DCRA has stimulated adherence to the protocols by providing benchmarked feedback on process indicators.³⁴ By finding few differences in process factors and finding differences in culture and teamwork, our study suggests that even though the standardized processes and protocols (for example, ERAS protocol) are implemented nationwide in the Netherlands, the culture around these protocols still differs and thus may be responsible for differences in their effectiveness.

The current study focused on patients with a serious complication, a situation in which protocols are not always applicable. Some studies are attempting to catch the diagnostics and interventions in patients with a serious complication in protocols,^{35,36} but our study suggests that in those situations, standardization is not sufficient. It is the teamwork, culture, and short lines of communication that are especially crucial. The importance of teamwork and teamwork training was previously shown in several papers on crew resource management (CRM), suggesting that the implementation of simulation-based CRM training is associated with better clinical outcomes.^{37–39} Our study confirmed this importance of teamwork, culture, and communication within the team.

Our study further showed the importance of the involvement of a whole team in improvement projects. This is consistent with another Dutch study describing barriers and facilitators of morbidity and mortality (M&M) meetings on surgical wards, reporting “empowerment” as an important facilitator for learning and improving after M&M meetings.⁴⁰ Because the whole team is involved in the consequences of improvement cycles, it seems only logical to also involve the nurses in these meetings. Both our study and other research⁴¹ confirmed this by showing that in BPHs, nurses are involved in improvement projects.

Finally, our study confirmed the importance of the role of the patient. In BPHs, it was found to be very important to actively involve the patient in the perioperative process. This is in accordance with previous literature showing that a well-informed patient is more likely to be compliant during postoperative recovery. Involvement of a patient is suggested to make it easier for a doctor to maintain a constructive relationship in case of postoperative complications.⁴²

These findings have some implications for the future. First, they demonstrate the importance of a specialized ward with colorectal surgeons that have time for patients (on the ward) and for quality improvement projects. These activities should not be seen as in addition to regular work, and surgeons should be scheduled to spend a certain amount of time on these activities. Also, the results show the need for regular team training (for example, CRM training) with the specialized team to establish clear roles and short lines of communication.^{19,37–39} Our study showed the importance of easily accessible and understandable feedback information on different levels of care. For hospital boards, this adds to the conclusions of Jones et al. by finding importance in prioritizing quality improvement, using data to substantiate these improvements, engaging staff and patients, and encouraging a culture of continuous improvement of care.⁴³

This study has some limitations. First, qualitative research is never meant to prove hypotheses, but rather to help explain what might be happening, in this case to help explain the quantitative findings and seek cultural factors that may contribute to observed differences in outcomes. Differences in

communication, teamwork, and culture are difficult to measure in quantitative research (if at all possible), so that this can only be done using qualitative evaluation. Furthermore, although the current study investigated an extended list of processes, it could not cover every process. This makes it possible that some processes responsible for good performance were missed. Because processes found important by Dutch surgeons were investigated, they might be too focused on those processes that they have control over and not consider other processes possibly equally or more important. Also, it is unclear to what extent the factors mentioned actually contribute to good performance. Not all “best practice” will lead to better performance, and bad practice might even lead to better performance in good circumstances, but that seems less likely. The present study was conducted in a selection of Dutch hospitals, which could negatively influence generalizability. On the other hand, this study is in line with previous research (in other countries/other wards) claiming culture, teamwork, and communication to be very important and could also be of importance on other wards.^{19,37–39} Finally, despite the selection of better and worse performance on serious complications and FTR, the responding hospitals did not differ significantly in FTR but only in mortality (Table 2), which might explain why some factors were not significantly different.

In conclusion, it seems that practices leading to better performance on serious complications and FTR after colon cancer surgery include an open culture, where there is a low threshold to escalate care, with short lines of communication and a sense of urgency for continuous improvement. This open culture is easier to create on a specialized ward, with personnel present at the ward and committed to this specific care.

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TABLES AND FIGURES

Table 1. Factors potentially leading to good outcomes in colon cancer surgery, and where to potentially find them. The ten most important factors perceived by colorectal surgeons are indicated with *.

Potential factors influencing outcomes in colon cancer surgery	Variables known in DCRA	Potentially found in record review	Potentially found in interviews
Preoperative			
Preoperative screening of patients for malnutrition, followed by dietary measures*		+	+
Preoperative screening of elderly by a geriatrician		+	+
Preoperative visit of the patient to an anaesthesiologist		+	+
Preoperative opportunity to discuss a complex patient in a preoperative discussion with an intensive care doctor or anaesthesiologist			+
Preoperative counselling patients to quit smoking		+	+
Preoperative pulmonary training		+	+
The surgeon visits the patient the day before the surgery, or has seen the patient at the preoperative consultation		+	+
Preoperative visit of patients to a multidisciplinary outpatient clinic		+	+
The anaesthesiologist that performs the anaesthesia visits the patient the day before the surgery, or sees the patient at the preoperative consultation		+	+
Intra-operative			
Elective surgery is performed by surgeons with a specialization in gastrointestinal oncology*		+	+
A hypovolemic situation during the surgery is actively avoided		+	
The ratio between laparoscopy and laparotomy in an elective setting	+		

Table 1. Continued

Potential factors influencing outcomes in colon cancer surgery	Variables known in DCRA	Potentially found in record review	Potentially found in interviews
The percentage of patients with elective surgery that receive a definite ostomy	+		
The percentage of patients with laparoscopic surgery that has to be converted to laparotomy	+		
The percentage of patients that receive epidural anaesthetics		+	+
Emergency or urgent surgery is performed by surgeons with specialization in gastrointestinal oncology*		+	+
The percentage of patient that receive an anastomosis in emergency or urgent surgery	+		
The ratio between laparoscopy and laparotomy surgery in emergency or urgent setting	+		
Postoperative			
Presence of a protocol for early recognition of anastomotic leakage*			+
Accessibility of a surgeon specialized in gastrointestinal oncology to also review a patient, during business hours (beyond ward rounds) *			+
Daily ward rounds by the surgeon that performed the surgery or an other surgeon specialized in gastrointestinal oncology*		+	+
Patients are postoperative admitted on a ward specialized in gastrointestinal and oncological surgery		+	+
Presence of a protocol for testing CRP and consequences according to outcomes		+	+

Table 1. Continued

Potential factors influencing outcomes in colon cancer surgery	Variables known in DCRA	Potentially found in record review	Potentially found in interviews
Presence of a case manager who contacts the patient after hospitalization			+
Complications/re-interventions			
Reoperation is performed by surgeons with a specialization in gastrointestinal oncology*		+	
Time elapsed between first symptoms of a complication and a re-intervention*		+	
Number of re-interventions per patient with a serious complication		+	
The ratio between radiologic and surgical re-intervention	+		
Evening, night and weekend shifts			
24/7 a surgeon specialized in gastrointestinal oncology is 'on call' (he/she does not have to be in the hospital, though is available for consultation)*			+
A surgeon specialized in gastrointestinal oncology is present at ward rounds in weekends			+
Surgeon 'on call' is present at the evening report			+
The emergency room is 24/7 accessible			+
Presence of a surgeon in the hospital 24/7			+
Presence of a resident in the hospital 24/7			+
Communication			
Communication between nurses and interns, residents or surgeons			+
Communication between surgeons			+

Table 1. Continued

Potential factors influencing outcomes in colon cancer surgery	Variables known in DCRA	Potentially found in record review	Potentially found in interviews
At least monthly discussion of outcomes (including discussion of complications)			+
Communication between surgeon and anaesthesiologist			+
Health care providers			
Average experience of nurses on the wards			+
Average experience of interns and residents responsible for the wards			+
The hospital is a referral centre for colorectal surgery			+
Number of nurses per patient (nurse/patient ratio)			+
Number of surgeons specialized in gastrointestinal oncology in a hospital			+
Hospital structure			
Number of colorectal surgeries (both benign and malignant) performed in the hospital annually*	+		
Presence of Emergency intervention team (EIT)			+
Accessibility of an intervention radiologist			+
The ICU-level of the hospital			+
The operating team also performs other high-complex surgeries			+

Table 2. Structural hospital characteristics of responding better and worse performing hospitals, and characteristics of patients treated in better or worse performing hospitals in 2011-2013.

	Better performing hospitals		Worse performing hospitals		
Hospital level					
	N=4		N=5		
	N	%	N	%	
ICU-level					
1 (lowest)	0	0%	3	60%	
2 (medium)	2	50%	1	20%	
3 (highest)	2	50%	1	20%	
Volume (number of colon cancer resections/year)					
<60	2	50%	2	40%	
60-100	0	0%	2	40%	
>100	2	50%	1	20%	
Teaching status					
Academic	1	25%	2	40%	
Teaching	2	50%	1	20%	
General	1	25%	2	40%	
Patient level					
Patient characteristics 2011 - 2013					
	N=1117		N=1231		
	N	%	N	%	p-value
Gender					
Male	557	49,90%	624	50,70%	0,69
Female	560	50,10%	607	49,30%	
BMI					0.032*
Unknown	113	10,10%	86	7,00%	
<18.5	22	2,00%	23	1,90%	
18.5-25	440	39,40%	470	38,20%	
25-30	391	35,00%	451	36,60%	
30+	151	13,50%	201	16,30%	

Table 2. Continued

	Better performing hospitals		Worse performing hospitals		
Age					0.010
<=60	231	20,70%	207	16,80%	
61 - 70	358	32,10%	360	29,20%	
71 - 80	353	31,60%	439	35,70%	
>=81	175	15,70%	225	18,30%	
Charlson comorbidity score					0.072
0	534	47,80%	631	51,30%	
1	263	23,50%	298	24,20%	
2+	320	28,60%	302	24,50%	
ASA score					0.005*
I - II	818	73,20%	940	76,40%	
III	268	24,00%	278	22,60%	
IV - V	31	2,80%	13	1,10%	
Tumour characteristics 2011 - 2013					
	N	%	N	%	p-value
Location of the tumour					0.024*
Caecum	200	17,90%	279	22,70%	
Appendix	9	0,80%	14	1,10%	
Ascending colon	198	17,70%	247	20,10%	
Hepatic flexure	67	6,00%	72	5,80%	
Transverse colon	83	7,40%	92	7,50%	
Splenic flexure	36	3,20%	30	2,40%	
Descending colon	71	6,40%	63	5,10%	
Sigmoid colon	453	40,60%	434	35,30%	
Pathological T stage					0.000*
0	2	0,20%	37	3,00%	
1	76	6,80%	67	5,50%	
2	166	14,90%	181	14,80%	
3	629	56,60%	675	55,10%	
4	238	21,40%	265	21,60%	

Table 2. Continued

	Better performing hospitals		Worse performing hospitals		
Metastasis					0.074
No	942	84,30%	1070	86,90%	
Yes	175	15,70%	161	13,10%	
Preoperative tumour complication					0.000*
No	439	39,30%	612	49,70%	
Yes	678	60,70%	619	50,30%	
Treatment characteristics 2011 - 2013					
	N	%	N	%	p-value
Urgency					0.416
Elective	926	82,90%	1035	84,10%	
Urgent/Emergency	191	17,10%	195	15,90%	
Additional resections for metastasis					0.267
No	1044	93,50%	1136	92,30%	
Yes	73	6,50%	95	7,70%	
Additional resection for tumour growth					0.000*
No	964	86,30%	1089	88,50%	
Limited	70	6,30%	97	7,90%	
Extensive	83	7,40%	45	3,70%	
Outcomes 2011 - 2013					
	N	%	N	%	p-value
Serious complications	157	14,10%	331	26,90%	0.000*
FTR	28	17,83%	58	17,52%	0.933
Mortality	28	2,50%	58	4,70%	0.005*

Table 3. Most illustrative quotes (and factors they illustrate) of health care providers in better and worse hospitals. Quotes are grouped in themes.
S=specialized surgeon, R=resident or specialized nurse functioning as doctors of the ward, N=nurse, M&M=morbidity and mortality meeting, DCRA=Dutch ColoRectal Audit.

Theme	Better		Worse	
	Quote	Nr	Quote	Nr
Preoperative screening/preparation				
Quit smoking/alcohol/start nutrition/up and go				
	We advise patients to quit smoking, despite that there is no proof yet. Smoking is very difficult to register and prove. We advise patients that they have to stop for 3 weeks. Also alcohol use should not be excessive. We started to be much stricter about this after one patient. This patient drank a lot a couple of days before colorectal surgery and had a lot of complications, although the surgery was easy and uncomplicated. That is why we started with this advice. (S7)	B1.1	Yes, we advise patients to stop smoking, but it is an already stressful period with the surgery. Then also quitting smoking is very hard. I can imagine it is a hard time. We tell the patient that it is a good time to try to quit and we sometimes give nicotine patches, if people tell us they will try. We tell them it is better for wound healing. But they have to do it themselves. (N8)	W1.1
	I noticed if you have a good look at those patients with a complication you could always find something to have done better. For example, I had a young patient who had an anastomotic leakage. Very vital, 45 years, nothing wrong. We performed surgery and afterwards his friend said: " Yes, but he also smokes like a mad man." He smoked 30 cigarettes a day. From that day on, everyone had to stop. We do not see that many patients who smoke over 70, but everyone had to stop. (S7)	B1.2	What is important is that you can advise based on numbers. Risks for frail elderly are important to investigate. Now we do that with preoperative screening by the anesthesiologist and sometimes with consultations of the geriatrist. It would be nice to have some sort of checklist. (S5)	W1.2

Table 3. Continued

Theme	Better	Worse	
	Quote	Nr	Quote
			Nr
	We prepare everyone better. We tell every patient to walk stairs and stop drinking alcohol. Many young people also sit still a lot. Also with them, you have to pay attention. We tell patients to start walking 3 times a day for half an hour. Maybe they do it twice and that's a lot more than nothing. (S7)	B1.3	We do not have special programs for preoperative training to gain strength before surgery. We do not have a clinic to give advice about quit smoking. It would be good. Especially in rectal surgery, because you have a lot of time (due to radiotherapy), but we never came to it. (S2)
			W1.3
Intraoperative			
Intraoperative changes			
	Intraoperatively for example, the surgeon uses a device [to hold the bowel to the side] where the patient does not have to be tilted with the head down. An "endosponge," which keeps the bowel out of the small pelvis. The "Bair Hugger" is used against hypothermia. And they are very careful with making an anastomosis; in an emergency situation we do not choose an anastomosis over (temporary) ostomy easily. (R7)	B2.1	
Specialized surgeon present			
			Since 2013, not every surgeon does colorectal surgery anymore. (S1)
			W2.2

Table 3. Continued

Theme	Better		Worse	
	Quote	Nr	Quote	Nr
Postoperative monitoring				
Fast recognition				
	It is important that the people standing by the bedside recognize complications. I cannot really complain about that. Some residents are slightly less good at this, but then you will always have a nurse who has all kinds of scores. They more often call too many times than they call too late. (S4)	B3.1	It has happened that we saw a very ill patient in the morning who did not need a CAT scan, but should have gone straight to the operating theater. The ward doctor arranged everything and then let go. This patient ended up receiving surgery at 6 pm in a very bad condition. Only the nurses had seen the patient during the day. That is hard to avoid I am afraid. I believe that no other hospital has that sorted out perfectly. (S5)	W3.1
Presence at ward rounds				
	Everyday a surgeon does the ward round. Although at what time they do this really varies. We know if they are performing surgery, then they come to the ward in between surgeries. The patients always really want to know when the surgeon comes, but we don't know. But every day the patients are seen by the surgeon. (N6)	B3.2	If all goes well, there is a supervisor present at that ward rounds. This is a resident or gastrointestinal surgeon. He/she can signal problems. It is intended that someone is present every day. In practice, circumstances make it go differently. But someone is scheduled for this task. (R5)	W3.2
	The surgeon is accessible all day. He/she has the emergency phone for the rest of the day. But in practice, he/she is present at the ward from 8:15 am to 11 am or noon. And at the end of the day again (before the afternoon report). Furthermore, that surgeons' only responsibility is emergency surgeries and that is not a lot during the daytime. Most of the emergency surgery happens in the evening and at night. One can work out a lot of overdue administration in that shift on the ward. But you are immediately available if you are required. (S3)	B3.3	We hope to have a supervisor [specialized surgeon] 2-3 times a week, but it is in one week more than in the other. The agreement is that the supervisor [specialized surgeon] should be there, from the first to the last patient. However, that is hard to realize. But it is better, because you get a plan right away instead of with a delay. (N8)	W3.3

Table 3. Continued

Theme		Worse	
Better			
Quote	Nr	Quote	Nr
Protocol and experience			
We have protocols and the Condor (study) is done on the ward. For this study, every day we register a score for patients who received an anastomosis. If you suspect anastomotic leakage, these scores make you more alert. It is meant to make one more aware of possible complications (before calling the Rapid Response Team [RRT]). (R7)	B3.4	Due to the protocols, we take measurements for the protocol, but we do not know what it means anymore. If someone has pain on the wound site, we do not push on the wound anymore, but we give painkillers right away. (N1)	W3.4
Communication			
Short lines of communication			
You approach each other easy and always get to speak to each other, this is a bit because of the size of the hospital, that makes it possible. I also sometimes perform surgery in a larger hospital. There you will get to speak to people too, but you do not meet each other much (by running into them). (S6)	B4.1	Communication goes via a lot of people, which is not always good. We have agreements among each other. If you have to wait half an hour until you can consult the resident you can call the surgeon yourself. That's good; otherwise, you're waiting endlessly. I think that really does happen. Still, there are certain times during which delays may occur. (R5)	W4.1
Threshold to escalate care			
On the gastrointestinal ward, the nurses have a strong opinion. They sometimes go against the ward doctors if they do not trust the situation. They say: "I want you to consult with your supervisor and if you do not do that, I will call him." If one person in the chain is worried, it will be scaled up to a layer with more experience. And if I do not know what to do, I ask for help as well. Steps are also skipped sometimes. There is no threshold and there are short lines, so you can always call everyone. (N4)	B4.2	Nurses may also be afraid that they are troublesome. They might have had one bad experience, which makes them restrained to approach a doctor/surgeon. Or some do not trust in the doctor much. Certainly ward doctors who just started. And supervisors are always very busy. (N1)	W4.2

Table 3. Continued

Theme	Better	Worse	
	Quote	Nr	Quote
	Nr		Nr
Learning from each other			
	What we do now, because we have a lot less experienced nurses. We form couples in the morning, which means that you have responsibility for a certain part of the ward. Before you begin, you agree with each other what kind of patients you have and what you have to do and who can do that best. With the student we discuss where they can learn from and where they want to observe. I think, it is important to see every patient at the beginning of the shift, to see how they are doing. If anyone has a high Early Warning Score (EWS) of 6 or above, then you will go to the patient in this couple. Then you will go step by step through ABCD. This way you develop clinical reasoning. (N3)	B4.3	As a nurse we are not trained in clinical reasoning. Maybe nowadays they do that better, but the older nurses never learned that. You learned to care and recognize by experience. We never learned about how to communicate questions. (N1)
	We are increasingly working together, we no longer only have our own patients, but we have to do it together. Together you notice more. We work not with 1 nurse for 5 patients but with 2 nurses for 10 patients. You are responsible for more patients and have to know more, but I think that it is nice and you learn from each other. (N4)	B4.4	W4.3

Table 3. Continued

Theme	Better	Worse	
	Quote	Nr	Quote
	Nr		Nr
Auditing, improvement cycle			
Statistical difference			
	For example, a while ago, we had a high number of anastomotic leakages. It was not statistically significant yet, but you do not want to wait until the difference is statistically significant. We have intervened. Even qualified surgeons, even senior staff, were to make the anastomosis with a second surgeon present. It is not that innovative but it keeps you alert. You can learn from someone else again. After this intervention, it [the high number of anastomotic leakages] was gone again. (S3)	B5.1	Of our patients with rectum carcinomas, more than half are referred to us and these are not the easiest patients. Besides the fact that we only register primary colorectal carcinomas in the DSCA, we get a lot of complicated patients referred. The strange thing is that there is no compensation at all for reference. So that is why transparency has failed in my eyes. (S9)
	W5.1		
Learning from M&M			
	I started turning it around, if someone got a complication, I tried to find out, was it technical, can I avoid this in the next patient. And not only it's not my fault or not. We have been able to think of all these things. This gives you a completely different approach to a patient. (S6)	B5.2	Well, I have to say that I had a look at our data. Delirium is not such a big problem. Percentually, it's only a little bit higher than the criteria, it's between 4 and 10%, that's not much. We have also looked at people at risk of getting delirium. It's hard to predict. I doubt the value of that screening. (S5)
	W5.2		

Table 3. Continued

Theme	Better	Worse	
Quote	Nr	Quote	Nr
Learning from registrations/DCRA			
All complications are registered by the doctors, but if there is an increase, the nurses notice that too.	B5.3	The doctors register it, but what is being done is unclear for us. Changes happen on a different level. I have not noticed any protocol adjustment. (N9)	W5.3
Together with the supervision (doctor/surgeon), we have a look at what we can do in the medical field and the nursing field. For example, our patients had some problems with pain and the epidural pain block. We noticed that and communicated this to the anaesthetist and pain nurse. After some research, we changed some things. It is nice to see that when we apply changes, the outcomes indeed improve. (N3)			
Implementation of improvement			
If there are important points for improvements, things will be added to a weekly newsletter sent by the head of the department. Because everyone works irregularly, it's hard to reach people. That is why we have this newsletter once a week. If you read this, you will be aware of new developments. (N7)	B5.4	We do not necessarily hear changes in the department. But maybe they [doctors] do not always know it either. (N8)	W5.4

Table 3. Continued

Theme	Better		Worse	
	Quote	Nr	Quote	Nr
Structural hospital factors				
Planning	For us, the planner keeps free space in the schedule. That way people can be scheduled fast. That way the cholecystectomies do not block the whole program, and the patients with colorectal cancer do not have to wait 20 weeks. If the patient is planned, we have time, depending on the radiotherapy and chemotherapy and waiting time. We really make sure to stick to the planning. When a patient has a positive biopsy, we can get the radiotherapy planned within 3 weeks in the academic center. And then after 1 week we have to be able to give them a date for surgery. We always make a schedule. (S4)	B6.1	We are a referral center and get a lot of local advances in recurrent tumors and those all need radiotherapy. At least almost all. And then you give radiotherapy and then have to wait 10-12 or 16 weeks before we perform surgery. The referred patients start with 2-3 weeks' delay. Patients with colon carcinoma are hard to plan because we have patients that need synchronous liver surgery. I would propose that in referred patients, the waiting time should start after referral. (S9)	W6.1
Hospital volume	It has to do with dedication and that the surgeon is a little handy. If there is dedication and continuity of care can be assured, then the size of the hospital does not make a difference. For example, obesity in the USA, there are very few clinics that do that very well (that's also because there's not a good IC behind), while surgeons are doing it all day there. (S6)	B6.2	But centralization gives more improvement than morbidity and mortality meetings. (R1)	W6.2

Table 3. Continued

Theme Better		Worse	
Quote	Nr	Quote	Nr
Last year I performed 200-250 colorectal surgeries, and the year before two. That is important, I know this might be a little much. We perform 3 colorectal surgeries a day, a minimum of 2 days a week. It can be a little less, but I think it is important you perform a minimum of 150 surgeries per year. If you only perform one now and then, you do not notice the complications much. If you do so much and you have 10% anastomotic leakage, then you have an AL every week. Then I have to do a lot of bad news conversations. And I have to go to the ICU and explain to my colleagues. So if you perform the surgery so much, you will notice the differences. You get a better feeling for it. (S7)			
B6.3			
Dedication of the team			
Dedicated team			
Patients are prepared in a very meticulous way. All patients get extra nutrition. Then there is a dedicated team, the personnel assisting the surgery, surgeons, and anaesthetist. (S3)	B7.1	We do not have dedicated anaesthesiologists. (S1)	W7.1
On the day of surgery, we always visit the patient on the recovery ward. We explain the surgery and how it went. If the patient is already gone from the recovery ward, I will go to the gastrointestinal ward. I make sure I have seen the patient on the day of surgery. And 9 out of 10 times I'll see the patient again the next day. Because people often cannot remember it anymore. (S4)	B7.2	The downside of every day one of the surgeons to be present at the ward rounds is that it can also be a breast surgeon or oesophageal surgeon. We do not see all our own patients. (S5)	W7.2

Table 3. Continued

Theme Better		Worse	
Quote	Nr	Quote	Nr
We show pictures of everyone who is working on that day. We make sure the responsibilities are clear. You share a phone with a "buddy." I think we work very structured. At other departments they drink coffee at half past 12, with us the first group drinks coffee at 10 am. We are working very structured to get the job done. The closets are all structured, that is the plan, everything has its own place. The supporting issues are neat and well arranged. (N7)	B7.3	I do not know the names of the ward doctors/ residents, it changes so much. (S9)	B7.3
Specialized ward			
On the wards we have ward doctors and physician assistants. They [PAs] are actually the most important for maintaining continuity on the ward. They ensure that we do not lose continuity with the change of ward doctors. That important role is expanding. (R7)	B7.4	Well, our specialized nurses are here for 10-12 years, they do not need teaching. (S2)	W7.4

Table 3. Continued

Theme	Better	Worse	
	Quote	Nr	Quote
		Nr	Nr
	The nurses at the GI ward are experienced. Not a lot pf "flex workers" work there, it is a super-specialized ward. The nurses have experience with gastrointestinal surgery, they know the ins and outs of the matter. They call quickly if something is not good, but also handle some things themselves. They often know if they can remove a gastric tube or not. They often communicate with the ward doctors, but they have good ideas. They actually know exactly what should happen, so that's very nice. (R4)	B7.5	We had general nurses, not specialized in oncologic care. (R1)
	We try to be trendsetters in everything, but that may even depend on who is in charge of the wards and who leads the team. (N7)	B7.6	You could notice that nurses are really conservative. They did not like the ERAS (enhanced recovery) protocol for example; they thought the doctors were crazy. Now they are more cooperative, but that takes time. (S1)

Table 3. Continued

Theme		Better		Worse	
		Quote	Nr	Quote	Nr
Role of the patient					
Preparation					
		We started preparing the elderly by saying that the postoperative period is very hard work. You will be weak, sick, and nauseous; you have to be prepared to fight even then. If you don't want to live anymore, we have to know that before the surgery. I have had some patients whom I told the risk of surgery and they said: "No problem. I have lived my life, it is OK if I die." But that group always got complications. Even when you are fine before, after surgery both physical and psychological status are hit. If you are old and it is OK to die, you will die. Young and active patients who do not want to die do not die that easily. It is important that people understand they will have a hard time. But if they fight, they will be all right 2-3 weeks after surgery. It is a temporary thing, it is normal that they are tired and nauseous. It is not the case that the results got better, because we stopped performing surgery on the elderly. In the end, patients want to fight. I registered this and only one patient did not want the surgery (but that was wise, the surgery would have been not wise with the condition the patient was in). We call it neurolinguistic programming.	B8.1	What I notice is that all the information is a lot. It doesn't really get through. And if you need a stoma and you have to go to the anesthesiologist. That way the information becomes a blur. There is no time to really ask for an opinion. The little time for the information to settle in. (N1)	W8.1

Table 3. Continued

Theme	Better	Worse	
	Quote	Nr	Quote
	We try to make patients aware that they have to do something. That activates the patients. I try my best, but you have to as well. The patients will be actively involved in the healing process. (S7)		
Calendar	I think we need to make a calendar of what is expected from day to day for patients and from patients and what can be expected from us. Then the patient can keep the nurse sharp. The population is older and they tend to forget a lot. Then a guideline is also very useful. (R6)	B8.2	What we should add is patients' participation. If you don't help, people will stay in bed. In 2012-2013, we had a high percentage of prolonged hospital stays. (S5)
			W8.2

Table 4. Processes performed in patients with serious complications in 2013 in better and worse performing hospitals, compared with univariate analyses. All significant factors are tested in a multivariate analysis for each theme. Significant factors ($p \leq 0.05$) are indicated with *

	Patients in better performing hospitals (n=53)	Patients in worse performing hospitals (n=114)	Uni- variate Chi- square	Multivariate OR [95%CI]
Preoperative				
Dietary measures performed when			<0.05*	
- preoperative screening for malnutrition is unknown, or when				
- dietary measures are needed based on malnutrition score				
	No	37 (70%)	46 (40%)	1
	Yes	8 (15%)	22 (19%)	0.53 [0.12-2.22]
	Not applicable	8 (15%)	46 (40%)	0.46 [0.10-2.20]
Preoperative screening of elderly by a geriatrician			0.15	
	No	28 (53%)	49 (43%)	
	Yes	0 (0%)	4 (4%)	
	Missing	2 (4%)	14 (12%)	
	Not applicable	23 (43%)	47 (41%)	
Preoperative screening of elderly by an internist			0.26	
	No	27 (51%)	48 (42%)	
	Yes	2 (4%)	14 (12%)	
	Missing	1 (2%)	5 (4%)	
	Not applicable	23 (43%)	47 (41%)	
Preoperative visit of the patient to an anaesthesiologist outpatient clinic			<0.05*	
	No	11 (21%)	12 (11%)	1
	Yes	39 (73%)	80 (72%)	1.22 [0.29-5.15]
	Missing	3 (6%)	22 (19%)	0.02 [0.001-0.28]*

Table 4. Continued

	Patients in better performing hospitals (n=53)	Patients in worse performing hospitals (n=114)	Uni- variate Chi- square	Multivariate OR [95%CI]
Preoperative counselling patients to quit smoking		n=15	0.76	
Patients that stopped smoking, when pre- operative smokers				
No	6 (11%)	10 (9%)		
Yes	0 (0%)	1 (1%)		
Missing	3 (6%)	4 (4%)		
Not applicable	44 (83%)	99 (87%)		
Counselling to stop smoking		100% missing -> interviews		
Preoperative pulmonary training			<0.05*	
No	47 (89%)	84 (74%)		1
Yes	0 (0%)	18 (16%)		xx
Missing	6 (11%)	12 (11%)		0.26 [0.03-2.75]
The surgeon visits the patient the day before the surgery, or has seen the patient at the preoperative consultation			<0.001*	
No	15 (28%)	10 (9%)		1
Yes	28 (53%)	51 (45%)		0.53 [0.14-2.02]
Missing	10 (19%)	53 (46%)		0.14 [0.03-0.71]*
Preoperative visit of patients to a multidisciplinary outpatient clinic		100% missing -> interviews		
The anaesthesiologist that performs the anaesthesia visits the patient the day before the surgery, or sees the patient at the preoperative consultation			<0.001*	
No	19 (36%)	84 (74%)		1
Yes	4 (7%)	2 (2%)		6.97 [0.96-50.49]
Missing	30 (57%)	25 (24%)		16.40 [3.83-70.23]*

Table 4. Continued

	Patients in better performing hospitals (n=53)	Patients in worse performing hospitals (n=114)	Uni- variate Chi- square	Multivariate OR [95%CI]
Intra-operative				
Elective surgery is performed by a surgeon with a specialization in gastrointestinal oncology			0.97	
No	6 (11%)	12 (11%)		
Yes	32 (61%)	71 (62%)		
Not applicable	15 (28%)	31 (27%)		
A hypovolemic situation during the surgery is actively avoided		100% missing -> interviews		
The percentage of patients that receive epidural anaesthetics			0.07	
No	18 (34%)	25 (22%)		
Yes	28 (53%)	81 (71%)		
Missing	7 (13%)	8 (7%)		
Emergency or urgent surgery is performed by surgeons with specialization in gastrointestinal oncology			0.36	
No	7 (13%)	8 (7%)		
Yes	8 (15%)	23 (20%)		
Not applicable	38 (72%)	83 (73%)		
Postoperative				
Daily ward rounds by the surgeon that performed the surgery or an other surgeon specialized in gastrointestinal oncology		100% missing -> interviews		
Patients are postoperatively admitted on a ward specialized on gastrointestinal and oncological surgery			<0.001*	
No	4 (8%)	45 (41%)		1
Yes	47 (92%)	65 (59%)		6.95 [1.57-30.70]*

Table 4. Continued

	Patients in better performing hospitals (n=53)	Patients in worse performing hospitals (n=114)	Uni- variate Chi- square	Multivariate OR [95%CI]	
Missing	2 (4%)	4 (4%)			xx
Presence of a protocol for testing CRP and consequences according to outcomes (CRP testing is known, but not clear if this was due to protocol, and what is done with it)		100% missing -> interviews			
Complications/re-interventions					
Reoperation (all reoperations) is performed by surgeons with a specialization in gastrointestinal oncology	n=27	n=55	0.09		
No reoperation	26 (49%)	59 (52%)			
No	20 (38%)	27 (24%)			
Yes	7 (13%)	28 (25%)			
Time elapsed between first symptoms* and a reintervention was less than a day. Reasons for reintervention being: anastomotic leakage, abscess, bleeding, iatrogenic injury of the bowel, injury of the bladder.	n=14	n=11	<0.05*		
No reintervention	39 (74%)	103(90%)			1
<1 day	11 (21%)	4 (4%)		9.99 [1.54-64.91]*	
≥1 day	3 (6%)	7 (6%)		4.87 [0.45-53.10]	
≥1 day vs <1day (ref)				0.49 [0.03-8.56]	
Number of re-interventions per patient with a serious complication			0.94		
None	26 (49%)	54 (48%)			
1	18 (34%)	38 (33%)			
2 or more	9 (17%)	22 (19%)			

* First symptoms were scored according to the 'den Dulk' score.

Figure 1. A schematic description of the design of the study

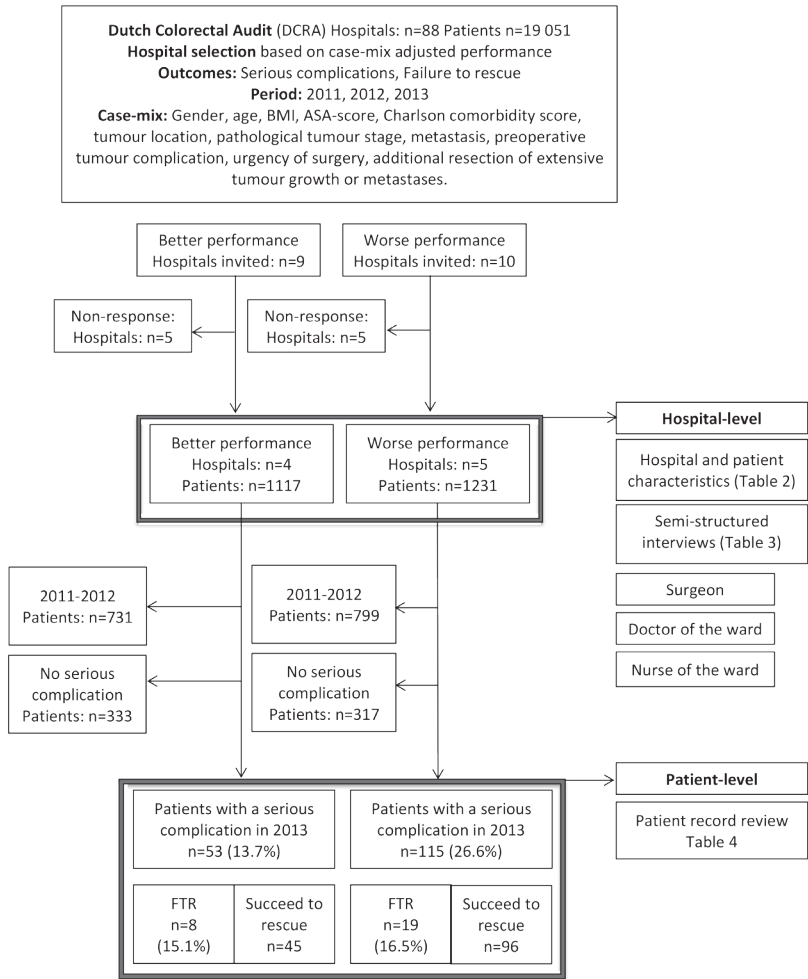


Figure 2. Selected better and worse performing hospitals on the outcomes: serious complications and failure to rescue in 2011, 2012 and 2013.

H=hospital, n= number of patients in the denominator of the indicator, %=percentage of outcome corrected for care-mix, Q=quintile

Quintiles are given colors according to their number, from green for quintile 1, to yellow for average and red for quintile 5.

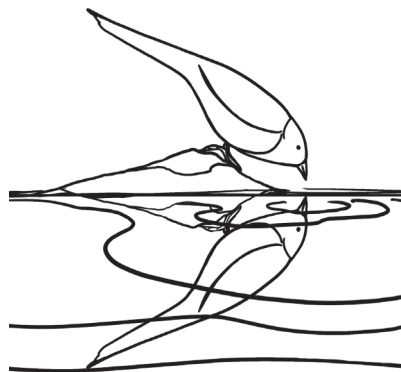
Formula weighted score = $(Q_{\text{serious complication 2011}})^2 + (Q_{\text{serious complication 2012}})^2 + (Q_{\text{serious complication 2013}})^2 + (Q_{\text{FTR 2011}})^2 + (Q_{\text{FTR 2012}})^2 + (Q_{\text{FTR 2013}})^2$

H	Serious complications									Failure to rescue									Weighted score:
	2011			2012			2013			2011			2012			2013			
	n	%	Q	n	%	Q	n	%	Q	n	%	Q	n	%	Q	n	%	Q	
1	57	14%	2	64	14%	2	77	14%	2	9	8%	1	9	12%	2	12	7%	2	21
2	39	15%	2	56	12%	2	49	8%	1	7	17%	3	7	16%	2	4	0%	1	23
3	41	5%	1	34	12%	2	39	17%	3	2	0%	1	4	0%	1	7	19%	3	25
4	106	14%	2	125	15%	2	123	13%	2	15	21%	3	19	20%	3	17	6%	1	31
5	31	33%	5	42	10%	1	24	15%	2	9	11%	2	4	0%	1	3	0%	1	36
6	129	15%	2	124	20%	4	145	16%	3	18	5%	1	25	14%	2	24	12%	2	38
7	52	19%	3	43	16%	3	49	19%	4	10	9%	1	6	0%	1	10	10%	2	40
8	63	15%	2	70	9%	1	54	4%	1	10	21%	3	6	46%	5	2	0%	1	41
9	54	12%	1	60	15%	2	61	15%	2	6	16%	2	11	15%	2	9	34%	5	42
Hospitals 11 until 81																			
82	88	22%	4	84	26%	5	84	25%	5	23	14%	2	23	25%	4	27	16%	3	95
83	73	27%	5	62	17%	3	57	22%	4	21	23%	4	12	27%	4	15	21%	4	98
84	91	25%	5	93	27%	5	100	26%	5	26	14%	2	25	11%	2	25	15%	3	99
85	67	24%	4	60	37%	5	48	17%	3	14	48%	5	19	0%	1	8	28%	5	101
86	44	30%	5	49	25%	5	64	23%	5	14	21%	3	13	26%	4	14	8%	2	104
87	109	28%	5	124	33%	5	124	31%	5	31	17%	3	33	30%	4	35	10%	2	104
88	30	16%	2	46	19%	3	49	20%	4	5	36%	5	8	43%	5	10	47%	5	104
89	25	30%	5	45	16%	3	45	16%	3	8	44%	5	8	31%	5	7	23%	4	109
90	94	62%	5	99	18%	3	73	22%	4	61	87%	5	18	29%	4	15	31%	5	116
91	12	34%	5	98	20%	4	145	23%	5	4	0%	1	20	37%	5	30	29%	5	117

Which practice is associated with best performance on serious complications and FTR

Chapter 9

Summary, general discussion and future perspectives



Colorectal cancer is a major health problem worldwide, with surgical resection being the cornerstone of treatment. However, colorectal cancer surgery has high rates of morbidity as well as a risk of mortality and reduced quality of life.¹⁻³ To evaluate and improve quality of colorectal cancer care, nationwide clinical audits have gradually been introduced in several countries.³⁻⁵ The goals of the clinical audits are

- 1) feeding back benchmarked process and outcome information to clinicians,
- 2) nationwide insight and evaluation of quality of care, and
- 3) learning from 'best practice'.

The aim of the thesis was to contribute to improvement of colorectal cancer care by increasing knowledge on factors contributing to best performance, in other words increasing learning from 'best practice'. The approach was to first identify best performing hospitals and then investigate which structure, processes and/or context factors are correlated with best performance.

IDENTIFYING BEST PERFORMANCE BASED ON OUTCOMES

Defining best performance

The first step was to identify best performing hospitals, from which other hospitals could learn and subsequently improve their own performance. Individual outcomes are usually indicators for the quality of a certain aspect in colorectal cancer care. However, in our attempt to identify a best performing hospital, we were searching for a comprehensive measure of overall performance of a hospital. Previous literature describes multiple outcomes being relevant in colorectal cancer care and investigators have searched for a set of most important indicators (i.e. a core outcome set) defining overall quality of colorectal cancer care. However, this core outcome set is not yet defined.⁶

One of the reasons that best performance is hard to define is that there are multiple stakeholders. Patients, health care insurers and providers have different views on what constitutes good quality and therefore also have different views on importance of outcome measures and different needs for information.⁷ The Quality Chasm 2001 of the Institute of Medicine describes that there often is a difference between care that patients receive and care

that fits their preferences, values and wishes, showing a need for more individualized medicine.⁸ In other words, the definition of best performance could very well differ for each patient. To illustrate, 'textbook outcome' (TO) is a comprehensive measure trying to capture several desired outcomes. TO for colon cancer surgery was defined by Kolfsooten et al. as in-hospital or 30-day survival, radical resection, no reintervention, no ostomy, no adverse events and a hospital stay of less than 14 days.⁹ However, in this proposed definition of TO, placement of an ostomy is no TO, while in frail elderly patients with high risk of incontinence or anastomotic leakage, placement of an ostomy could be a better choice than a primary anastomosis. So, for these frail elderly patients TO is not desirable, and thus not best performance.

Challenges of identifying best performance

There are also methodological challenges of identifying a best performing hospital. Traditionally, hospitals are compared to what is expected based on their case-mix in so-called funnel plots. Some hospitals may perform significantly better than expected. However, to facilitate learning it may be sufficient to identify a hospital that is at least better than the hospital that wants to improve their performance, rather than being the absolute best performer. Ranking hospitals on their outcomes is a way of comparing each hospital with each other, and thus to identify a hospital which is ranked higher. However, it is very important to take into account the uncertainty of this ranking. This can be done by calculating expected ranks. The expected rank (ER) of a hospital can be interpreted as the number of hospitals (out of the total) that is expected to perform better (e.g. an ER of 4 implies that at most 4 hospitals in the sample are expected to do better than this hospital).^{10–13} The overall reliability of ranking a particular outcome can be expressed as the rankability. This rankability can be interpreted as the percentage of between-hospital variation in an outcome that might be due to true hospital differences instead of chance. It is computed by relating the variation between hospitals to total within and between-hospital variance.^{10,11,13}

In **chapter 2** (this thesis) we investigated the extent to which it is possible to identify a best performing (group of) hospital(s) in colorectal cancer surgery.

We found that outcomes like mortality and Failure To Rescue (FTR), now used for feedback information and national hospital comparison in the DCRA, may not be very suitable for national hospital comparison due to low rankability. For an outcome to reliably measure quality, the event rate and/or the number of patients included in the comparison must be sufficiently high, which is not the case with mortality after colorectal cancer surgery in Dutch hospitals.^{14,15} The composite indicator TO was shown to be better rankable, consistent with previous literature.^{10,16} However, a composite measure has the disadvantage of loss of specific information on the individual indicators included in this composite measure.^{17,18} For example, the correlation between mortality and TO is low, even though mortality is included in TO (**chapter 2**, this thesis). In other words, a hospital can perform well on TO while having a high mortality rate. This study further showed that rankability of every outcome increased when more years of data are combined.^{10,16} However, for an effective audit cycle, feedback information preferably contains recent and specific information to enable professionals taking action to improve. This shows the vulnerable balance between reliability of the data and the relevance of the feedback. It could be risky to let outcomes with low rankability become transparent to the general public as hospitals could then be unjustly stigmatized for outcomes that are mostly based on chance. Furthermore, risks of transparency are 'gaming' and risk adverse behavior.^{19–21} Although this was not seen up until now in the colorectal audit in The Netherlands²², a difference in information for public versus health care providers should be appreciated.

Also in **chapter 2** (this thesis) we showed that hospital rankings on different outcomes were only correlated when those outcomes were also related on patient level (e.g. FTR and mortality) and vice versa (e.g. TO and FTR). As a result it is not possible to identify one hospital performing best on all outcomes. If outcome indicators would measure the same concept of 'quality of care', we would expect the outcomes to be correlated (even if they are not related to each other on patient-level).²³ One of the reasons for this low correlation is that quality indicators are always a simplification of reality and try to capture a very complex chain of health care processes in a simple combination of measures. Another reason could be that different quality indicators measure

different aspects of quality of care. To illustrate, the lack of correlation between TO and FTR could be explained by the fact that in TO the pre- and intra-operative chain of processes are measured trying to prevent adverse events, while in FTR mainly the postoperative chain of processes are measured trying to prevent a patient from dying after a serious adverse event has occurred. Furthermore, the more specific an outcome is influenced by a certain chain of health care processes, the easier it is to know where to start improving. For example, a high mortality rate is dependent on so many processes, patient characteristics and even noise (death from other causes) that it is hard to know where to start improving.²¹ A high FTR rate on the other hand, suggests starting improvements on the processes that are initiated when a complication occurs, e.g. timely recognition of symptoms of a complication and adequate treatment of that complication.²⁴

Specific targets for improvement

Regarding FTR, one of the most important complications in colorectal cancer surgery is anastomotic leakage (AL), which still has a high fatality rate. But even better than preventing the AL to be fatal, is to prevent occurrence of AL altogether. Unfortunately, it is not clear which (combination of) process(es) might prevent occurrence of AL. Some risk factors for AL are known from literature²⁵, although earlier research has also shown that patient characteristics do not seem to have much influence on a hospital's AL rate.²⁶ So, which factor should surgical teams focus on when trying to improve the AL rate? In **chapter 3** (this thesis) we showed evidence that early AL might be more related to technical failure, whereas late AL is more related to healing deficiencies typically in high risk or frail patients. Improving early AL or late AL would thus require different improvement strategies. Hospitals with a high rate of early AL need to focus on improvement of surgical techniques, while hospitals with high rate of late AL need to focus on improvement of preoperative screening and preparation of patients prone for healing deficiencies. By incorporating this distinction between early and late AL in the feedback information to hospitals, hospitals receive information better tailored on where to start improvement, thereby enabling learning from real-world data.

IMPORTANCE OF STRUCTURAL FACTORS TO ACHIEVE BETTER PERFORMANCE

As described by Donabedian: ‘Structure denotes the attributes of the settings in which care occurs’. Structural factors include material resources, human resources and organizational structure.²⁷ To be able to learn from best practice, it is thus important to assess whether some structural factors are necessary prerequisites for better performance.

Procedural volume

High procedural hospital volume has often been considered to be an important structural factor correlated with high quality of care. It is considered a proxy for high level care processes and experience of a team with the surgical procedure and perioperative care. As is shown in **chapter 7** (this thesis), Dutch colorectal surgeons still deem procedural hospital volume as one of the 10 most important factors associated with high performance on serious complications, FTR and mortality in colorectal cancer care. Procedural hospital volume indeed has shown to play a role in some specific groups of colorectal cancer surgery.^{28,29} However, the evidence for better outcomes in high volume hospitals with non locally advanced colon cancer in Europe is not that convincing.³⁰ More importantly, high hospital volume is no guarantee for optimal outcomes.^{31,32} When looking at hospital variation, some hospitals are able to perform very well despite the lack of these structural factors and some hospitals perform worse despite having these structural factors in place.^{31,33} At this moment the Association of Surgeons in the Netherlands (ASN) considers a minimum annual hospital volume of 50 colorectal resections and 20 rectal resections necessary to keep performing colorectal cancer surgery. This is a consensus-based quality standard, an ideal, evidence-based volume cut-off has not been described in literature yet and is probably arbitrary.³⁴

Hospital teaching status

Another structural factor that might explain why some hospitals perform better than other hospitals is their teaching status. In the Netherlands three hospital teaching types are distinguished, with their own structural characteristics and associated annual hospital volumes. If further centralization is considered, as

a solution to improve quality of care, colorectal cancer care would mostly be taken away from general hospitals. In **chapter 4** (this thesis) we show that on average patients treated in general hospitals have lower serious complication rates than patients treated in teaching hospitals, after adjustment for patient characteristics, and patients treated in teaching and academic hospitals have lower failure to rescue rates than patients treated in general hospitals. Furthermore, considerable between-hospital variation was shown regardless of teaching status. This supports previous literature on centralization arguing that it is possible to deliver excellent care (and low quality care) in each hospital teaching type.^{31,32,35} In **chapter 8** (this thesis) we selected better and worse performing hospitals based on serious complication and failure to rescue rates in three years. These selected hospitals were also found to vary in structural characteristics (annual hospital volume and teaching status), again supporting the idea that those structural factors are not decisive for good performance.

Specialization

However, both in **chapter 7 and 8** (this thesis), we found that caring for patients on a specialized ward with a specialized surgeon present at ward rounds seems important to obtain good outcomes. In **chapter 8** (this thesis) this is illustrated by surgeons reporting in interviews that procedural volume of a surgeon or the team does increase experience of the team with recognizing complications and finding starting points for improvement. This is in accordance with previous literature showing the individual volume and specialization of the team to be important, in terms of better survival, better adherence to guidelines and better use of appropriate surgical techniques.^{36,37} Findings in **chapter 8** (this thesis) also suggest that a low threshold to escalate care, short lines of communication and sense of urgency to perform continuous improvement cycles, are easier to be created on a specialized ward, with commitment of all medical personnel. Interviewees suggest procedural volume of the team (not the hospital) as an instrument to reach better care, instead of as a goal itself (**chapter 8**, this thesis). However, a specialized team does not have to be large. Group cohesiveness is more quickly developed in small groups and thus communication might even be easier in a smaller team.^{8,38,39}

Digitalization

Another structural factor that could support achieving good outcomes, by improving communication, is digitalization. Digitalization of records filled out by nurses of the ward, makes that information is available at any time, in any place, for all the health care providers involved. Even when specialized surgeons are not present at the ward, they could monitor patients through the information given in the electronical medical record. If they see alarm signs noted they could decide to visit that patient an extra time that day or contact the doctor or nurse of the ward. Some surgeons may use the electronic system to monitor their postoperative patients during off duty hours, even from outside the hospital. In **chapter 5** (this thesis) we show that digitalization on a ward (in the shape of availability of clinical software for the nurses on the ward (EMRAM stage 3 and higher)) is associated with a shorter length of stay, suggesting more efficient care. After adjusting this effect for serious complications, the effect decreases, meaning that serious complications explain part of the effect. In other words, digitalization on the ward seems to decrease serious complications and with that decreases LOS. So availability of clinical software on the wards does not only correlate with more efficient care, but also better quality of care (**chapter 5**, this thesis). We realize this is only a small step in suggesting that improving digitalization could support improvement of quality of care. However as described by Porter in his paper on the strategy that will fix health care, a right kind of technology could really help providers improve their quality of care.⁴⁰ Furthermore, structured reporting in a well-designed electronical medical record could also help with solving some of the administrative burden, by re-using or prefilling information already registered. Also, by re-using information, it could enable continuous monitoring of clinical processes and outcomes, enabling continued improvement of care by an effective audit cycle without adding to the administrative burden.^{41,42} However, digitalization also has a risk that focus of health care providers shifts to the computer instead of giving patients the attention they deserve. This should be taken into account when developing the system.⁴³

IMPROVING PROCEDURAL FACTORS TO ACHIEVE BETTER PERFORMANCE

Donabedian described processes as denoting what is actually done in giving and receiving care, including patients and providers activities.²⁷

Guidelines and protocols

'Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care in specific clinical circumstances.'⁴⁴ In other words, a guideline describes a combination of processes that may lead to better outcomes for a certain group of patients, supported by the best evidence available at that moment. So, adherence to guidelines could be the way to achieve best performance. 'Real-time' feedback information on guideline adherence by clinical auditing has been shown to be valuable.^{22,45,46} To illustrate, audit information on national guideline adherence in rectal carcinoma showed that patients in the Netherlands were more often treated with radiotherapy than in the rest of Europe.⁴⁷ Awareness of this fact increased a professional environment in which new guidelines could be introduced and thereafter tested on implementation. The audit showed rapid implementation of the revised guideline in the Netherlands, leading to a considerable reduction in the use of radiotherapy without an exacerbation of oncologic outcomes.⁴⁸

Guidelines are usually clear processes, easy to register and easy to improve if adherence is low. However, with guidelines, it is important to carefully account for specific groups with an indication for non-adherence to these guidelines. In **chapter 6** (this thesis) we show an example of guideline-adherence research. Local excision is an innovative (less invasive) technique that becomes more and more important with the increasing population of early stages of rectal cancer and the increasing interest in organ saving surgery. We found large non-adherence to the guideline in patients that do have an indication for a completion TME (cTME) after local excision of rectal cancer. Determinants for guideline adherence were low Charlson scores and younger patients, which is in accordance with literature stating that guidelines are usually followed in young relatively healthy patients but that adherence decreases with age.⁴⁹

However, in our study, still a substantial part of young and healthy patients were not treated according to the guideline, even though chances of guideline adherence were higher. This chapter thus provides national feedback to providers showing them the high rate of non-adherence to completion TME after local excision of 'high risk' rectal cancer. The aim was to make providers more aware of the risks of not performing a cTME, and prompt them to really discuss the possibly compromised oncological outcomes for a patient if the guideline is not followed. However, guideline non-adherence is not always in contrast with 'best practice'. Deciding not to adhere to the guideline can be the result of a carefully informed patient-doctor decision process, taking his or her comorbidities, prognosis, functional status and personal preferences into consideration. If guideline non-adherence is the result of a discussion in a multidisciplinary team followed by shared decision making with well-informed patients and doctors it could very well be 'best practice' (**chapter 6**, this thesis).

As with guidelines, protocols are developed to ensure every step in the care process is taken at the right moment, in the right way, by the right professional, resulting in the best chance of achieving the best outcome possible for every patient. A protocol for recognition of AL is crucial to achieve best performance on serious complications, FTR and mortality after colorectal cancer surgery according to the surgeons in **chapter 7** (this thesis). Fast recognition of a complication is necessary to be able to treat the complication early, resulting in better chances on good outcomes. However, the in depth interviews suggest that protocols for recognition of AL (e.g. DULK score⁵⁰), as well as standardized care programs (e.g. ERAS)⁵¹⁻⁵³, should be used as a tool to reach good outcomes and not as a goal itself (**chapter 8**, this thesis). Not the presence of a protocol, but the way the nurses and doctors of the ward use it - to develop a clinical view or to lower the threshold for communicating with a surgeon - seems to make the difference. Furthermore, in preoperative care, when comparing hospitals performing better and worse on serious complications and FTR, the difference seems to be in the way the screening and preparation is addressed (**chapter 8**, this thesis). Surgeons found risk assessment and personalized preparation an important factor to reach best performance (**chapter 7**, this thesis). Surgeons in better performing hospitals addressed this by trying to make every step

perfect, even with very little evidence present. Surgeons in worse performing hospitals wait for evidence or guidelines and even then do not always believe the measures will have effect (**chapter 8**, this thesis).

Specialization, dedication and culture

Another very important factor to reach good performance according to the specialized surgeons is the specialized surgeon him/herself (**chapter 7**, this thesis). Surgeons perceive it to be important that a specialized surgeon instead of a general surgeon performs the surgery, in both elective and emergency situations and in case of a reoperation. At the time of our investigation, a general (or vascular or trauma) surgeon sometimes performed a colorectal resection, especially outside office hours. The importance of a specialized surgeon being part of the operating team is confirmed by literature^{54,55} and the interviews in this thesis (**chapter 8**). However, whether a specialized colorectal surgeon was part of the operating team did not differ between better or worse performing hospitals based on reviewing patient records (data not shown, **chapter 8**, this thesis), even though there was a difference between the reported reasons for the presence of this specialized surgeon. Surgeons in better performing hospitals reported that specialization helped them to create a cycle of continuous learning. They sometimes operated together with another specialized colleague, so they could learn from each other. In contrast, surgeons in worse performing hospitals reported specialization as a goal in itself (**chapter 8**, this thesis). Furthermore, when discussing presence of a specialized surgeon on the ward, the difference between better and worse performing hospitals seemed to be the dedication of the specialized surgeon to specific tasks, not presence itself. In some better performing hospitals a surgeon is scheduled for nothing else in the morning (a dedicated task), versus in worse performing hospitals where the nurses hope that a surgeon will be present a couple of times that week.

Improving care by learning from best practice therefore does not seem to be reached by a checklist of processes but rather by the way the processes are addressed (**chapter 8**, thesis).^{56,57} In **chapter 8** (this thesis) we found that adherence to postoperative protocols, preventive measures, early recognition

and better treatment of complications, teamwork, culture and the level of experience of the team with the specific disease were very important reported themes to reach good performance. This is previously shown in the Matching Michigan study trying to implement a 'best practice' checklist in other hospitals than where the list was constructed, but failing to reach the same results.⁵⁶ The culture and dedicated team around the checklist seemed to be at least as important as the checklist itself.^{56,58-61} Although standardized processes and protocols are implemented in the Netherlands for colorectal cancer care, the culture around these protocols still seems to differ (**chapter 8**, this thesis). Interestingly, in **chapter 7** (this thesis) colorectal surgeons did not choose the factors 'communication' or 'experience of health care providers' as most important, suggesting that colorectal surgeons might not be aware of these cultural differences. However, these differences in culture, teamwork and dedication as a reason for variation in outcomes, especially FTR (**chapter 8**, this thesis), are described in previous studies.^{57,60,62} To reach good outcomes, resources, attitude and behaviour are described as important domains.⁶² Our study adds to these suggestions, by showing importance of a specialized ward with a specialized team (resources). Both previous literature and our study (**chapter 8**, this thesis) show a need for team training, making all healthcare providers aware of their role in the process and when it is required to escalate care to senior staff.⁶²⁻⁶⁵ Timely escalation of care seems to be dependent on a safety culture (attitude). Escalation and culture can be improved by escalation protocols, increased supervision by or availability of a specialized surgeon and communication skill training (**chapter 8**, this thesis).⁶⁶⁻⁶⁸ But, as discussed before, it will be the culture and attitude surrounding those protocols that are most important to achieve good outcomes. Hospital staff safety behaviour includes a continuous search for improvement to be important to reach good outcomes. Collecting and analysing information and thus finding errors, or starting points for improvement, indeed seem to improve patient outcomes?⁶² Our study adds to that by suggesting that in better performing hospitals the whole team was reported to be involved in this continuous search for improvements (**chapter 8**, this thesis). Many improvements involve nurses or doctors on the wards. So, because 'empowerment' and 'targeting provider behavior' are important facilitators for improvement to be implemented,

nurses and doctors on the ward should be involved in the planning of these improvements.^{69,70} Furthermore, nurses and doctors on the ward could also be the first to find starting points for improvements and to see results after improvements. This is likely to be far more effective than giving people information or telling them what to improve or where to start.

Continuous improvement of care is something that should have high priority, meaning that this should not be seen as additional to regular work, but providers should be scheduled to spend a certain amount of time on activities evaluating and improving care. For these activities the entire staff should be engaged and use data to see direct results of their interventions.⁷¹

Apart from engaging the whole team (and board) in striving for best performance, the patient should be engaged in this as well. **Chapter 8** (this thesis) shows the importance of patient involvement, making him/her more aware of possible complications, and consequences.⁷² It is previously suggested that involvement helps the constructive relationship between doctor and patient in case of a postoperative complication. Also, a well-informed patient is more likely to be compliant during postoperative recovery.⁷² This suggests that a well-informed patient would be more compliant to preoperative preparation as well, which was shown to be very important (**chapter 8**, this thesis).

FUTURE PERSPECTIVES

IMPLEMENTING 'BEST PRACTICE' IN COLORECTAL CANCER CARE

This thesis has thus shown that the focus on improvement by learning from best performing hospitals should not only be on structural hospital factors or on a checklist of processes, but rather on creating specialization, dedication, a safe culture and creating an attitude for continuous improvement.

Implementing 'best practice' is not just following a checklist of ingredients. While specialization of a colorectal surgeon has certain certifications, specialization of a ward or team is not strictly defined. There are some instruments to reach specialization, dedication and a safe culture, but most importantly these should only be used as a tool rather than as a goal in itself. The main question that hospitals should think about is why this is needed and what can be achieved as a result. Availability of the specialized surgeon is important, as it brings certain expertise to the ward, but could also help in creating lower threshold for escalation of care. Standardized processes, protocols^{52,73-75} and experience can help to reach specialization of nurses and doctors of the ward, which is needed to enable early signaling of complications because of that specialized expertise. This may also help to lower the threshold for communication by asking help when the experience is not present. These future 'best practice' wards should regularly train with their team to establish clear tasks and short lines of communication.⁶²⁻⁶⁵ Actively encouraging escalation is not enough to establish a low threshold. A flattened hierarchy is important, attained by training, escalation protocols and increased senior presence and availability.^{67,68,76}

A future 'best practice' team should be prone to learn from their own data and to keep on learning even when they are already doing well. An essential competence to continuously trying to improve is the capability to reflect.⁷⁷ Furthermore, **chapter 8** (this thesis) adds to the suggestion that it is important that the whole team is involved in this reflection, not just one person of the staff who is responsible for this. A safe environment and a just culture is very important to let reflection rise from an individual activity to a team activity.⁷⁷ Team discussion could also contribute to performance improvement by

improving inter-collegial relationships.^{77,78} Continuous quality improvement will be essential for any future specialist trying to deliver excellent care, so it should be embedded in the specialist training. It has been shown that quality of care is positively affected if residents are trained to implement quality improvement in their daily practice.^{79,80} However, as this was not included in the past training of current surgeons, it could be relevant to also give them training in analysing data and implementation of quality improvement initiatives. It might be interesting to let data experts on DCRA data go to hospitals to teach health care providers how to evaluate their quality of care and to use these data for improvement. It is important to make health care providers aware of, and interested in their outcomes.

These Quality improvement activities should not be seen as additional to regular work, but surgeons should be scheduled to spend time on these activities. These activities should be prioritized by hospital boards to facilitate this entire process.⁷¹

CONTINUOUS IMPROVEMENT CLINICAL AUDITING

This thesis also shows the importance of accessible and understandable feedback information for health care providers. To keep stimulating improvement, it is important for a clinical audit to keep searching for additional factors that might be relevant quality information. Examples from this thesis include the distinction between early and late anastomotic leakage and (non) adherence for cTME completion in patients with and indication. This future quality information should be rankable and actionable to support quality improvement cycles, which should be further tested.

Feedback of process and outcomes information

Feedback information on guidelines should be continued, making health care providers aware of (non-)adherence but specifically for patients who are indicated. Especially when introducing new techniques, it is important to use real-world data to monitor the implementation. This 'real-life' information could lead to a new discussion among specialists about risks and benefits of this new treatment. It is especially important in certain groups of patients who might not

be included in the trials that contributed to the evidence in the guidelines, but are included in the audit. If long-term results and/or Patient Reported Outcome Measures (PROMs) could be added to the audit results, real-time data would add even more to the existing research.

Development of PROMs might help the future clinical decision making process, but also has the potential to be important to stimulate improvements.^{81,82} There are some challenges to overcome before implementation. For example, response rates are low in most studies. To improve this it is important to implement the collection of PROMs in normal work routines and have adequate infrastructure supporting the use of PROMs in daily care. Discussion of individual PROMs results with patients as part of the routine visit could make them more relevant for patients and motivate them to fill in these questionnaires.⁸³ However, when the challenges are overcome this patient perspective will provide essential extra information to doctors to further improve quality of care, for instance whether treatment also had an effect on daily functioning and quality of life.

Feedback of combinations of outcomes

Feedback information for health care providers does not have to be captured in one composite measure, but it can be shown in several measures, but together in one dashboard. Such future feedback information could show a combination of a composite measure (to ensure high rankability) with the individual measures included in that measure (to make them actionable).^{16,84} Furthermore, it would be relevant to show the association between outcomes, as this may indicate different starting points for improvement. For example, associating early and late AL (**chapter 3**, this thesis) or associating TO and FTR (Figure 1). To illustrate, a scatterplot between TO and FTR is shown in figure 1. A hospital wants to be in the right lower quadrant, because then it would have a high rate of TO and a low rate of FTR. If a hospital is in the lower left quadrant, (Hospital B) that hospital should thus start improvement projects on pre- and intraoperative care (to improve TO), while a hospital in the upper right quadrant (Hospital A) should start improving postoperative care (to improve FTR). Such

a figure could be a relevant starting point for further investigations on exactly which processes need improvement.

Presentation of feedback

The format of presenting feedback can influence the interpretation of the data.⁸⁵ Traditionally, health care providers have been informed on their quality of care by funnelplots (Figure 2). These funnelplots use 95% control limits around an indicator, and compare the observed value of that indicator to the expected value given the case-mix of the population. Using this method enables to identify outliers, that is hospitals performing significantly worse than expected, thereby giving these hospitals an incentive to improve. However, when a hospital does not significantly differ from expected, the funnelplot gives no incentive to improve. While future feedback information should stimulate improvement for all hospitals, it could be interesting to compare with the expected values based on the 20% best performing hospitals on that outcome. To illustrate, in figure 2 the orange hospital has no incentive to improve, it does not differ significantly from average. However when based on what would be expected among the best 20% of the hospitals (figure 3), a lot of hospitals (including hospital x) would be stimulated to improve.

Furthermore, to be able to learn from the data, a hospital should be able to zoom in on their own data. If a hospital performs worse than average on a certain outcome, it should be possible to search for reasons for that performance. If, for example, the hospital specifically has a high serious complication rate in patients over 70 years, a hospital could focus on better preparing those elderly. Also, outcomes vary over time and the capability to improve continuously is important to reach good performance at a certain period. To stimulate continuous improvement it would be interesting to feed back development of quality indicators over time.⁸⁶ A cumulative sum technique (CUSUM) is an example of a method to show development over time. It shows the cumulated difference between observed and expected outcomes for each patient over time. Such a CUSUM is designed to detect a certain difference, e.g. doubling of the mortality, and can generate a signal when a pre-set limit is crossed. The settings and design of a CUSUM require attention to optimize having

not too many false-positive signals but also not to miss any signals.⁸⁷ When surgical teams get CUSUMs fed back, they will be able to immediately notice when performance is in the right direction (i.e. better than expected) and act when performance crosses a limit to the wrong direction. Furthermore, at this moment a problem with reaching an effective audit cycle is that a lot of hospitals only register their patients at the end of the year. Feeding back a CUSUM will stimulate surgical teams to regularly register their data, as they get rewarded with seeing their development.

PUBLIC QUALITY INFORMATION

This thesis shows there may be a difference between suitable information on quality for the general public versus health care providers. Public quality information should not be influenced heavily by chance, to prevent hospitals from unjustly being stigmatized.²¹ This means that rankability of future public indicators should be high (>70%).¹¹ Combining more years or more outcomes could increase rankability¹⁶. In the past years, the DCRA started with combining 2 or 3 years. However, this results in a longer feedback loop, reducing the relevancy of these data and the potential for timely improvement based on this feedback (**chapter 2**, this thesis). Combining outcomes to increase rankability, results in loss of specific information on the individual outcomes. This might be solved by showing the composite measure in combination with the individual measures^{16,84}, but that could make information more complicated to understand for the general public. However, the question remains: 'Which (combination of) outcome(s) define(s) best performance?' (**chapter 2**, this thesis) So, although, transparency of data could have positive effects^{19,88}, it might be wise to leave the era of inspection and control and to enter a new era towards appropriate trust in health care providers and to let them focus on quality improvement of the care they provide.⁸⁹ In his article on the changes for medicine and health care that are needed to reach this new era of appropriate trust, Berwick describes that transparency is essential. However, it is also defensible that transparency of data with low rankability to the general public could lead to insecurity and distrust of the public and makes doctors hesitant in providing all the right information.^{19,21}

No combination of outcomes might ever be fully applicable to every patient. Patients have been shown to have individual preferences even in type of presentation and understanding of information.⁸⁵ For future information for patients to base their hospital choice on, it could be interesting to let a patient individually choose outcomes that are important to him/her and select a hospital scoring good on those specific outcomes.

CONCLUSION

This thesis shows that the concept of best performance and best practice may be too simplistic in everyday practice. It was not possible to reliably define a best performing (group of) hospitals on a combination of outcomes. However, specific outcomes could be helpful to identify starting points for improvement.

Furthermore, it was not possible to identify a combination of structural or process measures necessary for good performance. To reach good outcomes, higher minimum annual hospital volume does not seem to necessarily improve care, but specialization and dedication of the ward and the team seem to be important. To reach best performance, 'best practice' seems to be: a specialized team with the right attitude and culture, effective teamwork and dedication to continuous improvement supported by continuous learning from reliable national and hospital specific data.

FIGURES

Figure 1. Scatterplot, with on the x-axis that adjusted percentage of textbook outcome (TO) and on the y-axis the adjusted percentage of failure to rescue (FTR) for each hospital. The ideal place is in the lower right corner, with high TO and low FTR. Hospital A (green) needs to focus improvement on FTR (postoperative process). Hospital B (yellow) needs to focus improvement on TO (pre/intraoperative process).

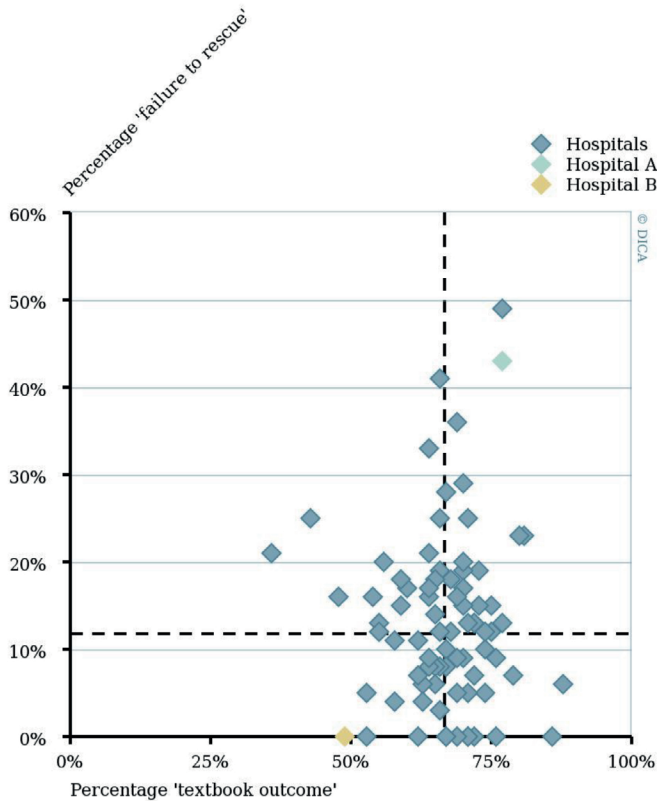


Figure 2. Funnelplot of serious complications in patients that received surgery for colon cancer. Each dot is a hospital, the dashed line is the Dutch average, the blue lines are confidence intervals around the Dutch average. The orange hospital x does not significantly differ from the Dutch average.

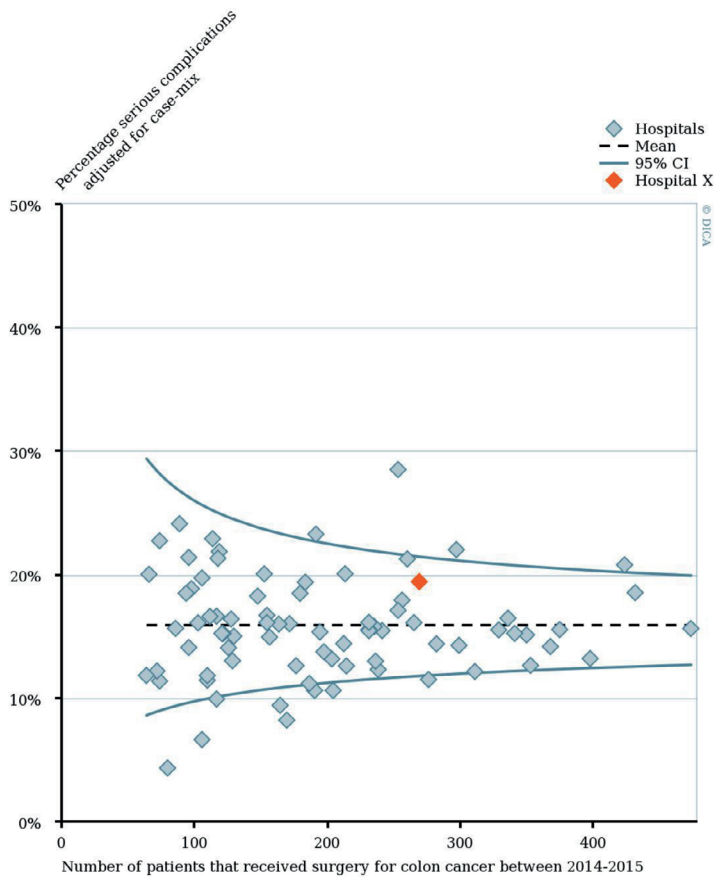
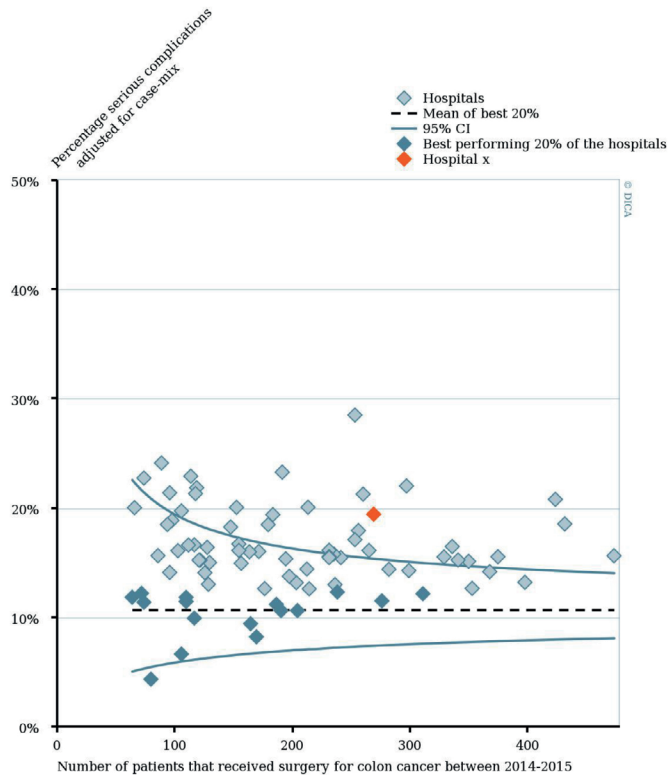


Figure 3. Funnelplot of serious complications in patients that received surgery for colon cancer. Each dot is a hospital, the dashed line is the average of the best 20% hospitals, the blue lines are confidence intervals around that average. The orange hospital x does significantly differ from the average of the best 20% of hospitals on serious complications.



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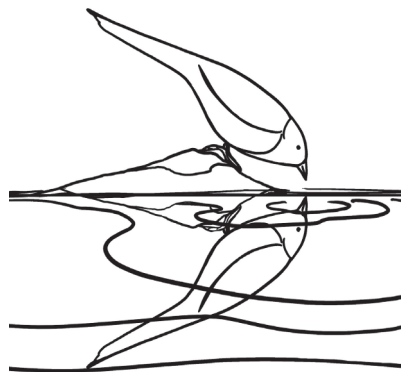
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Chapter 10

Dutch Summary



LEREN VAN DE BESTE PRESTEERDERS IN DE COLORECTALE KANKER ZORG

Dikke darm en endeldarmkanker is een groot gezondheidsprobleem wereldwijd, met een incidentie van 15.121 patiënten in 2016 in Nederland.^{1,2} Chirurgische verwijdering van de tumor, het aangedane stuk darm, de bloedvoorziening en de lymfedrainage is nog steeds de belangrijkste behandeling. Deze darmkanker chirurgie geeft een hoge kans op postoperatieve complicaties, risico op overlijden en verminderde kwaliteit van leven.³⁻⁵

In 2007 werd door de werkgroep Kwaliteit van kankerzorg geadviseerd dat complexe of hoog-risico oncologische procedures moeten worden verricht in een gespecialiseerde setting met de juiste infrastructuur, voldoende volume en adequate expertise. Verder moeten uitkomsten teruggelinked worden naar behandelaren. Dit leidde tot de introductie van volumennormen van 50 dikke- en endeldarmoperaties en 20 endeldarmoperaties per jaar en tot normen voor certificatie van oncologische en colorectale chirurgen.⁶ Hierbij werd een landelijke klinische audit geïntroduceerd door de Nederlandse Vereniging van Heelkunde (NVvH), waarin alle patiënten met dikke- en endeldarmkanker werden geïncledeerd. De Dutch Surgical Colorectal Audit (DSCA) startte in 2009 en binnen 2 jaar includeerden alle Nederlandse ziekenhuizen hun patiënten. Geleidelijk aan, door het multidisciplinaire facet van darmkanker werd de DSCA uitgebreid, zodat niet alleen chirurgen, maar ook radiotherapeuten, oncologen en pathologen betrokken waren. In 2017 veranderde de naam van de audit dan ook naar de multidisciplinaire Dutch ColoRectal Audit (DCRA).^{5,7}

Voor het evalueren en verbeteren van de kwaliteit van darmkanker zorg werden in verschillende landen klinische audit systemen geïntroduceerd.^{5,8,9} Een klinische audit heeft als doel de kwaliteit van zorg te verbeteren door:

- 1) terugkoppelen van proces en uitkomst informatie aan clinici
- 2) landelijk inzicht in, en evaluatie van kwaliteit van zorg, en
- 3) leren van 'best practice' (welke werkwijze brengt ziekenhuizen tot beste resultaten)

Het doel van dit proefschrift was bijdragen aan de verbetering van darmkanker zorg door kennis vergaring over factoren in een ziekenhuis die bijdragen aan goede resultaten van dat ziekenhuis. In andere woorden het doel van de thesis was leren van 'best practice'. Dit werd gedaan door eerst te identificeren welke ziekenhuizen de beste resultaten hadden en daarna te onderzoeken welke structuur, proces en context factoren gecorreleerd zijn met deze beste resultaten.

IDENTIFICEREN ZIEKENHUIZEN MET BESTE RESULTATEN

De definitie van 'beste resultaten'

De eerste uitdaging bij het zoeken naar best presterende ziekenhuizen is de vraag hoe deze 'beste resultaten' te definiëren. Eerdere literatuur beschrijft meer dan 766 verschillende uitkomst indicatoren.¹⁰ Deze uitkomsten meten elk de kwaliteit van een specifiek aspect in de darmkanker zorg. Een ziekenhuis zou echter goede resultaten kunnen hebben op de ene uitkomst (bijv. 30-dagen-mortaliteit) en op het zelfde moment slechte resultaten op een andere uitkomst maat (bijv. radicale resectie). Een combinatie van uitkomsten zou passender kunnen zijn, om iets te zeggen over het geheel van darmkanker zorg.

Patiënten, zorgverzekeraars en zorgverleners kunnen verschillende opvattingen hebben over wat goede kwaliteit maakt en daardoor over het belang van bepaalde uitkomstmaten. De definitie van beste resultaten van een bepaalde behandeling verschilt ook per individuele patiënt. Ter illustratie, 'textbook outcome' (TO) is een samengestelde maat die verschillende gewenste uitkomsten in één maat probeert te vatten. TO voor dikke darmkanker, is gedefinieerd door Kolfshoten et al. als ziekenhuis- en 30-dagen overleving, radicale resectie, geen re-interventie, geen stoma, geen complicatie en een ziekenhuisopname van minder dan 14 dagen.¹¹ In deze voorgestelde definitie van TO wordt het plaatsen van een stoma dus gezien als geen TO, terwijl bij kwetsbare oudere patiënten met een hoog risico op incontinentie of naadlekkage, een stoma mogelijk een betere keus kan zijn dan een primaire anastomose. Voor deze kwetsbare ouderen is TO niet het beste resultaat. Een eenduidige definitie van het beste resultaat is dus moeilijk te bepalen.

Methodologische uitdagingen voor identificeren ‘beste resultaten’

Voor het identificeren van een ziekenhuis met ‘beste resultaten’ zijn er ook methodologische uitdagingen. Het is belangrijk dat de data die worden gebruikt voor het berekenen van de indicatoren betrouwbaar zijn, met name als deze publiek worden gemaakt. Interne en externe verificatie heeft laten zien dat de DCRA data zeer accuraat en compleet zijn.^{5,7} Verder hebben eerdere studies laten zien dat het belangrijk is om te corrigeren voor de ‘case-mix’, ofwel de patiënt karakteristieken van dat bepaalde ziekenhuis, wanneer je uitkomsten met elkaar vergelijkt. Als laatste is het van belang rekening te houden met toeval.¹²⁻¹⁴

In **hoofdstuk 2** van dit proefschrift werd gekeken naar de mogelijkheid om betrouwbaar te identificeren wat een best presterend ziekenhuis is in dikke darmkanker chirurgie in Nederland. In dit hoofdstuk (**hoofdstuk 2**) werd gevonden dat het ordenen van ziekenhuizen op basis van uitkomsten als mortaliteit en ‘failure to rescue’ (het percentage patiënten dat overlijdt na een complicatie, FTR), voor een groot deel gebaseerd is op toeval. Een samengestelde indicator zoals TO bleek betrouwbaarder te ordenen. Echter, een samengestelde maat heeft het nadeel dat er specifieke informatie verloren gaat over individuele indicatoren die geïnccludeerd zijn in deze samengestelde maat. Het kan zijn dat een van de individuele indicatoren in grote mate de TO bepaalt of juist nauwelijks. In **hoofdstuk 2** werd bijvoorbeeld getoond dat de correlatie tussen TO en mortaliteit erg laag is. In andere woorden, een ziekenhuis kan goede resultaten hebben op TO terwijl dit ziekenhuis op hetzelfde moment een hoge mortaliteit heeft.

Hoofdstuk 2 laat verder zien dat betrouwbaarheid van elke uitkomst toeneemt als er meerdere jaren worden geïnccludeerd. Echter, voor een effectieve audit cyclus heeft feedback informatie recente en specifieke informatie nodig om mogelijk te maken dat aanpassingen effect sorteren. Dit laat een kwetsbare balans tussen betrouwbare data en relevante feedback informatie zien; de informatie is betrouwbaarder als er meerdere jaren worden meegenomen maar de relevantie kan afnemen als patiënten uit de eerdere jaren bijvoorbeeld anders werden behandeld. Wat betreft het transparant

maken van uitkomstindicatoren naar zorgverzekeraars, patiënten of andere partijen speelt deze betrouwbaarheid ook een grote rol. Het zou riskant kunnen zijn om uitkomsten waarbij de ordening een lage betrouwbaarheid heeft transparant te laten worden voor algemeen publiek, aangezien ziekenhuizen dan gestigmatiseerd kunnen worden door uitkomsten die voor een groot deel gebaseerd zijn op toeval.

In **hoofdstuk 2** wordt verder getoond dat ziekenhuis resultaten op verschillende uitkomsten alleen gecorreleerd zijn wanneer deze uitkomsten ook op patiënt-niveau met elkaar te maken hebben. Dit resulteert in het niet kunnen identificeren van een (groep) ziekenhuis(zen) dat over het geheel (van verschillende uitkomsten) beter presteert dan andere ziekenhuizen.

Specifieke indicator voor het starten van verbetering

Om effectief te kunnen verbeteren is het belangrijk dat een uitkomst specifiek is. Hoe specifiek een uitkomst wordt beïnvloed door een duidelijke ketting van processen, hoe makkelijker het is om te weten waar de verbetering moet komen. Een ernstige en veel voorkomende complicatie bij darmkankeroperaties, met een grote bijdrage aan postoperatieve mortaliteit, is naadlekkage.¹⁵ Het voorkomen van naadlekkages is een uitdaging en operatieteams weten vaak niet wat precies verbeterd moet worden om het aantal naadlekkage te reduceren. Er zijn risicofactoren bekend, echter er is aangetoond dat deze niet van grote invloed zijn op het aantal naadlekkages op ziekenhuisniveau.¹⁶ In **hoofdstuk 3** van dit proefschrift zijn meer specifieke risicofactoren voor naadlekkage onderzocht, door onderscheid te maken op basis van de timing waarop de naadlekkage zich voordoet. Vroege naadlekkage is meer gecorreleerd met technisch falen, terwijl late naadlekkage meer gecorreleerd is met een verminderde genezingsdens.**(hoofdstuk 3)** Bij een hoog aantal vroege naadlekkages is het goed om verbetering te zoeken in chirurgische techniek, terwijl een ziekenhuis met hoge aantallen van late naadlekkage eerder moet focussen op verbetering van screening en voorbereiding van patiënten met een verhoogd risico op verminderde genezingsdens.

DETERMINANTEN VAN BESTE RESULTATEN

Na het identificeren van beste resultaten heeft dit proefschrift gezocht naar de 'best practice', welke werkwijze brengt ziekenhuizen tot beste resultaten. Dergelijke factoren worden meestal onderverdeeld in grofweg twee categorieën. Structurele factoren ofwel de setting van het ziekenhuis, kunnen meestal maar beperkt beïnvloed worden door artsen, maar wel door lokale of nationale beleidsmakers. Procesfactoren zijn de daadwerkelijke activiteiten die plaatsvinden in een ziekenhuis en kunnen worden beïnvloed door zorgverleners.¹⁷

Structurele factoren

Teaching status

Een vaak genoemde structurele factor die zou kunnen verklaren dat sommige ziekenhuizen het beter doen dan anderen is de 'opleidingsstatus' van het ziekenhuis.¹⁸⁻²⁴ In **hoofdstuk 4** werd onderzocht op welke manier de opleidingsstatus van het ziekenhuis gecorreleerd is met uitkomsten voor patiënten die in dat ziekenhuis zijn behandeld. In Nederland zijn er 3 verschillende typen ziekenhuizen met eigen structurele karakteristieken en ziekenhuisvolume. Academische ziekenhuizen functioneren als tertiaire doorverwijscentra voor een geselecteerde groep patiënten en zijn verbonden met de Nederlandse universiteiten en hebben naast zorg ook research en onderwijs voor oa medische studenten als kerntaak. Deze ziekenhuizen lopen in het algemeen voorop in innovatie en onderzoek en bieden hoog-complexe laag-volume zorg. Opleidingsziekenhuizen zijn verbonden met een academisch ziekenhuis in hun regio en werken samen bij het faciliteren van opleiding voor chirurgen. Deze ziekenhuizen zijn meestal hoog volume ziekenhuizen. Niet-opleidingsziekenhuizen of algemene ziekenhuizen bieden toegankelijke zorg met de mogelijkheid om waar nodig naar opleidings- of academische ziekenhuizen te verwijzen. Dit zijn meestal laag volume ziekenhuizen.^{18,25} In **hoofdstuk 4** werd gevonden dat patiënten die in algemene ziekenhuizen worden behandeld gemiddeld minder vaak ernstige complicaties hebben dan patiënten die in opleidings- en academische ziekenhuizen worden behandeld na correctie voor case-mix, en patiënten die in opleidings- en academische ziekenhuizen worden behandeld, overlijden minder vaak aan een ernstige complicatie dan

patienten behandeld in algemene ziekenhuizen. Bovendien werd er aanzienlijke variatie tussen de ziekenhuizen waargenomen ongeacht de opleidingsstatus. Dit ondersteunt eerdere literatuur die stelt dat het mogelijk is om uitstekende zorg (en zorg van lage kwaliteit) te bieden in elk type ziekenhuis.^{26–28}

Digitalisering

Een andere structurele factor die het bereiken van goede resultaten zou kunnen ondersteunen is digitalisering. In een tijd waarin technologie overal aanwezig is, lijken de ICT systemen in ziekenhuizen niet optimaal ingezet. Digitalisering van dossiers die worden ingevuld door verpleegkundigen van de afdeling, zorgt ervoor dat deze informatie altijd en overal beschikbaar is voor alle betrokken zorgverleners. In **hoofdstuk 5** werd laten zien dat digitalisering op een afdeling (in de vorm van beschikbaarheid van klinische software voor de verpleegkundigen op de afdeling) geassocieerd is met een kortere verblijfsduur. Dit duidt op efficiëntere zorg. Nadat er ook werd gecorrigeerd voor ernstige complicaties, neemt het effect af, wat betekent dat ernstige complicaties een deel van het verschil in verblijfsduur verklaren. Met andere woorden, digitalisering op de afdeling is geassocieerd met kortere verblijfsduur op de afdeling en dat wordt mogelijk deels verklaard door minder ernstige complicaties. De beschikbaarheid van klinische software op de afdelingen correleert dus niet alleen met efficiëntere zorg, maar ook met een betere kwaliteit van zorg (**hoofdstuk 5**). Dit suggereert dat het verbeteren van de digitalisering de verbetering van de kwaliteit van zorg zou kunnen ondersteunen.

Proces factoren

Richtlijn naleving

Een richtlijn beschrijft een combinatie van processen die kunnen leiden tot goede resultaten voor een bepaalde groep patiënten, ondersteund door het beste bewijs dat op dat moment beschikbaar is.²⁹ ‘Real-time’ feedback informatie over richtlijn naleving door klinische audits is in het verleden waardevol gebleken.^{7,30,31} Richtlijnen zijn meestal duidelijke processen, makkelijk te registreren en te verbeteren als de naleving laag is. **Hoofdstuk 6** is een voorbeeld van een onderzoek naar richtlijn naleving. Lokale excisie is een minder invasieve techniek voor de behandeling van endeldarm kanker,

welke verminderde morbiditeit en mortaliteit geeft ten opzichte van de totale mesorectale excisie (TME, op dit moment de gouden standaard). Lokale excisie van een endeldarm tumor kan worden verricht als een alternatief voor een TME bij patiënten met een laag risico tumor, gedefinieerd als T1cN0M0 met gunstige histopathologische eigenschappen. Volgens de Nederlandse richtlijnen moeten patiënten met een hoger T stadium, of ongunstige histopathologische eigenschappen, alsnog een completerende TME (cTME) ondergaan, wegens verhoogde kans op lokaal recidief en mogelijk verminderde overleving.³² In **hoofdstuk 6** werd gevonden dat de richtlijn in veel gevallen niet werd nageleefd bij patiënten die hier wel een indicatie voor hebben. Bepalende factoren voor het wel naleven van de richtlijnen waren lage Charlson-scores en jonge patiënten, wat in overeenstemming is met de literatuur waaruit blijkt dat richtlijnen meer worden gevolgd bij jonge, relatief gezonde patiënten, maar dat de therapietrouw afneemt met de leeftijd.³³ Echter, in de studie in **hoofdstuk 6** is er nog steeds sprake van een aanzienlijk deel jonge en gezonde patiënten die niet werden behandeld volgens de richtlijn. Het doel van deze studie was om zorgverleners bewust te maken van de risico's van het niet uitvoeren van een cTME, en het belang te benadrukken van het bespreken van de mogelijk oncologische risico's voor een patiënt. Als afwijking van richtlijnen het resultaat is van een bespreking in een multidisciplinair team, gevolgd door gedeelde besluitvorming met goed geïnformeerde patiënt en arts, zou dit heel goed 'best practice' kunnen zijn (**hoofdstuk 6**).

Diepte-onderzoek

In **hoofdstuk 7** werden Nederlandse darmkanker chirurgen gevraagd naar hun mening over processen die bijdragen aan het behalen van goede resultaten na darmkanker chirurgie. In **hoofdstuk 8** werden ziekenhuizen geselecteerd met een aantal jaren de beste en minder goede resultaten op het gebied van ernstige complicaties en FTR na darmkanker chirurgie. Vervolgens werd in die ziekenhuizen statusonderzoek gedaan en werden interviews afgenomen met verschillende behandelaren (zaalarts, verpleegkundige en chirurg) om te zien hoe deze twee groepen ziekenhuizen verschilden op de processen en factoren die eerder door de darmkanker chirurgen waren aangegeven als mogelijk bepalend voor goede resultaten.

Gespecialiseerd chirurg

Een zeer belangrijke factor om goede prestaties te bereiken volgens de darmkanker chirurgen is de gespecialiseerde chirurg zelf (**hoofdstuk 7**). Chirurgen ervaren het als een belangrijke factor dat een gespecialiseerd chirurg in plaats van een algemeen chirurg deel uit maakt van het operatie team.^{34,35} Hoewel het geen verschil maakte of een gespecialiseerde darmkanker chirurg deel uitmaakte van het operatieteam, (gegevens niet getoond, **hoofdstuk 8**), verschilden de ziekenhuizen wel in redenen die ze rapporteerden waarom de aanwezigheid van deze gespecialiseerde chirurg in het team zo belangrijk was. Chirurgen in beter presterende ziekenhuizen meldden dat specialisatie hen hielp om een cyclus van continu leren te creëren. Door goed samen te werken met collega's, konden ze van elkaar leren. Daarentegen rapporteerden chirurgen in minder goed presterende ziekenhuizen specialisatie als een doel op zich (**hoofdstuk 8**). Tevens werd aanwezigheid van een gespecialiseerd chirurg op de afdeling zeer belangrijk gevonden. Ook hierbij leek het verschil tussen beter en minder goed presterende ziekenhuizen te zitten in de toewijding aan het continu verbeteren van de zorg en niet in de aanwezigheid zelf. In sommige beter presterende ziekenhuizen staat een chirurg 's ochtends voor niets anders gepland, terwijl in minder goed presterende ziekenhuizen de verpleging hoopt dat een chirurg die week een paar keer aanwezig zal zijn.

Gespecialiseerd team

In **hoofdstuk 7**, werd laten zien dat darmkanker chirurgen in Nederland ziekenhuisvolume nog steeds één van de 10 meest belangrijke factoren vinden geassocieerd met beste resultaten. Uit de literatuur blijkt dat ziekenhuisvolume inderdaad een rol heeft gespeeld in specifieke groepen van colorectale kankeroperaties.^{36,37} Het bewijs voor betere resultaten in hoog volume ziekenhuizen met darmkanker zonder lokale doorgroei is in Europa echter niet zo overtuigend.³⁸ Nog belangrijker, hoog ziekenhuisvolume is geen garantie voor optimale resultaten.^{18,26} De normen die op dit moment in Nederland gelden zijn op consensus gebaseerd. Een ideale, op bewijsmateriaal gebaseerde volumenorm is nog niet in de literatuur beschreven en zal waarschijnlijk altijd enigszins arbitrair blijven.³⁹ Wel werd zowel in **hoofdstuk 7** als in **hoofdstuk 8** gevonden dat het voor goede resultaten belangrijk is om patiënten op een

gespecialiseerde afdeling op te nemen. In **hoofdstuk 8** rapporteerden chirurgen dat het procedurele volume van een chirurg of het team, de ervaring van het team met het herkennen van complicaties en het vinden van verbeterpunten vergroot.^{40,41} De resultaten in **hoofdstuk 8** suggereren ook dat een lage drempel om zorg te escaleren, korte communicatielijnen en gevoel voor urgentie om continue verbeteringscycli uit te voeren, gemakkelijker kan worden gecreëerd op een gespecialiseerde afdeling, met inzet van het hele medische team. Een gespecialiseerd team lijkt dus te werken als een instrument om betere zorg te bereiken, maar niet als het wordt gezien als een doel op zich (**hoofdstuk 8**). Een gespecialiseerd team hoeft echter niet groot te zijn. Groepscohesie wordt sneller ontwikkeld in kleine groepen en communicatie kan zelfs gemakkelijker zijn in een klein team.⁴²⁻⁴⁴

Protocollen

In **hoofdstuk 7** vonden chirurgen dat een protocol voor herkenning van naadlekkage cruciaal is om de beste resultaten te bereiken. De interviews in **hoofdstuk 8** suggereren dat niet de aanwezigheid van een protocol, maar de manier waarop de verpleging en artsen van de afdeling dit protocol gebruiken – om een klinische blik te ontwikkelen of om de drempel voor communicatie met een chirurg te verlagen – het verschil lijkt te maken. Chirurgen vonden ook risico screening en persoonlijke voorbereiding een belangrijke factor om de beste prestaties te bereiken (**hoofdstuk 7**). Het verschil lijkt ook hier te liggen in de manier waarop de screening en voorbereiding wordt aangepakt (**hoofdstuk 8**). Behandelaren in beter presterende ziekenhuizen pakten dit aan door te proberen elke stap perfect te maken, zelfs wanneer er weinig bewijs aanwezig is voor deze stappen. Behandelaren in minder goed presterende ziekenhuizen wachtten op bewijs of richtlijnen en denken zelfs dan niet altijd dat de maatregelen effect zullen hebben (**hoofdstuk 8**).

Cultuur

Uit **hoofdstuk 8** blijkt dat hoewel gestandaardiseerde processen en protocollen geïmplementeerd zijn voor darmkankerzorg in Nederland, de cultuur rond deze protocollen nog lijkt te verschillen (**hoofdstuk 8**). De continue verbetercultuur en het toegewijde team rond een combinatie van processen blijkt tenminste net zo

belangrijk als de checklist zelf, wat veelal een middel lijkt om als team effectief te kunnen werken.⁴⁵⁻⁴⁹ Interessant is dat in **hoofdstuk 7** colorectale chirurgen geen van de factoren rondom 'communicatie' of 'ervaring van zorgverleners' als meest belangrijk hebben gekozen, wat suggereert dat colorectale chirurgen zich niet bewust zijn van het belang van deze cultuur verschillen.

Continu zoeken naar verbetering

Een continue zoektocht naar verbetering is belangrijk voor het behalen van goede resultaten. Informatie verzamelen en analyseren en daardoor fouten of verbeterpunten vinden, lijken inderdaad de resultaten van het team te verbeteren (**hoofdstuk 8**).⁵⁰ In de interviews in **hoofdstuk 8** wordt gesuggereerd dat in goed presterende ziekenhuizen het hele team betrokken was bij deze voortdurende zoektocht naar verbeteringen (**hoofdstuk 8**). Veel verbeteringen hebben betrekking op verpleegkundigen of artsen op de afdelingen. Omdat 'empowerment' en 'targeting provider-gedrag' belangrijke factoren zijn in het faciliteren van verbetering, moeten verpleegkundigen en artsen op de afdeling worden betrokken bij de planning van deze verbeteringen.^{51,52} Voortdurende verbetering van de zorg is iets dat hoge prioriteit moet hebben. Het zou dus niet als een aanvulling op regulier werk moeten worden gezien, maar er zou gepland moeten worden om een bepaalde hoeveelheid tijd door te brengen aan activiteiten die de zorg evalueren en verbeteren. Voor deze activiteiten moet het volledige personeel worden ingeschakeld en moeten gegevens worden gebruikt om directe resultaten van hun interventies te zien.⁵³

Betrekken van de patiënt

Naast het betrekken van het hele team bij het streven naar beste prestaties, moet de patiënt hier ook bij betrokken worden. In literatuur is al gesuggereerd dat betrokkenheid de constructieve relatie tussen arts en patiënt helpt bij postoperatieve complicaties. Ook is het waarschijnlijker dat een geïnformeerde patiënt compliant is tijdens postoperatief herstel.⁵⁴ **Hoofdstuk 8** bevestigt het belang van bewustwording van de patiënt over mogelijke complicaties en gevolgen van een darmkanker operatie. In **hoofdstuk 8** bleek tevens dat het voor behalen van goede resultaten een goede pre-operatieve voorbereiding van belang is, een goed geïnformeerde patiënt zou hier ook aan kunnen bijdragen.

CONCLUSIE

Dit proefschrift laat zien dat het concept van de beste prestaties en 'best practice' in de dagelijkse praktijk te simplistisch kan zijn. Het was niet mogelijk om op betrouwbare wijze een best presterende (groep van) ziekenhuizen te definiëren op basis van een combinatie van uitkomsten. Specifieke resultaten kunnen wel nuttig zijn om uitgangspunten voor verbetering te identificeren.

Het was tevens niet mogelijk om een combinatie van structuur of proces factoren te identificeren die noodzakelijk zijn voor goede prestaties. Om goede resultaten te bereiken, lijkt een hoger minimum jaarlijks ziekenhuisvolume de zorg niet per se te verbeteren, maar specialisatie en toewijding van de afdeling en het team om continu te verbeteren lijken belangrijk. Om de beste prestaties te bereiken, lijkt 'best practice' te zijn: een gespecialiseerd team met effectief en veilig teamwork en toewijding aan voortdurend verbeteren ondersteund door voortdurend leren van betrouwbare nationale en ziekenhuis specifieke gegevens.

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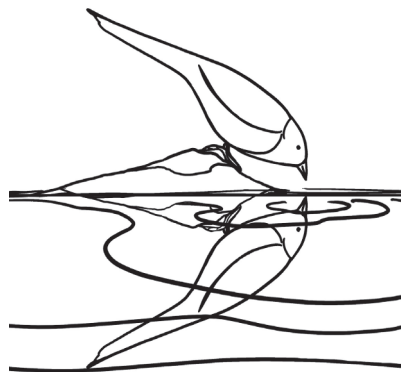
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Chapter 11

Curriculum Vitae

List of publications

Dankwoord



CURRICULUM VITAE

Julia van Groningen was born on August 23rd of August 1986 in Amsterdam. After graduating from the St. Vituscollege in Bussum, she started the study Medicine at the University of Amsterdam in 2004. In 2008/2009 she did a research project of 6 months about children with Inflammatory Bowel Disease and their knowledge of their health, under supervision of dr. Laurie Fishman at Childrens' Hospital Boston/Harvard Medical School. She did a clinical rotation in tropical medicine at Sengerema Hospital in Tanzania.

After obtaining her medical degree in 2012, she worked as a medical doctor (not in training) at the surgical departments of the Amstelland hospital in Amstelveen and of the Antonius hospital in Nieuwegein.

In 2014 she started the combined PhD program at Dutch Institute for Clinical Auditing (DICA) and the Leiden University Medical Center (LUMC). She performed her research under the supervision of her promotor prof. R.A.E.M. Tollenaar and co-promotores dr. M.W.J.M Wouters and dr. P.J. Marang-van de Mheen. Her research was focused on the Dutch Surgical Colorectal Audit (DSCA), later called the Dutch ColoRectal Audit (DCRA) and partly funded by the Dutch Cancer Society (KWF kankerbestrijding).

After her PhD program, she worked as a medical doctor at the surgical department in the Haaglanden Medical Center in Den Haag and on the wards of the nursing home 'het Reinaldahuis' in Haarlem.

In September 2019 she started her training to become a general practitioner (GP) at the Amsterdam UMC, location AMC. During her training she is conducting postdoctoral research about audit and feedback in the GP setting.

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