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Achievements in colorectal cancer care during 8 years of auditing in The Netherlands

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ABSTRACT

Introduction: The efficacy of auditing is still a subject of debate and concerns exist whether auditing promotes risk averse behaviour of physicians. This study evaluates the achievements made in colorectal cancer surgery since the start of a national clinical audit and assesses potential signs of risk averse behaviour.

Methods: Data were extracted from the Dutch ColoRectal Audit (2009–2016). Trends in outcomes were evaluated by uni and multivariable analyses. Patients were stratified according to operative risks and changes in outcomes were expressed as absolute (ARR) and relative risk reduction (RRR). To assess signs of risk averse behaviour, trends in stoma construction in rectal cancer were analysed.

Results: Postoperative mortality decreased from 3.4% to 1.8% in colon cancer and from 2.3% to 1% in rectal cancer. Surgical and non-surgical complications increased, but with less reintervention. For colon cancer, the high-risk elderly patients had the largest ARR for complicated postoperative course (6.4%) and mortality (5.9%). The proportion of patients receiving a diverting stoma or end colostomy after a (L)AR decreased 11% and 7%, respectively. In low rectal cancer, patients increasingly received a non-diverted primary anastomosis (5.4% in 2011 and 14.4% in 2016).

Conclusions: No signs of risk averse behaviour was found since the start of the audit. Especially the high-risk elderly patients seem to have benefited from improvements made in colon cancer treatment in the past 8 years. For rectal cancer, trends towards the construction of more primary anastomoses are seen. Future quality improvement measures should focus on reducing surgical and non-surgical complications.

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Introduction

Clinical auditing is increasingly considered as an important tool for quality assessment and improvement [1–6]. In an audit, baseline risk adjusted and benchmarked feedback information on performance is provided to professionals, thereby facilitating improvement cycles [7–9]. Additionally, auditing can also be used to evaluate guideline implementation and to monitor new treatments. This is illustrated by one of the first audits in rectal cancer that evaluated the implementation of Total Mesorectal Excision for rectal cancer [10].
However, the effectiveness of audits is still a subject of debate. A Cochrane review published in 2012 reported a positive but small effect of auditing on healthcare outcomes [11]. However, the magnitude of improvements varied strongly between studies. Although auditing can lead to overall improvements in outcomes over time, a still largely unresolved question is whether clinically relevant subgroups equally benefit from the advances made in colorectal cancer (CRC) treatment. Furthermore, critics have argued that improvements might also be related to patient selection by excluding high risk patients from surgery as a result of auditing, a phenomenon called risk aversion. Another example of risk averse behaviour could be avoiding the risks related to anastomotic leakage by performing more end-colostomies instead of low anastomoses.

Therefore, the purpose of this population-based analysis was to study outcomes of CRC treatment for different risk-stratified subgroups of patients since the start of the Dutch ColoRectal Audit (DCRA). In addition, potential risk averse behaviour was evaluated by determining proportions of surgically treated CRC patients over time based on the Netherlands Cancer Registry (NCR) and by analysing time trends of the proportion constructed colostomies in surgically treated (low) rectal cancer patients.

Materials and methods

Data were extracted from the DCRA, formerly known as the Dutch Surgical Colorectal Audit (DSCA). This audit collects information on patient, tumour, treatment and short-term outcome characteristics of all patients undergoing a resection for primary CRC in the Netherlands [12]. Every year, each hospital makes several structure, process and outcomes measures transparent on a hospital level to health care payers.

To enable a comprehensive view of CRC treatment over time and possible patient selection as a sign of risk averse behaviour, another independent source of data on both surgically and non-surgically treated CRC patients in the Netherlands was consulted: the NCR. The NCR uses the digital pathology archive (PALGA) and the National Registry of Hospital Discharge Diagnoses to notify of a newly diagnosed CRC [13].

Patients

For this study, no ethical approval or informed consent was required under Dutch law. All patients (n = 78,866) undergoing a surgical resection and registered in the DCRA between January 1st, 2009 and December 31st, 2016, were evaluated. Minimal data requirements were information on tumour location, date of surgery and 30-day/in-hospital mortality (n = 78,416). For the purpose of this study, it was decided to include only planned (elective) surgical resections and excluding multiple synchronous colorectal tumours [14]. Patients diagnosed through the CRC screening programme, which started in 2014, were also excluded. The screening population was considered a different (more favourable) CRC population that might influence on the studied outcomes over time, making interpretation of auditing effects more difficult [15,16]. This resulted in a total eligible number of 59,857 patients.

Data extraction and outcome parameters

The following data were extracted from the DCRA: patient and disease characteristics, procedural characteristics and post-operative outcome within 30 days after resection or in-hospital events. To evaluate overall trends in treatment for CRC, data on type of treatment for all registered CRC patients were extracted from the NCR. Type of treatment in the NCR was categorized as; resection - elective, resection - non-elective, local excision, polypectomy, (chemo)radiotherapy (no resection), systemic therapy, radiotherapy and systemic therapy, only metastasectomy and/or radiotherapy for metastasis, no treatment, resection for other indication (incidental finding), treatment unknown.

Outcome parameters consisted of complicated postoperative course (post-operative complication resulting in a hospital stay >14 days and/or reintervention and/or postoperative mortality), in-hospital or 30-day mortality, surgical complication, non-surgical complication, reintervention (surgical, endoscopic or radiologic), postoperative length of stay (LOS), and readmission.

Data analysis

Analyses were performed separately for colon and rectal cancer. The first two years (2009–2010) were excluded from trend analyses, because different variables of interest, such as type of complication or reinterventions, were not yet registered and because of not-registered eligible patients in the DCRA of >5% compared with the NCR [12]. For 2009–2010, patient and tumour characteristics were only provided for informative purposes. To evaluate changes over time, data from the years 2011–2012 were compared to 2015–2016 and tested for statistical significance with a non-parametric Mann Whitney U test for non-normally distributed continuous variables (e.g. LOS, with a Bonferroni correction for multiple testing) or chi²-test for categorical variables.

To evaluate differences in outcomes, uni and multivariable logistic regression analysis was used. The following factors were included in the multivariable analysis to adjust for differences in risks: sex, age, American Society of Anesthesiologists (ASA) score, Charlson comorbidity score, Body Mass Index (BMI), any pre-operative abdominal surgery (not further specified in the DCRA), tumour related complications, and pathological(p)T-stage. For colon cancer, the location of the tumour within the colon was added to the risk adjustment model, and for rectal cancer the tumour distance from the anal verge, clinical(c)T-stage, pre-operative radiotherapy (no radiotherapy, short course radiotherapy or chemoradiotherapy) and surgical procedure (LAR, APR or other) were added to the risk adjustment model. Further details on the risk adjustment model as used in the DCRA are described in previous studies [17].

Risk stratified analysis of raw data was done to be able to determine the absolute (ARR) and relative risk reductions (RRR) over the years for different subgroups. Ten subgroups of patients were defined based on relevance for surgical treatment (tumour stages: non-locally advanced/non-metastatic (T1-3N0-2M0), locally advanced/non-metastatic (T4N0-2M0) and metastatic (T1–4N0-2M1)) and on known risk factors for postoperative outcomes (ASA score (I–II vs. III–IV) and age (<60, 61–70, 71–80, ≥81 years)).

A p-value of less than 0.05 was considered statistically significant. All analyses were performed in SPSS 24.0 Statistics for Windows (Armonk, NY: IBM Corp).

Results

Baseline characteristics

A total of 40,004 colon cancer and 19,853 rectal cancer patients were included for analysis. Table 1 shows the characteristics of colon and rectal cancer patients per two years during the period 2009–2016. For colon and rectal cancer, patients in 2015–2016 compared to 2011–2012 had a higher ASA (III+), Charlson comorbidity score (3+) and BMI(30+).
<table>
<thead>
<tr>
<th></th>
<th>Colon</th>
<th>Rectum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 60</td>
<td>1479 (18)</td>
<td>1057 (26)</td>
</tr>
<tr>
<td>61–70</td>
<td>2349 (28)</td>
<td>1343 (33)</td>
</tr>
<tr>
<td>71–80</td>
<td>2894 (34)</td>
<td>1185 (29)</td>
</tr>
<tr>
<td>≥ 81</td>
<td>1734 (21)</td>
<td>444 (11)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>4403 (52)</td>
</tr>
<tr>
<td>ASA score</td>
<td>I–II</td>
<td>6301 (76)</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>&lt; 18.5</td>
<td>111 (22)</td>
</tr>
<tr>
<td>Tumour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location of Tumour</td>
<td>Ascending colon up to and</td>
<td>3885 (42)</td>
</tr>
<tr>
<td></td>
<td>including hepatic flexure</td>
<td>(46)</td>
</tr>
<tr>
<td></td>
<td>Transverse colon up to and</td>
<td>823 (44)</td>
</tr>
<tr>
<td></td>
<td>including splenic flexure</td>
<td>(47)</td>
</tr>
<tr>
<td></td>
<td>Descending colon</td>
<td>450 (39)</td>
</tr>
<tr>
<td></td>
<td>Sigmoid colon</td>
<td>3000 (36)</td>
</tr>
<tr>
<td>Distance from anal verge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 5 cm</td>
<td>1385 (36)</td>
<td>1385 (36)</td>
</tr>
<tr>
<td>6–10 cm</td>
<td>1551 (39)</td>
<td>1551 (39)</td>
</tr>
<tr>
<td>&gt; 10 cm</td>
<td>814 (41)</td>
<td>814 (41)</td>
</tr>
<tr>
<td>Pre-operative tumour complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>816 (10)</td>
<td>287 (7)</td>
</tr>
<tr>
<td>Clinical tumour T-stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ct1</td>
<td>147 (4)</td>
<td></td>
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<tr>
<td>ct2</td>
<td>875 (25)</td>
<td></td>
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<tr>
<td>ct3</td>
<td>1947 (24)</td>
<td></td>
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<tr>
<td>ct4</td>
<td>395 (52)</td>
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<td>Pathological T stage</td>
<td>(y)pT0-1</td>
<td>679 (8)</td>
</tr>
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<td></td>
<td>(y)pT1</td>
<td>1447 (17)</td>
</tr>
<tr>
<td></td>
<td>(y)pT2</td>
<td>1447 (18)</td>
</tr>
<tr>
<td></td>
<td>(y)pT3</td>
<td>1447 (18)</td>
</tr>
</tbody>
</table>
An overview of 97,254 CRC patients diagnosed with primary CRC in the Netherlands between 2009 and 2015 based on the NCR (2016 not yet available) is provided in Table 2. Total number of patients and corresponding proportions for each specified type of treatment are displayed for each year, with screening patients included since 2014. The number of elective resections increased, but with a relative decrease of 4% compared to other types of treatment, mainly related to the absolute and relative increase in endoscopic therapy. *Pathological stage was used for colon, clinical stage was used for rectum. Stage 0-X includes stage 0 or stage X (unknown or not judgeable). MDT: Multidisciplinary Team Meeting. SCRT: short course radiotherapy with immediate surgery (IS, ≤3 weeks) or delayed surgery (DS; >3 weeks). CRT: chemoradiation therapy. *Pathological stage was used for colon, clinical stage was used for rectum. Stage 0-X includes stage 0 or stage X (unknown or not judgeable).
Postoperative outcomes

Overall, postoperative complicated course and mortality decreased 3.0% and 1.6% in colon cancer, respectively, and 3.8% and 1.3% in rectal cancer, respectively, since 2011–2012. For colon cancer, multivariable analysis showed a significant reduction in the risk of a complicated postoperative course (AOR 0.74, 95% CI 0.69–0.80), as well as the risk of postoperative mortality (AOR 0.49, 95% CI 0.41–0.59). Similarly, a reduction was found for reinterventions for a surgical complication in 2015–2016 compared to 2011–2012 (Adjusted Odds Ratio (AOR) 0.67, 95% Confidence interval (CI) 0.58–0.77) (Table 3). The risk of non-surgical complications significantly increased between 2011–2012 and 2015–2016 (AOR 1.15, 95% CI 1.07–1.24).

For rectal cancer, multivariable analysis showed a significant decrease for complicated postoperative course (AOR 0.80, 95% CI 0.72–0.88) and mortality (AOR 0.41, 95% CI 0.29–0.57) when comparing 2015–2016 with 2011–2012 (Table 3). A significant increase was found for non-surgical (AOR 1.18, 95% CI 1.06–1.30) and surgical (AOR 1.15, 95% CI 1.04–1.27) complications, without a significant difference in reinterventions for surgical complications (AOR 0.90, 95% CI 0.67–1.21).

Risk stratified comparison of outcomes

Fig. 1 shows the ARR and RRR for each of the predefined 10 subgroups when comparing postoperative outcomes after colon cancer resection in the period 2015–2016 with 2011–2012.
In colon cancer, the risk on a complicated postoperative course was lower in nine subgroups, with the largest ARR of 6.4% (RRR 22.3%) in high-risk elderly patients (group 8; T1-3N0-2M0, /C21 81 yrs, ASA III-IV). The ARR on postoperative mortality was lower for all subgroups, with again the largest ARR of 5.9% (RRR 52.8%) in the high-risk elderly patients (group 8). Surgical as well as non-surgical complications showed a slight increase in most subgroups, but mostly not statistically significant. The risk of undergoing a reintervention for a surgical complication decreased in all subgroups, with a significant ARR of 15.8% in the high-risk elderly patients (group 8). Readmissions did not markedly change.

For rectal cancer, a reduced risk of complicated postoperative course was observed in nine subgroups, with the largest ARR of –20.0% (RRR 53.8%) in group 5 (T1-3N0-2M0, ≤60 yrs, ASA III-IV). The ARR on mortality was lower for all subgroups, with patients of group 7 (T1-3N0-2M0, 71–80 yrs, ASA III-IV) having the highest ARR of 6.0% (RRR 71.8%). As in colon cancer, similar changes over time were observed for the other outcome parameters, with reduction in reintervention for all subgroups and a highest ARR of 28.6% for group 7 (T1-3N0-2M0, 71–80 yrs, ASA III-IV).

Overall, median postoperative LOS decreased from 7 to 5 days for colon (p < 0.001) and from 8 to 6 days for rectal cancer (p < 0.001). Fig. 3 shows that the median decrease in LOS, with its corresponding distribution, was significant in 9 out of 10 subgroups in both colon and rectal cancer patients. The largest decrease in the
75th interquartile range (IQR) in both colon and rectal cancer was found for group 7 (T1-3N0-2M0, 71–80 yrs, ASA III–IV). Their 75th IQR percentage dropped from 14 to 10 days and from 19 to 12 days, respectively.

**Trends in surgical procedures for rectal cancer**

Comparing 2011 with 2016, the proportion of patients receiving a diverting stoma after a (L)AR with primary anastomosis decreased from 51.3% to 40% (Fig. 4A). Also, (L)AR with end-colostomy (Hartmann’s procedure) decreased from 26.3% to 19.4%. In contrast, the proportion of (L)AR with primary anastomosis without diverting stoma increased from 22% to 40.4%. Reintervention for anastomotic leakage was 5.6% in 2011 and 6.0% in 2016.

In low rectal cancer (<5 cm from the anal verge), patients increasingly received a non-diverted primary anastomosis (5.4% in 2011 and 14.4% in 2016; Fig. 4B). The proportion of reintervention for anastomotic leakage in low rectal cancer did not change: 2.3% in 2011 and 2.4% in 2016. The proportions of both APR and LAR with end-colostomy (Hartmann’s procedure) decreased over the years 2011–2016, from 66.3% to 50.8% and 14.2% to 10.3%, respectively.

**Discussion**

This study provides insights in eight years of auditing of CRC surgery in the Netherlands. The risk profile of patients undergoing surgery for primary CRC remained largely unchanged, with even a slight increase in ASA, Charlson comorbidity score and BMI. In addition, NCR data did not suggest that patients were not registered in the DCRA or not operated upon because of high risk (risk aversion). Only small changes in surgical treatment were observed, mainly related to introduction of screening in 2014.
Overall improvements in mortality and complicated post-operative course were seen. Remarkably, both surgical and non-surgical complication rates did not reduce and even revealed a slight increase for several subgroups of patients. However, surgical complications seemed to become less severe in both colon and rectal cancer surgery, as illustrated by the reduced reintervention rates. The high-risk elderly patients appeared to have benefited the most from improvements made in CRC treatment. Regarding surgical procedures for rectal cancer, a reduction in construction of temporary diverting stomas and end-colostomies was observed, even for the group of patients with low rectal cancer. The unchanged risk profiles of patients and the striving for more bowel continuity in rectal cancer by surgeons did not suggest any risk aversion.

Postoperative mortality is one of the most important quality indicators in CRC surgery. Overall, postoperative mortality decreased from 3.4% to 1.8% in colon cancer and from 2.3% to 1% in rectal cancer since 2011. The largest absolute risk reduction in mortality was achieved in the patients at highest operative risk; from 11.2% to 5.3% (ARR 5.9%) in colon cancer patients of 81 years and ASA III–IV, and from 8.4% to 2.4% (ARR 6.0%) in rectal cancer patients of 71–80 years and ASA III–IV. However, smaller improvements in other patient categories might have a significant impact if it concerns a substantial population in absolute numbers.
In line with the findings of Henneman et al., who already showed that non-surgical complications were a target for improvement based on DCRA data between 2011 and 2012 [1], we found a further increase in complication rate. Better registration or better recognition of complications [18] could have contributed to this observation. Furthermore, baseline characteristics revealed a slight increase in comorbidity and BMI, which might increase the a priori risk of postoperative complications. Nevertheless, one would have expected any impact of increased awareness and several improvement measures in perioperative care (i.e. prehabilitation, Enhanced Recovery After Surgery (ERAS), geriatric consultation) on this outcome parameter. Therefore, non-surgical complications should remain an area of attention for the coming years. However, complications seem to become less severe and probably better managed considering the observed decreases in reinterventions for a surgical complication, LOS and postoperative mortality. This also explains the observed improvements for the composite endpoint of complicated postoperative course. This benefits both the patients as well as the healthcare system, as severe complications are large cost drivers, aside from the initial treatment [19].

Patell et al. showed that patients with benign and malignant diseases undergoing a low anterior resection with an anastomosis within 5 cm from the anal verge have the highest risk group for an anastomotic leak, with ultra-low anterior anastomoses having the highest (8%) risk of a leak [20]. The systematic review of Huser et al. showed that constructing a diverting stoma in patients undergoing a low anterior resection reduces the rate of clinically relevant anastomotic leakage [21]. However, like Snijder et al. also previously demonstrated, despite the decreasing construction of a (diverting) stoma, we found no difference in the rate of reintervention for anastomotic leakage over time, [22]. Furthermore, this finding contrasts with the suggested existence of a risk averse strategy by surgeons promoted through nationwide auditing. In fact, auditing might have been one of the driving forces behind further specialization of surgeons, thereby improving the capability of managing high risk patients. Decreasing rates of APR and Hartmann’s procedure in distal rectal cancer are likely an effect of this specialization. This is also illustrated by the increase in the use of laparoscopic surgery for both colon and rectal cancer resection. In a previous study, we hypothesized that lower mortality rates after minimally invasive surgery compared to open surgery might not purely be related to the surgical technique, but also reflects expertise of surgeons and the hospital setting in which the procedure is performed [23].

In our study, we found a decreased LOS for colon as well as for rectal cancer, without an increase in readmission. In agreement with Pucciarelli et al. [24] and other studies [25], patients with colon cancer were at lower risks of a prolonged LOS and 30-day readmission compared to with rectal cancer. Damle et al. looked at the 30-days readmissions of colorectal resections for multiple indications and found half of the readmissions occurring within 7 days, with readmitted patients costing double compared to those not being readmitted [26]. Furthermore, Greenblatt et al. found an association between readmissions and 1-year mortality after colectomy for cancer [OR 2.44, 95% CI 2.25–2.65]. The lower LOS and readmission rates again benefits both the patients as well as the healthcare system.

One can imagine that the success of an audit depends largely on the quality and intelligibility of the feedback data, as well as on the users’ appreciation of the received data and own efforts in putting it into practice in the form of improvement cycles [27,28]. When interpreting the results, it is important to realize that the outcome measures are only externally reported on a hospital level and not, as might be the case in other audits, on surgeon level. Besides, as in many examples of observational research, causality is a major issue. Without a control group, the possible impact of auditing cannot be proved. It cannot be excluded that time itself is a confounder and that improvements would have occurred without auditing and reporting. The relative contribution to the improvements of evolving insights and techniques, such as the impact of surgical centralization and specialization [29] and the increasing use of new techniques such as laparoscopic surgery [23,30], is almost impossible to quantify when looking at overall trends in time. However, the consistency of demonstrated trends suggests that auditing matters and leads to new insights. Furthermore, substantial improvements in process indicators within a relatively short time period, such as preoperative MDT discussion, MRI imaging in rectal cancer and reporting of CRM, can without a doubt be attributed to auditing [12]. Besides, auditing facilitates international comparison on treatment patterns and outcomes, enabling valuable discussions about inter-hospital variability and identifying best practise [31]. An example of this was the observed overtreatment by preoperative radiotherapy in the Netherlands compared to other countries, with substantial inter-hospital variability [32], leading to guideline revision, with subsequent rapid implementation as monitored by the DCRA [33].

The strength of this study is the large numbers of patients and external validity related to the population-based data reflecting daily practise. But there are also some limitations. A certain degree of missing data is inevitable in population-based studies. Considering risk adjustment, there is always a possibility that not all contributing factors were included. For the purpose of this study, we decided to exclude patients referred through the national colorectal cancer screening program. This may have led to an understimation of the demonstrated improvements. Also, a better registration over the years and training of surgeons/data managers could have had a certain influence on the reported data. Finally, the DCRA does not provide information beyond 30 days or admission.

Conclusion

An overall improvement of outcomes has been demonstrated during the period of auditing, without signs of risk averse behaviour (e.g. patient selection). Although the severity of complications is decreasing, areas of future attention remain the surgical and non-surgical complications. In colon cancer, especially the high-risk elderly patients have benefitted most of the improvements made in the past 8 years. For rectal cancer, an increasing trend is seen in the proportion of (L)AR with primary anastomosis without diverting stoma and decreasing rates of APR and low Hartmann’s procedure in distal rectal cancer, possibly reflecting specialization.

Conflicts of interest statement
We have no conflict of interest to declare.

Additional information and declarations

Authorship statement

Availability of data and material

The data that support the findings of this study are available from the Dutch Institute for Clinical Auditing (DICA) but are not publicly available. Data are however available from the authors upon reasonable request and with permission of the Dutch Institute for Clinical Auditing and the Dutch Colorectal Audit Board.

Ethics approval and consent to participate

The DCR includes an obligatory audit from the inspectorate of healthcare, which required no informed consent from patients for data collection. Data analyses were performed on an anonymized dataset and does not need ethical approval according to Dutch law.

References