Quality assessment, assurance and improvement through clinical auditing

The colorectal cancer case

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CHAPTER 10

Thesis summary
The demand for rigorous evaluation of care by healthcare professionals in conjunction with the patient, together with informing society about the achieved outcomes, is a firm trend that started a couple of years ago.[1] This is also seen in colorectal cancer (CRC) care, one of the most prevalent types of cancer and a major health burden in Western countries. In the continuous effort to improve the quality of prevention of CRC and provided care for CRC patients, several measures were taken over the last years. Among others, these measures consisted of the implementation of clinical audits. Registries used for clinical auditing can provide benchmarked insights in performance and practice variation, which is supposed to incite quality improvement initiatives.[2, 3] The research in this thesis report on a wide range of quality-of-care related issues in the prevention and care of CRC, mainly using data from audit registries.

**PART I Quality of diagnosis and treatment of benign precursor lesions of CRC**

**Colonoscopy audit**

At the start of this thesis, local or screening-specific quality registries for colonoscopy already existed, mostly collecting well-defined and validated quality measures for clinical practice.[4-6] However, these registries only included a limited number of colonoscopies; e.g. 25-30% of the total colonoscopies are performed in the context of a CRC screening program.[7, 8] Those initiatives often required additional efforts to retrieve all relevant information from patient records and an extra registration burden, leading to implementation resistance among gastroenterologists.[9] In chapter 2, the organization and implementation of an automated colonoscopy audit registry is described; the Dutch Gastrointestinal Audit (DGEA). This audit automatically extracts a limited number of uniformly registered quality measures from local endoscopy reporting systems of all colonoscopies performed. The aim of the DGEA is to provide benchmarked insight in performance, to encourage local improvement initiatives and to support the discussion on quality of care regarding colonoscopies at a national level. Since the implementation of the DGEA, more than 300,000 coloscopies were registered, with a maximum missing value of <1%. Even though this study presents the very first results of the audit, which therefore should be interpreted cautiously, a per hospital variation in the adenoma detection rate and polyp detection rate was seen in screening colonoscopies, ranging from 62%-85% and from 65%-87%, respectively.

**Benign lesions**

Although only a small proportion of adenomas and sessile serrated lesions found during colonoscopy develop into CRC, it is currently not possible to reliably recognize those who will. Therefore, currently all those lesions are removed.[10-13] Colonoscopic resection of those lesions are associated with a relatively low risk of complications.[10, 11] Lesions that are considered to be “too complex” for endoscopic removal, i.e. lesions having a high risk for incomplete resection
Thesis summary

or a procedural complication, are often referred for surgery. It has been shown that the number of referrals to surgery for benign lesions has risen since the introduction of screening programs. [14, 15] In chapter 3, we performed a multicenter study that investigated the reasons for referral for surgery of benign lesions in further detail as well as the outcomes of the surgical resections. The most common reported reasons for surgical referral of benign lesions consisted of size and a suspicion of invasive growth. Overall, more than 80% of the lesions in referred patients could be considered as ‘complex’ for safe and complete removal. Referral to another center for the reassessment of the possibility of an endoscopic (re-)resection only occurred in 2% of the colon and 8% of the rectal lesions. Colonic lesions were operated according to formal oncologic resection in more than 90% of the patients. In contrast, 61% of the patients with a lesion located in the rectum were not treated by formal oncologic resections, but by performing a local excision. In total, 11% of the patients with a colonic lesion versus 3% of patients with a rectal lesion experienced a severe postoperative event. Three patients who underwent a resection for a benign colonic lesion died postoperatively (1%). The results of our study could be used to guide and optimize further referral and treatment strategies.

To place these results in a broader context, a systematic review on postoperative morbidity and mortality of benign lesions, in which benign was assessed by histopathological examination of the resection specimen, was performed in chapter 4. In this review, 26 studies published between 1980 and 2017 were included, describing 139,897 patients. The heterogeneity between studies was substantial. Our review showed that, if surgery was performed, this was often done according to formal oncologic resections. Pooled one-month complication and mortality rate of studies that included patients after the year 2000 was 24% (95%CI 15%-36%) and 0.7% (95%CI 0.6%-0.8%), respectively. Severe complications (Clavien Dindo 3+) were reported in 6 studies and was found in up to 10% of the patients. By the development of more advanced local resection possibilities for complex polyps, the indication for segmental bowel resections is likely to decrease and could possibly be further prevented by organizing expert referral centers.[16]

PART II Referral of CRC for surgery

Impact of screening
During the first years of the FIT-based screening program, an increased number of CRCs were detected. It can be expected that this had an impact on multiple healthcare resources. The larger than expected increase in patient volume for colonoscopy led to an overstretched endoscopic capacity in the first year of the screening program, and measures were taken to ensure timely access.[17] The impact of the first two years of the screening program on surgical resources in terms of volume and access (waiting times) were described in chapter 5. The volume differences between hospitals in 2014-2015 compared to 2013 ranged from -38% up to 122%. Despite
the overall increase in volume, waiting time between first tumor-positive biopsy and surgery decreased in 2014-2015 compared with 2012-2013 ($\beta$: 0.94; 95%CI: 0.93-0.95). In addition, no differences in waiting times were seen between screen-detected patients and non-screen-detected patients in the years 2014-2015. So, although no profound monitoring program of the surgical capacity was set in place during the implementation of the screening program, this research demonstrates that the volume increase of CRC patients following the implementation of the screening program was well absorbed by the surgeons and hospitals. However, it is not clear how this capacity was created and if this had any effect on the availability of resources for other patients.

Waiting times
During the last decade, timely access to oncologic care receives increasing attention. As one might expect, a diagnosis of (potential) cancer can cause psychological distress in patients and concerns about tumor progression over time often exist.[18] However, longer waiting might also reflect good quality of care, because the complexity of the patient and/or disease sometimes requires additional time to enable optimal treatment, e.g. (physical/psychological) preparation of the patient for treatment, but also for referral to another hospital. These referrals, with centralization as an underlying motivation, are also encouraged by the national guidelines.[19] In chapter 6, we investigated to what extent centralization has taken place at a national level. As one might expect, patients referred to a tertiary care hospital had more complex diseases and pre-surgical treatments. Standards for waiting times were overall hard to meet for both non-referred and referred patients, and this was especially the case for tertiary care hospitals. Remarkably, a higher percentage of referred patients were treated within maximum time standards compared to non-referred patients. Although we have to keep putting effort in reducing waiting times, reaching waiting time standards in CRC care as a quality indicator should be handled cautiously. This could prevent possible redundant interference with the delivery of high quality of care. Care, that takes into account the patients’ personal preferences, needs and capacity to appropriately cope with the disease.

PART III Quality assessment, assurance and improvement of surgical CRC treatment

Outcome comparison
To enable outcome comparison between healthcare providers, it is important to use statistical models that correct the data for the complexity of provided care.[20] This casemix correction model should include patients’ risk factors associated with the outcome of interest. Factors to include in the casemix model are (largely) restricted to the data registered. Patients’ risk factors can be assessed statistically, but also clinically relevant factors need to be considered. For CRC patients, an extensive casemix-correction model was developed in 2011 and further attuned
However, with the implementation of the national CRC screening program in 2014, a possible ‘new type’ of patient was introduced in the CRC field. **Chapter 7** demonstrated that patients with screen-detected colon cancer had more favorable case-mix adjusted outcomes compared to patients with non-screen-detected CRC in terms of non-surgical complications (Adjusted Odds Ratio (AOR) 0.81, 95% Confidence Interval (CI) 0.73-0.91), surgical complications (AOR 0.80, 95%CI 0.72-0.89) and complicated course (AOR 0.80, 95%CI 0.71-0.90). For rectal cancer, screen-detected CRC was not associated with better outcomes compared to non-screen-detected. One might conclude from these findings that the factor ‘screening’ seems to represent differences in unknown factors, e.g. tumor biology or non-registered patient characteristics such as smoking, nutritional status and socio-economic class. Adding ‘screening’ as a variable in future case-mix models should be considered when benchmarking surgical outcomes of CRC treatment.

**Monitoring treatment**

Besides the quality assessment and assurance on hospital levels, audits can also be used for monitoring the implementation of new treatment (techniques) on a national level. In the Netherlands, adoption of laparoscopic surgery occurred relatively fast, placing our country on the front side of this development.[22, 23] **Chapter 8** demonstrates an impressive and continuous increase in the use of laparoscopic surgery from ~50% in 2011 to more than 80% of the patients in 2015, accompanied by a decrease of conversion to <9% of the patients. Conversion rates between hospitals varied substantially and was independently associated with annual laparoscopic hospital volume. Around 50% of the conversions occurred ≤30 min from the start of surgery, and the overall leading cause for conversion consisted of exposure difficulties. Only for colon cancer, conversion was independently associated with higher odds on a complicated course if compared to open surgery. No difference was found for the risk of mortality between converted procedures or primary open resections. From this study, we could conclude that laparoscopic surgery has become the standard in the Netherlands, and it seems that experience in terms of procedural volume aid in (the estimation of) successfully completing laparoscopic surgery. Although the conversion rate is decreasing, colon cancer patients that are converted seem to have a slightly higher risk on detrimental effects of conversion and this finding deserves further attention. More research is needed to evaluate additional risk factors and long term effects, preferably using the new consensus definition of types of conversion reported by Blikkendaal et al.[24]

**Real world data**

New treatments modalities or strategies, like laparoscopic surgery, are usually compared with the current treatment modality in the setting of a Randomized Controlled Trial (RCT). However, carefully selected and relative healthy study populations that are evaluated in an RCT not necessarily reflect the true characteristics of patient populations for which the treatment will
be considered after the trial. Therefore, it’s safety and effectiveness could differ from the findings in RCT’s. Furthermore, in the setting of an RCT, the execution of new techniques or strategies might not have the same level of quality as in the ‘real world’, and in addition these techniques might also evolve or pass their learning curve during the trial. Observational registries might be able to fill this (real world information) gap. Especially for multimorbid elderly patients, evidence to support new treatments is limited and observational registries could be of added value.

[25] An overview of advancements in outcomes of CRC care of different subgroups of patients is provided in chapter 9. Over the years 2011-2016, overall postoperative mortality for colon cancer decreased from 3.4% to 1.8% and overall postoperative complicated course decreased from 16.9% to 13.9%. For both outcomes, the largest Absolute Risk Reduction (ARR) was seen in the high-risk, multimorbid elderly patients with a non-locally advanced tumor (ARR of 5.9% and 6.4%, respectively). For rectal cancer, overall postoperative mortality decreased from 2.3% to 1% and overall postoperative complicated course decreased from 22.9% to 19.1%. The largest ARR for mortality in rectal cancer was found in the in the multimorbid patients between 71-80 years old with a non-locally advanced tumor (ARR 6.0%) and for postoperative complicated course in the young (≤60yrs), multimorbid patients, again with non-locally advanced tumors (ARR 20%). Although the overall reintervention rate for a complication decreased, both non-surgical and surgical complications increased, indicating this as an area of potential improvement for the coming years. In this study, we did not discover signs of risk averse behavior. Actually, a decrease in the construction of stomas was observed for rectal cancer, without an increase in reinterventions for anastomotic leakages. These findings were supported by Vallance et al., who found no evidence that the introduction of public reporting of surgeon specific 90 day postoperative mortality in elective CRC surgery had led to risk averse behavior or “gaming” of data.[26]
REFERENCES


19. [www.oncoline.nl]


