Monitoring and improving quality of colonoscopy

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Chapter 8

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THEESIS SUMMARY

Colorectal cancer (CRC) is one of the most commonly diagnosed cancers in the western world. High quality colonoscopy has the potential to reduce CRC mortality by detecting carcinomas in early, treatable stages and reduce its incidence by detecting and removing its main precursor lesions, adenomas. However, colonoscopy will never completely prevent CRC. Besides accelerated progression of polyps into cancer, variability in quality of colonoscopies can lead to colonoscopy interval carcinomas, which are carcinomas that are detected within a proposed surveillance-interval. In an effort to optimize the quality of colonoscopy and reduce the incidence of interval carcinomas, several quality indicators have been established. Reporting on these quality parameters should be used for feedback and benchmarking, and will be helpful to target quality improvement. The research reported in this thesis covers a wide range of issues, all related to reporting, monitoring and improving the quality of colonoscopy.

The quality of colonoscopy can only be assessed if colonoscopy reports are complete and include all quality parameters. In chapter 2 we describe the development of a new, structured colonoscopy reporting system, EndoALPHA documentation (Endobase) version 11.6. The aim of this reporting system was to generate standardized and complete colonoscopy reports, including all key quality indicators and endoscopic findings. Because all items in the reports are coded, this system can be used for statistical analysis to measure the quality indicators for both the colonoscopy unit as well as for individual endoscopists. To create reliable quality reports, all colonoscopies should be reported using the fixed, structured terminology. In 2011, all endoscopists in our colonoscopy center were trained for adequate use of the reporting system. From 2012, 94% of all colonoscopies performed in our center were completely reported using the coded terminology, facilitating reliable reporting of the cecal intubation rate and ADR. The cecal intubation rate of all colonoscopies performed in 2012 was 98% and the ADR was 35%. The colonoscopy reporting system is currently used to provide feedback to individual endoscopists about their quality and also for benchmarking.

In chapter 3 we assessed the interobserver agreement of the Paris classification of colonic polyps among Western expert endoscopists. We created 85 short video clips depicting polyps. Seven endoscopists assessed each video and scored the Paris classification with categories pedunculated, sub-pedunculated, sessile, slightly elevated, completely flat, slightly depressed and excavated. After a digital training module on the optimal use of the Paris classification, the same 85 polyps were assessed again. The interobserver agreement of the initial assessment was moderate with a Fleiss kappa of 0.42, and after the training the interobserver agreement had not improved and was fair (Fleiss kappa of 0.38). We concluded that the Paris classification seems unsuitable
for comparative research on polyp morphology. Also the use of the Paris classification in daily practice is questionable and we therefore suggested a simplified classification system which has to undergo the same testing before its general use.

In chapter 4 we compared adenoma detection in colonoscopy with the use of an Endocuff, a new endoscope cap with two circular rows of plastic “hairs”, with conventional colonoscopy. The Endocuff is a special cap that is placed on the tip of a standard colonoscope, and the plastic projections straighten the colonic folds when the scope is pulled back, thereby potentially revealing more polyps located behind those folds. We demonstrated that Endocuff increased the mean number of adenomas detected per patient with 21.4% compared to conventional colonoscopy, which were mainly diminutive and flat adenomas. The ADR was high (53%) in our population, and Endocuff did not further increase this parameter. In 4.2% of Endocuff-assisted colonoscopies, intubation beyond the sigmoid was impossible. After removing the cuff, cecal intubation was possible in 86% of those procedures. Cecal intubation time was reduced by 1.5 minutes with Endocuff, probably by facilitating easier straightening of the endoscope and loop-prevention. We concluded that Endocuff-assisted colonoscopy increases the yield of colonoscopy and could therefore play a role in reducing interval carcinomas.

Because ADR is known to vary largely among endoscopists, in chapter 5 we evaluated whether this variance is already present during colonoscopy training of gastroenterology fellows (GI-fellows). We also assessed if ADRs during training can predict ADR in later practice as a consultant. During training, the ADR of the fellows ranged from 13.5%-36.1%, and differed significantly between the fellows (p<0.001). After adjusting for patient’s age, gender and colonoscopy indication, the odds to detect an adenoma for each fellow ranged from 0.64-0.29 when compared to the fellow with the highest ADR. In other words, the lowest detecting fellow had an OR of 0.29 for detecting an adenoma compared to the highest detector. After registering as GI-consultants, their ADR ranged from 19.8%-40.2%. Only 2 fellows significantly improved their ADR after registering as a consultant, the ADR of the other fellows did not change after finishing the training. Another observation from our study was that the fellow that had an ADR below 20% during the training period, also had a low ADR during consultancy. Our study suggested that the ADR of a GI-consultant can already be predicted during their training. This suggests that feedback and benchmarking of all quality indicators, including ADR, should be implemented early during training hopefully resulting in optimal performance as a consultant.

Adenomas are not the only precursor lesions of CRC. Research from the last decade suggests that serrated polyps (SPs) are responsible for 15-30% of all CRCs. Based on these findings, additional quality indicators besides ADR are necessary to assure high quality colonoscopy. Previous studies evaluated the proximal SP detection rate (PSPDR; the percentage of patients with at least 1 proximal SP) among different endoscopists.
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and found a broad range. In chapter 6 we compared the PSPDR among endoscopists, and additionally the rate of relevant SPs (RSPDR) and the association between both new parameters and ADR. We observed a range in ADR from 23%-49%, PSPDR ranged from 2.9%-18.6%, and RSPDR from 4.3%-20.9%. We demonstrated significant correlations between the PSPDR and the ADR (ρ 0.55, p=0.03) and between the RSPDR and the ADR (ρ 0.48, p<0.05). The correlation between PSPDR and RSPDR was very high (ρ 0.94; p<0.001). We concluded that besides a variation in the prime quality indicator ADR, also the PSPDR is widely variable among endoscopists, indicating a high miss-rate for low detectors. Because the PSPDR and RSPDR are so strongly correlated, we suggested that PSPDR, that is easier to assess, should be used as quality indicator.

A recent study from the USA demonstrated that 10% of all neoplastic lesions are incompletely resected.² This study confirms that besides missed precursor lesions or carcinomas, incomplete resection of neoplastic polyps is another important cause for interval carcinomas. To measure quality of polypectomy technique, the Direct Observation of Polypectomy Skills (DOPyS) was developed for the purpose of formal training and assessment of basic and advanced polypectomy.³⁴ In most countries systematic training in polypectomy for GI-fellows is currently not provided, and skills are acquired through apprenticeship and experiential learning. In chapter 7 we evaluated the effect of a lecture-based training course about colonic polyps and polypectomy techniques on polypectomy skills of GI-fellows in training, measured with the DOPyS. For the purpose of this study, 8 GI-fellows recorded five polypectomy videos before, and five videos after attending the course. Before training 25% of the polypectomies were scored as “passed”, compared to 37.5% after training, a non-significant difference (p=0.56). None of the individual DOPyS competency parameters improved after training. Based on these results we concluded that a short lecture based curriculum is insufficient to improve polypectomy skills. We concluded that direct feedback and hands-on training in the endoscopy-suite are needed, preferably provided by well-trained teachers.

FUTURE PERSPECTIVES

In January 2014, a national CRC screening program was started in the Netherlands. Asymptomatic persons aged 55-75 years are invited biannually to perform a fecal immunochemical test (FIT) at home and send it by postal mail to a central laboratory. The participants with a positive test-result are invited to undergo colonoscopy. Because FIT is used to preselect participants with advanced adenomas and carcinomas, a large number of polyps are detected in these FIT-positive participants, and some of the polyps are quite large. Therefore, screening participants often undergo a therapeutic colonoscopy. Quality of colonoscopy should always be high, however this is especially important if
asymptomatic persons are invited to a screening program and undergo a burdensome and invasive examination with potential complications. If persons are offered screening they should be able to expect a safe and high quality examination that protects them from developing CRC.

Several years ago, the benefit of an accreditation process for screening colonoscopists has been demonstrated in the UK. In 2004, before the start of a national British FOBT-screening program, the shortcomings of colonoscopies were revealed. An analysis of colonoscopies that were performed in daily practice demonstrated a disappointing adjusted cecal intubation rate of only 56%, clearly demonstrating the urgent need for quality improvement. After this national audit, several measures were introduced aiming to improve the quality of colonoscopy. These included an organized national training programme for endoscopy, defined targets for endoscopy training and the establishment of national endoscopy standards (defined by the Joint Advisory Group). Besides, an accreditation process for colonoscopists in the FOBT-based bowel cancer screening was developed. In 2012 an audit of colonoscopy quality indicators within the NHS Bowel Cancer Screening Program was performed and demonstrated great improvement compared to 2004 with a cecal intubation rate of 95% and had a high mean ADR of 46.5%.

In line with results from the UK, scarce data before the start of the Dutch screening program demonstrated a large variance in colonoscopy quality in the Netherlands. In an effort to ascertain quality, a formal accreditation process for endoscopy units and endoscopists for FIT-positives in the screening program was implemented. The establishment of this accreditation process already increased awareness on the importance of high quality colonoscopy in the Netherlands. Besides, regular audits are organized and to provide data, participating screening centers and endoscopists are obliged to deliver all screening data, including colonoscopy data, to a national screening database (ScreenIT). The set-up of this database facilitates quality monitoring of all participating endoscopists. Besides the national screening program, the Dutch Society of Gastroenterologists (NVMDL) has started an initiative to collect key quality indicators of all other, non-screening colonoscopies in our country. This will enable auditing and benchmarking of quality of colonoscopies and hopefully result in improvement of quality where necessary.

The Dutch national FIT-based CRC screening program will in all probability lead to a reduction in CRC related mortality, and eventually also to a decrease in incidence of CRC. However, screening will never be perfect and will never lead to a 100% reduction in CRC mortality. First of all, FIT is not perfect in preselecting participants that should undergo colonoscopy. The sensitivity of FIT for detecting advanced neoplasia is well below 100%, and approximately a quarter of all advanced lesions are missed.
Besides, FIT is not very sensitive to detect either non-bleeding adenomas or serrated lesions, also a known precursor of CRC. To overcome this flaw, another option is to offer a colonoscopy to everyone. In other western countries, for example the United States and Germany, primary colonoscopy is the screening method of choice. This way, the risk of missing cancers with the use of a preselecting screening test is avoided. If every screening invitee would accept this offer, if no colonoscopy capacity problems or financial barriers would exist, and if colonoscopy was perfect: CRC might be eradicated within the screening population. The final step in this scenario is that colonoscopy should be perfect and unfortunately we know it is not. In the last decade many studies, including those described in this thesis, have been conducted to improve the quality of colonoscopy. Besides improving quality of colonoscopy, e.g. optimal bowel preparation and performing complete colonoscopies, many new endoscopic imaging techniques and devices have been studied for their potential to improve polyp detection. Currently, polyp detection reflected by the ADR is the only quality indicator that has an established association with interval cancer. Therefore, in the recent years the main aim of many studies in the field of colonoscopy has been to improve ADR. Several new technical tools (e.g. cap-assisted colonoscopy, Third-Eye Retroscope, etc.) and new colonoscopes with improved image quality (e.g. high definition resolution, narrow band imaging, etc.) were developed in order to improve detection rates. These techniques aim to improve image quality during colonoscopy and enable colonoscopists to detect subtle, small and flat adenomas. However, it is unknown if these techniques indeed result in a lower number of interval carcinomas in the long term.

Current colonoscopy capacity in the Netherlands precludes the option of offering colonoscopy to all screening participants. However, it can be debated whether the effort of offering everyone a colonoscopy is worthwhile, as in a substantial part of colonoscopies no relevant lesions are detected and thus will not influence the risk for CRC of those persons. The ultimate goal of screening and colonoscopy is to protect from CRC. It is important to keep in mind that colonoscopy is not a harmless procedure, and complications might occur after colonoscopy and polypectomy. Improved quality and improved techniques will lead to an increase in ADR, but this will mainly reflect increased detection of small adenomas and not many advanced adenomas. As these small adenomas have a low risk to develop into cancer, the additional value of detecting these extra non-advanced adenomas might be questioned. If those small adenomas ultimately develop into cancer, this progression will usually take many years (estimated 10-15 years) with a long period in which the polyps could be detected. Besides, according to current surveillance guidelines, increased adenoma detection rates will result in more patients who are advised to undergo a surveillance colonoscopy. This in turn will increase the demand for colonoscopies, while capacity is already limited by the screening program. Rather than offering repeated surveillance to each patient with non-advanced adeno-
mas, only patients that would benefit most should receive a colonoscopy. If the quality of colonoscopy is sufficient, with optimal detection and resection of all relevant polyps, occurrence of interval carcinomas will hopefully be prevented. We then would also be able to safely expand surveillance intervals. Regrettably, prospective randomized trials on optimal surveillance strategies are lacking and just now being initiated.

A possible solution to colonoscopy capacity problems, are nurse endoscopists. In 1977 nurse endoscopists already performed flexible sigmoidoscopies in the UK, and currently many nurse endoscopists have been trained to perform colonoscopies. Nurse endoscopists can perform colonoscopies as safely and accurately as physicians and substantially reduce costs.\(^{11-14}\) While studies revealed a similar ADRs for nurses and gastroenterologists, some studies even concluded that nurses received better pain and satisfaction scores by patients.\(^{15}\) If screening participants in a primary colonoscopy screening program receive a colonoscopy performed by a nurse, this could be used to preselect patients with advanced neoplasia. Only patients with multiple lesions or lesions larger than 2 cm should be referred for a gastroenterologist-performed colonoscopy for resection of already detected lesions.

One of the most important factors in the quality of colonoscopy, is the endoscopist him/herself. The wide variation in detection rates among different endoscopists suggests a high miss-rate for low detectors. Tandem studies showed that 10% of all advanced adenomas are missed, which in time could lead to interval cancers. Another potential cause of interval carcinomas is incomplete resection of colorectal lesions. A recent study demonstrated that 10% of all neoplastic lesions are not completely resected.\(^2\) As currently little is known about optimal polypectomy techniques, future studies should focus on this aspect of colonoscopy. To prevent a false sense of security, all lesions should be resected completely.

Monitoring, feedback and benchmarking are the basis for continuous quality improvement of endoscopists. Inadequate quality should be detected so specific actions for improvement of underperformers can be taken. It might be possible to improve the quality of underperformers by stricter rules, for example by making it obligatory for those endoscopists to perform at least 1000 colonoscopies per year, or to exclude them from practice. However, it is unlikely that such measures will create only perfect colonoscopists, who detect all colonic lesions. Maybe we should acknowledge that colonoscopy might never be perfect. Are there any other options?

Less invasive imaging such as CT and MR colonography techniques are able to detect polypoid lesions with a similar accuracy as colonoscopy.\(^{16-18}\) These methods could also be helpful in preselecting participants for colonoscopy. An important disadvantage of those radiologic techniques is their inaccuracy for the detection of flat lesions, and especially those flat lesions have a high risk of being an early cancer. The current radiologic imaging techniques are able to estimate the size of lesions, but cannot predict if lesions
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contain high-grade dysplasia or villous features, both also features of advanced neoplasia. Also, radiologic imaging techniques are still quite labour-intensive and expensive. The perfect imaging technique would be patient-friendly and safe, without the need for any bowel preparation and without exposure to ionizing radiation. MR-colonography could be a candidate, preferably faster than current MR-systems. Sensitivity for CRC and advanced adenomas should be approximately 100%, and ideally MR-colonography should also be able to discriminate between advanced and non-advanced adenomas, so that only patients with advanced adenomas are referred for colonoscopy. Maybe it could be possible to use a biomarker that highlights any advanced lesion at MR-colonography, regardless of its size or morphology. Then only those patients could be referred for a therapeutic colonoscopy. And at the time of the advised surveillance interval, instead of a repeat colonoscopy, a new MRI with biomarker could then be performed.

An even more patient-friendly screening method than MRI, would be a fecal test that can be performed at home. In contrast to FIT, this fecal test should be able to detect all advanced neoplasia (optimal sensitivity). It should also have a specificity of 100%, indicating that there are no false positive tests leading to 'unnecessary' colonoscopies in participants that appear to have non-advanced lesions only. Recent studies have evaluated the yield of fecal biomarkers, for example DNA-tests, in detecting CRC and advanced adenomas. A fecal biomarker that would detect all advanced lesions and furthermore could be performed at home, would be a perfect method to select participants that should undergo colonoscopy. If only participants with an advanced lesion are scoped, detection rates will increase to nearly 100% and no more unnecessary diagnostic colonoscopies will be performed. Unfortunately, the perfect fecal biomarker does yet not exist. Nevertheless, the quest for a highly sensitive and specific stool marker for advanced neoplasia is important and could save many persons from undergoing unnecessary colonoscopies. Another exciting development is the e-nose (electronic nose, Cyranose 320), a method in which analysis of gaseous carbon-based chemicals originating from breath and feces are used to detect CRC and advanced adenomas. The scarce data available have shown that this analysis can discriminate between patients with and without CRC and advanced adenomas with promising accuracy. Future research should further explore the possibilities of this novel screening method for early detection of advanced neoplasia.

Most screening methods aim to reduce CRC-related mortality by early detection. Colonoscopy has the potential to prevent the occurrence of CRC by detecting and resecting its precursor lesions. However, an even better approach would be to stop the growth of adenomas or even their occurrence at all. Recent studies have described an association between aspirin/NSAID use and a lower risk of CRC, and also statins have been suggested to protect for CRC. In the last decades, a number of other chemopreventive drugs have been tested, including sulindac, celecoxib, and mesalazine, but are still
controversially discussed. The idea that a drug, that ideally should be cheap and have negligible side-effects, might be able to prevent CRC and maybe even other cancers, is very tempting. Persons with a high risk at CRC, for example patients with Familial Adenomatous Polyposis or Lynch Syndrome, could start at an early age using this medicine. Persons with an average risk for CRC would only have to participate in one screening round at e.g. age 50, with a non-invasive test like MR-colonography, fecal biomarker or e-nose, if necessary followed by a therapeutic colonoscopy. If advanced adenomas are resected they would start taking the medicine and would be relieved from surveillance and screening, and from their risk for CRC. Future research will hopefully provide us with more insight of the possibilities of pharmacologic prevention of CRC.

Regrettably, the scenario that I described above will not yet be feasible in the near future. Until then, colonoscopy will remain the gold standard for the detection of CRC and its precursors. To optimize its quality, continuous monitoring, feedback and benchmarking is essential. A reporting system that facilitates both standardized reporting as well as systematic delivery of quality indicators is the basis for continuous quality monitoring. Such systems should be widespread available and used in all colonoscopy centres in the Netherlands, ideally even in Europe. This will allow for benchmarking on a larger scale and colonoscopy will gradually become a quality-focussed practice.
REFERENCES


