

Quality assessment of colonoscopy in Flanders : a voluntary survey among Flemish gastroenterologist

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Abstract

Colonoscopy is an important endoscopic examination for the diagnosis and treatment of pathological conditions of the colon, like polyps and colorectal cancer. However, several factors determine the quality of colonoscopy and thus the quality of polyp and colorectal cancer detection. The Flemish Society of Gastroenterology (VVGE) performed a voluntary on-line registry among its members to identify quality of colonoscopy in Flanders, Belgium. 64 gastroenterologists voluntarily registered 4276 consecutive colonoscopies performed during a 3 month study period. Colonoscopy quality indicators were prospectively collected and analysed. Results showed a low voluntary participation rate (17%), acceptable overall adenoma detection rate of 20,5% and colorectal cancer interval rate of 5,4%. Complications were low (perforation 0,1% and major bleeding 1,5%). The current study showed that in Flanders, Belgium on-line registration of colonoscopy quality indicators is feasible and that quality of colonoscopy in daily practice meets the expectations of (inter)national guidelines. However, further improvement of the registry and an open debate on the quality control of colonoscopy in Flanders is warranted (Belgian Registry B30020096548). (*Acta gastroenterol. belg.*, 2015, 78, 18-25).

Key words : screening, colorectal carcinoma, quality and colonoscopy.

Introduction

Colorectal cancer (CRC) is a major cause of cancer mortality worldwide. In 2008 CRC was the most frequent malignancy (436000 cases) and the second most frequent cause of cancer death in Europe after lung cancer (1). Nevertheless, CRC incidence and mortality rate decrease by an effective screening program (2,3). Endoscopic removal of adenomatous polyps decreases CRC incidence and mortality rate (4).

However, there is no consensus on the optimal modality of screening and the approach differs in different countries : stool-based tests or endoscopy (sigmoidoscopy or colonoscopy). While colonoscopy is performed after a positive faecal occult blood test (FOBT), some experts and scientific societies advocate colonoscopy also as a first line screening method (5-9). Although there is good evidence for the positive impact of colonoscopy in the prevention of CRC, there are some drawbacks. The major complications of colonoscopy are colonic perforation and major bleeding. However, the reported rate of perforation in diagnostic colonoscopy is low (0.01-0.1%) (10-14). Also, the colonoscopy miss rate for cancers and adenomatous polyps remains a concern, especially when located in the right colon (16-22). It is recognized that

the effectiveness of colonoscopy is dependent on the quality of the procedure (23-24). Therefore, a number of key quality indicators has been recommended.

In 2002, the American Society for Gastrointestinal Endoscopy/American College of Gastroenterology (ASGE/ACG) published quality indicators for colonoscopy, which were further adjusted in 2006. (25-26). The most commonly used indicators are adenoma detection rate (ADR) and caecal intubation rate (CIR). ADR is an independent predictor of the risk of interval colorectal cancer (19). In addition, a reporting system for colonoscopy was developed to assist endoscopists in monitoring quality indicators in their practice (27). European guidelines for quality assurance in CRC screening and diagnosis have also recently been published (28). Based on these international guidelines, national colonoscopy quality guidelines for Belgium were developed and published in 2009 (29).

Since no information exists on the quality of colonoscopy in Belgium, a prospective voluntary registry was set up on behalf of the Flemish Society of Gastroenterology (Vlaamse Vereniging voor Gastro-enterologie VVGE) regarding the quality of colonoscopy in Flanders (the Dutch speaking Northern part of Belgium). Based on national social security data, approximately 100.000 colonoscopies are performed in Flanders each year, and approximately 20% with polypectomy. We analysed the quality indicators for colonoscopy and compared them to the proposed international standards.

Patients/material and methods

Participants and study period

The entire study consisted of 3 chapters. First, colonoscopy quality guidelines were developed and published by a task force in 2009 (29). Following this publication, an awareness campaign was organized by means of local meetings to inform all 368 Flemish gastroenterologists

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Submission date : 07/08/2014

Acceptance date : 08/01/2015

who are member of the VVGE. Invitation to participate was sent by post and email, and information on this project was given on several meetings before and during the project. In the second chapter, the multicentre registry was carried out over a 13-month period, from 1/10/2009 to 31/10/2010. And finally, at the end of the study period, every participating gastroenterologist was informed about personal results in comparison with the entire group.

Informed consent

The Ethical Committee of the Antwerp University Hospital approved the project (EC 9/19/80 and Belgian Registry B30020096548), and every participating gastroenterologist obtained approval from their local ethical committee. Each patient was asked to participate at the time of colonoscopy and gave written informed consent for the study.

Data collection

A central electronic database was set up in collaboration with TNS Global Information and Consultancy Group (Brussels). Data were displayed on a password-protected website. Participating gastroenterologists re-

ceived a link to this website, a log-in and password to register the data online, and were blinded for the data registered by other gastroenterologists. Financial support was provided by the VVGE.

Each participating gastroenterologist was asked to register all colonoscopies (irrespective of the indication) performed during three consecutive months, except when patients did not give their consent. After each colonoscopy, an electronic online form with parameters related to the procedure was completed by the gastroenterologist, including endoscopic findings and possible complications (Table 1). Pathology reports were entered by the gastroenterologist in the electronic database at a later time point whenever available (Table 1). Patient satisfaction score cards were sent back by the patients as a prepaid questionnaire card 7 to 10 days after the colonoscopy to the central address of the VVGE (Table 1).

The on-line data form was validated by a panel of 6 gastroenterologists. It contained colonoscopy quality indicators as suggested by published literature and health authority guidelines (25-26). Complete colonoscopy was defined as ileoscopy (intubation of the terminal ileum) or identification of the ileocaecal valve, appendicular orifice and caecum. Photo documentation with time indication of caecal intubation and retrovision of the rectum was

Table 1. — Recorded quality parameters immediately after colonoscopy

Age and sex patient
Referring doctor
Familial history of CRC
Previous medical history
Previous colonoscopy and time frame
Medication at home – discontinued ?
Indication colonoscopy
Preparation
Premedication
Conscious or deep sedation
Monitoring during colonoscopy
Hospitalization during colonoscopy
Completeness examination
Reason incomplete examination
Difficulty examination
Photo documentation of caecum and rectum
Withdrawal time, inclusive and exclusive biopsies/polypectomy
Results examination : polyps – CRC-inflammatory bowel disease – diverticulosis – others
Number of polyps and location, morphology, diameter and resection of each polyp
Number of CRC and location, diameter, biopsies
Complications during examination
Recommendations for patient
<i>Pathology report</i>
For each polyp : histological type – diameter – completeness excision – resection margins
For each CRC : histological type – resection ? – resection margins if applicable
Recommendations for patient
<i>Questionnaire card for patient (10-point scale)</i>
Are you satisfied with the examination ?
Did you have pain during the examination ?
Did you have pain after the examination ?
Did you have problems after the examination ?
Did you get a clear recommendation ?

collected, in order to confirm complete colonoscopy and to calculate withdrawal time. Incomplete procedures due to poor bowel preparation or stenotic lesions were not excluded from analysis, but reasons for incomplete procedures were recorded.

Statistical analysis

Categorical data were summarized in numbers and percentages, ordinal scale data were presented as median and their lower and upper quartile. Chi square tests were used to compare categorical data between subgroups. For the comparison of withdrawal time, patient satisfaction, pain and age between two subgroups a Mann-Whitney U test was performed. P values of $\leq 0,05$ were considered to be statistically significant.

Results

Participating gastroenterologists

Of the 368 Flemish gastroenterologists invited for the study, 69 voluntarily participated. 5 recorded data of less than 10 colonoscopies. Since the results of these 5 gastroenterologists were not considered reliable, they were excluded from the analysis. Therefore, 64 (17%) gastroenterologists voluntarily participated for the duration of the study and included *all* (irrespective of the indication) colonoscopies they performed during 3 consecutive months (except when patients did not consent to the study).

Colonoscopy procedures

4276 colonoscopies were included in the registry during the study period, and 21 colonoscopies were excluded (performed by gastroenterologists who recorded less than 10 colonoscopies in 3 months). In total 4255 colonoscopies were withheld for statistical analysis. 2419 pathology reports with follow-up advice were recorded. However, 300 pathology reports were recorded without colonoscopy data recordings, and were excluded from the analysis. Therefore, 49,8% of colonoscopies were accompanied by a pathology report. 2915 patients returned the satisfaction questionnaire card by mail. However, of those 1000 satisfaction questionnaire cards were received without colonoscopy data recordings, indicating that at least 1000 patients gave informed consent for the study but the colonoscopy was not recorded in the database by the participating gastroenterologists. Therefore, 45,0% of colonoscopies were accompanied by a returned patient satisfaction questionnaire card.

Patients

Median age of the patients was 58.6 years (Q1-Q3 = 47,5-68,9). There were 2292 (53,9%) female patients (32,8% younger than 50 years) and 1963 (46,1%) male patients (26,5% younger than 50 years). 2587 (60,8%) patients underwent colonoscopy for the first

time. The most common indications for colonoscopy were changes in bowel habits (36,9%) and abdominal pain (28,4%). 138 (3,2%) patients were treated with heparin or coumarin derivatives and 97 (2,3%) patients with antiplatelet agents (ticlopidine, clopidogrel). Anticoagulant medication was stopped before the procedure in 44,0% of the cases. Bowel preparation was performed with macrogol substrate in 87,6% (51,7% with Moviprep®, 35,9% with Kleanprep®). Oral Phosphosoda fleet was used in 6,9%. Most patients (58,9%) took the bowel preparation at home since the majority of procedures (81,7%) was performed on an outpatient base. There was no significant correlation between the site of preparation and the detection of polyps ($p = 0,8413$; $X^2 = 0,35$).

Sedation and monitoring

Conscious sedation with midazolam (Dormicum®) was used in 54,6% of the colonoscopies, and an additional opioid (Dolantine®, Rapifen® or Fentanyl®) was used in 52,3%. Deep sedation with propofol (Diprivan®) without endotracheal tube ventilation was used in 41,9% and 0,9% of the procedures were performed under general anaesthesia with endotracheal tube ventilation. Significantly more polyps were detected when midazolam and opioids were used for sedation ($p = 0,0301$ and $p = 0,0011$). Significantly more polyps were detected in the absence of deep sedation (propofol and general anaesthesia) ($p = 0,0217$).

Quality indicators

Bowel preparation

Bowel preparation for colonoscopy was graded excellent in 52,5%, good in 33,7% and moderate in 11,5%. The detection rate of polyps ($p = 0,3574$; $X^2 = 3,23$) and adenomas ($p = 0,1810$; $X^2 = 4,88$) was not influenced by the bowel preparation. On the contrary, a significant correlation was found between the detection of CRC and the bowel preparation. The colon of patients with CRC was less well prepared ($p = 0,0056$).

Participants were also asked about the difficulty of the examination. Examinations were graded difficult, moderate or easy. Examinations were considered difficult by the performing endoscopist in 328 procedures (7,7%), moderate in 773 procedures (18,2%) and easy in 3154 (74,1%). There was no significant relationship between the difficulty of the examination and the detection of polyps ($p = 0,0515$) or adenomas ($p = 0,1297$). However, in case of CRC the procedure was significantly more difficult ($p = 0,0235$; $X^2 = 7,50$) with a significant relationship between the difficulty of the procedure and the bowel preparation. Excellent or very good preparation renders colonoscopy significantly easier ($p < 0,0001$; $X^2 = 341,1$). Also, a significant relationship between the difficulty of the procedure and gender and age was found. Examinations in women and older patients are significantly more difficult ($p < 0,001$ and $p < 0,0001$ respectively).

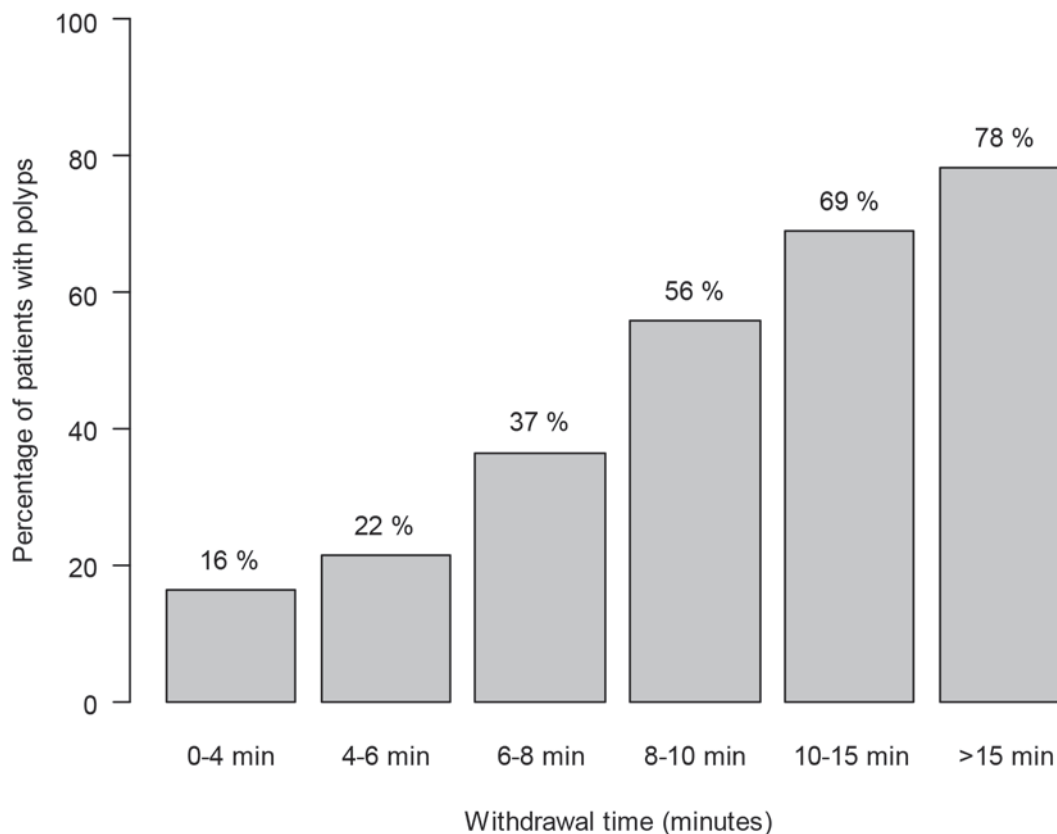


Fig. 1. — Polyp detection and withdrawal time

Caecal intubation

Unadjusted CIR was used. Intubation of the caecum or terminal ileum was achieved in 4135 patients (97,2%). Reasons for failure included long redundant colon in 34 patients (28,3%), fixed sigmoid in 29 patients (24,2%) or poor bowel preparation in 22 patients (18,3%). CIR was significantly higher when bowel preparation was excellent (98,3%), in comparison with poor preparation ($p < 0,0001$). In case of a complete examination, significantly more polyps were detected ($p = 0,012$; $X^2 = 6,26$).

Withdrawal time (Fig. 1-2)

Withdrawal times (excluding time for polypectomy or biopsy) was < 6 minutes in 1128 patients (26,5%), between 6-8 min in 2039 patients (47,9%), and > 8 minutes in 1088 patients 25,6%. Withdrawal times were significantly correlated with polyp detection rate: significantly more polyps were detected with longer withdrawal time ($p < 0,0001$) (Fig. 1). Also, a significant correlation between withdrawal time and the detection of adenomas was found ($p < 0,0001$) (Fig. 2). No significant relationship was found between withdrawal times and the detection of CRC ($p = 0,6695$).

Polyps

In 1655 patients (38,9%) one or more polyps were detected. Of these 1655 individuals, 1391 patients (84,1%) were older than 50 years. Pathology reports of resected

polyps were missing in 301 (18,2%). Overall 3367 polyps were endoscopically detected, of whom 2736 polyps were histologically described. However, of 401 resected polyps no tissue or no polypoid tissue was found on histopathology examination (14,7%). Villous tissue was present in 216 polyps (7,9%), 1256 tubular adenomas were described (45,9%) and 751 polyps were hyperplastic (27,4%). 119 serrated adenomas were resected (4,3%). High grade dysplasia was detected in 70 polyps (2,6%). Of the 3367 endoscopically described polyps 67,4% was < 6 mm whereas size measurement by the pathologist revealed a diameter of < 6 mm in 1669 polyps (72,6%). Polyps were estimated to be completely resected in 89,2% of cases and recuperated for pathology in 76,1% of cases. Completeness of resection was not always mentioned in the pathology report. In addition, the risk for polyp detection was significantly lower in case of diarrhoea, constipation, abdominal pain, anorexia or inflammatory bowel disease. On the contrary, risk for polyps and CRC was higher in case of melena, anaemia and follow-up examinations for polyps or CRC.

Adenoma detection rate

ADR is calculated as the detection of adenomas in index colonoscopies. Of all colonoscopies, 2872 colonoscopies were index colonoscopies (no previous colonoscopy). In 1058 index colonoscopies (36,8%) a total of 2152 polyps were detected. From 870 patients with at

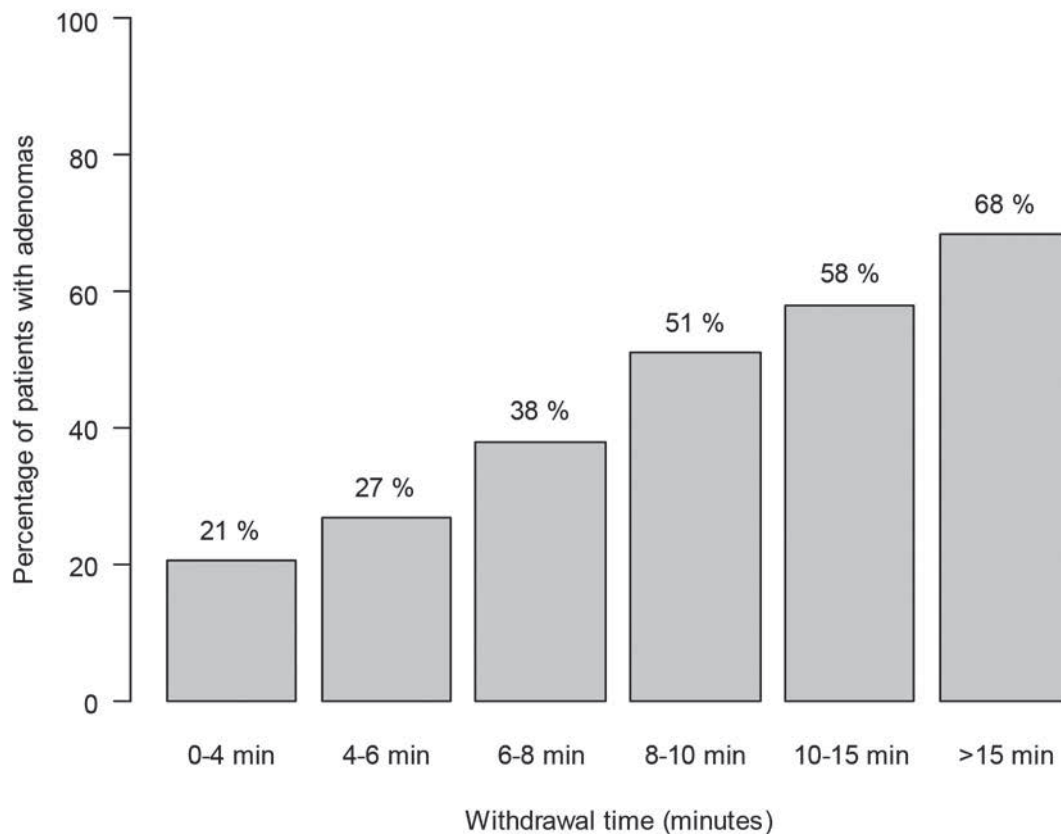


Fig. 2. — Adenoma detection and withdrawal time

least one resected polyp the pathology report was available. In 583 patients at least one (histologically proven) adenoma was detected, resulting in an ADR of 20,3% (583 patients with adenomas in 2872 index colonoscopies). In 287 patients no adenomatous tissue was present in the polyps. ADR in men was 25,7% (329 adenomas in 1279 men) and 15,9% in women (254 in 1593) in index colonoscopies. ADR was 27,1% for patients older than 50 years undergoing an index colonoscopy (507 in 1872).

Colorectal carcinoma

CRC was detected in 129 patients (3,0%). CRC was detected in 78 men (3,9%) and in 51 women (2,2%). Four CRC's were detected in patients of less than 40 years old and 118 in patients over 50 years of age. In 118 patients undergoing index colonoscopy, one or more CRC's were detected (4,1%). Ten patients with CRC diagnosis had undergone a previous colonoscopy, of whom 7 less than 3 years before diagnosis. One patient had a colonoscopy between 3 and 5 years before diagnosis. This results in a 5,4% CRC interval rate (Fig. 3). Five of them were located in the right colon (caecum, ascending and transverse colon).

Most CRCs were located in the rectosigmoid (71 cases, 55,0%). Pathological analysis revealed mostly adenocarcinoma (83,5%), and only sporadically signet-ring carcinoma or a carcinoid carcinoma. In patients with CRC relatives, the risk of polyps was significantly

increased ($p = 0,0482$). More CRCs were detected in case of a first colonoscopy ($p = 0,0001$). With a time interval of more than 10 years between the previous and current colonoscopy, risk of CRC was not significantly increased.

Complications

No complications were encountered in 95,3% of patients. Bleeding occurred in 64 patients (1,5%), which could all be managed conservatively or endoscopically without surgical intervention. Perforation was encountered in 6 cases (0,1%), and endoscopic closure by clipping was possible in 3.

Questionnaire

Overall, 2915 patient satisfaction questionnaire cards were returned by mail, of whom 1915 could be related to a registered colonoscopy procedure. The vast majority of patients (82,5%) was very satisfied with the examination. After colonoscopy 113 patients (5,9%) had abdominal complaints, especially when the examination was difficult. 108 patients (5,6%) reported late problems with the need of seeking medical help. There was no difference between men and women concerning pain during the examination and satisfaction, but female patients had significantly more pain after the examination ($p < 0,0001$). No data are available on the use of air versus CO₂ insufflation during colonoscopy in the present registry.

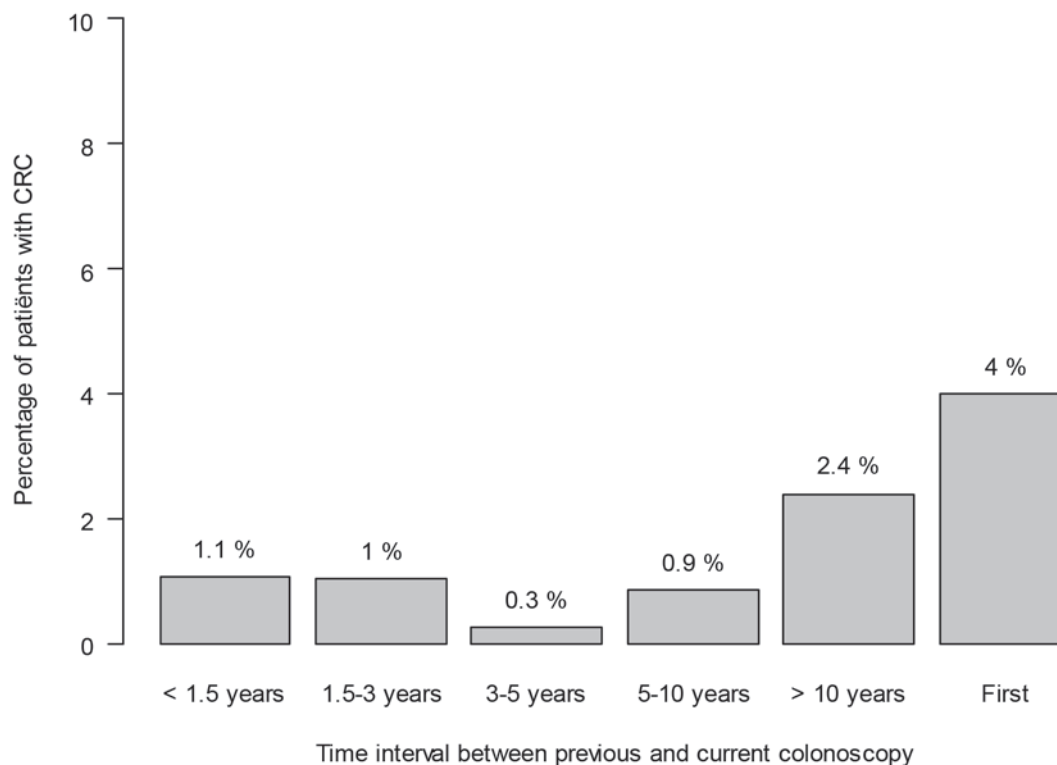


Fig. 3. — Interval colon cancer

Discussion

Colonoscopy is widely used for colorectal cancer screening, but its miss rate for (advanced) adenomas and neoplastic lesions remains a concern (30). Public health authorities demand feasible, simple, cost effective quality and safety guidelines, driven towards effectiveness and improved public health. Until now no colonoscopy quality guidelines were implemented in Belgium and no data are available about performance of colonoscopy in our country. Literature data show differences in quality of colonoscopy, depending on practice variables and physician variables, with notable differences reported between practice types (i.e., private office, academic, community hospitals), physician specialties, and colonoscopy volumes (30,31). We report a multicentre, prospective study for the evaluation of the quality of colonoscopy in Flanders, Belgium. The study consisted of three chapters, starting with the development of national quality guidelines followed by an awareness campaign. Next gastroenterologists were invited to participate in a voluntary colonoscopy quality registry during 3 consecutive months. Finally, feedback was provided and all participating gastroenterologists were informed about their personal quality results in relation to the overall results. Internationally recommended criteria for colonoscopy procedures were analysed, including ADR, CIR, rate of interval CRC, bowel preparation quality, complication rate and patients' satisfaction.

In total 4255 colonoscopies performed for various indications by 64 certified gastroenterologists were pro-

spectively collected and analysed. Despite the efforts made to motivate gastroenterologists during the information and awareness campaign, only 69 of 368 gastroenterologist voluntarily took part in the study. Five of them were excluded because of early dropout of the study. During the last phase of feedback, reasons not to participate were openly discussed. The extra workload without financial compensation and the fear of 'Big Brother' interference in personal professional affairs were the 2 most important comments. Therefore, only a selected group of motivated gastroenterologists participated in this study, leading to a possible bias in the results. The low participation rate (17%) warrants for future initiatives to collect nationwide quality data in endoscopy.

All consecutive colonoscopies (not only screening colonoscopies) had to be reported. In index colonoscopies the ADR was 25,7% in men and 15,9% in women. ADR was 27,1% in patients older than 50 years undergoing a first colonoscopy, which is an acceptable result. In the national colonoscopy audit in the UK polyp detection rate was 32,1%, not to be mistaken with the ADR (32). In US screening studies ADR was set at a minimum of 25% for men and 15% for women (19). In the UK NHS Quality Assurance guidelines the standard ADR was even set at 35% (33). The fact that in the present study not all pathology reports could be collected probably results from the delay between polypectomy and final histopathological diagnosis. Therefore, participating gastroenterologists had to log in a second time to the online database to add the histopathological findings. Apparently, this effort was not made systematically.

The quality of the bowel preparation can impact ADR (15). In the present study, we found no significant influence of bowel preparation on the detection of polyps. In case of CRC, bowel preparation was significantly worse, probably due to the tumorous substenosis. Unadjusted CIR (97.2%) is comparable to 93–99% reported in the literature. And complete colonoscopy was achieved more often when bowel preparation was excellent in comparison with poor preparation.

Withdrawal time is an important quality parameter. In the present study, significantly more polyps and adenomas were detected in relation to a longer withdrawal time. However, in 26,5% of the colonoscopies, withdrawal time was less than 6 minutes, which should be avoided according to literature data (24). No relationship was found between withdrawal time and CRC detection. One of the most important colonoscopy quality indicators is the rate of interval cancers. However, this indicator is difficult to determine. In 129 patients CRC was detected. Seven patients had undergone colonoscopy less than 3 years before the diagnosis of CRC. Therefore the interval cancer rate in our patient cohort is 5,4%. Recent meta-analysis of 12 studies revealed a mean interval CRC rate of 3,7% (95% CI 2,8-4,9%) (34).

Safety indicators included perforation and major bleeding rates. There were no colonoscopy-related fatalities reported in the present study. The rate of perforation (0,1%) and postpolypectomy bleeding (1,5%) is comparable to the literature data (10-14).

Although participants were asked to report all consecutive colonoscopies performed during a 3 month period, bias is possible because of the self-registration without external control. This is illustrated by the 1000 completed patient questionnaires which were sent back without any related colonoscopy report recorded. Although we have not tried to collect these missing colonoscopy reports, one might speculate that participants may not have registered difficult, incomplete or complicated colonoscopies. So it is possible that only the easy and total colonoscopies were reported or that complications were overlooked.

The present study also highlights the difficulties encountered when setting up a nationwide quality control programme. Voluntary self-registration has several disadvantages (extra workload) and is prone to serious bias (missing data). Even with a structured report generator, several key quality fields were often incomplete, including bowel preparation, caecal intubation and pathology reports. Together with the low participation rate (17%), these findings should be taken into account for future colonoscopy quality initiatives.

Conclusion

The present study provides a snapshot of quality of colonoscopy reporting in Flanders. It demonstrates that quality indicators of colonoscopy can be measured in the flow of clinical practice on a web-based on-line register

and that current colonoscopy quality in Flanders meets with national and international standards. Routine measurement of quality indicators could lead to a process of quality improvement in the practice of colonoscopy. However, the present study also demonstrated that voluntary participation rate is low, due to several reasons. Extra workload may have to be financially compensated. The importance of quality control of colonoscopy is reflected by the interval cancer rate of 5,4%, cancers that could have been avoided. It is our hope that validated quality indicators for colonoscopy and continuous awareness for quality assessment will find its way into the daily endoscopic practice in Flanders. The most important quality indicators like ADR, withdrawal time, photo documentation and registration of complications, should become standard practice. However, a good operational and easy on-line registration system is necessary with individual feedback and multicentric evaluation of complications and detection of colorectal cancer.

Acknowledgement

We wish to thank the following gastroenterologists who participated in this study :

Baert F., Berghmans B., Botelberge T., Bulté K., Caenepeel Ph., Callens J., Claessens Ch., Decaestecker J., Delen S., Delooze D., De Schepper B., De Vos M., De Wulf D., Dewyspelaere J., D'Haens G., Dutre J., Feys C., Gevers A., Ghillebert G., Goetstouwers P., Harlet R., Humblet E., Janssens J., Kums R., Macken E., Moreels T., Nijs J., Peeters H., Pen J., Poelmans L., Potvin Ph., Reynaert H., Rondou T., Schoenaers P., Sierens B., Simoens M., Sprengers D., Staessens D., Stoens N., Struyf N., Thorrez K., T'Syen M., Valgaeren K., Van Aken E., Van Besien B., Vandecandelaere P., Van de Mierop F., Vanden Bogaert E., Vandensteen G., Vandewoude M., Van Gool S., Van Lierde S., Van Outryve M., Van Outryve S., Van Overbeke L., Van Overberghe B., Van Roey G., Van Vaerenbergh W., Verbist L., Verdonck V., Vermeersch B., Wauters J., Weyn F.

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