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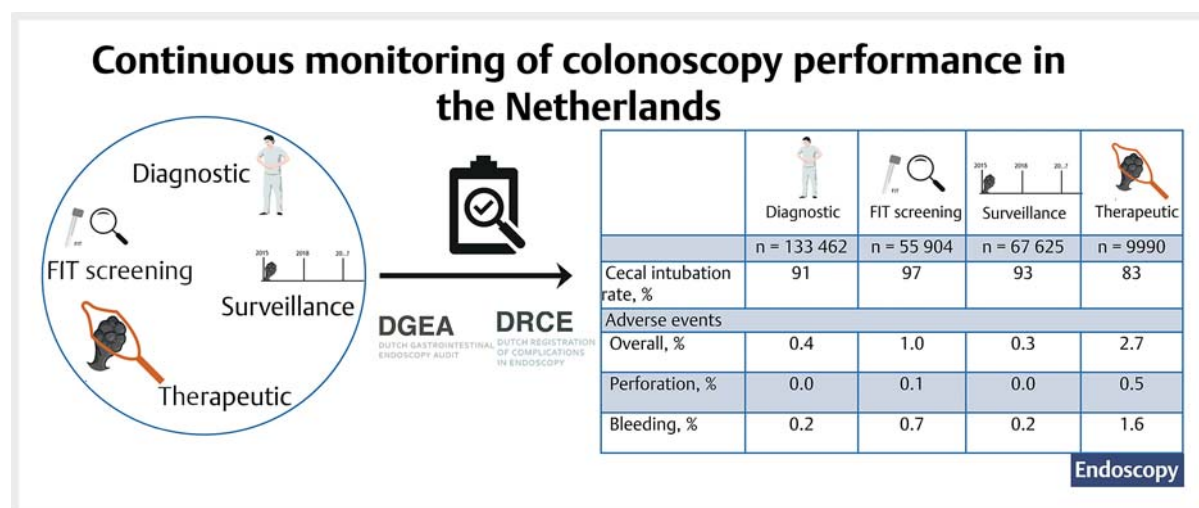
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Continuous monitoring of colonoscopy performance in the Netherlands: first results of a nationwide registry

GRAPHICAL ABSTRACT



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Tables 1 s–4 s

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ABSTRACT

Background To optimize colonoscopy quality, several performance measures have been developed. These are usually assessed without distinction between the indications for colonoscopy. This study aimed to assess the feasibility of linking two national registries (one for colonoscopy and one for adverse events of gastrointestinal endoscopies in the Netherlands), and to describe the results of colonoscopy quality per indication.

Methods This retrospective study was conducted with prospectively collected data of the Dutch Gastrointestinal Endoscopy Audit (DGEA) and the Dutch Registration of Complications in Endoscopy (DRCE). Data between 01–01–2016 and 01–01–2019 were analyzed. To calculate adverse event rates, data were linked at the level of endoscopy service.

Results During the 3-year study period, 266 981 colonoscopies were recorded in DGEA. Of all indications, cecal intubation rate was highest in fecal immunochemical test (FIT)-positive screening colonoscopies (97.1 %), followed by surveillance (93.2 %), diagnostic (90.7 %), and therapeutic colonoscopies (83.1 %). The highest rate of adequate bowel preparation was observed in FIT-positive screening colonoscopies (97.1 %). A total of 1540 colonoscopy-related adverse events occurred (0.58 % of all colonoscopies). Bleeding and perforation rates were highest for therapeutic (1.56 % and 0.51 %, respectively) and FIT-positive screening (0.72 % and 0.06 %, respectively) colonoscopies. The colonoscopy-related mortality was 0.006 %.

Conclusion This study describes the first results of the Dutch national colonoscopy registry, which was successfully linked to data from the national registry for adverse events of gastrointestinal endoscopies. In this large dataset, performance varied between indications. Our results emphasize the importance of defining benchmarks per indication in future guidelines.

Introduction

Colonoscopy is the reference standard for the detection of colorectal diseases. Detection and removal of adenomas during colonoscopy reduces the risk of colorectal cancer (CRC)-related mortality [1–3]. To optimize the quality of colonoscopy, several performance measures have been developed [4]. Of these, cecal intubation rate (CIR), the percentage of colonoscopies with adequate bowel preparation, and adenoma detection rate are clearly defined, the best validated, and the most frequently reported [4]. Unsuccessful cecal intubation results in increased healthcare costs and inconvenience as the procedure must be rescheduled or an alternative investigation organized [4]. Similarly, the quality of bowel preparation not only influences the accuracy of a colonoscopy, but inadequate bowel preparation is also associated with unsatisfactory patient experience and results in increased healthcare costs [5]. In addition to these parameters, the adverse event rate is regarded as an important performance measure for the minimization of colonoscopy-related risk for patients. All performance measures are usually monitored in a heterogeneous population, without distinction between different indications for colonoscopy, or in a specific subgroup such as a screening population.

To facilitate up-to-date feedback on endoscopy performance, continuous monitoring of performance measures is preferred. In the Netherlands, this is accomplished by two registries: the Dutch Gastrointestinal Endoscopy Audit (DGEA) and the Dutch Registration of Complications in Endoscopy (DRCE). The DGEA focuses on the quality of colonoscopy. Data of all colonoscopies in participating endoscopy services are automatic-

ally extracted from standardized endoscopy reports without additional administrative burden [6]. The DRCE is a national web-based adverse event registry for all gastrointestinal endoscopies.

This study aimed to assess the feasibility of linking the DGEA and the DRCE. Furthermore, we aimed to describe the quality of colonoscopy within this large Dutch colonoscopy cohort per indication by assessing rates of cecal intubation, adequate bowel preparation, and adverse events.

Methods

Organization

The DGEA and DRCE are facilitated by the Dutch Institute for Clinical Auditing, which was founded in 2011 to facilitate and organize nationwide audits in a uniform format [7,8]. The DGEA and DRCE were developed in 2016 and the steering committee of the registries is mandated by the Dutch Society of Gastroenterologists. Details about the DGEA have been described previously [6]. In short, patient and endoscopy characteristics of all colonoscopies performed in participating endoscopy services are automatically extracted from the endoscopy reporting system and recorded in the DGEA dataset. A national structured and standardized colonoscopy reporting system was developed to record this data uniformly [6]. Therefore, there is no additional registration burden for endoscopists.

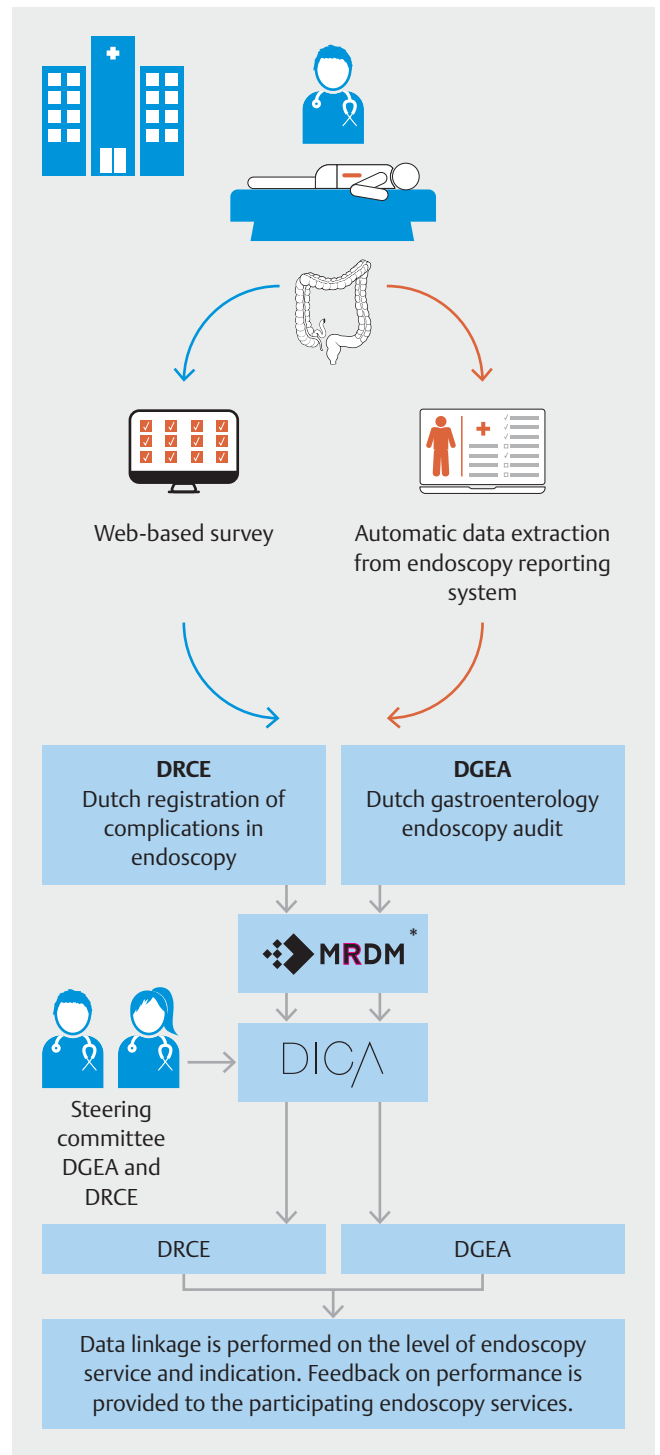
The DRCE is a national web-based registry of all adverse events occurring in gastrointestinal endoscopy. Registration of adverse events in the DRCE is mandatory for all endoscopy services participating in the Dutch CRC screening program. The

content of the registry is mainly based on recommendations from the American Society for Gastrointestinal Endoscopy (ASGE) 2008 workshop on endoscopic adverse events [9]. All adverse events occurring within 30 days after endoscopy are manually recorded by endoscopists in the DRCE. For colonoscopies, the following types of adverse events are registered: cardiovascular, pulmonary, thromboembolic, perforation, bleeding, infectious, allergy/intolerance, pain, and an option for recording adverse events other than aforementioned. The severity grading system for adverse events as proposed by the ASGE is used [9]. The likelihood of the adverse event being related to the endoscopy is recorded as “related,” “likely related,” “possibly related,” or “unlikely related” to the procedure. Thus, the all-cause adverse event rate can be monitored. In addition to adverse events, a limited set of patient and endoscopy characteristics is recorded in the DRCE, such as indication for colonoscopy. The indications for colonoscopy in the DRCE are similar to the indications used in the DGEA. High-quality data entry is ensured by providing clearly defined options for data entry. Validation rules and conditions are added for data entry points.

Data from both registries are sent via a secured web service function to a certified trusted third party: Medical Research Data Management (MRDM) (► Fig. 1). MRDM is responsible for data collection, encryption, storage, and processing, and is therefore compatible with the specific registry [7]. MRDM facilitates data linkage by providing a uniform endoscopy service key for both registries. Participating endoscopy services retain ownership of their data. Anonymized data are provided for quality assurance and research purposes. Furthermore, all data are subjected to several validation processes, during recording of data in the web-based registration system for the DRCE and in the endoscopy reporting system for the DGEA, and feedback on missing data is provided in regular reports to participating endoscopy services for both registries. Systems to record, monitor, and evaluate the data are provided by the DGEA and DRCE. These systems are accessible for all participating endoscopy services. Coverage of the DGEA and DRCE is estimated at 80.5 % and 96.1 %, respectively, of all endoscopy services in the Netherlands.

Study design and study population

This retrospective study was conducted with prospectively collected colonoscopy and adverse event data of the DGEA and DRCE. Colonoscopy and adverse event data from endoscopy services participating simultaneously in both registries (DGEA and DRCE) between 01-01-2016 and 01-01-2019 were analyzed. Data from an individual endoscopy service were included in the study from the moment the service participated in both registries. Records were excluded from both datasets when data were missing for variables essential for data linkage, namely endoscopy service identification and endoscopy date. Follow-up screening colonoscopies within 8 weeks after the index colonoscopy and records with missing data about the indication for colonoscopy were also excluded. Furthermore, records were excluded from the DRCE dataset when the adverse event date was missing or when the interval between endoscopy and adverse event was more than 30 days.



► **Fig. 1** Organization of the Dutch Gastrointestinal Endoscopy Audit (DGEA) and Dutch Registration of Complications in Endoscopy (DRCE). *MRDM is a certified third trusted party, responsible for data collection, encryption, storage, and processing. DICA, Dutch Institute for Clinical Auditing; MRDM, Medical Research Data Management.

Data linkage

Every record in the DRCE contains data about a single adverse event, including indication for colonoscopy. In order to calculate adverse event percentages per endoscopy service, data about the total number of performed colonoscopies per endoscopy service were required. Therefore, data of the DGEA and DRCE were linked at the endoscopy service level to indication for colonoscopy. We used the data of the DGEA as denominator for the DRCE records, as the number of performed colonoscopies per endoscopy service was used to calculate the adverse event rates per endoscopy service. Furthermore, as both registries contain similar indications for colonoscopy, data per indication from the DGEA were also used as denominator to calculate adverse event rates per indication.

Definition of variables

CIR was defined as the proportion of colonoscopies in which the cecum was reached and visualized. Colonoscopies with missing data on cecal intubation were excluded from the denominator for calculation of the CIR. The unadjusted CIR was used in this study; no adjustments were made for inadequate bowel preparation or impassable strictures. Adequate bowel preparation was defined as a Boston Bowel Preparation Scale score of at least 2 per segment [10, 11]. Colonoscopies with missing data on the quality of bowel preparation or when quality of bowel preparation could not be assessed, were excluded from the denominator for calculation of the adequate bowel preparation rate. The indications for colonoscopy were categorized into four groups: diagnostic, fecal immunochemical test (FIT)-positive screening, surveillance, and therapeutic colonoscopies. Diagnostic colonoscopies included the following indications: changed bowel habits, rectal blood loss, iron deficiency, abdominal complaints, (suspected) inflammatory bowel disease (IBD), and incidental abnormality found at imaging or perianal examination. FIT-positive colonoscopies are the diagnostic procedures in participants with a positive FIT in the Dutch national CRC screening program. Surveillance colonoscopies include the following indications: surveillance after removal of an adenoma or CRC, surveillance for IBD, increased familial risk of CRC caused by polyposis, CRC, Lynch syndrome, and increased familial risk not further specified. Therapeutic colonoscopies are colonoscopies planned for removal of a known colorectal lesion (i. e. piecemeal endoscopic mucosal resection, endoscopic submucosal dissection, or endoscopic full-thickness resection) or dilation of a known colonic stricture. For categorization, the indication recorded in the endoscopy report was used.

For colonoscopies within the Dutch CRC screening program, the number of polyps detected per colonoscopy was added to the DGEA. Furthermore, the Dutch CRC screening program requires the recording in the DRCE of whether a polypectomy was performed during a screening colonoscopy in which an adverse event occurred. Therefore, the adverse event after polypectomy was calculated for FIT-positive screening colonoscopies by dividing the number of adverse events after polypectomy from the DRCE by the number of colonoscopies in which at least one polyp was detected from the DGEA.

Statistical analyses

Non-normally distributed continuous variables were presented as median and interquartile range (IQR). Categorical variables were expressed as numbers and percentages. Categorical variables were compared using the chi-squared test, and the Mann–Whitney *U* test was used for the comparison of non-normally distributed continuous variables. All statistical tests were two-sided at an α level of 0.05. All statistical analyses were performed by using R statistical software, version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria. www.R-project.org/).

Results

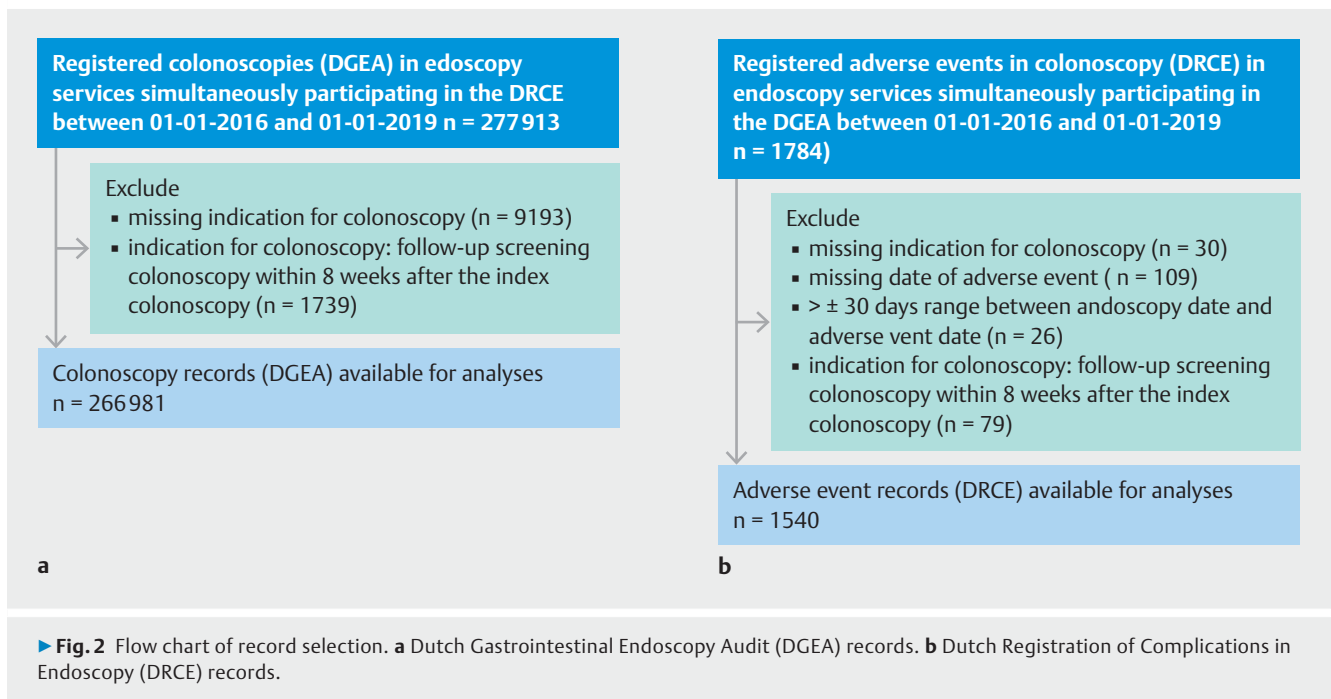
During the 3-year study period, 52 endoscopy services were simultaneously participating in both registries. A total of 277 913 colonoscopies were recorded in the DGEA and 1784 adverse events of colonoscopy were recorded in the DRCE. After exclusion, data of 266 981 colonoscopies and 1540 adverse events were available for analysis (► **Fig. 2**). The median age of patients undergoing colonoscopy was 64 years (IQR 55–71 years) and 50.3% of patients were male. American Society of Anesthesiologists (ASA) score of III or more was observed in 6.2% of the patients. Most colonoscopies were performed in a nonacademic hospital (82.5%), 7.0% in an academic hospital, and 10.5% in a private endoscopy service. ► **Table 1** summarizes patient and endoscopy service characteristics per indication. Patient and endoscopy service characteristics and outcomes for the diagnostic category with and without the IBD subcategory are shown in **Table 1s**, **Table 2s**, and **Table 3s** in the online-only Supplementary material.

Adequate bowel preparation and cecal intubation

The CIR in the total study population was 92.4%. The highest CIR was observed in FIT-positive screening colonoscopies (97.1%), followed by surveillance (93.2%), diagnostic (90.7%), and therapeutic (83.1%) colonoscopies ($P < 0.001$). Data on cecal intubation were missing in 0.8% of all colonoscopies in the total study population. Overall, the rate of adequate bowel preparation was 95.1%. The highest rate of adequate bowel preparation was observed in FIT-positive screening colonoscopies (97.1%), followed by surveillance (95.6%), diagnostic (94.2%), and therapeutic (90.8%) colonoscopies ($P < 0.001$). The quality of the bowel preparation was missing in 1.0% of all colonoscopies. The quality of bowel preparation was not assessable in 4.2% of all colonoscopies and in 19.7% of the therapeutic colonoscopies specifically.

Adverse event rates

Data from the DGEA and DRCE were successfully linked at the endoscopy service level. Overall, 1540 colonoscopy-related adverse events were recorded (0.58% of all colonoscopies). In the total study population of 266 981 colonoscopies, 939 (0.35%)



colonoscopy-related bleedings, and 173 (0.06%) perforations occurred. Colonoscopy-related bleeding and perforation rates were highest for therapeutic (1.56% and 0.51%, respectively) and FIT-positive screening (0.72% and 0.06%, respectively) colonoscopies (► **Table 2**). For FIT-positive screening colonoscopies, adverse event rates for colonoscopies with polypectomy were calculated. The overall adverse event rate, the colonoscopy-related bleeding rate, and the perforation rate after polypectomy in FIT-positive screening colonoscopies were 1.17%, 0.93%, and 0.06%, respectively.

When regarding the severity of adverse events, 811 mild adverse events (0.30%), 546 moderate adverse events (0.20%), 137 severe adverse events (0.05%), and 28 fatal adverse events (0.01%) were recorded. Grading of severity was missing in 18 events. Regarding the probability of an adverse event being related to the procedure, 82% of all recorded adverse events were related or likely related to the colonoscopy. Of the 28 fatal adverse events, 4 were related to colonoscopy, 9 likely related to colonoscopy, 4 possibly related to colonoscopy, 10 unlikely related to colonoscopy, and in 1 fatal adverse event the likelihood was missing, giving a colonoscopy-specific mortality of 0.006% (1/266 981). The types of fatal adverse events according to the likelihood of the adverse event being related to the colonoscopy are shown in **Table 4s**.

Discussion

This study describes the first results of a large cohort of patients in the Dutch national colonoscopy registry, generated without any additional effort from endoscopists and which was successfully linked to the national registry for adverse events of gastrointestinal endoscopies. The overall quality of colonoscopy was high with low rates of adverse events. Performance

measures varied between indication categories for the colonoscopy procedure.

A strength of our study is that we studied a large, nationwide cohort of colonoscopies, with linkage to adverse event data, facilitating evaluation of the quality of colonoscopy per indication and enabling the calculation of adverse event rates using real-world data. The nationwide coverage of both the DGEA and DRCE reflects the overall quality of colonoscopy in the Netherlands. Furthermore, our results may contribute to the definition of new benchmarks for well-known performance measures per indication. These benchmarks may help in defining minimum and target standards for colonoscopy performance measures per indication in future guidelines. In current guidelines, minimum and target standards are defined for a heterogeneous population. The definition of minimum and target standards for performance measures per indication may improve the quality of colonoscopy, as audit and feedback has proven to be most effective when specific targets are formulated [12].

The overall CIR in this study reached the minimum standard of ≥90%, proposed by the European Society of Gastrointestinal Endoscopy (ESGE) [4]. Therapeutic colonoscopies had a lower CIR than the other indications. This was expected, however, as reaching the cecum in these endoscopies is not always intended unless the lesion is located in the right colon. Nevertheless, the specific lesion should be reached during therapeutic colonoscopy, and performance on this definition of completeness should be monitored. A complete colonoscopy should be performed prior to the therapeutic colonoscopy; if not, the cecum should be reached during therapeutic colonoscopy instead. Therefore, the intention of the level of completeness (i.e. cecum or specific lesion) should ideally be reported at the start of the endoscopy.

► **Table 1** Patient and endoscopy service characteristics per indication from 1/1/2016–1/1/2019.

	Diagnostic (n = 133 462)	FIT-positive (n = 55 904)	Surveillance (n = 67 625)	Therapeutic (n = 9990)	P value
Age, median (IQR), years	61 (49–72)	65 (61–71)	66 (56–72)	67 (58–73)	<0.001
Sex, n (%)					<0.001
▪ Male	59 991 (44.9)	32 930 (58.9)	36 126 (53.4)	5353 (53.6)	
▪ Female	73 470 (55.0)	22 974 (41.1)	31 499 (46.6)	4637 (46.4)	
▪ Missing	1 (<0.1)	0 (0.0)	0 (0.0)	0 (0.0)	
ASA score, n (%)					<0.001
▪ I	49 378 (37.0)	17 641 (31.6)	22 972 (34.0)	1246 (12.5)	
▪ II	68 885 (51.6)	35 215 (63.0)	40 199 (59.4)	3381 (33.8)	
▪ ≥III	9810 (7.4)	3011 (5.4)	2845 (4.2)	770 (7.7)	
▪ Missing	5389 (4.0)	37 (0.1)	1609 (2.4)	4593 (46.0)	
Hospital type, n (%)					<0.001
▪ Academic hospital	8621 (6.5)	3321 (5.9)	6044 (8.9)	578 (5.8)	
▪ Nonacademic hospital	111 640 (83.6)	41 446 (74.1)	57 899 (85.6)	9349 (93.6)	
▪ Private endoscopy service	13 201 (9.9)	11 137 (19.9)	3682 (5.4)	63 (0.6)	

FIT, fecal immunochemical test; IQR, interquartile range; ASA, American Society of Anesthesiologists.

► **Table 2** Overall adverse event rates, colonoscopy-related bleeding rates, and perforation rates per indication.

	Diagnostic (n = 133 462)	FIT-positive (n = 55 904)	Surveillance (n = 67 625)	Therapeutic (n = 9990)	P value
Adverse events, n (%)	515 (0.39)	532 (0.95)	220 (0.33)	273 (2.73)	<0.001
▪ Colonoscopy-related bleeding	257 (0.19)	401 (0.72)	125 (0.18)	156 (1.56)	<0.001
▪ Perforation	60 (0.04)	32 (0.06)	30 (0.04)	51 (0.51)	<0.001

FIT, fecal immunochemical test.

The overall rate of colonoscopies with adequate bowel preparation also reached the minimum standard of $\geq 90\%$ proposed by the ESGE [4]. In this study, the rates of adequate bowel preparation per indication were higher than described in a previous publication [13]. Further studies are needed to assess the association between the quality of bowel preparation and patient and endoscopy characteristics, such as indication. The quality of bowel preparation was not assessable in 19.7% of the therapeutic colonoscopies. This relatively high number can be explained by not reaching all three segments of the colon, precluding assessment of the quality of bowel preparation in all colon segments, as the Boston Bowel Preparation Scale is scored per segment [11].

In this large, Dutch, colonoscopy cohort, all-cause adverse events occurred in 0.58% of the colonoscopies, regardless of colonoscopy indication. This rate is higher than that reported in most studies (range 0.20%–0.31%) [14–17]. These higher numbers may, at least partially, be explained by the fact that all types of adverse events are recorded in our database, rather

than solely colonoscopy-specific adverse events. In addition, adverse event rates are difficult to compare directly because of the lack of a universal, uniform definition for reporting adverse events. Furthermore, the all-cause adverse event rate will probably overestimate the actual adverse event rate because all adverse events occurring within 30 days after the procedure are recorded, including events not necessarily related to the colonoscopy. For example, cardiac arrhythmia occurring 25 days after a colonoscopy will be recorded as an adverse event of the colonoscopy. The probability of the adverse event being related to the colonoscopy is recorded in DRCE after discussion during regular morbidity and mortality meetings at each center. In this large, Dutch, colonoscopy cohort, 82% of the recorded adverse events were related or likely related to the colonoscopy. Furthermore, minimum or target standards for adverse events are not set, mainly due to the different definitions of adverse events [4]. Evaluating the all-cause adverse event rate is less vulnerable to subjective interpretation than the colonoscopy-specific adverse event rate, where colonoscopy-specific ad-

verse events are directly attributable to an endoscopic procedure.

As expected, the adverse event rate in therapeutic colonoscopies was higher than in the other groups. The same was true for the adverse event rate in FIT-positive participants in the Dutch CRC screening program. These patients, preselected by FIT, have higher percentages of adenomas and CRC requiring interventions than patients with diagnostic and surveillance colonoscopies [18, 19], and indeed, interventions are associated with a higher risk of adverse events [20].

The colonoscopy-related bleeding rate varied between indications in our cohort, from 0.18% in surveillance colonoscopies to 1.56% in therapeutic colonoscopies. In the literature, bleeding rates of up to 8.4% have been reported after therapeutic colonoscopies [20]. In our study, the colonoscopy-related bleeding rate in FIT-positive screening colonoscopies was 0.72%, which is higher than the overall bleeding rate of 0.65% within the English Bowel Cancer Screening Programme (BCSP), based on the guaiac fecal occult blood test [21]. However, the polypectomy-related bleeding rate was 0.93% in our FIT-positive screening population, lower than the polypectomy-related bleeding rate of 1.14% reported in the English BCSP [21]. The perforation rate in our study was in line with current literature and varied between indications, from 0.04% in diagnostic and surveillance colonoscopies to 0.51% in therapeutic colonoscopies [20]. In our study, the perforation rate in FIT-positive screening colonoscopies was 0.06%, a rate equal to the reported overall perforation rate in the English BCSP [21].

Colonoscopy-related mortality was 0.006%. Mortality after colonoscopy has been only rarely reported in the literature and is expected to be underreported in adverse event registries [22]. A recent ASGE review reported a range of colonoscopy-related death rates from 0.002% to 0.011% [20].

To fully appreciate our findings, some limitations need to be addressed. First, our analyses were not based on data primarily collected for scientific purposes. Therefore, data quality and completeness cannot be assured at the same level as in clinical studies. In contrast to the automated data extraction in the DGEA, the DRCE, a web-based registry of adverse events, requires manual input of adverse event data. However, linkage with the DGEA enables feedback on adverse event rates, which requires only the manual input of the adverse events, as the denominator data from the DGEA is obtained without any additional effort. Furthermore, the DRCE is designed to minimize administrative burden for gastroenterologists, and registration of all adverse events is given much attention in our national society. Nevertheless, there remains a possibility that adverse events are underreported in the DRCE. To increase the attractiveness of entering data, the DRCE is designed to generate a real-time overview of all registered adverse events for each endoscopy service, facilitating discussion in regular departmental meetings on endoscopy-related morbidity and mortality [4]. Second, the European Union General Data Protection Regulation prohibits data linkage between different registries to the patient level in the Netherlands. Therefore, we could not examine potential confounding factors in this study, and data linkage between DGEA and DRCE is currently limited to

the level of endoscopy service. Third, colonoscopies for the indication IBD are included in the category of diagnostic colonoscopies. The indication IBD includes colonoscopies for both suspected IBD as well as for the assessment of disease activity in known IBD. However, sensitivity analyses for the main outcomes did not differ between the indication of diagnostic colonoscopies with or without IBD (**Table 1 s**, **Table 2 s**, **Table 3 s**).

Future efforts should focus on reaching national coverage for the DGEA. In this study, data were used from 52 endoscopy services that were simultaneously participating in both registries. However, we did not capture all colonoscopies performed in these endoscopy services, as not all endoscopy services were participating from the start of both registries. In total, 77 academic hospitals, nonacademic hospitals, and private practices perform colonoscopies in the Netherlands. Automated cross-linking with the national pathology database was not yet available for all participating endoscopy services in the DGEA. In the future, we aim to give feedback on the adenoma detection rate in the DGEA as well. Furthermore, in addition to the successful linkage of the DGEA and DRCE for colonoscopies, the steering committee of both registries aims to facilitate feedback on performance measures, including adverse event rates, for all endoscopic procedures in the Netherlands. Therefore, we aim to expand the DGEA to include all endoscopic procedures (i.e. gastroscopy and endoscopic retrograde cholangiopancreatography) in the coming years. As registration burden may still temper registration of adverse events in the DRCE, the steering committee of the DRCE aims to integrate the DRCE into hospital and/or endoscopy reporting systems in the near future.

In conclusion, this study describes the successful linkage between the Dutch national colonoscopy registry and the national adverse event registry of endoscopies, representing daily colonoscopy practice in the Netherlands. Results of well-known performance measures varied between indications. Therefore, benchmarks for these performance measures should be defined per indication; our results may contribute to the definition of these benchmarks. Furthermore, the definition of minimum and target standards for performance measures per indication in future guidelines may improve the quality of colonoscopy.

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Competing interests

Evelien Dekker has received endoscopic equipment on loan, a research grant, and consultancy honorarium from FujiFilm. She has also received consultancy honoraria from Olympus, Tillots, GI Supply, and CPP-FAP, and speaker's fees from Olympus, Roche, GI Supply, and Norgine. Paul Fockens has received consultancy honoraria from Olympus and Cook Endoscopy, and research support from Boston Scientific. The remaining authors declare that they have no conflict of interest.

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