Data quality of the German Screening Colonoscopy Registry

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Background and study aims: The German screening colonoscopy program is accompanied by a central registry that records the main outcome quality indicators, namely colonoscopy completion rate, adenoma detection rate (ADR), and complication rate. The aim of the present study was to assess the quality of these registry data by comparing them with data from a prospective quality assurance study based on a self-reporting audit and patient feedback of screening colonoscopy.

Patients and methods: The completeness of registry information was analyzed by comparing it with prospective data gathered by audit and patient feedback in a previous quality assurance study (ClinicalTrials.gov registration number: NCT00860665) between October 2006 and March 2008. The main outcome parameters were colonoscopy completion rate, ADR, and complication rate. Complications were recorded in three steps in the audit study using case report forms (immediate and subsequent documentation by physicians [CRF-1 and CRF-2], and patient follow-up [CRF-3]), but were documented in the registry without differentiation.

Results: A total of 12 134 individuals (mean age 64.5 years; 47 % men) who underwent screening colonoscopy at 19 private practices in Berlin over the 18-month period were included in the audit study. Patient feedback was obtained for 90.1 %. A total of 12 150 cases had been recorded in the registry by the same private practices during the same period. Colonoscopy completion rate and ADR data were comparable in the audit study and registry (completion rate 98.2 % vs. 97.7 %; ADR 21.0 % vs. 20.5 %). However, compared with the registry data, the complication rate was 3.1-fold higher in the audit (0.46 % vs. 0.15 %; $P<0.001$), and double (0.33 % vs. 0.15 %; $P<0.05$) when patient feedback was not included.

Conclusions: Of the screening colonoscopy quality parameters, colonoscopy completion rate and ADR, but not complication rates, were reliably documented in the German national screening colonoscopy registry. Data on complications need to be appropriately standardized and audited in order to be used for credentialing and benchmarking purposes.

Introduction

Screening colonoscopy has been included in national guidelines due to its presumed ability to reduce colorectal cancer (CRC) incidence and mortality [1, 2]. The necessary quality control of such a measure requires several parameters to be determined, such as the colonoscopy completion rate and adenoma detection rate (ADR), as well as procedural complications. These parameters have been used in studies and are included in local quality assurance programs in various countries such as the USA, Canada, and Germany [3–7]. There are various methods of data acquisition within quality assurance programs, including self-reporting in registries or comparative analyses of different databases (e.g. hospital and insurance databases).

In Germany, a national screening colonoscopy program was started at the end of 2002, accompanied by a large screening colonoscopy database – the screening colonoscopy registry of the Central Research Institute of Ambulatory Health Care (Zentralinstitut [ZI] registry) – which includes details of about 4 million screening colonoscopies carried out since the implementation of the program [8]. The data collected in this registry are based on self-reporting by physicians and are not audited. Therefore, the validity of data of quality assurance parameters gathered in this and similar registries is not known. Nevertheless, there is an

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increasing scientific and public interest in quality assurance data for a variety of medical procedures including screening colonoscopy; these data even form the basis of hospital and physician guides in public media [9–11].

The aim of the present study, therefore, was to assess the validity of the German screening colonoscopy registry with respect to the three main quality parameters – colonoscopy completion rate, ADR, and complication rate. Data collected and audited within a previous prospective study were used as the reference standard. Data collected and audited within a previous prospective study called Berlin Colonoscopy Project (BECOP) were used as the reference standard; this analysis was performed as BECOP-4 project.

Patients and methods

Data from the central German screening colonoscopy database (ZI registry) on all screening colonoscopies performed by 19 gastroenterology offices belonging to the interest group of private practice gastroenterologists in Berlin (about 60 members) between 1 October 2006 and 31 March 2008 were included in the present study. The registry includes data from all German offices irrespective of the number of endoscopists involved. The sample for the present study included two offices with two endoscopists each; the remaining offices were run by a single endoscopist and thus, 21 endoscopists were included in the study.

Within the German screening colonoscopy program, all examinations have to be documented on a one-page case report form (CRF) issued by the Central Research Institute of Ambulatory Health Care, Berlin, (Zentralinstitut der Kassenärztlichen Vereinigung); forms have been submitted online since 2007. This central data collection (registry) is based on self-reporting by participating physicians at variable time points after colonoscopy (at the discretion of the endoscopist) and contains pseudonymized (office and patient number) data on patients, colonoscopy findings (cecal intubation, polyps, cancer), and complications (classified into different complication types and management; time point of data recording not defined). In cases with histological examination, information is probably mostly recorded (or can be updated) when histological results are received and entered into the database. No audit is performed other than annual feedback requests for cancer details and complications that required hospital admission.

These registry data were compared with data from a previous prospective audit study that was performed by the same offices during the same time period. These study data served as both audit and gold standard for the assessment of data quality in the registry. Within this audit study, which was designed to analyze factors affecting ADR [12], all persons willing to undergo screening colonoscopy during the audit period were asked to participate in this quality assurance study. The study was approved by the Charité Ethical Committee (EA 02/019/07).

Study data were audited for completeness of included cases by comparing them with reimbursement data. The completeness of physician CRFs (CRF-1 and CRF-2, see below, and complications) was checked and missing data were sought by checking endoscopy reports or other files as well as histopathology reports for ADR. Patient feedback was also sought by means of a questionnaire (patient CRF, CRF-3), which was issued to the patient when they left the office with instructions to return the completed form after 1–2 weeks. Missing patient CRFs were identified by the study nurse from the respective offices and chased up by letter and telephone.

Participating colonoscopists provided written agreement to the use of their individual quality control data (anonymized on a patient basis) in the prospective audit study. They were not aware of the comparison between registry and study data at the beginning or during the study, as the decision to conduct the comparison was not made until after study completion. Thus, the present study is a post hoc analysis using data of a prospective quality assurance study [12] as audit for the registry data.

The following outcome parameters were analyzed from both the registry and the audit study: patient age, sex, and family history of CRC; cecal intubation (representing colonoscopy completion rate); number and other characteristics of adenomas and other polyps with histological confirmation (in the registry, only the rate of patients with at least one adenoma including size, form, and histology of the most advanced lesion is included); complications attributable to screening colonoscopy, as defined below.

Definitions and method of documentation

Colonoscopy completion rate was defined as reaching the cecum and was based on self-reporting; cecal and ileal intubation were grouped together.

The ADR was defined as the rate of patients with at least one adenoma with histological confirmation; the most advanced pathology or biggest size were indicated in the registry, whereas more detailed data (number, form, size, location, histology) were recorded in the audit study.

Complications were defined for the present study according to those used in the registry, and were reviewed and agreed upon during a consensus meeting of participating colonoscopists before the start of the study. Thus, complications were defined as follows.

- Perforation requiring interventional management such as endoscopic or surgical closure; thus, all cases of perforation that had been clipped immediately during endoscopy were also included. Data on prophylactic clipping or post-polypectomy burn syndrome were not included on the CRF.
- Bleeding requiring endoscopic intervention either during colonoscopy/polypectomy (CRF-1), or during a second intervention such as a further endoscopy or surgery and/or hospital admission without intervention (CRF-2).
- Cardiovascular and respiratory complications requiring intervention and interruption or cessation of the procedure, or which happened after patient discharge and required medical attention.

Timeline of complication documentation

For the registry, there is no time limit for physicians to record complications and patient feedback of complications is not included. It can be assumed that in colonoscopies without polypectomy, only immediate complications are documented. As histology of removed polyps has to be documented, complications known to the physician at a later time could still be included. The registry data were only included after they were deemed to be complete and without the likelihood of further input.

In the audit study, complications were systematically recorded in three steps, as follows.

1. After colonoscopy, colonoscopists completed the CRF for complications that occurred during and immediately after colonoscopy until patient discharge (physician CRF colonoscopy; CRF-1).

2. A second CRF included data that were brought to the attention of the gastroenterologist after the patient had left the practice and within 30 days (physician CRF after colonoscopy; CRF-2), although there was no systematic follow-up of screenees by colonoscopists at this study stage. Data from both these CRFs and, in particular, the completeness of patient inclusion were monitored by the study nurse at each practice.
3. Patients were given a questionnaire (patient CRF; CRF-3) to complete and return 2 weeks after colonoscopy, with questions regarding complications, as well as other issues such as acceptance of bowel preparation and colonoscopy itself. Patient replies were checked by the study nurse and the colonoscopist, and patients and/or referring physicians were contacted by the colonoscopist if there were inconsistencies. Complications not leading to any intervention and any reported hospital admissions that were due to treatment of cancer were not counted as complications.

Statistical analysis

Baseline characteristics are reported as means (with SD and range) for continuous variables and as quantities and percentages for nominal/ordinal variables. For comparison of percentages between groups, Fisher's exact test (two-tailed) was used. All statistical analyses were carried out using SAS software version 9.1 (SAS Institute Inc., Cary, North Carolina, USA).

Results

A total of 12 856 screening colonoscopies were performed by the participating colonoscopists during the study period (as audited from practice software systems), and 12 134 cases were included in the present study. For a variety of reasons, the remaining patients did not consent to inclusion. Demographic characteristics of patients and colonoscopy findings within the audit study are shown in **Table 1**. During the same period, 12 150 cases were recorded in the anonymous ZI registry by the participating offices.

Participating colonoscopists had a mean experience of 21.4 ± 6.7 years (range 13 – 36) of performing colonoscopies; their mean annual screening colonoscopy case volume during the study period was 463.4 ± 242.5 (range 110 – 1005). A total of 7211 polyp removals were recorded in the study; 36.7 % were removed by snare and 58.1 % by forceps (no precise information was available for 5.2 %).

Colonoscopy completion rates

There was a statistically significant difference in colonoscopy completion rate between the audit study (98.2 %) and the registry (97.7 %) (P = 0.001). However, of the 19 participating practices, completion rate was not significantly different in 14 (73.7 %); in three offices, the completion rate was higher in the study (by 2.2 %, 8.6 %, and 6.5 %, respectively), and in two it was higher in the registry (by 3.3 % and 4.7 %, respectively).

Adenoma detection rates

The mean ADR of all participating offices based on study cases (N = 12 134) was 21.0 %, whereas in the registry data (N = 12 150) the mean ADR was 20.5 % (P = 0.18). Statistically significant differences between ADR in the two datasets were found in 5 of the 19 participating practices. These differences were borderline significant (P = 0.045; ADR 15.2 % vs. 18.3 %) in one case, were massive in another case (ADR 25.3 % study vs. 8.5 % in registry), and different by 15 % – 40 % in the remaining three cases. Overall, there were three practices with differences of > 15 % between both ADR datasets (i. e. 15.7 % of 19 participating practices in the study).

Table 1 Data from prospective audit.

Patients	
Number	12 134
Age, mean ± SD, years	64.5 ± 4.1
Age groups, %	
5 – 64 years	52.5
65 – 74 years	38.5
75 – 84 years	8.4
85 + years	0.6
Sex, m/f, %	47/53
Family history, %	
CRC	7.67
Colon polyp	0.43
Medication, %	
Anticoagulation	1.8
ASA	10.4
NSAID	1.6
Colonoscopy	
Colon cleanliness good/sufficient, %	87.5
Cecal intubation rate, mean (range), %	98 (93 – 99)
Examination times, mean ± SD, minutes	
Introduction	8.8 ± 6.55
Withdrawal	8.4 ± 5.2
Colonoscopy findings	
ADR, mean (range), %	21.0 (8 – 33)
Adenoma size, mean (range), cm	0.59 (0.06 – 4.47)
Adenomas > 1 cm, mean (range), %[1]	20.5 (10 – 25)
Adenomas with HGIN, mean (range), %[1]	3.7 (1 – 25)
Advanced adenomas, mean (range), %[1]	29.7 (16 – 44)
Cancers, n	103

ADR, adenoma detection rate (i. e. patients with at least one adenoma); ASA acetylsalicylic acid; CRC, colorectal cancer; HGIN, high-grade intrapeitheial neoplasia; NSAID, nonsteroidal anti-inflammatory drugs.
[1] Of all adenomas. Definition of advanced adenomas: adenomas > 1 cm and/or with villous histology and/or HGIN.

Complications

Complication rates measured during the three study data acquisition steps and those registered in the registry are shown in **Table 2**. Patient feedback (CRF-3) was obtained in 90.1 % of cases. It can be seen from **Table 2** that the complication rate increased from 0.15 % in the registry to a total of 0.46 % when all information sources in the prospective study (CRF-1 – 3) were taken together (P < 0.001); in addition, the study complication rates registered by colonoscopists (CRF-1 and -2: 0.33 %) were significantly higher than those documented in the registry (0.15 %; P < 0.05). It should be noted, however, that one case of perforation (after polypectomy) and one cardiovascular complication were recorded in the registry but not included in the audit study, probably due to lack of patient consent (data not individualized). All other registry complications were accounted for in the audit study data.

Compared with the registry data, the complication rates in the study data were 3.1 times greater for all complications, 3.5 times greater for bleeding, 1.5 times for perforation, and 4.3 times greater for cardiovascular/respiratory complications.

Only a third of the patients with bleeding episodes but all patients with perforation and some patients with cardiovascular/

Table 2 Complication rates documented during the various steps of study documentation including those leading to hospital admission. Denominator for the percentage calculation is the total number of study cases (n = 12134; see text).

	Study data								Registry data	
	CRF-1 CRF colonoscopy		CRF-2 CRF after colonoscopy		CRF-3 CRF patient		All study data			
	Total	Hospital admission	Total	Hospital admission	Total	Hospital admission	Total	Hospital admission	Total	Hospital admission
All complications	0.21 %	8/25	0.11 %	5/14	0.14 %	10/17	0.46 %	23/56	0.15 %	9/18
Bleeding	0.115 %	2/14	0.02 %	2/2	0.01 %	1/1	0.14 %	5/17	0.04 %	2/5
Perforation	0.02 %	3/3	0.01 %	1/1	0.01 %	1/1	0.03 %	5/5	0.02 %	3/3
Cardiovasc./resp.	0.05 %	1/6	0.07 %	1/9	0.05 %	4/6	0.17 %	6/21	0.04 %	1/5
Others	0.02 %	2/2	0.02 %	1/2	0.07 %	4/9	0.11 %	7/13	0.04 %	3/5

Explanations of different case report forms (CRF) according to time point of data collection:
CRF-1 is the CRF with physician data from colonoscopy until the time the patient left the office (CRF colonoscopy).
CRF-2 is the CRF with later information from the patient's further course known to the physician (CRF after colonoscopy).
CRF-3 is based on audited data from patient questionnaires (CRF patient).

respiratory complications were admitted to hospital. If only complications leading to hospital admission were analyzed, the registry under-reported in all complications: 9 in the registry vs. 23 in the study for all complications (39 %), 2 vs. 5 for bleeding (40 %), and 3 vs. 5 for perforation (60 %). Generally, the rate of hospital admission was similar in the entire patient population recorded (41 % in the study and 50 % in registry) as well as in subgroups (data not shown).

Notably, only 2 of the 6 perforations encountered in both study and registry occurred after polypectomy. Of these, one occurred at the index colonoscopy during removal of a 25-mm adenoma, and the second occurred at repeat colonoscopy in a different patient, but performed in hospital by the same colonoscopist on removal of a large adenoma (26 mm) with high-grade intraepithelial neoplasia (HGIN). It may be debatable whether this latter complication was directly attributable to the index screening colonoscopy, but it happened as a result of screening colonoscopy. The remaining four perforation cases occurred during diagnostic colonoscopy. Of the six perforations, four were recognized immediately and two patients were admitted later (at 24 and 48 hours, respectively).

Bleeding occurred in 0.53 % of cases (14/2647) after snare polypectomy and in 0.05 % of cases (2/4187) after forceps removal of polyps ($P<0.01$). Of the 6506 cases with polyp removal without any anticoagulant medication, 12 bleedings occurred (0.18 %). Bleeding occurred in 1 out of 54 polypectomy cases on cumarine (1.9 %) and in 3 out of 764 polypectomy cases on acetylsalicylic acid/nonsteroidal anti-inflammatory drugs (0.4 %). The latter rate was significantly different from the rate of the group without any anticoagulant medication (0.4 % vs. 0.18 %; $P<0.01$). This difference was independent of polypectomy method (snare vs. forceps $P=0.26$).

Discussion

Colonoscopy has been advocated as the most effective test for CRC screening and prevention. Quality control is therefore an important issue and there is common consensus on suitable quality parameters [3 – 5]. Whereas colonoscopy completion and complication rates measure performance quality, ADR can be considered the most important parameter for measuring outcome quality [13 – 15].

In Germany, the national screening colonoscopy program introduced at the end of 2002 (with general reimbursement of screening colonoscopy above the age of 55 years) has been accompanied by a quality assurance program from the start. This program is mostly based on self-reporting and includes central registry documentation of all cases with respect to the three main outcome parameters [8]. Annual feedback is provided to all participating physicians as a benchmark. Despite the widespread use of the registry and public claims to make such data freely available [9 – 11], the reliability of such registry data is not known. In an attempt to assess the quality of data collected in this German nationwide registry, the present study compared the three main outcome parameters from data recorded by the same physicians in both the registry and a prospective and audited study conducted during the same period in the city of Berlin.

The present study showed evidence that colonoscopy completion and ADR are realistically recorded in the registry, but that documentation of complications is insufficient. These results raise the following important issues.

Documentation adherence: There could be a general tendency of under-reporting in the registry. However, the high concordance between registry and study with regard to colonoscopy completion rate and ADR suggests that there is no substantial lack of documentation discipline in general. Although completion rates were different overall by 0.5 %, a significant difference could be calculated due to the very high case number included in the study. However, 74 % of practices did not have significantly different rates, and in the remaining five, three showed under-reporting and two showed over-reporting in the registry; therefore, this does not point towards a systematic under- or over-documentation. However, as study participation itself may represent a positive selection bias, it cannot be concluded that documentation may be worse overall than in the prospective audit study. We could not elucidate the differences in a few practices with regard to ADR reported in the registry compared with the audit. In only one individual case was the difference so massive (and not in favor of the colonoscopist), that a documentation mistake had to be assumed at the registry or reporting side.

Definition issues: In contrast to the ADR, which is well defined and backed up by an independent gold standard such as histology, the definition of complications as well as the time limits for reporting are more difficult to standardize and have not been standardized in the registry.

Patient follow-up: Complications of a diagnostic test that is performed as an outpatient procedure may escape recognition by the performing physician. Although the full picture of complications has to include patient feedback, a mandatory inclusion of such feedback information into a nationwide quality assurance program is probably unrealistic. However, the present study also showed that, even if patient feedback is discarded and only physician information (i.e. CRF-1 and -2) is used as a basis for comparison between study and registry data, complications were still significantly under-reported in the registry (0.15% vs. 0.33%; $P<0.05$). Generally, if complication rates are ever to become part of a benchmark program, documentation should be standardized and to some extent also audited. However, this cannot be done without providing additional resources. Although we are convinced that the audit we conducted during the prospective study represented the best means of quality control of quality parameters it is not practical in daily practice.

An important limitation of the present study was the self-selection of gastroenterologists for participation in the prospective trial rather than random selection; however, this limitation cannot be overcome. It is debatable whether this self-selection bias might have led to better results than in the general gastroenterologist population in Berlin. The same limitations, however, apply to all measures of voluntary quality control.

The present results may lead to the conclusion that self-reporting is not the best means of recording complications. Alternative efforts to more reliably document complications include linking colonoscopy databases to other databases from insurances (e.g. hospital admissions for complications) or other national sources (cancer incidence after screening colonoscopy from National Cancer databases) [6]. Thus, it has recently been suggested that administrative data can be used to define endoscopist quality in a study from Canada [16]. Similarly, a US database was linked to medical insurance data for similar purposes [17]. Significant complications could be defined as those requiring hospital admission or repeated interventions if done on an outpatient basis, which could be derived from medical insurance data. However, documentation quality in such administrative databases is difficult to assess and depends on a variety of factors, such as who documents which parameters at which time for which patients and the details of the coding system (e.g. there is no International Classification of Diseases [ICD] code for post-colonoscopy perforation). Furthermore, the legal situation in some countries does not allow automatic linkage of different databases, which may present a significant obstacle to the use of administrative data without individual patient consent.

In comparing the present study results with those in the published literature, there is a wide range of studies dealing with the three main outcome parameters of colonoscopy. Quality standards for colonoscopy completion rates have been defined to reach 90% or more in recent US and European guidelines on colonoscopy quality [18, 19], but study results were quite variable depending on country, program, and performers [20]. Poor results with regard to cecal intubation in the UK published in 2004 [21] have led to enormous efforts to assess and improve colonoscopist quality [22]. In Canada, colonoscopy completion rates in 2000 of 87% [23] prompted quality programs that improved reported cecal rates to 95% some 10 years later [7]. Colonoscopy completion rates may be different for physicians [24] and specialized gastroenterologists. ADRs, as the main outcome quality parameter, also vary widely from study to study (from 9.4% in Poland [25] to 37.5% in the USA [26], with also lower US rates such as 23.5% [27] or 14.5% [28]), and within studies from endoscopist to endoscopist [29, 30].

The complication rates in the present study were also substantially higher than those published in most previous papers. Previous studies focusing on complications of screening colonoscopy – not including diagnostic colonoscopy – were summarized in a recent meta-analysis [31]. However, these studies either did not report on complications at all [32 – 34], had a zero complication rate [35, 36], or reported rates well below 0.01% [37 – 41]. A study published in 1999 compared 30-day complications with those discussed at morbidity and mortality conferences (with unclear selection criteria). The study showed much higher complication rates at 30 days (20 vs. 3), but only included a limited number of cases (n = 1169) and did not report screening colonoscopy separately [42]. Studies focusing on 30-day complications with various methodology and in various settings [43, 44] did not compare them with records of early complications.

Finally, two further studies that were published recently also provided data on patient follow-up. One paper with a 30-day follow-up did not report on any complications among 1244 screening colonoscopy cases [45]. The other study, a large database analysis including a 7- and a 30-day follow-up, showed a low complication rate (0.2%), less than half that reported in the present study. In that study, however, both screening and diagnostic colonoscopies were included and less than half of the eligible patients (18 271 out of 40 637) were analyzed [46]. The conditions of data acquisition in that particular study may be different from those of a prospective study, but possibly comparable to the quality assurance concept of the German registry, with some notable improvements such as patient follow-up.

In summary, the present study suggests that, based on self-reporting, two of the three colonoscopy quality parameters can be reliably documented in large registries – colonoscopy completion rate as a measure of performance quality and ADR as an outcome quality parameter. Significant under-reporting, however, was found for the third parameter of complication rate. It is therefore conceivable that differences in reported complication rates in large registries may only be partly due to real differences but probably primarily arise from methodological issues such as definition and timeline uncertainties, and probably also a different adherence to documentation discipline. If complications are to be included in quality assurance programs, quality assurance of data acquisition and audit should be standardized and published alongside complication data. It remains to be seen whether self-reporting with auditing and/or patient follow-up – as suggested by recent European guidelines [19] – or linkage of different databases will be the final solution; this probably mostly depends on local factors such as database quality and data protection issues.

Competing interests: None

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