Original Article | Journal of INTERNAL MEDICINE

doi: 10.1111/j.1365-2796.2008.01977.x

Endoscopy in Barrett's oesophagus: adherence to standards and neoplasia detection in the community practice versus hospital setting

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Abstract. Pohl H, Aschenbeck J, Drossel R, Schröder A, Mayr M, Koch M, Rothe K, Anders M, Voderholzer W, Hoffmann J, Schulz H-J, Liehr R-M, Gottschalk U, Wiedenmann, B, Rösch T (Charite University Hospitals, Humboldt Hospital, and Maria Heimsuchung Hospital, Berlin, Germany). Endoscopy in Barrett's oesophagus: adherence to standards and neoplasia detection in the community practice versus hospital setting. *J Intern Med* 2008; **264**: 370–378.

Objective. Potential process differences between hospital and community-based endoscopy for Barrett's oesophagus have not been examined. We aimed at comparing adherence to guidelines and neoplasia detection rates in medical centres (MC) and community practices (CP).

Design. Retrospective analysis.

Setting. All histologically confirmed Barrett cases seen over a 3-year period in six MC and 19 CP covering a third of all upper gastrointestinal endoscopies (n = 126 000) performed annually in Berlin, Germany.

Main outcome measure. Rate of relevant neoplasia (high-grade intraepithelial neoplasia or more) in both settings in relation to adherence to standards.

Results. Of 1317 Barrett cases, 66% were seen in CP. CP patients had a shorter mean Barrett length (2.6 cm vs. 3.8 cm; $P < 0.001$) with fewer biopsies taken during an examination (2.5 vs. 4.1 for Barrett length ≤2 cm; $P < 0.001$). CPs also provided fewer complete esophagogastroduodenoscopy documentation (25.1% vs. 57.8%, $P < 0.001$). Neoplasias were found more commonly in MCs compared to CPs (9.2% vs. 0.8%; $P < 0.001$). However, on exclusion of all referred patients with known neoplasia (65%) or those examined for other reasons (27.5%), the detection rate at MCs decreased to 1.3%, not different from the one seen at CPs (0.8%, $P = 0.43$). Only 13% were found during surveillance, but 57% were diagnosed at an early stage.

Conclusions. Referral bias and not better adherence to guidelines could explain the higher neoplasia prevalence in Barrett's oesophagus at hospital centres. Despite a generally poor adherence to guidelines, most neoplasias found were at an early and potentially curable stage.

Keywords: Barrett's oesophagus, oesophageal adenocarcinoma, quality of endoscopy, screening, surveillance.

Introduction

Barrett oesophagus is considered the main risk condition for the development of oesophageal adenocarcinoma. Its incidence has been rapidly increasing in the industrialized world over the past three decades [1–3]. Annual transitional risk from Barrett to adenocarcinoma is assumed to be 0.5% [4]. It is noteworthy that

studies on the incidence and prevalence of Barrett-associated neoplasia almost exclusively originate from medical centres (MC) [5–11]. In addition, there is a lack of data on the magnitude and procedural characteristics of Barrett examination in community practices (CP) where most of the patients with Barrett's oesophagus are seen.

Although the ultimate outcome of endoscopic-bioptic surveillance of Barrett is still discussed controversially [12, 13], endoscopic surveillance with four quadrant biopsies is considered current standard for patients with Barrett's oesophagus [14–18]. Several analyses have however shown that adherence to guidelines is mostly low [19–22], although special quality improvement programmes may at least temporarily improve this situation [23]. Recently, the American Endoscopy and Gastroenterology societies have published procedural quality indicators for endoscopy in patients with Barrett's oesophagus. These include proper indication, documentation of Barrett length, and adherence to the Seattle protocol with at least four quadrant biopsies per 2 cm Barrett length [14, 24, 25]. However, it has not been examined whether and to which extent adherence to this process measures of endoscopic-bioptic surveillance may translate into better outcome. Outcome parameters for Barrett surveillance have not been clearly defined and validated. Similar to colonoscopy, where adenoma detection rate (alternatively, the rate of advanced neoplasia) appears to be an established quality indicator [26], it may be logical to use neoplasia detection rate. Because of inconsistencies in the histopathological diagnosis of low-grade neoplasia [27–29], it may be wise to use advanced neoplasia [high-grade intraepithelial neoplasia (HGIN) or more] as a provisional parameter.

In Germany as well as in many other countries, endoscopies are performed in the hospital as well as in the CP setting. There are no comparative data on the process of endoscopy for Barrett's oesophagus with regard to adherence to current guidelines and outcome. Within a regional endoscopy quality assurance programme, we therefore retrospectively compared the adherence to guidelines and rate of Barrett-associated neoplasia (HGIN or oesophageal adenocarcinoma) between MC and CP.

Patients and methods

Patient inclusion and data basis

Data were retrospectively collected during a 3-year period (2003–2005) as part of a regional quality programme on Barrett's oesophagus that involved cooperation between CP interest groups and Charite University Hospitals, Berlin. Nineteen Berlin CP that had a particular focus on gastroenterology and endoscopy and six referral centres, consisting of three university and three larger teaching hospitals in Berlin, participated in this retrospective study.

Coverage of Berlin area

Estimates were based on figures obtained for the year 2005 [30, 31]. In this year, the 19 participating CP performed 26 591 upper endoscopies representing a third (36%) of all 74 000 practice-based upper endoscopies performed in Berlin in that year (population of 3.5 million). With respect to referral centres, 17 159 upper endoscopies were carried out in 2005. This also represents approximately a third (33%) of all 52 500 such procedures performed in Berlin referral centres in 2005 [30].

Data collection

Participating centres and practices searched their endoscopy and histology databases to identify all Barrett's oesophagus patients encountered between January 2003 and December 2005. Patients were included only if both endoscopy and histology (showing intestinal metaplasia with goblet cells) were consistent with Barrett's oesophagus. We excluded patients who had previously undergone oesophageal resection or endoscopic treatment of either HGIN or oesophageal adenocarcinoma. We obtained detailed data on 1103 patients in CP and 491 in MC. Figure 1 provides information on further exclusion of cases. Eight hundred and eighty-three patients from CP and 434

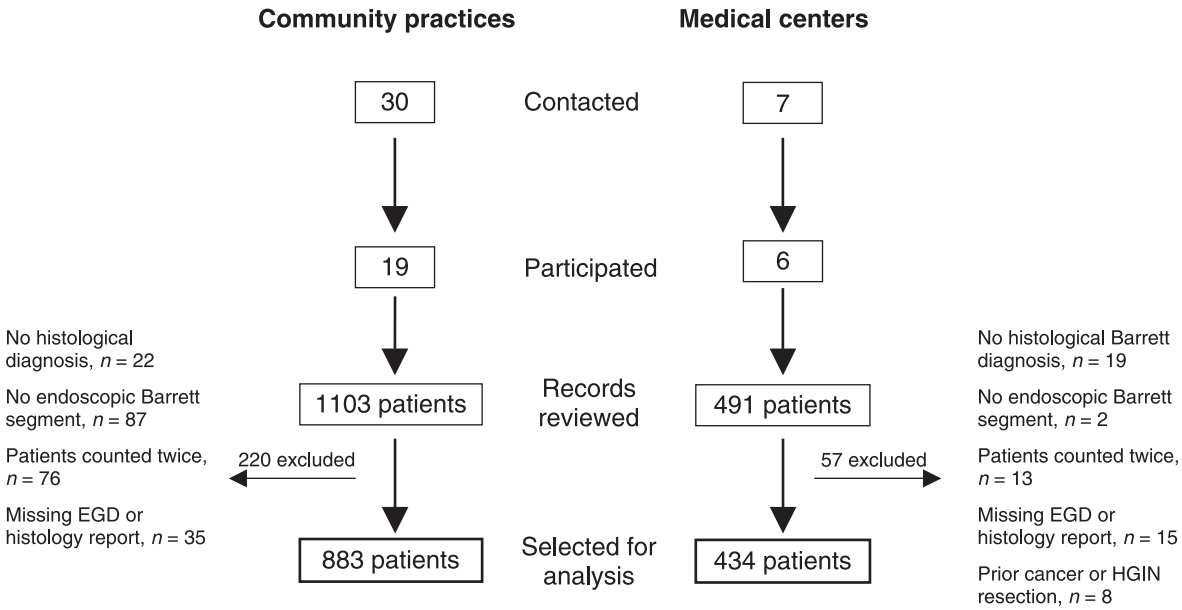

Fig. 1 Participation of referral centres and gastroenterology community practices and selection of patients. EGD, esophagogastroduodenoscopy; HGIN, high-grade intraepithelial neoplasia.

patients from referral centres were enrolled in the final analysis. A total of 20 histopathology institutions were involved in the diagnosis of Barrett's oesophagus. All HGIN diagnosed at academic MC were reviewed by a second pathologist. However, we did not have sufficient information whether this was also done in CP. All data were acquired from endoscopy and histology reports. Additional chart review was done for all patients with HGIN or carcinoma.

Outcome variables

As primary outcome measure we used the proportion of advanced neoplasia (HGIN or carcinoma) seen in CP in comparison with referral centres, both during index endoscopy (incidence) as well as surveillance in patients with known Barrett (prevalence). Process measures were based on the published quality guidelines [14, 24, 25] and included documentation of Barrett length, presence and extent of hiatal hernia, number of biopsies per 2 cm of Barrett length. We also recorded information on the proportion of patients with known Barrett's oesophagus at index endoscopy including duration of disease, completeness of documentation on Barrett's oesophagus history and stages of neoplasia found in both settings.

Data analysis

Continuous variables were analysed using the Student's *t*-test if they were normally distributed or with the Mann–Whitney test if not normally distributed. Categorical variables were assessed using either the chi-squared test or the Fisher exact test as appropriate. We used logistic regression analysis to examine our main outcome for potential confounding by Barrett length, number of biopsies and age.

Results

Patients

Details of the inclusion process are displayed in Fig. 1; data on all 1317 included patients are shown in Table 1. Two-thirds of all evaluated patients were seen in CP. Based on the number of reported Barrett patients and the total number of all esophagogastroduodenoscopies (EGDs) performed in the participating centres from

Table 1 Baseline characteristics of Barrett patients by setting

	Community practices (n = 883)	Medical centres (n = 434)	P
Barrett patients (n = 1317)	67.0%	33.0%	
Age, mean (SD)	59.3 (13.0)	63.4 (13.1)	<0.001
Men	69.1%	68.7%	0.88
Barrett length, mean cm (SD)	2.6 (2.1)	3.8 (3.2)	<0.001
Long-segment Barrett	29.9%	46.7%	<0.001
Hiatal hernia ≥3 cm	22.3%	41.0%	<0.001

Table 2 Documentation (data completeness) of endoscopy reports at community practices and medical centres

Complete documentation	Community practices, % (n = 833)	Medical centres, % (n = 434)	P
Complete documentation[a]	25.1	57.8	<0.001
Previous Barrett history	33.3	30.5	0.849
Indication for EGD	58.2	77.0	<0.001
Barrett length	42.2	77.9	<0.001
Number of biopsies	74.4	87.8	<0.001

EGD, esophagogastroduodenoscopy.
[a]Only considering basic information on indication, Barrett length and number of biopsies.

each setting relative to the total number of all EGDs performed in Berlin in 2005 (see Patients and methods section), it can be deduced that approximately 80% of all Berlin Barrett cases were seen in CP. In our series patients in CP were on average 4 years younger. In both settings about two-thirds of patients were men. Overall, patients in CP had a shorter Barrett segment, a lower proportion of long-segment Barrett and a lower proportion of large hiatal hernias.

Process evaluation

Quality of Barrett examination and documentation. Key elements of documentation were missing in reports from both settings, with MC having more complete records (Table 2). Only a quarter of reports from CP contained complete basic information on indication, Barrett length and number of biopsies, whereas about half of MC reports contained complete basic documentation. Fewer records in CP contained information on indication, number of biopsies or Barrett length. Information on previous Barrett history was available in only about one-third of all Barrett patients. Therefore, the rate of tumour detection during surveillance (incident cases) could not be determined.

Figure 2 summarizes the number of biopsies independent of Barrett shape (circular, tongue or combined) according to the length of Barret's oesophagus. Significantly fewer biopsies were taken per 2-cm Barrett segment in CP compared to MC. The difference persisted with increasing Barrett length. Information on additional staining techniques was available in 56.7% in CP and 52.1% in MC (NS); it was rarely applied, but more frequently in MC (4.9% vs. 0.2%, $P < 0.001$).

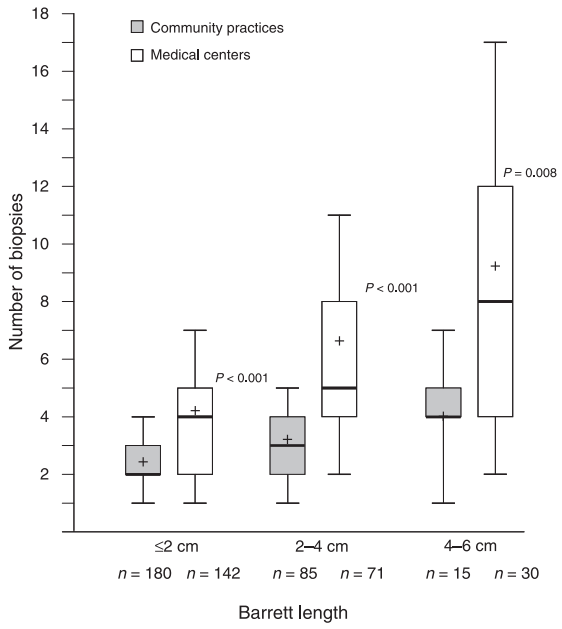

Fig. 2 Number of biopsies per 2-cm Barrett length in community practices and medical centres. Boxplot of medians (–) with 25% and 75% range and means (+).

Outcome evaluation

Neoplasia prevalence. Advanced neoplasia (HGIN or carcinoma) was seen in 0.8% of patients in CP

Table 3 Proportion of patients with neoplasia by settings

	Community practices (n = 883)	Medical centres (n = 434)	P
Barrett, no IN	695 (78.7)	358 (82.5)	<0.001
LGIN	181 (20.5)[a]	36 (8.3)	<0.001
HGIN	3 (0.3)	8 (1.8)	0.001
Carcinoma	4 (0.5)	32 (7.4)	<0.001
Early (T1)	2 (0.2)	14 (3.2)	
Advanced (≥T2)	2 (0.2)	18 (4.1)	

Values within parenthesis are expressed in percentage. IN, intraepithelial neoplasia; LGIN, low-grade intraepithelial neoplasia; HGIN high-grade intraepithelial neoplasia.
[a]When excluding one community practice where the majority of patients were diagnosed with LGIN, the proportion decreases to 4.5% (P = 0.02).

Table 4 EGD indications for patients with HGIN or carcinoma

	Community practice cases (n = 7)	Medical centre cases (n = 40)
Referred for further evaluation	–	26 (65.0)[a]
Barrett surveillance	1 (14.3)[b]	3 (7.5)[c]
Heartburn	2 (28.6)	–
Cancer of unknown primary	–	3 (7.5)
GI bleeding, anaemia	–	4 (10.0)
Dysphagia	3 (42.8)	1 (2.5)
Nausea/vomiting	–	1 (2.5)
Unknown	1 (14.3)	2 (5.0)

Values within parenthesis are expressed in percentage. EGD, esophagogastroduodenoscopy; HGIN, high-grade intraepithelial neoplasia; LGIN, low-grade intraepithelial neoplasia; GI, gastrointestinal.
[a]Indications: established cancer (11), suspected cancer (4), Barrett with HGIN, LGIN or ulcer (4), dysphagia (4), GI bleeding or anaemia (2), unknown (1). Of these 11 had a known history of Barrett oesophagus but only two for more than 1 year.
[b]Barrett known for 4 years.
[c]Barrett known for 0.5, 1 and 4 years respectively.

(7 of 833) and in 9.2% in MC (40 of 434) (Table 3). Adjustment for age, Barrett length, size of hiatal hernia or number of biopsies per 2 cm of Barrett's segment did not affect the main outcome.

The majority of patients with advanced neoplasia (HGIN or carcinoma) detected at referral centres (65%) had been referred for further evaluation and management of suspected or already detected neoplasia (Table 4). Of the remaining patients, seven were assessed for an acute condition requiring hospitalization (bleeding, anaemia or evaluation of suspected malignancy outside the gastrointestinal tract), and upper endoscopy was performed for reasons other than nonspecific upper abdominal symptoms, reflux or for surveillance of known Barrett's oesophagus. Correcting for referred patients, and for those with an acute illness, the proportion of patients with advanced neoplasia at referral centres decreased to 1.3% (5 of 399), not significantly different from the 0.8% (7 of 883) advanced neoplasia rate in CP (P = 0.43). Given the limited number of patients with advanced neoplasia additional testing for possible confounders was not appropriate.

Neoplasia incidence and surveillance. Only six of 47 advanced neoplasia patients represent true surveillance cases with a known Barrett history for more than 1 year (12.8%); five were detected in MC and one in a CP. Nevertheless, of the 47 patients with neoplasia encountered during the study period and examined for a variety of reasons, 27 (57.4%) had early-stage disease (HGIN, T1 carcinoma).

Discussion

As part of a regional quality programme on the diagnosis and surveillance of Barrett's oesophagus in MC and CP, we retrospectively analysed data from more than 1300 Barrett patients. These represented approximately a third of all upper gastrointestinal endoscopies performed in the Berlin area annually. In our study, approximately two-thirds of Barrett patients were seen in the CP setting, whilst – excluding referral cases – two-thirds of HGIN or carcinoma cases were seen in MC.

Adherence to procedural quality guidelines as complete documentation and number of biopsies per cm of Barrett length was significantly lower in CP. One potential reason for this detected difference is the

difference in knowledge of guidelines for Barrett evaluation. However, we think this does not play a major role. All participating colleagues in CP are part of a gastroenterology interest group with regular meetings also discussing quality aspects. Vice versa, three of the participating hospitals are university hospitals with some scientific interest in Barrett's oesophagus and thus probably higher adherence to guidelines. We would speculate that time constraints in private practice as well as limited evidence behind Barrett guidelines could both contribute to this difference in adherence. It has been shown that guidelines are better accepted if they are practicable and based on good evidence. A study in the Netherlands examined adherence to 47 various guidelines in 61 private practitioners. Sixty-one per cent of almost 13 000 evaluated decisions were congruent with the current guidelines. Controversies existed if guidelines appeared vague and nonspecific or if they required a change in current practice. Guidelines that were not evidence based were followed less frequently (35–57%) [32].

One of the questions of our study was whether process and quality differences might have translated into a better outcome, i.e. a higher rate of neoplasia detection in MC compared to CP. Our initial finding of a more than 10-fold higher neoplasia rate in MC might have suggested this association. This idea might have also been supported by the difference in possible underlying risk factors such as age, Barrett length and size of hiatal hernia. It should also be noted that measurements of Barrett length and size of hiatal hernia are unreliable and are incorrect in 21% of cases by at least 1 cm [33, 34]. It could be speculated that more accurate measurements were obtained at MC with scientific interest in the topic, but that other factors such as referral pattern might play a role. Adjustment for Barrett length, size of hiatal hernia and age did not affect the major outcome. However, when considering the referral pattern, the detected difference in neoplasia rate decreased substantially with loss of statistical significance, as 65% of MC cases were detected elsewhere and referred for further evaluation and management. Minor differences could still exist, so that our case number might not be enough to make firm conclusions about the association between an adequate number of biopsies and the detection of advanced neoplasia. However, it is still surprising that the difference in process (adherence to guidelines with quality differences) did not translate to a difference in outcome, when neoplasia detection rate was used as an outcome surrogate parameter. Our study further suggests that reported neoplasia prevalence and perhaps also risks rates may partially be exaggerated by referral bias. Several aspects require further discussion.

1 Barrett's examination and procedural documentation lacked sufficient quality in both settings for Barrett diagnosis and Barrett surveillance. First, a larger number of patients with histology of intestinal metaplasia but no endoscopic evidence of Barrett were seen in CP (87 of 220 vs. 2 of 57 in MC). We speculate that there was a greater uncertainty about whether to biopsy the Z line (e.g. an irregular Z line) irrespective of the endoscopic definition of Barrett being fulfilled or not. The relevance of the so-called ultrashort Barrett (only histology positive) has been discussed extensively [35–38]. Examiners at MC might have been familiar with the actual scientific discussion, especially as one of the authors had performed a study some years ago which showed that follow-up of endoscopically negative intestinal metaplasia at the cardia/Z line may not be worthwhile [36].

2 As far as Barrett surveillance is concerned, we also found procedural quality differences between CP and MC. Several papers focusing on quality assurance analyses and doctor interviews showed a variable rate of complete four-quadrant biopsies for every 2 cm of Barrett length between 26% and 77% [19, 21, 22, 39, 40]. Although we generally assume that adherence to guidelines will improve the efficacy of Barrett surveillance, this has never been proved in a prospective study. Perhaps careful endoscopic inspection under adequate patient sedation may be more important, as the role of 'invisible' neoplasia is still controversial [41] and endoscopic technology has been considerably improved compared to 15 years ago, when the Seattle biopsy protocol was first developed. The total case number and the rates of neoplasia in our study were probably not high enough to assess possible differences in neoplasia detection in relation to

adherence to standards. Furthermore, incomplete documentation, *per se* a possible indicator of poorer quality, prevented complete information on the patients' previous Barrett history including previous endoscopies.

3 After correcting for referral, an additional 27% of MC patients with advanced dysplasia were examined for other reasons such as gastrointestinal bleeding, cancer of unknown origin, malignant dysphagia or vomiting, and most of these patients required admission. Thus, patients with advanced neoplasia seen at MC presented with a more severe conditions than patients examined in CP where the main indications were heartburn and unclear dyspepsia. When patients with acute indications were eliminated from the MC group, the prevalence of Barrett-associated neoplasia was similar in both settings.

4 Only 13% of patients with HGIN or carcinoma were detected during surveillance. These results confirm previous reports that most Barrett carcinomas are diagnosed outside a surveillance programme [42], an argument generally raised against the effectiveness of Barrett surveillance. However, despite this obvious inefficiency of Barrett surveillance and the quality deficits, almost 60% of the detected Barrett neoplasias were in an early and potentially curable stage. The proportion of early-stage carcinomas in our study is higher than the average proportion for early-stage disease observed at diagnosis (31%) [3]. The discrepancy between the insufficient quality of Barrett examination in our study and the detection of most Barrett-associated carcinoma at early stages is striking and not explicable by our data. There are several potential reasons, such as improved endoscopy technology with much better image quality, increased awareness of early Barrett lesions found under surveillance or a more liberal use of open-access endoscopy, and these need to be analysed separately.

5 Our study shares with other similar studies inherent limitations of a retrospective analysis. Assessment of the quality of examinations for patients with Barrett's oesophagus relied on available documentation and assessment of quality indicators. For instance it was not possible to determine the appropriateness of the indication based on surveillance intervals. That above all limited the information on neoplasia incidence cases. On the other hand, prospective assessment of quality data might not reflect reality as prospective performance *per se* increases awareness and certainly adherence to guidelines.

In summary, there are substantial quality deficits in Barrett's oesophagus surveillance programmes in routine use, both in CP and in medical referral centre setting. The almost ten times lower rate of HGIN or carcinoma in Barrett patients in CP compared to MC can mainly be explained by referral bias. Thus, in addition to the publication bias reported a few years ago [4], a referral bias might perhaps contribute to an exaggeration of neoplasia risk in Barrett patients. In future studies, more emphasis should be placed on previous diagnostic workup, because patients found to harbour no neoplasia at two previous endoscopies might have a lower risk of further progression than those without such a history [24]. In addition and probably more importantly, standards of care have to be improved for the management of Barrett's oesophagus. Nevertheless, the influence of general quality improvement programmes on the final outcome – i.e. better cancer prevention/survival, or, as a surrogate parameter, a higher rate of advanced neoplasia – needs to be proved. Markers may help to better stratify patients into high and low-risk groups and increase the yield of neoplasia found at early stages, but these have not yet been reliably identified.

Conflict of interest statement

No conflict of interest was declared.

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Appendix

List of participating centres and physicians:

Medical centres:

Charité University Hospital Campus Benjamin Franklin

Charité University Hospital Campus Mitte

Charité University Hospital Campus Virchow

Oskar-Ziethen Hospital/Sana Hospitals

Humboldt Hospital/Vivantes Hospitals

Hospital Maria Heimsuchung.

Community practices:

Dr J. Aschenbeck

Dr E. Baumgart

Dr P. Berndt

Dr R. Drossel

Dr H.D. Gentz

Dr M. Gynz-Rekowski

Dr A. Hager

Dr S. Hochfeld

Dr F. Kater

Dr V. Koch/Dr V.Kaatz

Dr S. Müßig

Dr H. Rodewald-Marx

Dr W. Rubatscher/Frau Dr C. Marten-Sparmann

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