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Quality control in colorectal cancer screening: Systematic microbiological investigation of endoscopes used in the NORCCAP (Norwegian Colorectal Cancer Prevention) trial

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Abstract

Background: Endoscopic colorectal cancer (CRC) screening is currently implemented in many countries. Since endoscopes cannot be sterilised, the transmission of infectious agents through endoscopes has been a matter of concern. We report on a continuous quality control programme in a large-scale randomised controlled trial on flexible sigmoidoscopy screening of an average-risk population. Continuously, throughout a two-year screening period, series of microbiological samples were taken from cleaned ready-to-use endoscopes and cultured for bacterial growth.

Results: 8573 endoscopies were performed during the trial period. Altogether, 178 microbiological samples (2%) were taken from the biopsy channels and surfaces from the endoscopes. One sample (0.5%) showed faecal contamination (*Enterobacter cloacae*), and 25 samples (14%) showed growth of environmental bacteria.

Conclusions: Growth of bacteria occurs in a clinical significant number of samples from ready-to-use endoscopes. Pathogenic bacteria, however, were found only in one sample. Improvement of equipment design and cleaning procedures are desirable and continuous microbiological surveillance of endoscopes used in CRC screening is recommended.

Background

Colorectal cancer (CRC) is a major cause of personal suffering and death in the developed world. Screening for CRC by gastrointestinal endoscopy (flexible sigmoidoscopy or colonoscopy) has been recommended for the average-risk population [1], and is currently implemented in many Western countries. For the time being, endoscopes commonly used for diagnostic and therapeutic as well as for CRC screening purposes, are reusable tools. The

endoscopes have to be cleaned manually and/or by using washing machines especially designed for this purpose [2]. The design and material of the endoscopes do not allow sterilisation. Cleaning and disinfection of the devices has been a subject of concern, as transmission of infectious material cannot be entirely dismissed [3]. In 2002, the New York Times reported on the possible transmission of *Pseudomonas* infection to 400 patients after examination with bronchoscopes that were not

adequately designed to ensure proper cleansing and disinfection [4]. Only most recently, outbreaks of bacterial infection associated with flexible bronchoscopes have been confirmed [5,6]. In a multicentre trial in Germany bacterial growth was found in 49% of cleaned endoscopes, and inadequate cleaning facilities and/or routines were found in more than 50% of endoscopy centres [7].

According to current WHO guidelines, all screening tests should be designed to ensure that the test itself does not cause any harm to screenees. Substantial efforts should therefore be made to minimize any risk of contamination of endoscopes. This is especially important in CRC screening where presumptively healthy individuals are exposed to endoscopy.

NORCCAP is a large-scale randomized controlled trial for CRC prevention by flexible sigmoidoscopy (FS). Twenty-one thousand individuals, age 50–64 years, were randomly drawn from the Norwegian Population Registry and invited to an FS screening examination [8]. Screening was performed between 1999 and 2001 at two centres in South East Norway. As part of a continuous quality control programme in the NORCCAP trial, microbiological samples were systematically taken from cleaned endoscopes throughout the trial. The aim of the present study was to investigate the quality of cleaning of endoscopes used in CRC screening.

Results

During the 2-year study period, 8573 examinations were performed (3798 at centre I, 4775 at centre II). One hundred and seventy eight samples (2% of 8573) were taken for microbiological investigation.

Bacterial growth was observed in 16 out of 107 (15%) samples from the biopsy channels and in 10 out of 71 (14%) samples from the endoscope surface. At centre I, we observed growth in 7 out of 41 biopsy channel samples (17%), and in 3 out of 35 (9%) surface samples. At centre II, 9 out of 66 (14%) samples from the biopsy channel and 7 out of 36 (19%) surface samples showed bacterial contamination. One sample (at centre I) showed growth of *Enterobacter cloacae*, indicating faecal contamination. This endoscope was re-tested after two weeks without any findings of contamination. The other bacteria found were low- or non-virulent species of the environment:

- *Staphylococcus epidermidis* in 8 biopsy channel samples and 7 surface samples
- Micrococci in 2 biopsy channel samples and 3 surface samples

- *Bacillus* sp. in 3 biopsy channel samples
- *Pseudomonas stutzeri* in 1 biopsy channel sample
- *Weeksellia virosa* in 1 biopsy channel sample

Discussion

Also after cleaning and disinfection adhering to current guidelines [2], a considerable number of microbiological samples taken from cleaned ready-to-use endoscopes showed bacterial growth. The vast majority of microbes found were environmental bacteria. In one out of 178 samples (0.5%), however, *Enterobacter cloacae* was found, indicating faecal contamination of the endoscope. We did not search for any viruses or *Mycobacteria* in the present trial. However, the finding of faecal bacteria is an indicator for other pathogenic organisms potentially present in that particular endoscope. In a recent study on *Helicobacter pylori* contamination of gastroscopes, the authors report on one contamination out of 128 samples of manually cleaned endoscopes [11].

Our results show that the risk of transmission of infections by endoscopy is real, but probably small when following current cleaning guidelines and using endoscope washing machines. Continuous microbiological investigation of endoscopes should be performed in any CRC screening programme. After the finding of enterobacteria in one of our endoscopes, we improved the cleaning process by adding a detergent solution to the tap water used for flushing the biopsy channel by suction immediately after each endoscopy procedure, to destroy any debris or biofilm containing microorganisms. This procedure is recommended in the ESGE guidelines [2], but is not common practice in Norway.

Additionally, we started rinsing the biopsy channels of all endoscopes with alcohol at the end of each session, to improve the drying of the inner surfaces. This procedure is additional to the cleaning and disinfection procedures currently recommended by the ESGE. However, this measure is mentioned as an add-on procedure in a 1992 working party report by the British Society of Gastroenterology Endoscopy Committee [9]. Surprisingly, a similar recommendation is also found in a former version of the ESGE guidelines (published in 1995) [10]. In the current version, for some reason, this paragraph has been deleted [2]. In the light of the present study, it might be re-incorporated in future ESGE guidelines. However, it is not clear whether contamination of endoscopes in our trial was due to inappropriate procedures or individual failure to adhere to the procedures.

Table 1: Comparison of the cleaning and disinfection procedures recommended by the European Society for Gastrointestinal Endoscopy (ESGE) [2] and those used in the present trial.

	ESGE guidelines	Policy in the present trial
1. Manual cleaning	<ul style="list-style-type: none"> • Flushing air/water channel with water • Immersion in water and detergent, external cleaning and brushing/rinsing of instrument channels • Flushing air/water channel with detergent (facultative) 	<ul style="list-style-type: none"> • Flushing air/water channel with water • Immersion in water and detergent, external cleaning and brushing/rinsing of instrument channels • Flushing air/water channel with detergent*
2. Automatic disinfection	<ul style="list-style-type: none"> • Washing, disinfection and drying according to the manufacturer specification 	<ul style="list-style-type: none"> • Washing, disinfection and drying according to the manufacturer specification
3. Before storage	-	<ul style="list-style-type: none"> • Flushing biopsy channel with 70% alcohol*

*Comprehensive procedures, incorporated in local policy after finding of *Enterobacter cloacae* in one endoscope.

Conclusions

In the present study, growth of bacteria was observed in a significant number of samples from endoscopes cleaned in accordance to current guidelines. Pathogenic bacteria, however, were found only in one out of 178 samples. Transmission of infectious agents through endoscopes cannot be excluded. Systematic microbiological investigation of endoscopes is recommended, especially in CRC screening, exposing presumptively healthy individuals to potentially infectious material. For the future, endoscopes with disposable sheaths, providing every screenee with a sterile endoscope may be desirable to prevent transmission of infectious agents [3,12].

Methods

Type of endoscopes used

Video colonoscopes (CF-VI and CF 140, Olympus Europa, Hamburg, Germany) were used for all examinations. Generally, at each of the two centres, seven endoscopes were available. Occasionally, however, endoscopes have been away for service or repairs.

Cleaning and disinfection of endoscopes

Cleaning personal consisted on four endoscopy assistants at each centre. Before the start of the trial, all cleaning staff was trained practically and theoretically, including two weeks of training at a certified endoscopy lab, and a one-day course on endoscopy cleaning procedures. Additionally, written methods on the cleaning and disinfection procedures have been made available for all employees. Our cleaning and disinfection policy followed current guidelines by the European Society of Gastrointestinal Endoscopy (ESGE) [2], table 1.

For cleaning and disinfection of endoscopes, automatic washer-disinfectors (ETD-2 plus, Olympus Europa, Hamburg, Germany) were used according to the manufacturer's specifications, after first using tap water flushing of the air/water channel, and manual surface cleaning and brushing of biopsy channels, adhering to current guidelines [2]. After the finding of *Enterobacter cloacae* in one

of our endoscopes, we extended our policy by two additional procedures (table 1):

1. Adding a detergent solution (3-E zyme, Medisafe, Herfordshire, UK) to the tap water used for flushing the biopsy channel immediately after each endoscopy procedure. This is recommended as a facultative add-on procedure in the ESGE guidelines [2].

2. Rinsing of the biopsy channels with 70% alcohol at the end of each session. This procedure is not mentioned in the current ESGE guidelines [2], but is recommended as add-on in a former version of the ESGE guidelines, and in guidelines of the British Society of Gastroenterology [9,10].

There were no differences between the two NORCCAP screening centres regarding the type of endoscopes used and the cleaning and disinfection routines.

Microbiological sampling

Microbiological samples from all available NORCCAP endoscopes were taken at eight different Monday mornings throughout a 2-year screening period, the endoscopes not having been used or cleaned after the preceding Friday session. The dates of sampling were chosen randomly by the heads of the NORCCAP trial and the screening centres. All endoscopes available at the respective centres on the day chosen were examined in the following way: samples were taken from both the tip of the endoscopes, and from sterile water flushings through the biopsy channels of the endoscopes. The samples from the endoscope surface were cultured by pressing the surface of the endoscopes onto McConkey and CLED medium present on the commercially available Uricult dip-slide system (Orion Diagnostica, Espoo, Finland) originally designed to grow bacteria from urine. The biopsy channels were flushed with sterile saline which was subsequently applied to both blood agar and CLED agar plates. The dip-slides and the plates were grown at 37°C. Any growth of microorganisms was identified according to standard procedures. The

laboratory performing the sampling and identification of microorganisms is an independent laboratory, not connected to the NORCCAP trial in any way.

The study was part of the NORCCAP trial. The NORCCAP protocol has been approved by the regional ethics committee. Written informed consent was given by all NORCCAP participants before entering the trial.

Competing interests

None declared.

Authors' contributions

Michael Bretthauer is the corresponding author of the study. He took part in designing the study, performed the data analyses and drafted the manuscript.

Anita Jørgensen co-designed the study, organised the data sampling at one of the screening centres, and gave critical comments to the manuscript.

Bjørn Erik Kristiansen co-designed the study, was responsible for the microbiological investigation of the samples collected, and co-drafted the manuscript.

Bjørn Hofstad organised the data sampling at one of the screening centres, and gave critical comments to the manuscript.

Geir Hoff had the idea and designed the study. He supervised the sampling of data at the screening centres, and co-drafted the manuscript.

All authors read and approved the final version of the manuscript.

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