

# Use of a Disposable Sheath System for Flexible Sigmoidoscopy in Decentralized Colorectal Cancer Screening

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**Background and Study Aims** : To prevent transmission of infectious agents and to reduce instrument reprocessing time, the use of disposable sheath systems instead of conventionally reprocessed endoscopes has been promoted for flexible sigmoidoscopy. This trial primarily investigated the feasibility of a disposable sheath system for flexible sigmoidoscopy in decentralized colorectal cancer screening.

**Patients and Methods** : In an ongoing colorectal cancer screening trial, 226 consecutive participants were randomly allocated to have their flexible sigmoidoscopy performed with either a fiberoptic sigmoidoscope covered with a disposable sheath ("EndoSheath group") or a conventional video colonoscope ("standard colonoscope group"). All examinations were performed at a temporary screening center. The patients' experience was documented using a questionnaire. The feasibility of running temporary screening units was evaluated.

**Results** : Examinations beyond the 60-cm level were excluded. Thus, 113 patients (examined with the disposable instrument) and 87 (standard instrument) were eligible for analysis. When the sheathed system was used, all the devices needed could be satisfactorily transported. A screening center could be set up within a few hours. No differences were observed in patient discomfort. Fewer patients with polyps were observed in the EndoSheath group (48 [42%]), compared with 55 (63%) in the standard colonoscope group;  $P = 0.005$ ). No significant differences were observed for polyps larger than 5 mm (14 [12%] in the EndoSheath group, 13 [15%] in the standard colonoscope group;  $P = 0.6$ ).  
**Conclusions** : Using the disposable system, decentralized colorectal cancer screening was easily established. However, fewer polyps were found, possibly due to the fiberoptic nature of the instrument. Sheathed video instruments are desirable and may increase the diagnostic yield.

## Introduction

In Western countries there is an increasing demand for colorectal cancer screening by endoscopy [1]. Flexible sigmoidoscopy is currently recommended for the average-risk population in some countries [2]. At present, reusable endoscopes are commonly used for this purpose. Cleaning and disinfection of these devices has been a subject of concern, as transmission of infectious material cannot be completely excluded. Moreover, reprocessing of endoscopes is time-consuming and expensive. Finally, decentralized screening is difficult because the design of endoscopy racks

and washing machines does not favor mobility. Recently, an endoscope with disposable sheaths (EndoSheath), which does not require conventional reprocessing and which is possibly transportable has been described [3,4]. According to the colorectal cancer screening committee of OMED (Organisation Mondiale d'Endoscopie Digestive), use of a disposable sheath is generally desirable [5].

The primary aim of the present study was to test the possibility of decentralized colorectal cancer screening, in which such devices would be used in temporary flexible sigmoidoscopy screen-

ing centers. In addition, we compared the EndoSheath system with a conventional video endoscope with regard to polyp findings and patient satisfaction.

## Patients and Methods

### Participants

NORCCAP (Norwegian Colorectal Cancer Prevention) is an ongoing population-based flexible sigmoidoscopy screening trial for the prevention of colorectal cancer. A total of 21000 men and women, aged 50–64 years, living in two areas in South-East Norway, have been randomly drawn from the Population Registry and invited to attend for flexible sigmoidoscopy [6]. Two main screening centers have been established, one in the city of Oslo and one in Porsgrunn, Telemark county. In addition, a satellite screening center was established in the distant mountain area of Rjukan for 4 weeks each autumn in 1999 and 2000, to serve the population in these most outlying and rural parts of Telemark county. The satellite center was to be completely self-supported. All the equipment needed to carry out flexible sigmoidoscopy screening was moved from one of the main centers, except for an endoscope washing machine (for cleaning of the conventional endoscopes), which was provided by the local hospital. All endoscopists and staff working in the satellite center were recruited from the main screening centers.

### Interventions

A total of 226 consecutive participants attending for flexible sigmoidoscopy at the satellite center were randomly assigned to procedures using either a conventional 140-cm video colonoscope (Olympus 140/VI; Olympus Europa, Hamburg, Germany) or the 60-cm fiberoptic sigmoidoscope system with disposable sheaths (SS-F32/S-F100 EndoSheath; Vision Sciences, Natick, Massachusetts, USA). With the exception of the control wheels, the reusable core of the EndoSheath endoscope is covered by a disposable sheath to protect working surfaces from contamination. Air, water and biopsy channels are incorporated in the sheath. The sheath is to be discarded after each examination to provide every patient with a sterile endoscope.

The sequence of participants for flexible sigmoidoscopy was randomly allocated by the Population Registry. Allocation of participants to one of the two treatment groups was generated by randomization at the screening center. Bowel cleansing was limited to a 240-ml Sorbitol enema (Klyx; Ferring, Copenhagen, Denmark), administered on attendance. Three experienced endoscopists (who had done more than 1000 colonoscopies each) performed all the examinations. No sedation was used. To adjust for the different lengths of the endoscopes, patients in the standard colonoscope group with examinations beyond 60 cm were excluded from analysis.

Participant and procedure characteristics, such as age, gender, examination time, depth of insertion and quality of bowel preparation, were recorded by the endoscopist immediately after the procedure. Depth of insertion was defined as the minimum length inserted when the tip of the endoscope would start to retract on withdrawal. Good or adequate bowel cleansing was defined as absence of feces at least distal to the descending sigmoid junction. Number, size, and histological diagnosis of all detected

polyps was recorded. The term “polyp” is defined as any circumscribed protruding or flat lesion of the mucosa. According to the NORCCAP protocol, tissue samples for histological evaluation were taken from all detected polyps, using a disposable biopsy forceps (Radial Jaw 3, Boston Scientific, Watertown, Massachusetts, USA). The term “adenoma” is defined histologically as a lesion showing a certain degree of dysplasia (mild, moderate, or severe).

Questionnaires asking for overall satisfaction with the procedure (yes/no) and discomfort during the examination (verbal rating scale containing four alternatives for discomfort: none, slight, moderate, or severe) were handed out to all participants immediately after the procedure. The questionnaires were to be filled in on the following day and returned by mail.

### Statistics

To compare the two groups, the chi-squared test was used for categorical data and the two-sample *t*-test for continuous data. For statistical analyses, SPSS 10.0 (SPSS, Chicago, Illinois, USA) was used. Statistical significance was defined as  $P < 0.05$  using two-tailed tests.

### Ethics

The present study is part of the NORCCAP trial. The regional ethics committee approved the NORCCAP protocol. Informed written consent was obtained from all participants before they entered the study.

With regard to funding, no conflicts of interest exist. All equipment was purchased, without any donation. None of the authors are linked to any of the companies involved.

## Results

A total of 226 patients were randomly allocated and examined, with 113 in each arm of the study. In the standard colonoscope group, 26 patients were examined beyond the 60-cm level. These patients were excluded, leaving 87 individuals eligible for analysis compared with 113 in the EndoSheath group.

No differences were observed between the groups regarding age and gender. The mean age was 58.5 years in both groups, and the proportions of women were 53% (EndoSheath group) and 56% (standard colonoscope group). The depth of insertion was slightly greater when the EndoSheath was used (Table 1). The examination was quicker when the standard instrument was used (Table 1). The quality of bowel preparation was judged as good or adequate more frequently in the EndoSheath group compared with the standard group ( $P < 0.001$ ; Table 1). The three trial endoscopists performed 110, 66 and 24 examinations, respectively. More patients with polyps and adenomas were identified in the standard colonoscope group compared with the EndoSheath group, although statistical significance was reached only for patients with polyps (Table 2).

Out of 200 participants, 185 (92%) returned the questionnaire (102 [90%] in the EndoSheath group and 83 [95%] in the standard colonoscope group). Among the respondents, 173 patients (94%) were generally satisfied, and 180 (98%) would recommend the

Table 1 Examination characteristics in the two treatment groups

	EndoSheath (n = 113)	Standard colonoscope (n = 87)	P-value (95% CI for difference)
Examination time, mean ± SD, min	6.6 ± 2.5	5.5 ± 2.2	< 0.01 (0.4; 1.8)
Depth of insertion, mean ± SC, cm	43.5 ± 12	40 ± 12	0.05 (– 0.004; 6.7)
Quality of bowel preparation, no. of participants (%)			
Good or adequate	107 (95%)	66 (76%)	< 0.001
Partly poor or generally poor	6 (5%)	21 (24%)	

SD, standard deviation; CI, confidence interval.

Table 2 Detection rates for polyps and adenomas in the two treatment groups

	EndoSheath (n = 113)		Standard colonoscope (n = 87)		P
	n	%	n	%	
Patients with polyps	48	42	55	63	0.005
Patients with adenomas	14	12	19	22	0.07
Patients with polyps ± 5 mm	14	12	13	15	0.6
Patients with adenomas ± 5 mm	9	8	12	14	0.18

procedure to others, with no differences between the groups. The vast majority of all patients reported no discomfort (78 [76%] in the EndoSheath group, and 62 [75%] in the standard colonoscope group), or only slight discomfort (17 [17%] in the EndoSheath group, and 15 [18%] in the standard group), with no difference between the groups. Seven patients (7%) in the EndoSheath group reported moderate discomfort, compared with six (7%) in the standard group. None of the individuals examined reported severe discomfort during the examination.

The EndoSheath system worked adequately during the trial. However, difficulties were observed when inserting the biopsy forceps through the biopsy channel. Passage of the forceps through the distal part of the instrument was difficult with the tip fully flexed. For passage and subsequent withdrawal of the forceps, the tip of the endoscope had to be straightened. An advantage of the EndoSheath system is its stronger suction pump, allowing more improvement on any suboptimal bowel cleansing, when compared with the standard system.

By using the EndoSheath system, it was possible to move a completely self-supported flexible sigmoidoscopy screening unit by car from Porsgrunn to Rjukan (200 km), with two employees, and to be operational the same day.

## Discussion

Safety of the procedure, high examination quality, and acceptable cost-effectiveness are important requirements in population-based flexible sigmoidoscopy colorectal cancer screening.

Despite meticulous cleaning, following recommended guidelines, the transmission of infectious material cannot be completely

excluded when conventional endoscopes are used [7]. The use of disposable sheath systems minimizes this risk. Additionally, the time- and cost-intensive reprocessing, which is mandatory when using conventional reusable endoscopes, is not necessary with a disposable system. Thus, recently, the flexible sigmoidoscopy subcommittee of the OMED colorectal cancer screening committee concluded that a “disposable sheath would be generally desirable” [5]. Several trials have reported a significant decrease in reprocessing time, favoring the EndoSheath system [3, 4, 8]. However, in the only study published on the cost-effectiveness of the EndoSheath system compared with a conventional sigmoidoscope, the total costs were higher when using the EndoSheath (US \$47 vs. US \$33). This analysis was based on the relatively high costs of the sheath (US \$45) [3]. To our knowledge, no trials have been published which address the suitability for transport and diagnostic performance of a disposable sheath system compared with a standard system in colorectal cancer screening. The primary aim of the present study was to assess the feasibility of performing decentralized colorectal cancer screening using the EndoSheath system by establishment of a temporary colorectal cancer screening center.

We compared the 60-cm EndoSheath sigmoidoscopy with a conventional 140-cm colonoscope. For practical and economic reasons, the NORCCAP organization used colonoscopes only, both for flexible sigmoidoscopy and subsequent follow-up colonoscopy. Standard sigmoidoscopes were not available at the centers. To reduce bias due to the different ranges of the instruments, all examinations in which the endoscope had passed the 60-cm level were excluded from analysis. Nevertheless, the results may still be biased by the greater length of the available standard endoscope, which allows a longer reach before straightening and recording of polyp location level within 60 cm. However, if the 26 patients in the standard colonoscope group who had been ex-

amed beyond the 60-cm level were to be included, the results would not differ substantially from those presented.

The present trial showed that patient satisfaction and the degree of discomfort during flexible sigmoidoscopy were similar in the two groups. Thus, lower compliance for flexible sigmoidoscopy screening because of patient discomfort should not be a matter of concern when the EndoSheath system is used.

Maybe the most important advantage of the disposable system is its transportability. We were able to easily establish a temporary satellite screening unit, as the system does not require any large cleaning facilities and all the devices needed can be easily transported in a medium-sized car. It would have taken more than 2 hours' driving for people living in the remote parts of the screening area to get to the nearest main screening center. By establishing the satellite unit, we were able to maintain a high compliance rate also in those areas. Thus, the use of easily transportable disposable sheath systems, set up in temporary screening centers, may contribute to high attendance rates for colorectal cancer screening in outlying areas also. In rural countries in particular where endoscopy facilities are very distant, the use of the disposable sheath system could be crucial for the success of future colorectal cancer screening programmes.

Polyp and particularly adenoma detection is a major issue in endoscopic screening. Therefore, it is important to address the diagnostic performance of new instruments introduced to the market. This is the first study comparing the diagnostic yield of the EndoSheath system with that of a standard video colonoscopy. A statistically significantly lower polyp detection rate was observed when using the EndoSheath system, compared with the standard video instrument. It has been suggested that video instruments with their better imaging quality may be more likely to detect polyps than fiberoptic endoscopes [9,10]. There is nothing to indicate that use of the disposable sheath itself should contribute to poorer polyp detection rates. The lower detection rate observed may be due to the fiberoptic nature of the instrument rather than to the disposable sheath concept. Thus, development of a video version of a sheathed endoscope system is desirable.

In some endoscopy screening protocols, identification of an adenoma of less than 5 mm does not trigger any further action [11]. In the present study, numbers were too small to detect any differences in pick-up rates for adenomas greater than or equal to 5 mm, which may be the most relevant size.

The present study is to be regarded as a feasibility study. The numbers of patients in the two groups was determined by the circumstances at the satellite screening center where this study was performed. Here, only one endoscope washing machine was available. This would not have been sufficient to provide conventional endoscopes for all examinations. Moreover, using only conventional endoscopes, we would have had no back-up in case of breakdown of the single washing machine. No power calculation has been performed, because the primary aim of the present study (feasibility assessment) is not quantitative. Thus, follow-up trials with proper power calculations are needed to confirm our results regarding the diagnostic yield.

Although it is delivered in a sterile condition, it is unlikely that the EndoSheath is sterile when entering the patient, after it has been handled with unsterile gloves by the endoscopy assistant and endoscopist. Mayinger and co-workers addressed this problem [12]. In their study on the use of EndoSheath gastroscopes, microbiological swabs were taken from different parts of the insertion tube of the EndoSheath. Evaluation revealed contamination with apathogenic bacteria, commonly occurring in the environment in 16% (n=8) of cases. No contamination with pathogenic micro-organisms was found. In this trial, we did not evaluate possible sheath contamination from handling the endoscope.

In agreement with others, the endoscopists in the present trial stated that they would favor a video system over a fiberoptic system [4]. One reason for this is the better ergonomics of video endoscopes, which reduce the risk of work-related health problems. Additionally, good hygiene should also be maintained for the endoscopist who is working with disposable endoscopes. In our opinion it is not acceptable that the face of the endoscopist has to be close to the anus of the patient when a 60-cm EndoSheath fiberscope is used. Hygienic practice in endoscopy should take account of the needs of both the patient and the endoscopist. We therefore agree with others in encouraging instrument manufacturers to develop video versions of disposable sheath-based instruments [5]. The combination of high-resolution video imaging with the advantages of the disposable sheath would be a big step forward in gastrointestinal endoscopy.

In summary, the disposable EndoSheath system has been shown to be a practicable tool in the present population-based colorectal cancer screening study, providing good patient satisfaction. Decentralized screening was easily established when the EndoSheath system was used. However, less polyp findings were observed when compared with a standard video endoscope, probably due to the lower optical resolution of the fiberoptic system. Additionally, concern has been expressed about possible disadvantages for the endoscopist when using fiberoptic sigmoidoscopes. In the future, disposable video endoscope systems might be highly appreciated.

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