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Participation in clinical trials increases the detection of pre-malignant lesions during colonoscopy

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- Authors' Contributions

AOF was responsible for the study design, data collection and analysis and manuscript writting

MPCS collaborated in the study design analysis and manuscript critical review

CG and BM collaborated in data collection and manuscript critical review

LG collaborated in the study design and manuscript critical review

MC collaborated in the study design and manuscript critical review

JC collaborated in the study design and manuscript critical review

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ABSTRACT

Background: Colorectal adenoma detection has been associated with cancer prevention effectiveness. Clinical trials have been conceived to determine the role of several interventions to increase the detection of pre-malignant lesions. We hypothesized that colonoscopy in the setting of such trials have higher pre-malignant lesion detection rates.

Methods: We performed a cross-sectional study comparing the detection of pre-malignant lesions in 147 randomly sampled non-research colonoscopies and 294 from the control groups of two prospective trials. We included outpatients aged 40-79 who had no personal history of CRC.

Results: Baseline characteristics were similar between the two groups. The pre-malignant lesion detection rate in the trial vs control group was 65.6% vs 44.2% (OR 2.411; 95% CI 1.608-3.614; p<0.001), the polyp detection rate was 73.8% vs 59.9% (OR 1.889; 95% CI 1.242-2.876; p=0.003), the adenoma detection rate was 62.6% vs 44.2% (OR 2.110; 95% CI 1.411-3.155; p<0.001) and the sessile serrated lesion detection rate was 17% vs 4.1% (OR 4.816; 95% CI 2.014-11.515; p<0.001). The mean number of pre-malignant and sessile serrated lesions was 1.70 vs 1.06 (p=0.002) and 0.32 vs 0.06 (p=0.001) lesions per colonoscopy. In a multivariate analysis with each single potential confounder, there was no significant change in any of the study outcomes.

Conclusions: Patients involved in colonoscopy trials may benefit from higher quality examinations, as shown by the higher detection rates. Institutions should consider supporting clinical research in colonoscopy as a simple means to improve colonoscopy quality and colorectal cancer prevention.

KEY WORDS: Colonoscopy. Quality. Research. Adenoma.

INTRODUCTION

Colorectal cancer is one of the leading cancers and accounts for over 860,000 deaths worldwide.[1] Colonoscopy has been shown to decrease both CRC incidence[2] and mortality by detecting and allowing the removal of adenomas.[3-8] The magnitude of this effect is related to the detection rate of pre-malignant colorectal lesions, especially the adenoma detection rate (ADR), which is highly variable.[9-13] Sessile serrated lesions are another subset of colorectal lesions that also harbour malignant potential[14] and are harder to detect, suffering from even higher variability between endoscopists[15].

Quality in colonoscopy is therefore a major issue in digestive endoscopy, with significant efforts being made by international societies such as the European Society of Gastrointestinal Endoscopy (ESGE)[16] and the American Society of Gastrointestinal Endoscopy (ASGE)[17] to set the standards. Both societies set the adenoma detection rate as one of the most important indicators of colonoscopy quality.

In the last few decades, endoscopists and researchers have tried to improve the detection of pre-malignant lesions through technological advancements, such as high-definition imaging, electronic chromoendoscopy,[18] wide view lenses[19], devices[20,21] or artificial intelligence,[22] as well as through simple interventions such as educational sessions, feedback[23], benchmarking, changing the patient position[24], performing the colonoscopy underwater[25] or administering butylscopolamine[26] or simethicone[27]. Several of the trials of these interventions reported ADRs above 50% in some groups, including in the “placebo” arms.[18,28,29] These results are well over the proposed threshold of 25% and above our department’s own indicators with an ADR of 36% and a Sessile Serrated Lesion detection of 1%,

as published in 2017.[30]

We hypothesized that patients whose colonoscopy was performed in a clinical trial setting may have higher pre-malignant lesion detection (adenomas and SSL) than patients under routine care. To our knowledge, there are no data to assess the impact of clinical research projects on quality performance in endoscopy units.

Our aim was to assess the colonoscopy quality indicators in patients who were included in a control group for an endoscopic clinical trial at our institution and compare them with a sample group from the same institution.

MATERIALS AND METHODS

Patients and Setting

We conducted a retrospective cross-sectional study comparing a colonoscopies performed in a clinical trial setting and a group of "routine" colonoscopies.

Inclusion Criteria

The inclusion criteria for the control group were similar to those for the trials with registered protocols, which included patients aged 40 to 79 undergoing outpatient colonoscopies. Bowel preparation quality was determined with the Boston Bowel Preparation Score (BBPS) and deemed adequate if at least 2 points were reached in each segment. One of the trials excluded patients with one or more segment with a BBPS below 2, but the other trial randomized patients before the colonoscopy preparation, and preparation quality was not an exclusion criterion. To control for bowel preparation quality, we decided to include only cases with BBPS scores of at least 2 in each segment.

Patients with polyposis syndromes, primary sclerosing cholangitis, inflammatory bowel disease, a personal history of colorectal cancer or surgery or failure to reach the caecum were excluded.

All patients provided informed written consent before their procedures and a specific consent form was completed for those who were participants in the trials. The Institutional

Review Board approved the collection of data for this observational study.

Case Selection

Routine colonoscopies for the control group were randomly selected from our department's database of routine colonoscopies. For the "trial group", colonoscopies were randomly selected from the control arms of two trials performed at our institution (NCT03856957 and NCT02876133). A computer-generated algorithm was created for case selection. Cases were selected from our 2019 colonoscopy database of outpatient colonoscopies performed in subjects aged 40-79 years during 2019. If the cases did not meet the study criteria, they were excluded from the selection.

In the clinical trials we defined a cut-off of 300 colonoscopies to allow the participation of an endoscopist which allowed the participation of senior endoscopists and two residents. In the control group colonoscopies from nine senior endoscopists and the same two "senior" residents were included.

Study Outcomes

The primary outcome was the pre-malignant lesion detection rate, and the secondary outcomes were the polyp detection rate**,** ADR, sessile serrated lesion (SSL) detection rate, number of pre-malignant lesions, adenomas and SSL per colonoscopy and number of serrated lesions >9 mm.

Sample Size Calculation and Statistical Analysis

We decided to use a 2:1 trial group to control group ratio since we already had the trial database with over 1000 cases and calculated a sample size of 294 trial colonoscopies and 147 control colonoscopies to have 80% power to detect a difference based on our own preliminary data. For the control group, we assumed a 36% ADR from our own series,[30] and for the study group, we assumed a 60% ADR based on our Endocuff trial (NCT03856957) and the recently published ADENOMA trial, an RCT also studying Endocuff.[31]

To determine the "clinical trial" effect more accurately, we adjusted the study endpoints for age, sex, bowel preparation, sedation depth and personal history of polyps using multivariate logistic regression analysis. We adjusted individually for each confounder and then tested all variables in a single model.

The mean and standard deviation are shown for continuous variables with a normal distribution. These were compared using an independent t-test. Categorical variables are presented as proportions (%) and compared with the Fisher's exact or χ^2 test. Logistic regression was used to determine the effect estimates, which are presented as odds ratios and 95% confidence intervals. Missing data were resolved by pairwise deletion. Statistical analysis was conducted with the SPSS software package, version 21 (Statistical Package for the Social Sciences, IBM Corporation, Armonk, NY, USA).

The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee.

RESULTS

Patients

A total of 441 colonoscopies were selected, of which 294 were included in the clinical trial group and 147 were included in the control group. Baseline characteristics are depicted in Table 1.

Most baseline characteristics (age, sex, colorectal cancer family history and personal history of polyps) were similar between the two groups. Sedation was significantly different because in the clinical trials group, all cases were performed under deep sedation.

Outcomes

The study outcomes are summarized in Table 2. All lesion types were more frequently detected in the trial group. The pre-malignant lesion detection rate was 65.6% vs 44.2% (OR 2.411; 95% CI 1.608-3.614; p<0.001), the polyp detection rate was 73.8% vs 59.9% (OR 1.889; 95% CI 1.242-2.876; p=0.003), the adenoma detection rate was 62.6% vs 44.2% (OR 2.110; 95% CI

1.411-3.155; p<0.001) and the sessile serrated lesion detection rate was 17% vs 4.1% (OR 4.816; 95% CI 2.014-11.515; p<0.001). The mean number of pre-malignant and sessile serrated lesions was higher in the research group, with 1.70 vs 1.06, p=0.002 and 0.32 vs 0.06 (p=0.001) lesions per colonoscopy, respectively. The mean number of lesions (overall) was not significantly different between the groups.

In a multivariate analysis with each single potential confounder, there was no significant change in any of the study outcomes.

The effects on the main quality indicators (ADR, SSL and pre-malignant lesion detection rate) were adjusted in a single model including age, sex, sedation depth and history of polyps (Table 3). In this model, the detection odds ratios were kept at a significant level for pre-malignant lesions (OR 2.316; 95% CI 1.307-4.102; p=0.004), SSL detection rate (OR 6.810 95% IC 1.588-29.210; p=0.010) and ADR (OR 2.002; 95% IC 1.129-3.549; p=0.018).

DISCUSSION

Our study compared the main colonoscopy quality indicators in two separate groups comprising 441 colonoscopies performed at our institution. In one group, patients underwent routine colonoscopy and were not participants in any clinical trial. They were later selected, and their data were retrospectively recorded without any prior knowledge of group membership by the intervening clinical team. In the other group, we had colonoscopies that were selected from the control groups of clinical trials, where the clinical team was aware that the outcomes would be systematically recorded and analysed.

In this study, we observed higher ADR, SSLDR and lesion detection in colonoscopies that were performed in a clinical trial setting. The results showed high lesion detection rates in both groups; these rates were well above the thresholds proposed by the leading endoscopy societies (ESGE and ASGE).

CRC is a leading cancer in the Western world. Effectively increasing the ADR by just 1% has been shown to decrease CRC incidence by 3%; however, there is remarkable inter-endoscopist variability in this metric, with rates ranging between 7.4% and 52.5%.[9] There have been significant efforts to establish quality indicators to guide endoscopy practitioners in

their quest to maximize the effectiveness of colorectal cancer screening, and although it can be argued, currently, the best indicators of quality are probably adenoma detection rate and mean adenomas per colonoscopy.[16,17] The ADR is the most studied and widely accepted quality measure,[17,32] but the mean adenoma number may be more discriminative and more resistant to gaming. The SSLDR suffers from even more variability between endoscopists, as these lesions may be harder to detect than conventional adenomas.[33,34] In one study, this variability was 20-fold, ranging from 0.3% to 6.7% among endoscopists from the same group.[34] Furthermore, evidence is also increasing to support sessile serrated lesion detection as an important quality metric, especially for the proximal colon due to their association with interval cancer due to missed lesions.[35,36]

Studies have shown that when endoscopists are audited, publicly report their indicators and receive feedback, their performance increases up to 45%.[37-39] This type of intervention, if effective, is potentially more cost-effective than using artificial intelligence equipment or single-use devices such as the third eye or even the Endocuff cap. In our department, we have been interested in determining our own quality indicators and published them as a benchmark reference.[30] We have also performed several trials on colonoscopy quality in the last few years,[40] one of which is currently recruiting participants (NCT02876133). This study was initiated after we noticed high rates of detection in these trials.

We acknowledge some important limitations inherent to the study design. The endoscopists in the trial group were not aware of this particular study, but they were not blinded to the research protocols as they were aware of the trial in which they were involved. The control group data were retrospectively collected; thus, some potentially relevant confounders, such as family history of CRC or withdrawal time, were not accounted for, as the data were not available. Only in 2019 did the electronic reporting system start to automatically record the withdrawal time. Moreover, the groups were not properly matched even though the baseline characteristics were quite similar. We tried to overcome that limitation by adjusting the outcomes for known potential confounders such as age, sex and sedation. Bowel preparation was controlled with by including only colonoscopies with at least 2 BBPS points in each bowel segment. Furthermore, with the multivariate analysis, we were able to see an

association of age, male sex and personal history of polyps with higher lesion detection. The model also allows us to confirm that the association of being in a trial with higher lesion detection rates is independent of age, sex, personal history of polyps and sedation depth.

The strengths of our study include being the first to analyse the impact of participating in an endoscopy trial and showing a significant benefit of participating in clinical trials. There have been a few other studies on the impact of research in other areas, such as cancer[41,42] and women's health,[43] although these studies have had conflicting results.[44]

In conclusion, this study showed, for the first time, that being involved in research, specifically in colonoscopy clinical trials, may lead to a significant improvement in the detection of pre-malignant lesionseven if the subjects are allocated to control/placebo groups. Should our results be confirmed among other centres/study groups it could help to foster clinical research in colonoscopy quality with the added clinical benefit of decreasing CRC burden.

CONFLICTS OF INTEREST

The authors have no conflict of interest to declare.

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TABLES

Table 1. Baseline characteristics of the study population

	Trial Group (n=294)	Control Group (n=147)	p-value
Age, y	62.16 (9.81)	61.97 (9.97)	0.802
Male sex, n (%)	161 (54.8)	70 (47.6)	0.157
CRC family history, n (%)	65 (22.4)	26 (18.1)	0.294
Previous colonoscopy, n (%)	133 (45.4)	74 (50.7)	0.295
Personal history of polyps, n (%)	87 (29.7)	44 (30.3)	0.888
Deep sedation, n (%)	294 (100)	65 (44.2)	0.001
Conscious sedation, n (%)		62 (42.2)	
No sedation, n (%)		20 (13.6)	
Indication			0.050
• Screening	53 (17.3)	24 (16.3)	
• FOBT/diagnostic	214 (69.9)	89 (60.5)	
• Surveillance	39 (12.7)	34 (23.1)	

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Table 2. Primary and secondary outcomes

	Trial Group (n=316)	Control Group (n=182)	p-value
Mean polyp number (se)	2.21 (0.14)	1.74 (0.12)	0.062
Mean pre-malignant lesion number (se)	1.70 (0.12)	1.06 (0.16)	0.002
Mean adenoma number (se)	1.38 (0.10)	1.00 (0.15)	0.032
Mean SSL number (se)	0.32 (0.02)	0.06 (0.02)	0.001
Mean number of serrated lesions >9 mm (se)	0.06 (0.019)	0.02 (0.015)	0.158
Polyp detection rate, %	73.8	59.9	0.003
Pre-malignant lesion detection rate, %	65.6	44.2	<0.001
Adenoma detection rate, %	62.6	44.2	0.0002
Sessile serrated lesion detection rate, %	17.0	4.1	0.0001

Table 3. Logistic regression to control for potential confounders for pre-malignant lesion detection

Variables	Odds ratio	Robust standard errors	p
Trial group	2.316 (1.307-4.102)	0.292	0.004***
Age	1.043 (1.021-1.065)	0.011	0.0001***
Sex:			
female	0.478 (0.315-0.725)	0.213	0.001***
Sedation:			
no	0.892 (0.447-1.779)	0.352	0.745
Polyp history:			
yes	1.610 (1.005-2.578)	0.240	0.048*
Wald χ^2 test	*54.436****		
Pseudo R^2	*0.158*		

*** denote p-values < 0.01, ** denotes p-value < 0.05.