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One or two operator technique and quality performance of colonoscopy: A randomised controlled trial☆

Silvia Paggi, Emanuele Rondonotti, Arnaldo Amato, Alessandra Baccarin, Giancarlo Spinzi, Franco Radaelli*

Division of Gastroenterology, Valduce Hospital, Como, Italy

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ABSTRACT

Background: The two-operator technique for colonoscopy, with the endoscopy assistant actively advancing and withdrawing the scope, is still commonly practiced in Europe. As uncontrolled data has suggested that the one-operator technique is associated with a higher adenoma detection rate, we tested the hypothesis that the two-operator-technique can achieve comparable performances in terms of adenoma detection.
Methods: Non-inferiority trial in which consecutive adult outpatients were randomised to undergo colonoscopy by one (one-operator) or by four endoscopists. Each performed half the procedures by one-operator and half by two-operator technique independently of routine clinical practice. Main outcome measure was adenoma detection rate.
Results: 352 subjects (49% males, mean age 60 ± 12.1 years) were randomised to one ($n = 176$) or to two-operator technique ($n = 176$) colonoscopy. No significant differences were found in adenoma detection (33% vs. 30.7%, $p = 0.65$), or cecal intubation rate, procedure times, and patient tolerability. No differences were found in the subgroup analysis according to routinely adopted colonoscopy technique.
Conclusions: This study does not confirm a higher adenoma detection rate for one-operator technique colonoscopy. Changing current practice to improve adenoma detection rate for endoscopists routinely using two-operator technique is not warranted.

1. Introduction

The adenoma detection rate (ADR) is now regarded as the main quality indicator for colonoscopy, given its significant correlation with core colonoscopy outcomes, such as interval cancer [1]. A wide variation of adenoma detection has been reported among endoscopists [2], and this might be related to differences in procedure performance. Although attention was mainly focused on the withdrawal phase of the examination, as concerns time or technique for mucosal inspection [3–5], the impact of other technical aspects on adenoma detection has been less explored.

Colonoscopy is usually performed with the 1-operator technique (1OP); in this method, the endoscopist's right hand remains on the colonoscope shaft, with or without intermittent removal to adjust the right-left knob, and steering is accomplished primarily with the use of the up-down knob alone accompanied with right-left torque of the colonoscope shaft. Another option is the two-operator technique (2OP); in this case, the endoscopy assistant handles the scope shaft during the insertion and withdrawal phases, and both the endoscopist's hands are used to move the knobs in order to direct the scope. Despite the 1OP technique is recommended by professional societies and represents standard practice in the United States [6], the other option is still commonly adopted in some European and Eastern Countries [7–9]. In a recent Italian colonoscopy survey [10], about half of the procedures were performed with the assistance of the nurse to hold the scope. Data from GastroNet quality assurance program in Norway reported that 2OP technique was practiced by about 20% of endoscopists. According to this survey, the 1OP technique seems to be associated with a higher adenoma detection rate [7]; other observational studies were not consistent with this finding [8,9]. If a higher ADR for 1OP technique was confirmed by a randomised controlled trial, this would represent a reason to force endoscopists performing 2OP technique to change their practice. Therefore, we designed

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* Corresponding author at: Divisione di Gastroenterologia, Ospedale Valduce, Via Dante 11, 22100 Como, Italy. Tel.: +39 03132400; fax: +39 031308047.
E-mail address: francoradaelli@virgilio.it (F. Radaelli).

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a randomised controlled trial to evaluate 1OP versus 2OP technique in terms of adenoma detection.

2. Materials and methods

This prospective, randomised, single-blind study was conducted in a community hospital. The protocol was approved by local Ethics Committee; written informed consent was obtained from all participants. The study was registered at Clinicaltrials.gov (NCT01816126).

2.1. Study population

All consecutive 18–80 year-old individuals referred to our Gastroenterology Unit for outpatient colonoscopy were considered eligible. Exclusion criteria were previous colorectal resection, urgent colonoscopy, inadequate bowel preparation, bi-directional endoscopy and refusal or inability to provide informed consent.

2.2. Study procedure

All procedures were performed under conscious sedation (intravenous midazolam plus meperidine) by four board-certified gastroenterologists, performing at least 300 colonoscopies/year in the last 5 years and with an ADR, unrestricted to screening procedures, exceeding 30%. In routine clinical practice, two of them usually perform colonoscopy by the 1OP technique (*A.A.*, *E.R.*), whereas the other two by the 2OP technique (*S.P.*, *F.R.*). The 1OP technique endoscopists were both 39 years of age and were board-certified gastroenterologists since 2003; the 2OP technique endoscopists were 35 and 45 years of age and were Board-certified Gastroenterologists since 2006 and 1996, respectively. All the four operators were taught 1OP technique during endoscopy training, then the 2OP endoscopists modified their technique according to Hospital routine practice.

However, before study initiation each endoscopist underwent a 1-month preliminary training, in order to get acquainted with the technique not usually applied. All endoscopy assistants had an experience of at least 3 years of everyday colonoscopy practice. For all the study procedures, high-resolution wide-angle, adult videocolonoscopes (Olympus HD 180 series, Olympus Corp, Hamburg, Germany) were used. Colon preparation was accomplished by using low-volume polyethylene glycol solutions, provided by a split dose or previous day regimen according to colonoscopy scheduled time.

Before colonoscopy initiation, patients were randomly assigned to 1OP or 2OP procedure; 1:1 randomisation in blocks of four with stratification of investigators was obtained by means of a computer-generated random number sequence; allocation was concealed and kept in a sealed envelope. In order to ensure patient blinding, randomisation was made after the administration of sedation/analgesia. The success of cecal intubation was verified by the endoscopist and the GI assistant by the identification of the ileocecal valve and the appendix orifice and pictures of cecal landmarks were taken. The quality of bowel cleansing was rated by the endoscopist as excellent, good, sufficient and inadequate, according to the validated Aronchik scale [11]. During the withdrawal phase and mucosal inspection, the endoscopist carefully explored the whole colon, from the cecum to the rectum. A withdrawal time >6 min for diagnostic procedures was recommended. In order to avoid the bias of a potential less active involvement in the procedures performed by 1OP technique of endoscopy assistants, whose participation to mucosal inspection increases ADR [12], they were invited to continuously check the screen through the entire duration of the procedure, regardless of the technique used.

Whenever the endoscopy assistants identified a polyp missed by the endoscopist, the colonic segment (right, transverse or left) was re-explored "back-to-back". No attempt was made to systematically detect polyps during insertion; all polyps were relocated and removed during the withdrawal phase and sent to pathology in separated jars. Histologic features were used to discriminate non-adenomatous from adenomatous lesions, and endoscopic and histologic features to categorize adenomas into non-advanced or advanced (diameter $\geq$1 cm and/or villous component of at least 25%, and/or high grade dysplasia). Due to their malignant potential, sessile serrated lesions were considered as adenomas for the purpose of the study.

The following procedural data were recorded: cecal intubation, polyp size and morphology (according to Paris classification) [13], insertion and withdrawal times, medication doses (midazolam and meperidine). In case of technical difficulty, the endoscopist had the chance to switch from 1OP to 2OP technique or vice versa; the number of switches was recorded. Moreover, examination tolerability was assessed during the examination by the endoscopy assistant as excellent (the patient did not moan for pain or discomfort, no change in vital signs occurred), good (the patient occasionally complained for pain or discomfort, no change in vital signs occurred), fair (the patient complained for prolonged pain or discomfort, a change in vital signs occurred) or poor (the patient asked for procedure interruption or staff judged unsafe to proceed with the procedure due to significant risks). Examination tolerability was also evaluated by patients by a self-administered questionnaire, given them before discharge: it was rated as excellent (no symptoms during the procedure), good (transient pain or discomfort), fair (persistent or intense pain) or poor (unbearable procedure).

2.3. Study end points

The primary end-point of this non-inferiority trial was to evaluate whether the routine use of 2OP technique provides an ADR (proportion of participants with at least one adenoma), comparable with 1OP technique.

Secondary outcome measures included: (a) the number of adenomas per subject, defined as the total number of detected adenomas in each group divided by the total number of participants; (b) the advanced adenoma detection rate, defined as the proportion of participants with at least one advanced adenoma; (c) the unadjusted cecal intubation rate, defined as the proportion of patients in which the cecum was reached (no adjustment made for poor bowel preparation or strictures); (d) cecal insertion time; (e) withdrawal time for diagnostic procedures; (f) mean medication doses (midazolam/meperidine), (g) procedure tolerability, as assessed by either the endoscopy assistant or the patient.

A subgroup analysis was also planned to evaluate study main outcome measures according to colonoscopy routine practice of endoscopists. At this purpose they were divided in two groups: one including the two endoscopists routinely performing 1OP technique (*A.A.*, *E.R.*), and the other one including the two endoscopists routinely performing 2OP technique (*S.P.*, *F.R.*).

2.4. Sample size and statistical analysis

In our Hospital, different endoscopists routinely practice 1OP or 2OP technique, according to their formal training; no difference in terms of adenoma detection and other quality measures has been observed in the internal quality assurance program. The sample size of present non-inferiority trial was calculated for the primary outcome variable, by considering a baseline ADR for 1OP endoscopists of 32%, which was derived from historical internal quality assurance program [14]. Taking into account an alpha level of 0.05, with beta 0.2, delta 0.05 and $n1/n2 = 1$, 174 subjects had to be included in each arm. Each of the four endoscopists was supposed to