



Patients' experience of screening CT colonography with reduced and full bowel preparation in a randomised trial

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Received: 18 July 2018 / Revised: 10 September 2018 / Accepted: 27 September 2018 / Published online: 6 November 2018
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Abstract

Objectives To assess patients' experience of bowel preparation and procedure for screening CT colonography with reduced (r-CTC) and full cathartic preparation (f-CTC) that showed similar detection rate for advanced neoplasia in a randomised trial.

Methods Six hundred seventy-four subjects undergoing r-CTC and 612 undergoing f-CTC in the SAVE trial were asked to complete two pre-examination questionnaires—(1) Life Orientation Test - Revised (LOT-R) assessing optimism and (2) bowel preparation questionnaire—and a post-examination questionnaire evaluating overall experience of CTC screening test. Items were analysed with chi-square and *t* test separately and pooled.

Results LOT-R was completed by 529 (78%) of r-CTC and by 462 (75%) of f-CTC participants and bowel preparation questionnaire by 531 (79%) subjects in the r-CTC group and by 465 (76%) in the f-CTC group. Post-examination questionnaire was completed by 525 (78%) subjects in the r-CTC group and by 453 (74%) in the f-CTC group. LOT-R average score was not different between r-CTC (14.27 ± 3.66) and f-CTC (14.54 ± 3.35) ($p = 0.22$). In bowel preparation questionnaire, 88% of r-CTC subjects reported no preparation-related symptoms as compared to 70% of f-CTC subjects ($p < 0.001$). No interference of bowel preparation with daily activities was reported in 80% of subjects in the r-CTC group as compared to 53% of subjects in the f-CTC group ($p < 0.001$). In post-examination questionnaire, average scores for discomfort of the procedure were not significantly different between r-CTC (3.53 ± 0.04) and f-CTC (3.59 ± 0.04) groups ($p = 0.84$).

Conclusions Reduced bowel preparation is better tolerated than full preparation for screening CT colonography.

Key Points

- Reduced bowel preparation is better tolerated than full preparation for screening CT colonography.
- Procedure-related discomfort of screening CT colonography is not influenced by bowel preparation.
- Males tolerate bowel preparation and CT colonography screening procedure better than females.

Keywords CT colonography · Virtual colonoscopy · Questionnaire

Abbreviations

CI Confidence interval
CRC Colorectal cancer

CTC CT colonography
f-CTC Full cathartic preparation CT colonography
FIT Faecal immunochemical test

Electronic supplementary material The online version of this article (<https://doi.org/10.1007/s00330-018-5808-1>) contains supplementary material, which is available to authorized users.

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LOT-R	Life Orientation Test - Revised
OC	Optical colonoscopy
OR	Odds ratio
r-CTC	Reduced cathartic preparation CT colonography

Introduction

CT colonography (CTC) is a radiological examination of the colon capable to detect colorectal cancer (CRC) and polyps. CTC has been recommended for opportunistic screening of CRC by the US Preventive Service Task Force, by the American Cancer Society, and by the European Society of Gastrointestinal Endoscopy jointly with the European Society of Gastrointestinal and Abdominal Radiology [1–3]. The potential role of CTC as a primary test for population screening of CRC has been evaluated in three randomised trials in Europe, one in the Netherlands, in comparison with optical colonoscopy (OC) (COCOS) [4], and two in Italy, one in comparison with flexible sigmoidoscopy (PROTEUS) [5] and the other in comparison with faecal immunochemical test (FIT) and OC (SAVE) [6].

The two key factors that determine the effectiveness of a screening test for CRC in an organised programme are the participation of target population and the diagnostic yield for advanced neoplasia (i.e. cancer and advanced adenoma). The European trials showed that CTC offered a significant advantage in terms of participation rate (range 25–34%) as compared to OC (range 15–22%), whereas its detection rate for advanced neoplasia (range 5.1–6.1%) was moderately lower than that of OC (range 7.2–8.7%) [7]. However, in the COCOS trial once the follow-up and removal of 6–9 mm polyps was considered, CTC actually detected as much advanced neoplasia as OC [8]. The participation rate for CTC was much lower than that for FIT (50%), which is a simple and home feasible test with lower detection rate [6].

Reasons for non-attendance to CRC screening include psychological, ethnical, and socio-economical factors as well as organisational barriers [9–11]. CTC, like colonoscopy, requires a bowel preparation, which was one of the most frequent reasons for non-attendance to screening CTC in the COCOS and PROTEUS randomised trials [12, 13]. However, CTC can be efficiently performed with reduced laxative preparations, retaining a high sensitivity and specificity for lesions ≥ 10 mm [6, 14, 15]. In the SAVE trial, the participation rate to reduced cathartic preparation CTC (r-CTC) was significantly higher than that to full preparation CTC (f-CTC) (28.1% vs. 25.2%), but no significant differences in the detection rate for advanced neoplasia were observed (5.5% vs. 4.9%). These data suggest a presumed positive effect of reduced bowel preparation on compliance to screening CTC, without detriment in the detection rate. However, it is to be ascertained if the increase in participation

rate to screening CTC observed for reduced preparations is really accompanied by a better patient tolerability of such preparations. Herein, we compared patient experience of bowel preparation and whole screening procedure between r-CTC and f-CTC in the context of a randomised trial (SAVE study).

Materials and methods

Study design

Data for the present report were collected within the SAVE study, a single-centre, randomised trial comparing four primary tests for population screening of CRC conducted in Florence, Italy. Sixteen thousand eighty-seven subjects aged 54–65 years, who had never been screened for CRC, were randomly assigned (8:2.5:2.5:1) and invited by mail to one of four interventions: (1) biennial FIT for three rounds; (2) single round of r-CTC; (3) single round of f-CTC; (4) single round of OC. CTC invitees had to make an appointment by phone or e-mail for a pre-examination consultation. During the consultation, they were informed about bowel preparation and CTC execution, and then they were scheduled for the test. Detailed study protocol is reported elsewhere [16]. The trial was approved by the Ethical Committee of the Local Health Unit of Florence (number 432/2010) and registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT01651624). All participants gave their written informed consent.

The primary endpoint of the present study was the tolerability of bowel preparation for screening CTC whereas the secondary endpoint was tolerability of the screening CTC procedure as assessed by specific questionnaires in the SAVE trial.

In the radiology department, after registration for CTC and before administration of iodinated oral contrast media for faecal tagging, two questionnaires were administered to all participants of r-CTC and f-CTC groups: (1) the Life Orientation Test - Revised (LOT-R) to assess psychological attitude of the subjects; (2) one questionnaire to assess specifically subject's experience of bowel preparation. Immediately after CTC execution, a post-examination questionnaire evaluating the whole screening procedure was administered to participants of both groups.

Bowel preparation and CTC execution

For both r-CTC and f-CTC groups, a 3-day low-fibre diet was required. Preparation for r-CTC consisted in drinking a glass of water with 13.8 g of macrogol 3350 (Movicol, Norgine) at the three main meals for 3 days before the examination. Preparation for f-CTC consisted in assuming a 2-l solution of polyetilenglycole (Moviprep, Norgine) followed by 2 l of clear liquid administered in split-dose the day before and the day of

the examination. Faecal tagging was obtained in subjects receiving r-CTC and f-CTC with 70 ml of iodinated oral contrast agent (Gastrografin, Bayer) that was administered 2–3 h before the procedure. Then, 20 mg of scopolamine butylbromide (Buscopan, Boehringer Ingelheim) was administered intravenously, if not contraindicated, and the colon was distended with an automatic carbon dioxide insufflator (PROTOCO2L, Bracco). CTCs were acquired with 64- and 128-slice CT scanners (Somatom Sensation 64 and Definition AS 128, Siemens) using a low-dose protocol (120 kVp, 50 effective mAs).

Questionnaires

LOT-R is a 10-item test with 5-point Likert scale (0 = strongly disagree, 1 = disagree, 2 = neutral, 3 = agree, and 4 = strongly agree). The test is a validated tool to measure dispositional optimism (score range 0 to 24), with higher scores corresponding to higher levels of optimism [17]. Bowel preparation questionnaire investigated compliance to diet restrictions and bowel preparation, and occurrence and severity of related symptoms (i.e. abdominal pain, abdominal bloating, nausea or vomit, anal irritation and faecal incontinence). It comprised 10 items, 5 with multiple-choice answers and 5 with 4-point Likert scale (0 = no, 1 = mild, 2 = moderate, and 3 = severe). Post-examination questionnaire evaluated pain, anxiety, and embarrassment perceived during the CTC screening procedure, and the intention to repeat the examination in the future. It comprised 6 items with 5-point Likert scale (0 = strongly agree, 1 = agree, 2 = neutral, 3 = disagree, and 4 = strongly disagree). Bowel preparation and post-examination questionnaires were partially mutated from the Score 3 trial [18] with a revision and then validated using the focus group technique. CTC participants were instructed by a radiology resident to complete questionnaires on their own. English translations of the three questionnaires are provided as [supplementary material](#).

Statistical analyses

LOT-R score was computed for each participant using an algorithm previously described [17] and average values for r-CTC and f-CTC groups were calculated. We used a multiple imputation method (i.e. chained equations in STATA software) for handling missing values.

For the bowel preparation and post-examination questionnaires, items were analysed separately, including those from incomplete questionnaires. A pooled analysis using a cumulative score was performed when appropriate. Comparisons between the r-CTC and f-CTC groups were investigated using *t* test and Pearson's chi-square test. Two-sided *p* values less than 0.05 were considered statistically significant. Ordinal and multinomial logistic regression models were used to evaluate the effect of gender and age.

Assuming a response rate to questionnaires of about 75% of the r-CTC and f-CTC participants, we were able to detect a statistically significant (at a 5% level of significance) absolute differences greater than 5% between the two groups in the frequency of reported bowel preparation and screening procedure effects.

Statistical analysis was performed using the STATA software 12.0.

Results

Demographic characteristics of subjects of r-CTC and f-CTC groups who completed LOT-R, bowel preparation, and post-examination questionnaires are summarised in Table 1. There were not significant differences concerning rate of response, gender, and age in the two groups.

LOT-R questionnaire

The LOT-R questionnaire was completed by 529 (79%) of 674 r-CTC participants and by 462 (76%) of 612 f-CTC participants ($p = 0.2$). There were no significant differences in the average scores between r-CTC and f-CTC, either considering only complete questionnaires (14.41 ± 3.60 vs. 14.55 ± 3.38 ; $p = 0.52$) or including those with missing values evaluated with multiple imputation (14.27 ± 3.66 vs. 14.54 ± 3.35 ; $p = 0.22$). After adjustment for other variables, LOT-R scores were significantly lower among females ($p = 0.004$), whereas age had no effect ($p = 0.096$).

Bowel preparation questionnaire

Bowel preparation questionnaire was completed in all items by 479 (71%) of 674 subjects in the r-CTC group and by 409 (67%) of the 612 subjects of the f-CTC group ($p = 0.1$).

In both groups, compliance to diet restrictions (r-CTC = 99% vs. f-CTC = 99%; $p = 0.634$) and bowel preparation (r-CTC = 95% vs. f-CTC = 98%; $p = 0.055$) was reported to be almost complete, without significant differences (Table 2). The interference of bowel preparation with daily activities was reported to be negligible by 243 (80%) of 458 subjects in the r-CTC group as compared by 414 (53%) of 520 subjects in the f-CTC group ($p < 0.001$) (Table 2). Regarding this item, no significant effect of gender (OR 0.92; 95% CI 0.70–1.22) or age (OR 0.98; 95% CI 0.94–1.02) was observed.

Overall, the effects of bowel preparation were considered negligible or mild by 497 (96%) of 520 subjects in the r-CTC group versus 349 (78%) of the 445 subjects in the f-CTC group ($p < 0.001$) (Table 2). Females reported moderate or severe effects with almost twice probability as males (OR 1.94; 95% CI 1.28–2.93), whereas age had no effect (OR 1, 95% CI 0.95–1.07).

Table 1 Demographic characteristics of r-CTC and f-CTC participants who completed LOT-R, bowel preparation, and post-examination questionnaires

	LOT-R		Bowel preparation		Post-examination	
	r-CTC	f-CTC	r-CTC	f-CTC	r-CTC	f-CTC
Participants to CTC	674	612	674	612	674	612
Respondents ^a (%)	529 (78)	462 (75)	479 (71)	409 (67)	525 (78)	453 (74)
	$p = 0.2$		$p = 0.1$		$p = 0.1$	
Gender						
Female (%)	268 (51)	248 (54)	238 (50)	219 (53)	266 (50)	243 (54)
Male (%)	261 (49)	214 (46)	241 (50)	190 (47)	259 (50)	210 (46)
	$p = 0.3$		$p = 0.2$		$p = 0.3$	
Age (years), mean (SD)	59.4 (3.5)	59 (3.5)	59.4 (3.6)	59 (3.6)	59.4 (3.5)	59 (3.5)

p values were calculated with Pearson's chi-square test

CTC CT colonography, *r-CTC* reduced cathartic preparation CT colonography, *f-CTC* full cathartic preparation CT colonography, *LOT-R* Life Orientation Test - Revised, *SD* standard deviation

^a Participants who completed all items of each questionnaire

All symptoms related to bowel preparation, including abdominal pain, abdominal bloating, nausea or vomit, anal irritation, and faecal incontinence, were significantly more burdensome in the f-CTC group rather than in the r-CTC group (all $p < 0.01$) (Fig. 1). Overall, 88% (403/458) of the subjects in the r-CTC group reported none of the above-mentioned symptoms as compared to 70% (268/383) of subjects of the f-CTC group ($p < 0.001$) (Table 3). Regression model analysis of the reported symptoms adjusted for gender and age is shown in Table 4. In particular, for each symptom, the probability to have a moderate or severe score was 1.5 to 3 times higher for females rather than for males.

Post-examination questionnaire

Post-examination questionnaire was completed in all items by 525 (78%) of the 674 participants in the r-CTC group and by 453 (74%) of the 612 participants in the f-CTC group ($p = 0.1$).

Figure 2 shows the results for each item. No significant differences in reported screening related pain, anxiety, and embarrassment were observed between r-CTC and f-CTC

groups (all $p > 0.1$), whereas the intention to repeat screening CTC in the future was rated more favourably in the r-CTC group than in the f-CTC group ("Strongly agree" and "Agree": r-CTC = 94% vs. f-CTC = 87%; $p = 0.02$). The probability to report pain, anxiety, and embarrassment was 1.5–2 times higher for females rather than for males, whereas no significant effect was observed for age (Table 5).

Overall, the average of the scores of first three items (i.e. pain, anxiety, embarrassment) was 3.53 ± 0.04 for r-CTC and 3.59 ± 0.04 for f-CTC, with no significant differences between groups ($p = 0.84$).

Discussion

In a sample representative of the socio-demographic characteristics of r-CTC and f-CTC participants of the SAVE trial [6], the present study demonstrates that reduced cathartic bowel preparation for screening CTC shows significantly better tolerability than full cathartic preparation, with much lower interference

Table 2 Compliance to dietary restrictions and bowel preparation, interference of bowel preparation with daily activities, and overall effects of bowel preparation as reported by r-CTC and f-CTC participants

Item	Answer	r-CTC <i>N</i> ^a (%)	f-CTC <i>N</i> ^a (%)	p value
Compliance to dietary restrictions	Complete	526/531 (99)	461/465 (99)	0.634
	Partial	4/531 (1)	4/465 (1)	
	No	1/531 (0)	0/465 (0)	
Compliance to bowel preparation	Complete	505/531 (95)	455/465 (98)	0.055
	Partial	25/531 (5)	9/465 (2)	
	No	1/531 (0)	1/465 (0)	
Interference of bowel preparation with daily activities	Complete	33/458 (2)	10/520 (7)	<0.001
	Partial	182/458 (18)	96/520 (40)	
	No	243/458 (80)	414/520 (53)	
Overall effects of bowel preparation	Severe	0/520 (0)	6/445 (1)	<0.001
	Moderate	23/520 (4)	90/445 (20)	
	Mild	51/520 (10)	64/445 (15)	
	Negligible	446/520 (86)	285/445 (64)	

p values were calculated with Pearson's chi-square test

r-CTC reduced cathartic preparation CT colonography, *f-CTC* full cathartic preparation CT colonography

^a Denominators represent the total number of subjects who filled each item

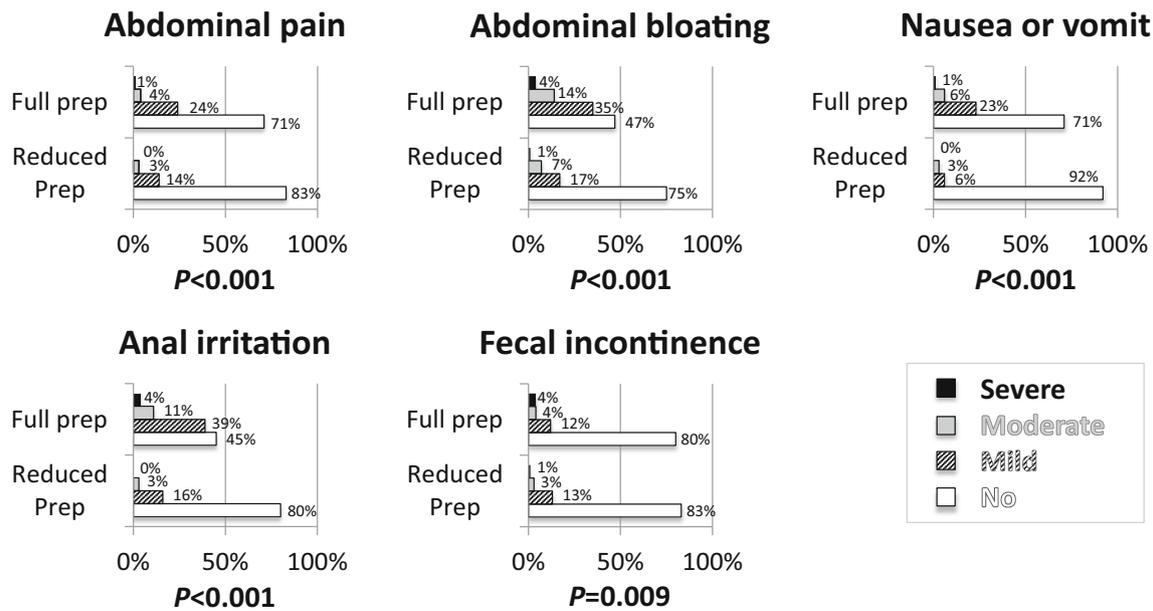


Fig. 1 Frequency of abdominal pain, abdominal bloating, nausea or vomit, anal irritation, and faecal incontinence related to bowel preparation as reported by participants to reduced and full preparation

CT colonography. The *p* values for the comparisons between groups were calculated with Pearson’s chi-square test

with daily life and fewer and milder gastrointestinal symptoms. Notably, reduced bowel preparation is also associated with increased intention to repeat screening CTC in the future. The discomforts reported after the CTC screening procedure, including pain, anxiety, and embarrassment, are not significantly different between the two bowel preparations.

Our results, obtained in the setting of a randomised trial and in a screening population, are in line with previous reports in which acceptability of reduced or non-laxative preparations for CTC in clinical settings was higher than that of full cathartic preparations for CTC (i.e. phospho-soda or polyetilenglycole) [19, 20] or for full cathartic preparation for colonoscopy (i.e. polyetilenglycole) [21]. Furthermore, in studies comparing different regimens of reduced bowel preparation, including combinations of various types and doses of mild laxatives and faecal

tagging agents, no significant differences in terms of patients’ tolerability were reported [22–24].

One of the strengths of our study was the adoption of the LOT-R to measure dispositional optimism. This permitted to

Table 3 Number of gastrointestinal symptoms attributed to bowel preparation as reported by r-CTC and f-CTC participants

Number of symptoms ^a	r-CTC N (%)	f-CTC N (%)
0	403 (88)	268 (70)
1	39 (9)	62 (16)
2	10 (2)	42 (11)
3	6 (1)	8 (2)
4	0 (0)	3 (1)
	458 (100)	383 (100)

r-CTC reduced cathartic preparation CT colonography, f-CTC full cathartic preparation CT colonography

^a Include abdominal pain, abdominal bloating, nausea or vomit, anal irritation, and faecal incontinence

Table 4 Logistic regression model for gastrointestinal symptoms related to bowel preparation adjusted for gender and age (r-CTC and f-CTC groups together)

Symptom	OR	95% CI
Abdominal pain		
Male	1.00	
Female	1.53	0.79–2.97
Age	1.03	0.94–1.13
Abdominal bloating		
Male	1.00	
Female	2.36	1.52–3.66
Age	0.99	0.94–1.05
Nausea or vomit		
Male	1.00	
Female	3.43	1.54–7.62
Age	0.97	0.88–1.06
Anal irritation		
Male	1.00	
Female	2.43	1.45–4.07
Age	0.95	0.89–1.02
Faecal incontinence		
Male	1.00	
Female	2.59	1.37–4.86
Age	0.99	0.91–1.07

Age was considered as a continuous variable

OR odds ratio, CI confidence interval

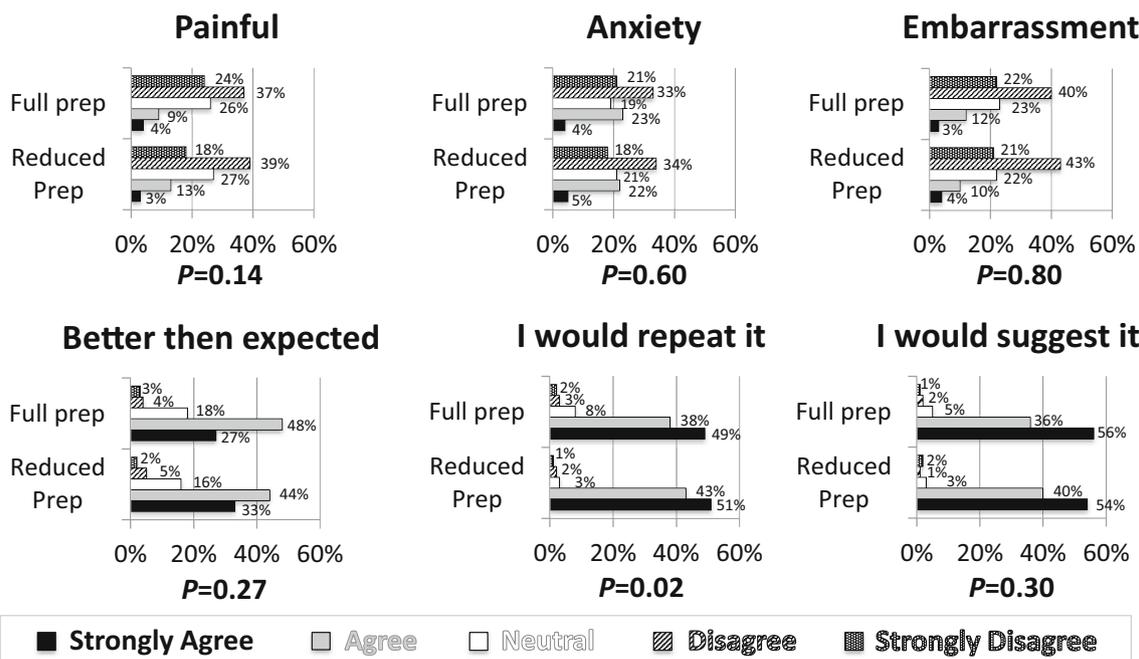


Fig. 2 Frequency of pain, anxiety, embarrassment, and intention to repeat the examination in the future as reported immediately after screening procedure by participants to reduced and full preparation CT

colonography. The *p* values for the comparisons between groups were calculated with Pearson’s chi-square test

Table 5 Multinomial logistic regression model for pain, anxiety, embarrassment, and intention to repeat the screening examination adjusted for gender and age (r-CTC and f-CTC groups together)

Item	OR	95% CI
Pain		
Female	1.88	1.28–2.77
Age	1.04	0.98–1.09
Anxiety		
Female	2.84	2.07–3.89
Age	1.02	0.97–1.06
Embarrassment		
Female	1.55	1.07–2.24
Age	1.00	0.95–1.05
It was better than expected		
Female	0.76	0.47–1.25
Age	0.99	0.93–1.06
I would repeat it in the future		
Female	0.77	0.39–1.51
Age	0.99	0.90–1.09
I would recommend it		
Female	0.73	0.31–1.73
Age	0.94	0.83–1.06

In the multinomial logistic regression model, the answers “strongly agree” and “agree”, as well as “disagree” and “strongly disagree”, were combined for each item. “Strongly disagree–disagree” was the referent. Age was considered as a continuous variable

OR odds ratio, CI confidence interval

exclude a possible bias due to imbalance in the psychological attitude of screening subjects between r-CTC and f-CTC respondents. In fact, LOT-R average scores were almost identical in r-CTC and f-CTC respondents, respectively 14.3 and 14.5, and in line with the average score of a European population of the same age range, namely 14.7 [25].

In the COCOS and PROTEUS trials, questionnaires assessing patients’ preferences were administered respectively 2 and 3 to 6 months after CTC execution [13, 26]. Conversely, in our study, questionnaires were administered the same day of CTC, thus avoiding possible memory biases.

Compliance to bowel preparation and to diet restrictions was reported to be almost complete in both groups. This favourable result could be at least partially attributed to the pre-examination consultation, in which a trained nurse gave detailed instructions about diet and bowel preparation to CTC screening subjects [27].

An important issue for compliance to a screening test is its interference with daily life. Almost 80% of subjects in the r-CTC group reported negligible interference of bowel preparation with daily activities as compared to 53% of those in the f-CTC group. This is supported by the fact that 88% of r-CTC subjects reported no gastrointestinal symptoms as compared with 70% of f-CTC subjects. Moreover, bothersome symptoms such as nausea/vomit or abdominal pain were reported by only 8% of r-CTC subjects versus 29% of f-CTC subjects and by 17% of r-CTC subjects versus 29% of f-CTC subjects respectively. These results are probably related to the large amount of fluid ingested with the full bowel preparation as compared to the reduced preparation. However, it has to be

pointed out that the reduced preparation employed in the SAVE trial, which comprises the administration of macrogol 3350 three times a day for 3 days and 70 ml of oral iodinated contrast media, is still relatively bothersome as compared to other reduced or laxative-free preparations [24]. Any future effort to develop a better minimum or non-laxative preparation could further increase patients' compliance and, ultimately, participation to screening CTC.

The fact that no significant differences in pain, anxiety, and embarrassment were detected between r-CTC and f-CTC groups in the post-examination questionnaire suggests that the answers to these items were mainly determined by what the subject perceived during CTC execution (i.e. undressing, receiving intravenous spasmolytic, rectal catheter, and colonic insufflation) rather than by the effects of bowel preparation.

Independently of randomisation group, males tolerated bowel preparation significantly better than females. Males also reported significantly less discomfort due to the CTC screening procedure in terms of pain, anxiety and embarrassment. In addition, it is remarkable that in both the Italian randomised trials, participation to screening CTC was higher for males than for females, namely 31% versus 26% in the SAVE study and 34% versus 27% in the PROTEUS study [5, 6]. Similarly, acceptability of endoscopic screening tests such as colonoscopy and sigmoidoscopy is higher for males than for females [28–30]. The advantage in terms of participation and acceptability of screening CTC observed for the male gender might be taken into account when planning screening strategies for CRC.

Notably, reduced bowel preparation is also associated with increased intention to repeat screening CTC in the future and this may be valuable when considering possible repeated rounds of CTC screening for CRC [31]. In this view, we have to consider that for the first CTC screening round, participation rate is affected by the “perceived” acceptability of the test, as invitees have never had CTC before, whereas for the subsequent screening rounds, it is the “actual” acceptability of the procedure that is more important, as subjects have already experienced the test. Regarding the first CTC screening round, data of the SAVE trial showed that r-CTC had higher attendance than f-CTC, indicating a better “perceived” acceptability [6]. For the second screening round, data from the questionnaires collected in the present study suggest that screening subjects would more likely re-attend r-CTC than f-CTC, consistent with a better “actual” acceptability. This could be proved actually offering a repeat CTC round to these two groups.

We recognise the following possible limitation of our study. Since it has been reported that reducing the dose of iodinated oral contrast media improves tolerability of bowel preparation [32, 33], the fact that bowel preparation questionnaire was administered before drinking iodinated oral contrast agent might have generally decreased the overall discomfort associated with CTC bowel preparations.

Bowel preparation was reported to be one of the most frequent reasons for non-attendance to screening CTC in the COCOS and PROTEUS randomised trials [12, 13]. In a UK survey on intentions to undergo screening CTC, non-laxative preparation was rated more positively than full-laxative preparations [34]. The SAVE trial showed that r-CTC had a mild (3%) but statistically significant higher participation rate than f-CTC with similar detection rate for advanced neoplasia. However, the use of reduced preparations may limit the detection rate of CTC, especially for flat and serrated polyps, as reported in the COCOS trial [35]. Results from the present study demonstrate that to the higher participation rate to r-CTC corresponds, from patient's perspective, a better tolerability for the reduced bowel preparation. Incidentally, a reduced bowel preparation is also less expensive than full bowel preparation [36].

Overall, these data support the view that screening CTC should be performed with a reduced bowel preparation.

Acknowledgements We acknowledge Dr. Matteo Cuccuni, Dr. Giacomo Gabbani, Dr. Giulia Grazzini, Dr. Giulia Scarpini, and Dr. Ilaria Vitali from Florence, Italy, for data collection.

The results of this study were presented at ECR 2018 (B-0521).

Funding This study has received funding by Tuscany Region, Italy (POR CREO FESR 2007–2013 LINEA D'INTERVENTO 1.1c, grant number 009DUA00000000089835900120000000002), and by the Cassa di Risparmio di Firenze Foundation (grant number 2012.0742A2202.3931).

Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Professor Mario Mascalchi.

Conflict of interest One author of this manuscript (Silvia Delsanto) declares relationships with the following company: Im3D, Turin, Italy.

All other authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

Statistics and biometry One of the authors has significant statistical expertise.

Informed consent Written informed consent was obtained from all subjects in this study.

Ethical approval Institutional Review Board approval was obtained.

Study subjects or cohorts overlap Socio-demographic characteristics of the SAVE trial invitees and participants, as well as participation rate and detection rate for advanced neoplasia after the first screening round, were previously reported in Sali L, Mascalchi M, Falchini M, et al Reduced and full-preparation CT colonography, fecal immunochemical test, and colonoscopy for population screening of colorectal cancer: a randomized trial. *J Natl Cancer Inst* 2015;108: 319.

Methodology

- Prospective
- Randomised controlled trial
- Performed at one institution

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