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Evaluating patients' preferences for type of bowel preparation prior to screening CT colonography: Convenience and comfort vs. sensitivity and specificity

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53

Abstract

Aims: Computed tomographic colonography (CTC) is currently the only whole-colon screening test for colorectal cancer (CRC) that can offer reduced or non-laxative forms of bowel preparation. These are likely to be less burdensome for patients compared with full-laxative purgation but may also reduce test sensitivity and specificity. This study explored the relative value patients place on comfort and convenience vs. test sensitivity and specificity in the screening context.

Materials and methods: Twenty semi-structured interviews were carried out with patients attending hospital for radiological tests unrelated to CTC. Preferences for CTC with different types of bowel preparation for CTC screening were examined and interviews were analysed thematically. The discussion guide included separate sections on CTC, bowel preparation methods (non-, reduced- and full-laxative), and sensitivity and specificity. Patients were given information on each topic in turn and asked about their views and preferences during each section.

Results: Following information about the test, patients' attitudes towards CTC were positive. Following information on bowel preparation, full-laxative purgation was anticipated to cause more adverse physical and lifestyle effects than using reduced- or non-laxative preparation. However, stated preferences were approximately equally divided, largely due to patients anticipating that non-laxative preparations would reduce test accuracy (because the bowel was not thoroughly cleansed). Following information on sensitivity and specificity (which supported patients' expectations), the predominant stated preference was for full-laxative preparation.

Conclusions: Patients are likely to value test sensitivity and specificity over a more comfortable and convenient preparation. Future research should test this hypothesis on a larger sample.

80 **Introduction**

81 Computed tomographic colonography (CTC) is a relatively novel radiological test for
82 detecting colorectal cancer (CRC) and precancerous polyps. It has the advantage of being
83 less invasive than colonoscopy and as such is often preferred by screening participants (1).
84 CTC has been recommended as a screening test based on data indicating that it achieves
85 similar sensitivity (the ability to detect disease when it is present) for important colonic
86 lesions (polyps ≥10mm or cancer) compared to colonoscopy, which is generally accepted to
87 be the current gold-standard whole-colon examination (2–4). However, CTC has lower
88 sensitivity for smaller polyps compared with colonoscopy (5) and it has lower specificity (i.e.
89 disease is more likely to be suspected when it is absent), giving a higher false-positive rate
90 that results in unnecessary follow-up testing.

91 A potential benefit of CTC is that it remains the only whole-colon investigation that allows
92 patients to avoid full-laxative purgation required by other modalities. This may represent a
93 major advantage because full laxative preparation is often reported to be the worst part of
94 the entire test experience (6,7) and patients' experience of reduced-laxative preparations
95 have been found to be superior compared with full-laxative alternatives (e.g. 8–10). It has
96 also been argued that offering full-laxative preparation for CTC discourages people from
97 undergoing the test, therefore reducing uptake and diminishing the population health
98 benefits (11).

99 A randomised controlled trial found that screening uptake was significantly higher following
100 an invitation to undergo CTC with a reduced-laxative preparation than full-laxative
101 colonoscopy (34% of 982 vs. 22% of 5924 participants; 12). A sub-study on acceptability
102 found that patients expected the preparation be less burdensome in the CTC arm (13).
103 However, as both bowel preparation and test varied between trial arms, it is not possible to
104 be certain that the preparation itself was a specific deterrent to uptake.

105 The potential downside of reducing the intensity of the laxative component of bowel
106 preparation is a reduction in test sensitivity and specificity for polyps (14). A small number of
107 studies have asked respondents to consider both outcome features of the test (such as
108 sensitivity) and process features (such as discomfort) before stating their preferences and
109 these studies suggest that patients prioritise 'accuracy' over test experience in both
110 screening and diagnostic contexts (15–17). Furthermore, even relatively small differences in
111 sensitivity may be considered to be important (18). It is therefore possible that sensitivity and
112 specificity of CTC would be prioritised over the discomfort and inconvenience of the bowel
113 preparation if patients were given this information.

114 Most studies of preferences and acceptability have not mentioned issues of sensitivity and
115 specificity to participants: A meta-analysis of patients' preferences for colonoscopy or CTC
116 after experiencing both tests (1) found that 17 out of 23 studies did not provide any
117 information on sensitivity. In the remaining studies, participants were informed that both tests
118 were equally sensitive, despite evidence that CTC has lower sensitivity for smaller pre-
119 cancerous polyps (e.g. 5). No study provided information on specificity directly although
120 three studies informed patients about a 20% referral rate for colonoscopy after CTC.
121 Participants in these studies may have made inaccurate assumptions (for example, that the
122 more recently developed CTC was most sensitive; 16). This lack of information may reflect a
123 common (but perhaps mistaken) assumption among medical staff that patients value comfort
124 over accuracy (19,20).

125 The aim of the present study was therefore to examine patient trade-offs between the
126 discomfort and inconvenience of the bowel preparation vs. sensitivity and specificity of CTC
127 in the screening context. We conducted semi-structured interviews in which patients were
128 asked to consider a hypothetical context where they were offered CTC for screening. We
129 provided information on three types of bowel preparation (non-, reduced- and full-laxative),
130 first focusing on the practicalities of each method, and then on their associated sensitivity

131 and specificity. Patients were asked to express preferences and discuss the reasons for their
132 choices at each point.
133

134 **Materials and Methods**

135 *Design and participants*

136 Following ethical approval by an NHS Proportionate Review Sub-committee, a research
137 assistant identified a consecutive sample of patients scheduled to attend an NHS teaching
138 hospital radiology department for ultrasonography or radiography for reasons unrelated to
139 the present study. Once identified, patients were mailed an information sheet and invitation
140 to participate in a face-to-face interview. Eligibility criteria were patients aged 45-59 years
141 (to eliminate effects of prior experience of CRC screening which starts at 60 years in
142 England); ability to read and speak English; no previous experience of CTC or other colonic
143 investigations and no personal history of CRC. Patients returning a reply slip expressing
144 interest were met on the day of their appointment by a research assistant (BLIND FOR
145 REVIEW) to answer questions, confirm eligibility, and take written consent. Those who
146 consented took part in a 45-60 minute interview shortly after their test or on another day
147 depending on their preference and were offered £10 remuneration.

148 *Measures*

149 Semi-structured interviews were carried out with (BLIND FOR REVIEW); patients received
150 key information in sections in order to monitor preferences at different stages and ensure
151 that they were not overburdened. The face-to-face nature of the interviews allowed the
152 interviewer to probe comprehension and provide more detail as necessary. Patients were
153 also able to ask questions and receive explanations of unfamiliar concepts (particularly
154 sensitivity and specificity) before responding. Verbal information was supplemented by a
155 visual presentation (in PowerPoint 2010 for Windows, Microsoft, Redmond, WA, USA) to aid

156 comprehension. The sections gave information on CRC screening, the percentage of polyps
157 that may turn into cancer (8% after 10 years; 24% after 20 years), the CTC test procedure, a
158 set of non-, reduced- and full-laxative preparation characteristics, representative quotes from
159 patients about their experiences with non- and full-laxative preparations (taken from a
160 previous interview study; 21) and the implications of how preparation affects sensitivity
161 (86%; 89%; 92% respectively) and specificity (89%; 90%; 91%) for pre-cancerous polyps.
162 The order in which each preparation was presented was determined randomly for each
163 participant to counteract possible order effects. Information was derived from the existing
164 literature (22–30) and local CTC information sheets developed by psychologists and
165 radiologists with experience in the area.

166 After each section, patients were asked questions based on a prepared discussion guide
167 (Tables 1-4). Age, gender, health and employment status were noted. After information on
168 CRC screening and CTC, patients were asked about perceived benefits and barriers
169 towards the test, and their willingness to have it in principle if it were offered in the next
170 month. This was followed with information on the practicalities of each method of bowel
171 preparation, after which patients were asked about expected physical and lifestyle effects.
172 They were also asked how they thought the preparations might affect the test (giving them
173 an opportunity to suggest that there might be differences in terms of sensitivity or specificity)
174 and their overall preferences. Information was then given on sensitivity, and patients were
175 asked about their impressions of this attribute and asked to consider their preferred
176 preparation again. They were also asked about their preferred preparation after receiving
177 information on colonoscopy (as the follow-up test that would be recommended if an
178 abnormality was suspected on CTC) and specificity (i.e. the possibility of false positives on
179 CTC that result in an unnecessary colonoscopy), as well as being asked about their
180 impressions of these aspects of testing. In the concluding section of the interview, patients
181 were asked about their overall impressions of CTC and their willingness to attend for
182 screening.

183 *Analysis*

184 Recordings were transcribed and a thematic analysis carried out (31). Qualitative research
185 software (NVivo 9 for Windows, QSR International, Cambridge, MA, USA) was used to read
186 participants' responses repeatedly and categorise them based on a framework
187 corresponding to the typical order of the interview (i.e. initial views of CTC, preparation
188 impressions and preferences after information on practicalities, sensitivity, specificity and
189 final views of CTC). Similar responses were grouped in order to detect common themes and
190 determine participants' preferences within each section of the interview.

191

192 **Results**

193 *Demographics*

194 Participants (n=20, 11 males) had a mean age of 52 years (range: 45-58 years) and 13 were
195 in full- or part-time paid employment. Sixteen reported their health quality to be good or fair.
196 Data on education and socioeconomic status were not collected. At the start of the interview,
197 participants often considered their existing knowledge of CRC or screening to be poor (*"I
198 don't really know anything about screening"*; male, 47). However, other participants often
199 referred to possible aims of screening (prevention and early detection) or established
200 screening programmes (*"I've always had a smear test dead on time, I've always had breast
201 cancer screening on time…I would think [the aim of CRC screening], like most screenings, is
202 to diagnose early, because the earlier diagnosed, the better chance you've got and to put
203 people's mind at rest as well"*; female, 54).

204 *Initial attitudes towards CTC screening*

205 After learning about the practicalities of CTC and having the opportunity to ask questions,
206 patients were generally positive towards the test, citing factors such as the potential to
207 provide reassurance (*"Be nice to have…satisfy myself that I've got no problems"*; male, 54

208 years), a personal sense of risk and the potential to prevent cancer (*"I think as you get older,*
209 *I think possibly it pays for you to look after your health and prevention is better than cure"*;
210 male, 56 years). There were some factors that diminished the perceived acceptability such
211 as possible scheduling difficulties, perceived low risk of CRC (*"I suppose I would query the*
212 *likelihood that it was relevant to me"*; male, 54 years) and concerns about risks associated
213 with the procedure (*"I would definitely give myself a few days, loads of 'Google-ling' to find*
214 *more information…looking at the risk of the scanning itself, looking at alternatives"*; male, 49
215 years).

216 *Preparation preferences after information on practicalities*

217 After receiving information on practicalities for each method of preparation, patients
218 perceived an apparent ordering in terms of physical effects. Non-laxative preparation was
219 expected to cause fewer adverse effects than reduced-laxative preparation and both were
220 perceived as more manageable than more full-laxative preparation (*"If the only effect the*
221 *[non-laxative preparation] has is to change the colour of the stool…I don't see how you'd*
222 *have any ill effects"*; male, 46 years). Full-laxative preparation was expected to cause the
223 most frequent and inconvenient physical effects including diarrhoea, increased bowel
224 frequency, urgency, cramping, dehydration and fatigue (*"You have a powerful laxative and*
225 *you're suffering from diarrhoea, you're going to feel pretty weak, aren't you?"*; male, 56
226 years). Physical effects from dietary restrictions were expected to be minor in comparison
227 and were generally anticipated to be an issue for reduced- and full-laxative preparations
228 only.

229 Non-laxative preparation was expected to cause some disruption to daily routine. This was
230 related primarily to work issues such as transporting medicine to the workplace, storing it
231 there and with how other colleagues would respond to it (*"If I, unfortunately, found myself*
232 *with clients, for example, I might find it more difficult…I wouldn't want to get my special*
233 *preparation out at the lunch table"*; male, 45 years).

234 The main lifestyle effects anticipated for reduced- and full-laxative preparations related to
235 change in bowel habit. This was expected to cause some slight disruption to social and
236 working life in the case of the former (*“If you’re basically caught short with no toilet, that’s the*
237 *obvious one”*; male, 47 years). The latter was expected to cause the most significant lifestyle
238 changes (*“I’d probably stay home for the day. Yes, I wouldn’t want to go out”*; male, 46
239 years). Full-laxative preparation was also expected to make travelling difficult. As with
240 anticipated physical effects, the effects of dietary restrictions were expected to be less
241 disruptive to lifestyle than the effects of change in bowel habit.

242 Despite this ordering of tolerability, when patients were asked to state their preferred
243 preparation (if any), opinion was divided among the three options. Those stating a
244 preference for reduced- or full-laxative preparations often asked about or guessed that there
245 were differences in accuracy between preparations (*“Say if your colon is a lot clearer, you’ll*
246 *be able to detect a lot more, that’s what I’m thinking…‘cause it’s clear of any debris”*; female,
247 54 years). At this stage, some patients viewed a reduced-laxative preparation as a good
248 compromise between convenience and the anticipated effect on the test performance.

249 *Preparation preferences after information on sensitivity*

250 After receiving information on sensitivity, patients perceived it to be a key attribute and
251 explained their view both in terms of providing greater reassurance that no pre-cancerous
252 polyps had been missed (*“If you want to have your bowel completely looked at, including*
253 *polyps you’re going to have to choose the one that shows everything or what’s the point in*
254 *having it? There’s no point in half doing it, you’ve got to have it done completely for peace of*
255 *mind”*; female, 54 years) and the harmful consequences of a false negative (*“How would you*
256 *feel if you settled for, say, the lowest one, [non-laxative preparation] and took that and they*
257 *came back and said ‘no, you’re all clear’ and then two years down the line, bang, ‘oh, you’ve*
258 *got bowel cancer’?”*; male, 56 years). There was a clear overall preference for full-laxative
259 preparation at this stage. Notably, several patients appreciated that the differences were

260 small but still regarded them as important (*“it doesn’t look statistically particularly much of a*
261 *difference but I would probably put my money on [full-laxative preparation], then…just*
262 *subjectively I would feel better about that”*; female, 58 years).

263 Interestingly, some patients reasoned that against the background of undergoing the test,
264 the differences between preparations would be minimal in terms of overall inconvenience (*“If*
265 *you’re going through all that hassle in some ways to actually have the test, then you might*
266 *as well get the most out of it. So, that’s why I would possibly change back to [full-laxative*
267 *preparation]”*; male, 55 years). Few participants expressed a preference for a less intensive
268 preparation at this stage and most cited external barriers (such as travel) as the reason for
269 their preference.

270 *Preparation preferences after information on specificity*

271 As part of the discussion guide, we also sought to identify views on false positives. After
272 receiving information on these attributes, patients generally had a negative view of
273 colonoscopy as a follow-up test, particularly in relation to issues around dignity and
274 invasiveness; these represented reasons to value specificity (*“I would really hate to have an*
275 *unnecessary colonoscopy…The sort of invasiveness of machines on the body, and I feel*
276 *that always is very hard”*; female, 49 years). They were also concerned about anxiety
277 associated with an abnormal test result (*“Emotionally…cancer’s a big sort of, like, no-no with*
278 *some people…you wouldn’t want to go down the route of…a false alarm, which is not only*
279 *upsetting to you, it’s upsetting to people around you who think they’re going to lose you”*;
280 male, 56 years).

281 As with sensitivity, there was a clear overall preference for full-laxative preparation in terms
282 of specificity; patients considered it worth undergoing in order to reduce the risk of a false
283 alarm (*“If you’ve got [full-laxative preparation] done, you stand a better chance of not being*
284 *called back…Yeah, [full-laxative preparation] seems to be the one that would give you more*

285 *peace of mind…so, obviously then, looking at that, it's essential that you use a laxative so*
286 *the medical staff can see every single thing";* female, 58 years).

287 *Final attitudes towards CTC*

288 After receiving all information at the end of the interview, participants generally felt that they
289 would be willing to have CTC for screening (*"I don't see any reason not to have it. I mean it*
290 *seems to me, if that were routine it would be fine"*; female, 56). Several participants
291 remained ambivalent about accepting any kind of CTC, particularly if they felt that CRC was
292 not as serious as other cancers or they did not consider themselves to be at high risk (*"I*
293 *think it's one of those things that's definitely, definitely manageable if you know you're*
294 *supposed to be having it done but not the sort of thing you're going to volunteer to have*
295 *without good cause"*; male, 47).However, there was no clear change in willingness to have
296 CTC compared to participants' initial attitudes (*"I think at the start…I was pretty confident I*
297 *would take up the offer, unless I found out something that would put me off but nothing I've*
298 *found out today has put me off"*; male, 46).

299

300 **Discussion**

301 These findings support other evidence that potential screening participants value sensitivity
302 and specificity highly in test decisions (15–18). Although full-laxative preparation was
303 expected to cause more adverse physical and lifestyle effects, patients felt they were
304 prepared to accept this additional inconvenience and discomfort in order to maximise the
305 benefits of testing and reduce the risk of harm. It was notable that patients were influenced
306 by even small differences in specificity and, in particular, sensitivity for polyps even though
307 they were informed that most polyps do not become cancers. These findings contribute to a
308 growing body of evidence suggesting that outcome features are valued over process
309 features in the screening and diagnostic contexts, in contrast with clinicians' assumptions
310 (19,20).

311 It has been argued that uptake of screening CTC may be optimised through the use of less
312 burdensome reduced-laxative preparations instead of standard full-purgation methods (11).
313 This reasoning was behind the decision to offer reduced-laxative preparation in a
314 randomised trial of screening CTC vs. colonoscopy (12). Our results support the trial findings
315 that non- and reduced-laxative preparations are perceived as more acceptable in terms of
316 the direct patient experience (10), but they suggest that reduced-laxative preparations may
317 ultimately run counter to patient' preferences if they also reduce sensitivity or specificity. If
318 the present results are confirmed, it may be necessary for policy-makers and researchers to
319 consider whether full-laxative preparations would be both more clinically advantageous and
320 more consistent with patients' priorities, or perhaps give patients a choice.

321 It should be noted that this study was based on the premise that an increase in tolerability is
322 associated with a decrease in sensitivity and specificity (14). However, the choice of
323 preparation would be clear for all stakeholders if it were possible to offer a superior patient
324 experience and optimised sensitivity and specificity simultaneously. Although this study
325 assessed perceptions of just three preparations, using estimates of their sensitivity and
326 specificity, many other regimens exist and there is considerable uncertainty regarding the
327 performance characteristics of such a diverse range (3). It is possible that alternative
328 preparations (perhaps developed in the future) would not require patients to compromise to
329 the same extent, if at all. Future research should aim to reduce these uncertainties and
330 determine whether a fully optimised preparation can be achieved.

331 Our findings regarding preparation preferences should also be put in the broader context of
332 perceptions of CTC and CRC screening: In our interviews, the value of the test itself and
333 factors such as perceived low risk of CRC were more significant barriers than the
334 preparation, suggesting that strategies to address these issues may be more effective at
335 optimising uptake overall than the choice of preparation.

336 This study has limitations. It was small-scale and exploratory, and therefore larger studies, in
337 other settings, are needed to confirm the findings. It is also possible that statistics on
338 sensitivity and specificity were particularly impactful on preferences because of the study
339 design in which the three types of preparation were presented in parallel, which may have
340 emphasised differences. A more naturalistic design in which only one method is described
341 without the reference points provided by alternatives, may find that participants focus on test
342 specificity and sensitivity to a lesser degree. The most robust validation of these findings
343 would be to evaluate actual screening behaviour outside of a hypothetical context.

344 **Conclusion**

345 The results of this study suggest that when given appropriate information, patients favour
346 methods of preparation for CTC screening that maximise test sensitivity and specificity and
347 thereby increase the chance of health benefits and reduce the need for further testing. This
348 suggests that patients attach greater priority to getting the best test than getting the best test
349 experience.

350

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436 **Tables and figures**

437

Key information on CRC screening
Aims to detect CRC early, when it is more treatable
Aims to prevent CRC cancer, through detection and removal of pre-cancerous polyps
8 out of 100 polyps become cancers after 10 years; 24 out of 100 after 20 years
Key information on CTC
Involves two scans being taken and read by a specially-trained doctor
Scanning is preceded by injections (muscle relaxant, intravenous dye) and rectal insufflation with gas
Testing takes 20-30 minutes
Carries a risk of radiation-induced cancer (same risk as smoking 140 cigarettes)
Carries a risk of a hole in the bowel wall (1 in 3,000)
Usually, results cannot be given on the same day
A follow-up test (colonoscopy) would be needed to assess/remove suspected abnormalities

438 Table 1. showing key information on CRC screening and CTC

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Key information on non-, reduced- & full-laxative preparation

Non-laxative preparation

Medicine: Powdered barium would be mixed with water and drunk with food three times a day on the two days before CTC while the mixture is kept in the fridge

Effects: This medicine is not a laxative but may turn stools pale

Diet: People would have to go without high fibre foods from two days before CTC until four hours before, after which no solid food could be eaten

Reduced-laxative preparation

Medicine: Liquid iodine would be mixed with water and cordial and drunk on the two evenings before CTC

Effects: This medicine is a mild laxative and carries a 1 in 250,000 risk of serious allergic reaction

Diet: People would have to go without high fibre foods from two days before CTC until one day before, after which no solid food could be eaten

Full-laxative preparation

Medicine: "Picolax" powder would be mixed with hot water and drunk on the morning and afternoon before CTC

Effects: This medicine is a powerful laxative

Diet: People would have to go without high fibre foods from two days before CTC until the day of the test and go without snacking between meals or supper on the day before CTC

450 Table 2. showing key information on preparation practicalities

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Representative quotes from patients' experiences with non and full-laxative preparation (21)

Non-laxative preparation

Diet: *"You had to go on a light fibre diet so that meant no fruit or vegetables, no red meat, no whole meal bread, no porridge…That was a bit hard for me because I eat a lot of food with fibre"* (female, 76)

"You couldn't eat any meat, which was not a big problem, I can eat meat or leave it alone...there was no vegetable or fruit…I could have poached eggs…It was just not what I would eat on a normal day but it was OK. It was bearable...It wasn't too much of a hardship" (female, 78)

Medicine: *"I had to drink [the mixture] three times a day…Morning, afternoon and evening…I didn't like it, of course. Well you don't like drinking that stuff. It says in the notes that it has a pleasant taste but…it's not really all that pleasant"* (female, 76)

"I had to drink this [mixture]…I didn't find that in any way strenuous…It wasn't too bad at all…I just drank it down and it made my mouth a bit dry but other than that it was alright" (female 78)

Full-laxative preparation

Diet: *"You pretty well starve while you're on this horrible stuff"* (female, 79)

"I managed all that…I just kept to the letter by not eating any solids on the day before and the day previous to that, I had made sure there was no fibre in my diet" (male, 76)

Medicine: *"Pretty, pretty awful. I didn't go to work that day 'cause I was running to the toilet…I couldn't have been at work, the toilet at work is down the stairs so you could never make it in time"* (female, 69)

"It was very effective, you know, but then I expected it...I didn't enjoy it particularly. It was necessary" (female, 81)

460 Table 3. showing quotes describing patients' experiences with non- and full-laxative preparation

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Key information on differences in sensitivity between preparations
If 100 people with polyps had a particular preparation:
86 would have their polyps found after non-laxative preparation
89 would have their polyps found after reduced-laxative preparation
92 would have their polyps found after full-laxative preparation
Key information on follow-up colonoscopy
Involves a small tube with a camera being passed through the bowel
The camera takes pictures that a doctor can see on a screen
Colonoscopy is preceded by injection of a muscle relaxant, painkiller and a sedative
Testing takes 30 minutes plus an hour for the sedative to wear off
Carries a risk of bleeding (1 in 150) and a hole in the bowel wall (1 in 1,000)
Can take samples and remove polyps
Key information on differences in specificity between preparations
If 100 people without polyps had a particular preparation:
11 would have an unnecessary colonoscopy after non-laxative preparation
10 would have an unnecessary colonoscopy after reduced-laxative preparation
9 would have an unnecessary colonoscopy after full-laxative preparation

470 Table 4. showing key information on sensitivity, colonoscopy and specificity