

T concentration to be associated with more severe strokes, as assessed by the Scandinavian stroke scale. However, we could not correlate computed tomography data with clinical outcomes. Computed tomography was usually performed in the first 24 hours to differentiate between ischaemic and haemorrhagic strokes. In the first 48 hours, however, the extent of an acute infarct is often poorly defined on computed tomography. A previous study found that infarct volume measured by computed tomography was poorly correlated with clinical measures of stroke severity and outcome.¹⁴

Troponin T concentration was measured in a single serum sample obtained 12 to 72 hours after admission to hospital. Serial measurement of troponin T concentration and creatine kinase MB over the following few days would be needed to determine the time course of myocardial damage after an ischaemic stroke.

Contributors: CJE initiated the study and contributed to the study design, analysis of the data, interpretation, and reporting. PJ collected the data and contributed to the study design, interpretation, and reporting. RMLW analysed the data and contributed to interpretation and reporting. JH helped to initiate the study and, with ARM and NEA, contributed to interpretation and reporting. All authors are guarantors.

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Single blind, randomised trial of efficacy and acceptability of oral Picolax versus self administered phosphate enema in bowel preparation for flexible sigmoidoscopy screening

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Abstract

Objective To compare the acceptability and efficacy of two methods of self administered bowel preparation for flexible sigmoidoscopy screening: a single phosphate enema and a single sachet of Picolax.

Design Single blind, randomised trial.

Setting Endoscopy units of two general hospitals.

Participants 1442 men and women aged 55-64 years who had agreed to be screened by flexible sigmoidoscopy.

Main outcome measures Attendance rates, compliance with allocated preparations, adverse effects, quality of bowel preparation, procedure time, and yield of neoplasia.

Results Compliance with the enema was higher than with the Picolax (608 (84%) v 566 (79%); difference 6%, 95% confidence interval 2% to 10%). Almost half of those who refused Picolax used an enema at home. Wind, incontinence, and sleep disturbance were more frequent in the Picolax group than the enema group; bottom soreness was more frequent in the enema group. Around 30% (187) found the diet restriction required by Picolax difficult; 78% (471) found the enema easy to administer. The quality of preparation

was better with the enema; the proportion of procedures complete to the descending colon was greater and the mean duration of the procedure was shorter. There was no significant difference in polyp detection rates.

Conclusion A single phosphate enema self administered around one hour before leaving home is a more acceptable and effective method of preparing the distal bowel for flexible sigmoidoscopy than Picolax.

Introduction

A randomised trial is in progress in the United Kingdom to examine the efficacy of a single flexible sigmoidoscopy screen in the prevention of bowel cancer.¹ At the start of the trial we wished to identify the most acceptable and effective method of bowel preparation, and we considered an enema or an oral laxative. Enemas are the preferred option since they quickly clear the lower bowel and require no dietary restriction, whereas oral preparations require a liquid diet for at least 12 hours before the procedure.²

In the United Kingdom the enema is generally administered by a nurse in the unit, but the trial did not

have the staff or toilet facilities. In the United States, the enema is often self administered at home,³ but the willingness or ability of asymptomatic British people to self administer an enema was not known, and we suspected that an oral laxative might be preferred.

We compared a single self administered phosphate enema (Fletchers' phosphate enema (long tube version for self administration), Pharmax, Bexley, Kent) with a single sachet of oral sodium picosulphate with magnesium citrate (Picolax). Two sachets of Picolax are used routinely for colonoscopy, but a single sachet is used for flexible sigmoidoscopy.⁴ A single phosphate enema is as effective as two enemas for sigmoidoscopy.⁵ The two preparations were compared in two separate populations to determine whether the findings could be generalised throughout the United Kingdom.

Participants and methods

Study design

The study was carried out in Welwyn Garden City in 1995 and Leicester in 1996 as part of the pilot studies for the UK flexible sigmoidoscopy screening trial.⁶ Approval for the studies was obtained from the hospitals' ethics committees. Men and women aged 55-64 who met the eligibility criteria⁶ and were randomised to an invitation for screening were further randomised to receive oral laxative or an enema after they had confirmed their appointment. Clear, detailed instructions were included, and a nurse was available for telephone advice if required. Participants were advised to use the enema about 1 hour before leaving home for the screening examination and not to eat after using the enema. Participants who were sent Picolax were advised to take it at either 2 pm or 6 pm on the day before screening for a morning or afternoon examination respectively and to have no solid food thereafter until after the examination.

Participants who cancelled their appointment after receiving their bowel preparation were offered an alternative. Those sent the enema could have the enema in the unit or Picolax, and those sent Picolax could have an enema at home or in the unit.

The endoscopists were unaware of the preparation used. After passing each 15 cm section of the bowel, they noted the percentage of mucosa area visible. At the end of the examination, the endoscopists rated the adequacy of the bowel preparation as excellent, good, adequate, or poor.⁷ If the preparation was poor, sigmoidoscopy was repeated after administration of an enema in the unit.

Participants were asked to complete a questionnaire in the unit just before screening. This asked about usual bowel habit, problems in the use of the allocated preparation, the severity of an itemised list of adverse effects, and whether they would be prepared to use the same preparation again. They were given an additional questionnaire to complete on the following morning asking about problems experienced during or after the procedure.

Randomisation

Block randomisation to Picolax or enema was performed centrally. Administrative staff at trial centres were responsible for posting bowel preparations. Both administrative staff and participants were asked not to disclose their method of bowel preparation to the endo-

scopist. Participants had given consent to take part in the screening trial, but we did not ask for separate consent for randomisation to different bowel preparation methods. This decision was made because both preparations are in routine use, the side effects are minor, and in the absence of this study all participants would have been allocated one of the preparations.

Statistical methods

Sample size calculations for the acceptability study were based on 85% compliance in the Picolax group and 75% in the enema group. For the efficacy study, calculations were based on good or excellent bowel preparation in 70% of subjects in the Picolax group⁴ and 85% in the enema group.⁸ We estimated that we needed a population of 1100 to achieve 98% power for the overall comparisons of the two treatment groups (with at least 75% power within each centre).

We calculated absolute risk differences (with exact 95% confidence intervals) to compare proportions in the enema and Picolax groups. Duration of examinations and visibility in each group were compared by *t* tests. Differences between centres were assessed by the Mantel-Haenszel test for homogeneity of odds ratios.

Results

We sent Picolax to 721 people (Welwyn Garden City: 299; Leicester: 422) and an enema to 721 (Welwyn Garden City: 290; Leicester: 431). The groups were well matched at entry. The average age was 61 years in both groups in Welwyn Garden City and 60 years in Leicester, and the proportion of men in the groups was similar in each centre (Welwyn Garden City: 45% (267); Leicester: 49% (421)).

Compliance

Compliance with the enema was higher than with Picolax (84% *v* 79%; difference 5%, 95% confidence interval 2% to 10%) (table 1). This effect was seen in both centres. There was no significant difference between the enema and Picolax groups in the proportions who used an alternative bowel preparation (3% in enema group *v* 4% Picolax). Of the 63 participants sent Picolax who requested an enema instead, 27 (43%) used it at home. By contrast, only 18 (27%) of the 67 who refused to use the enema at home asked to use the oral preparation; the remainder requested the enema in the unit. Only 49 (7%) participants sent the enema requested to have it in the unit.

Acceptability

Of those who used the allocated bowel preparation, about 90% of each group in each centre reported they would be willing to use the same preparation again (table 2). Most of those using the enema at home (471, 78%) found it easy to administer; 11 (2%) found it very difficult or needed it to be administered by someone else. Five hundred and forty three (96%) of those sent Picolax took the full sachet, but a third (187) found it difficult to cope with no food and 45 (8%) found it very difficult or had to have something to eat.

A higher proportion felt unwell after taking the enema than after the Picolax (88 (15%) *v* 39 (7%), 95% confidence interval for difference 4% to 11%), but over 80% of both groups felt quite normal. More of the

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Table 1 Attendance and use of allocated bowel preparation. Values are numbers (percentages) of participants

	Total			Welwyn Garden City		Leicester		P value*
	Enema	Picolax	Difference in % (95% CI)	Enema	Picolax	Enema	Picolax	
Sent bowel preparation	721	721		290	299	431	422	
Attended for screening	676 (94)	629 (87)	7 (4 to 10)	271 (93)	265 (89)	405 (94)	364 (86)	0.43
Attended and used allocated preparation at home	608 (84)	566 (79)	5 (2 to 10)	248† (86)	237 (79)	360 (84)	329 (78)	0.79
Attended but refused to use allocated preparation at home:								
Used alternative preparation at home	67 (9)	63 (9)	0 (-2 to 4)	23 (8)	28 (9)	44 (10)	35 (8)	0.28
Used enema in unit	18 (2)	27 (4)	-1 (-3 to 1)	4 (1)	12 (4)	14 (3)	15 (4)	0.15
Used enema in unit	49 (7)	36 (5)	2 (-1 to 4)	19 (7)	16 (5)	30 (7)	20 (5)	0.67

*Significance test for homogeneity of bowel preparation effect between Welwyn Garden City and Leicester

†One subject did not complete a bowel preparation questionnaire and is therefore not included in analyses of acceptability and efficacy.

itemised adverse effects were rated as moderate or severe in the Picolax groups, including wind, incontinence, and sleep disturbance, with two people complaining that the Picolax began to work in the middle of the night producing incontinence in bed. Of the adverse effects rated as moderate or severe in the enema group, only bottom soreness was reported more frequently than for Picolax.

In all, 94% (925/984) participants completed a further questionnaire on the morning after the test. Bottom soreness was the only adverse effect reported significantly more frequently in the enema group (table 3). This effect was seen in both centres. Rates of wind, incontinence, and sleep disturbance were not higher in the Picolax group on the morning after the test. There were no differences between the preparations in the pain experienced during the test.

Efficacy

On several measures, the enema performed better than the Picolax (table 4). The quality of preparation was assessed by endoscopists as excellent or good in a significantly higher proportion of participants using the enema in both centres. The mean visibility was also better with the enema in the first 45 cm from the anus in both centres. The proportion of examinations

reaching the descending colon or beyond was significantly higher and the duration of the examination was significantly shorter in the enema group in both centres. Despite the apparent better performance of the enema, the proportion of people in whom polyps, adenomas, or cancers were detected and the total number of polyps detected overall did not differ materially between the preparations.

Discussion

Bowel preparation for screening flexible sigmoidoscopy needs to be quick and easy and to cause the minimum of discomfort in order to increase compliance. It should ideally be undertaken at home to reduce the workload of nursing staff and the congestion in the endoscopy unit if a large number of people are screened at each session. Effective bowel preparation is essential to increase the chance of detection of neoplasms (particularly if the examination is to be undertaken only once, as we have proposed¹); to aid insertion of the endoscope to its maximal point; to reduce the time required for the examination; to reduce patient discomfort during endoscopy; and to reduce the need for repeat examinations, which would increase procedure costs and inconvenience.

Table 2 Acceptability of Picolax and self administered enema as reported on an itemised questionnaire completed before screening. Values are numbers (percentages) of participants

	Total			Welwyn Garden City		Leicester		P value*
	Enema	Picolax	Difference in % (95% CI)	Enema	Picolax	Enema	Picolax	
Total using allocated preparation	607	566		247	237	360	329	
Ease of administration of enema:								
Easy	471 (78)	NA		188 (76)	NA	283 (79)	NA	
Quite difficult	91 (15)	NA		50 (20)	NA	41 (11)	NA	
Very difficult	7 (1)	NA		4 (2)	NA	3 (1)	NA	
Given by another person	4 (1)	NA		4 (2)	NA	0	NA	
Coping with no food:								
No problem	NA	356 (63)		NA	160 (67)	NA	196 (60)	
A bit difficult	NA	142 (25)		NA	53 (22)	NA	89 (27)	
Very difficult	NA	43 (8)		NA	19 (8)	NA	24 (7)	
Couldn't manage, had something	NA	2 (0)		NA	1 (1)	NA	1 (0.3)	
Felt unwell	88 (15)	39 (7)	8 (4 to 11)	30 (12)	17 (7)	58 (16)	22 (7)	0.33
Adverse effects rated as moderate or severe:								
Abdominal pain or cramps	56 (9)	59 (10)	-1 (-5 to 2)	23 (9)	21 (9)	33 (9)	38 (12)	0.44
Nausea or vomiting	16 (3)	12 (2)	1 (-1 to 2)	7 (3)	8 (3)	9 (3)	4 (1)	0.25
Faintness or dizziness	22 (4)	14 (3)	1 (-1 to 3)	10 (4)	9 (4)	12 (3)	5 (2)	0.30
Wind	24 (4)	56 (10)	-6 (-9 to -3)	13 (5)	25 (11)	11 (3)	31 (9)	0.38
Bottom soreness†	82 (14)	50 (9)	5 (1 to 8)	27 (11)	21 (9)	55 (15)	29 (9)	0.32
Incontinence	8 (1)	28 (5)	-4 (-6 to -2)	6 (2)	12 (5)	2 (1)	16 (5)	0.10
Sleep disturbance	6 (1)	74 (13)	-12 (-15 to -9)	3 (1)	36 (15)	3 (1)	38 (12)	0.94
Willing to use same preparation again	543 (89)	501 (89)	0 (-3 to 5)	227 (92)	213 (90)	316 (88)	288 (88)	0.57

*Significance test for homogeneity of effect between Welwyn Garden City and Leicester.

†Includes pain or irritation in any of the following areas: rectum, anal canal, anus, skin around anus or buttock.

Table 3 Numbers (percentages) of participants reporting adverse effects as moderate or severe on morning after test

	Total			Welwyn Garden City		Leicester		P value*
	Enema	Picolax	Difference in % (95% CI)	Enema	Picolax	Enema	Picolax	
Used allocated preparation	607	566		247	237	360	329	
Sent questionnaire†	514	470		154	141	360	329	
Responded to questionnaire	490 (95)	435 (93)		149 (97)	139 (99)	341 (95)	296 (90)	
Abdominal pain	62 (13)	68 (16)	-3 (-7 to 2)	27 (18)	31 (22)	35 (10)	37 (13)	0.92
Nausea or vomiting	3 (1)	6 (1)	0 (-2 to 1)	1 (1)	2 (1)	2 (1)	4 (1)	0.96
Faint or dizzy	8 (2)	14 (3)	-2 (-4 to 0)	6 (4)	3 (2)	2 (1)	11 (4)	0.02
Wind‡	157 (32)	146 (34)	-2 (-8 to 5)	72 (48)	71 (51)	85 (25)	75 (25)	0.77
Bottom soreness§	53 (11)	26 (6)	5 (1 to 8)	14 (9)	5 (4)	39 (11)	21 (7)	0.42
Incontinence	28 (6)	21 (5)	1 (-2 to 4)	8 (5)	4 (3)	20 (6)	17 (6)	0.38
Sleep disturbance	29 (6)	26 (6)	0 (-3 to 3)	5 (3)	1 (1)	24 (7)	25 (8)	0.12
Pain during test	70 (14)	72 (17)	-2 (-7 to 2)	31 (21)	27 (19)	39 (11)	45 (15)	0.27

*Significance test for homogeneity of effect between Welwyn Garden City and Leicester.

†Questionnaires were sent out in only the later stages of the study in Welwyn Garden City.

‡Abdominal pain and wind were reported significantly more often in Welwyn Garden City than Leicester because in Leicester carbon dioxide rather than air was used for insufflating the bowel.⁶

§Includes pain or irritation in any of the following areas: rectum, anal canal, anus, skin around anus or buttock.

Our study in two populations has shown that a single phosphate enema, self administered around one hour before leaving home for the examination, is more acceptable and effective than a single sachet of Picolax taken the day before, with dietary restriction until after the procedure. The greater acceptability of the enema was shown by higher attendance rates in both centres and higher compliance with the use of the preparation at home as intended. These findings contradict those of Lund et al in Nottingham, who compared home and hospital administered enemas in symptomatic patients and found that almost half of those randomised to receive an enema at home refused to use it at home and were given it at the hospital (the equivalent proportion in our study was 7% in both centres).⁹ We did not compare hospital administered enema since, like many endoscopy units, our units did not have the facilities for all participants to be offered this option. Reasons cited in the Nottingham study for refusal to

use the enema at home were: seemed too difficult (34% of total offered home enema), fear of mess (14%), and lack of understanding of instructions (4%). In our study, 15% of those who attended after using the enema at home found it moderately difficult to use and 2% found it very difficult or needed to have help. Nevertheless, these participants had still used the preparation. Our success may have resulted from the carefully constructed information leaflet that was supplied and the availability of nursing support through a telephone advice line when required.

Adverse effects

More people reported feeling unwell immediately after using the enema, possibly because the enema acts within minutes whereas Picolax can take several hours to work. Overall, however, Picolax caused more adverse effects than the enema. The most important disadvantages of Picolax are, firstly, that it requires dietary

Table 4 Endoscopists' assessment of quality of bowel preparation. Values are numbers (percentages) of participants unless stated otherwise

	Total			Welwyn Garden City		Leicester		P value*
	Enema	Picolax	Difference in % (95% CI)	Enema	Picolax	Enema	Picolax	
No who used preparation at home	635	584		260	241	375	343	
Complete examinations (reaching descending colon or beyond)	527 (83)	445 (76)	7 (2 to 11)	226 (87)	192 (80)	301 (80)	253 (74)	0.53
Incomplete examinations due to poor bowel preparation	47 (7)	59 (10)	-3 (-6 to 0)	19 (7)	21 (9)	28 (7)	38 (11)	0.56
Quality of bowel preparation:								
Excellent	359 (57)	229 (39)		115 (44)	71 (29)	244 (65)	158 (46)	
Good	122 (19)	153 (26)		82 (32)	92 (38)	40 (11)	61 (18)	
Adequate	64 (10)	96 (16)	P<0.001 for trend	32 (12)	52 (22)	32 (9)	44 (13)	
Poor	62 (10)	92 (16)		17 (7)	22 (9)	45 (12)	70 (20)	
Not recorded	27 (4)	14 (2)		13 (5)	4 (2)	14 (4)	10 (3)	
Mean % mucosa visible† (No of patients) at:								
0-15 cm	95 (593)	91 (552)	4 (3 to 6)	94 (244)	92 (229)	96 (349)	91 (323)	
16-30 cm	92 (591)	87 (553)	5 (3 to 8)	91 (244)	87 (230)	93 (347)	87 (323)	
31-45 cm	88 (509)	82 (469)	6 (2 to 10)	87 (230)	82 (210)	89 (279)	82 (259)	
46-60 cm	70 (136)	60 (138)	10 (-1 to 20)	70 (57)	72 (63)	70 (79)	51 (75)	
Duration of examination (min)‡	4.9	5.4	—	4.3	5.0	5.2	5.6	
Yield at flexible sigmoidoscopy:								
Polyps	145 (23)	122 (21)	2 (-3 to 7)	55 (21)	52 (22)	90 (24)	70 (20)	0.42
Adenoma	57 (9)	55 (9)	0 (-4 to 3)	27 (10)	27 (11)	30 (8)	28 (8)	0.88
Cancer	5 (1)	2 (0)	0.5 (-0.4 to 1.3)	3 (1)	1 (0)	2 (1)	1 (0)	0.80
Total No of polyps	206	188	0.5 (0.5 to 0.6)§	84	79	122	109	

*Significance test for homogeneity of bowel preparation effect between Welwyn Garden City and Leicester.

†Includes examinations in which the scope was advanced to beyond the section of the bowel assessed unless the examination was terminated because of poor bowel preparation, in which case the % visible was set at 0% for subsequent sections.

‡Excluding examinations stopped due to inadequate bowel preparation and participants in whom polyps or cancer were detected.

§Binomial test for equality in two arms.

What is already known on this topic

Screening by flexible sigmoidoscopy requires good bowel preparation

Staff and toilet facilities in endoscopy units are insufficient to cope with the large numbers of people seen in a screening programme

In the United States enemas are often self administered at home, but the acceptability of this approach in Britain is unknown

What this study adds

In asymptomatic people being screened by flexible sigmoidoscopy the compliance rates were higher among those randomised to home administration of enema than those receiving oral laxative

The enema group experienced fewer side effects and bowel preparation was better

restriction, which 8% of our participants found unacceptable and around 25% found difficult, and, secondly, it causes sleep disturbance.

The only adverse effect seen more frequently in the enema group was bottom soreness. Irritation after use of the enema may result from the chemical effects of the hypertonic phosphate solution or, more rarely, mechanical damage caused by the nozzle.^{10 11} There was no evidence that any of the study participants had injured themselves during self administration of the enema; indeed injury seems less likely to result from self administration than administration by another person. The hypertonic solution can cause irritation of the skin of the buttock and the anorectum, and inflammatory changes have been noted in the distal bowel with small (1-3 mm) ulcers in occasional patients.¹²

Performance

There was no difference in the rate of detection of polyps or adenomas between the groups, although more cancers were detected in the enema group. However, by other measures the enema performed significantly better. The examination time was shorter, a greater proportion of examinations were judged to be complete, and the quality of preparation was rated as excellent or good in 10% more of those who used the enema.

The phosphate enema is not perfect. Around 7% of examinations (table 4) need to be repeated because of the inadequacy of the bowel preparation. Giving two enemas is not the answer since it produces more adverse effects with no improvement in performance.^{3 5} Adding a dose of magnesium citrate the night before reduced the need to repeat the procedure from 12% with two enemas to 4% in one study,⁷ although 16% complained of severe diarrhoea compared with only 6% receiving the enema alone. Administration of the enema in the unit by a nurse is not ideal, even if logistically feasible, since Thomas et al have reported that around 30% of people given an enema in the unit around 30 minutes before the procedure suffer incontinence of fluid or faeces on the journey home.¹³ Only 6% of our participants who used the enema complained of incontinence after sigmoidoscopy, a similar proportion to those using Picolax (5%) (table 3). However, in view of the unacceptability of this

potentially embarrassing side effect, perhaps a pad should be offered to all subjects after the procedure.

Based on the results of this study, we believe that a single, self administered enema is probably the best available preparation for flexible sigmoidoscopy screening, and we have used this regimen in the UK flexible sigmoidoscopy screening trial, in which 40 000 people aged 55-64 are being screened in 13 centres. The instructions used in this study have been incorporated into an illustrated booklet, and high compliance rates have been achieved.

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Endpiece

A wise physician

Remedies often make disease worse... It takes a wise doctor to know when not to prescribe.

Baltasar Gacian, 1601-58,
The Art of Wordly Wisdom

Submitted by T O Cheng, professor of medicine,
Washington DC

Commentary: participants should have been told they were being randomised

Henrik R Wulff

My personal “ethics meter” did not react very strongly, but it did react, when I read that the participants in this screening project had been randomised to two different cleansing procedures without their informed consent. The study was timely and the consequences for the patients were very small. However, informed consent is the rule, and violation of this rule must always be extremely well argued. The authors state that consent to randomisation was considered unnecessary as both methods were in routine use. This argument, taken in isolation, is certainly not valid. In some malignant diseases different chemotherapies are in current use, but that does not justify a randomised comparison of these regimens without the patients’ consent.

My “ethics meter” would have reacted less if the authors had explained the ethical dilemma and argued their case in some detail. They should have made it clear that they had balanced the participants’ right to self determination against the difficulty of securing informed written consent from 1400 people and the fact that the participants were exposed to no risk and no major inconvenience. However, many will still say that the right to self determination (the principle of

autonomy) is so fundamental that it cannot be out-balanced by these other factors, and some critics of clinical research may even feel that a study such as this one justifies their distrust in the research activities of the medical profession.

What should the investigators have done? I think that they should have trusted the willingness of these people, who had already consented to take part in the screening project, to provide additional information for the benefit of future patients. The investigators should have explained openly by letter what it was all about and that randomisation was the only way to find out which cleansing procedure was best. If nothing was concealed from those who took part, the investigators could in this case, I believe, have refrained from the formality of written consent. Randomised trials are needed, and the investigators also missed a chance to propagate that message in the general population.

I have considered only the ethics of the study and not its legal aspects. In Denmark it would have been illegal without the participants’ explicit consent.

Competing interests: None declared.

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Commentary: opportunity for patient partnership was lost

Marie Taylor

Over the past seven years PASS Direct, a generic advocacy service in Dumfries and Galloway, has helped over 2000 patients in their dealings with the NHS. Many of these people have come to us with the complaint that they were not informed about the risks, side effects, or possible outcomes of procedures, surgery, or treatment. In all of these cases the reason for information being withheld has been an assumption on behalf of clinicians that the patient did not need to know; it was such a small risk, it wasn’t worth mentioning; the patient would only worry; “I (the clinician) know best”; or the patient would not understand because he or she was not a doctor. Some of the patients were very angry that assumptions had been made about their ability to make choices for themselves, and all resolved to be better prepared in future.

The study by Atkin et al raises various issues about informing patients. It is my understanding that everyone who agreed to be screened was given an information leaflet describing the two methods. Therefore no one was uninformed that two methods were available. The issue seems to be that patients were sent a preparation rather than being asked which one they would like to try. However, having received a preparation they were given a choice of changing this or receiving assistance. I feel strongly that the intelligence of patients should never be underestimated and that in this case there was a lost opportunity to work in partnership with them.

As both preparations are widely used, and if we accept the fact that patients do not usually get either a choice or the support the patients in the trial received, the ethical issue, in my opinion, does not arise. When patients are kept well informed and given support, they are quite capable of asking questions. It is only when they are overly anxious, intimidated, or patronised that they lose the confidence to take part in what should be a shared decision making process.

The participants in this study seem to have been treated in a non-patronising manner and supported sensitively during the whole process. This in turn seems to have empowered them to ask for help or more information when they needed it. If, however, the participants had been suspected to have colorectal cancer, the situation would have been different. In these circumstances the patients would already have been disempowered and lacking in confidence and may have felt unable to ask questions. It would have been more appropriate in these circumstances to have given a straightforward choice after explaining both preparations.

In my experience as a patient’s advocate, any information on procedures which can help people make choices should always be published. This is a lay person’s perspective and may seem a little naive. However, had I been involved in this trial I would not feel that any code of ethics had been ignored, rather that the trial could have been a shared partnership one.

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