Colorectal cancer screening: prospective trial comparing a thinner 100cm prototype endoscope with a standard 60cm flexible sigmoidoscope

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Background

Previously, we used magnetic endoscope imaging (MEI) [1,2] to determine the anatomical location of the instrument tip and depth of insertion at non-sedated, screening flexible sigmoidoscopy using a standard 60cm Olympus flexible sigmoidoscope [3]. Similarly, we used MEI in an open study to evaluate two thin prototype endoscopes (Olympus MS230I and XCFSEV- Figures 1a, 1b) in symptomatic subjects [4]. These thinner and "floppier" endoscopes appeared to offer advantages over a standard 60cm flexible sigmoidoscope [4]. However, the study was scientifically flawed because a) it was not randomised and b) it was comparing symptomatic patients endoscoped by GDB with historical asymptomatic subjects endoscoped by JP [4].

Aims

To carry out a formal, prospective, single-operator, randomised study to see if the longer and thinner XCFSEV endoscope was superior to a standard diameter 60cm flexible sigmoidoscope when used for screening flexible sigmoidoscopy.

Figure 1a - The prototype Olympus MS230I and XCFSEV endoscopes

Methods

A prospective randomised trial was conducted in 54 average risk subjects aged between 55-65 years undergoing non-sedated screening flexible sigmoidoscopy as part of the MRC Multicentre Flexiscope trial. In 27 subjects, JP used a prototype Olympus 10mm diameter endoscope (XCFSEV) measuring 100cm in length (FS100) while in the remaining 27 he used a standard 60cm Olympus endoscope (FS60). Bowel preparation was classified from 1-4 (excellent, good, adequate or poor). The ease of conducting the examination was also assessed on a 1-4 scale (very easy, quite easy, quite difficult or very difficult). The site, size and nature of any polyps or cancers detected were recorded. Each patient completed a questionnaire assessment after the flexible sigmoidoscopy on a) discomfort *during* and b) abdominal discomfort/bloating *following* the procedure. MEI [1] was used in all 54 patients and the records stored for later analysis. The 54 MEI files were analysed by GDB and RSR using specially modified software [2,5] without knowledge as to within which group any individual fell. We recorded 1) depth of insertion, 2) the anatomical location of the instrument tip at the point of maximum insertion, 3) the time in seconds to reach the maximum point of insertion, and 4) presence or absence of loop formation in the sigmoid colon.

Figure 1b - The shaft of the two 10mm diameter endoscopes is shown beside a standard 12.8mm diameter flexible sigmoidoscope

Figure 2 - Diagram of the colon with the arbitrary scoring system adopted to assess the location of the endoscope tip. 1-rectum, 2-sigmoid colon, 3-sigmoid/descending junction, 4-lower DC, 5-mid DC, 6-upper DC, 7-splenic flexure, 8-left side TC, 9-mid TC, 10-right side TC, 11-hepatic flexure, 12-ascending colon and 13-caecum.

Statistics

The data was analysed using Arcus Quickstat Biomedical software. Abdominal discomfort both during and after the procedure was ranked by the patients on a 1-4 scale (1=none, 2=mild, 3=moderate and 4=severe). The data on depth of insertion and time to reach the maximum point of insertion were not normally distributed so non-parametric statistics were applied. To analyse the data on anatomical location of the instrument tip we used an arbitrary scoring system of 1-13 – see Figure 2. Sigmoid colon loop formation was classified as a) N-loop or sigmoid loop, b) alpha loop, or c) no loop. A chi-squared test was used to compare the FS60 and FS100 instruments in terms of type of sigmoid loop (or lack of it).

Results

As can be seen from Table 1, the FS60 and FS100 groups were well matched in terms of mean age and ratio of male to female subjects. As can be seen from Tables 2 and 3 and Figures 3 and 4, the two instruments gave markedly different results. The longer and floppier 10mm diameter XCFSEV endoscope could be inserted significantly further up the colon than the standard, thicker and shorter instrument.

	FS60	FS100	Statistical Significance
Mean(SD) Age	61.2(3.1)	61.3(2.7)	NS
Males/females	15males, 12 females	12 males, 15 females	NS
Mean(SD) Bowel preparation	2.7(0.5)	2.7(0.7)	NS

Table 1 - Demographic details of patients in FS60 and FS100 groups

	FS60	FS100	Statistical Significance
Mean(SD) distance inserted in cm	55.7(6.3)	77.3(15.8)	P<0.001
Number (%) in which tip of endoscope got beyond the splenic flexure	3/27(11.1%)	18/27(66.6%)	P<0.0001
Mean(SD) anatomical segment of colon reached	4.1(1.9)	7.0(2.5)	P<0.0001
Mean(SD) time in seconds to reach point of maximum insertion	153.7(56.4)	303.1(108.2)	P<0.0001
Mean(SD) ease of examination	2.2(0.6)	2.6(0.9)	NS
Mean(SD)Discomfort during procedure	2.0(0.8)	1.9(0.6)	NS
Discomfort/bloating following the procedure	1.8(0.8)	1.5(0.8)	NS

Table 2 - Results obtained with FS60 and FS100 flexible sigmoidoscopes

Loop formation in the sigmoid colon(%)	FS60	FS100
None	4	10
Sigmoid or N-loop	22	13
Alpha	1	4

Table 3 -Loop formation in the sigmoid colon. Overall Chi-squared test = 6.6857, DF=2, P=0.0353

The mean insertion depths for the FS100 and FS60 groups were 77.3cm (range 30-95cm) and 55.7 (range 32-60cm) respectively (p<0.001). The tip reached beyond the splenic flexure in 18/27 (67%)of the FS100 subjects but in only 3/27(11%) of the FS60 group (p<0.001). Adenomatous polyps or cancers were found in 8/27 of the FS100 group compared with 5/27 in the FS60 group (NS). The two main disadvantages of the thinner endoscope was a) that it was deemed slightly more difficult to use and b) took on average about 2.5 minutes longer to reach the point of maximum insertion.

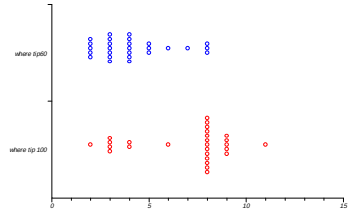

Figure 3 - Anatomical location of the tip of the endoscope at the point of maximum insertion. The horizontal axis represents the arbitrary 1-13 scale shown in Figure 2

Conclusions

The thinner, "floppier" 100cm prototype endoscope was well tolerated by patients undergoing non-sedated screening flexible sigmoidoscopy. The Olympus XCFSEV performed significantly better than a standard 60cm FS in terms of length of bowel examined and anatomical location of the instrument tip reached at the point of maximum insertion. A screening flexible sigmoidoscopy performed with the prototype thinner endoscope however took on average an extra 2.5 minutes more than with a standard 60cm instrument. A much larger study would be required to determine if the greater number of polyps detected as a consequence of using the FS100 would be clinically significant and thus justify the extra time taken to carry out the examination. Certainly the two subjects in the FS100 group who had moderately dysplastic adenomas > 1cm diameter detected in their transverse colons would probably not have had these discovered had a 60cm endoscope been used.

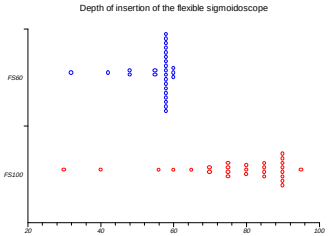

Figure 4 - The mean maximum insertion depths for the FS100 and FS60 groups were 77.3cm (range 30-95cm) and 55.7cm (range 32-60cm) respectively (p<0.001)

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