Flexible Sigmoidoscopy in Symptomatic Patients - There are Significant Benefits to Using a Paediatric Colonoscope in Female Patients

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Background

Flexible sigmoidoscopy is used to investigate active colorectal symptoms as well as for colorectal cancer screening. Previous studies in asymptomatic subjects undergoing screening flexible sigmoidoscopy have shown that a) women tend to experience more pain during the procedure and b) the median insertion depth is significantly less than in men [1,2]. In many hospitals, flexible sigmoidoscopy/limited left-sided colonoscopy is conducted using a full length adult colonoscope rather than a 60cm flexible sigmoidoscope [3,4]. We were particularly interested to see if the previously observed differences between male and female patients noted at non-sedated screening flexible sigmoidoscopy [1,2] would also pertain in symptomatic subjects and if so whether using a paediatric colonoscope conferred any advantage.

Aims

To 1) quantify the difference in shaft stiffness between a paediatric and typical adult colonoscope and 2) establish if there was any advantage to using a 'floppier' 130cm length paediatric endoscope rather than a stiffer 165cm adult colonoscope in symptomatic patients attending a "Fast Track" surgical flexible sigmoidoscopy list.

Methods

Flexural rigidity measurement

We used a modified beam deflection method [5] to measure the flexural rigidity of the colonoscopes used in the clinical trial. The endoscopes were either an 11.2mm diameter Olympus PCF240I 130cm long paediatric colonoscope (P-C) or alternatively a stiffer adult 165cm long instrument(A-C) in the form of an Olympus CF230L or CF240L colonoscope.

Power calculation

Based on our previous experience [2] we estimated that we would be able to perform a non-sedated flexible sigmoidoscopy at least to the sigmoid/descending colon junction in 75% of patients in the A-C group and 95% in the P-C group. The power calculation suggested that, in order to have a 90% chance of detecting a significant difference (P<0.05) between the A-C and P-C group, we would need to have 88 patients in each arm of the study. To allow for exclusions because of (inter alia) obstructing tumours or poor bowel preparation we elected to enter 105 patients into each arm of the study.

Clinical trial

We conducted a trial of 'Fast Track' surgical flexible sigmoidoscopy in 210 patients referred to either IC or JC with worrying lower GI symptoms. Patients' bowel preparation consisted of two Picolax sachets on the day prior to the examination. Patients were allocated strictly alternatively to have their flexible sigmoidoscopy carried out using either P-C or A-C. All the sigmoidoscopies were carried out by a single experienced endoscopist (GDB) on one of two weekly special 'Fast Track' endoscopy lists. Magnetic Endoscope Imaging [6-8] plus a specially designed 'painometer' [9] was used in all patients. Study approval was obtained from the Royal Sunderland Hospital Ethics Committee and informed consent given by all patients entered into the trial. We measured the following :-

1) Maximum insertion depth in cm (median and range)
2) Time in minutes to point of maximum insertion (median and range)
3) The depth of insertion before first episode of pain or discomfort experienced (median and range)
4) Anatomical segment of the colon reached in terms of percentage intubation to a) at least sigmoid or descending colon junction b) beyond splenic flexure and c) total to caecal pole
5) Total number of episodes of discomfort or pain (median and range) that occurred during the flexible sigmoidoscopy.

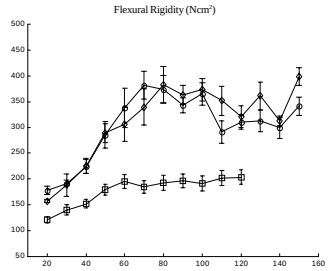

Figure 1- Mean (SD) shaft flexural rigidity measurements (N cm²) of the three different colonoscopes used in the clinical trial a) Olympus PCF 240I (squares) b) Olympus CF230L(circle) and c) Olympus CF240L (diamond)

Statistical comparisons

We compared the above 5 parameters in terms of :-

a) All male patients (A-C + P-C) vs all female patients (A-C + P-C)
b) All female patients (A-C + P-C) with a past history of hysterectomy vs all female patients who had not had a hysterectomy (A-C + P-C)
c) All male patients (P-C) vs all female patients (P-C)
d) All male patients (A-C) vs all female patients (A-C)
e) All male patients (P-C) vs all male patients (A-C)
f) All female patients (P-C) vs all female patients (A-C)
g) All female patients with hysterectomy (P-C) vs all female patients with hysterectomy (A-C)
h) All female patients with no history of hysterectomy (P-C) vs all female patients with no history of hysterectomy (A-C)

Mann-Whitney U, Fisher's Exact or Chi-squared test with Yates correction were used as appropriate.

Results (figures 1, 2 & tables 1-3)

Flexural rigidity measurement

This confirmed that the shaft of the Olympus 11.2mm diameter PCF240I colonoscope (P-C) was significantly less stiff (P<0.001) than either that of the 12.2mm diameter Olympus CF240L or 12.8mm diameter CF230L adult colonoscopes (A-C) at all points from 20-120cm from the distal bending tip -see Figure 1.

Clinical trial

Of the 210 patients entered into the study, there were 11 exclusions including 5 patients with obstructing tumours and 5 with inadequate bowel preparation. The two groups of patients were reasonably well matched in terms of age, gender ratio and, in the case of the female patients, a past history of hysterectomy - see Table 1. The median (range) time to pass the endoscope to the point of maximum insertion was very similar in the P-C and A-C groups at 6.2 (3.0-15.3) min and 6.3(2.6-12.6) min respectively.

	PCF240I GROUP N = 99	ADULT GROUP N = 100	Statistical significance
Age(SD) all patients	*61.8(11.4)*	*60.5(12.0)*	*NS*
Age range all patients	*40-87 years*	*40-90 years*	
Male/female ratio	*47/52*	*59/41*	*Fisher's exact test 0.1189*
Age(SD) male patients	*62.0(11.1)*	*61.2(12.4)*	*NS*
Age range male patients	*40-87 years*	*40-90 years*	
Age(SD) female patients	*61.3(12.5)*	*59.5(11.4)*	*NS*
Age range female patients	*40-87 years*	*40-85 years*	
Number(%) of female patients with previous hysterectomy	*20/52 (38.5%)*	*11/41 (26.8%)*	*NS Fisher's exact test 0.2735*
Consultant Surgeon to whom patient referred IC/JC	*46/53*	*51/49*	*NS*

Table 1 - Demographic details of the patients entered into the study comparing the paediatric PCF240I colonoscope with an adult colonoscope (CF240L or CF230L)

Male / female differences

Combining the results of the two arms of the study, female patients had more pain (P<0.0002) and a lower median insertion depth (P<0.0001) than males. Furthermore significantly more male patients than female patients were examined at least to a) sigmoid/descending junction (P=0.0059) b) to beyond the splenic flexure (P=0.0041) and c) to the caecal pole (P=0.0349).

Differences between the P-C and A-C groups

The P-C tended to cause less pain in both men (P<0.002) and women (P<0.244 NS) than the A-C .In a) all females and b) those with a hysterectomy the P-C permitted a greater insertion depth (P<0.02 and P<0.001, respectively) than the A-C - see Figure 2. Females in the A-C group who had had a previous hysterectomy had significantly more total episodes of pain/discomfort than those in the A-C group who had not undergone previous pelvic surgery.

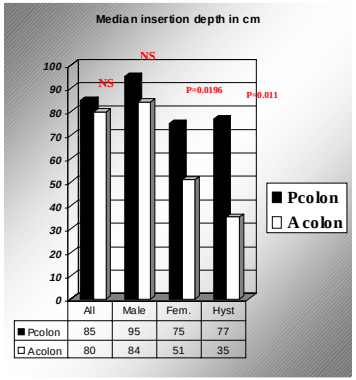

Figure 2 - Median insertion depth (cm) at the time of 'Fast Track' flexible sigmoidoscopy. The insertion depth achieved using the paediatric colonoscope was significantly greater than that obtained with an adult colonoscope in a) female patients and b) female

	PCF240I colonoscope	Number of observations	Adult colonoscope	Number of observations	Statistical significance
All male and female patients combined	*85 (32-135)*	*99*	*80 (27-141)*	*100*	*NS P =0.1068*
All female patients	*75 (32-129)**	*52*	*51 (27-139)***	*41*	*P =0.0196*
All male patients	*95 (49-135)**	*47*	*84 (35-141)***	*59*	*NS P =0.3385*
Female patients with previous hysterectomy	*77 (32-129) +*	*20*	*35 (27-94)++*	*11*	*P =0 .0011*
Female patients with no history of previous pelvic surgery	*73 (41-129)+*	*32*	*76 (27-139)++*	*30*	*NS P =0.4638*
Differences between patients who have or have not had a hysterectomy					*+ NS P =0.6511 ++ P = 0.0033*
Differences between male and female patients					** P =0.0041 ** P =0.0003*

Table 2 - Median (and range) insertion depth in cm achieved with the PCF240I colonoscope compared with an adult colonoscope at the time of unsedated flexible sigmoidoscopy

Conclusion

This study showed that at flexible sigmoidoscopy in symptomatic patients, women experience significantly more pain and have a lower median insertion depth than men. This confirms what had previously been shown at screening flexible sigmoidoscopy in asymptomatic subjects[1]. We believe than the method of assessing pain/discomfort used in the present study[9] is superior to the usual global visual analogue scale used in previous publications.

Over a quarter of women in our study had had a previous hysterectomy. With an adult colonoscope, these women had more pain and a lower insertion depth than women who have not had pelvic surgery. We have shown that it is possible to reduce the total amount of discomfort associated with non sedated flexible sigmoidoscopy as well as achieve a greater insertion depth by using a floppier paediatric colonoscope.

	PCF240I colonoscope	Number of observations	Adult colonoscope	Number of observations	Statistical significance
All male and female patients combined	*5 (0-18)*	*99*	*6 (0-11)*	*100*	*NS P =0.1214*
All female patients	*6 (1-15)**	*52*	*6 (2-11)***	*41*	*NS P = 0.2447*
All male patients	*4 (0-11)**	*47*	*5 (0-9)***	*59*	*P = 0.0021*
Female patients with previous hysterectomy	*5 (1-11) +*	*20*	*5 (2-6) ++*	*11*	*NS P = 0.4806*
Female patients with no history of previous pelvic surgery	*6 (2-15) +*	*32*	*7 (2-11) ++++*	*30*	*P = 0.0442*
Differences between patients who have or have not had a hysterectomy					*+ P = 0.751 ++ P =0.0028*
Differences between male and female patients					** P = 0.0003 ** P =0 .0298*

Table 3 - Median (and range) number of occasions patients reported pain/discomfort when a flexible sigmoidoscopy was carried out either using the PCF240I colonoscope or an adult colonoscope

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