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# Evaluation of a Novel Colonoscope Designed for Easier Passage Through Flexures : A Randomized Study

Backgr ound and Study Aims : A new colonoscope (XCF–Q160AW prototype, Olympus, Tokyo, Japan) has been deve loped, designed with an additional passiv e bendi ng function to ease in–tubation through the left colonic flexur e. In this study we inv es–tigated whether this function could be included in a standard co–lonoscope without jeopardizing gener al performance, particu–larl y passage through the sigmoid colon .

Patients and Methods : 280 outpatients refe rred for routine co–lonoscop y at Telemark Hospital wer e randomly allocate d to co–lonoscop y with a standar d colonoscope (Olympus 140 series) or the XCF–Q160AW pro totype. Sedation was given on demand. End points wer e cecal intubation and the patients' grading of pain in a questionnaire.

Results : Cecal intubation ra tes were 85 % and 87 % for standar d and pro totype endoscopes, respecti vel y (P = 0.57). On–demand sedation was given to nine (7 %) and 15 (11 %) of the patients, respecti vel y (P = 0.17). Of the patients, 256 (85 %) returned their questionnaire, with 87 (63 %) in the standard group and 109 (77 %) in the pro totype group rep orting that they had experi–enced 'no pain/slight pain' (P < 0.0 01). In a multiple logistic re–gression analy sis, this difference in experienced pain remain ed statistically significant afte r adjustment for inter endoscopist variation and the use of the endoscope–stiffening function. Two patients in the study , in whom there had previousl y been sever al unsuccessful attemp ts at negotiating the splenic flexure, wer e successfully examined with the pro totype colonoscope.

Conclusion : Examination with the Olymp us XCF–Q160AW pro–totype with a passiv e bending function caused less pain than use of a standar d Olympus 140 series colonoscope, without compro–mising other endoscope functions for colonic intubation.

## Introduction

A successful colonoscop y depends on completeness of the exam–ination and the tolerability to the patient. In spite of sedation, there is great variation in report ed cecal intubation rat es in rou–tine clinical wor k [1 - 4]. Refining the technology of colonoscopes is a continuous process to impro ve the endoscopist's prospect of painless negotiation of the tortuous course of the large bow el. The biggest challenge is usually passage through the sigmoid co–lon, but the splenic and hepatic flexur es may sometimes also present a problem.

Ordinary colonoscopes have a distal end that can be activ ely bent in all directions. The limitation of activ e bending to the very dis–tal end may be a disadv antage in the passage of flexures, as im–paction may occur . The anatom y in some curves, for example the left colonic flexure, is such that a trad itional endoscope may need maximal bending to visualize the lumen further proximal–ly . When the endoscope is pushed in this position, the direction of forc e may further the impaction of the endoscop e in the flex–ure ra ther than progr ession in the desir ed direction.

Recently , a new colonoscope has been developed (XCF–Q160AW pro totype, Olymp us, Tokyo, Japan) which, in addition to the dis–tal section that can be activ ely bent, also has a section that bends

passiv ely at an obtuse angle during endoscope insertion. The hy–pothesis to be test ed in the present study was that this endo–scope would make it easier to negotiate sharp curves, particular –ly in the flexures, and inflict less pain and discomfort on the pa–tient.

## Materials and Methods

One of the authors (G.H.) was approached by the manufacturer to provide his opinion about their XCF–Q160AW prototype colo–noscope. The request was accept ed with an expressed wish to evaluate its performance in a rand omized study.

### The Endoscope

The Olympus XCF–Q160AW prototype is, in effect, a standard, variable–stiffness Olympus colonoscope with one exception: Ap–proximatel y 10 cm proximal to the distal, activ ely bendable tip, there is a section which bends passiv ely at an obtuse angle in any directio n during insertion (Fig. 1). The intention behind this modification is to guide the force of insertion more in the desired direction through sharp bends, particularl y to prevent impaction of the sharply bent distal tip in flexur es.

### Study Design

A consecutiv e series of outpatients referr ed to Telemark Hospital for colonoscop y wer e candidates for randomi zation and exami–nation with either the prototype colonoscope or one of the hos–pital standard instruments (Olymp us 140 series; Olymp us). Pri–mary end points wer e the patients' evaluations of pain and rat e for reach ing the cecum.

Examinations were performed by experienced endoscopists (each having carried out more than 500 colonoscopies). $CO_2$ in–sufflation was used for all examinations. Endoscopists wer e dis–courag ed from using the stiffening function of the prototype since this was not an integrat ed function of the standard endo–scope. Each examination started without sedation, but on–de–mand sedation was allo wed as req uired.

Criteria for reach ing the cecum wer e identification of the ileoce–cal valv e or intubation of the distal ileum. Reasons for not reach –ing the cecum wer e categorized into 'stricture', 'poor bow el cleansing' and 'other reas ons'. The latter comprised non–me–chanical/non–obstructiv e rea sons (mainly looping and pain) relat ed largel y to the techniq ue of insertion.

Pain experienced by the patients during the examination was rat ed as 'no pain', 'slight pain', 'moder ate pain', and 'sever e pain', in a validated questionnaire to be filled in on the day after the examination [5]. Free–text area s in the questionnaire allo wed description of any sympt oms (e. g. suggesti ve of complications) within 24 hours after the examination. At Telema rk Hospital the rat e for use of sedation/analgesia is less than 10 % durin g colo–noscop y in the outpatient department [5].

The sy stematic recor ding of the 'endoscopist' s impression of loop formation,' 'the use of x–ray for visualization of positioning', and 'application of the endoscope stiffening function' was not intr o–duced in the pro tocol until after first 58 patients had been includ–ed. Thus, there was sy stematic rec ording of these variables in 222 persons (111 in each group).

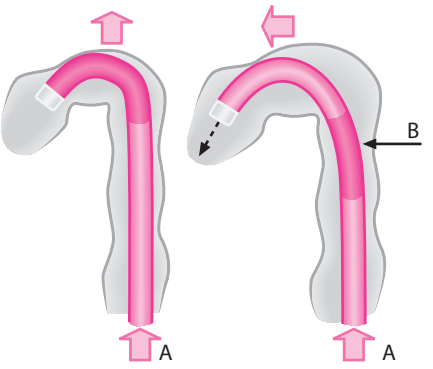


Figure 1 A conventional, endoscope, is shown on the left, and the prototype XPCF–160AWY endoscope on the right. The direction of force (A) tends to lodge the actively bent tip of conventional endo–scopes in the flexure. With the XPCF–160AWY, external pressure tends to bend the shaft of the endoscope passively at an obtuse angle at point B, thus facilitating further insertion rather than impaction.

### Pow er Analy sis

For analy sis, the pain categ ories wer e dichot omized into 'no or slight pain' versus 'mod erate or seve re pain', it being consider ed desirable to minimize the size of the latter group (critical fact ors being design of endoscope, endoscopist performance, and seda–tion/analgesia). To estimate the number of indiv iduals needed in the study, we performed a pow er analy sis based on information from the first 20 inclusions. We estimat ed that 130 patients would have to be included in each arm to detect a 20 %difference in pain with a statistical pow er of 90 % (alpha = 0.05). Inclusions wer e not stopped until after 280 patients, allo wing for some non–compliance in questionnair e rep lies.

### Ex clusion Criteria

Patients excluded wer e pregnant wom en, persons young er than 18 years, persons unable to comprehend the information given, and persons requesting sedation before starting the examina–tion, i. e. those who did not want sedation to be limited to 'on–de–mand' during the course of the examination. Also, patients with previous colorectal resections wer e excluded.

### Blinding

It was impossible to make this study double–blinded since, to the expert eye of an endoscopist, the appeara nce of the prototype was obviously different from that of the standard type. Patients wer e, how ever, blinded with regar d to which type of endoscope was used.

### Statistical Analy sis

The chi–squared test was used for statistical analy sis of categ ori–cal data and Student's t test for continuous variables (age, time to reach the cecum). A logistic regr ession model was applied using 'no or slight pain' vers us 'moderat e or sever e pain' as the depen–dent binary variable. Type of endoscope, endoscopist and the use of endoscope–stiffening function wer e included as categ orical variables. Statistical significance was defined as $P < 0.05$ using two–sided tests. The statistical packag e SPSS 11.0 was used (SPSS Inc., Chicago, Illinois, USA).

Ethical Considerations

The Regional Ethics Committee approved the study protocol. Written informed consent was obtained from all participants.

Results

There were no technical failures and no complications except for one case of vasovagal reaction that did not require intervention. The two groups were similar regarding age, gender, previous abdominal surgery, and the use of fluoroscopy during the examination (Tables 1 and 2). The cecal intubation rate was similar in the two groups, being 85 % and 87 % in the standard and prototype groups, respectively (Table 2).

A total of 256 patients (85 %) returned the questionnaire. There was a difference between the groups in patients' perception of pain, as none or only slight pain was reported by 63 % in the standard group and 77 % in the prototype group (P < 0.001), with no statistically significant difference between the groups regarding the use of on–demand sedation.

Also, the endoscopists' judgements of loop formation were similar in both groups. There was, however, a slight difference between the groups in the distribution of loops (judged subjectively by the endoscopists), as nearly all loop formations in the standard group occurred in the sigmoid colon, being 48 out of 50 loop events (96 %) compared with 37 out of 44 (84 %) in the prototype group (P = 0.05).

There was no statistically significant difference between endoscopists in their cecum intubation rate, overall or for each type of endoscope (data not shown). There was, however, a significant interendoscopist variation in the ability to perform examination with no or only slight pain, both for the standard endoscope (range 47 85 %, P = 0.006) and the prototype (range 57 89 %, P = 0.05). The stiffening function of the prototype endoscope was applied in 33 out of 111 documented examinations (30 %).

Table 1 Patient characteristics

| | Standard (n = 139) | Prototype (n = 141) | P value |
|---|---|---|---|
| Women, n (%) | 71 (51) | 70 (50) | 0.81 |
| Mean age (95 % CI) | 57 (54 60) | 56 (54 59) | 0.50 |
| Previous abdominal surgery, n (%) | 36 (26) | 38 (27) | 0.93 |

Table 2 Findings; n (%), unless stated otherwise

| | Standard (n = 139) | Prototype (n = 141) | P value |
|---|---|---|---|
| Cecal intubation | 118 (85) | 123 (87) | 0.57 |
| Time to reach cecum, minutes (median, range) | 14 (4 40) | 13 (3 36) | 0.55 |
| Patients' perception of pain during examination | | | |
| No pain/slight pain | 87 (63) | 109 (77) | < 0.001 |
| Moderate/severe pain | 43 (31) | 17 (12) | |
| Missing data on pain | 9 (7) | 15 (11) | |
| Fluorescent screen used | 41/111 (37) | 38/111 (34) | 0.76 |
| Endoscopist impression of loop formation | 50/111 (45) | 44/111 (40) | 0.45 |
| Use of on–demand sedation | 14 (11) | 8 (6) | 0.17 |
| Cecal intubation failure | 21 | 18 | |
| Stricture | 1 | 0 | |
| Poor bowel cleansing | 2 | 0 | |
| Other | 18 | 18 | |

In the multiple logistic regression analysis, the beneficial effect of the new prototype endoscope remained after adjusting for endoscopist and the use of the stiffening function (Table 3).

Two patients deserve particular mention: One was a lady who had undergone three previous attempts at colonoscopy, all fail–

Table 3 Crude and adjusted odds ratios (OR) with 95 % confidence interval (CI) of inflicting moderate or severe pain during colonoscopy, adjusting for endoscope, endoscopist and the use of endoscope–stiffening function

| | No. of examinations* | Crude OR | 95 % CI | Adjusted OR | Adjusted 95 % CI | P value |
|---|---|---|---|---|---|---|
| Colonoscope | | | | | | |
| Standard | 130 | Reference | | | | |
| Prototype | 126 | 0.32 | 0.17 0. 59 | 0.42 | 0.17 1.01 | 0.05 |
| Endoscopist | | | | | | |
| A | 99 | Reference | | | | |
| B | 56 | 7.18 | 3.10 16. 62 | 7.55 | 2.86 19.97 | < 0.001 |
| C | 23 | 3.89 | 1.29 11. 73 | 4.16 | 1.22 14.18 | 0.02 |
| D | 30 | 4.45 | 1.63 12. 12 | 3.70 | 1.17 11.75 | 0.03 |
| E | 4 | 8.90 | 1.13 70. 26 | | | |
| F | 23 | 0.85 | 0.17 4. 16 | 1.10 | 0.21 5.72 | 0.91 |
| G | 21 | 2.09 | 0.59 7. 46 | 1.66 | 0.17 16.04 | 0.66 |
| Use of endoscope–stiffening function | | | | | | |
| No | 174 | Reference | | | | |
| Yes | 27 | 0.79 | 0.28 2. 21 | 0.88 | 0.24 3.24 | 0.84 |

* 24 out of 280 patients did not return their questionnaire on pain.
Endoscopist E was dropped out in the statistical adjustment due to low numbers and missing data on endoscope–stiffening function.

ing to reach beyond the splenic flexure. At the most recent attempt she had been heavily sedated, but she still recalled this to have been a terrible experience. Four expert colonoscopists had tried in turn to negotiate the splenic flexure without succeeding. She was now randomly allocated to receive colonoscopy with a standard 140 series endoscope, and 40 minutes were spent trying to negotiate the splenic flexure, using every trick of the trade (apart from sedation), without succeeding. Fluoroscopy verified that the endoscope was impacted in the splenic flexure. The case was recorded as intubation failure. The XCF–Q160AW prototype was then used, and the cecum was reached easily without the use of the stiffening function and still without the use of sedation.

The second patient was a man who had undergone four previous colonoscopies, all with failure to reach the cecum. He was randomly allocated to the prototype group. Again, the cecum was reached without the use of sedation and without using the endoscope–stiffening function.

## Discussion

In the present consecutive series of outpatients referred for colonoscopy it was demonstrated that the Olympus XCF–Q160AW prototype colonoscope has an advantage over standard colonoscopes regarding the patients' comfort during the examination (low degree of pain/discomfort). The cecal intubation rates were similar for both types of endoscopes. Evaluation of the proposed advantage of the prototype in negotiating the splenic flexure was limited to two case reports within the study suggesting an advantage to that effect. It is worth noting that the presence of the additional bending section of the prototype did not increase the likelihood of sigmoid loop formation, but may even have reduced it.

The only difference reaching a statistically significant level was the patients' perception of pain, showing less pain for patients in the new prototype group. Also, pain was the only variable recorded by a blinded party involved in the study (the patient). There is, however, a possibility that the technical performance of the endoscopist may have been biased by the awareness of performing using 'a new tool' and thus taking more care. The greater interendoscopist variation in the standard group may support this view, whereas the tendency towards a shorter time to reach the cecum with the prototype, without more sedation, does not. In the multiple regression analysis, adjustments were therefore made for endoscopist and for use of the design difference which was not blinded (i. e. the endoscope–stiffening function). The statistically significant advantage of the prototype in terms of less pain for the patient retained borderline significance after these adjustments (Table 3). This may not be an issue in endoscopy centers where sedation is routinely given and a change in practice is not being considered. However, a decrease in the need for sedation may reduce costs and complications [6, 7].

A cecal intubation rate of less than 90 %may be considered low. A tradition of using none or only little sedation may explain some of this, although a survey from 68 centers in the UK (where practically all patients were sedated) showed cecal intubation rates of less than 80 % [2]. This should not, however, influence the comparative results between two endoscopes in a randomized trial. When pain is used as an end point, the routine use of medication may mask any relieving effect that might be contributed by progress in the development of endoscope functions and endoscopist performance, thus predisposing to a type II statistical error when possible progress in technique and technology is evaluated.

Patients were blinded to the type of endoscope used while the endoscopists were not. The feel of the endoscopes, including torque stability, was very similar for the endoscopists involved. Since the passive bending function does not require an additional control knob, it should be easy to perform a double–blinded study with this new function, but it would be necessary to make prototypes with and without the passive bending function. The adjustments made in the present multiple logistic analysis must be regarded as a compensation for the inability to apply a double blind design to the trial.

In conclusion, the Olympus XCF–Q160AW prototype colonoscope with a passive bending function caused less pain than a standard Olympus 140 series colonoscope, without compromising other functions of colonic intubation. This suggests that the present type of passive bending function may be safely incorporated in standard colonoscopes.

## Acknowledgment

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