**New generation high definition colonoscopes increase adenoma detection when screening a moderate risk population for colorectal cancer.**

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**Running title-** High definition colonoscopy increases adenoma detection

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**Contribution**

AB was responsible for data collection, analysis, writing and editing the manuscript. GF was responsible for data collection and editing. TC provided statistical support and analysis. CP, SS, NH and POT reviewed and edited the manuscript prior to submission. SS devised the study, wrote and edited the manuscript prior to submission.

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**Abstract**

**Background and Aim**. Adenoma detection rate (ADR) is the most important quality indicator for screening colonoscopy, due to its association with colorectal cancer outcomes. As a result a number of techniques and technologies have been proposed that have the potential to improve ADR. The aim of this study was to assess the potential impact of new generation high definition colonoscopy on ADR within the Bowel Cancer Screening Programme (BCSP).

**Method** This was a retrospective single centre observational study in patients undergoing an index screening colonoscopy. The examination was performed with either standard definition (SD) colonoscopes (Olympus Q240/Q260 series) or high definition (HD) colonoscopes (Olympus HQ290 EVIS LUCERA ELITE system) with the primary outcome measures of ADR and mean adenoma per procedure (MAP) between the 2 groups.

**Result**s. 395 patients (60.5% male, mean age 66.8 years) underwent screening colonoscopy with 45% performed with HD colonoscopes. The caecal intubation rate was 97.5% on an intention-to-treat basis and ADR was 68.6%. ADR with SD was 63.13%, compared to 75.71% with HD (p=0.007).The mean mean adenoma per procedure (MAP) in the HD group was 2.1 (+/-2.0), whilst in the SD group it was 1.6 (+/-1.8) (p=0.01). There was no significant difference in withdrawal time between the two groups. In regression multivariate regression model, only high definition scopes (p=0.03) and male gender (p=0.04) independently influenced ADR.

**Conclusion**. Olympus H290  LUCERA ELITE high definition colonoscopes improved adenoma detection within the moderate risk population. A 12% improvement in ADR might be expected to increase significantly the protection afforded by colonoscopy against subsequent colorectal cancer mortality.

**Microabstract**

This retrospect observational study of 395 patients undergoing colonscopy as part of the England Bowel cancer screening programme, demonstrated that theOlympus H290  LUCERA ELITE high definition colonoscopes improved adenoma detection within the moderate risk population. Moreover it did so when used by operators with a higher than average baseline adenoma detection rate.

**Clinical Practice Points**

* **What is already known?**

There is a positive correlation between ADR and improved outcomes in mortality and morbidity from colorectal cancer.

ADR is a key quality indicator of colonoscopy, new generation scopes have been shown to improve this for operators with low baseline ADRs

* **What are the new findings?**

Not only is a significantly greater ADR achieved with the high definition colonoscope, but this can also improve the ADR of those with an ADR that is superior to the national average. Thus improving the overall quality of colonoscopy in the BCSP.

* **How might it impact upon future clinical practice?**

Where possible high definition colonoscopy should be used, particularly in national screening programmes. This in turn has the potential to positively impact upon outcomes for colorectal cancer by reducing mortality and morbidity.

**Introduction**

Adenoma detection rate (ADR) (number of screening colonoscopies where at least a single adenoma was detected) is considered to be the most important quality assurance measure within screening colonoscopy. ADRs have been reported to vary greatly between operators1. Independent studies have shown an association between higher ADR and lower mortality risk from colorectal cancer (CRC) 2,3 . One such study demonstrated increased risk of interval cancer when the colonoscopy was performed by an endoscopist with an ADR below 20%2. A second, examined 314,872 colonoscopies and reported an inverse relationship between ADR and future risk of colorectal cancer, by demonstrating that with each 1.0% increase in ADR there was an associated 3.0% reduction in the risk of interval cancers and a 5% reduction in colorectal cancer mortality1. More recently, a microsimulation modelling study demonstrated that a higher ADR yielded clinical and financial benefits by reducing risk of colorectal cancer and colorectal cancer mortality without increasing overall costs4.

Several factors such as quality of bowel preparation5, use of antispasmodics6, use of sedation7, withdrawal time8, examination time of day8, continued medical education9 and new technologies or device adjuncts have been shown to improve ADR10. High definition scope systems are one such technology that has been proposed to improve ADR11–13. The American Society for Gastrointestinal Endoscopy (ASGE) endorses the value of such systems in enabling detailed visualization of the GI mucosa; helping to improve detection and classification of GI mucosal lesions and reducing the need for biopsies14. Their ability to improve ADR may also relate to an increased field of vision; (140 vs 170 degrees for the 260 and 290 series scopes respectively).

The aim of this study was to determine whether the new generation high definition colonoscopes can improve adenoma detection during colonoscopy of patients with a positive faecal occult blood test (FOBt) in the English Bowel Cancer Screening Programme (BCSP).

**Methods**

**Setting, Subjects and Materials** This study was performed in Royal Liverpool University Hospital which is a regional bowel cancer screening centre (Liverpool & Wirral Bowel Cancer Screening Programme). The programme offers colonoscopy to patients who have screened as FOBt positive, aged between 60-75 years of age. All colonoscopies were performed by one of four accredited bowel cancer screening colonoscopists. They were performed on dedicated screening lists, in the presence of a screening nurse practitioner, using ScopeGuide and CO2 insufflation as standard. All colonoscopes and systems used were Olympus (KeyMed) with 3 generation of colonoscopes 240 (CF–Q240DL), 260 (CF-Q260DL) and 290 (CF-HQ290L and PCF-H290) series. All 290 series colonoscopes were classed as high definition. Both PCF-H290 and CF-HQ290 colonoscopes were used in conjunction with a 290 series light-source and processor (Olympus EVIS Lucera Elite). The 240 and 260 colonoscopes were used in conjunction with either the 260 Lucera system or the 290 Lucera Elite system depending on the endoscopy room available. During the BCSP sessions, colonoscopes were allocated to the endoscopist on the basis of availability and the examination conducted as normal. The details of the procedure were recorded on an endoscopy database (Unisoft) and the national bowel cancer screening database (BCSS).

**Study Design:** This was a retrospective observational study performed over a 9 month period between Jan 2015 to Sept 2015. The patients were identified using the endoscopy database audit tool (Unisoft). All data was collected retrospectively from the Unisoft endoscopy reporting system and dedicated bowel cancer screening database (BCSS) using a standardised proforma. The data was collected by individuals independent of those involved in the procedure. Along with ADR, withdrawal time, patient demographics, individual endoscopists, quality of bowel preparation, use of sedation, use of antispasmodics and the time of the procedure were recorded. Polyps were only included as adenomatous after histological classification. The number of adenomas, size of the largest lesion and site were also recorded. The number of adenomas was subsequently represented as mean adenoma per procedure (MAP). Only conscious sedation was used (midazolam and fentanyl), there was no use of propofol or general anaesthetic.

**Study Approval:** The Royal Liverpool and Broadgreen University Hospital Trust research and development & audit committee approved this study as an in-service evaluation audit and deemed that ethical approval was not required.

**Statistics and data analysis**

For the purpose of analysis the data were divided into 2 comparative groups. The high definition group (HD),those procedures performed with the 290 series colonoscopes, and the standard definition group (SD) were procedures performed by either the 240 or 260 series colonoscopes. Continuous variables were represented as mean±SD and categorical variables as frequencies. A stepwise logistic regression was constructed to include the following variables: age, gender, scope, withdrawal time, endoscopist, quality of bowel preparation, use of sedation, use of an antispasmodic agent and time of list. Odds ratios (ORs) were estimated from the fitted model. JMP (SAS Inc.) v11.0.0 was used for the statistical analysis. Using Graphpad Prism 6 continuous variables were compared using the t test or Mann-Whitney test as appropriate. Proportions were compared using chi-squared test or Fisher’s exact test as appropriate. A *p* value of <0.05 was considered as statistically significant.

**Results**

**Demographics:** A total of 395 patients were included with a mean age of 66.8+/-4.4 years . Forty-five percent (n=178) were performed with the high definition 290 system (HD), the rest were performed with the 260/240 (SD) system. Their baseline characteristics and univarate analysis are summarised in Table 1. The percentage of procedures performed by each endoscopist was 23.6%,10.9%, 30.4% and; 35.1% for endoscopists 1, 2, 3 and 4 respectively.

**Caecal Intubation Rate:**  The caecal intubation rate (CIR) was 97.5%. Five of the 10 incomplete procedures were due to an obstructing lesion. There was no difference in CIR between the two scope systems (98.3% vs 96.6% for HD v non-HD systems respectively, P=0.3).

**Withdrawal Times**: The mean withdrawal time for the entire cohort was 16.75 minutes. There was a trend towards a shorter withdrawal time in the HD group (15.78 vs 17.5 minutes, p=0.05)(Figure 2A). There was no difference in the withdrawal times between the 4 individual endoscopists (Figure 2B). There was no significant difference for the withdrawal time in those who did (mean 16.9 minutes) and did not (mean 16.24 minutes) have an adenoma detected during their procedure (*p*= 0.4).

**Adenoma Detection:** The overall ADR for the 395 patients was 68.6%. 110 (28%) patients had adenomas detected in both the left and right colon, 51 (13%) had adenomas in the right colon only and 115 (29.1%) in the left colon alone. Seventeen patients (4%) were found to have a histologically confirmed malignancy. There was no significant difference for the location of adenoma detection when comparing the two scope systems (p=0.4). Overall ADR for all four endoscopists using the SD colonoscopes was 63.13%, compared to an ADR of 75.71% when using the HD colonoscopes (*p*=0.007). Twenty-five percent of patients had at least one adenoma greater than 1cm in size. Of those patients identified to have adenomatous polyps, 65% had between 1 and 4 of any size. The maximum number identified during one examination was 10 (Figure 1). The mean size of the adenoma detected was unaffected by the scope system used, with 115 patients having a least 1 adenoma <1cm in size in the HD group compared to 129 in the SD group (p=0.9). The mean number of adenomatous polyps per procedure in the HD was 2.1 (+/-2.0), whilst in the SD group it was 1.6 (+/-1.8) (p=0.01). When comparing the SD and HD systems the mean increase in ADR across the 4 endoscopists was 11.5% (range 7-16%).

Logistical regression analysis demonstrated HD colonoscope and male gender as the only measured variables that significantly impacted upon ADR, (p=0.03 and p=0.04, respectively) (Table 2). There was a trend towards a difference in the ADR and use of the HD scope between the four endoscopists, with endoscopist 1 having the greatest utility of the 290 scope and the largest ADR. However this failed to achieve statistical significance. Moreover, the endoscopist with the lowest use of the 290 system had the second highest overall ADR at 70%. Post hoc power calculation for the endoscopist suggested that we were under-powered for this specific aspect of our analysis (Table 3).

**List timings:** There was no significant difference in ADR when comparing the time of day at which the procedure was performed, Table 2. One hundred and seventy four colonoscopies were carried out on a morning list (ADR 67.2%), 151 on an afternoon list (ADR 66.8%) and 70 on an evening list (ADR 75.7%).

**Complications and Adverse Events;-** There were no adverse events reported for any of the 395 colonoscopies included in this study.

**Discussion**

This single centre retrospective observational study demonstrates improved adenoma detection (ADR and MAP) when using new generation high-definition colonoscopes for screening colonoscopies within the English BCSP.

A study from 2011,which preceded the use of new generation colonoscopes, of 36 460 examinations within the BCSP in England, reported a mean ADR across all colonoscopists of 46.5% (range 21.9% to 59.8%)15. Comparison with the ADR seen across all 4 of our BCSP accredited colonoscopists and all colonoscope systems demonstrates a superior baseline ADR within our study. Furthermore this superior baseline ADR can be further improve by the applicaiton of high definition colonoscopy systems. There is evidence from other studies that support our findings of improved ADR with high definitions systems. A meta-analysis involving 4422 patients concluded that high definition systems are superior in the detection of smaller polyps, without improving the detection of larger and higher risk lesions12. A further study also demonstrated a lower adenoma miss rate with high definition colonoscopy13. The beneficial impact of high definition systems upon ADR for those with lower baseline rates, particularly when <20%, has been clearly demonstrated11. Outside of dedicated screening services there is further evidence to support an increased ADR with high definition scopes. One such study directly compared high definition colonoscopy to standard definition reporting a higher ADR in the high definition group (28.8% vs 24.3%; p= 0.012), as too was the polyp detection rate (42.2% vs 37.8%; p= 0.026)16. Interestingly a study within the BCSP in England examining >900 colonoscopies performed with standard and high definition colonoscopes, failed to demonstrate a difference in ADR, but similar to our study demonstrated a greater number of adenomas per patient being detected in the HD group 17. Our results suggest, not only that high definition systems can improve ADRs, but they can also be improved within a group already operating at a superior level of ADR.

Logistic regression modelling demonstrated high definition colonoscopy and male gender to be the only measured variable to impact upon ADR. Within the UK the lifetime risk of colorectal cancer is reported as 1 in 15 for men and 1 in 19 for women, this supports our finding of increased ADR in males18. The included parameters within the logistic regression modelling were age, gender, use of sedation, use of antispasmodics, endoscopist, withdrawal time, quality of bowel preparation and time of day of the procedure. There are a number of studies looking at the impact of these intra-operative procedural variables on ADR. Systems within the BCSP are in place in order to improve compliance and thus quality of bowel preparation. Studies have shown increasing ADR, up to 35%, with improved bowel preparation quality19. Ninety five percent of the patients had satisfactory or good quality bowel preparation, suggesting that this element is well optimised, without significant variation across the procedural range. However there was significantly superior bowel prep in those undergoing colonoscopy with the 260/240 group. All patients had undergone the usual BCSP bowel preparation education . We did not find any significant impact upon ADR with the use of sedation or antispasmodics. More patients in the 260/240 group received antispasmodics in the univariate analysis but this did not impact upon ADR within the multivariate modelling. The literature relating to these two variables is rather inconsistent. With regards to sedation, the evidence appears to suggest, as the depth of sedation increases so too does the ADR but at the expense of an increasing complication rate7. Conversely, a study of 3252 colonoscopies showed no difference for those receiving propofol and conscious sedation (midazolam and fentanyl)20. A UK BCSP based study examining the use of antispasmodics reported an increase in the number of polyps, the detection of those greater than 1cm and all right sided polyps (p=<0.001)8. Contrary to this, a recent meta-analysis based upon the finding of 8 RCTs concluded antispasmodic use in patients undergoing colonoscopy does not appear to significantly increase the detection of adenomas6.

The time of day that the procedure is carried out has also been report to impact upon ADR8, we did not see this in our study. As a trust trying to find a balance between service provision and delivery of quality, this lack of impact from the time of day is reassuring for continued use of our three session day. A dedicated study examining this issue demonstrated that colonoscopy quality is not dependent on time of day or queue position in an extended 3 session day21. This supports our findings within the BCSP, using ADR as a key quality indicator. There was a trend, failing to reach statistical significance, towards an increase in adenomatous disease amongst males18. This finding is in line with other studies that have described increased ADR in males22,23

We did not demonstrate a significant difference in the size or location of adenomas detected by the HD colonoscopes. A study from 2011 comparing the ADR of HD and SD colonoscopy reported an increase in thedetection of flat and right sided lesions, (p=<0.05), when using the HD system. This study did specifically utilise narrow band imaging (NBI) as part of its study protocol and comparison, something that we did not do24. Within our analysis we did not identify any significant differences in withdrawal times. A withdrawal time of > 8 minutes has been reported to increase ADR in colorectal cancer screening colonoscopies25. Asecond study within the BCSP in England demonstrated a plateau effect after approximately ten minutes. The lowest ADR was demonstrated if the withdrawal was less than 7 minutes, with the maximum ADR, seen with a withdrawal time of 9-11 minutes8. The average withdrawal time for our cohort was 16.75 minutes, there was a difference in the withdrawal time between the two systems, however this did not translate to a difference in ADR, suggesting evidence of the plateau effect seen after 9-11 minutes.

The EVIS Lucera Elite CV-290 colonoscopes not only have a high definition processor and light source that have the potential to improve ADR and MAP, but they also have an increase visual field when compared to the 260/240 colonoscopes (170 vs 140°, respectively). This potential was explored by a study from 2014 assessing the factors that can impact upon ADR for trainee colonoscopists26. Stating only the use of the HD system with the 170° visual field had the potential to increase ADR for trainees. There has also been a reported reduction in adenoma miss rate during colonoscopy with a 170° field of vision27 Other technologies have been developed which have demonstrated the beneficial effects of substantially increasing the visual field, such as FUSE©, which increases the range to 330°. This system has been shown to have superior ADR when compared to both the SD and HD systems we have described10,28,29. The observe improved ADR seen in our study is likely to have been contributed to by the wider visual field seen with the EVIS Lucera Elite CV-290 colonoscopes.

Our modelling also suggested uniformity for ADR and withdrawal time across the four bowel cancer screening accredited colonoscopists. Individual ADRs ranged from 60.4% to 74% when using a combination of the two scope systems. A variety of different studies have questioned whether the individual colonoscopist affects ADR. One such study assessed factors that influence the quality of 12,000 screening colonoscopies finding that annual case volume and life experience did not affect ADR but continued medical education (CME) was the most influential, with those who attended most CME meetings having the highest ADR30. A second study, at the Mayo clinic, randomised half of their colonoscopist to an additional training program. In doing so they saw a 15% increase in the ADR of those undergoing this CME9. We must concede that a limitation of our study was that *post-hoc* power calculations suggested we were marginally underpowered from this element of our analysis. Two limitation of our study are its observational nature and the mode of colonoscope allocation. A prospective study whereby there was formal randomised allocation of the colonoscopes to the 4 endoscopists would be the ideal method, however service provision within the department would make this difficult.

In conclusion, our findings have the potential to significantly impact ADR within screening programmes and thus on the long-term outcomes of CRC. Corley et al demonstrated that for every 1% increase in ADR there is a 3% reduction in interval cancer and a 5% reduction in colorectal cancer associated mortality. Extrapolating these data to our findings of a12% increase in ADR via the use of the HD system, would translate to a reduction in interval cancers by 36%, and a reduction in colorectal cancer related mortality by 60% within our population1.

**Conflict of interest:**

There was no financial support or conflict of interest to report.

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**Titles and legends to figures**

Figure 1: Bar chart representing the number of patients and the number of polyps seen during their colonoscopy. Demonstrates a decline in the number of polyps identified with a plateau at 5 polyps per procedure.

Figure 2: A) Box and whisker plot demonstrating the withdrawal time stratified for the scope type used to perform the examination, *p value by* by Mann Whitney U test. B) Box and whisker plot demonstrating the withdrawal time stratified for the endoscopist performing the procedure, *p* value by Kruskal Wallis 1-way ANOVA and Dunn’s *post-hoc* analysis. No significant difference identified for withdrawal time when stratified by scope system or endoscopist.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Full cohort  | H290  | 260/240  |  | p value |  |  |
| Age (mean years) | 66.8 (SD+/-4.4) | 66.5 (SD+/-3.9) | 67.1 (SD+/-4.8) |  | 0.2 |  |  |
| Gender (n=) |  |  |  |  |  |  |  |
| - male | 239(60.5%) | 125 (70%) | 114 (52.5%) |  | **0.0004** |  |  |
| - female | 156(39.5%) | 53 (30%) | 103 (47.5%) |  |  |  |  |
| Mean withdrawal time (+/-SD)  | 16.75 mins (+/- 7.7) | 15.7 mins (+/-6.5) | 17.55 mins (+/-8.8) |  | **0.05** |  |  |
| Bowel preparation |  |  |  |  | **<0.0001** |  |  |
| - poor | 20 (5%) | 7 (4%) | 13 (6%) |  |  |  |  |
| - satisfactory | 295(74.6%) | 123 (69%) | 32 (18%) |  |  |  |  |
| - good | 80 (20.4%) | 48 (27%) | 172 (76%) |  |  |  |  |
| Sedation used |  |  |  |  | 0.1 |  |  |
| - yes | 250 (63.2%) | 105 (59%) | 145 (66.8%) |  |  |  |  |
| - no | 145 (36.8%) | 73 (41%) | 72 (33.2%) |  |  |  |  |
| Anti-spasmodic used |  |  |  |  | **0.002** |  |  |
| - yes | 253 (64%) | 99 (55%) | 154 (70.9%) |  |  |  |  |
| - no | 142 (36%) | 79 (45%) | 63 (29.1%) |  |  |  |  |
| Time of list |  |  |  |  | 0.2 |  |  |
| - morning | 174 (44%) | 85 (48%) | 89 (41%) |  |  |  |  |
| - afternoon | 151 (38.2%) | 57 (32%) | 89 (41%) |  |  |  |  |
| - evening | 70 (17.85) | 31(20%) | 39 (18%) |  |  |  |  |
| Caecum intubated |  |  |  |  | 0.3 |  |  |
| - yes | 385 (97.4%) | 175(98.3%) | 210 (96.7%) |  |  |  |  |
| - no | 10 (2.6%) | 3 (1.7%) | 7 (3.3%) |  |  |  |  |

Table 1: Univarate analysis and baseline characteristics of included subjects and outcomes for measured variables.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Variable |  | Odds ratio | Lower CI | Upper CI | p value |
| Scope  | 290: 260/240 | 1.62 | 1 | 2.64 | **0.03** |
| Endoscopist | E1 : E2 | 0.53 | 0.21 | 1.3 | 0.17 |
|  | E1 : E3 | 0.98 | 0.47 | 2 | 0.97 |
|  | E1 : E4 | 0.89 | 0.04 | 1.9 | 0.78 |
|  | E2 : E3 | 1.8 | 0.82 | 4.1 | 0.13 |
|  | E2 : E4 | 1.7 | 0.72 | 3.8 | 0.22 |
|  | E3 : E4 | 0.9 | 0.48 | 1.7 | 0.76 |
| Gender | M : F | 1.6 | 1 | 2.6 | **0.04** |
| Sedation | Yes : No | 1.17 | 0.69 | 2 | 0.5 |
| Anti-spasmodic | Yes : No | 0.86 | 0.48 | 1.6 | 0.6 |
| Time of List | Morning : Afternoon | 1.03 | 0.6 | 1.78 | 0.9 |
|  | Morning : Evening | 1.45 | 0.72 | 3 | 0.2 |
|  | Afternoon : Evening | 1.41 | 0.72 | 2.82 | 0.31 |
| Withdrawal time | Increasing time | 1.2 | 0.79 | 2.02 | 0.3 |
| Bowel Preparation | Good:satisfactory | 1.22 | 0.63 | 2.42 | 0.54 |
|  | Good:poor | 1.52 | 0.48 | 4.6 | 0.46 |
|  | Satisfactory:poor | 1.23 | 0.45 | 3.19 | 0.66 |

Table 2: Results of multivariate logistic regression analysis for the procedural variables and their impact on ADR.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scope | Endoscopist 1  | Endoscopist 2 | Endoscopist 3 | Endoscopist 4 | Total |
| 240 | 4 | 5 | 17 | 7 | 33 |
| 260 | 18 | 24 | 68 | 74 | 184 |
| 290 | 71 | 14 | 35 | 58 | 178 |
| Total | 93 | 43 | 120 | 139 | 395 |
| ADR | 74% | 60.4% | 70% | 66% | 68.6% |

Table 3: Frequency of the usage of each scope system and adenoma detection rate stratified by individual endoscopist.