Performance measures in inflammatory bowel disease surveillance colonoscopy

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PERFORMANCE MEASURES IN IBD SURVEILLANCE COLONOSCOPY- IMPLEMENTING CHANGES TO PRACTICE IMPROVES PERFORMANCE

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Running title: Improving quality in IBD surveillance

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Abbreviations:

DCE- Dye-based chromoendoscopy

IBD- Inflammatory Bowel Disease

CRC- Colorectal cancer

ADR- Adenoma Detection Rate

SCENIC- Surveillance for Colorectal Endoscopic Neoplasia Detection and Management in Inflammatory Bowel Disease patients: International Consensus Recommendations

ECCO- European Crohn’s Colitis Organization

ASGE- American Society of Gastrointestinal Endoscopy

ESGE- European Society of Gastrointestinal Endoscopy

PSC- Primary Sclerosing Cholangitis

SSA/P- Sessile serrated adenoma/polyp

FACILE- Frankfurt Advanced Chromoendoscopic IBD Lesions

NBI- Narrow Band Imaging

Abstract:

Background:

Dye-based chromoendoscopy (DCE) with targeted biopsies is recommended for Inflammatory Bowel Disease (IBD) surveillance. However, DCE has not been widely adopted into clinical practice yet. We aimed to evaluate quality indicators in IBD surveillance following introduction of structured changes in service delivery.

Methods:

In August 2016 we introduced a number of changes to IBD surveillance practice in our endoscopy unit. These included training using interactive videos/images in a structured module; DCE as standard by using a foot-pedal operated pump jet; allocation of 45-minute procedure slot; targeted biopsies (except high risk patients); scoring of endoscopic disease activity; lesion detection/morphology characterization. All IBD surveillance colonoscopies were allocated to a small team of four DCE trained endoscopists.

We compared quality measures for surveillance procedures performed pre- and post-August 2016. The two groups were compared using Chi-square statistics.

Results:

A total of 598 IBD surveillance procedures (277 pre-August 2016 and 321 post-August 2016) were performed and included in the study. Use of DCE increased (54.2% vs. 76.0% $p<0.0005$) whilst random biopsy surveillance reduced (12.3% vs. 3.1% $p<0.0005$). The use of Paris classification (26.1% vs. 57.0% $p<0.0005$) and Kudo pit pattern increased (21.7% vs. 59.0% $p<0.0005$). There was also an increased lesion detection rate (24.9% vs. 33.1% $p<0.05$).

Discussion:

Implementation of extensive changes in practice of surveillance colonoscopy resulted in significant improvement in quality indicators within a short period. Training, education and audit may continue to facilitate the adoption of DCE and improve quality of performance further in IBD surveillance.

Keywords:

Surveillance colonoscopy, Dye Chromoendoscopy, Key performance quality indicators, Colonic lesions detection and characterisation

Introduction:

Patients with Inflammatory Bowel Disease (IBD) are at an increased risk of colorectal cancer (CRC) [1-5]. The risk of CRC increases with duration of disease with a 1% risk after 10 years increasing to 14% after 30 years [6, 7]. Regular and high quality surveillance colonoscopy every 1-5 years, depending on risk profile and region of practice, is recommended for early detection and treatment of colonic lesions [8, 9]. In the bowel cancer screening population there are clear quality indicators that need to be met to perform screening colonoscopy; for example Adenoma Detection Rate (ADR), withdrawal time and cecal intubation rate (CIR)[10]. SCENIC (Surveillance for Colorectal Endoscopic Neoplasia Detection and Management in Inflammatory Bowel Disease Patients: International Consensus Recommendations) and ECCO (European Crohn's Colitis Organization) have guidance on how to perform IBD surveillance, for example recommending dye-based chromoendoscopy (DCE) but do not set out clear key quality indicators [9, 11]. This has likely caused variation in practice between individual endoscopists and between endoscopy units-due to a lack of expertise, adequate training, the need for different equipment, which increases the time required and costs [9]. The American Society of Gastrointestinal Endoscopy (ASGE) organized an educational event to optimize quality in endoscopy in IBD involving specialists in IBD and endoscopy. After this meeting over half of the participants (51.7%) adopted DCE in most surveillance colonoscopies, reinforcing the need for appropriate education [12].

Clear guidance on quality indicators is lacking in IBD surveillance and is currently an unmet need. Key quality performance indicators should be introduced and must be auditable, measurable and reflect good practice. They may also have a major impact on lesion detection but also characterization and management. New strategies should be developed introducing new roadmaps for future training and implementation of surveillance colonoscopy in IBD. Some of the elements from the recommendations mentioned above may be used as a preliminary guide to quality performance [9, 11]. The aim of this study was to identify performance in these key quality indicators, before and after service changes were made in IBD surveillance colonoscopy.

Methods:

A retrospective review of all IBD surveillance colonoscopies performed January 2014-October 2018 (58 months) in a tertiary referral unit (University Hospital Birmingham NHS Trust, UK) was completed. The audit was registered at the University Hospital Birmingham, UK (CARMS-14727).

Using the hospitals coding system, a list of patients having an IBD surveillance procedure was obtained from electronic medical records and clinical and endoscopic notes were reviewed. Colonoscopic assessment of disease activity and patients undergoing flexible sigmoidoscopy were excluded. . In the absence of specific IBD surveillance recommendations, we adapted the same quality measure domains as those developed by the European Society of Gastrointestinal Endoscopy (ESGE) including completeness of colonoscopy, lesion detection and management [(13)]. All colonoscopies included in the study were completed using Olympus (Tokyo, Japan) 260/290 series high-definition endoscopes.

To improve quality of IBD surveillance changes were implemented to the endoscopy service in August 2016. These included (a) Education in a structured training module; (b) DCE (as panchromoendoscopy) as a standard of practice; (c) introduction of foot pedal operated pump-jets for cleaning and application of dye spray; (d) allocation of 45-minute procedure slot; (e) targeted biopsies (except high risk patients); (f) formal scoring of endoscopic disease activity; (g) detection of lesions (neoplastic lesions: dysplasia, cancer, sessile serrated adenoma/polyp (SSA/P), adenomas and non-neoplastic lesions: pseudopolyps and hyperplastic polyps); (h) characterisation of lesion morphology. In addition to these changes all IBD surveillance colonoscopies were allocated to a small team of DCE trained endoscopists (n=4). Data collected included patient demographics (type of IBD, co-existence of Primary Sclerosing Cholangitis (PSC), duration and distribution of disease), procedural details (endoscopist, caecal intubation, sedation used, bowel preparation quality), type of surveillance used (DCE, standard white light, targeted or random biopsy surveillance), reasons DCE not used, endoscopic activity of disease score-such as Mayo Endoscopic Score[14], Ulcerative Colitis Endoscopic Index of Severity (UCEIS)[15] and the Simple Endoscopic Score for Crohn's Disease(SES-CD)[16], and lesion documentation (size, Paris classification[17], Kudo pit pattern[18], borders, presence of ulceration and dysplasia detection). Withdrawal times for procedures were not collected as these were not routinely recorded as a standard during the time of the study.

Training and education module:

The training module delivered was an interactive Microsoft PowerPoint (Microsoft Inc., Redmond, Washington, USA) (Video). The content of the module included SCENIC recommendations, the Paris modified Kudo pit pattern[11], Hazewinkel criteria for SSA/P[19], and the Frankfurt Advanced Chromoendoscopic IBD Lesions (FACILE) classification [20]. Representative interactive still images (50) and videos (10) of IBD-lesions including adenomas, SSA/Ps, cancer and inflammatory polyps were displayed. The training module described the process of performing a high quality IBD surveillance procedure, which is summarised by the roadmap in Figure 1. Training was delivered to the DCE-trained endoscopists.

Outcomes:

The primary outcome was the change in proportion of IBD surveillance colonoscopies using DCE (panchromoendoscopy) . Secondary outcomes included the change in lesion/dysplasia detection rate, random biopsy surveillance, formal endoscopic scoring of inflammatory activity and formal descriptors of lesion morphology documented.

Statistical analysis:

Statistical analysis was performed using STATA Version 15.1 (StataCorp, Texas, USA). A p value of <0.05 was considered statistically significant. Quantitative variables were expressed as medians and ranges and/or means ± SDs. Categorical variables were expressed as total number and frequencies. Performance in quality measures before and after changes to local IBD surveillance practice (August 2016) were compared using chi-square analysis for categorical data and Mann-Whitney U test for continuous data.

Results:

Demographic characteristics:

A total of 780 procedures were coded as IBD surveillance between January 2014 and October 2018, with 182 procedures excluded due to being a flexible sigmoidoscopy or assessment of IBD disease activity as the primary indication. There is no statistical difference in patient demographics between the pre-August 2016 and post-August 2016 groups (table 1). There was a high proportion of surveillance colonoscopies performed in PSC patients (39.4% pre-August 2016 vs. 41.7% post-August 2016 p=0.552) which reflects the tertiary referral nature of the unit. There was no significant difference between the two groups in terms of poor bowel preparation using the Boston Bowel Preparation Score (<2) [21] (14.4%

vs. 17.4% p=0.32). There was no difference in type of sedation used (conscious sedation 66.8% vs. 67.0% p=0.96) with the remainder using Entonox only. It was standard practice that colonoscopies were completed using CO2 insufflation therefore in this study all procedures were carried out in this manner.

Comparison of key quality indicators before and after changing practice

Comparisons of performance in key quality indicators during procedure in IBD surveillance between the two groups (pre- vs. post-Aug 2016) are highlighted in Table 2. There are significant differences between the groups (pre-August 2016 vs. all endoscopists post-August 2016/4 and DCE trained endoscopists post-August 2016) with a higher proportion of procedures completed to the terminal ileum (TI) (20.9% vs. 45.8/49.4%, p<0.0005). The primary outcome of the proportion of procedures using DCE increased (54.2% vs. 76.0/78.7% p<0.0005). One of the changes implemented included the use of DCE with Table 3 highlighting the reasons for not using DCE. Insufficient bowel preparation and persistent disease activity were the most common reasons for DCE not being carried out. There was a decrease in procedures not performed with DCE due to bowel preparation from 90.6% to 45.9% (p=0.018) between pre- and post-August 2016, however when combining with procedures not performed due to both disease activity and bowel prep, there was no significant difference in bowel preparation (90.6% vs. 64.9% p=0.199). There was a significant increase in the proportion of procedures performed without DCE due to disease activity between pre-August 2016 and post-August 2016 (6.3% vs. 27.0% p=0.037). The number of colonoscopies that had no formal surveillance technique (DCE/random biopsy collection) nor documented reasons why DCE could not be used was 61 (22.0%) pre-August 2016 and 30 (9.3%) post-August 2016 (p<0.005).

Procedures using random biopsy surveillance reduced (12.3% vs. 3.1/2.3% $p<0.0005$). Formal description of disease activity (2.5% vs. 46.4/49.8% $p<0.0005$), size of lesion documentation (65.2% vs. 79.0/80.5% $p<0.05$), use of the Paris classification (26.1% vs. 57.0/62.1% $p<0.0005$), use of Kudo Pit Pattern (21.7% vs. 59.0/66.7% $p<0.0005$) and descriptions of lesion borders (0.0% vs. 18.0/20.7% $p<0.0005$) all improved following the implementation of the changes previously described. Compared with all endoscopists pre-August 2016, the four DCE trained endoscopists had an improved lesion detection rate after training 24.9% vs. 33.1% $p<0.05$ (Table 2). Although there was an increase in the lesion detection rate, there was not a statistically significant increase in dysplasia detection rate between pre-August 2016 and post-August 2016 (table 2). Of the 20 dysplastic lesions detected in the pre-August 2016 group, 15 were located within a colitic area (75%) whereas 21 of the 32 dysplastic lesions detected in the post-August 2016 group were located within a colitic area (75% vs. 66% $p=0.563$). The breakdown of lesions detected is shown in Table 4.

Overall, 3 patients were diagnosed with adenocarcinoma in the present study. All were diagnosed after August 2016 and 2 had a previous colonoscopy <3 years prior to the cancer diagnosis (one-no data on previous colonoscopy). This gives an interval colorectal cancer rate of 0.7% in the pre-August 2016 cohort, however as we included colonoscopies performed until October 2018 we are unable to report the interval cancer rate in the post-August 2016 cohort.

Quality measures performance of non-experienced vs. DCE trained endoscopists post-August 2016

The performances of all endoscopists versus the four DCE trained endoscopists post-August 2016 are shown in Table 5. Improvements in the use of DCE (63.8% vs. 78.7% $p<0.05$), formal description of endoscopic activity (29.3% vs. 50.2% $p<0.01$), use of the Paris classification (23.1% vs. 62.1% $p<0.01$) and the Kudo Pit Pattern (15.4% vs. 66.5% $p<0.01$) were seen in the DCE trained group.

Discussion:

Surveillance colonoscopy in IBD is crucial for detecting and managing dysplasia/cancer, much like CRC screening programmes in the general population. The additional challenges are the background mucosal abnormalities, such as pseudopolyps and often subtle, flat lesions. Whilst there are guidelines on when and how surveillance should be performed, there is a lack of guidance regarding how to optimise surveillance and which key quality indicators should be considered in IBD patients [8, 9, 11]. The introduction of quality indicators in the colorectal cancer screening population has led to an improvement in performance [10], and has significantly impacted patients' clinical outcomes and quality of life. Quality measures should also be proposed and identified as a priority for surveillance colonoscopy in IBD, based on SCENIC and ECCO recommendations [9, 11].

DCE is recommended as standard and should be considered as a key quality indicator in line with SCENIC and ECCO recommendations [9, 11]. However, multiple barriers and practical issues are related with a lack of wide adoption of DCE which may be due to lack of adequate training, increased time and costs [12].

We have shown that after focussing on DCE as standard of care with dedicated lists and by restricting IBD surveillance to DCE trained endoscopists, introduction of foot pedal operated pump-jets and appropriate training led to a significant improvement in its use and therefore improved quality of IBD surveillance colonoscopy. Indeed, the proportion of procedures using DCE in our study significantly increased from pre-August 2016 to post-August 2016 in hands of DCE trained endoscopists after this implementation. Random biopsy surveillance reduced in favour of targeted biopsies.

The most common reason for not performing DCE was inadequate bowel preparation and the presence of disease activity, which is consistent with other studies [22]. There was overall no difference in the proportion of colonoscopies limited by poor bowel preparation pre- and post- August 2016, however the proportion of procedures not using DCE due to disease activity increased, which likely reflects the increase in DCE-trained endoscopists reporting, whom may feel more confident report colitis activity. Bowel preparation remains one of the main limitations to adopting DCE in >90% of IBD surveillance procedures. Endoscopy units may consider organising bowel preparation for IBD surveillance comparable to Bowel Cancer Screening Programmes to optimise procedural efficiency which will be cost effective and impact patients' quality of life.

Major emphasis should be focused on training, especially on the SCENIC recommendations on how to characterise IBD lesions with the use of Paris classification, Kudo pit pattern, FACILE classification, description of lesion margins and the presence of an ulcerated surface [11, 17, 18, 20]. At our centre an educational training module in IBD lesions led to a significant improvement in key quality indicators, in particular lesions detected with an increased use of morphology descriptors (table 2). Educational classification systems, such as FACILE

(Frankfurt Advanced Chromoendoscopic Ibd Lesions), which has been shown to improve diagnostic performance in all non-expert groups, will improve detection rate and accurate characterisation of IBD lesions[20]. Training and education can play a key role in improving the ability to detect, characterise IBD neoplasia and aid endoscopists to decide on the right therapeutic approach [23]. Moreover, they can also disseminate information and should be considered in endoscopy units to optimize quality of surveillance colonoscopy in IBD patients.

In our study despite the service changes and training provided, there were (9.3%) of procedures did not incorporate a formal surveillance technique nor documented reasons for not using DCE. Despite best efforts and given clinical service demands, some procedures were allocated to endoscopists whom are not formally trained in DCE, which may explain the 9.3% of procedures with sub-optimal surveillance practice. This highlights the need for well-structured strategies to ensure well trained specialists in IBD perform IBD surveillance colonoscopy by using DCE. International organizations should develop a curriculum on how surveillance should be performed and how detected colonic lesions are managed that will result in uniform high quality performance.

Our results are in line with other studies demonstrating the impact of an educational event increasing the use of DCE [12]. A study conducted at three Mayo Clinic sites involving six endoscopists without any experience in chromoendoscopy had shown that after training with images, the interobserver agreement for determination of polypoid abnormalities in patients with long-standing UC was excellent: k coefficients were 0.91 (95% CI 0.60-0.93) for WLE and 0.86 (95% CI 0.82-0.89) for DCE [24].

There is a significant focus on ADR in the screening population[10, 25] and lesion detection should be considered a quality measure in IBD surveillance with defined performance metrics. In our study there was an improvement in lesion detection between the pre- and post-August 2016 groups which may lead to an improved dysplasia detection rate over time.

There are limitations to this study. Firstly, being a single tertiary referral centre may make generalising the results to other units challenging. Secondly, the retrospective nature does bring potential bias, particularly as the audit is reliant on the data entered at the time of the procedure. . In our centre withdrawal times were not routinely documented during the period of the study and are not included in this dataset. The procedures performed in our centre used high-definition endoscopes (Olympus 260/290 series), without the use of magnifying endoscopy. Magnifying endoscopy is a promising modality in the optical diagnosis of IBD lesions [26, 27], however we are unable to comment on the role of this technology in IBD surveillance. However, given that magnifying endoscopy is not in widespread use in the West our results are likely to reflect “real-life” practice. The new generation of Olympus (Tokyo, Japan) 290 series endoscopes with near focus allows magnified images and is easier to use which may promote the adoption of magnification in the West. Given the retrospective design, it was not possible to comment on the influence of operator experience. All endoscopists were considered experienced however detailed statistics on lifetime colonoscopy numbers and number of procedures per annum was not possible.

In conclusion we have demonstrated that by implementing specific changes, performance in quality indicators can be improved. It highlights how education, training and dedicated DCE trained endoscopists performing IBD surveillance colonoscopies can significantly change practice. Areas to improve are ensuring all procedures are allocated to DCE-trained endoscopists, ensuring bowel preparation is optimum, colitis activity is recorded and is optimised for surveillance, lesion morphology and characterization descriptors as mandatory. These changes need to be implemented at a unit organisation level but also at the individual endoscopist level through effective educational modules. Further audit, training and education may improve adoption of quality indicators. More formal guidance on quality measures in IBD surveillance has been published [(25)], however international consensus on IBD surveillance measures will also ensure uniform high quality of colonoscopy.

Video. Example of the IBD surveillance-training module.

Figure 1. A roadmap on how to complete a high quality IBD surveillance procedure

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