

## **Computed tomography colonography: radiographer independent preliminary clinical evaluation for intraluminal pathology.**

### **Abstract**

*Introduction;* We evaluated the reporting competency of radiographers providing preliminary clinical evaluations (PCE) for intraluminal pathology of computed tomography colonography (CTC).

*Method;* Following validation of a suitable tool, audit was undertaken to compare radiographer PCE against radiology reports. A database was designed to capture radiographer and radiologist report data. The radiographer's PCE of intraluminal pathology was given a score, the "pathology discrepancy and significance" (PDS) score based on the pathology present, any discrepancy between the PCE and the final report, and the significance of that discrepancy on the management of the patient. Agreement was assessed using percentage agreement and Kappa coefficient. Significant discrepancies between findings were compared against endoscopy and pathology reports.

*Results;* There was agreement or insignificant discrepancy between the radiographer PCE and the radiology report for 1736 patients, representing 97.0% of cases. There was a significant discrepancy between findings in 2.8% of cases and a major discrepancy recorded for 0.2% of cases. There was a 98.4% agreement in the 229 cases where significant pathologies were present.

*Conclusion;* From a database of 1815 studies acquired over three years and representing work done in a clinical environment, this study indicates a potential for trained radiographers to provide a PCE of intraluminal pathology.

### **Abbreviations**

BCSP – bowel cancer screening programme

CAD – computer aided detection

CRC – colorectal cancer

CTC – computed tomography colonography

FIT – faecal immunochemical test

OC – optical colonoscopy

PCE – preliminary clinical evaluation

PDS – pathology discrepancy significance score

## **Introduction**

Colorectal cancer (CRC) is the third most common cancer and is the second most common cause of cancer death in the UK. It's incidence continues to rise with an ageing population [1]. Colonic imaging is undertaken in symptomatic patients to primarily detect the presence of three main pathologies: potentially pre-cancerous polyps, CRC, diverticular disease, and its complications. Presenting symptoms such as rectal bleeding, weight loss, abdominal pain, anaemia, change in bowel habit and a palpable mass are similar for all three pathologies and the severity of symptoms is not always in line with the severity of the disease or stage of CRC [2-4]. In order to manage CRC risk, bowel screening has also been undertaken by the NHS Bowel Cancer Screening Programme (BCSP) since 2006 to detect adenomas, a non-malignant precursor to the colonic tumour which accounts for 95% of colorectal tumours and polyps. [5]

Options for investigating patients lie within endoscopy and radiology. Optical colonoscopy (OC) [6] and flexible sigmoidoscopy [7] both offer diagnosis and therapeutic intervention through direct visualisation of the bowel mucosa and the opportunity for polypectomy and biopsy. Diagnostic radiology offers computed tomography colonography (CTC) [8] which provides accurate imaging of the colon [9]. It does not allow for therapeutic treatment or tissue sampling but carries a lower (0.005-0.059%) risk of perforation. [10-12]

CTC may be more acceptable to patients as it does not require sedation, does not require anticoagulants to be stopped, and when minimal preparation is used does not require adjustment of patient medications incompatible with full bowel preparation [13]. As such it is more suitable for a large subgroup of patients unsuitable for OC. [14, 15]

Use of CTC for the investigation of positive faecal occult blood (FOB) screening or positive faecal immunochemical test (FIT) in the BCSP has much to offer; [16] especially as the technology continues to improve to reduce scan times and radiation dose, and computer aided diagnosis (CAD) can be used to improve test sensitivity [17]. The test is certainly a more acceptable and safer option than OC for the frail and elderly [18, 19] and avoids the need for multiple screening tests to achieve

diagnosis. However, it is acknowledged that CTC accuracy is very dependent on the quality of the examination and the competence of the individual issuing the report [20-22]. Guidance from the BCSP describes the need for bowel preparation and faecal tagging, dual position scanning and bowel insufflation with CO<sub>2</sub> to ensure all segments of the bowel are clearly visualised.[16] They also recommend training for all reporting radiologist and there is a requirement for all BCSP approved radiologists to report a minimum of 100 studies per year to maintain skills. [16]

With increasing demand for CTC service provision, and well documented strain on radiologist reporting services,[23] it is essential that mechanisms for ensuring timely, accurate and cost-effective reporting of CTC examinations are investigated. An evaluation of endoscopy workload described a doubling in demand for lower GI endoscopy between 2012 and 2017.[24] Changes to NICE referral guidelines in 2015 [4] and increased uptake in the BSCP have been contributing factors. The 2<sup>nd</sup> round evaluation of the NBCSP suggests a 10-15% year on year increase in activity and acknowledges the impact this will have on workload for radiology and pathology.[24] Using reporting radiographers to provide preliminary clinical evaluations (PCE) for intraluminal pathology may support radiologists with this additional activity.

The aim of this study was to compare the findings of radiographers reporting CTC scans for intraluminal pathology against the radiologist report when working in a clinical setting. Other studies have been undertaken to look at the reporting skill of radiographers. These predominantly looked at participants following a period of training but with little experience, involved small numbers and were in a research setting rather than clinical.[25]

It was outside the scope of this study to identify radiographer accuracy in extraluminal pathology although this interpretation does form part of the final radiology report. This is because radiographers had not received formal training to undertake this task, their role and involvement in CTC evolved following transfer of previous barium enema services to CTC and they were primarily GI specialists.

## **Methods**

### Audit Approach

A retrospective audit was undertaken using a validated audit tool [26] and applying it to a database collated between February 2011 and April 2014. These data were used to evaluate the radiographer PCE reports when compared with radiologist reports; considered to be the reference standard for the purposes of this study. Audit approval was obtained from both the affiliated NHS Trust and University as appropriate.

Cases were reported by one of two radiographers, each with over 15 years GI experience and 4-5 years experience in reviewing CTC images. Both had previously attended an external course (a one week training programme including evaluation of over 50 endoscopically proven cases) and in-house training with their first 50 clinical PCE supervised by an experienced gastrointestinal radiologist.

In addition these 50 cases provided pilot data used to inform development of the audit tool which was then subjected to a process of validation as described previously in the literature [26]. Following approval from the lead radiologist, the radiographers then began offering a PCE as part of a clinical double reporting service, whilst continuing to use the audit tool.

### Examination Details

1815 consecutive cases were considered for inclusion in this audit. All patients undertook CTC performed on a 64 slice CT scanner (GE Lightspeed VCT, GE Healthcare, Waukesha, Wisconsin). Scans were performed to protocol with a collimation width and slice interval of 0.625mm. Patients were initially imaged in the prone position using 120kV and a modulated mA with a range of 100 – 500mA and a 0.5 second gantry rotation time. The acquisition in the supine and any supplementary scans were performed using a low dose technique of 120kV, 100mA and a 0.5 second scan gantry rotation time. Carbon dioxide bowel insufflation was used and distension assessed on the initial scout view. Intravenous contrast media (IVCM) was given if indicated at the time of request or following recognition of positive pathology on radiographer review of the initial prone scan. All patients received bowel preparation and faecal tagging with diatrizoate meglumine and diatrizoate sodium solution (Gastrografin, Bracco Diagnostics Inc., Princeton, NJ) unless contraindicated. [13, 27]

PCE was performed on a Vitrea Workstation™ using Vitrea® CT colon analysis software (V6.0, Vital Imaging, Minnetonka, MN). Radiographers were trained to view and measure pathology on the supine and prone scan using multiplanar reformats and a window width of 2500 and a window level of 250, and to use the 3D reconstructions to confirm findings. This PCE included the position, slice number, size and description of any pathology identified. The radiographer PCE was issued before and therefore blinded to the opinion of the radiologist and equally, the radiologist produced their provisional report blinded to the radiographer PCE. Following this, the final radiologist report was issued after review of the PCE.

### Reporting and Agreement Scoring

All scans for reporting were distributed evenly between four consultant radiologists experienced in CTC. All in-patient scans and scans with any significant pathology requiring an urgent review (as referred by radiographers) were completed within 24 hours. All CTC reporting radiologists had appropriate experience in CTC and 3 of the 4 had completed an accredited CTC training course.

A scoring system was developed to categorise PCE by three variants including the pathology (as outlined in Table 1 as P-Score descriptors), the level of agreement between the PCE and the radiology report, and the clinical significance of any discrepancy demonstrated between the opinions of the radiographer and radiologist. This was termed the “pathology, discrepancy and significance (PDS) score” [26] and is detailed in Table 2. It should be noted that where radiology reports described one or more pathology, the most significant was used to determine both the P-score and the resulting PDS score.

*Table 1 – P-Score descriptors categorising the clinical significance of pathology [26]*

<i>Score</i>	<i>Pathology</i>
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<i>P0</i>	Not scored, inadequate study
<i>P1</i>	No intra-luminal pathology reported
<i>P2</i>	Diminutive polyp ≤ 4mm, diverticula
<i>P3</i>	Small polyp 5mm – 9mm / diverticular disease to include wall thickening and stricturing
<i>P4</i>	Polyp ≥ 10mm, carcinoma, complicated diverticular disease (collection, fistula, abscess)

Table 2 – “Pathology, discrepancy and significance (PDS) score” descriptors [26]

<i>Score</i>	<i>Description</i>
<i>PDS0</i>	Not scored – inadequate study / missing data
<i>PDS1</i>	Report agreement (P1-P4 reports)
<i>PDS2</i>	Discrepancy with P2 reports (insignificant discrepancy)
<i>PDS3</i>	Discrepancy with P3 report
<i>PDS4</i>	Discrepancy with P4 report

A PDS score was recorded by the radiologist at the time of reporting. Studies changed to a CT abdo / pelvis because CTC was abandoned were given a P score of 0 and a subsequent PDS score of 0 (incomplete data) as were studies where a PCE was not issued before the final report. Because of the confidence held by radiologists in the value added by the radiographer PCE, the final report would normally be held back until the PCE was available to review so only 13 studies scored PDS0 for this reason. On issue of the final report a PDS score was assigned. Any studies with a PCE issued but not assigned a score by a radiologist at the time of double reporting were retrospectively scored by a CTC reporting radiographer to ensure inclusion of the data in the study.

This was undertaken because it was felt that omission to score at the time of reporting might occur more often for a normal or insignificant finding with no relevant feedback to give to the radiographer. Omitting this data could have introduced bias to the results

The PDS scoring system enabled the observational PCE data to be converted into categorical data with ordinal variables for input and interrogation of percentage agreement and Cohen's Kappa coefficient using IBM® SPSS® statistics (v21) data analysis software.[28]

## **Results**

The patients presenting for investigation represented symptomatic patients and asymptomatic positive BSCP patients. Table 3 describes the range and frequency of pathologies documented in the radiology reports within these groups, categorised as P-scores. This table demonstrates a good range of pathology across all the cases. Normal or insignificant findings were described in the radiology report for 1163 cases (64.1%). 640 (35.2%) cases had significant pathology described, these being either CRC, polyps >5mm, or diverticular disease. Records were not available for 12 (0.7%) of the 1815 cases as described above.

*Table 3: The range and frequency of pathology identified*

<b><i>P score</i></b>	<b><i>Pathology description</i></b>	<b><i>Number of cases</i></b>	<b><i>Percent</i></b>
<b><i>P0</i></b>	No record	12	0.7
<b><i>P1</i></b>	No pathology	387	21.3
<b><i>P2</i></b>	Polyp < or = 4mm, diverticula	776	42.8
<b><i>P3</i></b>	Polyp 5-9mm, diverticulosis, wall thickening, narrowed lumen.	411	22.6
<b><i>P4</i></b>	Polyp > 10mm, malignancy, complicated diverticular disease	229	12.6
<b><i>Totals</i></b>		1815	100.0

*Table 4: Summary of PDS scores (25 of 1815 cases have been excluded where the P or PDS scores were 0)*

<i>Score</i>	<i>Frequency</i>	<i>Percent</i>
<b><i>PDS 1 – match</i></b>	1619	90.4
<b><i>PDS 2 – insignificant discrepancy</i></b>	117	6.6
<b><i>PDS3 – significant discrepancy</i></b>	49	2.7
<b><i>PDS4 – major discrepancy</i></b>	5	0.3
<b><i>Total</i></b>	1790	100.0

Table 4 describes the frequency of the PDS scores assigned to the radiographer PCE's by the reporting radiologist. Of 1815 cases, 25 (1.4%) were assigned a PDS0 and excluded. These represented 12 cases where CTC was abandoned and an alternative scan offered and 13 cases where CTC was performed but the final report was issued before the radiographer PCE was completed.

Of the 1790 cases with first reads available for review, 1619 (90.4%) demonstrated agreement between the opinion of the radiographer and radiologist (PDS score 1). In 117 cases (6.6%) there was a disagreement of opinions but the discrepancies were felt to be clinically insignificant (PDS score 2). As such, pooling PDS1 and PDS2 results together indicates there was a 97.0% agreement between radiographers and radiologists, where any discrepancies were clinically insignificant.

In 49 (2.7%) cases there was felt to be a significant discrepancy between reports (PDS score 3) and in 5 cases (0.3%) the radiologist felt that a major pathology had been overlooked by the radiographer issuing the PCE (PDS score 4). These results should be considered in the context of the frequency of different P-score pathologies as demonstrated in Table 4, which recorded P3 or P4 level pathologies in 640 of 1815 cases (35.2%). The strength of agreement in these results is rated as very good with a Cohen's Kappa coefficient of 0.80.[29]

### *Significant Discrepancies*



Endoscopy and pathology reports were checked for all the PDS 3 & 4 scores to investigate the 54 (3%) of cases where the difference of opinions between radiographer and radiologist was felt to be of relevance to the management of the patient, summarised in Table 5.

*Table 5: Agreement between endoscopy, pathology and final double reported radiology reports for PDS3 and PDS4 scores.*

	<b>Compared interventions</b>	<b>Frequency</b>	<b>Percent</b>
<b>Valid</b>	No intervention	26	48.1
	Endoscopy / pathology matches radiology	23	42.6
	Endoscopy / pathology disputes radiology	5	9.3
	Total	54	100.0

Results were available for all 54 cases. For 26 of 54 cases the patient was managed conservatively without further investigation, therefore it was not possible to determine whether the final double reported radiology report was correct. For 23 of 54 cases endoscopy and/or pathology findings were in agreement with the final double reported radiology report.

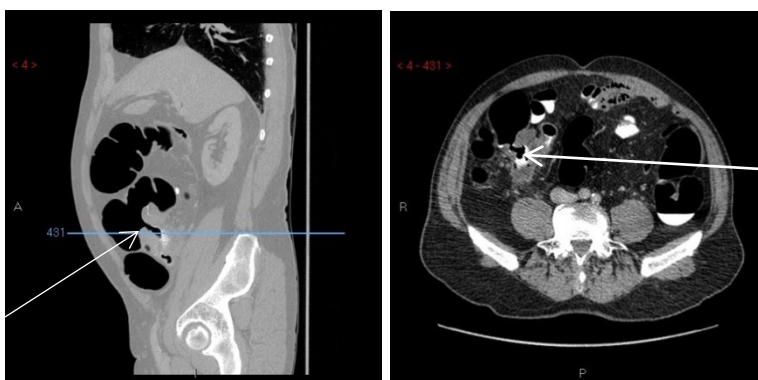
In 5 of 54 cases there was disagreement between the final double reported radiology report and findings at endoscopy. All of these cases had PDS scores of 3 indicating that findings were thought to be clinically significant but did not relate to major pathologies. It is important to remember that this study considers small polyps of 5-9mm to have clinical significance. These cases are described in table 6 below.

For all 5 cases (0.3%) given a PDS score of 4, indicating that the radiographer failed to identify a major pathology reported by the radiologist, there was agreement between the final double reported radiology report and endoscopy and/or pathology.

Table 6 describing PDS3 discrepancies

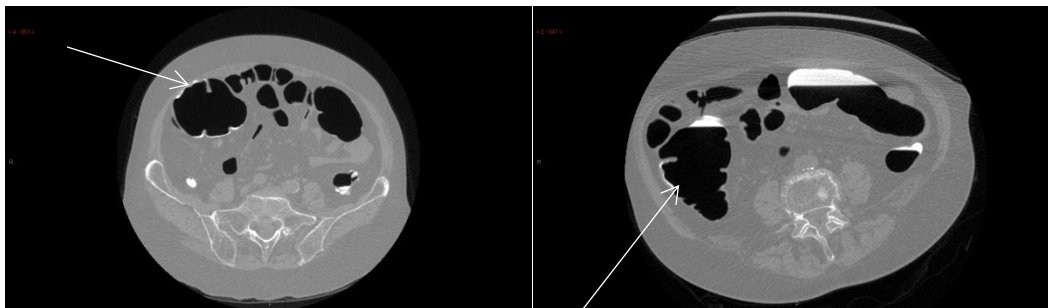
Case	Findings
1	The radiology report described two small (PDS score 3) polyps not identified by the radiographer. Of these polyps just one was confirmed at endoscopy with the pathology report describing a high grade dysplasia.
2	The radiology report described a 7mm caecal polyp which was not identified by the radiographer. The follow up endoscopy was normal.
3	The radiology report described a 6mm sigmoid polyp not identified by the radiographer. This polyp was not identified at endoscopy but a tiny (sub 5mm) caecal polyp, overlooked at CTC was removed.
4	The radiology report described a sigmoid polyp which was overlooked by the radiographer. Endoscopy confirmed the presence of this polyp and the pathology report described a high grade dysplasia. In this instance the radiology report significantly undersized the lesion.
5	The radiology report described two small polyps, not identified by the radiographer and a thickened bowel wall suggestive of colitis. The endoscopy and pathology reports described colitis but did not confirm the presence of polyps.

Again comparisons for these 5 cases were made between the radiology report and findings at endoscopy/pathology. Two patients went on to have surgery where the pathology report confirmed the radiology diagnosis of cancer. Looking more specifically at the imaging for these two lesions missed by the radiographer, both involved the caecum. One was a missed caecal polyp in a poorly prepared, under distended bowel, and the other a lesion at the terminal ileum, including the ileocaecal valve (fig 1a&b).



*Fig 1a&b Caecal tumour involving the ileocaecal valve and terminal ileum*

The remaining three had no further intervention but from review of the notes it can be concluded that the clinical team felt that further intervention was not appropriate. One case represented a false positive PCE, the radiologist did not support the findings of the radiographer and a sigmoid lesion was reported as faecal residue. Another case related to an 84 year old patient who was reported to have a 7mm pedunculated polyp. No intervention was recorded; the patient was frail and elderly and died a short time later. It should be noted that, on review of the radiology report, a PDS score of 4 was incorrectly assigned by the radiologist in this instance. A 7mm polyp should have represented a PDS of 3. Adjusting the data to reflect this resulted in an increase to 2.8% for significant discrepancies (PDS3) but a reduction to 0.2% for major discrepancies (PDS4). The final case referred to a 93 year old with multiple polyps of which some, but not all, were identified by the radiographer (fig 2a&b). Again, it was considered inappropriate to clinically intervene in this case.



*Fig 2a&b Subtle villus lesion in caecum.*

Overall, having adjusted for mislabelling of PDS scoring, radiographers missed four P4 pathologies out of 229 P4 cases, representing 98.4% agreement with the radiologist report for these clinically important “major” pathologies.

### **Discussion:**

This study demonstrates that radiographers can, with appropriate support and training, provide a PCE of intraluminal pathology to a standard comparable to that of experienced consultant radiologists. Given the increasing demand for CTC examinations and continued strain on Radiology departments for reporting CTC, it

appears radiographer role extension into contributing a PCE is an option worth considering for CTC reporting.

A joint document published in September 2012 by the Royal College of Radiologists and the Society and College of Radiographers supports the principle of double reporting through team working and evidences its success in many areas, including gastrointestinal imaging [30]. However, current advisory bodies do not recommend independent reporting of the colon by radiographers. The NHS BCSP state that all CTC reports provided for their patients should be issued by a radiologist who has sufficient expertise and has undertaken appropriate training [16, 31, 32]. The British and European Societies of Gastrointestinal and Abdominal Radiology also support the requirement for CTC reporting to be undertaken by an experienced consultant radiologist [31, 32], but do acknowledge the role of the radiographer in providing a preliminary read. This seems at odds with the acceptance of the essential role nurse endoscopists play in delivering an equivalent service for endoscopy [33].

Burling [34] describes low polyp detection rates of 72% by radiographers, long image interpretation times compared to radiologists, and lack of skills to interpret extracolonic findings as reasons to discourage independent reporting by radiographers. However, anecdotally radiologists involved in this study identified a reduction in their report time when they had a radiographer PCE available as they felt more confident when reporting.

A systematic review of the diagnostic accuracy of radiographer reporting of CTC examinations [25] did not support radiographers in the role of providing a single formal written report on the lumen of the bowel. This review looked at eight studies which provided data on the accuracy of radiographer reporting following training, with training recommendations being independent reporting of 50-75 cases [21,36]. However, three of the studies involved radiographers with experience of reporting between 61 and 200 cases and these were subject to subgroup analysis. They demonstrated a statistically significant 21% improvement in sensitivity for the detection of lesions  $\geq$  5mm, suggesting that radiographer reporting accuracy improves with experience. Likewise, this study looked at 1815 PCE's by 2 radiographers with up to 3 years experience. Our results support that with adequate

training and experience, radiographers can report intraluminal pathology to a high standard.

However, there appears to be a lack of consistency in the training available for would-be CTC reporting radiographers. Miller et al. 2011 looked at post graduate training for radiographers and concluded that:

*“much of the training provided for extended role activities is ad hoc and neither validated nor accredited”* p.60[36]

Miller also acknowledged that training for complex tasks was more likely to involve external training. As an indicator 90% of radiographers trained in performing and reporting barium enema's undertook an external course validated and or accredited with additional study over a 2yr period [36]. If comparable external training was offered to radiographers reporting CTC, the reporting accuracy may compare favourably with radiographer reporting skills in other areas. Law looked at radiographer reporting of barium enema studies and reported a sensitivity of 98% and specificity of 93% for CRC [37]. A comparable study by Culpan reported radiographer sensitivity of 90.6% compared with radiologist sensitivity of 98.7% for CRC [38]. These suggest that radiographers can reach and maintain acceptable clinical reporting standards for certain defined areas of practice [39,40]. These findings were supported for radiographer reporting of CTC in a recent small study undertaken by Thomsen et al. who recommended the use of radiographers as co-readers [41].

There is an argument that CAD may offer an alternative second read that could improve the reporting accuracy of reporting radiologists. However the evidence base demonstrates CAD may increase reporting times and decrease specificity [17]. CAD also does not address the need for timely PCE which may help guide CTC procedures or fast track urgent cases, a radiographer is likely to still be required to facilitate this, either through direct PCE or by highlighting to a reporting radiologist.

### Study Limitations

Limitations of this study include that the PDS score represents the reporting radiologist's interpretation of the difference between opinions and this was issued before any discussion or amendment of final reports. It was therefore not possible to

identify any discrepancies where the radiologist had overlooked a lesion correctly identified by the radiographer. This could lead to a bias potentially underestimating radiographer reporting accuracy. In addition, this study did not compare the time taken for radiographers or radiologists to review and report studies so no comparisons can be made between the two.

It is also important to note that this study took a cautious approach by considering small polyps of 5-9mm as having clinical significance. This reflected local practice at the time to report on all polyps. Practice at the study hospital has now changed to reflect the consensus that sub 6mm polyps are not clinically significant. Any bias introduced by the relatively cautious approach taken in this study to report polyps 5-9mm is likely to again underestimate the accuracy of radiographer reporting.

A final limitation of this study is that it is a single site study involving only two radiographers and four radiologists. However, having now developed a validated audit tool [26] and having demonstrated clinically acceptable accuracy results for reporting CTC radiographers in the context of a single site CTC service, larger multisite studies incorporating larger numbers of reporters and reflecting the variabilities in department services are warranted. Reporting CTC radiographers currently already work in many NHS Trusts and it is important that current barriers such as training opportunities and the potential benefits including improved cost-effectiveness, reporting efficiency and reporting accuracy in CTC service provision are explored in future research.

## **Conclusion**

This study has identified that experienced, well trained radiographers can have the necessary skills to provide a report of intraluminal pathology for CTC. They have the ability to potentially add value to the service by offering a preliminary clinical evaluation to support the radiologist report. There may be potential for competent radiographers to offer independent intraluminal reports in the future.

Training and auditing radiographers in PCE of intraluminal pathology has led to this department providing a radiographer led CTC service. Upon recognising pathology during the procedure, radiographers are able to undertake additional scans, give contrast as appropriate and arrange an urgent report as required, all without seeking advice from a radiologist.

## Conflict of interest

None

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