CT Colonography: Performance and Program Outcome Measures in an Older Screening Population

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Purpose:
To evaluate computed tomographic (CT) colonography performance and program outcome measures in an older cohort (65–79 years) of an established large-scale colorectal cancer screening program.

Materials and Methods:
This HIPAA-compliant study was approved by the institutional review board; informed consent waived. Retrospective analysis of the 65–79-year-old cohort (n = 577) from the University of Wisconsin CT colonography screening program (n = 5176) was undertaken. Performance and outcome measures including advanced neoplasia prevalence and colonoscopy referral, extracolonic finding, extracolonic work-up, and complication rates were obtained by using a CT colonography database and review of medical records. Comparisons between the older cohort and the general screening population were made by using the Student t, Pearson χ², and Fisher exact tests. A P value ≤ .05 was considered to indicate a significant difference.

Results:
With a 6-mm threshold for positivity, the overall referral rate to optical colonoscopy was 15.3% (88 of 577), leading to 277 polypectomies and the removal of 103 nondiminutive adenomas. For adenomas, the per-patient positivity rates were 10.9% (63 of 577) and 6.8% (39 of 577) at the 6- and 10-mm thresholds, respectively. The prevalence of advanced neoplasia was 7.6% (44 of 577). Fifty-four adenomas met advanced status, and five unsuspected cancers were detected. The advanced neoplasias identified were typically large, with a mean size of 21 mm. Potentially important extracolonic findings were seen in 15.4% (89 of 577) of patients, with a work-up rate of 7.8% (45 of 577). The majority of important extracolonic diagnoses were vascular aneurysms (n = 18). No major complications were encountered.

Conclusion:
CT colonography is a safe and effective screening modality for the older population.

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Computed tomographic (CT) colonography has matured into an effective screening technique. It has accuracy equivalent to that of optical colonoscopy (OC) for the detection of advanced neoplasia (1,2). Advanced neoplasia is an optimal target for colorectal cancer screening and is defined as (a) a large (≥10-mm) tubular adenoma, (b) an adenoma of any size with a substantial villous component or high-grade dysplasia (HGD), or (c) invasive cancer. CT colonography is now one of the preferred options in the American Cancer Society colorectal cancer screening guidelines (3). The recent addition of CT colonography may have a major effect on future public health, as up to 40% of the eligible population does not undertake screening with the traditional options (4). Reported screening adherence is even worse for the older cohort of Medicare patients (5). Evidence from several large CT colonography centers suggests that CT colonography may substantially increase overall screening numbers for a given population (6,7). Thus, CT colonography may be particularly helpful in the older population, representing a safer less invasive alternative to colonoscopy. However, there is limited age-specific data regarding utility in this cohort. Questions have arisen regarding whether factors such as performance, referral rate to colonoscopy, and the rate of incidental extracolonic findings could vary from the reported values in the general population and, thus, have a substantial negative effect on CT colonographic screening in this group (8). The purpose of our study was to evaluate CT colonography performance and outcome measures in the older age cohort (65–79 years) of an established large-scale colorectal cancer screening program.

### Materials and Methods

D.H.K. and P.J.P. are consultants for Viatronix and Medisight and cofounders of VirtuoCTC.

#### Study Group

Our retrospective study, which complied with the Health Insurance Portability and Accountability Act, was approved by the institutional review board at the University of Wisconsin. The requirement for informed consent was waived. Between April 2004 and July 2008, 5176 adults were enrolled in the University of Wisconsin CT colonography screening program. The patients were individuals at average risk who were referred for colorectal cancer screening from Madison, Wis, and the surrounding region. Patients with a prior history of cancer, inflammatory bowel disease, or polyposis syndrome and those who were under surveillance for prior adenomas were excluded. The 577 (11.1%) patients who were between 63 and 79 years old were included in our study cohort.

CT Colonography Reporting and Data System (C-RADS) conventions were prospectively applied to all CT examinations (9). Patients with examinations with no polyps or only diminutive (≤5-mm) polyps were deemed to have negative findings (ie, C-RADS category C1) and were relegated to routine screening at a 5-year interval. Patients with at least one polyp 6 mm or greater in size were considered to have positive findings and were given the option of therapeutic colonoscopy referral for polypectomy. Unless the patient had a contraindication, same day referral was attempted to allow removal of the polyp without the need for an additional bowel preparation. Patients with one or two 6–9-mm polyps (ie, C-RADS category C2) were also given the option to enroll in an institutional review board–approved surveillance protocol as an alternative to polypectomy.

#### CT Colonography Technique

The CT colonography technique used at the University of Wisconsin has been previously described in great detail (10). Briefly stated, the individual undergoes a combined laxative cleansing and contrast material tagging protocol for bowel preparation beginning 1 day prior to the scheduled procedure. During the study period, the laxative was a single dose (45 mL) of sodium phosphate (Phosphosoda; CB Fleet, Lynchburg, Va). Magnesium citrate (Sunmark, San Francisco, Calif) or polyethylene glycol (Golytely; Braintree Laboratories, Braintree, Mass) was substituted in a small number of patients. The contrast material tagging regimen included 250 mL of 2.1% wt/vol barium (Scan C; Covidien, Mansfield, Mass) and 60 mL of diatrizoate (Gastroview; Covidien). Since 2008, sodium phosphate has been replaced by magnesium citrate as the standard cathartic agent in the protocol owing to the rare but serious complication of acute phosphate nephropathy associated with sodium phosphate.

Colonic insufflation was achieved through automated delivery of carbon dioxide (Protoco; Bracco Diagnostics,
Princeton, NJ. There was continuous inflow of carbon dioxide throughout image acquisition. Scans were initiated after confirmation of adequate distention, which was determined by a combination of image review and measurements of attained intracolonic equilibrium pressures. No spasmolytics were administered.

Image acquisition was undertaken with a 16-section multidetector CT scanner (LightSpeed; GE Healthcare, Waukesha, Wis). Technique consisted of 1.25-mm section collimation, 5-mm reconstruction interval, 120 kVp, and either a fixed tube current–time product (50–75 mAs) or tube-current modulation (range, 30–300 mA) with the noise index set at 50. An additional reconstruction of the supine data with 5-mm section collimation and a 3-mm interval was undertaken to facilitate extracolonic review. Soft tissue, lung, and bone window settings were used when appropriate for the extracolonic review. All data were networked to a picture archiving and communication system and a three-dimensional workstation (V3D Colon; Viatronix, Stony Brook, NY) for postprocessing. Interpretation was undertaken by one of five radiologists (D.H.K., P.J.P., J.L.H., and two nonauthors). At the beginning of the study period, reader CT colonography experience ranged from 50 to over 200 pathologically proved CT colonography cases. At the conclusion of the study, all radiologists had experience with at least 700 CT colonography examinations.

**Colonic Findings**

For CT colonography–depicted polyps at least 6 mm in diameter, the characteristics of size, morphology, and location were prospectively determined and recorded in a customized CT colonography database (Access; Microsoft, Redmond, Wash). Size was determined by measuring the longest dimension by using both the two- and three-dimensional images. For pedunculated polyps, the longest dimension of the polypl head was measured, with the polypl stalk excluded. Polyp morphology was divided into sessile, pedunculated, and flat (plaque-like, raised ≤ 3 mm from the colonic surface) categories for polyps less than 3 cm in size. For masses ≥ 3 cm in size or larger, descriptive terms such as saddle, hemircumferential, annular, and carpet were used. Location was originally reported by colonic segments (ie, cecum, ascending, transverse, descending, sigmoid, or rectum). For the purposes of our study, these segmental locations were condensed into proximal and distal categories relative to the splenic flexure to mirror prior surgical and colonoscopic series. All examination findings were classified according to C-RADS conventions (9): C0 = nondiagnostic, C1 = negative findings (no or only diminutive polyps), C2 = one or two 6–9-mm polyps, C3 = one polypl 10 mm or greater in size or multiple (at least three) 6–9-mm polyps, and C4 = a colonic mass at least 3 cm in size.

At pathologic analysis, adenomas were classified as tubular, tubulovillous (25%–75% villous component), villous, or serrated. HGD was noted when present. Invasive carcinoma was defined as malignant extension past the muscularis mucosae. Advanced adenomas were defined as tubular adenomas at least 10 mm in size or adenomas of any size that had a substantial (>25%) villous component and/or HGD. Advanced neoplasia included both advanced adenomas and adenocarcinomas. The specimens were read by one of 11 pathologists with experience ranging from 5 to 30 years.

**Extracolonic Findings**

The reconstructed 5-mm image series was used for review of extracolonic findings, which were prospectively categorized according to C-RADS conventions and recorded in the CT colonography database. For individuals with more than one extracolonic finding, the examination was classified by the finding with the highest category score. In accordance with C-RADS, examinations limited by artifact were coded as E0. Examinations that demonstrated normal anatomy or an anatomic variant were coded as E1. Extracolonic findings that were clinically not important or did not require any additional work-up were coded as E2. In the clinical report, no additional imaging was recommended for patients with E2 findings. Findings that were likely not important but were incompletely characterized were coded as E3, and findings that were potentially important were coded as E4. For the E3 and E4 categories, a specific recommendation regarding further imaging evaluation was made in the clinical report. A review of the electronic medical record was undertaken to determine whether additional imaging examinations were undertaken and to confirm the final extracolonic diagnosis.

**Statistical Analysis**

For positive CT colonography examinations, an established matching algorithm was used to determine concordance between CT colonography and OC for a given finding (11). This algorithm allowed for a degree of uncertainty in localization and size at colonoscopy. A polyp had to be located in the same segment or the adjacent segment and be within 50% of the size reported with CT colonography to be considered a true match. Both neoplastic (eg, adenomas) and nonneoplastic (eg, hyperplastic, mucosal polyps) entities were considered true matches, whereas stool was not considered a match. The CT colonography–OC concordance rate was defined as the number of true structural matches between the two modalities divided by the total number of nondiminutive polyps reported at CT colonography.

Comparison between our older cohort and the general University of Wisconsin screening CT colonography population were made by using the Student t test for independent samples of continuous outcomes. The Pearson χ² and Fisher exact tests were used for categorical outcomes. A P value of less than or equal to .05 was considered to indicate a significant difference.

**Results**

The mean age in the older cohort (69.2 years ± 7.3; n = 5176) was significantly older than that in the entire screening population (56.9 years ± 7.3; n = 5176) (P < .001). In addition, there was a significant difference in the
gender proportions between our cohort (man-to-woman ratio, 51.8%:48.2%) and the general population (man-to-women ratio, 45.4%:54.6%) (£ < .001).

Table 1 shows selected program outcomes for our older cohort compared with those for the general CT colonography screening group inclusive of all ages. At a 6-mm threshold, the OC referral rate for the older age cohort was 13.3% (88 of 577). Overall, 277 polypectomies were performed in these referred patients, resulting in the removal of 103 nondiminutive adenomas and the biopsy of five unsuspected cancers. For adenomas, excluding cancers, the per-patient test positivity rate was 10.9% (63 of 577) at the 6-mm threshold and 6.8% (39 of 577) at the 10-mm threshold. The per-patient false-positive rates were 3.6% (21 of 577) and 2.1% (12 of 577) at the 6- and 10-mm thresholds, respectively. Patients with false-positive findings were those who were sent for OC and had findings of a nonadenomatous (hyperplastic or mucosal) polyp or had a polyp that was not seen. From the group of harvested lesions, 54 adenomas met advanced status criteria. When these were added to the cancers, there were 59 advanced neoplastic lesions with an overall prevalence of 7.6% (44 of 577) for the older age group. Not included in this analysis were the 30 patients enrolled in the institutional review board–approved surveillance protocol who had 37 small (6–9-mm) polyps. The CT colonography–OC concordance rate was 90.8% (158 of 174).

The characteristics of advanced neoplasia seen within the older cohort are summarized in Table 2. Size was a defining characteristic for this group. The majority were determined by size criteria alone; 94.9% (56 of 59) of lesions were 10 mm or greater in size (Fig 1). Only three advanced adenomas were smaller than a centimeter in size; all of these had a villous component. No HGD or invasive carcinoma was seen in the subcentimeter group. All cancers (n = 5) were large, with a mean size of 44 mm ± 13.4.

C-RADS classifications for colonic and extracolonic findings are presented in Figure 2. For extracolonic findings, E3 and E4 are the two categories that may lead to further imaging. In the older cohort, 15.4% (89 of 577) of patients fell into one of these categories. However, the actual work-up rate for incidental extracolonic findings seen at CT colonography was 7.8% (45 of 577). Overall, 3.6% (21 of 577) of these findings were substantial but unsuspected diagnoses. Vascular aneurysms (n = 18) constituted 85.7% of this group. Other diagnoses included an unsuspected lung cancer (n = 1), malrotation (n = 1), and a femoral hernia (n = 1). For the group of individuals for whom an additional study was recommended (E3 or E4) but none was undertaken, the mean duration of chart review to establish the lack

<table>
<thead>
<tr>
<th>Program Outcomes</th>
<th>Older Cohort (n = 577)</th>
<th>General Screening Group (n = 3120)*</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced neoplasia</td>
<td>44 (7.6)</td>
<td>100 (3.2)</td>
<td>£ .001</td>
</tr>
<tr>
<td>Referral for OC</td>
<td>88 (15.3)</td>
<td>246 (7.9)</td>
<td>£ .001</td>
</tr>
<tr>
<td>E3 or E4 findings</td>
<td>89 (15.4)</td>
<td>335 (10.7)</td>
<td>.0012</td>
</tr>
<tr>
<td>Extracolonic work-up</td>
<td>45 (7.8)</td>
<td>192 (6.2)</td>
<td>.14</td>
</tr>
</tbody>
</table>

Source.—Reference 2.

Note.—Unless otherwise specified, data are numbers of patients, with percentages in parentheses.

* Data from a previous analysis (2).

<table>
<thead>
<tr>
<th>Characteristics of Advanced Neoplasms</th>
<th>Older Cohort (n = 59)</th>
<th>General Screening Group (n = 123)*</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size (mm)</td>
<td>21.1 ± 15.5†</td>
<td>18.4 ± 12.6†</td>
<td>.88</td>
</tr>
<tr>
<td>Large (≥10 mm)</td>
<td>56</td>
<td>117</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>Small (6–9 mm)</td>
<td>3</td>
<td>5</td>
<td>.72</td>
</tr>
<tr>
<td>Diminutive (≤5 mm)</td>
<td>0</td>
<td>1</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>Histologic finding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tubular</td>
<td>23</td>
<td>59</td>
<td>.26</td>
</tr>
<tr>
<td>Tubulovillous</td>
<td>22</td>
<td>42</td>
<td>.74</td>
</tr>
<tr>
<td>Villous</td>
<td>6</td>
<td>4</td>
<td>.08</td>
</tr>
<tr>
<td>Serrated</td>
<td>3</td>
<td>4</td>
<td>.68</td>
</tr>
<tr>
<td>HGD</td>
<td>4</td>
<td>8</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>5</td>
<td>14</td>
<td>.54</td>
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<tr>
<td>Morphologic finding</td>
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<tr>
<td>Sessile</td>
<td>28</td>
<td>56</td>
<td>.81</td>
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<tr>
<td>Pedunculated</td>
<td>17</td>
<td>41</td>
<td>.54</td>
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<tr>
<td>Flat</td>
<td>3</td>
<td>12</td>
<td>.39</td>
</tr>
<tr>
<td>Other†</td>
<td>11</td>
<td>14</td>
<td>.18</td>
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<tr>
<td>Location‡</td>
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<td></td>
<td>.58</td>
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<td>Proximal</td>
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<td>49</td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>38</td>
<td>74</td>
<td></td>
</tr>
</tbody>
</table>

Source.—Reference 2.

Note.—Unless otherwise specified, data are numbers of lesions.

† Data from a previous analysis (2).
‡ Does not include polyps from patients undergoing CT colonographic surveillance.
§ Histologic findings sum to greater than the number of lesions in each category because HGD was used as a descriptive modifier for tubular, tubulovillous, villous, and serrated polyps when applicable.

Source:—Reference 2.
of further imaging was 724 days ± 461 (range, 202–1863 days).

No substantial complications were seen in the older cohort. Specifically, no perforations or major hemorrhage occurred either at CT colonography screening or at therapeutic OC for referred patients with positive CT findings.

Discussion

CT colonography has been shown to have performance equivalent to that of OC in both screening and higher risk cohorts in several large multicenter trials (1,11–13). In addition, it has been shown to enable more efficient detection of advanced neoplasia compared with OC when coupled with selective polypectomy strategies (2). Widespread implementation of CT colonography could potentially improve screening adherence by the general populace and may represent a more attractive screening option for older individuals owing to its less invasive nature. However, there are limited data specific to the older cohort. Questions have arisen whether the CT colonography performance seen in the large trials can be extrapolated to this older group, given the typically younger age of the participants in those trials (8). In addition, there are limited data regarding CT colonography program outcomes (eg, OC referral or extracolonic work-up rate), which may differ in the older group. Our study was undertaken to address these concerns and present benchmark values for this older (65–79 years) cohort.

At first glance, the determination of CT colonography performance within an observational study design may appear to be difficult to obtain. As opposed to a clinical trial, measurements such as sensitivity or specificity cannot be obtained because not all CT colonography examinations undergo a confirmatory test in the clinical setting. In other words, only patients with positive findings at CT colonography undergo OC for removal of detected polyps, while patients with negative examinations are relegated to routine 5-year follow-up. Thus, neither the CT colonography true- nor false-negative rate can be determined. However, CT colonography performance, particularly in regards to the relative performance within subgroups of the population, can be suggested through surrogate measures.

The prevalence of advanced neoplasia is a useful measure for evaluating CT colonography performance in the clinical setting. Several studies (14–16) have used advanced neoplasia yield to assess relative performance. In addition, as opposed to sensitivity and specificity measurements that give the expected performance when applied to a given clinical population, advanced adenoma yields are a concrete program outcome. They are the group of target lesions removed that is felt to most likely decrease future cancer incidence. In our study, the advanced neoplasia prevalence was 7.6% (44 of 577) for the older age group, which is more than double that which we had previously reported (2) in the general screening population (P < .001). The result suggests that relative CT colonography performance does not drop off in an older cohort, as would be suggested if yield had decreased or

Figure 1: Screening CT colonography in a 76-year-old woman with multiple comorbid conditions who was believed to be a sedation risk for OC. (a) Three-dimensional colon map shows an elongated tortuous colon. Blue arrow = start of center line, green line = computer-generated center line, red dot = position of a transverse polyp. (b) Three-dimensional endoluminal view shows a lobulated sessile 23-mm polyp. Large size was typical of advanced neoplasia in the older cohort. (c) Two-dimensional transverse view shows soft-tissue nature of polyp (arrow). Patient could not tolerate prone position due to her debilitated condition, so she was imaged in decubitus position. (d) OC image confirms CT colonography–detected polyp, which proved to be a large tubulovillous adenoma without HGD or cancer.
remained the same in relation to the general population. The overall increase in prevalence is expected, given the cohort demographics of increased age and increased percentage of men (17–19).

Other surrogate performance measures include the CT colonography–OC concordance rate (138 of 174, 90.8%) and the per-patient false-positive rate (21 of 577, 3.6%). As described previously, CT colonography–OC concordance rate is a per-polyp measure, while the false-positive rate is defined on a per-patient basis. The high CT colonography–OC concordance rate and low false-positive rate in our observational study both suggest that overdiagnosis of nondisease does not occur to a large extent in the older cohort.

A key program outcome regarding CT colonography use in the older cohort involves the referral rate to OC after a positive CT colonography examination. A high referral rate in this group could negatively affect the overall utility of CT colonography as a screening measure. We would expect an increase in colonoscopy referral in this subgroup given the increased adenoma prevalence (18, 19). We found a rate of 15.3% (88 of 577) for the 65–79-year-old cohort, which is a significant increase over that in the general population ($P < .001$).

However, this rate remains in a similar range as compared with other screening modalities. Lieberman et al (20) reported an OC referral rate from positive screening flexible sigmoidoscopy of 16.4% in an older population of men from the Veterans Administration. It is important to remember that, even with this increased referral rate, nearly 85% (489 of 577) of individuals in this age range who are screened with CT colonography avoid the need for OC, thus decreasing the possibility of major OC complications that are known to be increased in this older cohort (21).

The characteristics of advanced neoplasia seen in our older cohort were similar to those described in the general population (22). Concerns have been raised that the characteristics of advanced neoplasia, such as a small size or flat nature, may be different for this specific older age group, with potentially negative effects on CT colonography performance (8). Overall, most (56 of 59, 94.9%) of the advanced neoplasias were large (≥10-mm) lesions. A minority were subcentimeter lesions, typically meeting criteria with a villous component as opposed to the presence of HGD or cancer. Indeed, for this older cohort, there were no cases of subcentimeter polyps with foci of HGD or cancer. Other large colonoscopic-based series (23, 24) have shown similar results, with HGD or cancer seen infrequently in patients with small (6–9-mm) or diminutive (≥5-mm) polyps. In the Clinical Outcomes Research Initiative database (23), the cancer and HGD rates in diminutive (≥5-mm) polyps were each 0.03% (one of 3744), and no cancers were seen in the small-polyp (6–9 mm) group in a large colonoscopic series from Indiana (24).

Given these observations and the average life expectancy of this cohort, a strong argument could be made to set a larger size threshold for referral to OC. A 10-mm threshold would further decrease the referral rate while capturing close to 95% (56 of 59) of the advanced neoplastic entities in our study. The small number of subcentimeter advanced adenomas could be identified by demonstrating interval growth at surveillance imaging.

In our older cohort, the E3 and E4 categories constituted 15.4% (89 of 577) of the examinations with incident extracolonic findings. These were the patients for whom additional imaging could be recommended. In our practice, extracolonic findings placed in the E1 or E2 categories cannot have a recommendation for any further imaging in the formal report. Although the prevalence of E3 or E4 findings was higher in the older cohort than in the general screening group ($P = .0012$) and was slightly higher than the 7.4%–11.4% range of potentially important extracolonic findings reported in other series (25–28), the actual work-up rate that occurred in this cohort was 7.8% (45 of 577). This mirrors what has been noted in the general population, where the actual work-up rate is less than the extracolonic finding rate (29). There are a number of causes that may account for this observation. In some patients, the finding may be a known diagnosis, and in others, the work-up may be deferred owing to the patient’s specific clinical situation or comorbidities.

It is important to bear in mind the potential benefits regarding the extracolonic evaluation. In our study, 3.6% of examinations revealed an important but unsuspected extracolonic diagnosis; the vast majority of these were unsuspected vascular aneurysms ($n = 18$).
The early presymptomatic detection of such conditions would likely positively affect the individual. A recent modeling study (30) of CT colonographic screening in an older (≥65 years) population showed both clinical efficacy and cost effectiveness related to the added benefits of aortic aneurysm detection during extracolonic review.

The overall safety profile of CT colonography was excellent, with no perforations or major hemorrhages seen in this cohort. Unlike OC, for which complications may increase with increasing age (21), they remain an unlikely event at CT colonography, presumably related to its minimally invasive nature.

One limitation of our study is related to its observational design. As discussed above, this precludes the calculation of performance measurements such as sensitivity or specificity. The surrogate measures that can be obtained only provide indirect evidence regarding CT colonography performance. However, these measures, such as advanced neoplastic yield, have the advantage of representing concrete outcomes with real future clinical effect where the screening target lesion has been removed. Another study limitation involves the single center nature of our series. The generalizability of our results could potentially be debated, but the study cohort was large and interpretations were undertaken by multiple readers.

In conclusion, CT colonography performance is maintained in an older age cohort, as evidenced by the surrogate measure of advanced neoplasia prevalence. In addition, program outcome measures, such as OC referral and extracolonic work-up rates, remain in a similar range to other screened groups. In this cohort, CT colonography remains a safe modality. Overall, the observations from this clinical experience confirm that CT colonography may be a valuable screening modality in the older population.

References


