PRACTICE GUIDELINE

Practice Guideline for the Surveillance of Patients After Curative Treatment of Colon and Rectal Cancer

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The American Society of Colon and Rectal Surgeons is dedicated to ensuring high-quality patient care by advancing the science, prevention, and management of disorders and diseases of the colon, rectum, and anus. This Clinical Practice Guidelines Committee is charged with leading international efforts in defining quality care for conditions related to the colon, rectum, and anus by developing Clinical Practice Guidelines based on the best available evidence. These guidelines are inclusive, not prescriptive, and are intended for the use of all practitioners, health care workers, and patients who desire information about the management of the conditions addressed by the topics covered in these guidelines. Their purpose is to provide information based on which decisions can be made, rather than to dictate a specific form of treatment.

It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all the circumstances presented by the individual patient.

STATEMENT OF THE PROBLEM

More than 140,000 people in the United States are diagnosed annually with colorectal cancer.[1] Unfortunately, ~25% to 40% will develop a tumor recurrence despite a potentially curative operation.[2] Although it is well known that most recurrences occur within 5 years, the optimal strategy to accurately detect recurrences at the earliest stage remains controversial. The current recommendations for follow-up surveillance include a combination of history and physical examination, laboratory evaluation, imaging, and endoscopy on slightly varying schedules depending on the organization and stage of disease.[3–10] Further surveillance depends on the results of these examinations. Differing opinions also exist as to the cost-benefit as it relates to outcomes of high- versus low-intensity surveillance.[2,11–28] Potential benefits of high-intensity surveillance include earlier detection of recurrence, higher rates of reoperation for cure, and improved overall and disease-specific survival. Yet, these conceivable benefits must be weighed against potential negative physical (ie, more invasive testing), financial, and psychological consequences of surveillance.

Because the purpose of surveillance is the detection of curable recurrence, recommendations for surveillance should also be tempered by the ability and appropriateness of further major surgical resection and/or chemotherapy for an individual patient. For example, patients who are unable to tolerate surgical or adjuvant therapy owing to comorbidities should not undergo surveillance. Thus, factors to consider when recommending surveillance include patient comorbidity, activity level, age, patient preference, and compliance. In addition, the overall success of surveillance for early detection of curable recurrence will depend on a commitment for both providers and patients to adhere to the surveillance schedule. This clinical practice guideline provides evidence-based recommendations for health care providers following patients who have undergone a previous *curative* resection for stages I to IV colorectal cancer.

Methodology

These guidelines are built on the last set of the American Society of Colon and Rectal Surgeons Practice Parameters

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for the surveillance and follow-up of patients with colon and rectal cancer published in 2004.[9] An organized search of Medline (from 1950), PubMed, EMBASE (from 1980), and the Cochrane Database of Collected Reviews was performed through December 2014. Key word combinations included "colon cancer," "rectal cancer," "colorectal neoplasm," "surveillance," "strategies," "intensity," "cure," "CEA," "CT," "colonoscopy," "endoscopy," "proctoscopy," "ERUS," "follow-up," and related articles. MeSH headings included "colorectal neoplasms," "colonic neoplasms," "rectal neoplasms," "neoplasm recurrence, local," "neoplasms, second primary," and "neoplasm metastasis." Directed searches of the embedded references from the primary articles were also performed in selected circumstances. Although not exclusionary, primary authors focused on all English language manuscripts and studies of adults. Prospective, randomized, controlled trials (RCTs) and meta-analyses were given preference in developing these guidelines. Since the previous American Society of Colon and Rectal Surgeons (ASCRS) guideline, 6 RCTs[17–22] (Table 1) and 3 meta-analyses[2,27,28] have been published (Table 2). Selected embedded references from the primary articles were reviewed. Guidelines from other societies were considered in each case, particularly when a recommendation was changed.[3,4,7,8,29,30] Final recommendations based on stage for cases in which neoadjuvant therapy was given were based on pretreatment (ie, clinical) staging. Recommendations were formulated by the primary authors and reviewed by the entire Clinical Practice Guidelines Committee. The final grade of recommendation was performed using the GRADE system[31] (Table 3).

RECOMMENDATIONS

1. **Surveillance is recommended for stage II to III patients who have undergone a curative resection of colon or rectal cancer with or without neoadjuvant chemoradiation therapy. Risk-adjusted intensity of surveillance may be considered based on tumor- and patient-specific factors. Grade of Recommendation: Strong recommendation based on high-quality evidence, 1A.**

Eleven prospective RCTs[11–13,15–22] have assessed surveillance outcomes for patients who underwent R0 resection (Table 1). Although these randomized trials vary in the frequency of visits and investigations performed at each visit, and are limited in sample size, the studies that showed improved survival[16,17,20] have increased frequency of liver imaging by ultrasound and CT to every 3 to 6 months, in comparison with studies where liver imaging was performed annually or not at all.[11,13,15,19] Increased frequency of liver imaging was associated with improved resectability for cure of cancer recurrence and enhanced survival.[16,17,20] However, frequency of liver surveillance remains somewhat controversial because improved survival has not been uniformly demonstrated, with 1 small study that performed ultrasound every 6 months and CT annually showing *no* difference, despite earlier detection of recurrence.[12] Also, the recently reported Follow-up After Colorectal Surgery (FACS) trial concluded that more intensive surveillance by imaging, CEA testing, or both provided increased rates of resection with curative intent (8% CT vs 6.7% CEA vs 6.6% CT + CEA vs 2.3% minimum follow-up). However, mortality did not differ between groups.[22] Furthermore, the combination of CT and CEA was associated with no better survival outcomes than each individual test.

Two ongoing trials aim to provide further data on overall outcomes, quality of life, and cost-effectiveness of varying surveillance regimens. The GILDA trial began accrual in 1998; the final results are awaited. It randomly assigns patients with Dukes B and C (stage II/III) to a "minimalist" or standard approach, or more intensive follow-up regimen. The intensive regimen includes annual endoscopy, CEA, CA19-9, complete blood count, liver function evaluation, more frequent liver imaging, and increased proctoscopy and abdominal-pelvic CT imaging for patients with rectal cancer.[32] Preliminary results have demonstrated no difference in mortality (7% intensive vs 5% standard) between the 2 regimens.[18] The COLOFOL protocol (a pragmatic study to assess the frequency of surveillance tests after curative resection in patients with stage II and III colorectal cancer) similarly randomly assigns patients to either a low- or high-frequency testing strategy including CEA and multislice CT or MRI imaging in varying intervals.[33] It is currently ongoing; preliminary results are not available.

Seven meta-analyses have addressed the relationship between intensive surveillance and survival following resection of colorectal cancer[2,23–28] (Table 2) including an updated Cochrane analyses.[28] All meta-analyses report increased curative resections and improved survival in patients undergoing more intensive surveillance. One meta-analysis,[2] which included the largest number of cases (n = 2923), reported that more intense follow-up was associated with increased curative resection rate (24.3% vs 9.9%) and improved survival (78.2% vs 74.3%). In the most recent Cochrane analysis, improved chance of curative surgery for recurrence was associated with higher intensity of surveillance (OR, 2.41; 95% CI, 1.64–3.54).[28] However, there are difficulties with evaluating these studies because testing modalities and the definitions of "intense follow-up" vary. When evaluating the RCT and meta-analyses data in total, it appears that curative resection for recurrence uniformly increases with increased surveillance, whereas the survival advantage is more variable, and likely modest at best.

TABLE 1. Randomized controlled trials: surveillance for patients following resection of colorectal cancer

Study	*Year*	*Main surveillance strategy*	*Study outcome*
Ohlsson[11]	1995	• Intensive follow-up (CEA, endoscopy, CT, CXR) • None (FOB testing)	• 5-y survival (75% intensive vs 67% $p > 0.05$) • Reoperation (29% vs 17%; p = NR)
Makela[12]	1995	• Standard • More intensive CEA, colonoscopy, CT, hepatic US	• 5-y survival (59% intensive vs 54%; $p = 0.05$) • Reoperation for cure (23% intensive vs 14%; p = NR)
Kjeldsen[13]	1997	• Standard • More intensive examinations, colonoscopy, US, CT	• No difference in survival (70% vs 68%; $p = 0.48$), but earlier detection of recurrence • Resection for cure (20% vs 6%; $p = 0.01$) • Improved quality of life • Liver imaging not done; colonoscopy every 6 mo
Schoemaker[15]	1998	• Standard regimen • More frequent CXR, CT, colonoscopy	• No difference in survival (78% vs 72%; $p = 0.198$) • Annual liver CT, CXR, and colonoscopy
Pietra[16]	1998	• Standard regimen • More frequent physical examinations, CEA, colonoscopy, liver imaging, CT	• More frequent liver imaging associated with survival advantage (73% vs 58%; $p = 0.02$) • Increased curative reoperation (21% intensive vs 6% standard) • US every 3 mo for 3 y then every 6 mo for 2 y, CT, CXR, and colonoscopy annually for 5 y
Secco[a17]	2002	• Standard regimen • Risk-adjusted intensity: more frequent physical examinations, CEA, colonoscopy, liver imaging, CT, US	• Higher intensity increased curative reoperation (31% vs 13%) • Increased 5-y survival (63% vs 48%; $p = 0.05$)
Grossman[a18] (GILDA)	2004	• Minimalist regimen • More intensive liver imaging, additional CBC/CA 19-9, more frequent endoscopy	• Death rate 7% intensive vs 5% standard (p = NR) with 985 patients accrual in 2004 • United States and European trial not yet complete
Wattchow[a19]	2006	• General practitioner • Surgeon/hospital visits	• No difference in quality of life or satisfaction, recurrence or survival • Liver imaging not done, colonoscopy every 3 y
Rodriguez[a20]	2006	• Intensive investigation (CEA, CXR, liver imaging, colonoscopy) • CEA alone	• Higher rate of resectable recurrence (51% vs 29%) associated with increased survival (55% vs 44%) in stage II colon cancer and rectal cancers • CT/US every 6 mo for 2 y then annually for 3 y, CXR and colonoscopy annually for 5 y
Wang[a21]	2009	• Standard regimen • Standard plus intensive colonoscopy every 3 mo × 1 y then every 6 mo × 2 y, then yearly × 2	• No difference in 5-y survival (77% vs 73%; $p = 0.25$); • Higher rates of reoperation for attempted cure (69.2% vs 33.3%; $p = 0.048$)
Primrose[a22]	2014	• Minimal follow-up: no schedule except 1 chest/abdomen/pelvis CT scan at 12–18 mo (if requested at study entry) • CEA every 3 mo for 2 y, then every 6 mo for 3 y, with a single chest/abdomen/pelvis CT scan at 12–18 mo (if requested at entry) • Chest/abdomen/pelvis CT scan every 6 mo for 2 y, then annually for 3 y • Combined CEA testing and CT scan (as above)	• Surgical therapy with curative intent was improved in the CEA group (6.7%), CT group (8) and CEA + CT (6.6%) compared with 2.3% in the minimum follow-up • Mortality was not significantly different (CEA, CT, and CEA+CT; 18.2% (164/901)) vs the minimum follow-up group (15.9% (48/301); difference, 2.3%; 95% CI, −2.6% to 7.1%)

CXR = chest x-ray; US = ultrasound; FOB = fecal occult blood testing; CBC = complete blood count; NR = not reported.
[a]Denotes since 2002.

Other outcomes are not as well investigated. A single study demonstrated that improved quality of life was associated with more frequent surveillance visits.[14] However, a study that compared surveillance in the office setting by general practitioners with surveillance in the hospital setting by surgeons failed to demonstrate differences in depression, anxiety, quality of life, or patient satisfaction.[19] Similarly, cost-effectiveness has been difficult to determine based on the present literature,[28] but it should be a consideration.

A risk-adapted surveillance strategy based on prognostic factors has been studied, and the intensity of surveillance and costs could be reduced for patients with better prognosis.[17] High-risk criteria were defined as

TABLE 2. Meta-analyses: follow-up for patients following resection of colorectal cancer

Meta-analysis	*Year*	*Studies included*	*Benefit of intensive follow-up on survival (5-y mortality): OR (95% CI)*
Bruinvels[23]	1993	7 Nonrandomized	9% advantage
Rosen[24]	1998	2 RCTs, 3 nonrandomized (comparative cohort); 14 single cohort	6% advantage
Jeffery[25] (Cochrane)	2002	5 RCTs	0.67 (0.53–0.84)
Renehan[26]	2002	5 RCTs	0.81 (0.70–0.94)
Figueredo[a27]	2003	6 RCTs	0.80 (0.70–0.91)
Tjandra[a2]	2007	8 RCTs	0.74 (0.59–0.93)
Jeffery[a28] (Cochrane)	2007	8 RCTs	0.73 (0.59–0.91)

RCT = randomized controlled trial.
[a]Denotes since 2002.

any of the following: adenocarcinoma of the low rectum treated by low anterior resection, adenocarcinoma at the splenic flexure (Dukes-Kirklin B2 or T3), preoperative CEA >7.5 ng/mL, Dukes stage C, poorly differentiated (grade G3), and/or mucinous adenocarcinoma or signet cell carcinoma. Patients were randomly assigned to either a higher or lower intensity of surveillance versus a control group followed with physician interviews alone. The higher intensity surveillance consisted of increased office visits, CEA testing, ultrasound of the abdomen and pelvis, proctosigmoidoscopy, and chest radiograph (for patients with rectal cancer) in comparison with the standard regimen. Curative resection and survival were increased in both risk-adapted surveillance groups compared with controls. Although, on this basis, risk-adjusted intensity of surveillance may be considered, the follow-up strategies did not include modern modalities such as improved multislice contrast-enhanced CT that are widely used today. As such, the final recommendation for a risk-stratified approach warrants further evaluation (Table 4).

2. Patients with metastatic (stage IV) colorectal cancer who successfully undergo therapy with curative intent should typically be enrolled in a surveillance protocol. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.

The role of surveillance in stage IV patients remains somewhat controversial. The American Society of Clinical Oncology (ASCO) has recently endorsed[10] the Cancer Care Ontario (CCO) guidelines[34] on the follow-up and surveillance for survivors of colorectal cancer, which specifically exclude those patients with stage IV disease owing to the minimal data to provide guidance. Although there is a lack of robust data to support or refute this strategy, long-term survival following therapy in this population that undergoes therapy with curative intent is well documented in properly selected patients, especially those with isolated disease.[35,36] In addition, this includes the benefits of secondary intervention for recurrent disease.[37,38] Based on this, we agree with the National Comprehensive Cancer Network (NCCN) guidelines to continue surveillance in those with no evidence of disease.[7,8] The timing and duration of surveillance is debatable, and likely is best determined by the individual patient risk profile and performance status. Until better guidance is available, we suggest that curatively resected stage IV patients undergo the same surveillance as stage III patients with the same site of disease (colon vs rectal) (Table 4).

3. Selected patients with stage I colon and rectal cancer with increased risk factors should be considered for surveillance following resection with curative intent. Grade of Recommendation: Weak recommendation based on low-quality evidence, 2C.

Most surveillance protocols focus on patients with stage II and III disease, and those select stage IV patients with no evidence of disease following therapy.[7,8] There is significant debate on the utility of surveillance in stage I patients, with some societies such as the CCO recommending only annual clinic visits in the absence of symptoms. At the present time, CCO and ASCO do not recommend surveillance for stage I patients for colon or rectal cancer,[10] although it is unclear whether pathologic, clinical, or American Joint Committee on Cancer stage is intended to be used for assigning stage-specific surveillance plans for patients who have rectal cancer.

The National Comprehensive Cancer Network recommends no surveillance other than colonoscopy for patients with stage I colon cancer[7]; however, NCCN *does* recommend surveillance for stage I *rectal* cancer, including regular history and physical examination, CEA, colonoscopies, and proctoscopies, but no routine imaging.[8] It is not clear whether the initial clinical stage (ie, clinical/radiological or before3 neoadjuvant chemotherapy (cTNM)) or final pathologic stage (ypTNM stage) after resection should be used in deciding the ideal surveillance regimen. Although patients with more advanced stage (eg, clinical stage IIIB) rectal cancer may have a treatment response resulting in residual pathologic stage I disease after neoadjuvant therapy, their prognosis is generally improved in comparison with patients who did not have treatment response. At the present time, we recommend using the clinical stage to determine the surveillance regimen for locally advanced rectal cancers treated with neoadjuvant therapy and surgery. For clinical stage I rectal cancers that are ultimately confirmed to be stage I on pathology, the recommendations listed for stage I in Table 4 are recommended.

TABLE 3. The GRADE system-grading recommendations

	Description	*Benefit vs risk and burdens*	*Methodological quality of supporting evidence*	*Implications*
1A	Strong recommendation, High-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, Moderate-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, Low- or very low-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	Observational studies or case series	Strong recommendation but may change when higher-quality evidence becomes available
2A	Weak recommendation, High-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B	Weak recommendations, Moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C	Weak recommendation, Low- or very low-quality evidence	Uncertainty in the estimates of benefits, risks and burden; benefits, risk and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

GRADE = Grades of Recommendation, Assessment, Development, and Evaluation; RCT = randomized controlled trial.
Adapted from: Guyatt G, Gutermen D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Chest Physicians Task Force. *Chest* 2006;129:174–181.[31] Used with permission.

More recent randomized trials have excluded stage I disease,[20,32] although other RCTs of surveillance showing increased survival have included all stages I through III, and have not separated stage I from stage II and III disease. Thus, although controversy remains regarding the role of surveillance for stage I colorectal cancer because of the lack of data regarding its effectiveness, it is notable that recurrences can occur and surveillance-based detection is associated with potential for surgical salvage. A follow-up study from the Clinical Outcomes of Surgical Therapy (COST) laparoscopic versus open colon cancer study recommended that stage I colon cancer surveillance is appropriate, based on equivalent salvage rates as stages II/III recurrence.[39]

Recurrent cancer in stage I disease is relatively uncommon, but surveillance may be of value for higher-risk cases with poor prognostic factors such as lymphovascular invasion, positive margins, transanal excision (compared with anterior resection), poor differentiation, and T2 disease.[40–46] Furthermore, although increasing numbers of patients are treated with polypectomy alone for select low-risk malignant colon polyps (T1 adenocarcinoma arising in a polyp), surveillance in this population is not well described. Despite limited supporting evidence, it is logical that surveillance should be considered for patients who do not have segmental resection for higher-risk malignant polyps, such as those with adverse histologic features or questionable margins, given their higher risk for recurrence (see Recommendation 9).

Thus, although controversy remains regarding the role of surveillance for stage I colorectal cancer, because of the lack of definitive data regarding its effectiveness, it is notable that recurrences do occur and surveillance-based detection is associated with potential for surgical salvage. A strategy of identifying higher-risk stage I patients is recommended, such as those with rectal cancer status post local excision, those with higher-risk malignant polyps who do not undergo radical surgery, and patients undergoing radical surgery with lymphovascular invasion, positive margins, poor differentiation, and T2 disease.[47,48] Subsequently, providers are encouraged to discuss surveillance schedules with these patients, and implement scheduled periodic examinations in those whose health status and preferences favor surveillance. For patients with stage I

TABLE 4. Recommended schedule of surveillance for colon and rectal cancer (AJCC stage I (at increased risk for recurrence[a]), stage II, stage III, and stage IV (when isolated metastases are resected for cure))

Colon	*Rectum*[b]
Office visit and CEA Every 3–6 mo for 2 y, then every 6 mo until 5 y CT chest/abdomen/pelvis[c] Annually for 5 y[d] Colonoscopy 1 y after preoperative colonoscopy (or 3–6 mo after surgery if colon not preoperatively "cleared")[e]	Office visit and CEA Every 3–6 mo for 2 y, then every 6 mo until 5 y CT chest/abdomen/pelvis Annually for 5 y[d] Colonoscopy 1 y after preoperative colonoscopy (or 3–6 mo after surgery if colon not preoperatively "cleared")[e] Proctoscopy (+/– ERUS) Every 6–12 mo[f] for patients who underwent resection with anastomosis or every 6 mo for patients undergoing local excision for 3–5 y

AJCC = American Joint Committee on Cancer; ERUS = endorectal ultrasound; LN = lymph node; Nx = nodal; s/p = status post.
[a]High risk of recurrence is defined by the treating provider. High-risk factors may include margin positivity (≤1 mm), Nx status (rectal cancer s/p local excision, higher-risk malignant polyps that do not undergo radical surgery, inadequate LN sampling), lymphovascular invasion, poorly differentiated tumors (grade 3 or 4), and T2 disease.
[b]For patients who receive neoadjuvant therapy, these guidelines refer to clinical rather than pathologic stage.
[c]PET-CT is not typically recommended, although PET-CT or MRI might be considered for imaging in a patient with contraindication to intravenous-contrast-enhanced CT scanning or to follow-up abnormalities seen on CT scans.
[d]More frequent imaging may be considered for patients at particularly high risk for recurrence, including those with N2 disease, previous liver resection for metastasis, etc.
[e]Further colonoscopy frequency depends on the results of the 1-year colonoscopy, with repeat examination in 3 years for patients without adenomas and 1 year for patients with adenomas. Annual colonoscopy is generally recommended for patients with confirmed or suspected familial cancer syndromes that have not undergone total proctocolectomy.
[f]Patients at higher risk for local recurrence may be considered for the more frequent intervals, and for ERUS in addition to proctoscopy. Higher-risk patients may include those with poorer-risk tumors (eg, T2 or poor differentiation) who underwent local excision, those with positive margins (≤1 mm), and those with T4 or N2 rectal cancers.

disease who are assigned to surveillance, we suggest using the same strategy used for stage II patients with the same site of disease (colon vs rectal) (Table 4).

4. Regularly scheduled office visits and CEA testing should be included as a part of a comprehensive surveillance strategy. For patients with stage II or III colorectal cancers, the frequency should be every 3 to 6 months for the first 2 years, and then twice a year for a total of 5 years. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Randomized trials and meta-analyses have explored surveillance regimens that included office visits and investigations with varying frequency. More frequent office visits and investigations have been associated with improved survival and increased curative resection of recurrence.

Symptoms may be the first sign of recurrence for patients with colorectal cancer. Within prospective, randomized studies, 16% to 66% of patients were symptomatic at the time of diagnosis of disease recurrence.[12,13] Upon development of symptoms, investigations are indicated to determine whether cancer has recurred. However, fewer than 7% of patients with symptomatic recurrence have resectable disease.[13,49,50] Nonspecific symptoms can result in delays in evaluation that may result in finding unresectable disease at the time of diagnosis. In a recent meta-analysis, detection of asymptomatic recurrence was more frequent (18.9% vs 6.3%; $p < 0.001$) in high vs low surveillance intensity groups, and was associated with an increase in curative resections (10.7% vs 5.7%, $p < 0.0002$).[2] Similarly, the FACS trial found CEA testing either alone (OR, 3; 95% CI, 1.23–7.33) or in combination with CT (OR, 3.1; 95% CI, 1.12–8.71) was associated with an increase in the number of patients who could be treated with a curative intent.[22] The strategy of surveillance should be to perform investigations at a frequency that will detect recurrent cancer before symptoms develop.

In the previous ASCRS parameter, more frequent CEA testing was recommended to improve survival based on data from 1 randomized trial[16] and 3 meta-analyses.[23,24,26] The beneficial effect of increased CEA testing is now supported by an additional randomized trial[17] and 2 other meta-analyses.[2,27] However, improved survival in these studies was also associated with increased frequency of liver imaging and colonoscopy, so the effect of CEA testing alone could not be specifically evaluated. In a randomized trial, CEA in combination with increased frequency of liver imaging and colonoscopy was associated with improved outcome compared with CEA alone.[20] In contrast, the FACS trial was unable to identify a survival advantage for CEA in combination with CT imaging versus CEA alone (absolute difference, 2.3%; 95%CI, –2.6% to 7.1%), although the study may have lacked sufficient power for this end point.[22] Finally, the role of CEA monitoring among patients without previous elevation in CEA has not been clearly delineated. Although previous RCTs that showed survival benefit used the increased frequency of visits and CEA for 3 years, it is unknown if this effect was due to the CEA testing or the other testing modalities. So, although CEA surveillance remains supported by data from randomized trials and meta-analyses, its absolute benefit in isolation from other surveillance investigations remains difficult to determine.

To date no other tumor marker has been investigated in a randomized trial for the surveillance of colorectal cancer. Furthermore, no randomized trial or meta-analysis has reported a significant effect on survival from other common tests, including serum hemoglobin, liver function studies, or fecal occult blood. Therefore, these tests are not recommended as part of a surveillance regimen.

Decreasing the frequency of surveillance testing over time is supported by a pooled analysis from the ACCENT database of 18 clinical trials (1978–1999) of patients with stages II and III colon cancer.[51] In this study of 20,898 patients enrolled in 5-fluorouracil-based adjuvant studies, 5722 (33%) experienced recurrence. Among patients with recurrence, 62% were identified within the first 2 years, 80% within 3 years, and 92% within 4 years. After 5 years, the recurrence rate was less than 1.5% per year, and, after 10 years, the recurrence rate was less than 0.5% per year. Based on these and other data, for stages II and III patients, office visits and CEA testing are recommended every 3 to 6 months for the first 2 years and then twice a year for a total of 5 years**.** Of note, the ASCO also recommends office visits, physical examination, and CEA every 3 to 6 months for 5 years[10]; the NCCN recommends higher frequency of office visits, physical examination, and CEA (3–6 months) for the first 2 years only, followed by every 6 months for a total of 5 years[7,8]; whereas the CCO recommends physical examination with CEA every 6 months for 5 years.[34]

Patients who have colorectal cancer, especially those who are older, may have a higher risk of general ailments and other malignancies. Office visits provide the opportunity to review general health maintenance and screening for other malignancy that may improve overall survival. In addition, those with new or serial CEA elevation may prompt an earlier evaluation and workup outside these suggested guidelines.[7,8] Surveillance visits and CEA levels may detect an increasing CEA or symptoms concerning for recurrence, such as weight loss, abdominal, pelvic or back pain, or hematochezia. Furthermore, a significant increase in CEA may be appropriately evaluated by a repeat of the CEA level alone; persistent elevation is usually evaluated with CT scan of the chest, abdomen, and pelvis, or other radiological assessment for local and distant recurrence. Finally, symptoms concerning for an intraluminal recurrence may also be evaluated with endoscopy.

5. Routine radiographic surveillance should include cross-sectional chest and abdominopelvic imaging (eg, CT or MRI scans) annually for 5 years. Grade of Recommendation: Strong recommendation based on moderate-quality evidence from RCTs, 1B.

It is well known that the most common sites of systemic recurrence for colorectal cancer are the liver and the lung.[52,53] In the previous ASCRS parameter,[9] 3 randomized trials reported that resectable disease may be identified in up to 12% of patients with a chest x-ray.[11,12,15] However, it is now apparent that, especially for distal rectal cancers, the lung is actually the most common site of distant metastases.[54,55] Thus, surveillance imaging of the chest is recommended annually, and should be cross-sectional (ie, CT).[7,8,10,34]

Seven randomized trials have examined the impact of liver imaging on overall survival and recurren ce.[11,12,15–17,20,22] For overall survival, the OR in a meta-analysis was 0.64 (95% CI, 0.40–0.85) favoring surveillance.[28] Although no difference was observed in the rate of recurrence of hepatic metastases, curative reoperations were associated with more frequent with use of liver imaging, 24% vs 10%, $p = 0.0001$.[2] Whereas the previous ASCRS parameter and many earlier surveillance protocols recommended ultrasound as a liver imaging modality, the current recommendation is to perform abdominopelvic CT. Contrast-enhanced CT has greater sensitivity than ultrasound for identifying hepatic metastases early, and other nonhepatic intra-abdominal sites, such as the retroperitoneum or ovaries, can be better visualized with cross-sectional imaging. The current ASCRS clinical practice guideline is aligned with the ASCO[10] and NCCN[7,8] guidelines to include annual CT, as outlined below (Table 4).

A limitation of combining data from the randomized trials is the long time frame over which the studies accumulated data, from 1983 to 2006. During this interval, enhanced resolution of CT and MRI and the introduction of PET scanning have improved our ability to identify and assess the resectability of lung, liver, and other sites of metastases. Significant improvements in surgical techniques and chemotherapy have improved survival for lung and liver metastases, and further improvements may be possible in prospective surveillance trials.

To date, no surveillance trial has determined the optimal frequency of liver imaging. Improved survival in several RCTs was observed with abdominal ultrasound or contrast-enhanced CT scan at a frequency of every 3 to 6 months, but this has not been compared with a less frequent protocol.[16,17,20] No study has directly compared effectiveness of 6- vs 12-month liver imaging, particularly with modern modalities. There is insufficient evidence regarding the benefit, even with modern modalities, to recommend every 6-month cross-sectional imaging; although liver imaging every 6 months could be considered for very high-risk patients, such as those with prior resection of liver metastases, N2 disease, or indeterminate lesions on prior imaging. Therefore, in general, it is recommended that radiographic testing be performed annually.

In addition, the evidence regarding PET scan imaging is insufficient to recommend its use in lieu of traditional CT scanning.[7,8] It should be noted that even when obtained in combination with CT imaging, the lack of intravenous or endoluminal contrast enhancement may

result in decreased sensitivity for the detection of small lesions that mitigates the added benefit of FDG-based imaging. FDG-PET imaging may also result in false-positive findings because tracer uptake can be identified in areas of inflammation without malignancy. Therefore, PET is generally relegated to specific situations, such as identifying extrahepatic/extrapulmonary metastases or helping to differentiate between benign and malignant lesions. Expanding indications for use in routine surveillance of colorectal cancer awaits future improvement in results, especially with regard to sensitivity.

In summary, based on the natural history pattern of recurrence and protocols used in randomized surveillance trials, chest and abdominal (plus pelvic for patients with rectal cancer) imaging by contrast-enhanced CT is recommended annually for 5 years for stages II, III, and select stage I and IV patients (as above).

6. Surveillance colonoscopy is recommended at 1 year after curative resection for patients with surgically treated stage I to IV colorectal cancer. Subsequent colonoscopy should be performed every 3 to 5 years depending on the findings at the first postoperative examination. In cases of incomplete colon evaluation before surgery, the initial colonoscopy should be performed within 3 to 6 months or upon the completion of adjuvant therapy. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Earlier randomized trials showed low metachronous cancer rates of 0% to 1.9% and no survival benefit to surveillance colonoscopy.[11,12,15] In other previous studies, surveillance colonoscopy performed to identify anastomotic recurrence or metachronous lesions was also not shown to improve overall survival.[56,57] However, more recent randomized trials included annual colonoscopy in an overall monitoring strategy that included CEA and liver imaging, and this was associated with a higher rate of resectable recurrence.[16,20] A more recent meta-analysis also demonstrated an overall benefit to surveillance colonoscopy, although it was not able to specifically address timing because this varied in the individual studies.[2]

The National Polyp Study observed that colonoscopy every 3 years was as effective as annual colonoscopy for the *prevention* of colon cancer.[58] However, the detection of metachronous cancer and adenomatous polyps is highest within the first 24 months after surgery.[59,60] In addition, the overall rate of metachronous polyp detection is high, ranging from 17% to 50% in 5 years,[61,62] and is higher in comparison with the general population and patients with adenomatous polyps alone.[63] These issues should be carefully considered before generalizing the data from the National Polyp Study to surveillance after curative resection of colorectal cancer. More definitive data on the optimum frequency of surveillance colonoscopy is anticipated from the GILDA trial.[18,32]

Synchronous polyps should be cleared preoperatively or within 6 months postoperatively. The ASCRS concurs with the recommendations of the American Society for Gastrointestinal Endoscopy,[30] the American Cancer Society and US Multi-Society Task Force on Colorectal Cancer,[3] and NCCN[7,8] that each recommend colonoscopy at 1 year postoperatively. Recommendations regarding subsequent colonoscopy intervals depend on the findings and ability to remove all neoplastic lesions.[3] If synchronous polyps are cleared preoperatively, initial colonoscopy is recommended at 1 year after surgery. Subsequent colonoscopy should be performed every 3 to 5 years depending on whether further polyps are found, or more frequently for a worrisome polyp (high-grade dysplasia, polyp size greater than 1 cm, or more than 3 polyps). Patients older than 75 to 80 years and those with comorbidities suggesting a shortened life expectancy are unlikely to benefit from scheduled endoscopy in the absence of symptoms.[64] Patients at higher risk, such as those with a genetic or clinical diagnosis of hereditary colorectal cancer syndrome, should follow more intensive endoscopic surveillance (eg, annual colonoscopy) as delineated elsewhere.[65]

7. Surveillance proctosigmoidoscopy with or without endorectal ultrasound is recommended for all patients who have undergone curative resection with anastomosis for rectal cancer. Proctosigmoidoscopy is recommended every 6 to 12 months for 3 to 5 years for those undergoing low anterior resection, and every 6 months for 3 to 5 years for those with a higher risk of local recurrence. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Local recurrence after low anterior resection or transanal excision of rectal cancer is variable and reported up to 27%.[66–69] On this basis, the previous ASCRS parameter and guidelines from multiple societies included proctoscopy every 6 months.[9] However, the rate of identification of anastomotic recurrence at surveillance endoscopy has been only ~2%,[11,12] and no improvement in overall survival was demonstrated in earlier randomized studies. Furthermore, none of the randomized surveillance trials included proctoscopy or flexible sigmoidoscopy in addition to colonoscopy.

Widespread implementation of improvements in surgical techniques of rectal cancer excision (ie, total mesorectal excision) and the use of neoadjuvant chemoradiation for appropriate patients have resulted in local recurrence rates of less than 10%.[70–72] On the basis of these and other similar evidence, several organizations have articulated their consensus panel recommendations. American Society of Clinical Oncology no longer recommends proctoscopy every 6 months in patients treated with radiation for rectal cancer, but continues to recommend of proctoscopy every 6 months for rectal cancer not treated with radiation for 2 to 5 years.[4,10] On the other hand, NCCN continues to

recommend consideration for proctosigmoidoscopy every 6 months for 3 to 5 years for all patients undergoing low anterior resection.[8] The American Cancer Society and the US Multi-Society Task Force recommend sigmoidoscopy or endorectal ultrasound every 3 to 6 months [73–77] for the first 2 years after resection.[2] Those patients undergoing traditional abdominal resection (ie, low anterior resection) with certain risk factors such as male sex, distal lesions, close distal margins, inadequate total mesorectal excision, positive circumferential resection margin, positive lymph nodes, and high-risk tumor markers (eg, poorly differentiated, lymphovascular invasion, tumor ulceration)[78–81] have higher risk of recurrence and consideration should be given to more frequent surveillance during the initial surveillance period (every 6 months versus annually). Another important risk factor is poor response to neoadjuvant chemoradiation therapy.[82]

There are no clear data at the present time to quantify the exact benefit of the addition of endorectal ultrasound leading to the recommendation above, "with or without" endorectal ultrasound. To date, transrectal ultrasound has not been investigated in randomized surveillance trials. There is some evidence to suggest that endorectal ultrasound with fine-needle aspiration may help confirm nodal metastases or deep wall recurrence.[76,83] Surveillance of rectal cancer using endorectal ultrasound may be more sensitive in detecting locoregional recurrence, but impact on overall survival is not known.

8. Surveillance proctosigmoidoscopy with or without endorectal ultrasound is recommended every 6 months for 3 to 5 years for all patients who have undergone transanal local excision of rectal cancer. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.

Unfortunately, there are also no randomized trials of surveillance protocols for patients treated with transanal local excision, whether by traditional local excision, transanal endoscopic microsurgery, or transanal minimally invasive surgery. Although local recurrence has been reported to be lower with the minimally invasive approaches (ie, transanal endoscopic microsurgery and transanal minimally invasive surgery), it remains an issue with all transanal surgical approaches from 4% to 33%, depending on the stage of the lesion and length of follow-up.[84–86] Certain lesions such as T2-T3 lesions, T1 Sm3, >3 cm in size, those with positive margins, poorly differentiated, and/or lymphovascular invasion are associated with higher rates of local recurrence. National Comprehensive Cancer Network continues to recommend proctosigmoidoscopy every 6 months for 3 to 5 years for those treated by transanal excision.[8,48,87] Because of higher recurrence risk after transanal local excision at all T stages, proctosigmoidoscopy with or without endorectal ultrasound (which may increase sensitivity) is recommended every 6 months for 3 to 5 years.

9. Limited surveillance should be performed following endoscopic resection of a low-risk malignant polyp. More intense surveillance may be considered for higher-risk lesions that do not undergo segmental resection. Grade of Recommendation: Weak recommendation based on low-quality evidence, 2C.

Malignant polyps are defined by the presence of adenocarcinoma in a polyp that invades into the submucosa of the bowel wall and are, by definition, T1 tumors. Although most are benign in appearance and <1 cm in size, they have been reported in up to 12% of polypectomy series.[88] Sessile polyps and those >1.5 cm are risk factors associated with higher malignant potential.[89] In 1985, Haggitt and colleagues described a classification for both sessile and pedunculated polyps that is still in practice today, correlating the location of the malignant cells (ie, head, neck, stalk, base) with the presence of lymph node metastases.[90] Overall, lymph node metastases are present in 0% to 6% for Haggitt levels 1 to 3, whereas, in sessile polyps (by definition Haggitt level 4) and Haggitt level 4 lesions, this increases up to 27%.[91] Subsequent classification of sessile polyps involves the level of invasion of the submucosal level by cancer cells[92]—upper third (sm1), middle third (sm2), and lower third (sm3)—with sm3 lesions associated with lymph node metastases in up to 23%.[93] Current treatment guidelines for malignant polyps state that endoscopic treatment is adequate because of a low risk of intraluminal recurrence or lymph node metastases for many malignant polyps. According to current treatment guidelines, the characteristics of malignant polyps that are appropriately treated by endoscopic resection only are: Haggitt levels 1 to 3 (not level 4, which includes all sessile polyps), well-differentiated histology, >2 mm margins, and the absence of tumor budding and lymphovascular invasion.[94–96] For malignant polyps that do not meet these criteria, standard care includes referral to a surgeon for the consideration of surgical therapy.

There is currently a lack of data regarding the effectiveness of surveillance following successful endoscopic resection of a malignant polyp. Several organizations have set forth guidelines on endoscopic surveillance following polypectomy based on patient- and polyp-specific risk factors including size, morphology, and number of polyps.[97,98] These may be extrapolated to malignant polyps, with recommendations that include marking the polyp site (ie, India ink tattoo, which should be performed by repeat endoscopy as soon as possible after pathology available, if not done at the index colonoscopy), and repeat colonoscopy in 3 to 6 months to evaluate for local recurrence. Local recurrences of malignant polyps are an indication for a segmental resection after appropriate staging evaluation. Subsequent endoscopic surveillance interval varies depending on the findings of the entire colonoscopy. At present, routine radiological imaging such as CT scan or FDG PET/

CT does not have a role in the evaluation of malignant polyps meeting the criteria above because of their high false-positive rates and overall poor sensitivity.[99,100] However, if a patient with a malignant polyp that is higher risk (ie, fails to meet criteria for endoscopic treatment only) does not undergo surgical resection (such as the patient who chooses not to undergo surgery after consultation), consideration may be given to enrolling this patient in a surveillance program, such as that for patients who have stage II colon cancer treated with curative intent (Table 4).

SUMMARY

Current evidence suggests improved rates of curative secondary treatment following identification of recurrence among patients who participate in a surveillance program after initial curative resection of colon or rectal cancer. The newer data show that surveillance CEA, chest and liver imaging, and colonoscopy can also improve survival through early diagnosis of recurrence; thus, these modalities are now included in the current guideline. Although the optimum strategy of surveillance for office visits, CEA, chest and liver imaging, and colonoscopy is not yet defined, routine surveillance does improve the detection of recurrence that can be resected with curative intent. Recommended surveillance schedules are shown in Table 4. However, the factors to be considered when recommending surveillance include underlying risk for recurrence, patient comorbidity, and the ability to tolerate major surgery to resect recurrent disease or palliative chemotherapy, performance status, physiologic age, preference, and compliance. The success of surveillance for early detection of curable recurrence will depend on patient and provider involvement to adhere to the surveillance schedule and avoid unnecessary examination. It should be noted that, after curative resection of colorectal cancer, patients are still at risk for other common malignancies (lung, breast, cervix, prostate) for which standard screening recommendations should be observed and measures to maintain general health (risk reduction for cardiovascular disease, eg, cessation of smoking, control of blood pressure and diabetes mellitus, balanced diet, regular exercise and sleep, and flu vaccines) should be recommended.

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APPENDIX A

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