Complete Summary

GUIDELINE TITLE

ASGE guideline: the role of endoscopy in the diagnosis, staging, and management of colorectal cancer.

BIBLIOGRAPHIC SOURCE(S)

Davila RE, Rajan E, Adler D, Hirota WK, Jacobson BC, Leighton JA, Qureshi W, Zuckerman MJ, Fanelli R, Hambrick D, Baron TH, Faigel DO. ASGE guideline: the role of endoscopy in the diagnosis, staging, and management of colorectal cancer. Gastrointest Endosc 2005 Jan;61(1):1-7. [72 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
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IDENTIFYING INFORMATION AND AVAILABILITY
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SCOPE

DISEASE/CONDITION(S)

Colorectal cancer (CRC) including high-grade dysplasia (HGD), malignant colonic obstruction, malignant colonic polyps, and polyps with HGD

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Gastroenterology
Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To present a summary of recommendations on the role of endoscopy in the diagnosis, the staging, and the treatment of colorectal cancer (CRC)

TARGET POPULATION

Patients with suspected or confirmed colorectal cancer (CRC)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Colonoscopy
2. Flexible sigmoidoscopy
3. Endoscopic ultrasound (EUS)
4. Magnetic resonance imaging
5. Abdominal computed tomography (CT)
6. Endoscopic ultrasound-guided fine-needle aspiration (FNA)
7. Digital rectal examination
8. Staging of rectal cancer using the Primary**T**umor, Regional Lymph **N**odes, Distant **M**etastasis (TNM) staging system

Management

1. Endoscopic mucosal resection (EMR)
2. Standard snare polypectomy
3. Endoscopic colonic decompression
    - Placement of self-expandable metal stents (SEMS)
4. Laser therapy
    - Neodymium-yttrium aluminum garnet laser
5. Chemotherapy
6. Radiation therapy
7. Surgical resection

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Recurrence
- Survival
- Length of hospital stay
- Rate of postoperative complications
- Cost measures including cost-benefit analysis and total costs

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of identified articles and from recommendations of expert consultants.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Recently, a small retrospective study suggested that self-expandable metal stents (SEMS) placement offers a significant cost benefit in the management of malignant colonic obstruction by avoiding diverting colostomy and a two-stage operation in surgical candidates. Alternatively, a study evaluating the cost-effectiveness of SEMS placement vs. surgery for incurable obstructing cancers demonstrated similar total costs for both treatment options, given the significant cost of the metal endoprosthesis and the additional cost of endoscopic management of recurrent obstruction caused by tumor ingrowth and overgrowth of the stent.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations are followed by evidence grades (A-C) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

Diagnosis and Tumor Localization

During colonoscopy, every effort should be made to obtain a tissue diagnosis when encountering polyps, mass lesions, or colonic strictures. Pathologic confirmation of cancer should always be sought to provide the patient and the physicians the necessary information to make management decisions. In general, polypoid lesions found at the time of colonoscopy should be removed. Colonic lesions not amenable to endoscopic resection can be sampled with biopsy forceps. Biopsy specimens of broad sessile lesions or of large mass lesions should be obtained from different areas, including the edges and the center of the lesion, if possible. The addition of cytology brushings to forceps biopsies may increase the diagnostic yield, especially in the setting of obstructing tumors that cannot be traversed.

There are very few well-designed, prospective studies that address the optimal number of endoscopic biopsy specimens necessary to diagnose colorectal cancer (CRC). In a prospective study of 60 patients with malignant colonic lesions confirmed by surgical pathology, 4 biopsy specimens obtained during colonoscopy yielded a diagnosis of CRC in 68%, whereas 6 biopsy specimens yielded a diagnosis in 78%. There was no additional diagnostic yield from obtaining more than 6 biopsy specimens. In cases where endoscopic biopsy specimens are non-diagnostic and cancer is highly suspected, clinicians should consider obtaining a second opinion from an expert pathologist and/or performing repeat colonoscopy for additional tissue sampling. Surgery is indicated for suspicious lesions with nondiagnostic biopsy specimens.

Endoscopic mucosal resection (EMR) can be selectively used in the removal of colonic lesions that may potentially be malignant or may have high-grade dysplasia (HGD). EMR differs from standard snare polypectomy by the use of submucosal solution injection, which allows for the complete resection of the mucosa through the mid to deep submucosa. The inability to raise the base of a polyp after submucosal solution injection can indicate the presence of cancer invading deep into the submucosa and precludes endoscopic resection of the lesion. The use of chromoendoscopy with or without high-resolution endoscopes or magnifying endoscopes can assist in characterizing and delineating colonic lesions before EMR and may be helpful in predicting histopathology based on topography and pit pattern. Endoscopic ultrasound (EUS) also can serve as a useful tool in the evaluation of colonic lesions before EMR by determining depth of invasion and by detecting the presence of lymph nodes that may indicate malignancy. In one study, the accuracy of EUS for determining intramucosal location of colonic neoplasms was 77%.

In addition to its role in the diagnosis of CRC, colonoscopy has an important role in the localization of malignant lesions for subsequent identification at the time of surgery. Preoperative endoscopic marking can be helpful in localizing flat, small, or subtle colonic lesions that may be difficult to identify by inspection or palpation during surgery. Marking techniques currently available include endoscopic tattooing and metallic clip placement.

Staging of Rectal Cancer

CRC is staged according to the Primary **T**umor, Regional Lymph **N**odes, Distant **M**etastasis (M) (TNM) system established by the American Joint Committee on Cancer and the International Union against Cancer (see the table below titled "TNM Staging Classification of CRC"). Preoperative staging of rectal cancer is necessary to determine patient management. In 1990, the National Institutes of Health Consensus Conference recommended adjuvant chemoradiation therapy for those patients with advanced locoregional rectal cancer. Advanced locoregional cancers are defined as those tumors with extension into the perirectal fat (stage T3 N0 or T4 N0) and/or involvement of mesorectal or pelvic lymph nodes (stage TX N1 or TX N2). Several large studies have demonstrated a significant decrease in local cancer recurrence associated with preoperative radiation therapy in patients with advanced locoregional disease. A small number of studies also suggest that there may be a survival benefit associated with preoperative radiation therapy for advanced locoregional disease. Accurate tumor staging is essential for selecting the surgical approach to rectal cancers. Superficially, invasive small cancers (stage T1 N0 or selected T2 N0) may be resected transanally. More deeply invasive and node-positive cancers require low anterior resection or abdominoperineal resection, depending upon their location within the rectum.

The accuracy of EUS for T staging ranges from 80 to 95%. EUS has been demonstrated to be superior to computed tomography (CT) in determining the T stage of rectal cancer. Magnetic resonance imaging with endorectal coils has been compared with EUS in several small series of patients and appears to have similar accuracy for T staging except in differentiating between T1 and T2 tumors, where EUS may be superior. Abdominal computed tomography, in combination with EUS, appears to be the most cost-effective strategy in staging rectal cancer.

Correctly differentiating benign from malignant perirectal lymphadenopathy by EUS is difficult, because inflammatory nodes may be present in the setting of rectal cancer. The accuracy of EUS in nodal staging ranges from 70 to 75%. The sensitivity of EUS for identifying metastatic lymph nodes appears to decrease in nodes measuring less than 5 mm. EUS-guided fine-needle aspiration (FNA) of perirectal lymph nodes may be most helpful in the setting of T1 or T2 disease in which the presence of malignant perirectal lymph nodes would change patient management to include preoperative chemoradiation therapy.

Malignant strictures in the rectum that are not traversable may be difficult to evaluate by EUS. The use of miniprobes advanced through the endoscope channel or rigid rectal EUS probes may be helpful in these cases. The inability to completely transverse a cancerous lesion can result in understaging of the tumor. Stricture dilation before EUS is infrequently performed; however, this issue has not been studied. As seen in esophageal cancers, the finding of a nontraversable malignant stricture in the rectum may be predictive of advanced tumor stage (T3, T4 or TX, N1, N2).

The utility of EUS in restaging rectal cancer after preoperative radiation therapy for advanced locoregional disease is not clear. EUS restaging after radiation therapy can provide a measure of the treatment response, which may, in turn, change the surgical approach taken in selected cases. However, the accuracy of EUS in determining the extent of tumor invasion markedly decreases to 40% to 50% after radiation, because of inflammatory changes and fibrosis.

The role of EUS in the postoperative surveillance of rectal cancer has not been clearly defined. Local recurrence of rectal cancer after surgical resection occurs in 10 to 30% of patients, depending on stage and therapy given. Tumor recurrence often may present extraluminally and can be missed by routine surveillance with digital rectal examination and colonoscopy. The early detection of local cancer recurrence may lead to potentially curative surgical re-excision. Several studies have recently demonstrated that EUS and EUS-guided FNA are highly sensitive methods for the detection and the diagnosis of regional recurrence, although their impact on long-term survival is not known, and the optimal timing and frequency of EUS examination has not been studied.

Table: TNM Staging Classification of CRC

Primary tumor (T)	
TX	• Primary tumor cannot be assessed
T0	• No evidence of primary tumor
Tis	• Carcinoma in situ: intraepithelial or invasion of lamina propria
T1	• Tumor invades submucosa
T2	• Tumor invades muscularis propria
T3	• Tumor invades through the muscularis propria into the subserosa or into

Primary tumor (T)	
	nonperitonealized pericolic or perirectal tissues
T4	• Tumor directly invades other organs or structures, and/or perforates visceral peritoneum
Regional lymph nodes (N)	
NX	• Regional lymph nodes cannot be assessed
N0	• No regional lymph-node metastasis
N1	• Metastasis in 1 to 3 regional lymph nodes
N2	• Metastasis in 4 or more regional lymph nodes
Distant metastasis (M)	
MX	• Distant metastasis cannot be assessed
M0	• No distant metastasis
M1	• Distant metastasis

Endoscopic Management of Malignant Colonic Obstruction

Malignant obstruction of the colon can occur in 8 to 30% of patients with CRC. Endoscopic management of malignant obstruction with laser therapy or stent placement offers a safe and an effective alternative to surgery. Currently, there are two main indications for the endoscopic management of colonic obstruction: temporary colonic decompression as a bridge to surgery and palliation of patients who are deemed poor surgical candidates or who have incurable disease. Successful endoscopic decompression of acute obstruction allows for the stabilization of the patient and for evaluation of the patient's extent of disease and comorbid illnesses before surgery. In operative candidates, acute decompression avoids the need for a diverting colostomy and a second surgery for reanastomosis, because the tumor can be resected during a one-stage procedure after adequate bowel preparation.

Laser therapy has a high success rate in the treatment of malignant colonic obstruction ranging from 80 to 90%. In a large retrospective study of 272 patients treated with a neodymium-yttrium aluminum garnet laser for obstructing rectosigmoid tumors, successful relief of the obstruction was achieved in 85% of patients. The success of the procedure appears to be associated with tumor size, with large mass lesions being less likely to respond to treatment. The procedure may require several sessions to successfully relieve the obstruction, and repeat therapy may be needed for recurrent obstruction because of tumor regrowth. The most common complications associated with laser treatment include perforation, bleeding, fistula formation, pelvic abscesses, and pain.

The placement of self-expandable metal stents (SEMS) has recently evolved into a more widely used method of endoscopic colonic decompression. The success rate of stent deployment and the relief of malignant colonic obstruction have been reported to range from 70 to 95%. In a systematic review of publications on colonic SEMS from 1990 to 2000, endoscopic stent placement was successful in cancer palliation in 90% of 336 reported cases of incurable obstructing cancer. The use of SEMS for the management of acute colonic obstruction as a bridge to surgery appears to significantly reduce the rate of postoperative complications, including wound infections and intra-abdominal abscesses when compared with primary surgery. In two recent studies comparing preoperative decompression with SEMS placement with surgery, patients treated with SEMS had a significantly lower requirement for diverting colostomy and subsequently had shorter total hospital stay, fewer surgeries, and fewer complications. Despite the benefits of preoperative SEMS placement for resectable patients, there does not appear to be an improvement in overall survival after long-term follow-up. Recently, a small retrospective study suggested that SEMS placement offers a significant cost benefit in the management of malignant colonic obstruction by avoiding diverting colostomy and a two-stage operation in surgical candidates. Alternatively, a study evaluating the cost-effectiveness of SEMS placement vs. surgery for incurable obstructing cancers demonstrated similar total costs for both treatment options, given the significant cost of the metal endoprosthesis and the additional cost of endoscopic management of recurrent obstruction caused by tumor ingrowth and overgrowth of the stent.

The major complications associated with colonic stenting include perforation, bleeding, tumor ingrowth or overgrowth, and stent migration. Dilation of the malignant stricture does not appear to be necessary before SEMS placement and may be associated with a higher risk of perforation. Treatment with chemotherapy and radiation therapy after SEMS placement may be associated with an increased risk of complications (e.g., stent migration); however, this has not been well studied. Stent obstruction can occur because of stool impaction, tumor ingrowth, or tumor overgrowth, which all require endoscopic intervention. Tumor ingrowth or overgrowth can be managed by placement of additional stents through the original stent(s) or by treatment with neodymium-yttrium aluminum garnet laser. Patients should be advised to follow a low residue diet and to take laxatives, stool softeners, or mineral oil supplements to avoid stool impaction after SEMS placement.

Endoscopic Management of Malignant Colonic Polyps with HGD

Invasive carcinoma may be found in approximately 2 to 4% of colonic polyps removed endoscopically. Polypectomy or EMR may be curative in selected, superficially invasive colon cancers. A malignant polyp is defined as one containing invasive carcinoma penetrating through the muscularis mucosa into the submucosa. The reported rates of local lymph-node metastases associated with malignant polyps confined to the submucosa vary widely in several case series because of the heterogeneity of the histopathologic features of the cancers described. In a retrospective study of 353 cases of T1 cancers removed surgically, lymph-node metastases were found in 13% of cases. This study demonstrated that the rate of lymph-node metastasis was significantly associated with the depth of tumor invasion within the submucosa, with tumors invading the upper third, middle third, and lower third of the submucosa, having 2%, 9%, and 35% rates of

lymph-node metastasis, respectively. There are several histologic factors that also appear to be associated with a higher risk of lymph-node metastasis and local cancer recurrence after endoscopic resection of malignant polyps confined to the submucosa, including the following: poorly differentiated histology, vascular or lymphatic invasion, positive resection margins, and incomplete resection (see the table below titled "Unfavorable histopathological factors of malignant colonic polyps associated with high risk of lymph-node metastases and local cancer recurrence after endoscopic resection"). Pedunculated polyps with cancer confined to the submucosa and without evidence of unfavorable histologic factors have a 0.3% risk of cancer recurrence or lymph-node metastasis after complete endoscopic removal, whereas similar sessile polyps have a 4.8% risk. Pedunculated polyps confined to the submucosa, with no evidence of unfavorable histologic features, can be definitively treated with endoscopic resection, without the need for surgical resection. In cases of pedunculated polyps harboring unfavorable histologic features, demonstrating cancer within the resection margin, or extending through the submucosal into the deeper wall layers, surgery is recommended. Malignant sessile polyps confined to the submucosa, removed endoscopically en bloc (not piecemeal), and without evidence of unfavorable histologic features have a small increased risk of lymph-node metastasis compared with similar pedunculated polyps. Therefore, surgical resection should be considered in this subset of malignant sessile polyps, while recognizing that in most of these cases endoscopic resection is probably adequate. Surgery is indicated in cases of sessile polyps harboring unfavorable histologic features or demonstrating cancer through the submucosa into the deeper wall layers. Surgery should also be recommended in cases in which the sessile lesion was removed in a piecemeal fashion, and, therefore, the adequacy of the resection margin cannot be determined. The finding of a malignant polyp in patients with ulcerative colitis or Crohn's colitis should be considered an indication for total colectomy. Endoscopic resection of malignant polyps with unfavorable histologic features or piecemeal resection of large malignant polyps can be considered in patients deemed poor surgical candidates because of comorbid illnesses. Surveillance after the endoscopic removal of a malignant polyp should consist of a follow-up colonoscopy within 3 to 6 months after resection.

Polypectomy or EMR also can be used as the primary management of polypoid lesions with HGD. Previously known as carcinoma in situ or intramucosal cancer, HGD currently is defined as dysplastic neoplastic tissue confined within the mucosal wall layers without invasion of the submucosa. Endoscopic removal of lesions with HGD is adequate, provided that the endoscopist is confident in the completeness of resection. Surveillance after the endoscopic resection of a lesion with HGD should consist of repeat colonoscopy in 3 years. In the case of large sessile lesions, lesions removed in a piecemeal fashion, or when the endoscopist is unsure of the completeness of resection, repeat colonoscopy or flexible sigmoidoscopy should be performed within 3 to 6 months to rule out residual neoplastic tissue at the polypectomy site. If residual tissue is identified, this should be removed and a second follow-up examination should be performed within 3 to 6 months to verify complete resection. If a polyp cannot be removed completely within 1 to 3 examinations, surgery is recommended.

Table: Unfavorable histopathological factors of malignant colonic polyps associated with high risk of lymph-node metastases and local cancer recurrence after endoscopic resections*

Table: Unfavorable histopathological factors of malignant colonic polyps associated with high risk of lymph-node metastases and local cancer recurrence after endoscopic resections*
• Poorly differentiated histology • Vascular invasion • Lymphatic invasion • Cancer involvement of the resection margin • Incomplete endoscopic resection *Polyps described refer to malignant colonic polyps confined to the submucosal without invasion of the muscularis propria or deeper wall layers.

Summary

- Colonoscopy is essential in the diagnosis of CRC. **(B)**
- Multiple biopsy specimens should be obtained from all suspicious lesions, and polypoid lesions should be removed. **(A)**
- EUS is accurate in the preoperative locoregional staging of rectal cancer and is useful in guiding therapy. **(A)**
- Malignant colonic obstruction can be effectively treated endoscopically for palliation or as a bridge to surgery with SEMS or laser therapy. **(B)**
- Unfavorable histopathologic factors of malignant colonic polyps associated with a high risk of lymph-node metastasis or local recurrence after endoscopic resection include the following: poorly differentiated histology, vascular or lymphatic invasion, cancer at the resection margin, and incomplete resection. **(B)**
- Malignant pedunculated polyps confined to the submucosal can be considered to be adequately treated by endoscopic resection if removed completely and if there is no evidence of unfavorable histologic features. **(B)**
- Malignant sessile polyps confined to the submucosal and demonstrating no evidence of unfavorable histologic factors have a small increased risk of lymph-node metastasis and local recurrence compared with similar pedunculated polyps after endoscopic resection. Endoscopic resection of this subset of sessile polyps may be adequate if the resection was complete and en bloc; however, surgical resection should be considered to ensure definitive treatment. **(B)**
- HGD can be adequately treated with endoscopic resection. **(B)**

Definitions:

A. Prospective controlled trials
B. Observational studies
C. Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and classified for the recommendations using the following scheme:

A. Prospective controlled trials
B. Observational studies
C. Expert opinion

When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and effective utilization of endoscopy
- The use of self-expandable metal stents (SEMS) for the management of acute colonic obstruction as a bridge to surgery appears to significantly reduce the rate of postoperative complications, including wound infections and intra-abdominal abscesses when compared with primary surgery.

POTENTIAL HARMS

- The most common complications associated with laser treatment include perforation, bleeding, fistula formation, pelvic abscesses, and pain.
- The major complications associated with colonic stenting include perforation, bleeding, tumor ingrowth or overgrowth, and stent migration. Dilation of the malignant stricture does not appear to be necessary before self-expandable metal stents (SEMS) placement and may be associated with a higher risk of perforation. Treatment with chemotherapy and radiation therapy after self-expandable stent placement may be associated with an increased risk of complications(e.g., stent migration); however, this has not been well studied. Stent obstruction can occur because of stool impaction, tumor ingrowth, or tumor overgrowth, which all require endoscopic intervention.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Davila RE, Rajan E, Adler D, Hirota WK, Jacobson BC, Leighton JA, Qureshi W, Zuckerman MJ, Fanelli R, Hambrick D, Baron TH, Faigel DO. ASGE guideline: the role of endoscopy in the diagnosis, staging, and management of colorectal cancer. Gastrointest Endosc 2005 Jan;61(1):1-7. [72 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jan

GUIDELINE DEVELOPER(S)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Douglas O. Faigel, MD (*Chair*); Todd H. Baron, MD (*Vice Chair*); Raquel E. Davila, MD; Elizabeth Rajan, MD; Douglas Adler, MD; William K. Hirota, MD; Brian C. Jacobson, MD, MPH; Jonathan A. Leighton, MD; Waqar Qureshi, MD; Marc J. Zuckerman, MD; Robert Fanelli, MD (*SAGES Representative*); David Hambrick, RN, CGRN (*SGNA Representative*)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy (ASGE) Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 23, 2005. The information was verified by the guideline developer on March 31, 2005.

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