

## Open-access endoscopy

*This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature from January 1990 to January 2015 was performed by using PubMed by using the search terms “open-access endoscopy” and “direct access endoscopy.” Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When limited or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for the appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time that the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice. The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence (Table 1).<sup>1</sup>*

*This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient’s condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines. This guideline supplements and replaces our previous document on open-access endoscopy.<sup>2</sup>*

Open-access endoscopy (OAE) is defined as the performance of endoscopic procedures requested by referring physicians without a previous clinic consultation. Traditionally, physicians have requested consultations for their patients by an individual who performs endoscopy to determine whether endoscopic intervention was indicated.<sup>3,4</sup> However, in many instances, the need or benefit

of endoscopy is not in question (eg, colonoscopy for colorectal cancer screening) or may be easily determined by the endoscopist after reviewing the patient’s pertinent medical records. As the demand for endoscopic procedures has increased, OAE has become increasingly used to perform procedures in a timely and efficient manner. An ASGE survey from 1997 found that 60% of respondents used some form of OAE, comprising over 25% of practice for some physicians.<sup>4</sup> Since publication of that survey, OAE use has continued to expand. A 9-year audit of OAE in more than 20,000 patients demonstrated a more than fivefold increase in the number of open-access procedures from 2000 to 2008, corresponding to the widespread adoption of colonoscopy for colorectal cancer screening.<sup>5</sup>

The common use of OAE may reflect efforts to decrease costs related to endoscopy by eliminating potentially unnecessary office-based consultations. Moreover, the increasing demand for endoscopic procedures has affected endoscopist workload, and use of OAE allows for timely procedures that are deemed necessary. OAE is most commonly offered for colonoscopy for colorectal cancer screening, and most centers also perform OAE for other diagnostic procedures such as EGD and flexible sigmoidoscopy. Units may also offer OAE for advanced or interventional procedures including EUS, ERCP, and device-assisted enteroscopy on a case-by-case basis. Physicians referring an individual for OAE should be familiar with appropriate indications for endoscopy.<sup>6</sup> The referring provider should discuss the indication for the procedure with the patient to ensure mutual agreement to proceed with endoscopy before referral for OAE. Pertinent medical records should be made available to the OAE endoscopist before the procedure. It is important to note that OAE is not a substitute for consultation. If the referring provider or the endoscopist remains uncertain about the need for endoscopy, an office-based consultation rather than OAE is prudent. Similarly, decisions about the management of antithrombotic agents may require an office consultation, particularly if the procedural risk for bleeding is higher.<sup>7</sup> Individuals with chronic digestive disease symptoms often warrant an office consultation rather than OAE.

There are several pertinent issues that may arise in the use of OAE: (1) appropriateness of referral, (2) patient acceptance and preparedness for endoscopy, (3) informed consent, (4) diagnostic yield of the endoscopy, and (5) assurance of appropriate follow-up.

**TABLE 1. GRADE system for rating the quality of evidence for guidelines<sup>1</sup>**

Quality of evidence	Definition	Symbol
High quality	Further research is very unlikely to change our confidence in the estimate of effect.	⊕⊕⊕⊕
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	⊕⊕⊕○
Low quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.	⊕⊕○○
Very low quality	Any estimate of effect is very uncertain.	⊕○○○

## APPROPRIATENESS OF REFERRAL

Several studies have evaluated the appropriateness of referrals to endoscopy in an OAE system. Most authors have used the ASGE guideline entitled “Appropriate Use of GI Endoscopy” to determine appropriate referrals.<sup>6</sup> The reported rate of EGD or colonoscopy procedures performed for “generally not indicated” or unlisted indications worldwide ranged from 5% to 49%.<sup>8-15</sup> Most studies have found a significantly higher rate of inappropriate referrals by nongastroenterologists compared with gastroenterologists.<sup>16</sup> There are only a few published studies from U.S. centers evaluating OAE. Mahajan et al<sup>17</sup> studied 310 patients undergoing EGD or colonoscopy and found compliance with the ASGE guidelines in 95% of EGD and 81% of colonoscopy referrals. Zuccaro and Provencher<sup>18</sup> audited more than 3100 endoscopy reports in an OAE system and found that referrals by nongastroenterologists and gastroenterologists were appropriate in 81% and 85%, respectively. It should be noted that the current ASGE recommendations for appropriate use of GI endoscopy is meant to serve as a guideline and not a rule.<sup>6</sup> Clinical considerations may justify a course of action at variance with these recommendations. Therefore, the procedures in these studies deemed “inappropriate” may in fact have been justified. The ASGE/American College of Gastroenterology Task Force on Quality in Endoscopy has suggested that the frequency with which endoscopy is performed for an accepted indication according to a standard published list of appropriate indications should be a preprocedure quality indicator.<sup>19</sup> The goal performance target, including OAE should be greater than 80% for all procedures and greater than 90% for ERCP to reflect the higher incidence of serious adverse events with ERCP.<sup>19,20</sup>

Although communication of accurate medical information for patients participating in OAE is important,

endoscopy providers are responsible for performing a preprocedure assessment and obtaining informed consent for every patient. A 4-month study of referrals for OAE at a large academic medical center demonstrated that 8.8% of referrals contained inaccurate medical information.<sup>21</sup> In this study, all information errors were deemed errors of omission, such as not listing patient allergies, significant comorbidities, and medications that affect the risk of the procedure (ie, use of anticoagulants that increase bleeding risk).

## PATIENT ACCEPTANCE FOR PREPAREDNESS FOR OAE

Patients referred for OAE should receive adequate preprocedure instructions. This education improves patient compliance with and tolerance of the procedure and contributes to a successful endoscopy procedure.<sup>22,23</sup> Several studies have demonstrated the OAE model to be acceptable to patients, with no differences in understanding or patient satisfaction compared with individuals with previous office consultation.<sup>24-26</sup> In addition, there appear to be no differences in the rates of cancellation and no-shows for procedures scheduled by a gastroenterologist compared with those scheduled as open access.<sup>27</sup> Patients referred for screening colonoscopy cancel at higher rates than for other procedures, but the cancellation rate is similar between open access-referred and gastroenterologist-referred procedures. An informative brochure mailed to the patient before the procedure has been shown to improve adherence to open-access screening colonoscopy (69.0% vs 57.6%;  $P = .013$ ).<sup>28</sup>

Bowel preparations in OAE colonoscopy patients appear to be satisfactory. A study of 368 patients undergoing open-access colonoscopy noted that 87% of patients had a good or excellent bowel preparation.<sup>29</sup> In another study of 525 patients undergoing colonoscopy with a split-dose preparation in an OAE unit, 96% of the bowel preparations were deemed adequate to allow for standard screening or surveillance intervals after intraprocedural irrigation and cleansing was used.<sup>30</sup>

A few studies have expressed caution with OAE. A British study found that the majority of patients preferred an initial consultation in a specialty clinic and that additional diagnoses missed on OAE were detected during that clinic visit.<sup>31</sup> A small study of open-access colonoscopy demonstrated improved bowel preparation quality in patients with a previous office visit compared with those referred via OAE.<sup>32</sup>

## PERIPROCEDURAL EDUCATION AND INFORMED CONSENT FOR OAE

Many endoscopists provide preprocedure education during an office visit before the scheduled procedure. The OAE

model, however, does not readily permit this education to occur before the day of the procedure. Informed consent on the day of the OAE procedure is acceptable. However, 1 study showed that OAE patients are more likely not to be able to identify the planned procedure compared with patients scheduled through a GI clinic (24% vs 15%;  $P < .01$ ) at the time of check-in for their procedure.<sup>33</sup> This same study reported that OAE patients more frequently reported inadequate explanation of the test compared with patients scheduled after an office consultation (16% vs 5%;  $P < .005$ ) at the time of check-in for their procedure.<sup>33</sup> A study of 45 patients undergoing OAE noted that 16% were unaware of the indication for the planned endoscopic procedure.<sup>32</sup> An informed consent package given before the procedure can improve patient knowledge about the test.<sup>34</sup> Alternatively, patients can be provided with preprocedure education administered by the gastroenterology unit staff.<sup>35</sup> As with all endoscopic procedures, endoscopy providers should complete a preprocedure assessment and obtain informed consent before the OAE procedure.

## DIAGNOSTIC YIELD

Several studies have clearly shown that appropriate OAE referrals based on ASGE guidelines result in higher diagnostic yields of clinically relevant findings.<sup>5,13,15,16</sup> A prospective, multicenter Italian study of 6270 patients noted a significantly higher diagnostic yield for appropriate upper endoscopies (52% vs 29%; odds ratio 2.65; 99% confidence interval, 2.23-3.20).<sup>13</sup> In this study, 132 upper GI malignancies were diagnosed in appropriate OAE referrals compared with only 1 malignancy on upper endoscopies deemed “generally not indicated.”<sup>13</sup>

## FOLLOW-UP

After the OAE procedure, results of the examination, histopathologic analysis, and subsequent management recommendations should be communicated to the patient and the referring provider. A study of 168 patients undergoing open-access upper endoscopy and colonoscopy noted high rates of documented compliance with diagnostic (75%) and therapeutic (90%) recommendations.<sup>12</sup> In this study, there was little need for continued gastroenterology follow-up because a gastroenterology consultation was requested for only 7% of the patients.<sup>12</sup>

## SUMMARY

OAE is commonly used. The majority of patients referred for OAE are considered appropriate for endoscopy according to ASGE guidelines. Most patients undergoing OAE procedures are knowledgeable about

the study and are satisfied with the experience. Several potential problems have been identified, including inappropriate referrals, communication errors, and inadequately prepared or informed patients. OAE can be safely used if preprocedure assessment, informed consent, information transfer, patient safety, and satisfaction are addressed in all cases.

## RECOMMENDATIONS

- We recommend that referring providers using OAE understand the appropriate use of GI endoscopy and recognize when office consultation is necessary. ⊕○○○
- We recommend that referring providers discuss the indication for the procedure with the patient before referral for OAE. ⊕○○○
- We recommend that pertinent medical records be available to the endoscopist before the OAE procedure. ⊕○○○
- We recommend that endoscopy providers complete a preprocedure assessment of patients and obtain informed consent from all patients undergoing OAE. It is acceptable to obtain informed consent on the same day before the OAE procedure. ⊕○○○
- We recommend that endoscopy providers communicate results of the OAE and any subsequent recommendations to the patient and referring provider. ⊕○○○

## DISCLOSURE

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*Abbreviation: OAE, open-access endoscopy.*

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