# Guidelines for antibiotic prophylaxis for GI endoscopy



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

### GI ENDOSCOPY AND THE RISK OF INFECTIOUS COMPLICATIONS

The role of antibiotic prophylaxis is to reduce the possibility of a significant infectious complication. Randomized, double-blind, placebo-controlled trials, however, will likely never be performed. What can be extrapolated from the literature is the number of reports of infectious complications and the incidence of bacteremia associated with common endoscopic procedures. This review updates the 1995 ASGE guideline on this subject.<sup>1</sup>

Despite the large number of endoscopic procedures performed annually, there are few case reports of bacterial endocarditis seen after the procedure.<sup>2-</sup><sup>16</sup> Four of the reported 15 cases of endocarditis are associated with procedures at high risk for bacteremia, such as esophageal dilation<sup>4,8</sup> and esophageal sclerotherapy.<sup>11,14</sup> The remaining eleven case reports occurred with gastroscopy.<sup>2,3,9,13,15-16</sup> sigmoidoscopy,<sup>5-7,12</sup> and colonoscopy.<sup>10</sup> Other rarely reported infectious complications associated with esophageal sclerotherapy and dilations have included bacterial peritonitis, central nervous system (CNS) infections, and a perinephric abscess.<sup>17</sup>

High-risk procedures are those procedures associated with a high incidence of bacteremia.<sup>1</sup> Although bacteremia may occur and has been advocated as a



surrogate marker for endocarditis risk, clinically significant infections are rare. The highest bacteremia rates have been seen in patients undergoing esophageal dilation of a stricture and in sclerotherapy of esophageal varices.<sup>18</sup> Earlier estimates of the mean frequency of bacteremia encountered with esophageal dilation (45%) and esophageal sclerotherapy (31%) were based on the compilation of 4 studies each of 59<sup>19-22</sup> and 61 patients,<sup>23-26</sup> respectively. The majority of organisms isolated in blood cultures were mouth commensals such as Streptococcus viridans. However, in one study of patients undergoing bougienage, the source of bacteremia appeared to be from organisms isolated from the dilators and not from mouth commensals.<sup>19</sup> Because of the methodologic differences in each study, the true rate of bacteremia may have been overestimated.

Three recent prospective studies may represent a more accurate assessment of the true bacteremia rate after esophageal bougienage, and it is estimated to be between 12% and 22%.<sup>27-29</sup> In one study, blood cultures obtained before and after stricture dilation in 103 patients without valvular heart disease were compared with a control group of 50 patients undergoing endoscopy without dilation. The bacteremia rates were 21% vs. 2%, respectively. The organism isolated in 19 of the 24 positive blood cultures was S viridans. Of these 19 patients, bacteremia persisted for up to 30 minutes in two (10%).<sup>27</sup> There were no infectious complications noted.

In a second study involving 86 patients undergoing 100 total dilations, 22% had a positive postbougienage blood culture. Bacteremia was more frequent with dilation of a malignant stricture compared with a benign stricture, and during passage of multiple dilators compared with a single dilation. Organisms cultured from blood were not transmitted from the dilator. There were no infectious complications noted.<sup>28</sup>

In a third study investigating the efficacy of an oral antibiotic rinse, the total rate of bacteremia after esophageal dilation of benign and malignant strictures in 59 patients was 12%. All organisms isolated were mouth commensals. No infectious complications occurred.<sup>29</sup>

Endoscopic variceal ligation (EVL) generally has supplanted esophageal sclerotherapy because of its

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Patient condition	Procedure contemplated	Antibiotic prophylaxis
High risk: Prosthetic valve History of endocarditis Syst-pulm shunt Synth vasc graft (<1 y old) Complex cyanotic congenital heart disease	Stricture dilation Variceal sclerotherapy ERCP/obstructed biliary tree Other endoscopic procedures, including EGD and colonoscopy (with or without biopsy/ polypectomy), variceal ligation	Recommended Prophylaxis optional
Moderate risk: Most other congenital abnormalities Acquired valvular dysfunction (e.g., rheumatic heart disease) Hypertrophic cardiomyopathy Mitral valve prolapse with regurgitation or thickneed logflate	Esophageal stricture dilation Variceal sclerotherapy Other endoscopic procedures, including EGD and colonoscopy (with or without biopsy/ polypectomy), variceal ligation	Prophylaxis optional Not recommended
Low risk: Other cardiac conditions (CABG, repaired septal defect or patent ductus, mitral valve prolapse without valvular regurgitation, isolated secundum atrial septal defect, physiologic/functional/innocent heart murmurs, rheumatic fever without valvular dysfunction, pacemakers, implantable defibrillators)	All endoscopic procedures	Not recommended
Obstructed bile duct	ERCP	Recommended
Pancreatic cystic lesion	ERCP, EUS-FNA	Recommended
Cirrhosis acute GI bleed	All endoscopic procedures	Recommended
Ascites, immunocompromised patient	Stricture dilation Variceal sclerotherapy Other endoscopic procedures, including EGD and colonoscopy (with or without biopsy/ polypectomy), variceal ligation	No recommendation Not recommended
All patients	Percutaneous endoscopic feeding tube placement	Recommended (parenteral cephalosporin or equivalent)
Prosthetic joints	All endoscopic procedures	Not recommended
Cardiac prophylaxis regimens (oral 1 h before, IM or I Amoxicillin by mouth or ampicillin IV: adult 2.0 g, chil Penicillin allergic: clindamycin (adult 600 mg, child 20	V 30 min before procedure) d 50 mg/kg mg/kg), or cephalexin or cefadroxil (adults 2.0 g,	, child 50 mg/kg), or

Penicillin allergic: clindamycin (adult 600 mg, child 20 mg/kg), or cephalexin or cetadroxil (adults 2.0 g, child 50 mg/kg), or azithromycin or clarithromycin (adult 500 mg, child 15 mg/kg), or cefazolin (adult 1.0 g, child 25 mg/kg IV or IM), or vancomycin (adult 1.0 g, child 10-20 mg/kg IV).

Syst-pulm, Systemic-pulmonary; synth vasc, synthetic vascular; CABG, coronary artery bypass graft; IM, intramuscular; IV, intravenous.

greater efficacy and fewer associated complications.<sup>30</sup> Six studies with EVL have reported bacteremia rates ranging from 1% to 25%, with a mean frequency of 8.8%.<sup>31-36</sup>

The incidence of bacteremia also has been estimated in what generally are considered "low-risk procedures." During gastroscopy with or without biopsy, the range is from 0% to 8%, with a mean frequency of 4.4%.<sup>37-45</sup> The bacteremia observed usually was short lived (less than 30 minutes) and was not associated with any infectious complications. The rate of bacteremia associated with flexible sigmoidoscopy in two studies was low at 0% and 1%.<sup>46-47</sup> Rates of bacteremia associated with colonoscopy ranged from 0% to 25%, with a mean frequency of 4.4%.<sup>17</sup>

No studies, to date, that use antibiotic prophylaxis have demonstrated a clinically meaningful reduction in infectious complications during endoscopic procedures.<sup>29,48</sup> In addition, antibiotic prophylaxis for infective endocarditis in patients undergoing GI endoscopic procedures is not always successful.<sup>49</sup> One case-control study suggested that antibiotic prophylaxis may not affect the incidence of postprocedure endocarditis.<sup>50</sup> Other studies report that compliance with existing regimens is poor.<sup>51-53</sup>

Antibiotic guidelines established for prophylaxis against infective endocarditis should be reserved for those patients with the highest risk for infection (see Table 1). Indiscriminate use of antibiotics in association with GI endoscopic procedures is to be discouraged, as it adds unnecessary cost and the potential for adverse reactions.

### CONSENSUS STATEMENTS FOR ANTIBIOTIC PROPHYLAXIS DURING GI ENDOSCOPIC PROCEDURES

### Prophylaxis against infective endocarditis

Cardiac lesions proposed to be at high risk for the development of infective endocarditis include the following<sup>54</sup>: prosthetic cardiac valves, including bioprosthetic and homograft valves; previous bacterial endocarditis; surgically constructed systemic pulmonary shunts or conduits; complex cyanotic congenital heart disease (e.g., single ventricle states, transposition of the great arteries, tetralogy of Fallot).

Cardiac lesions or conditions that do not confer an increased risk of endocarditis over that of the general population include the following<sup>54</sup>: previous coronary artery bypass graft surgery; cardiac pacemakers and implanted defibrillators; mitral valve prolapse or previous rheumatic fever without valvular dysfunction or regurgitation; isolated secundum atrial septal defect (ASD); surgical repair of ASD, ventricular septal defect, or patent ductus arteriosus; physiologic, functional, or innocent heart murmurs; previous Kawasaki disease without valvular dysfunction.

Other cardiac lesions or conditions may be associated with an increased risk of infective endocarditis over the general population but less than the "highrisk" lesions listed above. These "intermediate risks" include the following<sup>54</sup>: most other congenital cardiac malformations (other than listed above); acquired valvular dysfunction (e.g., rheumatic heart disease); hypertrophic cardiomyopathy; mitral valve prolapse with valvular regurgitation and/or thickened leaflets.

### **Recommendations.**

- 1. For most endoscopic procedures, including upper endoscopy, sigmoidoscopy, and colonoscopy with or without mucosal biopsy, polypectomy, and/or nonvariceal hemostasis:
  - a. Antibiotic prophylaxis is not recommended for patients with lesions at intermediate risk for the development of endocarditis or those with lesions or conditions at no increased risk for endocarditis compared with the general population. For example, patients with mitral valve prolapse, with or without regurgitation, do not require prophylaxis for any of the above procedures.
  - b. There are insufficient data to recommend routine prophylaxis for patients at "high risk" for infective endocarditis. The endoscopist may consider prophylaxis on a case-bycase basis.

- 2. For endoscopic procedures associated with increased rates of transient bacteremia, including dilation of an esophageal stricture, varix sclerotherapy, and retrograde cholangiography with known or suspected bile duct obstruction:
  - a. Prophylaxis is recommended for patients at "high risk" for the development of endocarditis.
  - b. No prophylaxis is recommended for patients with those cardiac lesions and conditions at no increased risk for infective endocarditis over the general population. However, it is recommended that all patients with suspected or known biliary obstruction should receive prophylactic antibiotics before ERCP.
  - c. There are insufficient data to recommend routine prophylaxis for patients with cardiac lesions or conditions at intermediate risk for the development of infective endocarditis. The endoscopist may consider prophylaxis on a case-by-case basis.
- 3. Regimens<sup>54</sup>:
  - a. Standard general prophylaxis: amoxicillin 2.0 g by mouth (adult) or 50 mg/kg by mouth (child), 1 hour before the procedure. Alternative for those unable to take by mouth is ampicillin 2.0 g IV/IM (adult) or 50 mg/kg IV/IM (child), within 30 minutes before procedure.
  - b. Penicillin-allergic patients: clindamycin 600 mg by mouth (adult) or 20 mg/kg by mouth (child), 1 hour before procedure. Alternatives: cephalexin or cefadroxil 2.0 g by mouth (adult) or 50 mg/kg by mouth (child), 1 hour before the procedure; azithromycin or clarithromycin 500 mg by mouth (adult) or 15 mg/kg by mouth (child), 1 hour before the procedure.
  - c. Penicillin-allergic patients unable to take by mouth: clindamycin 600 mg IV (adult) or 20 mg/kg IV (child), within 30 minutes before the procedure. Alternative: cefazolin 1.0 g IV/IM (adult) or 25 mg/kg IV/IM (child) within 30 minutes before the procedure; vancomycin 1.0 g IV (adult) or 10-20 mg/kg (child).

### The patient with a synthetic vascular graft

Infection of synthetic vascular graft material is associated with devastating morbidity and mortality, but the risk of a graft infection decreases with time. In dogs infected with high inocula of *Staphlyococcus aureus* after replacement of an infrarenal aortic Dacron graft, graft infection occurred in all dogs 1 month after replacement of the graft, but in far fewer dogs 1 year after.<sup>55</sup> A single parental dose of antibiotic significantly decreased the infection rate, and infection did not occur in grafts after complete pseudointimal cover-

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age. It is reasonable to expect that pseudointimal coverage should be complete in 1 year.<sup>56</sup>

**Recommendation.** For up to the first year after placement of a synthetic vascular graft, antibiotic prophylaxis is recommended for patients undergoing esophageal stricture dilation, varix sclerosis, or retrograde cholangiography with known or suspected bile duct obstruction. For other endoscopic procedures, there are insufficient data to recommend routine prophylaxis. The endoscopist may consider prophylaxis on a case-by-case basis.

## The patient with a prosthetic joint or orthopedic prosthesis

Iatrogenic infection of prosthetic joints after endoscopic procedures is extremely rare. There has been only one case report of an infectious complication (pyogenic arthritis of the knee) associated with an endoscopic procedure (Nd:YAG laser treatment of an inoperable esophageal cancer).<sup>57</sup> A survey conducted among program directors of infectious disease training fellowships highlighted their practice recommendations with regard to infection prophylaxis for patients with prosthetic orthopedic devices undergoing GI procedures. Most respondents agreed that prophylaxis is not indicated at any time for these procedures. There was, however, an almost even split when confronted with the scenario of a colon polypectomy performed within 6 months of prosthesis insertion.<sup>58</sup>

**Recommendation.** There are insufficient data to recommend antibiotic prophylaxis for patients with prosthetic joints or orthopedic prosthesis undergoing GI endoscopic procedures.

## The patient with biliary obstruction, pancreatic pseudocyst, or pancreatic cystic lesion requiring FNA

Cholangitis and sepsis are known complications of ERCP, occurring in up to 3.0% of cases. Obstructed ducts and inadequate drainage increase the risk of clinically significant infection.<sup>59-69</sup> A variety of organisms have been shown to cause infection in such patients. Antibiotic testing of biliary cultures has demonstrated that most organisms are responsive to fluoroquinolones.<sup>70</sup> A recent meta-analysis demonstrated a trend toward decreased bacteremia in such patients with prophylactic antibiotics.<sup>71</sup> However, there appeared to be no significant differences in sepsis between those patients who received preprocedural antibiotics and those who did not. A recent decision analysis demonstrated fewer cases of cholangitis and a cost savings in those procedures that used prophylactic antibiotics.<sup>72</sup> In agreement with the above findings, many randomized, controlled trials have demonstrated conflicting results, although it appears that prophylactic antibiotics in those patients in whom biliary drainage has been compromised (choledocholithiasis, malignancy, etc.) may be beneficial.<sup>72-81</sup>

**Pseudocysts.** Retrograde pancreatography and, less clearly, EUS-guided FNA may introduce infection into pancreatic pseudocysts.<sup>62,66,82</sup> Definitive treatment is that of decompression and drainage. There are no randomized, controlled trials to compare antibiotic prophylaxis with placebo. However, because of their risk of infection, antibiotic prophylaxis appears prudent.

**EUS-guided FNA of solid/cystic lesions.** No clinically significant bacteremia was found in one study evaluating the efficacy of FNA during EUS of masses.<sup>82</sup> The use of prophylactic antibiotic administration in EUS-guided FNA of pancreatic cysts has not been clearly studied by randomized, controlled trials. A subgroup analysis of patients with cysts undergoing FNA demonstrated a 14% risk of infectious complications.<sup>83</sup>

**Recommendation.** All patients undergoing ERCP for known or suspected biliary obstruction or known pancreatic pseudocyst should receive antibiotics along with adequate drainage of the biliary obstruction or cyst. Endoscopic transmural drainage of pancreatic pseudocysts, similarly, may result in the introduction of infection into the cystic cavity. In addition, the EUS-guided aspiration of pancreatic cystic lesions also may result in introduction of infection. Although not supported by randomized, controlled trials, the use of prophylactic antibiotics before attempted drainage of such pseudocysts and similar pancreatic lesions is recommended. Antibiotics that cover biliary flora such as enteric gram-negative organisms, enterococci, and possibly Pseudomonas sp. are recommended. Prophylactic antibiotics do not appear to be necessary before FNA of solid masses.

## The endoscopic placement of a percutaneous feeding tube

Multiple prospective, randomized, controlled trials have demonstrated significantly lower peristomal wound infection rates when prophylactic antibiotics were administered 30 minutes before percutaneous gastrostomy tube placement.<sup>84-88</sup> However, a few randomized trials have demonstrated no significant reduction of peristomal wound infection with the administration of preprocedure antibiotics.<sup>89,90</sup> A recent meta-analysis evaluated seven trials, 3 of which were not blinded. The per-protocol analysis demonstrated a significant decrease in the peristomal wound infection rate in patients who received antibiotic prophylaxis compared with those who did not  $(6.4\% \text{ vs. } 24\%).^{91}$  **Recommendation.** All patients undergoing percutaneous endoscopic placement of a feeding tube should receive prophylaxis to prevent soft tissue infection. Parenteral cefazolin (or an antibiotic with equivalent coverage) should be given 30 minutes before the procedure. If the patient is already on an equivalent antibiotic, prophylactic antibiotic administration remains unnecessary.

### The patient with cirrhosis, ascites, and the immunocompromised patient

Aside from case studies and retrospective reports, there are few data to guide recommendations for the administration of prophylactic antibiotics before routine endoscopy in patients with cirrhosis, ascites, or immunosuppression.

Injection sclerosis. Bacteremia may occur in up to 50% of patients after sclerotherapy.<sup>23,25,32,47,92-96</sup> Clinically significant febrile episodes and/or bacterial peritonitis have been reported in up to 5% of patients during clinical trials.<sup>92-94,96-99</sup> Reported complications also have included CNS infections and pulmonary infiltrates. Bacteremia occurring after gastric variceal sclerotherapy was evaluated in one study and was found to be present in approximately 32% of the procedures. Roughly a third of this cohort developed fever and 50% of these patients were given antibiotics.<sup>100</sup> A few randomized, controlled trials of antibiotic therapy support the administration of antibiotics before sclerotherapy.<sup>48,101-103</sup> However, the investigators in these trials were not blinded to the administration of antibiotics vs. placebo. One randomized trial demonstrated a reduced incidence of peritonitis after sclerotherapy in those patients who received preprocedural cefotaxime.48

**Endoscopic variceal ligation.** Bacteremia has been reported to occur in up to 25% of patients after variceal ligation. The frequency of peritonitis reported to occur after variceal ligation appears to be less than 5%.<sup>31,33,35-36</sup> There are no randomized, doubleblind, placebo-controlled trials of antibiotic prophylaxis in this setting.

**GI hemorrhage.** Hospital admission for GI hemorrhage has been strongly associated with an increased risk for infections (especially bacterial peritonitis) in cirrhotic patients.<sup>31,48,94</sup> GI bleeding is presently considered an independent risk factor for the development of infection in cirrhotic patients.<sup>97</sup> Antibiotic administration has been shown to reduce infectious complications and mortality in cirrhotic patients presenting with GI hemorrhage.<sup>48,101-103</sup>

**Stricture dilation.** Stricture dilation in otherwise immunocompetant patients was discussed previously. The rate of clinically significant bacteremia in the immunocompromised patient after esophageal dilation remains to be determined.

**Recommendations.** Cirrhotic and otherwise immunocompromised patients are susceptible to infections from transient bacteremia, which occurs more often in high-risk invasive procedures.<sup>104-113</sup> The endoscopist should consider prophylaxis on a case-by-case basis in these high-risk procedures, such as esophageal sclerotherapy and stricture dilation. All cirrhotics presenting with GI bleeding should receive prophylactic antibiotics.<sup>31,48,94,100-102</sup>

For other endoscopic procedures, including prophylactic EVL, routine antibiotic prophylaxis is not recommended. However, the decision to administer antibiotic prophylaxis should be made on a case-bycase basis. Cirrhotic patients with ascites appear to be at a potentially higher risk for infection. In addition, transplant patients on high doses of steroids also appear to have increased susceptibility to infection. The choice of antibiotic should be tailored to the specific perceived risk.

### SUMMARY

For the following points: (A), Prospective controlled trials; (B), observational studies; (C), expert opinion.

- Antibiotic prophylaxis against infective endocarditis is recommended when a high-risk patient is undergoing an endoscopic procedure associated with a high incidence for transient bacteremia. (C)
- Patients undergoing high-risk endoscopic procedures who have a synthetic vascular graft less than 1 year old also should receive antibiotic prophylaxis. (C)
- There is no clear benefit or consensus in the use of prophylactic antibiotics in patients with a prosthetic joint or an orthopedic prosthesis undergoing any endoscopic procedure. (C)
- All patients undergoing ERCP for known or suspected biliary obstruction or known pancreatic pseudocyst should receive antibiotics with adequate drainage of the biliary obstruction (A) or cyst. (C)
- Prophylactic antibiotics are recommended for EUS-guided aspiration of pancreatic cystic lesions but not before FNA of solid masses. (C)
- All patients undergoing endoscopic placement of a percutaneous feeding tube should receive prophylactic antibiotics to limit the risk of soft-tissue infection. (A)
- All patients with cirrhosis who present with GI bleeding should receive prophylactic antibiotics to decrease infectious complications and mortality. (A)

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