Antibiotic Prophylaxis Clinical Practice Guideline: Supporting Documentation

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The American Society of Colon and Rectal Surgeons

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It should be recognized that these guidelines should not be deemed inclusive of all proper method 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 of the circumstances presented by the individual patient.

Bacterial endocarditis is a serious, potentially fatal condition that may be associated with endoscopic procedures. Antibiotic prophylaxis has been used to prevent endocarditis, but does involve risks. Endoscopists must assess the evidence and weigh the risks and benefits.

Endocarditis

Statement of the Problem

Infective endocarditis is an infection of the endocardium, most commonly caused by a gram-positive coccus, although gram-negative bacillus and fungus can also produce the disease. Before the introduction of antibiotics, endocarditis was, almost without exception, fatal. Modern medical and surgical treatments have altered the clinical course of the disease, and a cure rate of 80 percent with a 50 percent ten-year survival rate has been achieved.(1) Long-term follow-up of these "cured" cases reveals late morbidity in the form of heart failure or recurrent endocarditis that can require valve replacement, with a mortality rate of 5 to 10 percent.(2) Infective endocarditis comprises 0.3 to 3 percent of all hospital admissions. The statistical variation in the frequency is believed to be a result of inconsistencies in case definitions. The preponderance of endocarditis occurs in men (54-73 percent). The mean age has gradually increased from less than 39 years in 1943 to as old as 57 years.(3) In one study 55 percent of the patients were older than 60 years.(4) The majority of native valve endocarditis is caused by *Streptococcus viridans* (50 percent) and *Staphylococcus aureus* (20 percent).(5) In "early" prosthetic valve endocarditis *Staphylococcus epidermis* is the most frequent organism. Late-onset prosthetic valve endocarditis is similar to native valve endocarditis. Enterococcal endocarditis is usually

associated with malignancy or manipulation of the genitourinary or gastrointestinal tract. Recently the HACEK group (*Hemophilus, Actinobacillus, Cardiobacterium, Eikenella,* and *Kingella* species) are becoming more important causes of endocarditis.(6,7)

Do Gastrointestinal Endoscopic Procedures Cause Endocarditis?

The rate of endocarditis depends on the incidence and intensity of bacteremia and the organisms causing bacteremia. Bacteria vary in their capacity to colonize damaged heart valves. A review of endoscopic literature produced no evidence to implicate gastrointestinal procedures as a major precipitator of bacterial endocarditis. A survey of 123 endoscopy units in the United States revealed only four poorly documented cases of endocarditis, and a single, unconvincing case was found in the British medical literature.(8,9) It should be noted that most of the reviewed cases of endocarditis were reported after the advent of gastrointestinal endoscopy, but no evidence of an increase in the disease was offered.(10,11)

The phenomenon of transient bacteremia in human beings has been recognized for many years (Table 1). Hoffman and associates(12) detected bacteremia in 4 percent of their patients five minutes after rectal examination was performed. All isolates were anaerobic and contained in the normal fecal flora. As it related specifically to lower bowel endoscopy, the incidence of bacteremia ranges from 0 to 13 percent among patients undergoing rigid sigmoidoscopy.(13-16) LeFrock *et al.*(15) documented transient bacteremia in nearly 10 percent of their patients who underwent rigid sigmoidoscopy. Eleven of 19 of the transient bacteremia cases associated with sigmoidoscopy involved enterococci. The rate of bacteremia reported for patients with rectal disease was similar to that for patients without disease. In some cases bacteremia was observed within the first minute of the procedure and lasted for as long as 15 minutes. Bacteremia was not detected after 30 minutes. Efforts to reproduce these data have been unsuccessful.(17)

Table 1.

Representative Rates of Bacteremia

Procedure or Site	Incidence (Range), %
Tooth extraction	60 (18-85)
Brushing teeth	40 (7-50)
Upper endoscopy	4 (0-8)
ERCP	3 (0-6)
Barium enema	10 (5-11)
Colonoscopy	5 (0-5)
Flexible sigmoidoscopy	0
Rigid sigmoidoscopy	5 (0-13)

ERCP = endoscopic retrograde cholangiopancreatography.
Adapted from Durack DT. Prevention of infective endocarditis, *New England Journal of Medicine* 1995;332:38-44.(11)

Goldman *et al.*(18) reported a 1 percent incidence of transient bacteremia among 100 patients in whom flexible fiberoptic sigmoidoscopy was performed. Transient bacteremia rarely follows colonoscopy.(19-23) London *et al.*(24) reported a 4 percent incidence among 50 patients. There seems to be no correlation between biopsy or fulguration and bacteremia.(25) The 11 percent incidence of bacteremia after barium enema is similar to that associated with colonoscopy. All of these bacteremias are asymptomatic. In addition, organisms present in the blood stream are usually not ones typically associated with endocarditis.

Factors Associated with an Increased Risk of Endocarditis

Although there are few reported cases of endocarditis after gastrointestinal procedures, it is appropriate to assess which patients are at increased risk and to determine whether certain bacteremias are more dangerous than others. Just how endocarditis develops from transient bacteremia is not understood.(26) Although heart disease is regarded as a risk factor in the development of endocarditis, only approximately 50 percent of the cases observed had cardiac lesions.(27)

There are no data to support conclusively the suspicion that patients with prosthetic valves, complex congenital malformations, or surgically constructed systemic pulmonary shunts or those with a prior history of endocarditis are at greater risk. The consequences are dire, however, when high-risk patients do develop endocarditis. The mortality rate among patients with infected valve prostheses is reported to be 44 percent.(28) most investigators think that it is prudent to use prophylactic antibiotics in this select subset of patients. Prophylactic antibiotics are not recommended for cardiac lesions or other conditions considered at moderate or low risk (Table 2).

Table 2.

Conditions Associated with Endocarditis

High risk

- Prosthetic cardiac valves
- History of endocarditis
- Surgically constructed systemic pulmonary shunts
- Complex cyanotic congenital heart disease
- Vascular grafts (first 6 months after implantation)

Moderate risk

- Most other cardiac malfunctions
- Acquired valvular dysfunction
- Hypertrophic cardiomyalgia
- Mitral valve prolapse with valvular regeneration or thickened valves or both

Low risk

- Vascular graft material (6 months after implantation)
- Orthopedic prosthesis
- Central nervous system ventricular shunts
- Penile prosthesis
- Intraocular lens
- Pacemakers
- Local tissue augmentation material
- Isolated secundum atrial septal defect
- Previous coronary bypass
- Mitral valve prolapse without valvular degeneration
- Physiologic heart murmurs
- Previous rheumatic fever without valvular dysfunction
- Cardiac pacemaker

Efficacy of Antibiotics in Preventing Endocarditis

Antibiotics have successfully prevented endocarditis in animal studies.(29,30) The mechanism probably involves effects that occur after circulating bacteria have adhered to the endocardium. These experimental findings have led to recommendations for prophylaxis in humans.

However, despite accepted recommendations for prophylaxis and the decrease in the incidence of rheumatic heart disease, the number of reported cases of endocarditis has remained fairly constant. Whether this is because of poor compliance with published recommendations or the lack of efficacy, this finding suggests either that prophylaxis has not been practiced appropriately or that it is irrelevant.(31-33) Prospective studies are unlikely to be done because of the large number of subjects required and controversy about the ethics of a control group. One case-control study did suggest that antibiotic prophylaxis may not change the incidence of postprocedural endocarditis.(34) Therefore, recommendations for the use of prophylactic antibiotics are pragmatic.

The side effects of antibiotics must also be considered. Penicillin has been known to precipitate anaphylaxis even when given orally. The risk of anaphylactic shock ranges from 0.015 to 0.04 percent, with an associated mortality rate of approximately 10 percent.35, 36 It is also important to note that antibiotics given in a single prophylactic dose put the patient at risk for developing pseudomembranous enterocolitis, with all of its attendant sequelae.(37) Finally, the issue of unnecessary cost must be kept in mind.

Published Recommendations

Because bacterial endocarditis is a serious and often life-threatening infection, the goal of clinicians is to provide protection for patients at increased risk. The endoscopist must carefully weight the risk/benefit ratio, and specialty societies must consider the cost/benefit ratio of using antibiotic prophylaxis in large numbers of patients undergoing gastrointestinal endoscopic procedures. Several task forces have made recommendations about antibiotic prophylaxis.

Representatives of the American Heart Association (AHA), American Dental Association, Infectious Disease Society of America, American Academy of Pediatrics, and The American Society of Gastrointestinal Endoscopy recommended in 1997 that prophylactic antibiotics be considered for high-risk patients undergoing colonoscopy and sigmoidoscopy.(38)

1. Conditions considered high risk are
    a. Prosthetic heart valves;
    b. Complex cyanotic congenital cardiac malformations;
    c. Surgically constructed systemic pulmonary shunts; and
    d. Previous history of endocarditis.

2. Prophylaxis is not recommended for patients with
    a. Isolated secundum atrial septal defect;
    b. Secundum atrial septal defect repaired with a patch at least six months earlier;
    c. Patent ductus arteriosis--ligated and divided at least six months earlier;
    d. Postoperative coronary artery bypass graft surgery;
    e. Acquired valvar dysfunction;
    f. Mitral valve prolapse; and
    g. Cardiac pacemakers.
3. The Endoscopy Committee of the British Society of Gastroenterology has recommended antibiotic prophylaxis for high-risk patients only. Patients with a synthetic vascular graft less than one year old and patients with severe neutropenia were added to the AHA list of high-risk patients.(39)
4. The Working Party of the Society of Antimicrobial Chemotherapy recommends prophylaxis effective against streptococcus in patients with prosthetic heart valves who are undergoing colonoscopy, proctoscopy, sigmoidoscopy, or barium enema.(40)
5. The American Society of Gastroenterologists guidelines reflect those of the AHA.(41) Antibiotic prophylaxis may be considered on an individual basis for patients with
    a. Prosthetic heart valves;
    b. Previous endocarditis;
    c. Surgically constructed systemic pulmonary shunts; and
    d. Synthetic vascular grafts implanted within 12 months.
6. A statement appeared in *The Medical Letter* that asserted that "antimicrobial prophylaxis for gastrointestinal endoscopy, is unwarranted"(42) for patients with prosthetic heart valves.
7. A joint working group of the American College of Cardiology and the American Heart Association published ACC/AHA guidelines for the management of patients with valvular heart disease in 1998.(5) This group concurred with the AHA recommendations for prevention of bacterial endocarditis.

Compliance

There is great variation in the opinions expressed by members of the medical community as to which high-risk individuals should receive prophylaxis, particularly if compliance is used as a measure of those opinions. These differences were highlighted by the results of a survey conducted by Meyer.(43) Ninety-eight directors (67 percent) of infectious disease training programs responded to questions about the use of prophylactic antibiotics in colonoscopy. Fifty-four percent recommended prophylaxis for patients with rheumatic heart disease, 69 percent recommended it for those with valvular heart disease, and 78 percent recommended it for prosthetic valve patients. Of 52 cases of endocarditis prophylaxis failure reported to a national registry established by the AHA, only six (12 percent) had received antibiotic regimens recommended by the Association.(44)

A retrospective review of prophylactic antibiotic use in patients with prosthetic heart valves who were undergoing diagnostic or operative procedures showed only 30 percent compliance with the AHA's recommendations.(45) Other investigators believe that oral penicillin prophylaxis is of value in preventing endocarditis only in older adults with mitral valve prolapse, but at a cost of 2.6 million dollars for every patient spared.(46)

Nonvalvular and Noncardiac Prostheses

Statement of the Problem

The question of whether to recommend the use of prophylactic antibiotics for endoscopic patients who have nonvalvular or noncardiac prostheses is of tremendous significance in terms of both efficacy and cost-effectiveness. More than 1.6 million prostheses were inserted in 1989, and the number undoubtedly exceeds that today.

Vascular Prosthesis

The issue of whether or not to recommend antibiotic prophylaxis to endoscopy patients with nonvalvular prosthetic material in place has been addressed.(47) Two major vascular surgical texts recommend administration of broad-spectrum antibiotic coverage in patients with prosthetic vascular graft material,(48,49) based on previously cited catastrophic effects of major graft infections (60 and 30 percent mortality and amputative rates, respectively).(50) Other investigators recommend prophylaxis for at least one year after graft implantation, and subsequent antibiotic therapy is an option if deemed appropriate.(51,52) The AHA recommends prophylaxis be considered for the first six months after implantation.(38) This recommendation is based on animal studies showing that six months after implantation no bacterial colonization was demonstrated.(53)

Orthopedic Prosthesis

Several major orthopedic surgical texts make no recommendations regarding antibiotic prophylaxis in patients undergoing endoscopic procedures with prosthetic joints or appliances in place. Brause(54) has stated merely that the use of prophylaxis for these patients is controversial, and decisions regarding its use should be made on an individual basis. Jacobson and Matthews(55) reported a 1.1 percent late prosthetic joint infection rate among 2,693 patients in whom hip or knee prosthesis was in place. Segreti and Levin(56) have recommended against prophylaxis in these patients unless the surgery involves infected tissue or infection of the prosthetic joint itself. There is no hard evidence to support the routine use of prophylaxis in patients with orthopedic prostheses who undergo lower endoscopy.(57,58) The American Society of Gastroenterologists guidelines also state that there are no data suggesting an increased rate of infection in these patients.(41) *The Medical Letter* concurs that these patients do not require antimicrobial prophylaxis.(42)

Other

There is no evidence to support the use of antibiotic prophylaxis in patients with CNS prostheses, penile prostheses, intraocular lens, or pacemakers, and therefore, it is not recommended.

Reconstruction with Local Tissue Augmentation

Infections associated with reconstructive surgical procedures in which foreign materials are implanted to augment local tissue (breast augmentation or reconstruction, inguinal hernia repair, incisional hernia repair, and others) occur as a result of the local milieu of the wound, by contamination of the device at the time of implantation, or by direct extension of contiguous septic sites. Hematogenous spread of infection to such devices during the performance of a clean surgical procedure is virtually unknown.(59)

Immunocompromised Patients

There is very little data to direct efforts to prevent endocarditis in immunocompromised patients such as transplant or neutropenic patients. Practitioners tend to err on the conservative side because of the dire consequences of endocarditis in these patients, but no clear guidelines are available. The Endoscopy Committee of the British Society of Gastroenterology recommends prophylaxis for patients with severe neutropenia, defined as neutrophils |Ld100 |m~ 109/l.(39)

Prophylactic Regimens

It is impossible to make recommendations for all clinical situations. Practitioners must choose the anti-biotic and determine the dosage based on the special circumstances of each case. Adult prophylactic regimens (Table 3) are representative of recommendations made by the AHA. Although the other organisms may be cultured after lower endoscopy, enterococcus is the most likely cause of endocarditis; therefore, the prophylactic regimens are directed primarily against enterococci.(5,41)

Table 3. Adult Prophylactic Regimens

Drug	Adult Dosage Regimen
Ampicillin, gentamicin, and amoxicillin	Intravenous or intramuscular administration of ampicillin (2.0 g) plus gentamicin (1.5 mg/kg; not to exceed 120 mg) 30 minutes before procedure, followed by amoxicillin (1 g) orally 6 hr after initial dose or ampicillin 1 g IM or IV.
Vancomycin and gentamicin*	Intravenous administratio of vancomycin (1.0 g) over 1 to 2 hr plus intravenous or intramuscular administration of gentamicin (1.5 mg/kg; not to exceed 120 mg), complete infusion within 30 minutes of starting procedure.
Amoxicillin+ or ampicillin	Amoxicillin 2 g orally or ampicillin 2 g IM or IV within 30 minutes of starting procedure.

IM = intramuscularly; IV = intravenously.
* Ampicillin or amoxicillin or penicillin-allergic regimen.
+ Alternative moderate-risk regimen.

The complex nature of individualized patient care does not allow standards to be spelled out for every clinical category, and the risk of administering antibiotics must be weighed against the risk of infection for each patient. Although the treating physician may choose to administer prophylactic antibiotics for any patient, The Standards Task Force recommends prophylaxis for only the high-risk groups listed in Table 2.

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