Review Article

Prophylaxis against infective endocarditis

A review of current international guidelines

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ABSTRACT

الغرض من هذه الدراسة هو مناقشة الإرشادات العالمية المتعلقة بمنع حدوث التهاب الشغاف المعدي (IE). فالمتعارف عليه منذ زمن طويل أن مرضى القلب هم عرضة للإصابة بهذا المرض ولذلك يجب إعطائهم مضادات حيوية كعلاج وقائي عند تلوث الدم بالكائنات المسببة لهذا المرض. ومع ذلك فإن البراهين على ذلك تعد ضعيفة نسبيا ومبنية على تقارير حالات منفصلة وعلى اعتبارات نظرية وعلى تجارب عشوائية محدودة. وفي الفترة الأخيرة، تغيرت هذه الإجراءات لثلاثة أسباب رئيسية وهي: أولاً: يوجد دليل قوي بأن تلوث الدم من خلال الكائنات الدقيقة المسببة للمرض غالباً ما يحدث بعد القيام ببعض الأنشطة اليومية ومنها تفريش الأسنان. ثانياً: بعض الحالات القليلة المصابة بهذا المرض يوعز سبب إصابتها إلى إجراءات سابقة. ثالثاً: يجب أن توضع في الاعتبار النتائج السلبية المترتبة على تناول المضادات الحيوية. إن الإرشادات العالمية المعمول بها حاليا والمتعلقة بالقضاء على المرض قد تغيرت وأصبحت تطالب بمنع استخدام المضادات الحيوية أو أن يقتصر استخدامها على فئة قليلة وهي الحالات ذوي الخطورة العالية.

The purpose of this review is to discuss current international guidelines on the prevention of infective endocarditis (IE). It has long been considered that all patients with heart conditions predisposing to IE should receive antibiotic prophylaxis when undergoing procedures leading to bacteremia with organisms known to cause endocarditis. However, evidence for this is poor and based on isolated case reports, and on theoretical considerations, rather than on randomized controlled trials. Recently, thinking has changed for 3 main reasons. Firstly, there is now strong evidence that bacteremia with endocarditis-causing organisms frequently occurs following everyday activities, such as tooth-brushing. Secondly, few cases of endocarditis are directly attributable to a preceding procedure. Thirdly, adverse effects of antibiotic use should be given due consideration. Recent international guidelines have radically changed recommendations on this issue, advocating limited, or non-use of antibiotics in a very small group of high-risk individuals for a limited number of invasive procedures.

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Though infective endocarditis (IE) is rare, it is a serious disease causing significant morbidity and mortality. It results from colonization by infective organisms of native endocardium, or prosthetic heart implants in susceptible individuals. In 1909, Horder[1] observed that "infection is grafted upon a previously sclerosed endocardium. The source of the infecting agent, in most of the cases, is the mouth." Ever since, numerous studies have provided circumstantial evidence without conclusively proving a direct link between invasive procedures and IE. Clinical guidelines published since 1955 have aimed towards rational use of antibiotics to prevent IE following invasive procedures. However, evidence base for these guidelines was limited to case-control studies, animal data, and expert consensus opinion. Adequately powered, well-designed, randomized controlled trials have never been conducted since they would be impractical and unethical. Recent guidelines have challenged existing dogma by highlighting prevalence of bacteremias following everyday activities such as tooth brushing; lack of association between episodes of IE and prior interventional procedures; and inadequacy of antibiotic prophylaxis regimens. Revised guidelines published by various professional bodies have advocated prophylaxis

in a limited group of patients for a restricted group of invasive procedures. This review is intended to discuss the clinical implications of the 3 recent guidelines published by the European Society of Cardiology (ESC) in 2004,[2] American Heart Association (AHA) in 2007,[3] and National Institute for Health and Clinical Excellence (NICE) in 2008.[4]

Historical Perspective. The rationale for antibiotic prophylaxis to prevent IE depends upon 2 premises. Firstly, certain procedures, especially dental interventions, result in bacteremia with organisms that commonly cause IE. Secondly, certain cardiac conditions, both congenital and acquired, predispose an individual to the acquisition of IE. Hence, the need for antibacterial coverage for at-risk procedures in at-risk individuals has been recognized since over a century, and an accepted clinical dogma since the past 50 years. After Horder's[1] observation in his classic paper of 1909, a number of case reports and expert commentaries were published, providing circumstantial evidence of the association of IE and antecedent surgical, or dental procedure. The only studies of efficacy of antibiotic prophylaxis have been case-control analyses. Based on this feeble evidence, several national and international bodies have published guidelines since 1955, delineating at-risk groups and providing recommendations for antibiotic prophylaxis. These guidelines differed in detail, but not in principle. Overall, compliance with these guidelines has been poor.[5] Compliance rates of 15-35% have been reported for dental procedures,[5] but there are few data for compliance for non-dental procedures requiring antibiotic prophylaxis.

The value of prophylaxis in the prevention of IE has been questioned for several years, as there is little or no objective evidence that it is effective in preventing IE. Transient bacteremia occurs frequently during routine daily activity, often at rates exceeding those associated with dental, or non-dental procedures. Brushing and flossing teeth have been associated with rates of bacteremia of 20-68%, use of toothpicks with rates of 20-40%, and even activity that might be considered entirely physiological, such as, chewing food, has been associated with rates of bacteremia that range from 7-51%.[3] Given the relative rarity with which most individuals undergo invasive procedures compared to daily activities of brushing teeth, the risk of procedure-related bacteremia is trivial compared with the frequency of bacteremia encountered with routine daily activities. This provides a strong rationale for not administering antibiotic prophylaxis for IE before invasive procedures. A 2-year study of 275 patients in the Netherlands concluded that most cases of IE are not attributable to an invasive procedure, but to random bacteremia.[6] The authors suggested that even if antibiotic prophylaxis were fully effective, then it would only prevent an extremely small number of cases of IE. A similar French study showed that dental procedures were not associated with an increased risk of IE, and that the protective efficacy of antibiotic prophylaxis was not significant.[7] A study conducted in 54 hospitals in Philadelphia found that preceding dental treatment was no more likely in patients with IE than in controls.[8] Another study suggests that a huge number of prophylactic doses of antibiotics are necessary to prevent a very small number of cases of IE, and that the risk of developing IE after an unprotected dental procedure is extremely low.[9] A recent Cochrane review concluded that there was no evidence to demonstrate whether antibiotic prophylaxis is effective, or ineffective in preventing IE in at-risk patients undergoing invasive dental procedures.[10]

The recent rationalization of international guidelines is based upon these studies (**Table 1**). However, all these studies involved small numbers of subjects. Even if negative, these results fail to demonstrate that antibiotic prophylaxis of IE is ineffective. The absence of evidence does not mean evidence of absence. To settle this issue, a randomized controlled trial is called for. Such a trial, unless massive, would be inadequately powered to avoid type II error. This trial would therefore require more than 6000 at-risk participants, and would be highly expensive and arduous. Even the International Collaboration on Infective Endocarditis set up to monitor and study the disease worldwide, has a database of approximately 2200 patients, much less than required for an adequately powered trial.[11] Further, randomization of at-risk subjects for a serious outcome such as IE, would encounter strong ethical concerns.

Patient risk groups. The 3 guidelines differ in the way they have stratified risk groups among patients thought to be susceptible to this infection (**Table 2**). The ESC[2] considers that it is impossible to determine the relative risk of specific cardiac conditions. It has identified those conditions that are associated with an IE risk that is higher than that in the general population, including conditions that are associated with a worse prognosis if IE develops. Cardiac conditions requiring antibiotic prophylaxis have been classified into high and moderate-risk. High-risk individuals include those with prosthetic heart valves, complex cyanotic congenital heart disease, previous IE, and patients bearing surgically constructed systemic or pulmonary conduits. Patients with acquired valvular heart disease, mitral valve prolapsed with valvular regurgitation or severe valve thickening, hypertrophic cardiomyopathy, and non-cyanotic congenital heart disease including bicuspid aortic valves, but excluding secundum type atrial septal defect

Table 1 - Rationale for revision of guidelines.

European Society of Cardiology 2004[2]	American Heart Association 2007[3]	NICE 2008[4]
A great number of guidelines and expert consensus documents issued in recent years by different organizations have put at stake the authority and validity of guidelines.	Infective endocarditis (IE) is more likely to result from frequent exposure to random bacteremias associated with daily activities than from bacteremia caused by a dental, gastrointestinal or genitourinary tract procedure.	There is no consistent association between having an interventional procedure, dental or non-dental, and the development of IE.
Despite the fact that standards for issuing good quality guidelines and expert consensus documents are well defined, recent publications of these documents in peer-reviewed journals have shown that methodological standards were not complied with in the vast majority of cases.	Prophylaxis may prevent an exceedingly small number of cases of IE, if any, in individuals who undergo a dental, gastrointestinal or genitourinary tract procedure.	Regular toothbrushing almost certainly presents a greater risk of IE than a single dental procedure because of repetitive exposure to bacteremia with oral flora.
This guideline attempts to present its recommendations in an easily interpretable format	The risk of antibiotic associated adverse events exceeds the benefit, if any, from prophylactic antibiotic therapy.	The clinical effectiveness of antibiotic prophylaxis is not proven.
Implementation of these guidelines and subsequent improvement of the quality of clinical practice needs to be monitored.	Maintenance of optimal oral health and hygiene may reduce the incidence of bacteremia from daily activities and is more important than prophylactic antibiotics for a dental procedure to reduce the risk of IE.	Antibiotic prophylaxis against IE for dental procedures may lead to a greater number of deaths through fatal anaphylaxis than a strategy of no antibiotic prophylaxis, and is not cost effective.

NICE - National Institute for Health and Clinical Excellence

Table 2 - Individuals at high risk for developing infective endocarditis.

European Society of Cardiology 2004[2]	American Heart Association 2007[3]	NICE 2008[4]
Acquired valvular heart diseases	-	Acquired valvular heart disease with stenosis or regurgitation
Prosthetic heart valves	Prosthetic cardiac valve	Valve replacement
Complex congenital cyanotic heart disease Non-cyanotic congenital heart disease (CHD) (except secundum type atrial septal defect), including bicuspid aortic valves. Surgically constructed systemic or pulmonary conduits Mitral valve prolapsed with valvular regurgitation or severe valve thickening	Congenital heart disease • Unrepaired cyanotic CHD, including those with palliative shunts and conduits • Completely repaired CHD with prosthetic material or device either by surgery or catheter intervention during the first 6 months* after the procedure • Repaired CHD with residual defects at the site or adjacent to the site of a prosthetic patch or prosthetic device†	Structural CHD, including surgically corrected or palliated structural conditions (excluding isolated atrial septal defect, fully repaired ventricular septal defect or fully repaired patent ductus arteriosus, and closure devices that are judged to be endothelialized)
Previous infective endocarditis (IE)	Previous IE	Previous IE
Hypertrophic cardiomyopathy	-	Hypertrophic cardiomyopathy
-	Cardiac transplantation recipients who develop cardiac valvulopathy	-

NICE - National Institute for Health and Clinical Excellence, *prophylaxis is recommended since endothelialization of prosthetic material occurs within 6 months after the procedure, †prosthetic patch, or device inhibits endothelialization at the site of a residual defect in repaired congenital heart disease

are stratified as moderate-risk. Antibiotic regimens recommended for these 2 groups differ for procedures involving the gastrointestinal and genitourinary tract. Both AHA[3] and NICE[4] have defined high-risk groups based on the impact of underlying cardiac conditions on the outcomes of IE.

Interventions. **Table 3** lists the procedures that are considered high-risk for the development of IE, and in need of antibiotic prophylaxis in the 3 guidelines.

Respiratory tract procedures. Although a variety of organisms may cause bacteremia during respiratory tract procedures, there is no direct evidence that such procedures result in IE. The ESC[2] recommends antibiotic prophylaxis for rigid bronchoscopy, tonsillectomy, and adenoidectomy among high, and moderate risk patient groups. The AHA[3] guideline does not recommend routine antimicrobial prophylaxis for procedures, unless they involve incision or biopsy of the

respiratory tract mucosa. Examples of such procedures include tonsillectomy, adenoidectomy, or bronchoscopy with biopsy. In patients who undergo an invasive respiratory tract procedure as part of the treatment of an established infection, the ongoing antibiotic regimen should include an agent that is active against viridans group of *Streptococci*. In patients who have a respiratory tract infection that is known or suspected to be caused by *Staphylococcus aureus (S. aureus*), the regimen should include an agent active against *S. aureus*. The NICE[4] does not recommend antibiotic prophylaxis for procedures involving "upper and lower respiratory tract; this includes ear, nose, and throat procedures, and bronchoscopy."

Gastro-intestinal (GI) procedures. Invasive GI procedures, such as lower bowel endoscopy with biopsy, or endoscopic retrograde cholangiopancreatography, have a low risk of IE since bacteremia, due to organisms capable of causing endocarditis occurs in less than 5-10% of cases. An estimated 14.2 million colonoscopies, and 2.8 million flexible sigmoidoscopies and upper endoscopies are performed annually in the United States.[12] Only 15 cases of IE have been reported with a temporal association with an endoscopic procedure, though none of these demonstrate a clear causal link between the procedure and IE. Similarly, there are no data that demonstrate that antibiotic prophylaxis before endoscopic procedures protect against IE. The ESC guidelines[2] recommend antibiotic prophylaxis for procedures listed in **Table 3**, in moderate and high-risk individuals. Both AHA[3] and NICE[4] do not recommend antibacterial prophylaxis solely to prevent IE prior to any gastro-intestinal procedure. The AHA[3] however, advises that established GI-tract infections, in which *enterococci* may be part of the infecting bacterial flora (such as cholangitis) among high-risk individuals, amoxicillin or ampicillin (or vancomycin in individuals with allergy to penicillin) should be included in the antibiotic regimen for *enterococci* coverage.

Genito-urinary (GU) procedures. Several diagnostic and therapeutic procedures that involve the GU-tract are associated with transient bacteremia. However, the risk of bacteremia is significantly lower for invasive GU procedures such as dilation of strictures, insertions of catheters, and prostatectomy compared with dental, or respiratory tract infections. Though case reports involving single or small groups of patients of IE temporally associated with GU procedures have been published, the evidence is anecdotal and circumstantial. No published data have so far demonstrated a conclusive link between the performance of GU procedures and subsequent development of IE. Moreover, no study has demonstrated the effectiveness of antimicrobial prophylaxis in the prevention of IE following any GU procedure.

Risk factors for developing bacteremia in the obstetric setting include preterm delivery, chorioamnionitis, and septic abortion. However, the bacteremia during these procedures is short lived and involves *Gram-Negative bacilli* (such as, *Escherichia coli*), *Gram-Positive bacilli* (such as, *Gardnerella vaginalis*), *anaerobic Gram-Positive cocci* and *Streptococcus agalactiae* instead of the *viridian group of Streptococci*, *S. aureus*, or *Enterococcus faecalis*. In the latest UK confidential enquiry into Maternal and Child Health Report,[13] the leading cause of maternal death is cardiac disease. However, only 4 deaths were reported due to IE during pregnancy and the postpartum period, giving a maximal rate of fatal postpartum endocarditis of 0.14/100,000 deliveries. In contrast, the incidence of potentially fatal anaphylaxis from beta-lactam antibiotics is 1-3/100,000 exposures.[14] The AHA guidelines[3] recommend that patients with highest-risk cardiac conditions who also "have an established GI or GU-tract infection, or who receive antibiotic therapy to prevent wound sepsis associated with a GI or GU procedure; it may be reasonable that the antibiotic regimen include an agent active against *enterococci*." For those patients with an *enterococcal* urinary tract infection or colonization scheduled to undergo elective cystoscopy or urinary tract manipulation, eradication of the organism prior to the procedure should be attempted. In the absence of bowel injury or opening of the vagina, gynecological procedures are generally considered "clean." Prophylaxis is therefore, not recommended by AHA[3] solely to prevent IE for any GU-tract procedure. The NICE[4] iterates that "antibiotic prophylaxis against infective endocarditis is not recommended … for people undergoing non-dental procedures at the … genitourinary tract; this includes urological, gynecological, and obstetric procedures, and childbirth." In contrast, ESC[2] recommends antibiotic prophylaxis for several urological procedures including urethral instrumentation/dilatation, lithotripsy in addition to cystoscopy and gynecological procedures in the presence of infection "despite a lack of convincing evidence."

Antimicrobials. Over the years, antibiotics used in the prevention of IE involved complicated regimens and long duration of use. It is remarkable that the earlier versions of guidelines recommended 5 days of antibiotic "coverage" for a minor dental procedure. Both the number and duration of antibiotic use have been scaled down to a single dose of a single antibiotic in the new AHA guidelines,[3] though ESC guidelines[2] advocate a less simple regime for GI and GU procedures (**Table 4**).

Table 3 - Interventions requiring antibiotic prophylaxis.

European Society of Cardiology 2004[2]	American Heart Association 2007[3]	NICE 2008[4]
Dental procedures with the risk of gingival/mucosal trauma	All dental procedures that involve manipulation of gingival tissue or the periapical region of teeth or perforation of the oral mucosa	There is inconsistent association between recent interventional procedures and the development of infective endocarditis. Prophylaxis is not recommended for any interventional procedure solely to prevent infective endocarditis.
Tonsillectomy and adenoidectomy	Tonsillectomy and adenoidectomy	
Bronchoscopy (rigid instrument)	Drainage of lung abscess or empyema	
Esophageal dilation/sclerotherapy	Prophylaxis is not recommended for any gastro-intestinal or genito-urinary procedures solely to prevent infective endocarditis.	
Instrumentation of obstructed biliary tracts		
Biopsy of urinary tract/prostate		
Cystoscopy during urinary tract infection		
Transurethral resection of prostate		
Urethral instrumentation/dilation		
Lithotripsy		
Gynecologic procedures in the presence of infection		

NICE - National Institute for Health and Clinical Excellence

Table 4 - Antibiotic prophylaxis regimes for dental procedures in at-risk adults.

Mode of administration	Patient group	ESC 2004[2]	AHA 2007[3]	NICE 2008[4]
Oral	Standard prophylaxis	Amoxicillin 2 gm	Amoxicillin 2 gm	Antibiotic prophylaxis is not recommended for any group of patients for any procedure solely to prevent infective endocarditis
One hour before procedure	If allergic to penicillins*	Clindamycin 600 mg, or Azithromycin/ Clarithromycin 500 mg	Cephalexin 2 gm, or Clindamycin 600 mg, or Azithromycin/ Clarithromycin 500 mg	
Injection intramuscular or intravenous (if unable to take oral medication)	Not allergic to penicillins	Amoxicillin or Ampicillin 2 gm	Ampicillin 2 gm, or Cefazolin or Ceftriaxone 1 gm	
30 minutes before procedure	Allergic to penicillins*	Clindamycin 600 mg	Cefazolin or Ceftriaxone 1 gm, or Clindamycin 600 mg	

ESC - European Society of Cardiology, AHA - American Heart Association, NICE - National Institute for Health and Clinical Excellence, *Cephalosporins should not be used in patients with history of anaphylaxis, angioedema, or urticaria with penicillin or ampicillin

The impact of antibiotic prophylaxis on the selection of drug resistance among human flora is not known. However, the concern is real in this era of increasing drug resistance among a variety of bacteria. Adverse events due to the use of antibacterial agents is another concern. There are currently no data on the incidence and death rates due to anaphylaxis with single-dose amoxicillin use in IE prophylaxis. In different studies, allergy to penicillin in the general population is estimated to range from 1-10%.[11] The chance of an allergic reaction is estimated at 5% for high doses of oral amoxicillin.[11] It has been calculated that in such a large unselected patient population receiving amoxicillin prophylaxis, the risk of death from anaphylactic reaction is 5 times greater than from contracting IE. Drug events, including immediate and delayed-type reactions, due to the administration of antibiotics in IE prophylaxis deserve further study.

Patient concerns. Patients who have had antibiotic prophylaxis for many years are likely to be concerned when they are told that it is no longer necessary. They should be properly counseled on the benefits of good dental hygiene, and a discussion is undertaken and documented. Risks or benefits of antibiotic prophylaxis should be adequately explained to the patients, and an explanation provided as to why antibiotic prophylaxis is no longer recommended. The risks of undergoing invasive procedures, including non-medical procedures, such as, body piercing or tattooing should be explained. Symptoms of IE should be explained to the patient, and advice provided when to seek expert help.

All the 3 updated guidelines are based on current best evidence. Though many case reports of IE preceded

by invasive procedures were published in the past, they have not been supported by any properly conducted randomized studies. Recent major studies have failed to demonstrate a causative link between invasive procedures and IE. Evidence suggests that there is no consistent association between an invasive dental or non-dental procedure, and the development of IE. The risk of IE due to normal daily activities such as brushing of teeth, or chewing is considerably greater than from a single dental procedure.[8] Therefore, even if we assume that antibiotic prophylaxis is highly effective in the prevention of IE, its benefit would still be negligible. In fact, it has been shown that antibiotic prophylaxis has not reduced the incidence of this condition.[15] Further, the clinical effectiveness of antibiotic prophylaxis is not proven and antibiotics may, in fact, lead to a greater number of deaths from fatal anaphylaxis. There is a real risk of antibiotic resistance with inappropriate antibiotic use and there are continued reports of failed prophylaxis.[6] Compliance with prophylaxis guidelines also has remained limited, with low numbers of patients who require prophylaxis actually taking or receiving antibiotics.[5]

Further, the past 2 decades have witnessed major changes in the demography of IE in the developed countries, with increasing frequency of *S. aureus* acquired as a result of nosocomial infection or intravenous drug abuse; and a falling incidence of IE secondary to oral *Streptococci*. It should also be noted that IE often arises in patients without previously documented cardiac disease when the question of prophylaxis is irrelevant. Regular and proper oral hygiene is, therefore, the best approach to minimize the risk of IE.[15] Though international guidelines still vary in their recommendations for antibiotic prophylaxis, consensus is slowly progressing towards avoidance of use of antibiotics for prevention of this condition.

Implications for Saudi Arabia. In the developing countries including Saudi Arabia, the demographic characteristics of IE markedly differ from those prevalent in the developed world. Though there is a lack of data on the epidemiology of this potentially fatal disease in Saudi Arabia, it is assumed that rheumatic heart disease still constitutes the major chunk of valvular heart disease. Nashmi and Memish[16] in a recent review at the King Abdul Aziz Medical City, found a preponderance of rheumatic heart disease (25%) in a cohort of 47 cases of IE over 10 years. It is notable that they found intravenous drug abuse and degenerative heart disease in less than 5% of their patients. Most of the patients were young, with a mean age of 32 years. This sharply contrasts with the demographic characteristics of IE in the West, where intravenous drug use (IVDU) and degenerative heart disease are major predisposing factors, and the disease is more common in an older age group. Etiologic agents such as *Brucella*, which are rare in the developed countries are more likely to be seen in patients hailing from areas endemic for *Brucellosis*. Another factor to consider is the poor dental hygiene of the local population. Dental care is not as stringent in this part of the world as in Europe and the US. International guidelines calling for cessation of antibiotic prophylaxis in patients with high standards of dental care in the West, may not be applicable to areas of the world, where dental hygiene is not of the same standard. It is believed that the radical recommendations of AHA[3] and NICE[4] are less applicable to the situation prevalent in this country than the ESC guidelines. However, any firm recommendation on this issue calls for a consensus among all the professionals involved after a thorough debate. It is hoped that this review will stoke the fire for such a debate.

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