



## Complete Summary

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### GUIDELINE TITLE

The role of endomyocardial biopsy in the management of cardiovascular disease. A scientific statement from the American Heart Association, the American College of Cardiology, and the European Society of Cardiology.

### BIBLIOGRAPHIC SOURCE(S)

Cooper LT, Baughman KL, Feldman AM, Frustaci A, Jessup M, Kuhl U, Levine GN, Narula J, Starling RC, Towbin J, Virmani R, American Heart Association, American College of Cardiology, European Society of Cardiology. The role of endomyocardial biopsy in the management of cardiovascular disease: a scientific statement from the American Heart Association, the American College of Cardiology, and the European Society of Cardiology. *Circulation* 2007 Nov 6;116(19):2216-33. [162 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Cardiovascular disease

- Heart failure
- Cardiomyopathy
- Cardiac tumors
- Ventricular arrhythmias
- Atrial fibrillation

## **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness  
Diagnosis  
Management

## **CLINICAL SPECIALTY**

Cardiology  
Pathology  
Pediatrics

## **INTENDED USERS**

Physicians

## **GUIDELINE OBJECTIVE(S)**

- To define the current role of endomyocardial biopsy (EMB) in the management of cardiovascular disease
- To provide an understanding of the range of acceptable approaches for the use of EMB while recognizing that individual patient care decisions depend on factors not well reflected in the published literature, such as local availability of specialized facilities, cardiovascular pathology expertise, and operator experience

## **TARGET POPULATION**

Adult and pediatric patients with cardiovascular diseases requiring endomyocardial biopsy

## **INTERVENTIONS AND PRACTICES CONSIDERED**

Endomyocardial biopsy

## **MAJOR OUTCOMES CONSIDERED**

Sensitivity and specificity of endomyocardial biopsy

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The recommendations contained in the present joint Scientific Statement are derived from a comprehensive review of the published literature on specific

cardiomyopathies, arrhythmias, and cardiac tumors and are categorized according to presenting clinical syndrome rather than pathologically confirmed disease.

#### **NUMBER OF SOURCE DOCUMENTS**

Not stated

#### **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

#### **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

##### **Levels of Evidence**

**Level A (highest):** Multiple randomized clinical trials.

**Level B (intermediate):** Limited number of randomized trial, nonrandomized studies, and registries

**Level C (lowest):** Primarily expert consensus.

#### **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic 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**

To define the current role of EMB in the management of cardiovascular disease, a multidisciplinary group of experts in cardiomyopathies and cardiovascular pathology was convened by the American Heart Association (AHA), the American College of Cardiology (ACC), and the European Society of Cardiology (ESC). The present Writing Group was charged with reviewing the published literature on the role of EMB in cardiovascular diseases, summarizing this information, and making useful recommendations for clinical practice with classifications of recommendations and levels of evidence.

The Writing Group identified 14 clinical scenarios in which the incremental diagnostic, prognostic, and therapeutic value of EMB could be estimated and compared with the procedural risks.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

### Classification of Recommendations

**Class I:** Conditions for which there is evidence or there is general agreement that a given procedure is beneficial, useful, and effective

**Class II:** Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment

**Class IIa:** Conditions for which the weight of evidence/opinion is in favor of usefulness/efficacy

**Class IIb:** Conditions for which usefulness/efficacy is less well established by evidence/opinion

**Class III:** Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

### METHOD OF GUIDELINE VALIDATION

Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was approved by the American Heart Association Science Advisory and Coordinating Committee on July 2, 2007; the American College of Cardiology Foundation Board of Trustees on May 21, 2007; and the European Society of Cardiology Committee for Practice Guidelines on April 3, 2007.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Endomyocardial biopsy (EMB) should be performed in the setting of unexplained, new-onset heart failure of <2 weeks' duration associated with a normal-sized or dilated left ventricle in addition to hemodynamic compromise. **Class of Recommendation I, Level of Evidence B.**

EMB should be performed in the setting of unexplained new-onset heart failure of 2 weeks' to 3 months' duration associated with a dilated left ventricle and new ventricular arrhythmias, Mobitz type II second- or third-degree atrioventricular (AV) heart block, or failure to respond to usual care within 1 to 2 weeks. **Class of Recommendation I, Level of Evidence B.**

EMB is reasonable in the clinical setting of unexplained heart failure of *>3 months'* duration associated with a dilated left ventricle and new ventricular arrhythmias, Mobitz type II second- or third-degree AV heart block, or failure to respond to usual care within 1 to 2 weeks. ***Class of Recommendation IIa, Level of Evidence C.***

EMB is reasonable in the setting of unexplained heart failure associated with a dilated cardiomyopathy (DCM) of any duration that is associated with suspected allergic reaction in addition to eosinophilia. ***Class of Recommendation IIa, Level of Evidence C.***

EMB is reasonable in the setting of unexplained heart failure associated with suspected anthracycline cardiomyopathy. ***Class of Recommendation IIa, Level of Evidence C.***

EMB is reasonable in the setting of heart failure associated with unexplained restrictive cardiomyopathy. ***Class of Recommendation IIa, Level of Evidence C.***

EMB is reasonable in the setting of suspected cardiac tumors, with the exception of typical myxomas. ***Class of Recommendation IIa, Level of Evidence C.***

EMB is reasonable in the setting of unexplained cardiomyopathy in children. ***Class of Recommendation IIa, Level of Evidence C.***

EMB may be considered in the setting of unexplained, new-onset heart failure of *2 weeks' to 3 months'* duration associated with a dilated left ventricle, *without* new ventricular arrhythmias or Mobitz type II second- or third-degree AV heart block, that responds to usual care within 1 to 2 weeks. ***Class of Recommendation IIb, Level of Evidence B.***

EMB may be considered in the setting of unexplained heart failure of *>3 months'* duration associated with a dilated left ventricle, *without* new ventricular arrhythmias or Mobitz type II second- or third-degree AV heart block, that responds to usual care within 1 to 2 weeks. ***Class of Recommendation IIb, Level of Evidence C.***

EMB may be considered in the setting of heart failure associated with unexplained hypertrophic cardiomyopathy (HCM). ***Class of Recommendation IIb, Level of Evidence C.***

EMB may be considered in the setting of suspected arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C). ***Class of Recommendation IIb, Level of Evidence C.***

EMB may be considered in the setting of unexplained ventricular arrhythmias. ***Class of Recommendation IIb, Level of Evidence C.***

EMB should not be performed in the setting of unexplained atrial fibrillation. ***Class of Recommendation III, Level of Evidence C.***

**Definitions:**

**Levels of Evidence**

**Level A (highest):** Multiple randomized clinical trials.

**Level B (intermediate):** Limited number of randomized trials, nonrandomized studies, and registries

**Level C (lowest):** Primarily expert consensus.

**Classification of Recommendations**

**Class I:** Conditions for which there is evidence or there is general agreement that a given procedure is beneficial, useful, and effective

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**Class IIb:** Conditions for which usefulness/efficacy is less well established by evidence/opinion

**Class III:** Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

**CLINICAL ALGORITHM(S)**

None provided

**EVIDENCE SUPPORTING THE RECOMMENDATIONS**

**TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of evidence supporting the recommendations is specifically stated for each recommendation (see 'Major Recommendations' field).

**BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

**POTENTIAL BENEFITS**

Appropriate use of endomyocardial biopsy in the diagnosis of cardiovascular disease

**POTENTIAL HARMS**

- The risks of endomyocardial biopsy (EMB) may be divided into those that are acute and those that are delayed. Immediate risks of biopsy include

perforation with pericardial tamponade, ventricular or supraventricular arrhythmias, heart block, pneumothorax, puncture of central arteries, pulmonary embolization, nerve paresis, venous hematoma, damage to the tricuspid valve, and creation of arterial venous fistula within the heart. The risks of EMB likely vary with the experience of the operator, clinical status of the patient, presence or absence of left bundle-branch block, access site, and possibly bioptome. The use of a long sheath that crosses the tricuspid valve may decrease the risk of bioptome-induced tricuspid valve trauma. Delayed complications include access site bleeding, damage to the tricuspid valve, pericardial tamponade, and deep venous thrombosis. Most complications are known from case reports, and therefore the precise frequency of these events is not known.

- The death rate associated with EMB is a result of perforation with pericardial tamponade. Patients with increased right ventricular systolic pressures, bleeding diathesis, recent receipt of heparin, or right ventricular enlargement seem to be at higher risk.

## 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

Getting Better  
Living with Illness

### IOM DOMAIN

Effectiveness  
Safety

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Cooper LT, Baughman KL, Feldman AM, Frustaci A, Jessup M, Kuhl U, Levine GN, Narula J, Starling RC, Towbin J, Virmani R, American Heart Association, American College of Cardiology, European Society of Cardiology. The role of endomyocardial biopsy in the management of cardiovascular disease: a scientific statement from the American Heart Association, the American College of Cardiology, and the European Society of Cardiology. *Circulation* 2007 Nov 6;116(19):2216-33. [162 references] [PubMed](#)

### ADAPTATION

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

**DATE RELEASED**

2007 Nov 6

**GUIDELINE DEVELOPER(S)**

American College of Cardiology Foundation - Medical Specialty Society  
American Heart Association - Professional Association  
European Society of Cardiology - Medical Specialty Society

**SOURCE(S) OF FUNDING**

American Heart Association

**GUIDELINE COMMITTEE**

Writing Committee

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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**FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

**Writing Group Disclosures**

<b>Writing Group Member</b>	<b>Employment</b>	<b>Research Grant</b>	<b>Other Research Support</b>	<b>Speakers' Bureau/Honoraria</b>	<b>Expert Witness</b>	<b>Ownership Interest</b>	<b>Consulting/Advisory</b>
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Renu Virmani	CV Path	None	None	None	None	None	Medtronic Guidant†; Laboratory W.L. Gore CryoVascular Systems, Inc.† Volcano Therapeutics Inc†; Precision Medical†; Medicon†; Cardiomem Direct Flow

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10,000 or more during any 12-month period, or 5% or more of

the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10,000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest

†Significant

### Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau	Expert Witness	Ownership Interest	Consultant, Advisory Board
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Eric Bates	University of Michigan	None	None	None	None	None	None
Fred Bove	Temple University	Penn Dept of Health	None	None	None	None	Insight Telehealth Systems*
Rihal Charanjit	Mayo Clinic	None	None	None	None	None	None
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Jose Diez	Baylor College of Medicine	None	None	None	None	None	Sanofi-Aventis*
Mark Eisenberg	McGill University	None	None	None	None	None	None
Gerasimos Filippatos	Evangelismos Hospital, Athens, Greece	None	None	None	None	None	None
Robert Harrington	Duke University	None	None	None	None	None	None
Mark Hlatky	Stanford University	None	None	None	None	None	None
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<b>Reviewer</b>	<b>Employment</b>	<b>Research Grant</b>	<b>Other Research Support</b>	<b>Speakers' Bureau</b>	<b>Expert Witness</b>	<b>Ownership Interest</b>	<b>Consultant, Advisory Board</b>
Johnson	Wisconsin						
Jay Mason	Covance Central Diagnostics	None	None	None	None	None	None
Walter Paulus	VU University Medical Center, Netherlands	None	None	None	None	None	None
Richard Schofield	University of Florida	None	None	AstraZeneca*; AtCor Medical*; Novartis*; Pfizer*; Scios*	None	None	Pfizer*
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Samuel J. Shubrooks, Jr	Beth Israel Deaconess Medical Center	None	None	None	None	None	None

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\*Modest

†Significant

## **ENDORSER(S)**

Heart Failure Society of America, Inc - Disease Specific Society

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [American Heart Association Web site](#), the [American College of Cardiology \(ACC\) Web site](#), and from the [European Society of Cardiology Web site](#).

Print copies: Available from the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596; Phone: 800-242-8721

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

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Date Modified: 3/16/2009

