Journal of the American College of Cardiology
© 2012 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 60, No. 7, 2012
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.06.011

EXPERT CONSENSUS DOCUMENT

HRS/ACCF Expert Consensus Statement on Pacemaker Device and Mode Selection

Developed in partnership between the Heart Rhythm Society (HRS) and the American College of Cardiology Foundation (ACCF) and in collaboration with the Society of Thoracic Surgeons

Anne M. Gillis, MD, FHRS,[1] Andrea M. Russo, MD, FHRS, FACC,[2] Kenneth A. Ellenbogen, MD, FHRS, FACC,[3] Charles D. Swerdlow, MD, FHRS, CCDS, FACC,[4] Brian Olshansky, MD, FHRS, CCDS, FACC,[5] Sana M. Al-Khatib, MD, MHS, FHRS, CCDS, FACC,[6] John F. Beshai, MD, FHRS, FACC,[7] Janet M. McComb, MD, FHRS,[8] Jens Cosedis Nielsen, MD,[9] Jonathan M. Philpott, MD,[10^] Win-Kuang Shen, MD, FHRS, FACC[11]

Introduction

The most recent American College of Cardiology Foundation/American Heart Association/Heart Rhythm Society (ACCF/AHA/HRS) guidelines related to pacemaker implantation were published as part of a larger document related to device-based therapy (1). While this document provides some comments on pacemaker mode selection and algorithms to guide selection, it does not provide specific recommendations regarding choices for single- or dual-chamber devices. Over the past 15 years multiple randomized trials have compared a number of cardiovascular outcomes among patients randomized to atrial or dual-chamber pacing vs. those randomized to ventricular pacing. The purpose of this 2012 consensus statement is to provide a state-of-the-art review of the field and to report the recommendations of a consensus writing group, convened by HRS and ACCF, on pacemaker device and mode selection. This document focuses on pacemaker device and mode selection in the adult patient; therefore, many of the recommendations may not be applicable to unique situations encountered in the pediatric population. These recommendations summarize the opinion of the consensus writing group, based on an extensive literature review as well as their own experience.

This document should be used as a supplement to the published 2008 guidelines document, functioning as a guide to facilitate the selection of single- vs. dual-chamber devices for patients who already meet guidelines for pacemaker implantation (1). **It should be emphasized that recommendations for device selection in the current document apply to situations where the clinical decision for pacing has already been made.** In addition, specific recommendations for cardiac resynchronization therapy are not addressed in this document as the indications for cardiac resynchronization therapy have been published previously and guideline updates related to these indications are also in progress (2,3).

This document is directed to all health care professionals who are involved in the selection of devices and pacing mode as well as the subsequent management of patients with pacemakers.

All recommendations provided were agreed upon by at least 81% of the writing committee by anonymous vote. Writing group members were selected by HRS or ACCF based on their expertise in the field. The 11 participating cardiac electrophysiologists or surgeons include representatives from the United States, Canada, and Europe. The grading system for class of indication and level of evidence was adapted from that used by the ACCF and the AHA (4). However, it is important to state that this document is not a guideline. Nevertheless, we present recommendations with

From [1]University of Calgary, Libin Cardiovascular Institute of Alberta, Alberta, Canada, [2]Cooper Medical School of Rowan University, Cooper University Hospital, New Jersey, USA, [3]Virginia Commonwealth University Medical Center, Virginia, USA, [4]David Geffen School of Medicine at UCLA, California, USA, [5]University of Iowa Hospital, Iowa, USA, [6]Duke University Medical Center, North Carolina, USA, [7]University of Chicago Hospitals, Illinois, USA, [8]Freeman Hospital, Newcastle-upon-Tyne, United Kingdom, [9]Skejby Hospital, Aarhus, Denmark, [10]Mid-Atlantic Cardiothoracic Surgeons, Virginia, USA, [11]Mayo Clinic College of Medicine, Arizona, USA.

^Representing the Society of Thoracic Surgeons.

Approved by the Heart Rhythm Society Board of Trustees, the American College of Cardiology Foundation Board of Trustees, the Society of Thoracic Surgeons, and the American Heart Association Science Advisory and Coordinating Committee in June of 2012. The American College of Cardiology Foundation requests that this document be cited as follows: Gillis AM, Russo AM, Ellenbogen KA, Swerdlow CD, Olshanky B, Al-Khatib SM, Beshai JF, McComb JM, Nielsen JC, Philpott JM, Shen WK. HRS/ACCF expert consensus statement on pacemaker device and mode selection. J Am Coll Cardiol 2012;60:682–703.

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class and level of evidence designations to provide consistency with familiar guideline documents.

Classification of Recommendations

- Class I: Conditions for which there is evidence and/or general agreement that a given pacing mode is beneficial, useful and effective.
- Class II: Conditions for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a specific pacing mode.
  - Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
  - Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
- Class III: Conditions for which there is conflicting evidence and/or general agreement that a pacing mode is not useful/effective and in some cases may be harmful.

Level of Evidence

- Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
- Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.
- Level of Evidence C: Only consensus opinion of experts, case studies, or standard of care.

The writing group was divided into three subgroups to review aspects of pacing mode selection for patients with 1) sinus node dysfunction (SND), 2) atrioventricular (AV) conduction block, and 3) other less common indications for pacing. All members of the writing group, as well as peer reviewers of the document, provided disclosure statements for all relationships that might be perceived as real or potential conflicts of interest. These tables are shown at the end of this document.

1. Pacemaker Device and Mode Selection for SND

Expert Consensus Recommendations (see Table 1 for a summary of consensus recommendations)

CLASS I

1. **Dual-chamber pacing (DDD) or single-chamber atrial pacing (AAI) is recommended over single-chamber ventricular pacing (VVI) in patients with SND and intact AV conduction (Level of Evidence: A) (5–9).**
2. **Dual-chamber pacing is recommended over single-chamber atrial pacing in patients with SND (Level of Evidence: B) (10).**

CLASS IIa

1. **Rate adaptive pacing can be useful in patients with significant symptomatic chronotropic incompetence, and its need should be reevaluated during follow-up (Level of Evidence: C) (11,12).**
2. **In patients with SND and intact AV conduction, programming dual-chamber pacemakers to minimize ventricular pacing can be useful for prevention of atrial fibrillation (AF) (Level of Evidence: B) (13).**

CLASS IIb

1. **AAI pacing may be considered in selected patients with normal AV and ventricular conduction (Level of Evidence: B) (14–16).**
2. **Single-chamber VVI pacing may be considered in instances where frequent pacing is not expected or the patient has significant comorbidities that are likely to influence survival and clinical outcomes (Level of Evidence: C) (5–8).**

CLASS III

1. **Dual-chamber pacing or single-chamber atrial pacing should not be used in patients in permanent or longstanding persistent AF where efforts to restore or maintain sinus rhythm are not planned (Level of Evidence: C) (1,5,10,17,18).**

SND is the most common cause of bradyarrhythmias requiring pacing therapy in North America and Western Europe. Arrhythmias associated with SND include sinus bradycardia, sinoatrial block, sinus arrest, chronotropic incompetence, and tachycardia–bradycardia syndrome characterized by paroxysms of supraventricular tachyarrhythmias (AF, atrial flutter, atrial tachycardia) alternating with bradycardia or asystole (17). Twenty percent of patients with SND will have some degree of AV block (8).

Two important developments in the natural history of SND should be emphasized: AV block and AF (17,19). The risk of developing AV block following pacemaker implantation within 5 years of follow-up is 3–35% (15,16,19,20). This risk varies with patient factors including age and comorbidities and likely increases further over time and with the addition of medications that have negative dromotropic effects. In patients with SND, the incidence of clinical AF at the time of initial diagnosis has been reported to range from approximately 40–70% (8,10,21). Among patients who do not have AF at initial diagnosis, the incidence of new AF in follow-up ranges from 3.9–22.3% (8,10,21). During long-term follow-up, 68% of patients receiving a dual pacemaker for SND have had AF documented by device diagnostics (21). The incidence of AF is significantly influenced by mode of pacing, percentage of ventricular pacing, and duration of follow-up (17,19,21).

In the absence of a reversible cause, the appropriate treatment for symptomatic SND is implantation of a permanent pacemaker. Available pacing modes include dual-chamber (DDD or DDI), ventricular single-chamber (VVI), and atrial single-chamber (AAI). Rate adaptive pacing may be programmed as required for symptomatic chronotropic incompetence. The optimal pacing mode for patients with SND has generated much debate until the completion and publication of several landmark clinical trials reporting the superiority of atrial or dual-chamber pacing over ventricular pacing with regard to their effect on some clinical outcomes.

Four major randomized clinical trials, specifically the Danish study, the Pacemaker Selection in the Elderly (PASE) study, the Canadian Trial of Physiologic Pacing (CTOPP), and the Mode Selection Trial (MOST), have compared atrial or dual-chamber pacing with ventricular pacing in patients with SND (5–8,14). These randomized controlled trials