Challenges for the Basis of Practice

Response to Coceani: Has CRT Earned a Class I Recommendation?

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In his provocative article, Dr Coceani raises several important issues about the validity of the class IA indication for cardiac resynchronization therapy (CRT) in current American Heart Association/American College of Cardiology/Heart Rhythm Society and European Society of Cardiology guidelines for device-based therapy and heart failure management. Recommendations from these documents include low ejection fraction, prolonged QRS duration, and New York Heart Association functional class III or ambulatory Class IV as criteria for the statement that a CRT device should be considered. Dr Coceani points out that a substantial fraction of patients who received biventricular devices fail to improve clinically and cites data showing that many factors can potentially influence responses to CRT. Factors such as intraventricular mechanical dyssynchrony, lead position, location and extent of myocardial scarring, ventricular anatomy, mitral regurgitation, the type of conduction abnormality, and so forth, have all been shown potentially to influence CRT response. Given these observations, Dr Coceani concludes that a class IA indication is not justified on the basis of current evidence.

In response to Dr Coceani, we would like to discuss 3 issues: (1) how guidelines are developed, (2) how guidelines should be applied by clinicians, and (3) how we use CRT guidelines in our practices.

Practice guidelines are written by panels of experienced clinicians who review and analyze available data to reach their conclusions. Significant efforts are made to make these deliberations and conclusions “evidence-based.” A Class IA or IB recommendation implies that the intervention, either a drug or procedure, has proven to be of overall benefit in the populations in which the intervention has been studied. This conclusion is typically based on the results of either multiple prospective, controlled studies (IA), or more limited but still highly convincing data (IB). This does not mean that every patient will necessarily benefit from the particular intervention. In describing the population to whom the recommendation should apply, the guideline writers typically adopt the entry criteria for the pivotal study or studies on which the recommendation is based. These criteria are, in general, fairly broad to facilitate patient enrollment. Although most studies report subgroup analyses, randomization is not usually stratified by subgroups and such analyses are only rarely appropriately powered or convincing enough to exclude conclusively from benefit groups of patients who met the original entry criteria. For this reason, guidelines are rarely restricted to subgroups.

Once a guideline is written, physicians must apply them to individual patients. For a pharmacological or behavioral intervention that carries a Class IA or IB indication, physicians usually should try the intervention unless there is some obvious contraindication. If the patient either does not respond or has an adverse reaction, the drug or intervention can typically be withdrawn without adverse long-term consequences. Device or surgical treatments, however, are not reversible in the same sense. With a device or surgical therapy, there is an up-front procedural risk and cost that is accrued by all patients. Thus, for device or surgical therapy, the physician must carefully weigh the potential for benefit against the probability of risk of the intervention for the individual patient.

How do we do this type of individual risk-benefit analysis regarding CRT in our practices? First, we assess whether the patient fits the general criteria listed in the recommendation. We then assess many of the factors discussed by Dr Coceani and estimate the probability that this individual patient will benefit from CRT. For example, we would almost certainly not recommend CRT to a patient with a left ventricular ejection fraction of 34%, class III heart failure, a QRS duration of 121 ms in the presence of a right bundle-branch block and a dense posterolateral scar, even though the patient meets basic guideline criteria. This patient has multiple factors that would predict lack of response and the risk of the added lead would outweigh the potential for benefit. Other factors such as risks for erosion or infection, vascular access, compliance with follow-up and desires of the patient are also part of our routine decision-making process. We try to determine if our patients resemble those in the clinical trials and, when they do not, see if the differences are important enough to discourage adopting the therapy.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association. This article is Part II of a two-part series. Part I appeared in Circulation: Heart Failure. 2010;3:460–461.

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(Circ Heart Fail. 2010;3:559-560.)

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Circ Heart Fail is available at http://circheartfailure.ahajournals.org

DOI: 10.1161/CIRCHEARTFAILURE.110.957548

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There are few if any guideline recommendations that should be implemented in 100% of those patients who meet the basic criteria list in the guideline. The Class I to III and A, B, and C designations listed in the guideline statements should not be considered to be absolute rules. Rather, they provide a structured framework in which individual patient decisions can be made.

Disclosures
Dr DiMarco received consultant fees and research support from Medtronic and research grants and speaker honoraria from St Jude Medical and Boston Scientific. Dr Gold received consultant fees from Boston Scientific and Medtronic, research support from Medtronic, Boston Scientific, and Sorin and speaker honoraria from Medtronic, Boston Scientific, St Jude Medical, Biotronik, and Sorin.

References

KEY WORDS: cardiac resynchronization † implantable defibrillators † heart failure
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Circ Heart Fail. 2010;3:559-560
doi: 10.1161/CIRCHEARTFAILURE.110.957548
Circulation: Heart Failure is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-3289. Online ISSN: 1941-3297

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circheartfailure.ahajournals.org/content/3/4/559

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