

Letter by Moreno Regarding Article, “Cost-Effectiveness Analysis of Continuous Flow Left Ventricular Assist Devices as Destination Therapy”

To the Editor:

There are concerns regarding a number of aspects of the publication by Rogers and colleagues¹ on the cost-effectiveness analysis of continuous flow left ventricular assist devices (LVADs) as destination therapy. The publication concludes that: “The cost-effectiveness associated with continuous flow LVADs for destination therapy has improved significantly relative to the pulsatile flow devices.”

Cost-effectiveness analyses commonly are used to support the reimbursement submission of a medical product. However, the limitations described next question the validity of the published results,¹ and thus their usefulness to aid reimbursement decision making.

First, all inputs used in a cost effectiveness analysis will be estimated with a degree of imprecision. Probabilistic sensitivity analyses in cost-effectiveness analysis are preferred because they reflect the full uncertainty associated with all input variables. The pharmacoeconomic guideline published in 2009 by the United States of America Academy of Managed Care Pharmacy recommended the probabilistic (nondeterministic) approach, particularly for more complex models such as Markov models.² Similarly, in the United Kingdom the 2008 NICE Guide to the Methods of Technology Appraisal, a guide that describes the methods that should be followed for all technology appraisals, mandated probabilistic sensitivity analysis in cost-effectiveness analyses submitted to the NICE Appraisal Programme.³

Conversely, in their cost-effectiveness analysis, Rogers and colleagues¹ prefer a deterministic (nonprobabilistic) sensitivity analysis. In deterministic analyses, input variables selected from the model are assigned point estimate values (eg, minimum, average, maximum), and so results interpretation is conditional on the assumed range of uncertainty. Hence, the main limitation of the deterministic approach is that the analyst has discretion as to which variables and what alternative values are included.⁴ Subsequently, results become more prone to selection bias than those from probabilistic analyses.

Second, another limitation¹ is how they derive the 2-year survival rate estimate for the optimal medical management (OMM) strategy. In the methods section, the authors report making an indirect comparison because no head-to-head trial has directly compared OMM with continuous flow LVAD HeartMateII, and so they use the OMM survival rate estimate directly from the REMATCH trial.

The authors do not discuss the limitations of the way the indirect comparison is derived, implying that the method used can provide accurate and precise results. As a matter of fact, they make a *naïve* indirect comparison by comparing survival rates of 2 single arms extracted from 2 different trials as if they were from the same randomized controlled trial. There is consensus in the literature that this *naïve* (or unadjusted) indirect comparison is inappropriate and should be replaced by an adjusted one.⁵

Last, the 2-year survival rate estimate is a key parameter in the cost-effectiveness analysis. The 0.25 estimate used for the pulsatile LVAD strategy is incorrect. The correct estimate as reported in the REMATCH trial is 0.23. Regrettably, the 2-year survival rate was confused with the 1-year rate.

In light of the above, this publication has methodological limitations that might lead health regulatory authorities to false judgments regarding the cost-effectiveness of the continuous flow LVAD HeartMateII.

Disclosures

None.

Santiago G. Moreno, PhD

Department of Evaluation of Innovation and New Technologies (Fundació Clínica), Barcelona, Spain

References

1. Rogers JG, Bostic RR, Tong KB, Adamson R, Russo M, Slaughter MS. Cost-effectiveness analysis of continuous flow left ventricular assist devices as destination therapy. *Circ Heart Fail.* 2012;5:10–16.
2. AMCP. The AMCP format for formulary submissions (Version 3.0): a format for submission of clinical and economic evidence of pharmaceuticals in support of formulary consideration. 2009; available from: www.amcp.org/WorkArea/DownloadAsset.aspx?id=9127. Accessed December 8, 2011.
3. NICE. Guide to the methods of technology appraisal. 2008; available from: www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf. Accessed December 8, 2011.
4. Baltussen RM, Hutubessy RC, Evans DB, Murray CJ. Uncertainty in cost-effectiveness analysis. Probabilistic uncertainty analysis and stochastic league tables. *Int J Technol Assess Health Care.* 2002;18:112–119.
5. Song F, Loke YK, Walsh T, Glenny AM, Eastwood AJ, Altman DG. Methodological problems in the use of indirect comparisons for evaluating healthcare interventions: survey of published systematic reviews. *BMJ.* 2009;338:b1147.

Letter by Moreno Regarding Article, "Cost-Effectiveness Analysis of Continuous Flow Left Ventricular Assist Devices as Destination Therapy"

Santiago G. Moreno

Circ Heart Fail. 2012;5:e50

doi: 10.1161/CIRCHEARTFAILURE.111.966085

Circulation: Heart Failure is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Copyright © 2012 American Heart Association, Inc. All rights reserved.

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/5/2/e50>

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in *Circulation: Heart Failure* can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the [Permissions and Rights Question and Answer](#) document.

Reprints: Information about reprints can be found online at:
<http://www.lww.com/reprints>

Subscriptions: Information about subscribing to *Circulation: Heart Failure* is online at:
<http://circheartfailure.ahajournals.org/subscriptions/>