thromboembolism. We⁵ also supported this strategy. ElBardissi and colleagues¹ are to be congratulated for their elegant, albeit retrospective institutional analysis that brings additional light to this controversial problem. Once again, there is a need to revise current guidelines that should not be taken as law.

Carlos-A. Mestres^a

José I. Aramendi^b

^aDepartment of Cardiovascular
Surgery
Hospital Clínico University of
Barcelona
Barcelona, Spain

^bDepartment of Cardiac Surgery
Hospital de Cruces
Barakaldo
Bizkaia, Spain

Disclosures: The authors were
co-investigators in the TRAC
prospective randomized trial
sponsored by J. Uriach & Cia SA
Laboratories

References

1. ElBardissi A, DiBardino DJ, Chen FY, Yamashita MH, Cohn LH. Is early antithrombotic therapy necessary in patients with bioprosthetic aortic valves in normal sinus rhythm? *J Thorac Cardiovasc Surg.* 2010;139:1137-45.
2. Heras M, Chesebro JH, Fuster V, Penny WJ, Grill DE, Bailey KR, et al. High risk of thromboemboli early after bioprosthetic cardiac valve replacement. *J Am Coll Cardiol.* 1995;25:1111-9.
3. Aramendi JJ, Mestres CA, Martínez-León J, Campos V, Muñoz G, Navas JC. Triflusal versus oral anticoagulation for primary prevention of thromboembolism after bioprosthetic valve replacement (TRAC): prospective, randomized, cooperative trial. *Eur J Cardiothorac Surg.* 2005;27:854-60.
4. Brueck M, Kramer W, Vogt P, Steinert N, Roth P, Grolach G, et al. Antiplatelet therapy early after bioprosthetic aortic valve replacement is unnecessary in patients without thromboembolic risk factors. *Eur J Cardiothorac Surg.* 2007;32:108-12.
5. Aramendi JJ, Mestres CA. Antithrombotic therapy after bioprosthetic aortic valve replacement. *Eur J Cardiothorac Surg.* 2008;33:529-30.

doi:10.1016/j.jtcvs.2010.04.032

Reply to the Editor:

We appreciate the comments from Drs Mestres and Aramendi regarding our retrospective institutional analysis,

which identified no difference in the overall incidence of thromboembolic events in patients who electively received anticoagulants after bioprosthetic aortic valve implantation.¹ Although we identified subsets of patients that may benefit from some form of antithrombotic therapy in the immediate postoperative phase (either antiplatelet therapy or a vitamin K antagonist with a goal international normalized ratio of 2 to 3), our findings differ markedly from the American Heart Association/American College of Cardiology (AHA/ACC) and other international cardiac organizations, which recommend anticoagulation with a vitamin K antagonist for the first 90 postoperative days.²

Since publication of the article by Heras and associates³ from the Mayo Clinic that ultimately inspired these aggressive anticoagulation recommendations, there have been a plethora of retrospective studies suggesting that anticoagulation is unnecessary and may be harmful. In fact, Sundt and colleagues⁴ recently updated and re-reviewed the Mayo Clinic series and found that anticoagulation did not provide additional protection from thromboembolic events. Our thorough analysis of the outcomes from the Brigham and Women's Hospital demonstrated that only high-risk groups may benefit from some type of antithrombotic therapy. It should be noted, however, that in these high-risk patients, the optimal form of early antithrombotic therapy is still up for debate.

In one of the few prospective, randomized, multi-institution studies examining this important clinical question, Aramendi and colleagues⁵ identified an important outcome that has not been demonstrated in most single-institution retrospective studies, including ours: patients who receive anticoagulation with a vitamin K antagonist have bleeding complications at a much higher rate than those who are treated with a platelet inhibitor.

Although these findings may be intuitive, they warrant recognition inasmuch as surgeons considering antithrombotic therapy in high-risk patients

should be cognizant of the potential bleeding complications after treatment with vitamin K antagonists in this specific group of patients. Further, high-risk patients in our analysis had a similar reduction in thromboembolic events irrespective of the mode of antithrombotic therapy (aspirin versus warfarin sodium [Coumadin]). These complementary findings suggest that antiplatelet therapy after bioprosthetic aortic valve replacement may provide the optimal balance between efficacy and safety.

The time may have come for the AHA/ACC to reconsider their antithrombotic therapy recommendations after bioprosthetic aortic valve replacement. There now exists a large amount of data that suggest widespread anticoagulation is not indicated, and perhaps more concerning, patients administered vitamin K antagonists may be at a significant risk of major bleeding complications.

Andrew W. ElBardissi, MD, MPH

Lawrence H. Cohn, MD

Division of Cardiac Surgery
Brigham and Women's Hospital
Harvard Medical School
Boston, Mass

References

1. ElBardissi AW, DiBardino DJ, Chen FY, Yamashita MH, Cohn LH. Is early antithrombotic therapy necessary in patients with bioprosthetic aortic valves in normal sinus rhythm? *J Thorac Cardiovasc Surg.* 2010;139:1137-45.
2. Bonow RO, Carabello BA, Chatterjee K, de Leon AC Jr, Faxon DP, Freed MD, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing Committee to Revise the 1998 guidelines for the management of patients with valvular heart disease) developed in collaboration with the Society of Cardiovascular Anesthesiologists endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2006;48:e1-148.
3. Heras M, Chesebro JH, Fuster V, Penny WJ, Grill DE, Bailey KR, et al. High risk of thromboemboli early after bioprosthetic cardiac valve replacement. *J Am Coll Cardiol.* 1995;25:1111-9.

4. Sundt TM, Zehr KJ, Dearani JA, Daly RC, Mullany CJ, McGregor CG, et al. Is early anticoagulation with warfarin necessary after bioprosthetic aortic valve replacement? *J Thorac Cardiovasc Surg.* 2005;129:1024-31.
5. Aramendi JJ, Mestres CA, Martinez-Leon J, Campos V, Munoz G, Navas C. Triflusal versus oral anticoagulation for primary prevention of thromboembolism after bioprosthetic valve replacement (TRAC): prospective, randomized, co-operative trial. *Eur J Cardiothorac Surg.* 2005;27: 854-60.

doi:10.1016/j.jtcvs.2010.05.006

REPORTING OF MORTALITY ASSOCIATED WITH PEDIATRIC AND CONGENITAL CARDIAC SURGERY

To the Editor:

We congratulate Furck and colleagues¹ for their excellent analysis of outcomes after the Norwood operation in patients with hypoplastic left heart syndrome, as described in their recent publication. However, we are concerned that the authors have reported the rate of mortality using a nonstandard strategy for this type of reporting. Furck and colleagues reported a 30-day mortality of 2.5% for the last 3 years. They stated that "Death after this period and until the subsequent palliative surgery, regardless of whether in or out of the hospital, was defined as interstage mortality." They reported interstage mortality of 15%. This manner of reporting of outcomes is not consistent with standardized reporting strategies. It can be potentially misleading and can create unrealistic expectations among referring physicians, caregivers, and families.

Collaborative international efforts have resulted in the establishment of standardized methodologies for the reporting of mortality and morbidity associated with pediatric and congenital cardiac surgery.^{2,3} Operative mortality is defined as any death, regardless of cause, occurring (1) within 30 days after surgical intervention in or out of the hospital and (2) after 30 days during the same hospitalization subsequent to the operation. Thus operative mortality includes all deaths

that occur during the initial hospitalization. Logically, interstage mortality encompasses all deaths that occur after the period of time included in operative mortality but before the stage 2 operation. Thus all mortality during the initial hospitalization should be classified as operative mortality and not interstage mortality.

The most recent analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database documents discharge mortality of 18.7% (447/2395 patients) after the Norwood (stage I) operation.⁴ By reporting only 30-day mortality and classifying deaths that occur after 30 days but during the initial hospitalization as interstage mortality, the authors have used a methodology not consistent with standardized methodologies of outcome reporting. If an author wishes to explore other means of presentation, one would assume that it would be done with a degree of emphasis that was not apparent in this article. We believe that the use of standard reporting strategies for mortality is crucial when reporting the outcomes after pediatric and congenital cardiac surgery.

Richard A. Jonas, MD^a

Jeffrey P. Jacobs, MD^b

Marshall L. Jacobs, MD^c

Constantine Mavroudis, MD^c

^aDepartment of Cardiac Surgery
Children's National Heart Institute
Children's National Medical Center
Washington, DC

^bChair, STS Congenital Heart Surgery
Database Task Force

Surgical Director of Heart
Transplantation and ECMO
The Congenital Heart Institute of
Florida (CHIF)

Department of Surgery
University of South Florida College of
Medicine

All Children's Hospital
Children's Hospital of Tampa
Cardiac Surgical Associates of
Florida (CSAoF)

St Petersburg and Tampa, Fla
^cCenter for Pediatric and Congenital

Heart Diseases
Department of Pediatric and
Congenital Heart Surgery
Cleveland Clinic Foundation
Cleveland, Ohio

References

1. Furck AK, Uebing A, Hansen JH, Scheewe J, Jung O, Fischer G, et al. Outcome of the Norwood operation in patients with hypoplastic left heart syndrome: a 12-year single-center survey. *J Thorac Cardiovasc Surg.* 2010;139: 359-65.
2. Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervakov CI, Lacour-Gayet FG, et al. What is operative mortality? Defining death in a surgical registry database: a report from the STS Congenital Database Task Force and the Joint EACTS-STs Congenital Database Committee. *Ann Thorac Surg.* 2006;81: 1937-41.
3. Jacobs JP, Jacobs ML, Mavroudis C, Maruszewski B, Tchervakov CI, Lacour-Gayet FG, et al. What is operative morbidity? Defining complications in a surgical registry database: a report from the STS Congenital Database Task Force and the Joint EACTS-STs Congenital Database Committee. *Ann Thorac Surg.* 2007;84:1416-21.
4. Jacobs JP, Jacobs ML, Mavroudis C, Lacour-Gayet FG, Tchervakov CI. Executive summary: the Society of Thoracic Surgeons congenital heart surgery database—Eleventh Harvest—(July 1, 2005–June 30, 2009). The Society of Thoracic Surgeons (STS) and Duke Clinical Research Institute (DCRI), Duke University Medical Center, Durham, NC; Fall 2009 Harvest.

doi:10.1016/j.jtcvs.2010.04.034

Reply to the Editor:

We thank Jonas and his colleagues for their interest in our study and for drawing our attention to the definition of operative mortality.¹

During the review process of the manuscript, we offered to recalculate our data on mortality of the Norwood operation according to the definition of The Society of Thoracic Surgeons Congenital Database Task Force and the Joint EACTS-STs Congenital Database Committee,² but as we gave data on both 30-day mortality and interstage mortality, we were allowed to leave the data as presented.

However, we agree with Jonas and colleagues that the way of reporting operative mortality should be consistent to simplify comparison between groups. We, therefore, recalculated