Comprehensive Hemodynamic Assessment of 305 Normal CarboMedics Mitral Valve Prostheses Based on Early Postimplantation Echocardiographic Studies

Lori A. Blauwet, MD, Joseph F. Malouf, MD, Heidi M. Connolly, MD, David O. Hodge, MS, Regina M. Herges, MS, Thoralf M. Sundt, III, MD, and Fletcher A. Miller, Jr, MD, *Rochester, Minnesota*

Background: Two-dimensional (2D) and Doppler-derived echocardiographic data on normal CarboMedics (CM) mechanical mitral valve prosthesis function have been reported but are limited.

Methods: Comprehensive retrospective 2D and Doppler echocardiographic assessment of 305 normal CM mechanical mitral valve prostheses (272 Standard and 33 Optiform) was performed early after implantation. The early postimplantation hemodynamic profiles of 80 patients were compared with profiles obtained by follow-up transthoracic echocardiography performed <1 year after implantation.

Results: CM Standard and Optiform prostheses had similar hemodynamic profiles. With mean ± 2 SDs used to define the normal distribution of values for hemodynamic variables, the calculated normal range of values was as follows: mean gradient, 2 to 7 mm Hg; peak early mitral diastolic velocity, 1.3 to 2.4 m/sec; time-velocity integral (TVI) of the mitral valve prosthesis (TVI_{MVP}), 20 to 50 cm; ratio of TVI_{MVP} to the TVI of the left ventricular outflow tract, 0.9 to 2.5; pressure half-time, 35 to 99 msec; and effective orifice area, 1.17 to 3.25 cm^2. Patients with severe prosthesis-patient mismatch (indexed effective orifice area ≤ 0.9 cm^2/m^2) had significantly higher mean gradients, peak early mitral diastolic velocities, TVI_{MVP}, ratios of TVI_{MVP} to the TVI of the left ventricular outflow tract, and pressure half-time values than values without severe prosthesis-patient mismatch, but none had pressure half-time values > 120 msec. Among the 80 patients with follow-up transthoracic echocardiography within 1 year after implantation, no significant differences were noted between early postimplantation findings and follow-up hemodynamic profiles.

Conclusions: This study establishes parameters (mean ± 2 SD) defining the distribution of findings for Doppler-derived hemodynamic data with normal CM mechanical mitral valve prostheses. Prostheses with hemodynamic values outside these parameters are likely dysfunctional; however, prosthesis dysfunction may be present even when hemodynamic values are within these ranges. (J Am Soc Echocardiogr 2012;25:173-81.)

Keywords: Echocardiography, Doppler, Prosthesis, Heart valves, Mitral valve

Two-dimensional (2D) echocardiography combined with Doppler is the principal noninvasive technique for obtaining prosthetic valve hemodynamic information. Previous studies[1-7] and recent recommendations from the American Society of Echocardiography (ASE) and the European Association of Echocardiography (EAE)[8] have indicated that clinically useful Doppler-derived measures of mitral prosthesis function include mean gradient (MG), peak early mitral diastolic velocity (E velocity), the time-velocity integral of the mitral valve prosthesis (TVI_{MVP}), the ratio of the TVI_{MVP} to the TVI of the left ventricular outflow tract (TVI_{LVOT}), pressure half-time (PHT), effective orifice area (EOA), and indexed EOA (IEOA). Several previous reports from other institutions[9-13] have examined Doppler-derived hemodynamic profiles of different sizes of normally functioning CarboMedics (CM; Sorin Group USA, Inc., Arvada, CO) mechanical mitral valve prostheses, but these study data are limited. A previous study from our own institution[6] examined data for all the pertinent hemodynamic parameters but evaluated only 79 prostheses.

The aims of the present retrospective study were threefold: (1) to establish the distribution of all the important Doppler-derived hemodynamic variables previously described in the medical literature for a large number of patients with normal CM mechanical mitral valve prostheses, (2) to compare hemodynamic parameters of normal CM mechanical mitral valve prostheses in patients with and without severe prosthesis-patient mismatch (PPM), and (3) to compare hemodynamic variable values for CM mechanical mitral valve prostheses obtained in the early postoperative period with values obtained for the same prostheses 1 to 12 months postoperatively.

From the Division of Cardiovascular Diseases (L.A.B., J.F.M., H.M.C., F.A.M.), the Division of Biomedical Statistics and Informatics (D.O.H., R.M.H.), and the Division of Cardiovascular Surgery (T.M.S.), Mayo Clinic, Rochester, Minnesota.

This study was funded by the Division of Cardiovascular Diseases, Mayo Clinic. Portions of this report have been previously published in J Am Soc Echocardiogr 2007;20:1125–30.

Reprint requests: Fletcher A. Miller Jr, MD, Mayo Clinic, Division of Cardiovascular Diseases, 200 First Street SW, Rochester, MN 55905 (E-mail: *miller.fletcher@mayo.edu*).

0894-7317/$36.00

doi:10.1016/j.echo.2011.10.015

Abbreviations

ASE = American Society of Echocardiography

BSA = Body surface area

CM = CarboMedics

EAE = European Association of Echocardiography

EOA = Effective orifice area

GOA = Geometric orifice area

IEOA = Indexed effective orifice area

MG = Mean gradient

PHT = Pressure half-time

PPI = Prosthesis performance index

PPM = Prosthesis-patient mismatch

SV = Stroke volume

TEE = Transesophageal echocardiography

TTE = Transthoracic echocardiography

TVI = Time-velocity integral

TVI_{LVOT} = Time-velocity integral of the left ventricular outflow tract

TVI_{MVP} = Time-velocity integral of the mitral valve prosthesis

2D = Two-dimensional

METHODS

The study was approved by the Mayo Clinic Institutional Review Board. All study patients provided written informed consent to allow use of their medical records for research purposes. No industry support was provided.

Patient Selection

From the cardiac surgical database of Mayo Clinic (Rochester, MN), we identified 456 patients aged ≥ 18 years who underwent mitral valve replacement with CM mechanical mitral valve prostheses between January 1, 1993, and December 31, 2008. Of these 456 patients, 10 with congenitally corrected transposition had replacement of their left-sided morphologic tricuspid valves, which is equivalent, from a hemodynamic standpoint, to mitral valve replacement. One hundred fifty-one patients met the prespecified exclusion criteria: 13 patients died within 30 days of surgery, five did not undergo intraoperative transesophageal echocardiography (TEE), 17 did not undergo transthoracic echocardiography (TTE) within 30 days of surgery, two had signs of impaired leaflet excursion on postoperative TTE, two had evidence of considerable mitral valve prosthesis or paraprosthetic regurgitation on postoperative TTE, 37 had heart rates ≥ 100 beats/min, and 75 had inadequate images for obtaining accurate and complete Doppler data on postoperative TTE. The remaining 305 patients constituted the study population. Two hundred seventy-two of these 305 (89%) had CM Standard mechanical mitral valve prostheses implanted, whereas 33 (11%) received CM Optiform mechanical mitral valve prostheses.

All prostheses appeared to be functioning normally on physical examination and by 2D and color-flow imaging on both intraoperative TEE and TTE <30 days after surgery. No patient had greater than mild mitral transprosthetic or periprosthetic regurgitation or aortic regurgitation by intraoperative TEE or postoperative TTE.

Echocardiographic Data

Left ventricular ejection fraction was obtained using either M-mode imaging or a modification of the 2D Quinones method.[14] If these measurements were inadequate, left ventricular ejection fraction was estimated visually. Also noted were the presence and severity of aortic regurgitation and mitral transprosthetic or periprosthetic regurgitation.

Doppler data were obtained either from tapes using the DigiView Image Management and Reporting System release 3.6.3 (Digisonics, Inc., Houston, TX) or from digital images using ProSolv software (ProSolv CardioVascular, Indianapolis, IN) for offline analysis by one investigator (L.A.B.).

Our standard practice is to average three cycles of the left-heart Doppler measurements if patients are in sinus rhythm and at least five cycles if patients have atrial fibrillation or other irregular rhythms. For patients with irregular rhythms, attempts are made to use periods of physiologic heart rate and to match the five cycle lengths for each parameter.[8] The number of cycles and individual measurements are approved by the supervising echocardiographer before inclusion in the final report.

The prosthesis EOA was calculated using the continuity equation (EOA = stroke volume [SV]/TVI_{MVP}). Continuous-wave Doppler velocity spectra were measured for MG, E velocity, PHT, and TVI_{MVP}. To establish values defining the distribution of hemodynamic values for patients with normal CM mechanical mitral valve prostheses, we calculated the mean ± 2 SDs for MG, E velocity, TVI_{MVP}, TVI_{MVP}/TVI_{LVOT}, PHT, and EOA.

SV was calculated as the product of left ventricular outflow tract area and TVI_{LVOT} measured from pulsed-wave Doppler. The prosthesis performance index (PPI) was calculated as the ratio of the EOA derived by the continuity equation to the geometric orifice area (GOA) provided by the manufacturer: 3.16 cm^2 for the 25-mm valve, 3.84 cm^2 for the 27-mm valve, and 4.44 cm^2 for the 29-mm, 31-mm, and 33-mm valves. Because GOA values are identical for 29-mm, 31-mm, and 33-mm CM mitral valves, we performed a subgroup analysis of these three valve sizes to determine whether their hemodynamic values varied. Other calculated variables included TVI_{MVP}/TVI_{LVOT} and IEOA.

The clinical and echocardiographic data were analyzed separately for the 272 patients with CM Standard prostheses and for the 33 patients with CM Optiform prostheses, as well as for all 305 patients combined.

PPM was assessed by calculating IEOA using the continuity equation. The threshold value for delineating severe PPM (IEOA ≤ 0.9 cm^2/m^2) was chosen on the basis of the classification used in previously published studies.[3,15-18]

Early Postimplantation Versus Follow-Up Hemodynamic Profiles

The Mayo Clinic written and electronic medical records for each of the 305 patients were searched to ascertain whether follow-up TTE was performed between 1 and 12 months after implantation of the CM mechanical mitral valve prosthesis. Follow-up TTE was performed in 84 of the 305 patients (28%). One patient was excluded because follow-up TTE showed evidence of significant obstruction, and three patients were excluded because follow-up TTE demonstrated probable significant periprosthetic mitral regurgitation. These suspected prosthesis-related abnormalities were confirmed by TEE in all four patients and by surgical inspection in two of these four patients, who underwent replacement of their CM mechanical mitral valve prostheses. Of the other two patients, one underwent percutaneous closure of a perivalvular leak, and one died before intervention. The remaining 80 patients were included in the comparative analysis of early postimplantation versus follow-up hemodynamic profiles.

Statistical Analysis

Continuous variables were compared among the five valve size groups using analysis of variance. Differences were considered