Comprehensive Hemodynamic Assessment of 368 Normal St. Jude Medical Mechanical Mitral Valve Prostheses Based on Early Postimplantation Echocardiographic Studies

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Background: Two-dimensional and Doppler-derived echocardiographic data on normal St. Jude Medical mechanical mitral valve prosthesis function have been reported but remain limited.

Methods: Comprehensive retrospective two-dimensional and Doppler echocardiographic assessment of 368 normal St. Jude Medical mechanical mitral valve prostheses was performed early after implantation. The early postimplantation hemodynamic profiles of 98 patients were compared with profiles obtained by follow-up transthoracic echocardiography performed <13 months after implantation.

Results: Using mean ± 2 SDs to define the normal distribution of values for Doppler-derived hemodynamic variables, the calculated normal ranges of values were as follows: mean gradient, 2 to 7 mm Hg; peak early mitral diastolic velocity (E velocity), 1.1 to 2.4 m/sec; time-velocity integral of the mitral valve prosthesis (TVI_{MVP}) 20 to 50 cm; ratio of the TVI_{MVP} to the time-velocity integral of the left ventricular outflow tract (TVI_{LVOT}), 0.9 to 2.5; pressure half-time, 35 to 99 msec; and effective orifice area, 1.12 to 3.24 cm^2. Patients with severe prosthesis-patient mismatch (ie, indexed effective orifice area ≤ 0.9 cm^2/m^2) had significantly higher mean gradients, E velocity, TVI_{MVP}, and TVI_{MVP}/TVI_{LVOT}. There was a trend for longer pressure half-times for patients with severe prosthesis-patient mismatch than for patients without severe prosthesis-patient mismatch, but none of these patients had pressure half-times > 130 msec. Among the 98 patients with follow-up transthoracic echocardiography <1 year after implantation, no significant differences were observed between early postimplantation findings and follow-up hemodynamic profiles.

Conclusions: This study establishes parameters (mean ± 2 SDs) defining the distribution of values for Doppler-derived hemodynamic data with normal St. Jude Medical 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 2013;■:■-■.)

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

Two-dimensional (2D) echocardiography combined with Doppler is the noninvasive method of choice for the evaluation of prosthetic valve function. Recent recommendations from the American Society of Echocardiography (ASE) and the European Association of Echocardiography (EAE)[1] specify that the Doppler-derived hemodynamic assessment of mitral prosthesis function should include peak early mitral diastolic velocity (E velocity), mean gradient (MG), pressure half-time (PHT), the time-velocity integral (TVI) of the mitral valve prosthesis (TVI_{MVP}), the ratio of the TVI_{MVP} to the TVI of the left ventricular outflow tract (TVI_{LVOT}), effective orifice area (EOA) calculated by the continuity equation, and indexed EOA (IEOA) calculated by the continuity equation. Several reports from other institutions[2-6] have examined Doppler-derived hemodynamic profiles of various sizes of normally functioning St. Jude Medical (SJM; St. Paul, MN) mechanical mitral valve prostheses, but the data from these studies are limited. A previous study from our own institution[7] examined data for all the pertinent hemodynamic parameters but evaluated only 119 prostheses and included several older models of SJM prostheses in the study group.

The purpose of the current retrospective study was threefold: (1) to establish the range of normal values for all the important Doppler-derived hemodynamic parameters previously described in the medical literature for a large number of patients with normal SJM mechanical mitral valve prostheses, (2) to compare hemodynamic parameters of normal SJM mechanical mitral valve prostheses

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This study was funded by the Division of Cardiovascular Diseases, Mayo Clinic (Rochester, MN).

Portions of this manuscript have been published in: J Am Soc Echocardiogr 2007;20:1125-30.

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0894-7317/$36.00

http://dx.doi.org/10.1016/j.echo.2013.01.015

Abbreviations

ASE = American Society of Echocardiography

BSA = Body surface area

EAE = European Association of Echocardiography

EOA = Effective orifice area

GOA = Geometric orifice area

IEOA = Indexed effective orifice area

LVEF = Left ventricular ejection fraction

LVOT = Left ventricular outflow tract

MG = Mean gradient

PHT = Pressure half-time

PPI = Prosthesis performance index

PPM = Prosthesis-patient mismatch

SJM = St. Jude Medical

SV = Stroke volume

SVI = Stroke volume index

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

in patients with and without severe prosthesis-patient mismatch (PPM), and (3) to compare hemodynamic variable values for SJM mechanical mitral valve prostheses obtained in the early postoperative period to values obtained for the same prostheses 1 to 13 months postoperatively.

METHODS

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

Patient Selection

From the cardiac surgical database of the Mayo Clinic (Rochester, MN), we identified 740 patients aged ≥ 18 years who underwent mitral valve replacement with SJM standard (model MECJ-502) mechanical mitral valve prostheses between January 1, 1993, and December 31, 2008. Of these 740 patients, nine with congenitally corrected transposition had replacement of their left-sided morphologic tricuspid valves, which is equivalent, from a hemodynamic standpoint, to mitral valve replacement. Three hundred seventy-two patients met the prespecified exclusion criteria: 30 died within 30 days of surgery, 105 did not undergo intraoperative transesophageal echocardiography (TEE), 105 did not undergo transthoracic echocardiography (TTE) within 30 days of surgery, one had signs of impaired leaflet excursion on postoperative TTE, three had evidence of considerable mitral valve prosthesis or periprosthetic regurgitation on postoperative TTE, 43 had heart rates ≥ 100 beats/min, nine were on vasopressors at the time of postoperative TTE, and 76 had inadequate images for obtaining accurate and complete Doppler data on postoperative TTE. The remaining 368 patients constituted the study population.

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

Echocardiographic Data

Left ventricular ejection fraction (LVEF) was obtained using either M-mode or a modification of the 2D Quinones method.[8] If these measurements were deemed insufficient, LVEF was estimated visually. The presence and severity of aortic regurgitation and mitral transprosthetic or periprosthetic regurgitation were assessed.

Doppler data were obtained either from videotapes 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.).

The standard practice in our echocardiography laboratory is to average three cardiac cycles of the left-heart Doppler measurements if patients are in sinus rhythm and at least five cardiac cycles if patients have atrial fibrillation or another irregular rhythm. For patients with irregular rhythms, attempts are made to use periods of physiologic heart rate and to match the five cardiac cycle lengths for each parameter.[1] The number of cardiac cycles and individual measurements are approved by the supervising echocardiography consultant 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} using image-guided and nonimaging probes. To establish values for defining the distribution of hemodynamic variables for patients with normal SJM mechanical mitral valve prostheses, we calculated the mean ± 2 SDs for MG, E velocity, TVI_{MVP}, TVI_{MVP}/TVI_{LVOT}, PHT, EOA, and IEOA.

SV was calculated as the product of left ventricular outflow tract (LVOT) area and the TVI_{LVOT} measured on 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 (SJM): 2.55 cm^2 for the 23-mm valve, 3.09 cm^2 for the 25-mm valve, 3.67 cm^2 for the 27-mm valve, 4.41 cm^2 for the 29-mm valve, and 5.18 cm^2 for the 31-mm and 33-mm valves. Because GOA values are identical for the 31-mm and 33-mm SJM mitral valves, we performed a subgroup analysis of these two valve sizes to determine whether their hemodynamic values varied.

PPM was assessed by calculating the IEOA using the continuity equation. The threshold value for defining severe PPM (IEOA ≤ 0.9 cm^2/m^2) was chosen on the basis of the classification used in previously published studies.[9-13]

Early Postimplantation versus Follow-Up Hemodynamic Profiles

The Mayo Clinic written and electronic medical records for each of the 368 patients were searched to determine whether follow-up TTE was performed between 1 and 13 months after implantation of the SJM mechanical mitral valve prosthesis. Follow-up TTE was performed in 120 of the 368 patients (33%). One patient was excluded because follow-up TTE showed evidence of prosthetic thrombosis, and three patients were excluded because follow-up TTE demonstrated evidence of 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, one of whom underwent replacement of the SJM mechanical mitral valve prosthesis and one of whom underwent surgical repair of the periprosthetic leak. Of the other two patients, one underwent percutaneous closure of a perivalvular leak, and one patient with prosthetic thrombosis was treated with