Comprehensive Echocardiographic Assessment of Normal Mitral Medtronic Hancock II, Medtronic Mosaic, and Carpentier-Edwards Perimount Bioprostheses Early after Implantation

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Background: Normal Doppler-derived hemodynamic data for mitral valve bioprostheses are limited.

Methods: To establish parameters for identifying normal function for each of the 3 types of bioprostheses examined, we conducted a comprehensive, retrospective, two-dimensional, and Doppler echocardiographic assessment of 179 patients who underwent implantation of the Medtronic Hancock II or the Medtronic Mosaic (Medtronic, Inc, Minneapolis, MN) porcine mitral valve bioprosthesis or the Carpentier-Edwards Perimount (Edwards Lifesciences LLC, Irvine, CA) bovine pericardial mitral valve bioprosthesis.

Results: All bioprostheses were normal by clinical examination, intraoperative transesophageal echocardiography, and postoperative transthoracic echocardiography. Regardless of valve type and body surface area, the pressure half-time was < 124 ms in all patients. Mean gradient < 9.5 mm Hg, mitral E velocity < 2.6 m/s, mitral valve prosthesis time-velocity integral < 69 cm, and ratio of the mitral valve prosthesis time-velocity integral to the left ventricular outflow tract time-velocity integral < 3.4 were recorded in nearly all patients.

Conclusion: These cutoff values (mean + 2 standard deviation) are specific, but not sensitive, for identifying mitral valve prosthesis dysfunction. Prostheses with hemodynamic values that are higher than these cutoff values are likely dysfunctional, but in select cases, mitral valve prosthesis dysfunction may be present even when hemodynamic values are lower than these thresholds. (J Am Soc Echocardiogr 2010;23:656-66.)

Keywords: Doppler, Echocardiography, Mitral, Prosthesis

Clinically useful Doppler-derived measures of function in mitral valve prostheses include mean gradient (MG), effective orifice area (EOA), indexed EOA (IEOA), pressure half-time (PHT), peak early mitral diastolic velocity (E velocity), ratio of the mitral valve prosthesis time-velocity integral (TVI_{MVP}) to the left ventricular outflow tract time-velocity integral (TVI_{LVOT}) (TVI_{MVP}/TVI_{LVOT}), and prosthesis performance index (PPI).[1-3] However, because of the large variability in these Doppler measurements for each prosthesis type and size, recent studies have focused on indexes that can separate normal from abnormal prosthesis function. Several studies, including those from the Mayo Clinic, have found the combination of E velocity < 1.9 m/s, TVI_{MVP}/TVI_{LVOT} < 2.2, and PHT < 130 ms to be highly predictive of normal function in mechanical mitral valve prostheses.[2,4-6]

Similar echocardiographic parameters for predicting normal function in mitral valve bioprostheses have been reported for the Carpentier-Edwards Duraflex (Edwards Lifesciences, LLC, Irvine, CA) porcine bioprosthesis[7] but not for other tissue mitral valve prostheses. The purpose of this retrospective study was to define normal function in the early postoperative period for patients who underwent implantation of the Medtronic Hancock II (HKII) or Medtronic Mosaic (MM) (Medtronic, Inc, Minneapolis, MN) porcine mitral valve prosthesis or the Carpentier-Edwards Perimount (CEP) (Edwards Lifesciences, LLC, Irvine, CA) bovine pericardial mitral valve prosthesis, using all the important Doppler-derived hemodynamic variables that have been described to date in the medical literature.

MATERIALS AND METHODS

Patient Selection

From the cardiac surgical database of Mayo Clinic, Rochester, Minnesota, we identified 2037 patients aged 18 years or more who underwent mitral valve replacement between 1995 and 2007.

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Conflict of interest: None.

Portions of this manuscript have been published in: Blauwet LA, Malouf JF, Connolly HM, Hodge DO, Herges RM, Sundt TM 3rd, et al. Doppler echocardiography of 79 normal CarboMedics mitral prostheses: a comprehensive assessment including time-velocity integral ratio and prosthesis performance index. J Am Soc Echocardiogr 2007;20:1125-30.

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0894-7317/$36.00

doi:10.1016/j.echo.2010.03.031

Abbreviations

CEP = Carpentier-Edwards Perimount

EOA = Effective orifice area

E velocity = Peak early mitral diastolic velocity

GOA = Geometric orifice area

HKII = Medtronic Hancock II

IEOA = Indexed EOA

MG = Mean gradient

MM = Medtronic Mosaic

PHT = Pressure half-time

PPI = Prosthesis performance index

PPM = Prosthesis-patient mismatch

SD = Standard deviation

TEE = Transesophageal echocardiography

TTE = Transthoracic echocardiography

TVI_{LVOT} = Left ventricular outflow tract time-velocity integral

TVI_{MVP} = Mitral valve prosthesis time-velocity integral

Of these 2037 patients, 755 (37%) had a bioprosthesis implanted. Of the 755 patients, 76 (10%) received HKII mitral valves, 122 (16%) received MM valves, and 80 (11%) received CEP valves. Of these 278 patients with an HKII, an MM, or a CEP valve, we excluded 26 patients who died within 30 days after surgery, 5 patients who did not undergo intraoperative transesophageal echocardiography (TEE), 52 patients who did not have a transthoracic echocardiogram (TTE) within 30 days after surgery, 6 patients who were on vasopressors at the time of their postoperative TTE, and 10 patients whose bioprostheses were deemed abnormal by intraoperative TEE or postoperative TTE. The remaining 179 patients constituted the study population: 36 patients with HKII bioprostheses, 86 patients with MM bioprostheses, and 57 patients with CEP bioprostheses.

The physical examination and appearance of the bioprostheses by both intraoperative TEE and TTE performed within 30 days after surgery showed them to be functioning normally in all 179 patients. No patient had greater than mild mitral valve prosthesis regurgitation or aortic valve regurgitation by intraoperative TEE or TTE.

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

Echocardiographic Data

It is standard practice in our laboratory to average the Doppler measurements of 3 cycles if a patient is in sinus rhythm and to average ≥ 5 cycles if a patient is in 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 5 or more cycle lengths that are used for each parameter whenever possible.[8] For all patients, the number of cycles is selected and the individual measurements are approved by the supervising echocardiographer before inclusion in the final report.

Doppler data were obtained by reviewing the postoperative TTE reports of patients. Missing measurements were obtained using offline analysis (DigiView Image Management and Reporting System, Release 3.0; Digisonics, Houston, TX) by 2 of the investigators (L.A.B. and F.A.M.).

The bioprosthesis EOA was measured using both the PHT method used to calculate the EOA for native mitral valve stenosis (EOA = 220/PHT) and the continuity equation (EOA = stroke volume/TVI_{MVP}) to compare these methods with each other and with in vitro EOA data for these specific prostheses. Other calculated variables included IEOA and TVI_{MVP}/TVI_{LVOT}. Cutoff values for MG, E velocity, TVI_{MVP}, TVI_{MVP}/TVI_{LVOT}, and PHT used to identify possible dysfunction in mitral valve bioprostheses in this series were determined by calculating the mean ± 2 standard deviations (SDs) for each variable.

The PPI was calculated as the ratio of the EOA derived from the continuity equation to the geometric orifice area (GOA) provided by the manufacturer. The GOAs for the HKII and MM mitral valves were 3.97 cm^2, 4.52 cm^2, 5.30 cm^2, and 6.15 cm^2 for the 25-mm, 27-mm, 29-mm, and 31-mm valves, respectively, and 7.07 cm^2 for the 33-mm MM valves. The GOAs for the CEP valves were 4.90 cm^2, 5.72 cm^2, and 6.60 cm^2 for the 25-mm, 27-mm, and 29-mm valves, respectively, and 7.54 cm^2 for the 31-mm and 33-mm valves.

Mitral valve prosthesis–patient mismatch (PPM) was assessed by calculating IEOA using the continuity equation. The threshold value chosen to define severe PPM (IEOA ≤ 0.9 cm^2/m^2) was based on the results of previously published studies.[3,9-11]

Statistical Analysis

Measurements were compared between the continuity equation and the PHT method by using a paired *t* test. Continuous variables were compared among the 5 valve size groups by using the analysis of variance procedure. Significant differences were investigated by adjusting for multiple comparisons using the Student Newman–Keuls procedure.

RESULTS

Clinical Characteristics

The characteristics of the 179 patients who had mitral valve bioprostheses implanted are listed in Tables 1 to 3. The indications for mitral valve replacement were mitral regurgitation in 99 patients (55%), rheumatic valve disease in 50 patients (28%), native valve endocarditis in 10 patients (6%), prosthetic valve regurgitation in 10 patients (6%), prosthetic valve endocarditis in 5 patients (3%), prosthetic valve stenosis in 2 patients (1%), prosthetic valve thrombosis in 1 patient (<1%), mixed prosthetic valve regurgitation and stenosis in 1 patient (<1%), and accessory mitral valve tissue in 1 patient (<1%). Of the 179 patients, 128 (72%) had TTE performed within the first week after mitral valve replacement. The heart rhythm was sinus in 104 of the 179 patients (58%), atrial fibrillation in 49 patients (27%), atrial flutter in 5 patients (3%), and paced in 21 patients (12%).

Doppler Data

Hemodynamic data, grouped by valve size, are detailed in Tables 1 to 3. Complete Doppler hemodynamic data were available for 149 (83%) of the 179 patients, including 17 patients with a heart rate ≥ 100 beats/min.

The calculated E velocity threshold values (mean ± 2 SD) for predicting probable normal bioprosthesis function were 2.5 m/s for the HKII bioprosthesis, 2.6 m/s for the MM bioprosthesis, and 2.2 m/s for the CEP bioprosthesis. Nearly all (170 [95%]) of the 179 patients in this study had an E velocity below these parameters. The threshold E velocity value for all 3 bioprosthesis types combined was 2.5 m/s. A total of 172 (96%) of the 179 patients had an E velocity ≤ 2.5 m/s.