Assessment of Small-Diameter Aortic Mechanical Prostheses

Physiological Relevance of the Doppler Gradient, Utility of Flow Augmentation, and Limitations of Orifice Area Estimation

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Background—Noninvasive assessment of functionally stenotic small-diameter aortic mechanical prostheses is complicated by theoretical constraints relating to the hemodynamic relevance of Doppler-derived transprosthetic gradients. To establish the utility of Doppler echocardiography for evaluation of these valves, 20-mm Medtronic Hall and 19-mm St Jude prostheses were studied in vitro and in vivo.

Methods and Results—Relations between the orifice transprosthetic gradient (equivalent to Doppler), the downstream gradient in the zone of recovered pressure (equivalent to catheter), and fluid mechanical energy losses were examined in vitro. Pressure-flow relations across the 2 prostheses were evaluated by Doppler echocardiography in vivo. For both types of prosthesis in vitro, the orifice was higher than the downstream gradient (P<0.001), and fluid mechanical energy losses were as strongly correlated with orifice as with downstream pressure gradients (r²=0.99 for both). Orifice and downstream gradients were higher and fluid mechanical energy losses were larger for the St Jude than the Medtronic Hall valve (all P<0.001). Whereas estimated effective orifice areas for the 2 valves in vivo were not significantly different, model-independent dynamic analysis of pressure-flow relations revealed higher gradients for the St Jude than the Medtronic Hall valve at a given flow rate (P<0.05).

Conclusions—Even in the presence of significant pressure recovery, the Doppler-derived gradient across small-diameter aortic mechanical prostheses does have hemodynamic relevance insofar as it reflects myocardial energy expenditure. Small differences in function between stenotic aortic mechanical prostheses, undetectable by conventional orifice area estimations, can be identified by dynamic Doppler echocardiographic analysis of pressure-flow relations. (Circulation. 1998;98:866-872.)

Key Words: prosthesis • echocardiography • hemodynamics

More than two thirds of mechanical aortic prostheses inserted annually in the United States are small and functionally stenotic (valve size ≤23 mm, effective orifice area <2.0 cm²).1 Assessment of these prostheses is complicated by physical constraints that preclude or inhibit direct measurement of transprosthetic pressure gradients as well as theoretical constraints relating to the application of the Bernoulli model to flow velocities that frequently are not uniformly distributed across the plane of the prosthetic valve orifice.2–4 Specifically, the hemodynamic relevance of the Doppler-derived transprosthetic gradient (which frequently exceeds the catheter-derived manometric gradient) has been challenged,5,6 and invasive verification by catheter in patients with elevated Doppler gradients is hampered by the requirement for transprosthetic catheter placement or septal puncture. Moreover, the sensitivity of conventional valve orifice area estimates for detection of small changes or differences in hemodynamics, such as might occur in the early stages of pannus formation (tissue ingrowth) and/or thrombotic occlusion, has not been meaningfully evaluated.

This study was designed to examine these issues. Two types of small-diameter mechanical aortic prostheses of different design (namely, tilting-disk 20-mm Medtronic Hall prosthesis and bileaflet 19-mm St Jude valve) were used as the vehicles for this hemodynamic assessment. These valves, both of which are functionally stenotic even when disk/leaflet excursion is normal,7 were chosen for their high relative prevalence among mechanical aortic valves inserted in the United States8 and their similar hemodynamic profiles.9

First, an in vitro model was constructed that would simulate in vivo pressure-flow relations across the 2 prostheses in the aortic position. The relation between the maximal transprosthetic pressure difference just distal to the valve orifice (analogous to the Doppler gradient)2 and the gradient...
in the zone of recovered pressure measured further downstream of the orifice (analogous to the in vivo catheter gradient) was studied. The physiological relevance of each of these gradients (ie, orifice and downstream) was evaluated in terms of the associated fluid mechanical energy losses incurred during transprosthetic fluid transit for both the St Jude and Medtronic Hall valves. Next, the physiologically validated Doppler-derived gradients were determined in vivo and applied to the estimation of valve orifice areas for the 2 prostheses to ascertain whether or not the known small hemodynamic differences between the 2 prostheses could be identified. Finally, the 2 prostheses were compared by a novel model-independent analysis of pressure and flow data, performed over a range of incremental flows. This method circumvents the limitations inherent to conventional model-based orifice area estimations and avoids potentially confounding effects of low flows.

**Methods**

**In Vitro Study**

**Model**

Hemodynamic measurements were made in vitro with a physiologic pulsatile flow system driven by a piston pump (Superpump SPS3891 Vivitro, Inc). To facilitate prosthetic valve insertion, a straight model was used with circular cross-sectional inlet and outlet areas of 5.07 cm² (Figure 1). The piston was controlled with a PC-based analog motion controller (R4005, Rapid Systems, Inc). Peripheral resistance and compliance were simulated by PVC ball valves and flexible tubing, respectively. Compliance and resistance values remained constant throughout the experiments. All experiments were performed at a heart rate of 60 bpm with systolic duration equal to one third of the total cycle time. Data were acquired at incremental stroke volumes between 40 and 120 mL. For purposes of acoustic reflection, a saline solution of kinematic viscosity (1×10⁻⁴ m²/s) with 1%cornstarch particles (by volume) was used for all experiments. Measurements were made for the 20-mm Medtronic-Hall tilting-disc valve and the 19-mm St Jude bileaflet prosthesis (internal orifice areas of 1.74 and 1.21 cm², respectively).

**Energy Loss Measurements**

Fluid mechanical energy loss was defined as energy lost to viscous dissipation (heat) that was no longer able to cause fluid motion. Fluid mechanical energy losses were assessed by use of control volume analysis to calculate the energy flux entering and leaving a volume that spanned the entire prosthesis model from inlet to outlet. The control volume extended from a pressure tap 5.8 cm upstream of the valve to a pressure tap 17.9 cm downstream of the valve. Pump work (Wₚ) was defined as energy entering the control volume and energy

![Figure 1. Pulsatile flow system designed to simulate physiologic transaortic flow.](image)

loss as the difference between energy entering and leaving the control volume during 1 cardiac cycle:

\[ \text{Energy Loss} = W_\text{in} - W_\text{out} \]

The energy leaving the control volume (Wₚ) was defined as the energy available to drive blood through the systemic circulation. The energy crossing each boundary of the control volume was calculated by integrating flow rate (Q) and the total pressure of the fluid at the control volume boundary over the cardiac cycle:

\[ W = \int QP_z \, dt \]

The total pressure (P₀) is equal to the static pressure (P) plus the dynamic pressure or kinetic energy (1/2 ρv²):

\[ P_z = P + \frac{1}{2} \rho v^2 \]

All calculations were based on a control volume form of conservation of fluid mechanical energy. The derivation of equations 1 through 3 involves the following assumptions: (1) The fluid in the control volume is incompressible. (2) The control volume is coincident with the internal surfaces of the model and perpendicular to the cross section at the inlet and outlet. (3) Cycle-to-cycle increases in stored energy within the control volume are negligible, so that flow through and within the control volume does not change from cycle to the next over the measurement period (this was verified experimentally by repeating measurements over 10 consecutive cardiac cycles).

**Data Acquisition**

Pressures were measured simultaneously at 3 wall-mounted pressure taps, sited respectively at the inlet (5.8 cm upstream of the valve), just distal to the prosthetic valve orifice (0.76 cm from the downstream edge of the valve), and at the outlet (17.9 cm downstream of the orifice), with strain gauge pressure transducers (Uniflow, Baxter Healthcare). Flow rate was measured with an in-line electromagnetic flow probe (EP680, Carolina Medical) attached to a flowmeter (FM501, Carolina Medical). The pressure and flow rate signals were filtered at 100 Hz to remove high-frequency noise and displayed by a physiological signal recorder (Cardiomed 4008, Medi-Stim, Inc). Fluid velocity was measured with a custom-made 10-MHz Doppler ultrasound needle probe, operating in high-pulse-repetition frequency mode and interfaced with an ultrasound signal processor (SD-100, Vingmed A/S). Doppler ultrasound velocity was automatically tracked on-line and outputted as a digital signal. Pressure and flow rate signals from the Cardiomed 4008 were outputted as analog signals and were digitized at 1 kHz. Ten consecutive simulated heart cycles were collected and averaged at each pressure-tap location. All data were collected with a 12-bit A/D board (DAQPad-1200, National Instruments, Inc) connected through the parallel port to a PC (Latitude Xpi, Dell Computers Corp) with the use of custom data collection software (LabVIEW 3.0, National Instruments, Inc). Data were analyzed off-line. Mean systolic pressure differences between the upstream and orifice pressure taps and between the upstream and downstream pressure taps were calculated numerically by use of FORTRAN programs. Work and fluid mechanical energy losses were calculated through numerical integration of the flow rate, pressure, and Doppler ultrasound velocity signals over the cycle duration by use of the trapezoidal rule.

**In Vivo Study**

**Patients**

Nineteen patients were studied 6 to 96 months after insertion of 19-mm St Jude (n=11) or 20-mm Medtronic Hall (n=8) aortic prostheses for management of critical aortic stenosis. Patients ranged in age from 42 to 86 years (mean, 72±10); 18 (95%) were female. All were in NYHA functional class I or II without a history of angina. All had normal left ventricular systolic performance as...
assessed by 2-dimensional–targeted M-mode echocardiography (ie, shortening fraction >30%). Normal prosthetic leaflet or disk excursion was confirmed in every patient by cineangiography or 2-dimensional echocardiography.

Doppler Echocardiography

Two-dimensional echocardiographic and Doppler data (pulsed wave and continuous wave) were acquired in the left lateral decubitus position with a Hewlett Packard Sonos 1500 echocardiographic imaging system using 2.5-MHz and Pedoff transducers. The internal diameter of the prosthetic valve ring was measured from 2-dimensional images in the parasternal long-axis view. Flow velocities at the level of the prosthetic valve ring and just distal to the prosthetic valve leaflets or disk were determined in the apical 5-chamber view by pulsed and continuous-wave Doppler, respectively. All data were recorded as the average value determined from 3 consecutive Doppler or 2-dimensional echocardiographic images. Data were acquired at baseline and during incremental dobutamine infusion (2.5, 5.0, 7.5, and 10.0 \( \mu g \cdot kg^{-1} \cdot min^{-1} \)). A 3-minute equilibration period was allowed before data acquisition after each dobutamine dose adjustment.

Calculations

Stroke volume (SV) was determined from Doppler echocardiographic data as

\[
SV = VTI_{PA} \times \pi \left( \frac{D_{PA}}{2} \right)^2
\]

where VTI_{PA} is the velocity-time integral across the prosthetic valve annulus and D_{PA} is the prosthetic valve annular diameter.

Cardiac output (CO) was calculated as the product of stroke volume and heart rate. The mean transprosthetic gradient was determined by the extended Bernoulli equation (MPG_b)

\[
MPG_b = \frac{4}{T} \left[ \sum_{t_0}^{T} V_{2t}^2 - \sum_{t_0}^{T} V_{1t}^2 \right]
\]

where T is the duration of ejection, t_0 is the onset of ejection, and V_{2t} and V_{1t} are the instantaneous velocities at time t across the valve leaflets or disk and the valve annulus, respectively.

The effective prosthetic valve orifice area (EOA_G) was calculated by the Gorlin formula as

\[
EOA_G = \frac{Q}{C \times C \times \sqrt{2g \times MPG_b}}
\]

where Q is the transprosthetic flow rate (cm\(^3\) · s\(^{-1}\)) calculated as stroke volume divided by ejection time, C is the coefficient of orifice contraction across the prosthetic valve disk, C is the velocity coefficient, and g is the acceleration due to gravity (980 cm · s\(^{-2}\)). The product of C and C has been termed the empiric constant,\(^{11}\) which approximates a value of 1.

Statistical Analysis

Differences in energy losses, orifice pressure gradients, and recovered pressure gradients between the 2 prostheses were assessed by 2-sample \( t \) tests with 95% CIs. A \( P \) value <0.05 was considered statistically significant. Relations between downstream and orifice gradients were assessed by linear regression analysis. Relations between pressure gradients and energy losses were assessed by best-fit (second-order polynomial) regression analysis.

Baseline hemodynamic variables for the 2 mechanical prostheses in vivo were compared with nonparametric statistics (Mann-Whitney). A multiplicative model was used to examine pressure-flow relations. These relations for the 2 prostheses were compared by ANCOVA, with pressure as the covariate, to identify if either conferred a hemodynamic advantage over the other in respect of the transvalvular flow that would result from a common transvalvular driving pressure.

Results

Orifice and Downstream Pressure Gradients

Mean systolic orifice and downstream pressure gradients for both prostheses over a wide range of stroke volumes are shown in Figure 2 (upper and middle panels). For both valves, mean transprosthetic gradients (orifice and downstream) increased with increasing stroke volume. Orifice gradients for the Medtronic Hall valve ranged from 6.9 mm Hg (at a stroke volume of 40 mL) to 41.8 mm Hg (at a stroke volume of 120 mL). At the same values for stroke volume, orifice gradients across the St Jude valve were 8.2 and 58.6 mm Hg, respectively. Over the entire range of stroke volume values, orifice gradients were higher for the St Jude bileaflet 19-mm valve than for the Medtronic Hall tilting-disk 20-mm valve.

At all stroke volumes, the orifice gradient was higher than the downstream gradient (\( P < 0.001 \)), reflecting significant pressure recovery during fluid transit across both types of prosthesis. The downstream (recovered) pressure gradient for the Medtronic Hall valve ranged from 3.7 mm Hg (at a stroke
volume of 40 mL) to 20.5 mm Hg (at a stroke volume of 120 mL). At the same values for stroke volume, downstream gradients across the St Jude valve were 4.5 and 38.8 mm Hg, respectively. For all stroke volumes >40 mL, downstream gradients were significantly higher for the St Jude than for the Medtronic Hall valve.

Downstream and orifice gradients were strongly correlated for both prostheses ($r^2=0.99$ for both). For a given orifice gradient, the downstream gradient tended to be lower for the Medtronic Hall than the St Jude valve (Figure 3).

**Fluid Mechanical Energy Losses**

Figure 2 (lower panel) shows the fluid mechanical energy losses over the range of stroke volume values for the 2 prosthetic valves. Predictably, the energy losses, which define the physiological workload of each valve, increased with increasing stroke volume. At each stroke volume value, the energy lost during fluid transit across the St Jude valve was higher than that dissipated during transit across the Medtronic Hall valve ($P<0.001$).

**Relations Between Transprosthetic Pressure Gradients and Fluid Mechanical Energy Losses**

Fluid mechanical energy losses were as strongly correlated with orifice as with downstream transprosthetic pressure gradients for both valves ($r^2=0.99$ for both the Medtronic Hall and St Jude valves) (Figure 4). Relations between orifice gradient and fluid mechanical energy losses were similar for the Medtronic Hall and St Jude valves at low stroke volumes. At higher stroke volumes, the energy losses incurred for a given driving pressure (ie, orifice gradient) tended to be larger for the St Jude than for the Medtronic Hall prosthesis (Figure 4, upper panel).

**In Vivo Study**

**Hemodynamic Effects of Flow Augmentation**

Representative continuous-wave Doppler data at increasing dobutamine doses are shown in Figure 5. In all cases, incremental dobutamine caused a stepwise increase in cardiac output ($4.1 \pm 0.8$ versus $6.5 \pm 1.2$ L/min, baseline versus peak), accompanied by a corresponding progressive increase in mean transprosthetic gradient (MPGA) from $13 \pm 6$ mm Hg at baseline to $26 \pm 10$ mm Hg at peak dobutamine.
respectively). Because no significant differences were detectable in baseline mean transprosthetic gradient values for the 2 valves (12.6±4 mm Hg for Medtronic Hall and 15.6±8 mm Hg for St Jude), effective orifice areas estimated by the Gorlin formula were also similar (1.25±0.27 and 1.07±0.17 cm² for Medtronic Hall and St Jude, respectively). Incremental flow augmentation did not influence effective orifice area estimates (Figure 6). Even at peak dobutamine doses, differences between estimated effective orifice areas for the 2 valves were not significant.

For both valves, the power function \( y = bx^a \) was the best-fit model for analysis of pressure-flow relations. The slope (a) of the derived linear logarithmic relation (log x versus log y) gives the exponentiality of the pressure-flow relation for each prosthesis. Accordingly, the linear relation between log cardiac output and log mean pressure gradient was used for quantitative analytical comparison of pressure-flow relations across the 2 valves over a wide range of hemodynamic conditions induced by dobutamine (Figure 7). The slopes of the 2 lines were similar, but the y intercepts were different. For any given transprosthetic flow rate, the transprosthetic gradient was higher across the 19-mm St Jude than the 20-mm Medtronic Hall valve (\( P < 0.05 \)).

**Discussion**

**Determination of Transprosthetic Pressure Gradients From Flow Velocity Data**

Doppler-based estimation of pressure gradients across stenotic lesions invokes the fundamental physical principal of energy conservation. As blood accelerates across the constricted valve orifice, energy that is being expressed as hydrostatic pressure is converted to kinetic energy, manifested as velocity. Previous studies have demonstrated that as the poststenotic jet expands, some degree of pressure recovery may occur. Therefore, if standard manometric techniques are used, the maximal pressure gradient across a stenotic orifice will be identified only if the distal manometer is sited exactly in the region of minimal pressure/maximal velocity (ie, at the vena contracta, where the streamlines are maximally constricted). Continuous-wave Doppler, on the other hand, routinely detects the maximal velocity over a range of sample sites. Derivation of the pressure gradient by application of the Bernoulli equation to continuous-wave Doppler flow velocity data, therefore, generally provides the maximal pressure gradient in the region of flow velocity interrogation. It follows that if there is significant pressure recovery, pressure gradients derived from continuous-wave Doppler flow velocity data are likely to exceed manometric measurements. Our in vitro data confirm previous reports of significant pressure recovery across small-caliber St Jude valves. However, this phenomenon was also observed with 20-mm Medtronic Hall valves, a finding that has not been emphasized previously. For both types of prosthetic valve, pressure gradients detected by manometers positioned 17.9 cm distal to the prosthetic valve orifice were systematically lower than those detected by manometers positioned just distal to the orifice, as shown in Figure 2. Previous studies have shown excellent agreement between the Doppler-derived gradient and the orifice gradient detected by manometers positioned just distal to the prosthetic valve orifice for both the 19-mm St Jude and the 20-mm Medtronic Hall valves. That continuous-wave Doppler provides an accurate assessment of the orifice gradient is not in doubt; it is the physiological relevance of this Doppler gradient that has been challenged.

**Physiological Relevance of the Orifice Gradient**

The in vitro portion of this study showed an excellent correlation between the orifice pressure gradient and fluid mechanical energy losses incurred during ejection for both prostheses, implying an association between the Doppler
gradient and myocardial energy expenditure. Because this relationship was as powerful as that between the more distally determined transprosthetic gradient (measured in the zone of recovered pressure) and fluid mechanical energy losses, our data suggest that the Doppler-derived gradient across these small-caliber prostheses has similar hemodynamic relevance to the catheter gradient that is conventionally measured in the zone of recovered pressure. Both these gradients are related to energy losses and accurately reflect the hemodynamic workload placed on the left ventricle by the valve. Indeed, because the gradient value is so highly dependent on the position of the distal catheter, it might be argued that Doppler, by consistently providing access to the maximal pressure gradient, is the method of choice for serial assessment of the function of small-caliber mechanical prostheses.

Hemodynamic Assessment of Prosthetic Valve Function

By clinical convention, the estimated valve orifice area, which incorporates simultaneous measurements of transvalvular pressure gradient and flow, is considered the “gold standard” for in vivo hemodynamic evaluation of stenotic cardiac valves.

Aris et al\textsuperscript{21} recently reported significant differences in valve orifice area between 19-mm St Jude and 20-mm Medtronic Hall prostheses. Although valve orifice area values in the present study were similar to those of Aris et al, differences between the 2 valves did not reach statistical significance, either at rest or at peak exercise. Because the value for effective valve orifice area is derived indirectly from an analysis of pressure-flow relations, the accuracy of this parameter is entirely dependent on the accuracy of the pressure and flow measurements. Differentiation of 1 orifice area from another requires greater accuracy in gradient (and hence, velocity) measurements when values for flow are low, irrespective of the model used (Figure 8). At the low-flow rates that frequently prevail in elderly aortic stenosis patients with small aortic roots, small hemodynamic changes that might occur with early pannus or thrombus formation may not be detected by serial estimates of valve orifice area determined at the baseline hemodynamic state.

A multiplicative model was therefore used to examine pressure-flow relations, making none of the assumptions that are inherent to valve orifice area estimation, either with respect to the relation between pressure and flow or in regard to the coefficients of orifice contraction and velocity. This dynamic analysis, conducted over a range of values for flow and pressure gradient, demonstrated that the head of pressure required to drive a column of blood across the St Jude valve was significantly greater than that necessary to generate the same flow across the Medtronic Hall valve. This type of hemodynamic evaluation appears to detect minor hemodynamic differences more sensitively than conventional orifice area estimations that are based on data traditionally acquired under only a single condition of pressure and flow. The importance of generating a range of incremental flow values is highlighted further by the in vitro observation that even under the most carefully controlled hemodynamic conditions, the differences in fluid mechanical energy losses across the 2 types of prosthetic valve were difficult to detect at lower stroke volume values. The noninvasive imaging laboratory is an ideal environment in which to perform this type of physiological evaluation. The time constraints that are inherent to invasive procedures performed in the cardiac catheterization laboratory would limit the application of such studies. Moreover, the noninvasive nature of this approach lends itself to serial evaluations.

Our data suggest that serial comparisons of families of pressure-flow relations generated for each hemodynamic condition (ie, at the time of each Doppler echocardiographic assessment) will facilitate detection of minor differences or changes in valve function that may not be detected by estimation of valve orifice area alone.

Summary

1. The transprosthetic pressure gradient measured just distal to the orifice of small-caliber mechanical prostheses tends to be higher than that measured further downstream in the ascending aorta. This phenomenon, which pertains to both bileaflet and tilting-disk prostheses, is due to initial hydrostatic pressure loss and then pressure recovery of blood transiting the proximal aorta.

2. The higher proximal gradient, which can be measured either by continuous-wave Doppler or by a properly positioned manometer, correlates as well with fluid mechanical energy losses across small-caliber mechanical prosthetic valves as the lower distal gradient (in the zone of recovered pressure) measured by conventional manometric techniques in the catheterization laboratory. Both measurements therefore reflect the hemodynamic burden imposed by the valve.

3. The pressure gradient required to drive a given flow volume and the fluid mechanical energy losses incurred during flow transit are slightly greater for the 19-mm St Jude
than for the 20-mm Medtronic Hall prosthesis in the aortic position.

4. Small changes in the hemodynamic function of stenotic aortic valves can be more sensitively detected by direct analysis of pressure-flow relations or calculation of fluid mechanical energy losses over a range of incremental flow values than by conventional valve orifice area estimations.

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References


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