Effect of Prosthetic Valve Malfunction on the Doppler–Catheter Gradient Relation for Bileaflet Aortic Valve Prostheses

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Background. Considerable discrepancies between Doppler and catheter gradients caused by localized and pressure recovery have been reported for normal bileaflet aortic valve prostheses.

Methods and Results. To examine whether this Doppler–catheter gradient relation is affected by prosthetic valve malfunction, a 19-mm CarboMedics aortic valve was simultaneously studied with continuous-wave Doppler and catheter technique in normal function and in various states of malfunction ranging from slightly restricted opening to total occlusion of one leaflet. For each functional status, peak and mean gradients were measured at eight different flow rates (cardiac output, 2.0–6.0 L/min). Excellent correlation between Doppler and catheter gradients was found regardless of the valve function ($r=0.99,\ SEE=1.0–3.3$ mm Hg). However, the relation between Doppler and catheter gradient was highly dependent on the function of the valve as shown by a variation of slopes from 1.08 to 2.08. For the normally functioning valve (angle between flow axis and leaflet 5°), peak and mean Doppler gradients were approximately twice the catheter gradients (slope, 2.08 and 2.03 for peak and mean gradients, respectively). Slightly restricted opening of one leaflet (22°) significantly altered the Doppler–catheter gradient relation, and slopes decreased to 1.69 ($p<0.01$) and 1.52 ($p<0.001$) for peak and mean gradients, respectively. The differences between Doppler and catheter gradients significantly decreased with further restriction of valve opening, and slopes ranged from 1.25 to 1.41 for angles between 34° and 52°. When one leaflet was totally occluded, the slope finally dropped to 1.08 for both peak and mean gradients, and Doppler gradients were only slightly greater than catheter gradients. Gradients increased with malfunction of the valve caused by reduction of the effective orifice area. However, the increase of Doppler gradients was considerably smaller than the increase of catheter gradients.

Conclusions. The discrepancies between Doppler and catheter gradients that have been reported for normally functioning bileaflet aortic valve prostheses may be reduced or even disappear in patients with malfunctioning valves. Furthermore, the increase of Doppler gradients caused by malfunction of the valve may underestimate the true hemodynamic changes. (Circulation 1993;87:1320–1327)

KEY WORDS • prostheses, heart valve • Doppler echocardiography • hemodynamics

Although good agreement between Doppler and catheter gradients has been shown for native aortic valve stenosis,1–3 clinically relevant discrepancy between the two techniques has been found for some mechanical aortic valve prostheses.4–7 The Doppler–catheter gradient relation has indeed been shown to depend on the geometric prosthetic valve design.8 Although good agreement between Doppler and catheter measurements has been reported for some valve types, as Medtronic-Hall tilting disc and Hancock bioprosthetic valves, significant discrepancy was found for others, such as St. Jude bileaflet valves and Starr-Edwards caged-ball valves.8 For the bileaflet valve, these discrepancies have been shown to be due to the occurrence of localized high-velocity jets between the two leaflets and to pressure recovery.7 Since Doppler records these localized high velocities, the calculated gradients are significantly greater than catheter gradients measured downstream from the valve.7 The occurrence of this phenomenon is due to the specific flow characteristics of normally functioning bileaflet valves and may be altered by malfunction of the valve with restricted valve opening. However, to our knowledge, the effect of prosthetic valve malfunction on the Doppler–catheter gradient relation has not been evaluated for bileaflet valves.

To address the hypothesis that differences between Doppler and catheter gradients that have been found in normal bileaflet aortic valve prostheses may decrease or even disappear in malfunctioning valves, a bileaflet valve was simultaneously studied with continuous-wave Doppler and catheter technique in normal function and in various states of malfunction ranging from slight restriction to total occlusion of one leaflet.

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catheter gradients, peak and mean Doppler gradients, and cardiac output were calculated. Peak catheter gradient was defined as maximal instantaneous difference between proximal and distal pressure. Peak Doppler gradients (Δp) were calculated from the maximal instantaneous velocity (v_i) with the simplified Bernoulli equation (Δp=4v_i^2). The experimental setup did not allow direct measurement of the proximal velocity (v_i).

The peak proximal velocities as calculated from flow rate and tubing size ranged from 0.35 to 1.40 m/sec. To exclude distortion of the results caused by the use of Δp=4v_i^2, peak gradients were also estimated using the equation Δp=4(v_i^2-v_e^2) using these calculated proximal velocities. The mean systolic catheter gradient was obtained by integrating the differential pressure wave over the systolic time period. Mean Doppler gradients were calculated by averaging the instantaneous Doppler gradients throughout the ejection period using the on-board quantitation package. Since hand tracing of the spectral display velocity curve was used, interobserver and intraobserver variability were evaluated. Gradients calculated by observer 1 and 2 correlated well (r=0.99, y=0.38±0.99, SEE=2.2 mm Hg); the mean difference was 0.1±2.1 mm Hg. Two independent measurements by one observer correlated well, also (r=0.99, y=−0.24±1.00x, SEE=0.9 mm Hg), and the mean difference was only 0.2±1.0 mm Hg. Each set of measurements was obtained by averaging the calculations of three consecutive beats.

Heart Valve Prosthesis, Alteration of Valve Function

A CarboMedics aortic valve was used for the experiments. This bileaflet valve has flat leaflets similar to the St. Jude valve. The manufacturer’s specified leaflet angle of separation is 10° in the open position (angle between axis of flow and leaflet, 5°). It has been shown previously for St. Jude valves with sizes from 19 to 27 mm that the discrepancy between Doppler and catheter gradients caused by localized high gradients and pressure recovery occurs independently of the valve size.7,8 Since the greatest range of gradients can be expected for a 19-mm valve,8 a valve of this size was selected for the experiments. A special mechanism has been designed to allow definable restriction of leaflet opening (Figure 2): A Lucite ring with a stop pin was put between the valve and the “aorta.” The stop pin reached into the valve and was adjustable along the valve ring as shown in Figure 2. In position a (coaptation line), the stop pin did not affect the valve function while it caused total occlusion of one leaflet in position b. Four stop pin positions between a and b that resulted in various degrees of restricted leaflet opening were studied (Figure 2). Valve closure was not affected by the stop pin.

For each functional status, the angle between axis of flow and the affected leaflet was evaluated by fluoroscopy. The valve was taken out of the flow model for these measurements. Tangential views of the maximally open valve were obtained for each stop pin position. For the normally opening leaflet, an angle of 5° was confirmed. The four intermediate stop pin positions resulted in angles of 22°, 34°, 45°, and 52° between axis of flow and open leaflet. An angle of 67° was measured when the leaflet was totally occluded.
FIGURE 2. Schematic of the CarboMedics prosthesis (view from the aortic side) is shown at left: The stop pin (shown without mounting ring) can be adjusted along the valve ring from position a (no interference with leaflet opening) to position b (total occlusion of one leaflet). Schematic of the CarboMedics prosthesis (tangential view) is shown at right: The right leaflet is shown in normal open and closed position. The left leaflet is shown in normal open position (stop pin position a), the four grades of restricted leaflet opening, and the totally occluded position (stop pin position b). Angles between axis of flow and leaflet were a, 5°; 1, 22°; 2, 34°; 3, 45°; 4, 52°; b, 67°.

Test Protocol

The valve was studied in normal function and in five different states of malfunction ranging from slightly restricted opening to total occlusion of one leaflet (Figure 2). For each functional status of the valve, driving pressure and filling characteristics of the ventricle, outflow compliance and outflow resistance were varied to obtain eight different flow rates while maintaining physiological downstream pressures. Cardiac output ranged from 2.0 to 6.0 L/min. This maximal cardiac output could be obtained for the normally functioning valve but not for all states of malfunction. Heart rate was maintained at 60 beats per minute, and ejection time was maintained at 300 msec. Peak and mean gradients were simultaneously measured with continuous-wave Doppler and catheter technique at each flow rate.

To provide information on the change in Doppler and catheter gradients with malfunction of the valve at constant flow rate compared with the normal baseline state, peak flow was maintained at 251±4, 298±4, and 351±2 mL/sec while valve function was varied. The normally functioning valve and the five different degrees of leaflet restriction described above were tested. Doppler and catheter gradients were simultaneously measured, and the mean percent increase in gradient as compared with normal baseline state was calculated for each functional status of the valve.

Statistical Analysis

The Doppler–catheter gradient relation was assessed by linear regression analysis. Pearson correlation coefficients were calculated. The hypothesis about two regression lines was tested with a two-tailed t test.

Results

Correlation Between Doppler Gradients and Catheter Gradients

The correlation both between peak Doppler and peak catheter gradients and between mean Doppler and mean catheter gradients was excellent regardless of the functional status of the valve ($r=0.99$, $SEE=1.0–3.3$ mm Hg for peak gradients; $r=0.99$, $SEE=0.6–1.5$ mm Hg for mean gradients). However, the relation between Doppler and catheter gradients was highly dependent on the opening angle of the valve as demonstrated by a variation of slopes from 1.08 to 2.08 for the various functional states in which the valve was tested (Table 1, Figures 3 and 4).

For the normally opening valve (angle between axis of flow and leaflet 5°), peak and mean Doppler gradients were approximately twice as high as the catheter gradients (slope, 2.08 and 2.03 for peak and mean gradients, respectively). Slight restriction of the opening of one

<table>
<thead>
<tr>
<th>Valve function (opening angle*)</th>
<th>Correlation between peak Doppler gradients and peak catheter gradients</th>
<th>Correlation between mean Doppler gradients and mean catheter gradients</th>
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<tbody>
<tr>
<td></td>
<td>Correlation</td>
<td>(mm Hg)</td>
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<tr>
<td>Normal (5°)</td>
<td>$r=0.99$</td>
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<tr>
<td>Grade 1 (22°)</td>
<td>$r=0.99$</td>
<td>3.0</td>
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<td>Grade 2 (34°)</td>
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<td>Grade 3 (45°)</td>
<td>$r=0.99$</td>
<td>2.1</td>
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<td>Grade 4 (52°)</td>
<td>$r=0.99$</td>
<td>0.7</td>
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<td>Total occlusion</td>
<td>0.99</td>
<td>2.7</td>
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*Angle between axis of flow and leaflet (second leaflet opened normally).
leaflet (angle between axis of flow and leaflet 22°) significantly altered the Doppler–catheter gradient relationship. The slopes decreased to 1.69 for peak gradients ($p<0.01$) and to 1.52 for mean gradients ($p<0.001$). The differences between Doppler and catheter gradients decreased with further increase of the angle between flow axis and leaflet. For an angle of 34°, the slopes significantly dropped to 1.37 ($p<0.002$) for peak gradients and 1.25 ($p<0.001$) for mean gradients. Further restriction of leaflet opening that resulted in angles of 45° and 52° did not significantly alter the results (all probability values $>0.1$). Slopes were 1.35 and 1.41 for peak gradients and 1.35 and 1.31 for mean gradients. However, total occlusion of one leaflet again caused significant alteration of the results. The slopes decreased to 1.08 for both peak and mean gradients ($p<0.001$). Doppler gradients were now only slightly greater than catheter gradients. Results were statistically identical when proximal velocities $v_i$ (calculated from flow rate and outflow tract dimensions) were considered in the Bernoulli equation.

**Change of Doppler and Catheter Gradients With Prosthetic Valve Malfunction Compared With Normal Baseline State**

The shape of the flow curve considerably changed with incremental occlusion of one leaflet. Therefore, the mean flow rate increased significantly while the peak flow was held constant. The change in gradient caused by malfunction that occurs independently of changes in flow rate can therefore only be reported for instantaneous gradients. Both Doppler and catheter gradients considerably increased with incremental occlusion of one leaflet. However, this increase markedly differed for simultaneous Doppler and catheter gradients (Figure 5). Compared with the normal baseline state, catheter gradients increased by 47%, 113%, 145%, 208%, and 357% on average with incremental occlusion of one leaflet. The simultaneously measured Doppler gradients, on the other hand, increased by only 24%, 55%, 75%, 115%, and 160%.

**Discussion**

**Discrepancy Between Doppler and Catheter Gradients Across Heart Valve Prostheses**

Although good agreement between Doppler and catheter gradients has been found for native aortic valve stenosis,1-3 this has not always been the case for heart valve prostheses.4-6 Particularly for mechanical valve prostheses, conflicting results have been reported. Some authors have demonstrated good agreement between Doppler and catheter measurements.10-12 However, others have found that Doppler gradients substantially overestimated catheter gradients.4-6 Recent in vitro studies5 have demonstrated the dependence of the Doppler–catheter gradient relation on the geometric design of valve prostheses. Whereas acceptable agreement was found for normal Medtronic-Hall tilting disc and Hancock bioprosthetic valves, Doppler gradients significantly exceeded catheter gradients in normal St. Jude bileaflet and Starr-Edwards caged-ball valves. For St. Jude valves, it has also been demonstrated that these discrepancies between Doppler and catheter gradients are not due to erroneous measurements by either technique but to spatial variation of pressure within and distal to the valve.7 Catheter pullback measurements showed that Doppler gradients accurately reflected the highest obtainable catheter gradient, which was a localized gradient occurring between the two leaflets of the valve (but not in the side orifices).7 However, when distal pressures were measured 30 mm downstream from the valve, catheter gradients decreased and were significantly smaller than Doppler gradients. The difference between Doppler and catheter measurements was therefore due to localized high gradients and pressure recovery and to the fact that the two techniques measured gradients in different locations.7 Doppler gradients reflected the highest gradient along the interrogation line, whereas catheterization measures a recovered pressure further downstream from the valve. It has been suggested that the differing results of previous studies regarding the agreement between Doppler and catheter gradients may be due to the fact that studies reporting good agreement may
not have included the appropriate combination of valve type, valve size, and flow rate to detect clinically relevant differences between the two techniques. However, another possible explanation could be that there were differences in the functional status of the valves studied. Authors reporting substantial discrepancy between Doppler and catheter gradients for bileaflet valves tested normally functioning prostheses in vitro. These in vitro results seem to be applicable to the clinical setting because high Doppler gradients similar to those found in vitro have also been reported in clinical studies of normal St. Jude valves. However, the results may not be applicable to the setting of malfunctioning valves. Indeed, the effect of prosthetic valve malfunction on the Doppler–catheter gradient relation has not been evaluated previously.

**Effect of Malfunction of Bileaflet Valves on the Doppler–Catheter Gradient Relation**

Although the present study used a different bileaflet valve (CarboMedics) and a different in vitro system, the results for the normally functioning valve were similar to those previously reported for normal St. Jude valves: Doppler peak and mean gradients were approximately twice as high as the catheter gradients. However, this relation was significantly altered by malfunction of the valve. With increasing restriction of one leaflet’s opening, the differences between Doppler and catheter gradients decreased and eventually almost disappeared when one leaflet was totally occluded. Therefore, the occurrence of substantial differences between Doppler and catheter gradients across bileaflet valves seems to require a regularly opening valve. It has been hypothesized that marked spatial variation of pressures within and distal to a bileaflet valve is due to the specific geometric design and flow characteristics of this valve type: The two open leaflets of the valve create a central “tunnel.” The complex flow characteristics and the role of pressure recovery in causing apparent overestimation of pressure gradients by Doppler has been shown for several settings of tunnellike flow obstructions. The “central tunnel” of bileaflet valves apparently allows the development of a localized low-pressure field in the proximal part of the central flow channel. In this “tunnel” with reversed conical shape (angle, 10°), flow expands gradually back into a larger lumen, and significant pressure recovery can occur. The phenomenon of pressure recovery is based on the physical principle of the conservation of energy. As fluid flows through a stenosis, flow accelerates and kinetic energy increases. The total amount of energy, however, is constant, and a corresponding decrease in potential energy (i.e., lateral pressure) has to occur. Where the velocity is highest (i.e., the vena contracta), the pressure is lowest. Downstream from the stenosis, flow velocity decreases with resultant reconversion of kinetic energy to potential energy. In an ideal system without viscosity and no flow separation at the stenosis, kinetic energy downstream from the stenosis would completely be converted to potential energy, and pressure would fully recover. In reality, however, the extent of pressure recovery is significantly reduced because viscosity needs to be considered and because turbulences and some conversion of kinetic energy to heat do occur. The importance of the outflow angle of gradually expanding stenoses for the magnitude of pressure recovery and its effect on Doppler–catheter gradient comparisons has been demonstrated recently in vitro. Pressure recovery increased with decreasing outflow angle and caused substantial differences between Doppler and catheter gradients when the angle reached 20°. Although the flow characteristics of bileaflet valves with their three orifices are more complex, the changes of the central “tunnel" geometry may be one possible explanation for the dependency of the Doppler–catheter gradient relation on prosthetic valve function: It could be hypothesized that regular valve opening with an angle of 10° between the two leaflets results in the greatest magnitude of pressure recovery and therefore the greatest differences between Doppler and catheter gradients. However, when the opening of one leaflet is restricted, the magnitude of pressure recovery and therefore the difference between Doppler and catheter gradient decreases. This may be explained by an increase of flow separation and turbulences that cause increasing loss of kinetic energy by dissipation to heat.

**Changes of Flow Patterns Through the Separate Orifices Caused by Prosthetic Valve Malfunction**

Pressure recovery and the fact that Doppler and catheter measurements are obtained at different distances from the valve are one source of discrepancy between Doppler and catheter measurements. An additional reason for the marked differences between Doppler and catheter gradients across bileaflet valves is the inhomogeneity of the pressure field across the valve orifice. Catheter pullback measurements have shown a considerably lower pressure (i.e., higher pressure gradient) between the two leaflets as compared with the side orifices. The occurrence of a discrete high-velocity region between the two leaflets and considerably lower velocities in the side orifices has recently been confirmed with numerical and in vitro methods. From the results of the present study, it could be hypothesized that the difference between the maximum velocity and the average velocity across the orifice of bileaflet valves decreases with incremental occlusion. Figure 6 shows examples of color Doppler images and three-dimensional profiles of flow across a normally functioning bileaflet valve, a valve with partial occlusion, and a valve with total occlusion of one leaflet. Although these images were obtained in a steady-flow model at relatively low flow rates, they may support this hypothesis. The normal valve shows high velocities at the entrance of the central orifice that considerably exceed the velocities in the side orifices. Central velocity still rapidly decreases between the two leaflets while velocities in the side orifices slightly increase and reach their maximum distal to the leaflet tips. At this distance, side orifice velocities seem to be even slightly higher than the central velocity. This velocity profile is similar to the one that has been reported previously using particle flow visualization. The valve with a partially occluded leaflet still shows a central velocity clearly above average, although the differences between central
velocity and velocities in the side orifices appear to be reduced. However, in the valve with total occlusion of one leaflet, only small differences between the central velocity and the velocity in the remaining side orifice can be noted. Although the central velocity appears to be slightly higher at the valve entrance, velocities in the side orifice still increase and seem to reach a similar level farther downstream.

Turbulences caused by leaflet occlusion also can be noted. The occurrence of turbulences again may suggest that pressure recovery distal to the valve may decrease compared with the normal state. The change in the ratio of effective orifice area to aortic cross-sectional area also suggests a reduction in pressure recovery. Thus, significant changes in the velocity distribution across the orifice and changes in pressure recovery effects may explain the variation of the Doppler–catheter gradient relation that was observed with incremental occlusion of one leaflet in the present study.

**Increase of Doppler and Catheter Gradients Caused by Malfunction of Bileaflet Valves**

When valve opening is restricted, the net pressure drop across heart valve prostheses increases primarily because of reduction of the effective orifice area. For a constant flow rate, the increase of this gradient reflects the severity of prosthetic valve malfunction and the deterioration of the hemodynamic performance.

Because Doppler gradients across normal bileaflet valves reflect a localized gradient rather than the net pressure drop across the valve, the gradients observed in vitro and in vivo are considerably higher than those reported from hemodynamic studies. Because the difference between the highest localized gradient as measured by Doppler and the net gradient as measured by catheter markedly decreases with increasing restriction of one leaflet’s opening, the increase of Doppler gradients caused by malfunction was considerably smaller than the increase of simultaneously measured
catheter gradients in the present study. For example, compared with the normal baseline state, the average peak Doppler gradient increased by 160%, whereas the catheter gradient increased by 357% when one leaflet was totally occluded. Therefore, the increase of Doppler gradients underestimated the true hemodynamic changes.

“Normal” Doppler gradients vary widely because of their marked flow dependence. Therefore, flow-independent parameters such as valve orifice area calculated by the continuity equation have been proposed for the assessment of prosthetic valve function. Because these calculations are also based on localized high velocities between the two leaflets rather than on the average velocity across the orifice, Doppler valve area underestimates the true effective orifice area of bileaflet valves. Because differences between localized high velocities and average velocities across the orifice decrease with incremental occlusion, the decrease of Doppler valve area caused by restricted leaflet opening will also underestimate the true change in the effective orifice area.

Limitations

Because in vitro models like the one used in this study cannot precisely duplicate all characteristics of the complex flow dynamics occurring in patients with an aortic prosthetic valve, the results should be applied to clinical situations with some caution. For example, the differences between Doppler and catheter gradients caused by pressure recovery are also influenced by the size of the aorta and the precise location of the distal pressure measurement. However, the relative changes of the Doppler–catheter gradient relation with valve malfunction should not be influenced by these parameters. Furthermore, the stoppin itself may have affected the flow characteristics. However, this is unlikely, because results were not statistically different when studying the normally opening valve with and without this device. The opening angles were measured without flow across the valve. Because of bearing tolerance of the leaflet, they may have been slightly different when the valve was studied in the flow model.

Clinical Implications

The results of the present study suggest that the previously reported discrepancy between Doppler and catheter gradients across normal bileaflet aortic valve prostheses may be reduced or even disappear in patients with malfunctioning valves. This is due to the marked dependence of the Doppler–catheter gradient relation on the opening angle of the valve. The increase of gradients caused by malfunction of the valve is considerably smaller for Doppler gradients compared with catheter gradients. This may lead to underestimation of the true hemodynamic changes that occur with restricted leaflet opening. This reduced increase of Doppler gradients caused by prosthetic valve malfunction may also contribute to the overlap between “normal” and “abnormal” Doppler gradients. In addition to the flow dependence of gradients, this phenomenon complicates the definition of “normal” gradients for bileaflet valves and the distinction between normal and abnormal valve function based on Doppler gradients.

Because other Doppler parameters that are thought to be flow independent, such as the continuity valve area, are also affected by the varying occurrence of localized high-velocity jets in this valve type, one should exercise caution when trying to assess the function of bileaflet aortic valve prostheses solely on the basis of Doppler data. Additional information on the opening angle would be helpful. However, particularly in the aortic position, opening angles of bileaflet valves are difficult to evaluate with two-dimensional echocardiography. Therefore, the additional use of other techniques, such as digital cinefluoroscopy, which allows the precise measurement of opening angles, may be necessary for an accurate noninvasive assessment of bileaflet prosthetic valve function.

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