Doppler Assessment of Prosthetic Valve Orifice Area
An In Vitro Study

Helmut Baumgartner, MD; Steven S. Khan, MD; Michele DeRobertis, RN; Lawrence S. Czer, MD; and Gerald Maurer, MD

Background. Although Doppler echocardiography has been shown to be accurate in assessing stenotic orifice areas in native valves, its accuracy in evaluating the prosthetic valve orifice area remains undetermined.

Methods and Results. Doppler-estimated valve areas were studied for their agreement with catheter-derived Gorlin effective orifice areas and their flow dependence in five sizes (19/20–27 mm) of St. Jude, Medtronic-Hall, and Hancock aortic valves using a pulsatile flow model. Doppler areas were calculated three ways: using the standard continuity equation; using its simplified modification (peak flow/peak velocity); and using the Gorlin equation with Doppler pressure gradients. The results were compared with Gorlin effective orifice areas derived from direct flow and catheter pressure measurements. Excellent correlation between Gorlin effective orifice areas and the three Doppler approaches was found in all three valve types (r=0.93–0.99, SEE=0.07–0.11 cm²). In Medtronic-Hall and Hancock valves, there was only slight underestimation by Doppler (mean difference, 0.003–0.25 cm²). In St. Jude valves, however, all three Doppler methods significantly underestimated effective orifice areas derived from direct flow and pressure measurements (mean difference, 0.40–0.57 cm²) with differences as great as 1.6 cm². In general, the modified continuity equation calculated the largest Doppler areas. When orifice areas were calculated from the valve geometry using the area determined from the inner valve diameter reduced by the projected area of the opened leaflets, Gorlin effective orifice areas were much closer to the geometric orifice areas than Doppler areas (mean difference, 0.40±0.31 versus 1.04±0.20 cm²). In St. Jude and Medtronic-Hall valves, areas calculated by however technique did not show a consistent or clinically significant flow dependence. In Hancock valves, however, areas calculated by both the continuity equation and the Gorlin equation decreased significantly (p<0.001) with low flow rates.

Conclusions. Doppler echocardiography using either the continuity equation or Gorlin formula allows in vitro calculation of Medtronic-Hall and Hancock effective valve orifice areas but underestimates valve areas in St. Jude valves. This phenomenon is due to localized high velocities in St. Jude valves, which do not reflect the mean velocity distribution across the orifice. Valve areas are flow independent in St. Jude and Medtronic-Hall prostheses but decrease significantly with low flow in Hancock valves, suggesting that bioprosthetic leaflets may not open fully at low flow rates. (Circulation 1992;85:2275–2283)

Key Words • heart valve prostheses • Gorlin formula • Doppler echocardiography

Accurate assessment of prosthetic heart valve function is complicated by the flow dependence of valvular pressure gradients.1–5 Since high pressure gradients may occur across normal prosthetic valves if they are studied at high flow rates, valve gradients may reflect the patient’s hemodynamic state (high or low cardiac output) as much as they do intrinsic valve function. Valve area, which incorporates both flow rate and pressure gradient data, may be a better indicator of prosthetic valve function. Valve areas have traditionally been calculated using the Gorlin equation6 and hemodynamic data measured invasively in the cardiac catheterization laboratory. The advent of Doppler echocardiography has allowed calculation of valve areas noninvasively using the continuity equation, and the accuracy of Doppler-derived valve areas has been well established in stenotic native valves.6–10 However, the accuracy of Doppler in evaluating prosthetic valve area remains undetermined. Promising results have been reported by Rothbart et al11 for bioprosthetic valves. Chafizadeh et al,12 however, used the continuity equation to calculate orifice areas of normal St. Jude mechanical valves and reported valve areas substantially smaller than those published in prior in vivo and in vitro studies.2,13–16 We recently described the presence of localized high velocities in St. Jude bileaflet valves.17 This phenomenon is not usually present in bioprostheses and is not common to all mechanical valves. The

From the Division of Cardiology and Cardiovascular Surgery, Cedars-Sinai Medical Center and UCLA School of Medicine, Los Angeles.

Supported in part by the Western Cardiological Foundation.

H.B. was supported by a grant from the Fonds zur Förderung der wissenschaftlichen Forschung, Vienna.

Address for correspondence: Helmut Baumgartner, MD, Second Department of Internal Medicine/Cardiology, Krankenhaus der Barmherzigen Schwestern, Seilerstätte 4, A-4020 Linz, Austria.

Received August 27, 1991; revision accepted February 13, 1992.
development of localized high velocities appears to depend on the specific geometric valve design.\textsuperscript{18} The continuity equation assumes that there is a homogeneous velocity distribution across the orifice whose area is being measured or at least that the velocity measured by Doppler reflects the mean velocity averaged across the orifice. Thus, localized high velocities may be an important source of error when applying the continuity equation.

To address the hypothesis that Doppler valve area calculation is accurate in some prosthetic valve types but may substantially underestimate valve areas in others where localized high velocities occur, Doppler valve areas were compared with Gorlin effective orifice areas and geometric orifice areas by studying St. Jude bileaflet, Medtronic-Hall tilting disk, and Hancock bioprosthetic aortic valves in a pulsatile flow model.

\textbf{Methods}

Prosthetic valve areas were determined in vitro using a pulsatile flow model that has previously been described in detail.\textsuperscript{17} Briefly, the prosthetic valves were mounted between the “ventricular” and “aortic” sections of the flow model, which was driven by a reciprocating pump allowing variation of stroke volume, rate, and ejection time. Aortic pressures of 120–150/50–70 mm Hg were maintained by varying the outflow resistance and the outflow compliance. A 70% H\textsubscript{2}O–30% glycerol solution with 10 g/l cornstarch facilitated Doppler measurements (viscosity, 3.5 cp).

Flow was measured with an ultrasonic flowmeter (Transonic System Inc., model T201) mounted on the inflow tube of the ventricular chamber. Aortic and ventricular pressures were measured with fluid-filled catheters connected to pressure taps 25 mm upstream and downstream from the valve. Pressures were measured with electronic pressure transducers (Abbott Critical Care System) using a 12-channel physiological recorder system (Electronics for Medicine, VR-12).

Flow and pressure tracing were calculated on an image analysis computer (Microsonics CAD 886). Mean systolic flow rates were obtained by integrating flow curves over the systolic time period (defined as the time period during which forward aortic flow occurs). Mean systolic pressure gradients were calculated by integrating the difference between the simultaneously recorded aortic and ventricular pressure waves over the systolic time period.

\textbf{Doppler Echocardiography}

Continuous wave (CW) Doppler measurements were performed with an Ultramark 4 CAD system (Advanced Technology Laboratories) using a Duplex probe (3.5 MHz imaging, 2.0 MHz continuous wave Doppler). An adjustable clamp system allowed fixation of the Doppler transducer in the position where the highest velocities were found. Velocity time integrals, peak Doppler gradients, and mean Doppler gradients were calculated with the on-board quantitation package. Doppler gradients ($\Delta p$) were calculated with the simplified Bernoulli equation: $\Delta p = 4v^2$, where $v$ is velocity. Because the in vitro setting used in this study precluded Doppler measurements upstream from the valve, velocities proximal to the lesion were calculated from the measured peak and mean flow rates and tubing size and ranged from 0.10 to 0.60 m/sec. They were, therefore, neglected in the Bernoulli equation.

Doppler measurements were made on three beats and averaged. Doppler velocities were recorded on paper (Videographic Printer YP 1810) and videotape.

\textbf{Test Protocol}

Five sizes of St. Jude bileaflet (19–27 mm) and Medtronic-Hall tilting disk (20–27 mm) mechanical aortic prostheses and Hancock bioprosthetic valves (19–27 mm) were studied. The sizes 19–25 mm of the Hancock valve were modified orifice models (model 250), whereas the 27-mm Hancock was a standard orifice model (model 242).

For each valve size and type, the mean systolic flow rate was increased in eight steps from 77±8 to 255±18 ml/sec (peak flow rates, from 133±10 to 411±32 ml/sec) by increasing the stroke volume. The heart rate was maintained between 50 and 65 beats per minute. Systolic aortic pressures were maintained between 120 and 150 mm Hg, and diastolic pressures were maintained between 50 and 70 mm Hg. The systolic time periods increased with increasing stroke volume and ranged from 150 to 370 msec.

CW Doppler velocities, ventricular and aortic pressures, and flow rates were recorded simultaneously at each flow rate.

\textbf{Calculation of Prosthetic Valve Orifice Area}

Valve areas were calculated using Doppler data as well as catheter-derived data.

\textbf{Doppler.} Three methods were used to calculate Doppler orifice areas.

First, the standard continuity equation is used:\textsuperscript{7–10}

$$EOA = \frac{SV}{VTI} = \frac{\int Q(t)dt}{\int V(t)dt}$$

(1)

where EOA is effective orifice area, SV is stroke volume (derived from direct flow measurement), VTI is velocity time integral of flow across the prostheses (measured by CW Doppler), $Q$ is flow, and $V$ is velocity.

Second, the simplified continuity equation is used:\textsuperscript{10,20}

$$EOA = \frac{Q_p}{V_p}$$

(2)

where $Q_p$ is peak flow and $V_p$ is peak flow velocity across the valve.

Third, the Gorlin equation is used:

$$EOA = \frac{Q}{44.3\times\sqrt{\Delta p}}$$

(3)

where $Q$ is mean flow and $\Delta p$ is mean Doppler pressure gradient.

\textbf{Catheter method.} The Gorlin equation was used (see Equation 3). Measurements with catheter gradients <1 mm Hg were excluded from subsequent area calculations due to difficulties in accurately measuring these very small pressure differences.
The empiric constant 44.3 has been widely used in the Gorlin equation for stenotic native aortic valves and prosthetic valves. For theoretical reasons, a different constant of 51.6 has been used in in vitro studies of prosthetic valves (assuming a value of unity for the discharge coefficient). We therefore also calculated Gorlin areas using a constant of 51.6.

Geometric calculation of mechanical valve areas. In Medtronic-Hall valves, actual valve areas were calculated as proposed by Cannon et al.23 for Björk-Shiley prostheses. The area of the full orifice such as determined from the inner diameter was reduced by the projected area of a 15° tilted-disk ellipse (measured from the axis of flow).

In St. Jude valves, the full orifice area was obtained by planimetry, since the valve is not perfectly circular (personal communication, St. Jude Medical Inc.). The projected area of the open leaflets was estimated as the area of two half-ellipses tilted 5° using the measured major and minor axes of the disks. The projected area of the leaflets was then subtracted from the full orifice area. Although these assumptions are not perfectly correct due to the more complex geometry of the valve, the error should be acceptable since the projected areas are very small due to the small angle between flow axis and leaflet of 5°.

Previously published clinical and in vitro orifice areas of valves tested in the present study were tabulated for comparison (including Hancock orifice areas obtained from planimetry of photographed orifices).

Statistical Analysis

The relation between Doppler and catheter valve areas was assessed by linear regression analysis, and Pearson correlation coefficients were calculated. To better test the agreement between the two techniques, the mean difference between Doppler and catheter valve areas (±SD) was calculated.24 The flow dependence of Doppler and Gorlin valve areas was evaluated using an ANCOVA for each valve type. Valve area was modeled as a function of valve size (i) and flow rate (F) where size was a grouping variable and flow rate was a covariate. This resulted in the following model: area = A_i + B(F) + ε, where area is the area of the ith valve size, A_i represents the valve size effects (the mean valve area for valve size i), B is the slope of the overall relation of area to flow, and ε is a random error term. The ANCOVA model tests to determine whether the slope of the overall flow relation, B, is different from 0. If the slope is significantly different from 0, we can conclude that there is a significant change in area with flow rate. All calculations were done with program BMDFP-1V (BMDP Statistical Software, Westwood, Calif.).

Results

The valve areas calculated with the different methods are summarized in Tables 1–3 for each valve size and type. Valve areas reported in previous studies2-13,16,21,22,25-29 are also shown for comparison.

Table 1. St. Jude Aortic Valve Orifice Area

<table>
<thead>
<tr>
<th>Size</th>
<th>19 mm (±SD)</th>
<th>21 mm (±SD)</th>
<th>23 mm (±SD)</th>
<th>25 mm (±SD)</th>
<th>27 mm (±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuity area</td>
<td>0.77±0.04</td>
<td>0.93±0.06</td>
<td>1.21±0.05</td>
<td>1.58±0.07</td>
<td>2.15±0.10</td>
</tr>
<tr>
<td>Modified continuity area</td>
<td>0.88±0.04</td>
<td>1.09±0.04</td>
<td>1.45±0.08</td>
<td>1.83±0.11</td>
<td>2.50±0.04</td>
</tr>
<tr>
<td>Doppler Gorlin area*</td>
<td>0.71±0.03</td>
<td>0.87±0.05</td>
<td>1.11±0.07</td>
<td>1.45±0.06</td>
<td>1.99±0.20</td>
</tr>
<tr>
<td>Doppler Gorlin area†</td>
<td>0.82±0.03</td>
<td>1.01±0.05</td>
<td>1.29±0.08</td>
<td>1.69±0.07</td>
<td>2.32±0.23</td>
</tr>
<tr>
<td>Catheter Gorlin area*</td>
<td>0.94±0.03</td>
<td>1.11±0.05</td>
<td>1.43±0.08</td>
<td>2.21±0.10</td>
<td>3.20±0.02</td>
</tr>
<tr>
<td>Catheter Gorlin area†</td>
<td>1.10±0.04</td>
<td>1.30±0.06</td>
<td>1.67±0.09</td>
<td>2.58±0.12</td>
<td>3.73±0.03</td>
</tr>
<tr>
<td>Geometric orifice area</td>
<td>1.48</td>
<td>1.87</td>
<td>2.32</td>
<td>2.81</td>
<td>3.33</td>
</tr>
<tr>
<td>Published in vitro data‡</td>
<td>1.4</td>
<td>1.77±2.08</td>
<td>2.19</td>
<td>2.66±3.23</td>
<td>3.16±4.09</td>
</tr>
<tr>
<td>Published in vivo data‡</td>
<td>0.9±1.4</td>
<td>1.40</td>
<td>2.32±0.04</td>
<td>2.62±0.17-2.60–3.67</td>
<td>3.28±1.53</td>
</tr>
</tbody>
</table>

*Gorlin areas calculated with constant 51.6.
†Gorlin areas calculated with constant 44.3.
‡References 2 and 13–16.

Comparison Between Doppler Valve Areas and Catheter Gorlin Valve Areas

The three Doppler approaches and catheter-derived valve areas were compared using linear regression analysis, and the results are summarized in Table 4. Figure 2 shows the correlation between Doppler areas (standard continuity equation) and catheter Gorlin areas (constant, 44.3) for the three valve types.
Table 2. Medtronic-Hall Aortic Valve Orifice Area

<table>
<thead>
<tr>
<th>Size</th>
<th>20 mm</th>
<th>21 mm</th>
<th>23 mm</th>
<th>25 mm</th>
<th>27 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuity area</td>
<td>1.15±0.09</td>
<td>1.10±0.07</td>
<td>1.46±0.09</td>
<td>1.69±0.09</td>
<td>2.40±0.15</td>
</tr>
<tr>
<td>Modified continuity area</td>
<td>1.36±0.12</td>
<td>1.33±0.11</td>
<td>1.73±0.10</td>
<td>2.02±0.08</td>
<td>2.82±0.07</td>
</tr>
<tr>
<td>Doppler Gorlin area*</td>
<td>1.06±0.08</td>
<td>1.04±0.06</td>
<td>1.40±0.12</td>
<td>1.56±0.12</td>
<td>2.30±0.24</td>
</tr>
<tr>
<td>Doppler Gorlin area†</td>
<td>1.24±0.09</td>
<td>1.22±0.07</td>
<td>1.63±0.14</td>
<td>1.82±0.14</td>
<td>2.67±0.27</td>
</tr>
<tr>
<td>Catheter Gorlin area*</td>
<td>1.15±0.05</td>
<td>1.13±0.08</td>
<td>1.37±0.04</td>
<td>1.80±0.14</td>
<td>2.35±0.10</td>
</tr>
<tr>
<td>Catheter Gorlin area†</td>
<td>1.34±0.06</td>
<td>1.32±0.09</td>
<td>1.60±0.05</td>
<td>2.10±0.17</td>
<td>2.74±0.11</td>
</tr>
<tr>
<td>Geometric orifice area</td>
<td>1.49</td>
<td>1.49</td>
<td>1.88</td>
<td>2.33</td>
<td>2.91</td>
</tr>
<tr>
<td>Published in vitro data‡</td>
<td>...</td>
<td>1.80</td>
<td>...</td>
<td>2.99</td>
<td>3.66</td>
</tr>
<tr>
<td>Published in vivo data‡</td>
<td>...</td>
<td>1.56–1.85</td>
<td>2.17–2.20</td>
<td>2.11–2.47</td>
<td>2.25–2.60</td>
</tr>
</tbody>
</table>

*Calculated with constant 51.6.
†Calculated with constant 44.3.
‡References 14, 23, and 24.

valve areas. The mean difference between Doppler continuity and catheter Gorlin area using the constant 44.3 was 0.003 and 0.01 cm², respectively; with the constant 51.6, it was 0.19 and 0.25 cm², respectively. In St. Jude valves, however, Doppler areas were consistently lower than catheter valve areas with differences as great as 1.6 cm² (mean difference, 0.33±0.28 and 0.57±0.39 cm² depending on the constant used in the Gorlin equation).

Agreement Among the Three Doppler Methods

Although the differences were relatively small in absolute terms, Doppler valve areas calculated with the modified continuity equation (peak flow/peak velocity) were consistently larger than those derived from the standard continuity equation in all three valve types (mean±SD difference: St. Jude, 0.22±0.11 cm²; Medtronic-Hall, 0.29±0.12 cm²; Hancock, 0.17±0.07 cm²). Doppler Gorlin areas using a constant of 51.6 yielded the smallest values (mean difference between modified continuity equation areas and Doppler Gorlin areas: St. Jude, 0.32±0.16 cm²; Medtronic-Hall, 0.38±0.17 cm²; Hancock, 0.27±0.08 cm²). With a constant of 44.3, the calculated Doppler Gorlin areas were between standard and modified continuity equation areas.

Mathematically Obtained Geometric Orifice Areas

The mathematically obtained geometric orifice areas of St. Jude and Medtronic-Hall valves are shown in Tables 1–3. Of all of the measured orifice areas, catheter Gorlin areas using a constant of 44.3 were closest to these theoretical orifice areas but still were slightly smaller. The mean difference was 0.40±0.31 cm² in St. Jude valves and 0.20±0.11 cm² in Medtronic-Hall valves. Doppler valve areas (standard continuity equation) were slightly smaller than geometric orifice areas in Medtronic-Hall valves (mean difference, 0.46±0.15 cm²). However, Doppler areas were substantially smaller in St. Jude valves (mean difference, 1.04±0.20 cm²).

Valve Area–Flow Relation

Catheter (Gorlin) valve areas and Doppler (continuity equation) valve areas are plotted versus flow rate for the three valve types in Figures 3 and 4. In St. Jude and Medtronic-Hall valves, no consistent relation between flow and valve area was found. The scatter of the calculated areas increased with increasing valve size due to the low velocities and gradients of larger St. Jude and Medtronic-Hall valves. Since these numbers occur in the denominator in Gorlin and continuity equation,

Table 3. Hancock Aortic Valve Orifice Area

<table>
<thead>
<tr>
<th>Size</th>
<th>19 mm</th>
<th>21 mm</th>
<th>23 mm</th>
<th>25 mm</th>
<th>27 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuity area</td>
<td>0.74±0.09</td>
<td>0.93±0.14</td>
<td>1.16±0.19</td>
<td>1.34±0.27</td>
<td>1.07±0.17</td>
</tr>
<tr>
<td>Modified continuity area</td>
<td>0.82±0.09</td>
<td>1.10±0.13</td>
<td>1.32±0.17</td>
<td>1.56±0.23</td>
<td>1.31±0.16</td>
</tr>
<tr>
<td>Doppler Gorlin area*</td>
<td>0.67±0.09</td>
<td>0.84±0.14</td>
<td>1.06±0.18</td>
<td>1.20±0.25</td>
<td>0.98±0.15</td>
</tr>
<tr>
<td>Doppler Gorlin area†</td>
<td>0.78±0.10</td>
<td>0.98±0.16</td>
<td>1.22±0.21</td>
<td>1.39±0.29</td>
<td>1.15±0.18</td>
</tr>
<tr>
<td>Catheter Gorlin area*</td>
<td>0.68±0.07</td>
<td>0.92±0.13</td>
<td>1.26±0.10</td>
<td>1.32±0.16</td>
<td>1.13±0.15</td>
</tr>
<tr>
<td>Catheter Gorlin area†</td>
<td>0.80±0.09</td>
<td>1.07±0.16</td>
<td>1.46±0.13</td>
<td>1.54±0.19</td>
<td>1.31±0.17</td>
</tr>
<tr>
<td>Published in vitro data‡</td>
<td>0.90–1.13</td>
<td>(0.90) 1.40</td>
<td>1.73</td>
<td>1.41–2.35</td>
<td>1.74±0.13</td>
</tr>
<tr>
<td>Published in vivo data‡</td>
<td>0.89</td>
<td>1.61±0.54</td>
<td>1.46±0.28</td>
<td>1.72</td>
<td>1.78–2.10</td>
</tr>
</tbody>
</table>

*Calculated with constant 51.6.
†Calculated with constant 44.3.
‡References 25–28.
small errors in these variables cause greater variation of valve areas.

In Hancock valves, Gorlin and Doppler valve areas increased consistently and significantly ($p<0.001$) with flow rate. The Doppler areas increased 0.31–0.79 cm$^2$ (52–104%), and the catheter areas increased 0.27–0.57 cm$^2$ (27–54%). The greatest increase in Hancock valve areas occurred at low flow rates. The Hancock Doppler valve areas increased only slightly at higher flow rates with valve areas reaching a plateau level.

**Discussion**

**Assessment of Effective Orifice Area**

Because Doppler velocities and pressure gradients across prosthetic valves are highly flow dependent, an adjustment for flow rate by calculation of effective prosthetic orifice areas is desirable. The ability of Doppler echocardiography to calculate valve areas using the continuity equation has repeatedly been reported for stenotic aortic valves.$^7$-$^10$ However, few data are available regarding the applicability of this technique to prosthetic valves. A recent study$^{11}$ found good correlation between Doppler continuity equation valve areas and invasively derived valve areas in 22 patients with aortic bioprostheses. These results are in good agreement with our in vitro findings for Hancock valves. Because bioprosthetic valves have fluid dynamics similar to those of native valves, it is not surprising that methods for evaluating native aortic stenoses are also accurate in bioprostheses. The fluid dynamics of mechanical valves, however, are more complex, and the homogeneous velocity distribution across the orifice assumed by the continuity equation may not be present.

The present study compared Doppler valve areas with simultaneous Gorlin effective orifice areas in the two most commonly implanted mechanical valves—the St. Jude and the Medtronic-Hall valves. In the latter, the agreement between catheter and Doppler techniques was good, showing results similar to those with bioprostheses. In St. Jude valves, however, Doppler significantly underestimated the catheter valve areas with differences as great as 1.6 cm$^2$. This finding can be explained by the previously reported phenomenon of localized high velocities in this valve, which may be substantially higher than the average velocity across the orifice.$^{17}$ Our results suggest that the applicability of the continuity equation to prosthetic valves, therefore, depends on the valve type: Doppler is relatively accurate in evaluating Gorlin effective orifice areas for bioprostheses and certain mechanical valves such as the Medtronic-Hall tilting disk valve. However, Doppler may significantly underestimate valve areas in prostheses such as the St. Jude bileaflet valve that have localized high velocities detectable by Doppler. The clinical significance of these in vitro results has indirectly been confirmed by a recently published clinical
Among the Three Medtronic-Hall valves; H, vivo studies using velocity integrals of St. Jude valve underestimation. This suggests areas.2

These localized velocities in vitro in study found in the other than those published in all prior in vitro and in vivo studies using methods other than Doppler.2,13-16 This suggests that the localized high velocities observed in vitro in this study are also found in patients by CW Doppler. These localized velocities may also cause underestimation of St. Jude valve areas when the continuity equation is used in patient studies.

Agreement Among the Three Doppler Approaches

For aortic stenosis, application of the continuity equation using velocity integrals and the simplified modification with employment of peak velocities have been reported to be equally accurate.10,20,30 In the present study, modified continuity equation areas were consistently larger than Doppler valve areas calculated from the original continuity equation, although the magnitude of this difference was small (mean, 0.17-0.29 cm²) and may not be of clinical significance. One possible explanation for the difference between the Doppler continuity methods is that the modified continuity equation reflects the peak, fully open valve area when dv/dt=0. The original continuity equation, however, reflects an average valve area during systole. As the valve leaflets open and close, the area available for flow is necessarily smaller than the fully open area.

When the Gorlin equation was used with Doppler-derived gradients and a constant of 44.3, the calculated

**TABLE 4. Correlation and Mean Difference Between Doppler and Catheter Valve Area**

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>R</th>
<th>SEE</th>
<th>Regression equation</th>
<th>Mean difference</th>
<th>Maximal difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. Jude aortic valve</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity area‡</td>
<td>0.99</td>
<td>0.08</td>
<td>0.24+0.54x</td>
<td>-0.57±0.39</td>
<td>-1.57</td>
</tr>
<tr>
<td>Modified continuity area‡</td>
<td>0.98</td>
<td>0.11</td>
<td>0.34+0.57x</td>
<td>-0.40±0.37</td>
<td>-1.28</td>
</tr>
<tr>
<td>Doppler Gorlin area‡</td>
<td>0.99</td>
<td>0.08</td>
<td>0.26+0.57x</td>
<td>-0.49±0.36</td>
<td>-1.38</td>
</tr>
<tr>
<td>Continuity area§</td>
<td>0.99</td>
<td>0.08</td>
<td>0.24+0.62x</td>
<td>-0.33±0.28</td>
<td>-1.04</td>
</tr>
<tr>
<td>Modified continuity area§</td>
<td>0.98</td>
<td>0.11</td>
<td>0.34+0.63x</td>
<td>-0.15±0.26</td>
<td>-0.75</td>
</tr>
<tr>
<td>Doppler Gorlin area§</td>
<td>0.99</td>
<td>0.07</td>
<td>0.23+0.57x</td>
<td>-0.42±0.31</td>
<td>-1.19</td>
</tr>
<tr>
<td>Medtronic-Hall aortic valve</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity area‡</td>
<td>0.97</td>
<td>0.10</td>
<td>0.08+0.81x</td>
<td>-0.25±0.14</td>
<td>-0.72</td>
</tr>
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<td>Modified continuity area‡</td>
<td>0.96</td>
<td>0.15</td>
<td>0.09+0.97x</td>
<td>0.03±0.15</td>
<td>-0.48</td>
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<tr>
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<td>0.08+0.88x</td>
<td>-0.13±0.14</td>
<td>-0.69</td>
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<td>0.10</td>
<td>0.08+0.95x</td>
<td>0.0±0.10</td>
<td>-0.39</td>
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<td>0.08+1.13x</td>
<td>0.28±0.16</td>
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<td>-0.59</td>
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<td>Hancock aortic valve</td>
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<tr>
<td>Continuity area‡</td>
<td>0.93</td>
<td>0.10</td>
<td>0.06+0.80x</td>
<td>-0.19±0.12</td>
<td>-0.49</td>
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<tr>
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<td>0.11+0.90x</td>
<td>-0.02±0.10</td>
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</tr>
<tr>
<td>Doppler Gorlin area‡</td>
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<td>0.06+0.85x</td>
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<tr>
<td>Doppler Gorlin area§</td>
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<td>0.09</td>
<td>0.04+0.85x</td>
<td>-0.11±0.10</td>
<td>-0.38</td>
</tr>
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</table>

*Mean difference (Doppler and catheter)±SD (cm²).
†SEE and maximal difference in cm².
‡Compared with catheter Gorlin areas using constant 44.3.
§Compared with catheter Gorlin areas using constant 51.6.

**Figure 2.** Doppler (continuity equation) valve area vs. catheter Gorlin (constant, 44.3) valve area. SJ, St. Jude valves; MH, Medtronic-Hall valves; H, Hancock valves. The dashed line represents the line of identity.
areas were close to those calculated with the original continuity equation. With a constant of 51.6, the areas were significantly smaller than either set of continuity equation areas. This may question the use of the constant 51.6 to obtain prosthetic valve effective orifice areas.

Mathematically Obtained Geometric Orifice Areas

The mathematically obtained geometric orifice area in St. Jude and Medtronic-Hall valves was obtained by reducing the full orifice area (within the inner edges of the valve ring) by the projected area of the 5° tilted leaflets and of the 15° tilted disk, respectively (measured from the axis of flow). Considering the three-dimensional nature of the actual orifice and the small angle between flow direction and leaflet (disk) axis keeping resistance low, one might speculate that the calculated orifice areas are close to the effective orifice area available for flow. For theoretical reasons, a constant of 51.6 in the Gorlin equation has been proposed for the calculation of effective prosthetic valve orifice areas. The factor 51.6 was derived from the gravitational acceleration constant (44.3) and the conversion factor (V1.36). The latter is necessary to convert to units of millimeters of mercury and involves the density of mercury. The discharge coefficient was set to 1. In the pulse-duplicator system used in this study, the geometric orifice areas, however, showed the best agreement with catheter Gorlin valve areas when a constant of 44.3 rather than 51.6 was used. There are two possible explanations for this observation. First, the effective orifice area may still be significantly smaller than the geometric orifice area. A discharge coefficient smaller than 1 would then be needed to calculate this area with use of the Gorlin equation. Second, the geometric orifice area may indeed be close to the effective orifice area; however, an additional correcting factor (close to 0.85) may be needed for correct calculation of effective orifice area with the Gorlin equation. The second explanation might be supported by the fact that Doppler Gorlin areas using 44.3 rather than 51.6 also showed better agreement with continuity equation areas that are thought to reflect effective orifice areas rather than anatomic orifice areas.

Although the results of the present study support the use of the classic Gorlin constant, 44.3, in St. Jude and Medtronic-Hall valves in vitro, testing of the same valves under different in vitro conditions may yield different in vitro results. Nevertheless, this study confirms that the Gorlin equation is of acceptable accuracy in this use, whereas Doppler substantially underestimates the true orifice area in St. Jude valves.

Area–Flow Relation

In mechanical valves, the variation of calculated orifice areas with changing flow rates was small regardless of the technique used. No consistent flow–area relation was found. These results suggest that differences in flow do not explain the considerable scatter of reported valve areas, at least in St. Jude and Medtronic-Hall valves (Tables 1–3).

In Hancock valves, valve areas increased with increasing flow rate regardless of the technique used, particularly in the lower range of flow rates. Similar increases
in Gorlin effective orifice areas in bioprosthetic valves have been reported in vivo and in vitro for both Hancock and Carpentier-Edwards valves.\textsuperscript{3,5,26,31} One explanation is that valves may not fully open at lower flow rates. Chambers et al\textsuperscript{31} found that the maximal area in Carpentier-Edwards porcine mitral bioprostheses was attained above a mean flow level of approximately 10 l/min (166.7 ml/min), although there was individual variation. Gabbay et al,\textsuperscript{28} however, reported increases in Gorlin areas with increasing flow rates, although the planimetered orifice areas did not change significantly at the same time. Cannon et al\textsuperscript{29} found a flow dependence of Gorlin areas even with simple orifices with fixed areas.

Our results show a clear difference between mechanical prostheses, which demonstrated little variation of valve areas with increasing flow, and bioprostheses, where valve areas increased directly with flow. Consistent increases in Hancock orifice areas were found using both the Gorlin equation and the continuity equation. In tissue valves, which have relatively stiff leaflets after fixation, it is reasonable that orifice size actually increases with increasing flow and the concomitant expected increase in pressure against the valve leaflets. This would explain the different findings in mechanical and bioprosthetic valves and favors the presence of actual changes in orifice area as the cause of the flow dependence of bioprosthetic valve areas.

Limitations

One limitation of the present study is the standard of reference that was used to evaluate the accuracy of Doppler prosthetic valve areas. In mechanical valves, there is no method to estimate actual orifice area. This is particularly evident with the Starr-Edwards valve where the method of subtracting the projected area of the occluding ball from the full orifice area, used by Cannon et al\textsuperscript{23} to estimate anatomic valve area, results in a negative valve area. In addition, the actual area available for flow is smaller than the geometric area due to contraction of the flow stream downstream of the orifice,\textsuperscript{30} even for simple orifices. On the other hand, a tilted disk probably has less resistance than a flat ellipse of the same projected area. Presently, there is no available method that provides estimates of anatomic or effective prosthetic valve area, and therefore the Gorlin equation is routinely used by prosthetic valve manufacturers to provide an estimate of the "effective" orifice area. Due to the lack of alternatives and to allow comparison with previous reports, the Gorlin equation was also used in the present study. In the past, constants of either 44.3 (used mainly in in vivo studies)\textsuperscript{25,26,34} or 51.6 (used mainly in in vitro studies)\textsuperscript{13,21,22} were used. The Gorlin equation has repeatedly been criticized,\textsuperscript{31,32,35,36} and other approaches have been suggested,\textsuperscript{31,32,35,37} but they have not become generally accepted. Particular concern has been expressed about the numbers used for the Gorlin constant since pressure dependence\textsuperscript{32} and valve type dependence\textsuperscript{28,35} were observed. Nevertheless, catheter Gorlin areas showed relatively good agreement with geometrically calculated orifice areas in this study.

Another limitation of the present study is that Doppler velocities or gradients were combined with flow estimates obtained from flowmeter measurements to calculate valve areas. When the continuity equation or the Gorlin equation is used in clinical studies to estimate orifice areas from Doppler measurements, flow is obtained from velocity and dimension measurements of the left ventricular outflow tract or from right heart catheterization using the thermodilution technique. The in vitro setting used in this study precluded Doppler measurements upstream from the valve. It has already been established, however, that Doppler is capable of measuring stroke volume in the left ventricular outflow tract with reasonable accuracy.\textsuperscript{38} Our flow measurements were calibrated against timed collections and found to be accurate. It is very likely that the in vitro flow measurements used here were more accurate than the clinical measurements. The accurate assessment of flow allows us to specifically study the influence of prosthetic valve flow profiles and velocity measurements on the area calculation. Clinical application of the Doppler continuity equation may yield less consistent results due to errors in measuring flow and may explain the greater scatter of valve areas reported for a given valve size in clinical Doppler studies\textsuperscript{11,12} compared with our in vitro results.

Conclusions

The accuracy of Doppler echocardiography in determining effective prosthetic orifice areas depends on the valve type; Doppler may be accurate in bioprostheses and certain mechanical valves such as the Medtronic-Hall tilting disk valve but may significantly underestimate valve areas in prostheses with occurrence of localized high velocities such as the St. Jude bileaflet valve. In such valves, the maximal velocities detected by Doppler do not reflect the mean velocity distribution across the orifice.

Although the differences are small in absolute terms, Doppler valve areas calculated from the modified continuity equation (peak flow/peak velocity) are larger than those obtained from the original equation; Doppler Gorlin valve areas in vitro are similar to continuity equation areas when using a constant of 44.3.

Catheter Gorlin areas using the constant 44.3 show the best agreement with the mathematically calculated geometric orifice areas.

Prosthetic valve areas calculated by continuity equation and Gorlin valve areas (using catheter as well as Doppler gradients) are relatively independent of flow in St. Jude and Medtronic-Hall valves, but they increase significantly with flow rate in Hancock valves, particularly at low flow rates. This suggests that Hancock valves may not open fully at low flow rates. Flow rate must be considered in these valves when any form of valve area calculation is performed to assess prosthetic valve function.

References


