Assessment of the Björk-Shiley Prosthetic Valve Orifice Area in the Aortic Position

Atsushi Iguchi, MD; Koichi Tabayashi, MD

The actual orifice area of a valve is still considered to be a valuable index for assessing prosthetic valve function. Valve orifice area as calculated by Gorlin's formula is, however, not constant but changes in proportion to the transvalvular flow rate. The purpose of the present study was to examine the relationship between orifice area and flow rate across the Björk-Shiley prosthetic valve as calculated by Gorlin's formula, and to modify the formula in a series of patients with the Björk-Shiley prosthetic valve in the aortic position. Fifty-six patients who had received aortic valve replacement with a Björk-Shiley prosthetic valve underwent cardiac catheterization. Prosthetic valve orifice area was calculated by Gorlin's formula and then plotted against flow rate across the valve with respect to valve size. The relationship between orifice area and flow was linear. The discharge coefficient of Gorlin's formula was plotted against flow rate, and a linear correlation was obtained. By substituting Gorlin's formula for an empiric coefficient into the function for transvalvular flow rate, a modified formula that can predict the actual orifice area of the prosthetic valve is obtained. (Jpn Circ J 1998; 62: 97–101)

Key Words: Gorlin's formula; Björk-Shiley valve; Valve orifice area

Assessment of prosthetic valve area remains an unsolved clinical problem. Doppler echocardiography using a continuity equation is currently applied as a non-invasive alternative approach to the calculation of prosthetic valvular areas. The valve orifice area estimated by Gorlin's formula has been considered a reference standard, and is still used routinely in catheterization laboratories. However, Gorlin's formula has been proved to have limitations, and modified formulae for calculating valve orifice area, based on in vitro hydrodynamic studies, have been proposed by Asslid et al. and Gabbay et al. However, these revised formulae have not been widely adopted in the clinical setting because they require continuous measurement of transvalvular flow as well as pressure. Several other investigations have been performed to determine the flow dependence of Gorlin's formula for calculating prosthetic valve orifice area.

The purposes of the present study were (1) to examine the relationship between orifice area and flow rate across the Björk-Shiley valve calculated by Gorlin's formula and (2) to modify the formula to allow determination of the actual area of the orifice of the prosthetic valves in a series of patients fitted with Björk-Shiley prosthetic valves in the aortic position.

Subjects and Methods

Patients

The study group was made up of 56 patients who had undergone cardiac catheterization between 1989 and 1995.

Hemodynamic Measurements

Cardiac output (CO; ml/min) was measured using angiographic and thermodilution techniques, and systolic transvalvular flow (Q; ml/sec) was calculated from the formula:

\[ Q = CO / SEP \]

where SEP (sec/min) represents systolic ejection period per minute determined from pressure tracings. A pigtail catheter was positioned in the ascending aorta, and a Brockenbrough catheter was positioned in the left ventricle through the transseptal approach. Left ventricular pressure and ascending aortic pressure 5 cm above the aortic valve were recorded using micromanometer catheters (Camino distal pressure monitor Model 420, Camino Laboratories, San Diego, CA, USA). The mean transvalvular pressure gradient during systole was calculated by graphic techniques from recorded pressure tracings. Aortography was performed for quantitative assessment of aortic regurgitation. Complete opening to 60° and closure of the tilting disk were confirmed by cineangiograms. The sound spectral approach developed at our institution was applied for detection of thrombosis or tissue overgrowth in the prosthesis. Exclusion criteria included more than mild aortic regurgitation caused by perivalvular leakage, significant tricuspid regurgitation, or radiographically diagnosed prosthetic malfunction. Five patients were excluded from the study because of massive tricuspid regurgitation (2 patients), significant aortic
regurgitation caused by perivalvular leakage (2 patients), or a malfunctioning prosthetic valve (1 patient).

Aortic valve orifice area (cm²) was calculated from Gorlin's formula in its original form:

Aortic valve orifice area = F/[44.3 × √P]

where F is transvalvular flow rate (ml/sec) and P (mmHg) is mean transvalvular gradient. Based on previous investigations, we postulate that the empiric constant (C) in Gorlin's formula is a function of the transvalvular flow rate and could be used to calculate actual orifice area:

Actual orifice area = F/[C × 44.3 × √P]

As the empiric constant for each size of the prosthetic valve cannot be identified, C₀ is first calculated from the formula:

Actual orifice area = F/[C₀ × 44.3 × √P]

Therefore

Table 1 Patients' Demographics

<table>
<thead>
<tr>
<th>Size</th>
<th>n</th>
<th>Age (years)</th>
<th>BSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS21A</td>
<td>11</td>
<td>53 ± 6</td>
<td>1.41 ± 0.08</td>
</tr>
<tr>
<td>BS23A</td>
<td>15</td>
<td>56 ± 12</td>
<td>1.57 ± 0.01</td>
</tr>
<tr>
<td>BS25A</td>
<td>20</td>
<td>57 ± 8</td>
<td>1.74 ± 0.14</td>
</tr>
<tr>
<td>BS27A</td>
<td>10</td>
<td>57 ± 6</td>
<td>1.68 ± 0.08</td>
</tr>
</tbody>
</table>

BS, Björk-Shiley; n, number of patients; BSA, body surface area.

Table 2 Cardiac Catheterization Data

<table>
<thead>
<tr>
<th>Size</th>
<th>PG</th>
<th>Flow</th>
<th>Area 1</th>
<th>CO</th>
<th>HR</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS21A</td>
<td>25.8 ± 9.9</td>
<td>287 ± 80</td>
<td>1.35 ± 0.43</td>
<td>5.34 ± 3.10</td>
<td>77.7 ± 21.3</td>
</tr>
<tr>
<td>BS23A</td>
<td>17.7 ± 6.4</td>
<td>325 ± 75</td>
<td>1.71 ± 0.30</td>
<td>5.13 ± 1.32</td>
<td>77.5 ± 25.3</td>
</tr>
<tr>
<td>BS25A</td>
<td>19.9 ± 5.4</td>
<td>392 ± 77</td>
<td>2.01 ± 0.33</td>
<td>6.37 ± 2.05</td>
<td>70.0 ± 25.3</td>
</tr>
<tr>
<td>BS27A</td>
<td>12.4 ± 2.8</td>
<td>374 ± 63</td>
<td>2.43 ± 0.41</td>
<td>4.95 ± 1.64</td>
<td>63.6 ± 11.2</td>
</tr>
</tbody>
</table>

PG, pressure gradient across the aortic prostheses (mmHg); Flow, transvalvular flow rate (ml/min); Area 1, orifice area calculated by Gorlin's formula (cm²); CO, cardiac output (L/min); HR, heart rate (beats/min).

Fig 1.
Table 3  Constants C1 and C2 for Each Size of the Prosthetic Valve and Orifice Area Calculated by Modified Formula

<table>
<thead>
<tr>
<th>Size</th>
<th>C1</th>
<th>C2</th>
<th>R²</th>
<th>Value</th>
<th>Area 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS23A</td>
<td>0.124</td>
<td>0.0045</td>
<td>0.606</td>
<td>&lt;0.005</td>
<td>1.09±0.22</td>
</tr>
<tr>
<td>BS23A</td>
<td>0.549</td>
<td>0.00245</td>
<td>0.609</td>
<td>&lt;0.005</td>
<td>1.27±0.14</td>
</tr>
<tr>
<td>BS25A</td>
<td>0.518</td>
<td>0.00194</td>
<td>0.515</td>
<td>&lt;0.001</td>
<td>1.57±0.18</td>
</tr>
<tr>
<td>BS27A</td>
<td>0.482</td>
<td>0.00218</td>
<td>0.604</td>
<td>&lt;0.005</td>
<td>1.99±0.21</td>
</tr>
</tbody>
</table>

BS, Björk-Shiley; Area 2, orifice area calculated by the modified formula.

Fig 2.

Table 4  Difference Between Anatomic Orifice Area and Calculated Orifice Area

<table>
<thead>
<tr>
<th>Size</th>
<th>n</th>
<th>Difference</th>
<th>t</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS23A</td>
<td>11</td>
<td>0.34±0.43</td>
<td>2.60</td>
<td>0.027</td>
</tr>
<tr>
<td>Area 1</td>
<td>11</td>
<td>0.0018±0.22</td>
<td>0.03</td>
<td>0.977</td>
</tr>
<tr>
<td>Area 2</td>
<td>15</td>
<td>0.44±0.30</td>
<td>5.63</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BS25A</td>
<td>15</td>
<td>0.0012±0.14</td>
<td>0.03</td>
<td>0.983</td>
</tr>
<tr>
<td>Area 1</td>
<td>20</td>
<td>0.44±0.33</td>
<td>6.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Area 2</td>
<td>20</td>
<td>0.0012±0.18</td>
<td>0.03</td>
<td>0.975</td>
</tr>
<tr>
<td>BS27A</td>
<td>10</td>
<td>0.57±0.34</td>
<td>5.26</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Area 1</td>
<td>10</td>
<td>0.0009±0.21</td>
<td>0.01</td>
<td>0.991</td>
</tr>
</tbody>
</table>

BS, Björk-Shiley; n, number of patients; Difference, difference between anatomic orifice area and calculated orifice area (cm²).
Area 1, orifice area calculated by the Gorlin's formula; Area 2, orifice area calculated by the modified formula.

C₀ = calculated orifice area/actual orifice area
In this equation, the prosthetic valve orifice area derived by Gorlin's formula is applied as a calculated orifice area. The actual orifice area is calculated using the inner ring radius. The area of the full orifice was reduced by the projected area of a tilted-disk ellipse, as shown by Cannon et al. As mentioned above, the empiric constant (C) in Gorlin's formula is a function of the transvalvular flow rate,

Function C = f(F)

and is determined by plotting C₀ against transvalvular flow rate. The formula is then modified using function C.

Statistical Analysis
Values are expressed as means±standard deviation. The relationship between flow rate and discharge coefficient and orifice area was evaluated by linear regression analysis using the least-squares method. The level of significance was established as p < 0.05.

Results
Hemodynamic variables are summarized in Table 2.
Prosthetic valve orifice areas calculated by Gorlin's formula were plotted against transvalvular flow rate across the valve with respect to valve size (Fig 1). The relationship between orifice area and flow rate was found to be linear. The constant C0 was first calculated and C0 was plotted against flow rate across the prosthetic valve. The linear correlations were obtained and the regression line:

$$\text{Function } C = C_1 + C_2 \times F$$

and $R^2$ value were calculated by regression analysis techniques. $C_1$ and $C_2$ for each size of the Björk-Shiley prosthetic valve and $R^2$ are listed in Table 3. With this correlation, a modified formula may be represented as:

Aortic valve orifice area $= F/[(C_1 + C_2 \times F) \times 44.3 \times \sqrt{F}]$

Prosthetic valve orifice areas calculated by the modified formula are also shown in Table 3 for each size of prosthetic valve. Fig 2 and Table 4 show the difference between actual orifice area and calculated orifice area. Prosthetic orifice area calculated by Gorlin's formula tends to be higher.

**Discussion**

Prosthetic valve malfunction caused by thrombus formation or tissue overgrowth has been observed in a number of patients who have received Björk-Shiley aortic prostheses. Yonagathen et al. have suggested that, once thrombus formation or fibrous tissue overgrowth begins to occlude the minor outflow region of the Björk-Shiley prosthesis, the regions of stasis become larger and thrombus formation may accelerate further. Early diagnosis of prosthetic valve malfunction is, therefore, imperative before massive thrombotic occlusion of the prosthetic valve leads to catastrophic hemodynamic impairment. The sound spectral approach developed for screening of prosthetic valve thrombosis has been reported to be a valuable aid in the clinical setting. A ring-shaped radiopaque marker incorporated into the tilting disk of the Björk-Shiley prosthesis allows radiographic diagnosis of prosthetic valve malfunction. The calculation of the actual orifice area of the valve is still considered to be a valuable index of prosthetic valve function, because surgeons traditionally quantified the severity of the valve malfunction by valve orifice area.

Evidence is accumulating that the area calculated by Gorlin’s formula varies with changes in the transvalvular flow rate. Several investigators have attributed this phenomenon to an actual increase in anatomic orifice area with increase in transvalvular flow rate. In vitro studies and animal experiments have demonstrated that the anatomic orifice area of native stenotic valves or bioprostheses alters in response to changes in flow rate. Horstikotte et al. have calculated the orifice area of the Björk-Shiley prosthetic valve in the mitral position by Gorlin’s formula both at rest and during exercise. A substantial increase in prosthetic valve orifice area was found during exercise, and the increase in calculated orifice area was interpreted as an actual increase in the Björk-Shiley prosthetic valve. The tilting disk of the valve in the mitral position is not always fully opened in the resting condition, whereas exercise increases the transvalvular flow and enables the valve to open completely. In the present study, however, a cineradiographic study detected that the disk of the Björk-Shiley prosthetic valve in the aortic position was fully open during the entire ejection period; therefore, an increase in the calculated orifice area cannot be ascribed to an actual increase in the anatomic orifice area. An alternative hypothesis that accounts for the flow dependence of the prosthetic valve orifice area must therefore be considered.

It has been noted that the empiric constant in Gorlin’s formula is not constant but increases directly with an increase in the transvalvular volume flow rate. Gorlin’s formula, in its original form, attempted to calculate an actual orifice area rather than an effective orifice area or hydraulic valve area. Actual valve area and calculated valve area were compared in 11 autopsy or surgical specimens in the original publication. The empiric constant in Gorlin’s formula incorporates the discharge coefficient (Cd), the coefficient of orifice contraction (Cc), and a conversion factor.

The coefficient of orifice contraction is defined as the ratio of jet area (vena contracta) to actual orifice area. Previous studies have postulated that the flow dependence of the calculated orifice area can be explained by either the variability of the discharge coefficient or the coefficient of the orifice contraction. In an in vitro study using a porcine valve and a plate- or nozzle-type stenosis model, it was found that the coefficient of orifice contraction was constant but that the discharge coefficient increased with an increase in Reynolds’ number until a critical Reynolds’ number was reached. It remained constant, however, above the critical Reynolds’ number. The flow-dependent increase in the valve area of the stenotic nozzle- or plate-type valve will be observed only in patients with extremely low cardiac output. In studies of the Björk-Shiley prosthetic valve, the effect of the tilting disk on transvalvular flow was complicated; the tilting disk behaves as an occluder, and viscous losses may occur in the region of flow separation at ordinary flow rate. Therefore, the magnitude of viscous losses cannot be predicted theoretically. We assumed that, if the coefficient of the orifice contraction remained constant, with variation of transvalvular volume flow, then the flow dependence of the prosthetic valve orifice area could be interpreted as variability of the discharge coefficient.

On the basis of results from a clinical study of the Björk-Shiley prosthetic valve, Björk et al. have reported that the pressure gradient across the prosthetic valve is proportional to the transvalvular flow rates to the nth power. They found that n was not constant but depended on the size of the prosthesis: with a 21-mm Björk-Shiley prosthetic valve, $n = 1.39$, whereas with a 25-mm prosthesis $n = 1.30$. Other investigators have also found that the pressure gradient is more closely proportional to the transvalvular flow rate to the first power than to the second power. The orifice areas of the prosthetic valves were calculated using Gorlin’s formula with a constant empiric coefficient and, therefore, the orifice area was shown to increase with the increase in the flow rate. In the present study, the formula can predict actual orifice area of the prosthetic valve, by substituting Gorlin’s formula for an empiric coefficient into the function for transvalvular flow rate.

There are several limitations to the present study that must be addressed. First, the actual orifice area of the
Björk-Shiley prosthetic valve is not easily determined. The effect of the tilting disk on transvalvular flow was quite complicated and the fluid dynamic behavior of the Björk-Shiley prosthetic valve was not sufficiently thoroughly assessed to derive the actual orifice area on a theoretical basis. Second, the locations of the pressure measurements, either proximal or distal to the prosthetic valve, substantially influence the pressure gradient across the prosthetic valve;\textsuperscript{2−26} recovery of pressure does occur distal to the vena contracta. In the present study, a pigtail catheter was positioned 5 cm downstream from the prosthetic valve for the measurement of distal pressure. In patients with mild aortic stenosis, pressure recovery is less important, but we may have underestimated the pressure difference across the prosthetic valve. Third, the number of patients was small, and the patient population was not homogeneous. The patients in the present study underwent aortic valve replacement for either aortic insufficiency or aortic stenosis. Therefore, some patients had left ventricular dilation and other patients had concentric hypertrophy. Following aortic valve replacement, normalization of the left ventricular dimensions and regression of ventricular hypertrophy were observed in most patients. Differences in the geometry of the outflow tract of the left ventricle and the ratio of prosthetic valve orifice area to the area of outflow tract influence valve orifice calculation.\textsuperscript{11} Moreover, aortic diameter is a determinant of Reynolds’ number, and the ratio of prosthetic valve orifice area to aortic cross-sectional area is not exactly the same among patients. These factors were not considered in this study. Investigations with a larger sampling size are needed to confirm this result and determine the constants.

In conclusion, the flow dependence of Gorlin’s formula was explored in patients who had undergone aortic valve replacement using Björk-Shiley prosthetic valves. The formula for the discharge coefficient in terms of flow rate was determined as $C_1 + C_2 \times F$. Further studies are required to determine the constant $C_1$ and $C_2$ in order to predict more accurately the actual orifice area of the prosthetic valve.

References

5. Gorlin R, Gorlin SG: Hydraulic formula for calculation of the area of the stenotic mitral valve, other cardiac valves, and central circulatory shunts I. Am Heart J 1951; 41: 1–29