Mitral Ball-Valve Prosthesis
Dynamic and Clinical Evaluation

By Paul Kezdi, M.D., Louis R. Head, M.D., and Bruce A. Buck

Replacement of nonfunctioning valves is a significant recent advancement in the correction of cardiac valvular disease. The most widely used artificial device replacing the mitral valve is the Starr-Edwards ball-valve prosthesis. Its effectiveness was shown in recent reports by the marked clinical improvement in properly selected patients. However, cardiologists and cardiac surgeons are faced with several problems in the use of this valve, which can be answered only by careful studies of the flow dynamics of the ball-valve prosthesis and hemodynamic and clinical evaluation of the patient before and after surgery. Despite the effective correction of the regurgitation by the Starr valve, it is assumed that the resistance to blood flow through this mechanical device is greater than that of the normal mammalian leaflet valve. The normal mitral valve has a diastolic valve area of 3.5 to 5 cm² while the presently used Starr-Edwards prosthesis has an opening of 1.8 to 3.1 cm² measured at the inner ring of the valve cage. It is assumed that the “effective orifice” is even less, due to changed dynamics of flow during closure and opening of the ball valve. The “stenotic” orifice of the ball-valve prosthesis becomes even more significant during high cardiac outputs of exercise. Studies to determine the “effective orifice” of the Starr-Edwards valve during the diastolic flow and the dynamics of the flow during closure and opening of the valve are therefore important.

It is presumed that the ball-valve prosthesis with the largest “effective orifice” which a given heart will accommodate is the most desirable. This is determined primarily by the size of the mitral annulus into which the rigid ring of the ball-valve prosthesis is sutured. The metal cage of the prosthesis protrudes into the left ventricle. Therefore, the size of the left ventricular cavity is also important. In pure mitral stenosis left ventricular volume and the size of the mitral annulus are small. Depending on the degree of regurgitation, both become larger as regurgitation increases. To predict the size of the valve prosthesis that any given heart can accommodate, left ventricular volume and the size of the mitral annulus must be taken into consideration. Both of these determinations are best made prior to surgery.

The purpose of this study was to evaluate the “effective orifice” of the Starr-Edwards valve by observation of the flow dynamics in a mechanical system containing the valve in which diastolic and systolic phases of the cardiac cycle were simulated. Further, an attempt was made to estimate the size of the mitral annulus and left ventricular volume in candidates for mitral valve prosthesis by biplane left ventricular angiograms. Finally, hemodynamic studies were performed in patients with mitral valve prosthesis and the results were compared with those derived from the flow dynamic observations in the mechanical pulse duplicator.

Methods and Results

Dynamic Studies

A transparent plastic chamber was constructed in which an orifice or a ball valve could be mounted in a plastic diaphragm situated in the middle of a cylindrical chamber. The two chambers thus formed simulated the atrium and the ventricle and are thus labeled. For diastolic flow studies, the chamber was placed in a low-resistance (large-diameter tygon tubing) mechanical circuit.
Figure 1

Schematic drawing of the system used for diastolic flow studies of the ball valve.

containing a Pemco double-roller cardiac pump and connected to an atrial (Ra) and a ventricular (Rv) reservoir (fig. 1). The ventricular reservoir was adjusted so that the ventricular pressure had no effect on the pressure drop across the valve. With the pump forcing water continuously through the valve, pressure drop from the atrium to ventricle was measured by means of two water manometers (Ma-Mv). The resistance of various orifices could then be calculated by equation 1.

\[
\text{Resistance} = \frac{P_a - P_v}{\text{Flow}} \quad \text{Equation 1}
\]

Rather than to calculate the valve resistance directly, it was decided to determine the pressure drop across several known circular orifices of different sizes. Then, by comparison with this family of curves, the "effective orifice" of the ball valve could be determined in relation to its measured orifice. Thus a value is obtained that is more useful clinically than absolute resistance.

According to Gorlin and Gorlin,\(^3\) the area of the mitral valve orifice can be calculated from the formula:

\[
\text{Area} = \frac{\text{Flow}}{C \times \sqrt{P_a - P_v}} \quad \text{Equation 2}
\]

where C is an empirical constant and \(P_a\) and \(P_v\) are pressures in the respective chambers during diastolic flow. This formula assumes that the orifice is a short tube beginning and ending in larger chambers. This is the case in the stenotic mitral valve and also in the mechanical system used in the following determinations. It is seen from equation 2 that one may expect a parabolic curve if pressure drop is plotted as a function of volume flow. This has been found to be the case in a stenotic mitral valve with a large pressure drop.\(^4\) Figure 2, obtained from the data of this experiment, shows that the equation is also applicable to orifices greater than 1 cm.\(^2\), although the standard deviation of individual measurements is greater with the larger valves. This is understandable if one considers the small pressure differences involved and the difficulty in their measurement from water manometers. The curves in figure 2 were obtained by calculating the average constant, C, from the pressure drop measured on the more reliable portion of the curve (6,800 to 8,900 ml. per minute) and by using this value while drawing the ideal curve.

Two sizes of Starr-Edwards ball valve prosthesis, the smaller with an orifice of 1.45 cm. in diameter (1.65 cm.\(^2\)) and the larger with an orifice of 2.00 cm. in diameter (3.14 cm.\(^2\)) were compared with circular orifices of the same size but without the ball valve. For mechanical system used in the following determinations. It is seen from equation 2 that one may expect a parabolic curve if pressure drop is plotted as a function of volume flow. This has been found to be the case in a stenotic mitral valve with a large pressure drop.\(^4\) Figure 2, obtained from the data of this experiment, shows that the equation is also applicable to orifices greater than 1 cm.\(^2\), although the standard deviation of individual measurements is greater with the larger valves. This is understandable if one considers the small pressure differences involved and the difficulty in their measurement from water manometers. The curves in figure 2 were obtained by calculating the average constant, C, from the pressure drop measured on the more reliable portion of the curve (6,800 to 8,900 ml. per minute) and by using this value while drawing the ideal curve.

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obtaining a curve, a similar method was used as for the curves in figure 2. Figures 3 and 4 show the results. As can be seen, the curves do not overlap. The value for C obtained with the simple orifice encompasses the energy loss in flow through that orifice. The mechanical obstruction of the ball and cage of the Starr-Edwards valve results in greater energy loss. This greater loss will be reflected in the constant (C') obtained from the ball valve curve. From equation 2 it is seen that the "effective area," or flow, varies directly with C at any given pressure. Comparison of C values from the experimental data gives the following:

\[
\frac{C'}{C} = \frac{27.6}{33.1} = 83.4 \text{ per cent}
\]

\[
\frac{C'}{C} = \frac{21.5}{24.2} = 88.9 \text{ per cent}
\]

The smaller valve used in this experiment had a larger percentage of the flow stream obstructed by the metal cage than the larger valve. It is therefore concluded that diastolic flow of water through a Starr-Edwards ball-valve mitral prosthesis is approximately 83 to 89 per cent of that through a similar orifice without the ball and cage. Or, in other words, the "effective orifice" is 83 to 89 per cent of the measured orifice.

The greater inertia of the ball valve might allow some regurgitation in early systole but no regurgitation during mid-systole. Therefore, it was decided to study the most important portions of systole, the periods during valve closure and opening. In order to estimate the dynamics involved at these times, the mechanical system was constructed as shown in figure 5. The cardiac cycle was simulated by adjusting the Pemco roller pump so that one of the two rollers was not occlusive and thus allowed free regurgitation retrograde through the pump. The ventricular reservoir was ele-
the valve was opened and water flowed from atrium to ventricle under pressure ($P_a$). The pressures, $P_a$ and $P_v$, were measured by Sanborn pressure transducers and recorded on a model-150 multichannel recorder. In this relatively rigid mechanical system (plastic, glass, tygon tubing), "resonance" produced great pressure fluctuations, even during adynamic portions of the cycle. This was partially corrected by a rubber tubing depulsator as described by Head et al.\(^4\) The time relationships of the pressure curves with use of a no.-4M Starr-Edwards valve (3.14 cm.\(^2\)) is shown in figure 6. This tracing illustrates characteristics that were present on all curves obtained. There is a definite time interval before the valve closes when the ventricular pressure suddenly increases. This period (S-C) is characterized by an average pressure less than systolic ventricular pressure, the ventricular pressure being, however, higher than the atrial. These

![Figure 5](http://circ.ahajournals.org/)

**Figure 5**

Schematic drawing of the system used for systolic flow studies of the ball valve.

![Figure 6](http://circ.ahajournals.org/)

**Figure 6**

Simultaneous pressures in the ventricular and atrial chambers of the mechanical system with a Starr-Edwards valve of 3.14 cm.\(^2\) orifice. S-C, time interval between beginning of pressure rise and closure of the valve; D-O, time interval between beginning of pressure drop and opening of the valve; X, point at which pressure in the ventricular chamber reaches that of the atrial chamber.

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facts indicate that there is flow from ventricle to atrium (regurgitation through the valve) during this period of time. The actual amount of regurgitation could not be measured with the system as it was constructed. Knowing the time interval S-C (0.32 second in this case), the pressure gradient between the ventricular and atrial chambers, and the area of the ball-valve opening, one might calculate the volume of regurgitation from the following equation:

\[ RF = \frac{VA \times C \times \sqrt{P_v - P_a}}{(S-C) \text{sec./min.}} \]

Equation 3

RF, regurgitant flow; VA, valve area in cm.\(^2\); C, constant. The calculated regurgitation in the illustrated valve was 14.1 ml. per cycle, which is rather large.

The second point of interest occurs with the unseating of the valve. Observation of the valve action in the transparent chamber showed that the ball was tightly wedged into the orifice with systolic pressure, and was forcibly ejected at the beginning of diastole. This is shown as the time interval X-O in figure 6. The ventricular pressure was lowered by the pump to a negative value before the ball was dislodged, and the chamber pressures were equilibrated at a pressure of \( P_a \).

Table 1 shows the time relationships obtained from the pressure tracings of the systolic experiments. It can be seen that the time required for dislodgment of the ball at the end of systole (X-O) varies mostly with the pump speed. This is directly proportional to the negative pressure attained by the pump and is probably an artifact of the mechanical system. The human ventricle does not attain such negative pressures. The time in which there is regurgitation through the valve (S-C) is seen to vary somewhat with atrial pressure. The higher the atrial pressure, the longer is the S-C interval. This is probably because the larger atrioventricular gradient forces closure of the valve with greater velocity. However, this S-C interval remains relatively constant as the speed of the pump increases and systole and diastole shorten, thus consuming a larger percentage of systole at high “pulse rates.”

Figure 7 illustrates a possible mechanism of the regurgitation through the ball valve. Sudden increase of systolic pressure, \( P_v \), exerts an equal pressure over all of the surface of the ball and starts a column of blood moving

### Table 1

<table>
<thead>
<tr>
<th>Valve area, cm.(^2)</th>
<th>Pump speed cycles/min.</th>
<th>Systole (S-D), sec.</th>
<th>Diastole (D-S), sec.</th>
<th>(S-C), sec.</th>
<th>(X-O), sec.</th>
<th>Atrial pressure, mm. Hg</th>
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<td>3.14</td>
<td>5</td>
<td>3.05</td>
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<td>0</td>
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<td>0.32</td>
<td>0.12</td>
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<tr>
<td>3.14</td>
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<td>2.96</td>
<td>4.10</td>
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<td>1.65</td>
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<td>1.30</td>
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<td>0.36</td>
<td>0.10</td>
<td>16</td>
</tr>
<tr>
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<td>20</td>
<td>0.98</td>
<td>1.44</td>
<td>0.32</td>
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<tr>
<td>1.65</td>
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<td>0.80</td>
<td>1.20</td>
<td>0.34</td>
<td>0.05</td>
<td>16</td>
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</table>

* Ventricular pressure was 90 mm. Hg in all of the above experiments.

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in a retrograde fashion through the orifice. The column is disturbed at the apex of the cage as the wires meeting in this area form an obstruction to retrograde flow. This causes a hydraulic "vacuum" between the cage and the ball, and blood flows around the ball toward the orifice. This diverted blood may set up eddy currents in front of the ball, further "holding" it to the apex of the cage. The ball would be less affected by these factors in a blood system than in the water system used because the Silastic ball more nearly approximates the density of blood and presents less inertia.

Evaluation of the Mitral Annulus by Angiocardiography

To determine in advance the size of the valve which the mitral annulus will accommodate, the annulus was measured from left ventricular angiograms. The angiocardiograms were all made by the Seldinger technic with the catheter passed retrograde through the aorta and into the left ventricle. After the bolus of dye was injected into the ventricle, serial biplane x-ray films were taken at a rate of six per second by means of a mechanical film changer (Schonander-Elema). Since most of these patients exhibited mitral regurgitation, this technic provided a good picture of both the atrium and the ventricle.

The mitral annulus in the normal heart lies in a plane perpendicular to the atrioventricular canal. Since this canal points forward, downward, and to the left, the plane of the annulus tilts downward on the right and posteriorly, upward on the left and anteriorly. This has been shown to be true radiographically by means of a radiopaque wire placed in the annulus of intact postmortem hearts. In the heart with left atrial enlargement, the left atrium has been shown to enlarge posteriorly and inferiorly, thus appearing below the mitral annulus and behind the left ventricle. Thus, in standard anteroposterior and lateral roentgenograms with good opacification of atrium and ventricle, one sees the globular atrium, a portion of which is superimposed upon the ventricle. However, the annulus can be outlined and measurements can be made with relatively good accuracy. Figure 8 shows one of the angiograms (patient 4) with indication where measurements were made.

Since angiocardiograms were not performed unless a patient had dynamically significant myocardial or valvular disease, there are no normal subjects in this study with which to compare. Those patients with congenital heart disease (no. 3, 13, 14, 15) and with arteriosclerotic heart disease (no. 16) also had single chamber or generalized cardiomegaly. Dilatation of the mitral annulus was present in most of these cases.

The average adult mitral annulus by angiocardiogram, in this selected series (omitting patients no. 13, 14), measured 4.22 cm. in diameter. Since measurements from x-ray films were made for systole and diastole, the averages of these are separately indicated. It is noted that, in all but two instances, the diastolic value is larger than the systolic. Considering the fibroelastic nature of the mitral ring, one would expect the annulus to dilate slightly during diastole when it has no support from the contracted, rigid ventricular musculature. The amount of dilation during the cardiac cycle is largely dependent upon the amount of scarring and calcification of the annulus. In those cases reported here, no roentgenographically demonstrable calcification of the annulus was present.

Eight of the patients included in this study underwent surgery. Seven of these had replacement of the mitral valve with a Starr-
Figure 8

*Left ventricular angiogram in mitral regurgitation. Between arrows is the mitral annulus where measurements were made. Systole (upper); diastole (lower).*

Edwards prosthesis, and one valve was repaired by means of valvuloplasty. The findings at surgery are listed below:

Patient 6 (E.J.): Operative report stated that "large annulus" was present. Valvuloplasty (plication of annulus performed).

Patient 2 (B.S.): Valve replaced with size 2M (outside diameter 3.3 cm.) prosthesis. Average diameter of annulus on angiogram was 4.48 cm.

Patient 9 (J.R.): Valve replaced with size 3M (3.55 cm.) prosthesis. (Annulus: 4.20 cm.).

Patient 7 (E.M.): Valve replaced with size 3M (3.55 cm.) prosthesis. (Annulus: 4.19 cm.). Patient had calcified chordae tendineae and papillary muscles.

Patient 8 (B.T.): Valve replaced with size 3M (3.55 cm.) prosthesis. (Annulus: 4.43 cm.).

Patient 11 (C.P.): Valve replaced with size 3M (3.55 cm.) prosthesis. (Annulus: 4.18 cm.).

Patient 12 (G.D.): Valve replaced with size 3M (3.55 cm.) prosthesis. (Annulus: 4.38 cm.).
Patient 10 (V.I.): Valve replaced with size 4M (3.8 cm.) prosthesis. (Annulus: 4.62 cm.).

Comparison of these data with table 2 shows that measurements made from angiograms corrected for distortion due to roentgenographic technic are only approximate measurements of the available annular space for prosthetic replacement. In removal of valve tissue for replacement with a Starr-Edwards prosthesis, a "cuff" of tissue must be left in place. The Teflon cuff of the valve is sutured to this tissue cuff. The figures show that approximately 0.8 cm. of the annulus as measured by the angiocardiogram is not utilizable for space for the prosthesis. This 0.8 cm. includes the tissue cuff left in place, but also represents a certain quantity of annular dilatation present in the physiologic heart, but not available in the surgically decompressed heart.

The measured size of the mitral annulus in this study is slightly larger than that measured from postmortem specimens of stenotic valves by Rusted et al.6,7 (table 3). This is as one would expect. While measurements obtained from the anteroposterior and lateral views may show somewhat higher values, one can predict

<table>
<thead>
<tr>
<th>Table 2</th>
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<tr>
<td>Measurements of the Mitral Annulus from Biplane Left Ventricular Angiograms in 17 Patients</td>
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<tr>
<th>Number</th>
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<th>Diameter of annulus Systole, cm.</th>
<th>Diameter of annulus Diastole, cm.</th>
<th>Average, cm.</th>
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MI, mitral insufficiency, MS, mitral stenosis, CA, coronary artery disease, IVSD, interventricular septal defect, PDA, patent ductus arteriosus.

<table>
<thead>
<tr>
<th>Table 3</th>
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<td>Measurements of the Mitral Annulus from Postmortem Specimens</td>
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<th>Normal valves</th>
<th>Women</th>
<th>Stenotic valves</th>
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<tr>
<td>Average circumference of valve ring (range)</td>
<td>9.9 cm.</td>
<td>8.5 cm.</td>
<td>10.4 cm.</td>
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<tr>
<td>Average diameter of ring (range)</td>
<td>3.15 cm.</td>
<td>2.7 cm.</td>
<td>3.3 cm.</td>
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<tr>
<td>Intercommissural diameter</td>
<td>2.5 cm.</td>
<td>2.1 cm.</td>
<td>1.9 cm.</td>
<td></td>
</tr>
</tbody>
</table>

Table from Rusted et al.6,7

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the diameter of the maximum size valve that could be inserted at surgery by subtraction of 0.8 cm. from the average measured annular diameter.

**Hemodynamic Studies in Patients with Mitral Ball-Valve Prosthesis**

Three patients were selected from our cases with mitral ball-valve prosthesis in whom hemodynamic measurements and left ventricular angiogram were performed by right, trans-thoracic left and retrograde left heart catheterization. Patients with small, medium, and large Starr-Edwards valves were selected for the hemodynamic study (size 2M, 3M, and 4M). The cardiac catheterization was performed 4, 5, and 14 months after surgery, respectively. The hemodynamic results were compared with the flow dynamic studies with the ball valve in the mechanical pulse duplicator. Two patients had predominant mitral regurgitation preoperatively, one had predominant mitral stenosis. The ages of the patients were 22, 44, and 45, respectively. All three showed dramatic symptomatic improvement and marked decrease of cardiac size following surgery.

Table 4 shows the hemodynamic results before and after placement of the Starr-Edwards ball valve. There was decrease of the pulmonary artery and left atrial or pulmonary capillary wedge pressures and increase of the resting cardiac output in all three cases following surgery. The end-diastolic pressures were normal in both ventricles in all three cases following surgery. There was a pressure gradient across the Starr-Edwards valve as measured by simultaneous pulmonary capillary wedge and left ventricular pressures in all three patients. The calculated diastolic area of the Starr valve in the functioning heart, from the Gorlin formula, was in each instance smaller than the measured area of the ball-valve cage.

The comparison of the difference between the calculated orifice and “effective orifice” of the ball valve in the patients with that obtained in the mechanical pulse duplicator showed good correlation. The “effective orifice” of size 2M ball valve was 81 per cent, of size 3M, 84 per cent, and of size 4M, 92 per cent of the mechanical orifice of the valve.
The left ventricular biplane angiogram with the Schonander machine and another angiogram using cinefluorography showed absolutely no evidence of regurgitation through the Starr valve in cases 1 and 2, while slight regurgitation was seen in case 3. A closer analysis of the pictures in this case indicated that the regurgitation was not through the valve cage but at one point a narrow jet could be seen passing around the outer ring of the cage. In spite of this slight regurgitation which was probably present since surgery, the patient showed a very marked and persistent improvement with marked decrease of cardiac size of 14 months' duration. The regurgitation was estimated by the density of the regurgi-
tating dye and was taken into consideration in the calculation of the valve area. Figure 9 shows the angiogram in one of the patients (J.R.) with the Starr valve in position in systolic and diastolic phase of the ventricle. The position of the ball can be recognized by the round-shaped decreased density of the dye during systole located in the ring and during diastole located in the cage of the valve.

Discussion

The flow dynamic studies of the ball valve in the mechanical pulse duplicator corresponded well with the studies of the implanted ball valve prosthesis in cardiac patients. The predicted "effective diastolic orifice" of 83 per cent for the small and 89 per cent for the larger valve in the mechanical system was close to the calculated orifice using cardiac catheterization data in patients with mitral ball-valve prosthesis. Although the absolute values are somewhat different in the hydrodynamic and the hemodynamic system, including constant C in equation 2, the percentage relationship between measured and effective orifice remains valid. In the normal valve, the flexibility of the leaflet and the mitral annulus probably allows an actual increase in the size of the atrioventricular canal, thus increasing the effective orifice at high flow rates. The ball valve prosthesis, just as the stenotic valve, maintains its rigid orifice also at high flow rates. Lombard and Cope showed that the diastolic filling period occupies 60 to 25 per cent of the cardiac cycle as the pulse rate increases from 70 to 115. Thus, at a resting cardiac output of 6 L./min., the flow would be 10 L./min. per diastolic period at a pulse rate of 70. It can be seen in figure 4 that this flow can be maintained with little pressure gradient (approximately 5 mm. Hg) across the ball valve. If, however, cardiac output triples, the parabolic nature of the curve is such that the pressure gradient becomes significant. Since the high gradient may not be maintained at high flows, the cardiac output will reach a maximum plateau as it does in the stenotic mitral valve.

It is obvious, therefore, that the larger valves will provide a better cardiac performance in regard to exercise and daily activity. With the use of left ventricular angiocardiography, the size of the ball valve which the mitral annulus will accommodate can be predicted with relatively good accuracy. This becomes important in younger active persons whereas in older retired individuals, this is perhaps less significant. It also shows that the larger valves with a greater "effective orifice" will more likely be accommodated by hearts which have a dilated mitral annulus and left ventricle as a result of regurgitation rather than by hearts with tight mitral stenosis and small left ventricle.

It was shown in the mechanical pulse duplicator, that there is regurgitation before closure of the ball valve in early systole. As seen in figure 6, the closing of the valve occupies one tenth to one third of the systolic period, depending upon the pulse rate. Angiocardiograms in patients with the ball valve, however, showed no evidence of regurgitation except in one patient in whom it was believed that the regurgitation was around the cage. The faster pressure generation and faster closure of the valve in the contracting left ventricle and the closer approximation of the density of the blood by the Silastic ball valve presenting less inertia, minimizes the amount of regurgitation. The blood regurgitated is only that which is between the ball valve and the cage and which does not contain contrast dye at the time of injection. Therefore, no dye can be seen in the atrium. Thus, the amount of regurgitation through the ball valve can be neglected from the practical point of view.

Summary

Flow dynamic studies were performed in a mechanical pulse duplicator with Starr-Edwards ball valves. It was shown that the "effective orifice" of the ball valve is less than the measured orifice of the cage of the valve. The orifice is decreased to 83 per cent of the measured orifice in the smaller and to 89 per cent in the larger valves. These measurements corresponded well with the measurements of the "effective orifice" of the valve implanted in patients who were examined by left and right heart catheterization and left ventricular
angiocardiograms several months after placement of the valve.

The closing regurgitation found in early systole in the mechanical system appears to be negligible in patients. Left ventricular angiograms did not show reflux of dye into the left atrium through the valve cage.

The size of the mitral annulus in patients was measured from left ventricular angiograms. The size of the mitral ball valve prosthesis which the mitral annulus will accommodate could be predicted with good accuracy from these measurements.

References

William Withering

The whole of his views are happily expressed in a quaint little verse written by him and which should be remembered in medical poetry.

The Foxglove's leaves, with caution given
Another proof of favouring Heav'n
Will happily display;
The rapid pulse it can abate;
The hectic flush can moderate
And, blest by Him whose will is fate,
May give a lengthen'd day.

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