Phonocardiographic Diagnosis of Aortic Ball Variance

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SUMMARY
Fatty infiltration causing changes in the silastic poppet of the Model 1000 series Starr-Edwards aortic valve prostheses (ball variance) has been detected with increasing frequency and can result in sudden death. Phonocardiograms were recorded on 12 patients with ball variance confirmed by operation and of 31 controls. Ten of the 12 patients with ball variance were distinguished from the controls by an aortic opening sound (AO) less than half as intense as the aortic closure sound (AC) at the second right intercostal space (AO/AC ratio less than 0.5). Both AO and AC were decreased in two patients with ball variance, with the loss of the characteristic high frequency and amplitude of these sounds. The only patient having a diminished AO/AC ratio (0.42) without ball variance at reoperation had a clot extending over the aortic valve struts. The phonocardiographic findings have been the most reliable objective evidence of ball variance in patients with Starr-Edwards aortic prosthesis of the Model 1000 series.

Additional Indexing Words:
Silastic poppet
Aortic opening sound to aortic closure sound ratio
Starr-Edwards aortic valve
Aortic valvular dysfunction
Heart sounds
Aortic prosthetic valve

In November 1964, Krosnick observed the first case of death due to changes in the silastic poppet of a Starr-Edwards aortic prosthesis. Pierie and associates in 1965 reported 16 additional cases of ball variance from among poppets that had been returned to the manufacturer. Most recently Herr and associates have recorded the clinical syndrome associated with ball variance, emphasizing the risk of this abnormality and the importance of early recognition and treatment with reoperation. That preliminary report noted phonocardiography to be an important adjuvant to auscultation in the diagnosis of ball variance. The present report describes in detail and quantitates the phonocardiographic findings of ball variance in Starr-Edwards aortic prostheses of the Model 1000 series (fig. 1).

For the present discussion ball variance will be defined as valvular dysfunction resulting from physical and chemical alterations in the silastic poppet in aortic valve prostheses. These alterations include poppet impingement on the cage struts, grooving, cracking, decreased diameter, or fragmentation of the poppet, or changes of the poppet core with the formation of fluid lakes (fig. 2C to F). Discoloration due to lipid infiltration, swelling of the poppet without impingement on the cage, and decreased elasticity of the silastic ball will not be included as ball variance in this discussion because, while they may represent early stages of poppet transformation, they...
have not been found to cause mechanical dysfunction of the valve (fig. 2A and B).

From March 1962 to January 1966, aortic valve replacement with Starr-Edwards prosthesis was performed on 189 patients at the University of Oregon Medical School who have now lived longer than 12 months after operation. Ball variance has been documented by autopsy or reoperation in 38 of these 189 cases (20%). In 14 of these cases ball variance was first discovered at autopsy. In six of these 14, ball variance was considered the cause of death. Ball variance has been documented at reoperation in 24 cases.4

**Methods**

**Study Population**

All patients had aortic valve replacement by the staff of the University of Oregon Medical School. Preoperative phonocardiograms were recorded on 12 patients with ball variance which was subsequently documented at reoperation. All had Model 1000 series Starr-Edwards aortic prostheses. The average time from aortic valve replacement to phonocardiographic diagnosis of ball variance was 40 months, with a range of 29 to 52 months.

Three groups were studied as controls. Fifteen patients were studied less than 12 months after aortic valve replacement with a Model 1200 series of Starr-Edwards aortic prosthesis. Eleven patients with Model 1000 series aortic valve were studied less than 12 months after the silastic poppet was replaced for ball variance by reoperation. Phonocardiograms were recorded on five patients who were reoperated upon more than 12 months following aortic surgery but were found not to have ball variance. Four did have discoloration and decreased elasticity of the poppet. Four of these five had Model 1000 series aortic prostheses and the fifth had a Model 1200 series valve.

The earliest case of ball variance at this institution was noted at 16 months after aortic valve replacement.3 Since the use of the Model 1000 series Starr-Edwards aortic prosthesis was discontinued over 2 years ago, there is no control group of recent implants for the study of ball variance. Patients with ball variance, who are operated upon and have a new silastic poppet inserted into the old prosthesis, have a prosthesis essentially the same as a newly inserted valve, except for the overgrowth of intima around the sewing ring. The intima and suture ends are trimmed at operation if they impinge on the poppet. However, these patients represent only those developing ball variance and are not a representative control group for the whole population. For this reason, patients with recently
<table>
<thead>
<tr>
<th>Initials</th>
<th>Sex</th>
<th>Age (yr)</th>
<th>Postop (mo)</th>
<th>2 RICS</th>
<th>Apex</th>
<th>AO/AC</th>
<th>R-R</th>
<th>Q-AO</th>
<th>Q-AC</th>
<th>MC-AO</th>
<th>AO-CP</th>
<th>AO-AC</th>
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<td>M</td>
<td>64</td>
<td>29</td>
<td>0.36</td>
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<td>0.92</td>
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<td>J.D.</td>
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<td>55</td>
<td>33</td>
<td>0.31</td>
<td>0.79</td>
<td>0.785</td>
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<td>35</td>
<td>0.23</td>
<td>0.37</td>
<td>0.885</td>
<td>0.115</td>
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<tr>
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<td>M</td>
<td>54</td>
<td>36</td>
<td>0.45</td>
<td>0.20</td>
<td>0.887</td>
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<td>0.51</td>
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<td>42</td>
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<td>0.792</td>
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<td>42</td>
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<td>48</td>
<td>0.34</td>
<td>1.01</td>
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<td>0.983</td>
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<td>0.894</td>
<td>0.121</td>
<td>0.427</td>
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<td>-0.003</td>
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<td>40</td>
<td>0.41±</td>
<td>0.71±</td>
<td>0.92±</td>
<td>0.129±</td>
<td>0.42±</td>
<td>0.071±</td>
<td>0.001±</td>
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<td>0.19</td>
<td>0.20</td>
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<td>0.092</td>
<td>0.383</td>
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<td>-0.006</td>
<td>0.266</td>
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<td>52</td>
<td>0.94</td>
<td>2.04</td>
<td>1.046</td>
<td>0.200</td>
<td>0.499</td>
<td>0.115</td>
<td>+0.019</td>
<td>0.402</td>
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</tbody>
</table>

Abbreviations: Postop months = time since aortic valve replacement; AO/AC = aortic opening sound to aortic closing sound ratio; 2 RICS = second right intercostal space at sternal edge; apex = cardiac apex; R-R = onset of QRS to onset of the next QRS; Q = onset of QRS; AO = aortic opening sound; AC = aortic closure sound; MC = mitral closure sound; CP = beginning of the carotid upstroke.
implanted Model 1200 prostheses were used as an additional control group. These two models are of similar materials. The Model 1200 has a convex rather than spherical poppet seat and no projecting feet forming a secondary seat (fig. 1). The Model 1200 valve also has a shorter cage and shorter poppet excursion.4

Phonocardiograms

Phonocardiograms were recorded in a sound-proof room (Industrial Acoustical) with a Sanborn Model 550 M phonocardiograph using the logarithmic setting.5 Photographic records were made at a paper speed of 100 mm/sec, which allowed analysis of the intervals to the nearest 0.005 sec. The frequency response of this system was from 100 to 290 cps within the minus 3 decibel range. Records were obtained with the patient in the supine position and with the breath held in midexpiration. Sanborn diaphragm microphones were placed over the second right intercostal space at the sternal edge (2 RICS) and at the cardiac apex. Simultaneous records were obtained of the electrocardiogram and of the indirect carotid pulse detected by a Sanborn bell pressed over the carotid artery.

Intensity of Aortic Prosthetic Sounds

The amplitude of the aortic opening sound (AO) and aortic closure sound (AC) was determined by measurement in millimeters of the maximum deflection of these sounds. Average values were obtained over 10 beats in patients with sinus rhythm and over 15 beats when atrial fibrillation was present. The ratio of the aortic opening sound to the aortic closure sound (AO/AC ratio) was derived from the average values of AO and AC at the 2 RICS and at the apex. Premature ventricular contractions and heart beats with an R-R interval less than 0.5 sec (rate greater than 120/min) were excluded from the study because of the decrease in the intensity of AO with short R-R intervals as previously noted by Dayem and Raftery.6

Figure 2

(A) A normal silastic poppet removed 19 months after aortic replacement from patient B.M. (B) An opaque ball removed from R.M. after 36 months. (C) A mildly eccentric and grooved ball removed after 35 months. (D) A grooved poppet removed after 36 months from R. McC. (E) A grooved poppet sticking in open position. Note the overgrowth of intima and suture ends. (F) A cracked poppet removed after 49 months from W.K.
Comparison of AO to AC (AO/AC ratio) was utilized to permit quantitative assessment of AO without introducing variations in intensity related to recording variables such as thickness of the chest wall, pressure over the microphone, and electrical amplification.

Time Intervals

The time intervals measured are illustrated in figure 3 and were as follows: Onset of the QRS to aortic opening sound (Q-AO), onset of the QRS to aortic closure sound (Q-AC), mitral closure sound to aortic opening sound (MC-AO), aortic opening sound to the beginning of the upstroke of the carotid pulse (AO-CP), and aortic opening sound to aortic closure sound (AO-AC). The average values for 15 complexes were obtained on patients with atrial fibrillation and for five complexes in patients with sinus rhythm.

Results

Intensity of Aortic Prosthetic Sounds

The most frequent finding in ball variance was a decrease in the amplitude of AO (fig. 4A). This varied from absence of AO to varying degrees of diminished intensity. The AO/AC ratio at the 2 RICS (table 1) was less than 0.5 in 10 of the 12 patients with confirmed ball variance. The ratio at the same intercostal space was greater than 0.5 in 30 of the 31 patients without ball variance (table 2), and greater than 0.7 in 27 of the 31. Figure 5 shows the distribution of the AO/AC ratio at the 2 RICS in the two groups. (For the ratios for patients B. A. and B. M., see text below.) Since the AO/AC ratios do not have normal distributions, the Mann-
Phonocardiograms. (A) Before operation, showing a decrease in the intensity of the aortic opening sound (AO) as compared to the aortic closure sound (AC). The AO/AC ratio is 0.36 at the 2 RICS. (B) Subsequent preoperative record showing a loss of intensity and the characteristic high frequency spikes of both the AO and AC. Because the intensity of both sounds is diminished the AO/AC ratio is no longer abnormal. (C) Postoperative record following replacement of an abnormal poppet with a new silastic ball. The AO and AC are of normal character and intensity.

Whitney U test was used to evaluate the data. This showed a significant difference: Z = 5.04; P = 0.001.

The changes observed in patients before and after ball change further indicate that the abnormal poppet is the cause of the decreased ratio. Preoperative and postoperative phonocardiograms were recorded on five patients who had silastic poppet replacement for ball variance. The AO/AC ratio increased in all five patients following insertion of a new silastic poppet. The mean preopera-
**Table 2**

Phonocardiographic Analysis of Patients Without Ball Variance

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age (yr)</th>
<th>Postop (mo)</th>
<th>AO/AC</th>
<th>2RICS</th>
<th>Apex</th>
<th>R-R</th>
<th>Q-AO</th>
<th>Q-AC</th>
<th>MC-AO</th>
<th>AO-CP</th>
<th>AO-AC</th>
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</thead>
<tbody>
<tr>
<td>Mean</td>
<td>8 F</td>
<td>55.5</td>
<td>6.8</td>
<td>1.14±</td>
<td>1.56±</td>
<td>0.755±</td>
<td>0.124±</td>
<td>0.373±</td>
<td>0.056±</td>
<td>0.004±</td>
<td>0.249±</td>
</tr>
<tr>
<td>SD</td>
<td>7 M</td>
<td>0.73</td>
<td>1.25</td>
<td>0.125</td>
<td>0.017</td>
<td>0.036</td>
<td>0.010</td>
<td>-0.005</td>
<td>0.170</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>37</td>
<td>2</td>
<td>0.71</td>
<td>0.47</td>
<td>0.560</td>
<td>0.091</td>
<td>0.305</td>
<td>0.037</td>
<td>-0.005</td>
<td>0.170</td>
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</tr>
<tr>
<td>60</td>
<td>12</td>
<td>3.26</td>
<td>5.98</td>
<td>1.052</td>
<td>0.172</td>
<td>0.441</td>
<td>0.072</td>
<td>0.017</td>
<td>0.313</td>
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</table>

**Group A:** 15 patients less than 1 year following replacement with a Model 1200 series Starr-Edwards aortic valve

**Group B:** 11 patients less than 1 year following silestic poppet replacement into a Model 1000 series Starr-Edwards valve

**Group C:** Records of miscellaneous patients more than 1 year following aortic valve replacement

| B.M. | F | 38 | 19 | 0.42 | 0.86 | 0.835 | 0.175 | 0.441 | 0.083 | -0.002 | 0.262 |
| I.O. | F | 56 | 29 | 0.69 | 1.08 | 1.116 | 0.118 | 0.448 | 0.059 | 0.333 |
| R.W. | M | 51 | 36 | 0.99 | 2.42 | 0.824 | 0.115 | 0.397 | 0.068 | -0.003 | 0.256 |
| R.M. | M | 49 | 36 | 0.80 | 0.73 | 0.797 | 0.146 | 0.405 | 0.065 | 0.0 | 0.264 |
| E.C. | M | 51 | 20 | 0.92 | 0.94 | 0.809 | 0.106 | 0.419 | 0.078 | +0.001 | 0.310 |
| 23 | 0.99 | 1.27 | 0.737 | 0.106 | 0.383 | 0.053 | +0.008 | 0.284 |

**Total patients without ball variance**

| Mean | 54.5 | 1.01± | 1.28± | 0.777± | 0.124± | 0.382± | 0.059± | 0.003± | 0.258± |
| SD | 0.54 | 0.87 | 0.125 | 0.017 | 0.032 | 0.010 | 0.004 | 0.036 |

Abbreviations used are the same as Table 1.
The AO/AC ratio, which was 0.46, increased to 1.19 following ball change, and was greater than 0.7 in each case.

Only one patient with an AO/AC ratio of less than 0.5 did not have ball variance at reoperation (B. M., table 2; figs. 2A and 6). At reoperation clot was found extending over portions of the cage struts. The clot was thought to be the cause of the diminished AO, as the normal silastic poppet was cushioned by clot during ejection and did not strike the metal struts. This patient was the only one in the present study with a Model 1200 series aortic prosthesis who was operated upon for suspected ball variance.

The AO/AC ratio showed greater variation when measured at the cardiac apex, and more overlap occurred between the groups with and without ball variance. The AO/AC ratio measured at the apex was 0.71 ± 0.48 with a range of 0.20 to 2.04 in patients with ball variance documented by reoperation. The AO/AC ratio was 1.28 ± 0.87 with a range of 0.47 to 5.98 in the patients without ball variance.

A second phonocardiographic pattern was seen in two instances with ball variance in which the AO/AC ratio was over 0.5. Loss of the characteristic high spiking frequencies of both aortic opening and closure sounds (fig. 4B) was apparent in both patients (W.E. and B.A., table 1). Since both the intensity and frequency of both sounds were reduced and they were changed proportionally, the AO/AC ratio was not abnormally decreased. This pattern has not occurred in any
AORTIC BALL VARIANCE

Phonocardiographic record of a patient (B.M., table 2) who had clot involving the Model 1200 series Starr-Edwards aortic valve and had a normal poppet at re-operation. The AO/AC ratio was 0.42 at the 2 RICS.

of the other 121 patients who had aortic valve replacement before January 1966 and have had phonocardiograms.

Variations in the intensity of AO were noted in a number of control patients. Gross variations in the intensity or configuration from beat to beat or over a series of beats have been observed in some patients with ball variance and have been considered a significant finding. However, three patients (R. W., I. O., and R. M., fig. 2B) who had variations in the amplitude of AO did not have ball variance at reoperation. Further, one patient who showed this finding and was found to have ball variance continued to have a varying AO after insertion of a new poppet.

Time Intervals

The MC-AO intervals for control patients and those with ball variance are shown in figure 7. Three patients with ball variance had MC-AO intervals 0.089 sec or longer, whereas the longest intervals in the control patients was 0.085 sec. However, there was an extensive overlap between the groups, with most patients with ball variance having short-

Discussion

Intensity and Frequency of Aortic Prosthetic Sounds

The sounds produced by the normal ball are characteristic, being of high frequency, short duration, and large amplitude. The AO in ball variance is diminished in intensity by auscultation and phonocardiography (fig. 8). In some cases, ball variance may be readily diagnosed by auscultation. In other patients this is difficult, and phonocardiography has been useful in providing objective evidence of prosthetic sounds, particularly when there is a difference of opinion between physicians as to whether ball variance is present as judged by auscultation. The phonocardiogram also provides a permanent record for comparison with later findings.

The significance of a variation of AO from beat to beat and from day to day is difficult to quantitate and is still uncertain. The intensity of AO varies with differing R-R intervals; therefore, variations of AO normally occur when atrial fibrillation exists. Because of this variation, the phonocardiogram is particularly helpful in the evaluation of AO in the patient with atrial fibrillation. Phonocardiographic records are also important in the
diagnosis of ball variance in patients with multiple prosthetic valves because of the difficulty in assessment of the closely related mitral closure sound and AO. In one patient, with double valve replacement, an absent AO was missed by auscultation.

Several factors seem to be related to the diminished AO. First, a progressive softening or a decrease in shore hardness is usually noted with increasing severity of ball variance (W. R. Pierie, personal communication). The effect of fluid lakes or splitting of the poppet will also change the sound generating properties of the poppet. Because the cage is narrowest at its apex, the poppet as it enlarges will impinge on the upper part of the cage earliest and cause a diminished opening sound (figs. 4A and 8A). As the poppet progressively expands, it will impinge for a greater portion of its excursion. If the poppet impinges on the cage throughout its excursion, one might expect a decrease in both AO and AC (fig. 4B).

Clinically and phonocardiographically, patients with ball variance have been noted to have an AO of lower frequency (that is, a thud rather than a click) than is usually found with this prosthesis (fig. 4B). This is apparent on inspection, but difficult to quantitate by standard phonocardiographic techniques. Frequency analysis of AO using high fidelity techniques and a bandpass filter is presently under study.

**Time Intervals**

Analysis of the time intervals of the cardiac cycle has not been as helpful as that of the intensity of the sounds in the differential diagnosis of ball variance. One fourth of our patients with ball variance had prolongation of the MC-AO interval to 0.089 sec or longer. The MC-AO interval includes both the period of isometric contraction and the time required for the poppet to move to the open position. Hence, a prolonged MC-AO could be due to a prolonged isometric contraction, such as that caused by a negative inotropic effect or by hypertension. It could also be prolonged by

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**Figure 8**

Phonocardiograms. (A) Before operation, showing a decrease in the intensity of the AO as compared to the AC. The AO/AC ratio is 0.23 at the 2 RICS. (B) Postoperative record following replacement with a new prosthesis.
Aortic Ball Variance

A slower movement of the ball to the upper part of the cage, as would be the case if the poppet were sticking severely. It seems more likely that impingement of the ball on the struts of the cage causes the prolonged MC-AO interval in ball variance.

Aortic Prosthesis

Ball variance has been noted with several types of aortic prostheses. Although the manufacturer has noted some minor changes of the silastic poppet in the 1200 series Starr-Edwards aortic prostheses, no valvular dysfunction due to ball variance has been noted (W. R. Pierie, personal communication). Since ball variance has been noted only in the Model 1000 series and earlier Starr-Edwards aortic valves, the criteria for the diagnosis of ball variance are applicable thus far only to these valves.

While a decrease in AO is documented in ball variance, techniques of recording sound to make objective measurements are difficult to standardize. Changes in the AO/AC ratio with other microphones and other phonocardiographs with different frequency responses are anticipated. However, since the AO/AC ratio is a comparison of sounds rather than being dependent upon the absolute intensity, changes with similar equipment may be minor.

The percentage of false positive diagnoses, as well as the number of patients who may develop ball variance without characteristic auscultatory or phonocardiographic findings, is not determined by the present study. One false positive diagnosis in a case of clot involving the cage of the prosthesis has been noted. In three patients operated upon because of varying intensity of the aortic opening sound, but without other criteria of ball variance, the diagnoses were also false positive. No deaths due to unsuspected ball variance have been noted among 123 patients who have had phonocardiograms and are being followed at this institution.

Presently, patients with aortic valves with silastic poppets, who have gone more than 1 year after replacement, are reexamined at 6-month intervals. Those developing dizzy spells, syncopal episodes, fatigue, angina, palpitations, congestive heart failure, hemolytic anemia, jaundice, or other symptoms associated with ball variance are examined immediately. Careful auscultation is performed with particular attention to the quality of AO, and a phonocardiogram is recorded.

The absence of the AO is considered an urgent indication for reoperation; one such patient died while awaiting surgery. Patients with an AO/AC ratio consistently less than 0.5 on two or more occasions are given a diagnosis of ball variance on phonocardiographic evidence. The significance of an AO/AC ratio in the 0.5 to 0.7 range is still being evaluated. Patients with AO/AC ratios in this range or those with the symptoms described above, but without phonocardiographic evidence of ball variance, are followed at frequent intervals.

References

9. Magovern, G. J.: Discussion. (G. J. Magovern,
In examining the heart by means of percussion, we can usually determine its left border, but we cannot find its lower border. Now let us see what can be done in this direction by means of the x-rays. The constant motion of the heart and diaphragm interferes with the use of radiography but renders fluoroscopy all the more valuable. The lungs and the organs adjacent to them are the parts of the body which best lend themselves to fluoroscopic examination, because of the great difference in density between the former and the latter, or, in other words, of permeability to the x-rays. The lungs being less dense than the neighboring organs allow the x-rays to pass through them more readily, and thus appear light against a darker background formed by the heart and parts of the liver and spleen, which, owing to their density, are less permeable by the rays and thus appear dark when seen through the fluoroscope, that is, there is contrast.

... A suitable position of the Crookes tube of course facilitates this end somewhat. It is desirable to see as much as possible of the heart at one time in order to best estimate its condition—then if necessary we may study one or another portion separately—and by means of this fluoroscopic examination we can follow a larger portion of its outline and gain more information as to its size, position and action than has hitherto been within our reach. I may add here that I have made an instrument that enables me to listen to the heart-sounds while watching the pulsating organ.—Francis H. Williams: A Method for More Fully Determining the Outline of the Heart by Means of the Fluoroscope Together with Other Uses of This Instrument in Medicine. In Willis, F. A., and Keys, T. E.: Classics of Cardiology, vol. 2. New York, Dover Publications, Inc., 1941, p. 701.
Phonocardiographic Diagnosis of Aortic Ball Varianc

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