A MECHANICAL PULSE DUPLICATOR FOR TESTING PROSTHETIC MITRAL AND AORTIC VALVES

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(RECEIVED FOR PUBLICATION NOVEMBER 14, 1961)

The purpose of a prosthetic cardiac valve is to restore the function of a diseased aortic or mitral valve, and its role in haemodynamics is a passive one: the opening and closing of such a valve is strictly regulated by the pressure differences in the cardiac chambers which communicate through this valve. Therefore we consider that a prosthetic valve should be tested under conditions simulating normal cardiac dynamics. We have designed and constructed a mechanical pulse duplicator with which it is possible to test artificial mitral and aortic valves, even simultaneously if so desired.

Davila, Trout, Sunner, and Glover (1956) described a pulse duplicator which had a controlled systolic-diastolic ratio, stroke volume, and cardiac rate. The apparatus described below (Fig. 1) is much simpler, smaller, and less expensive. An advantage, compared with other similar devices, is that one can adjust the systolic-diastolic range and the shape of the ventricular, atrial, and aortic pressure curves exactly as one wishes.

THE PULSE DUPLICATOR

The practical factors which must be assessed in the testing of a prosthetic cardiac valve are (1) competence; (2) resistance to flow; (3) alteration produced in pressure curves; and (4) material longevity.

In order to be able to give this information we decided that a pulse duplicator should have (1) a variable pulse rate; (2) a variable stroke volume; and (3) pressure curves closely approximating the physiological curves. The use of a rotating cam should be avoided in order to control and regulate the curves' amplitude and shape. Furthermore, we avoided a piston pump, since it produces a negative pressure phase and unphysiological pressure relationships between the ventricular, atrial, and aortic chambers. The evaluation of an artificial mitral valve requires a model of the circulation having no diastolic ventricular suction, since only a minimal negative pressure is found in the normal heart.

The pulse duplicator which we have devised consists of two non-communicating hydraulic systems. One is the pumping system (Fig. 2A and B) and the other is the testing system simulating the left ventricle, aorta, peripheral resistances, and left atrium.

THE PUMPING SYSTEM.—The power drive for the machine is provided by a one-third H.P. Leland motor with a speed ranging between 10 and 500 r.p.m. It gives a practical and accurate control of the pulse rate at a constant power-delivery. The motor rotates a one-arm modified roller pump designed to provide an impulse corresponding to the shape of the average ventricular pressure pulse. The duration of systole can be made to vary between 1/8 and 1/3 of the total revolution by adjusting the occluding wheels adjacent to the tube. This permits an occlusion-rang ranging between 45° and 120°.

The roller pump maintains the diameter of the rubber tube between 1/4 and 5/8 in. This gives a range in stroke volume of 14 to 56 ml.

FIG. 1.—The pulse duplicator. L.A.=left atrium; M.V.=mitral valve; L.V.=left ventricle; A.V.=aortic valve; A=elastic container; B=rigid container; P=pump; P.R.=peripheral resistance.

FIG. 2A

FIG. 2B

FIG. 2A and B.—The pumping system.

The roller pump acts on a closed system (pumping system) containing water (Fig. 2A and B) and consisting of an elastic container A, a connecting tube, and a rigid container B (Fig. 1). During systole (Fig. 2A) the pump forces the liquid from container A to container B, and during diastole (Fig. 2B) the liquid returns by gravity to container A. Diastolic suction can be controlled by varying the height between A and B.

THE TESTING SYSTEM.—The displacement pressure of the liquid in the pumping system is transmitted to the elastic bag, inserted into container B, which simulates the left ventricle. An ordinary rubber anaesthetic bag has been used for this purpose.

From the left ventricle analogue the testing circuit simulating the aorta and left atrium extends.

We have used the duplicator with water as a testing medium. The use of blood would be more physiological (Austen, Shaw, Scannell, and Thurlbeck, 1958), but it would then be impossible to watch the prosthesis in action. To obtain a transparent liquid with the viscosity of blood, a 40% glycerin solution could be used. We thought, however, that this was of secondary importance, since we can control curve amplitude and shape, peripheral resistances, and systolic and diastolic pressures in the left ventricular, aortic, and left atrial analogues.

Valves.—The prosthetic aortic and mitral valves to be tested are placed in lucite chambers with luer-lock connexions for obtaining pressure recordings across the valve (Fig. 3A and B). The inflow end of the ventricular analogue is fitted with the mitral valve container and the outflow with the aortic valve container. To establish reference curves a check valve is used alternately in the outflow and in the inflow tracts followed by replacement of the lucite chamber containing the experimental valve for evaluation.

Aorta.—The aortic analogue consists of a rubber tube 28 cm. long, 3.3 cm. in diameter, and 1.2 mm.

thick. Its length and quality were empirically selected after several attempts had been made to obtain a diastolic response to systolic distension which produced a curve approximating most closely to normal aortic curves. The aortic analogue is connected to the aortic valve container at one end and to the tube leading to the left atrial analogue at the other end.

Peripheral Resistances and Left Atrium.—Peripheral resistances are applied to the system by a screw clamp on the tube leading from the aorta to the open reservoir simulating the left atrium. By adjusting the clamp tension the systolic-diastolic difference in the aorta may be varied between 100/45 and 300/150 mm. Hg without any marked distortion of the pressure curve. A conspicuous reduction in flow per minute is, however, inevitable if the peripheral resistances are increased too much.

The left atrial analogue consists of an open reservoir collecting fluid from the aorta. This reservoir is placed 15 cm. above the mitral valve so as to provide a physiological pressure of some 10 mm. Hg to open the mitral valve in ventricular diastole.

TESTING THE VALVES

After the circuit has been emptied of air the transmitters are connected to the paper and oscilloscope pressure recorder and the duplicator is driven with check valves to establish reference curves. The mechanical adjustments (occlusion section of the pump, diastolic pressure in the left ventricular analogue, reservoir height above mitral valve, and peripheral resistances) are varied until the desired systolic and diastolic pressures are obtained across the valve and the recorded curves closely resemble normal curves. The check valves are then removed and the prosthetic valves inserted without further adjustment.

FIG. 3A.—Lucite chambers with luer-lock connexions and the experimental valve container.

FIG. 3B.—The chambers and valve container assembled.

FIG. 4A

FIG. 4B

FIG. 4.—(A) Tracing from a ball type aortic valve; (B) tracing from the same valve as in Fig. 4A, with the duplicator working at a higher pressure.

FIG. 5A

FIG. 5B

FIG. 5A and B.—Tracings from a ball type mitral valve.

Pressure waves are recorded with different types of prosthetic experimental valves in order to evaluate them. Fig. 4A shows the tracing from a ball type aortic valve in which only a slight stenosis is present; Fig. 4B shows a tracing from the same valve with the duplicator working at a higher pressure. No significant modification in the shape of the curve and in systolic-diastolic pressure relationship is seen.

Figs. 5A and 5B show the tracing from a ball type mitral valve, a modification of a Starr mitral ball valve. Nearly typical curves are seen.

The duplicator may also be used for a prolonged period of time and at a high speed to accelerate the testing programme for performance and durability of the material in question.

CONCLUSIONS

To evaluate cardiac prosthetic valves *in vitro* a pulse duplicator is needed which simulates the physiological dynamics of the left ventricle, aorta, and left atrium. It must provide pressure curves

similar in systole-diastole range and shape to physiological curves, and the valves to be tested must function under similar dynamic conditions. Therefore in order to test a mitral and aortic prosthetic valve in a pulse duplicator, diastolic pressure should be nil in the ventricular analogue, and the aortic pressure should reflect a normal systolic-diastolic pressure difference. The apparatus described in this paper fulfils these requirements. Its major limitation is an inability to reproduce annular motion: this factor, although important in the study of specimens for evaluation of normal atrioventricular and aortic valvular function (Starr, Schnabel, and Mayock, 1953), is not so necessary when one is dealing with a rigid, total valvular prosthesis.

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