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JANUARY, 1962

American Heart Journal

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Diastolic balloon pumping (with carbon dioxide) in the aorta—A mechanical assistance to the failing circulation

Spyridon D. Moulopoulos, M.D.

Stephen Topaz, B.S. Eng.

Willem J. Kolff, M.D.

Cleveland, Ohio

Mechanical assistance to the failing heart has been tried in a number of experiments.¹⁻⁷ Arterioarterial or venoarterial pumping was so timed by means of electronic devices that the ejection of blood into the vascular system could occur during the diastolic phase of the cardiac cycle. The purpose of diastolic pumping devices is to increase the flow of blood during diastole, especially through the coronary arteries, to decrease the end-diastolic pressure, and, therefore, to decrease the work of a failing left ventricle.

This report discusses experiments on dogs with a simple device that allows diastolic pumping without taking the blood outside the body.

Materials and method

A latex tubing* was tied around the end of a polyethylene catheter† with multiple side holes. The distal end of the polyethylene catheter was occluded so that the tubing could be inflated and de-

flated through the side holes in the catheter (Fig. 1).

A polyvinyl catheter balloon for use on human beings has recently been made available commercially.‡ The proximal (uncovered) end of the catheter was connected to an elastic Tygon tube with thick walls. This tube fits in an aluminum rigid-wall cylinder with two stoppers. The tubing, the catheter, and the balloon formed a closed system that was filled with carbon dioxide through a three-way stopcock attached to the aluminum cylinder.

Air pressure was applied intermittently to the tube in the cylinder, and the carbon dioxide was expelled to inflate the balloon. The pressure was regulated by means of a three-way solenoid valve.§ The dead space in the system was diminished by filling the cylinder surrounding the tube with sterile saline solution.

The solenoid valve was activated from the R wave of the electrocardiogram through a timing device that amplifies

From the Department of Artificial Organs, The Cleveland Clinic Foundation, and The Frank E. Bunts Educational Institute, Cleveland, Ohio.

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*Diameter 0.95 cm., length 20 cm. Penrose latex drainage tubing, A. S. Aloe Company, St. Louis, Mo.

†External diameter 3.25 mm., internal diameter 2.16 mm., length 60 cm. Polyethylene tubing, Intramedica, Clay-Adams, Inc., New York, N. Y.

‡U. S. Catheter Instruments Company, Glens Falls, N. Y.

§Skinner Electric Valve Division, Solenoid Valve Company, New Britain, Conn. Valve characteristics: 10W., 12 V., 50 p.s.i., inlet diameter 1/8 inch, outlet diameter 3/32 inch.

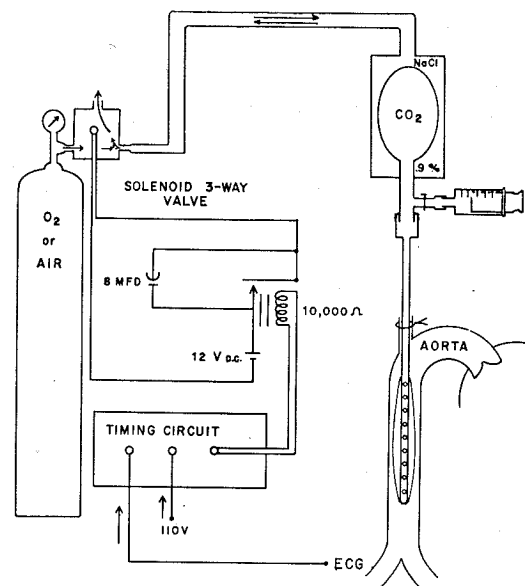


Fig. 1. Diagram of the entire setup, including the intra-aortic tube, the outside balloon, the air pressure system, and the electronic devices for the timing of the inflation. *NaCl* indicates the sterile 0.9 per cent solution of sodium chloride around the outside balloon to decrease the dead space in the system. The amount of carbon dioxide can be regulated with the syringe.

the R-wave voltage and activates the valve with an impulse of variable but pre-fixed duration, and variable but predetermined delay. A Cardiac Programmer* was used.⁸

The entire system could be sterilized with ethylene oxide.

Tests conducted in a mock circulation (Fig. 2). The balloon-carrying catheter was inserted into the mock aorta-Tygon tube (internal diameter 1.9 cm.), in which a diastolic pressure of 125 cm. of water was maintained. The inlet pressure was 20 cm. of water, and there was only one tricuspid polyurethane valve⁹ in the system, placed at the inlet. A flowmeter was used in the circuit so that the flow per minute could be read directly. Pressure tracings were obtained with Statham gauges from the catheter system and the Tygon tube. All testing was done with water of 37°C. instead of blood.

Several types of catheters were tested initially as to the number and location of the air-inlet holes and the number of constrictions of the latex tubing. We found that the number of holes was immaterial

*Cordis Corporation, Miami, Fla.

above a certain limit, and that the best flow was obtained when there was constriction at no point of the latex tubing.

The whole system was tested as to the following variables in relation to flow: air pressure in the rigid-wall cylinder, carbon dioxide in the catheter-balloon system, length of the latex tubing, length of the stroke, and diameter of the Tygon aorta. We found that the maximal "blood" flow (1,600 ml. per minute) was obtained under the following conditions (Fig. 3): air pressure of 1.961 grams per square centimeter (27 p. s. i.), volume of 25 ml. carbon dioxide, 20 cm. length of latex tubing, stroke duration of 120 milliseconds, and diameter of the Tygon aorta at least twice the diameter of the latex tube.

The optimal duration of the stroke varied with the air pressure and the amount of carbon dioxide in the system, as well as with the rate of pumping. The amount of carbon dioxide in the system may be varied with a syringe, and an optimum can be found. Low pumping rates (e.g., 60 strokes per minute) permit long stroke duration (e.g., 150 msec.), whereas with high pumping rates (e.g., 112 strokes per minute) the stroke had to be short (e.g., 70 msec.). Sufficient time had to be allowed for evacuation of the carbon dioxide from the latex tubing.

During this testing we also found that

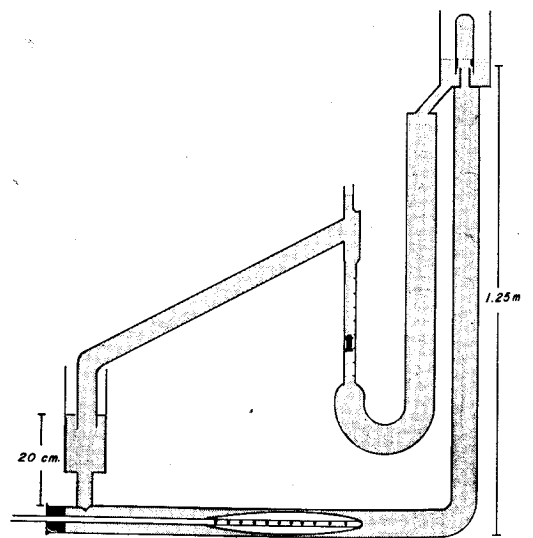


Fig. 2. Diagram of the mock circulation system used to test the intra-aortic pump.

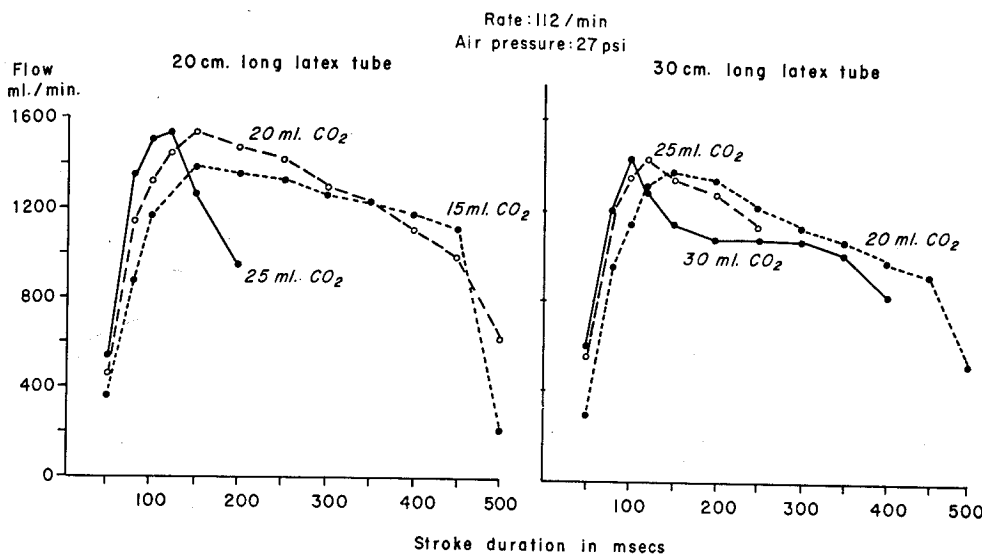


Fig. 3. Curves showing the changes in flow in the mock circulation after the changes in duration of the stroke. Various curves are obtained by varying the amount of carbon dioxide in the system and the length of latex tubing. The highest flow is obtained by a tube 20 cm. long which contains from 20 to 25 ml. of carbon dioxide.

the inflation and deflation of the latex tube could be rapid and complete if the amount of gas leaving the outlets of the solenoid valves was reduced. For this purpose the space in the rigid-wall cylinder was decreased by filling it with a 0.9 per cent solution of sodium chloride in water. In that way the pressure curves generated in the blood by the inflation of the latex tube became narrowed and their length came close to the stroke-length set on the timing device (from 20 to 40 msec. longer). For example, if the stroke length of the Programmer was set at 120 msec., the actual resulting pressure curve would be from 20 to 40 msec. longer, i.e., from 140 to 160 msec.

Testing in dead dogs. By pumping the latex tubing into the aorta of dead dogs, we were able to create a pulsating flow with a pressure of 80/60 mm. Hg, but only when an initial pressure of 40 mm. Hg had been created first in the arterial system by rapid infusion of a 0.9 per cent solution of sodium chloride in water.

Testing in live anesthetized dogs. A 20 cm. length of latex tube was inserted into the thoracic and abdominal aorta through the left carotid or subclavian artery. Mongrel dogs which had a body weight of 15 to 20 kilograms were anesthetized with Nembutal sodium. Pressures were

recorded by means of Statham gauges (P23Db, 12V, 0-75 cm. of Hg) from the left femoral artery, the right brachial artery, the left ventricle, and the left atrium. The left ventricle and the left atrium were catheterized through the left auricular appendix after left thoracotomy. The signal of the timing circuit was recorded, so that the exact location and length of the pump stroke are also indicated in the tracing. The blood flow was recorded by means of an electromagnetic flowmeter* at the left femoral artery and the brachiocephalic trunk.

The time of delay from the R wave of the electrocardiogram was regulated according to the heart rate. We found that it was practical to calculate the optimal delay by the formula: $D:RR'-(S+40)$, where RR' is the length of one cardiac cycle in milliseconds, and S is the stroke time in milliseconds. For example, when the cardiac cycle (RR') was 400 msec. (150 beats per minute) and the stroke was 120 msec., the delay was set at $400-(120+40)=240$ msec. Improper delay time caused the pump stroke to operate during systole, and to be superimposed on the heart pressure wave. As a result of this mistiming, the load imposed on the

*Microflo, FM-6, Medicon Division, Quality Precision Products, Inc., Los Angeles, Calif.

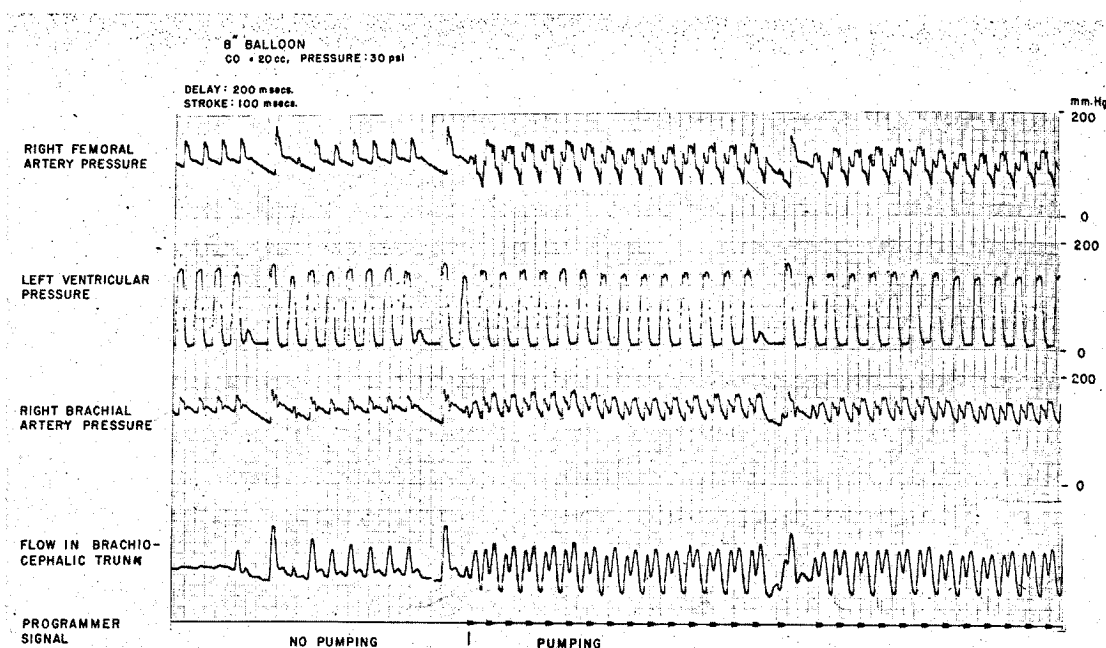


Fig. 4. Graphs of blood pressures and flow before and during intra-aortic balloon pumping. The pump pressure wave in diastole is higher than the heart wave, in both the femoral and the brachial arteries. The left ventricular pressure goes slowly down during the pumping. The end-diastolic pressure in the arteries is lower during pumping. The blood flow in the brachiocephalic trunk due to inflation of the balloon during diastole gives a higher wave than the one caused by contraction of the heart.

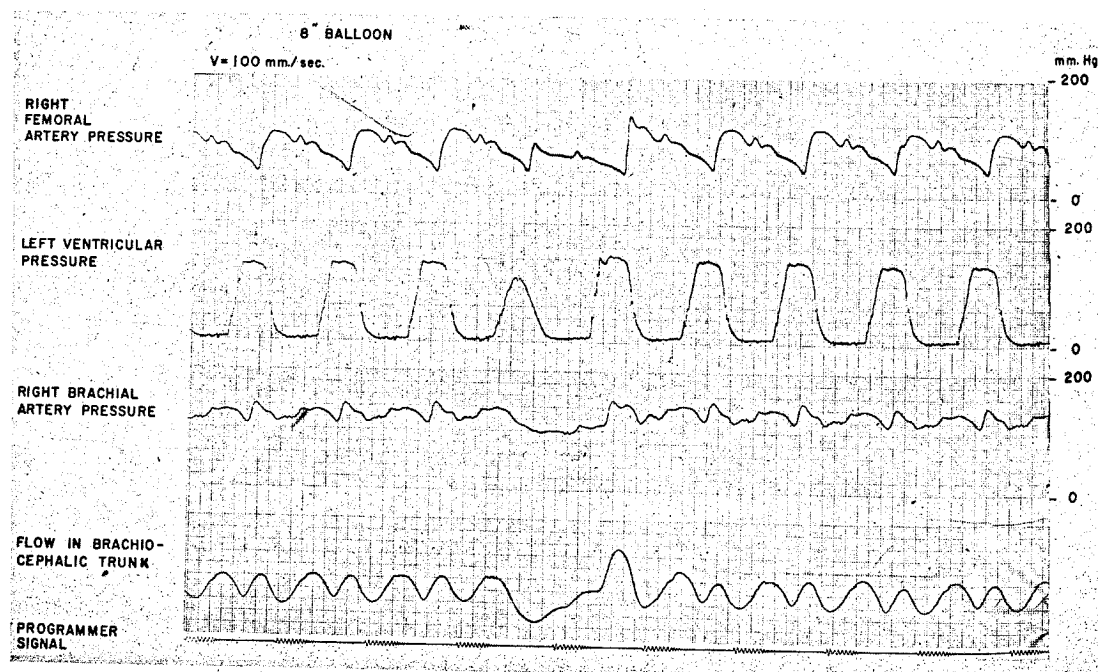


Fig. 5. Record made at high-speed during pumping. The end-diastolic pressure is low in the femoral artery. The flow through the brachiocephalic trunk is considerably increased during diastole.

ventricle was increased. Thereafter, the pump stroke was not initiated before the dirotic notch appeared on the aortic pressure tracing, which indicated closure of the aortic valve. The entire pump stroke had to be completed at least 20 msec. before the next ventricular systole began, in order to assure lowering of the end-diastolic pressure in the aorta (Fig. 4): only under these circumstances was the left ventricular pressure reduced.

The pressure waves corresponding to the pumping, recorded in the brachial and femoral arteries, were higher than those of the heartbeat (Fig. 4). The end-diastolic pressure in the arterial system was lowered. The flow through the brachiocephalic trunk was slightly increased, and the flow wave due to the pumping was larger than the one due to the heart action (Fig. 5). The systolic pressure in the femoral artery was sometimes reduced dur-

ing pumping, possibly because the deflated latex tubing presented an obstacle to the systolic flow in the aorta. However, the mean pressure did not change, and the flow curves demonstrated that the total flow through the femoral artery was not reduced.

When the ventricles were fibrillating, the intra-aortic pumping did not produce a significant increase in pressures; but if the arterial pressure was slightly elevated by cardiac massage, the effect of pumping was notable on the pressure tracings (Fig. 6).

Cineangiography in human cadaver. Finally, the balloon was inserted into the ascending aorta of a cadaver, half an hour after death. Radiopaque dye was injected by means of a common catheter into the ascending aorta. Cineangiographic film taken during pumping showed considerable movement of the dye toward the

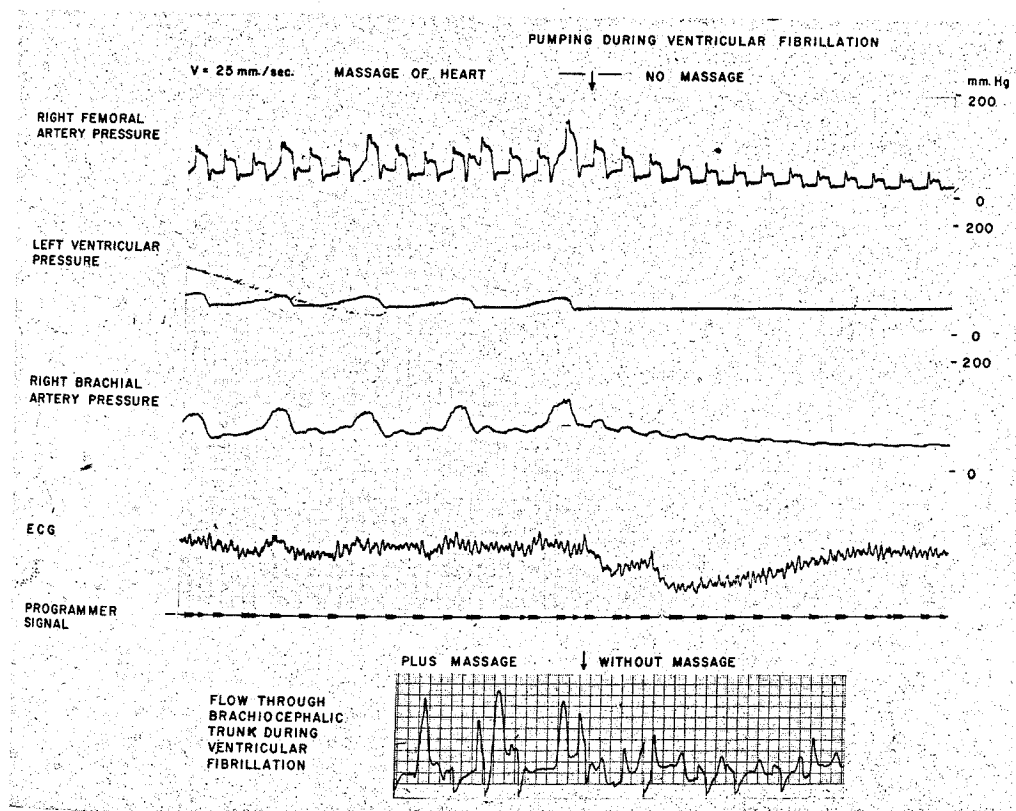


Fig. 6. Intra-aortic pumping during ventricular fibrillation. Significant pump waves are recorded only when a pressure of at least 40 mm. Hg is maintained by manual heart massage. Although the left ventricular pressure during manual massage does not rise above 50 mm. Hg, the pressures in the femoral and brachial arteries rise to about 100 mm. Hg. The flow in the brachiocephalic trunk during balloon pumping is also higher during massage.

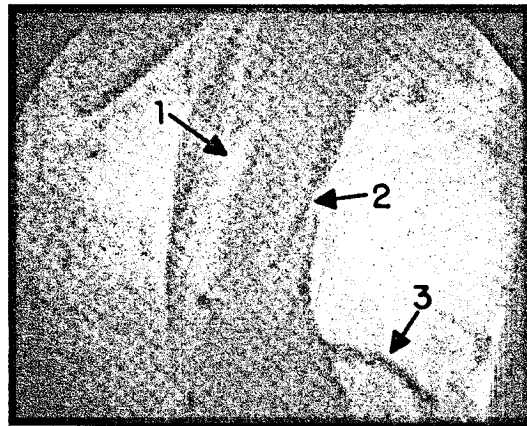


Fig. 7. An intra-aortic balloon in the ascending aorta of a human being. 1, The middle of the spindle-shaped, gas-filled space occupied by the inflated balloon. 2, A common catheter for injections. While the balloon is inflated, the radiopaque dye fills the coronary artery (3). The heart is in arrest. (Made in the Cardiovascular Laboratory of Dr. Sones.)

coronary (Fig. 7) and other peripheral arteries, although the heart was in complete arrest.

Comment

The mechanical device described was designed to assist the heart in maintaining the circulation, and to increase the coronary blood flow during diastole. Tests on anesthetized dogs in which we assumed that the circulation was normal showed that intra-aortic pumping with the balloon increased the flow of blood in the arterial system during diastole and lowered the end-diastolic arterial pressure. It is obvious that under these conditions the contracting left ventricle has less resistance to overcome in the arterial system. Thus, a part of the work of the heart is taken over by the mechanical pump.

The effect of intra-aortic pumping on a failing heart is not known. It is difficult to induce left ventricular failure in the dog without causing its death. There are indications, however, that intra-aortic pumping may be of help by relieving the left ventricle of some of its work, and by increasing the blood flow and possibly the coronary blood flow during diastole. Failure of the right side of the heart cannot be helped directly by intra-aortic pumping. Furthermore, intra-aortic pumping is not effective in ventricular fibril-

lation or in instances of very low arterial pressure; in that case the combination of pumping and heart massage increased pressure and flow.

The danger of rupture of the intra-aortic latex tube and of gas embolism in the patient is minimal since, even though the tube is filled, it is not distended during pumping. The pressure is not applied directly on the latex tube but on the thick-walled balloon outside the body; a safety device is provided. Moreover, the closed latex tube system is filled with carbon dioxide, which would be relatively harmless in case of a leak.

The diastolic arterial support to the circulation as described would probably be contraindicated in cases of aortic insufficiency.

The advantages of pumping by means of an intra-aortic balloon are these: (1) No blood is handled outside the body. (2) Only one vessel is cannulated. (3) No blood is needed for priming the device. (4) The device is very simple.

Summary

A device to provide mechanical assistance to the failing circulation is described. It consists of a catheter in a long, narrow latex tube that was inserted into the descending aorta of an anesthetized dog. The latex tube was rhythmically inflated with carbon dioxide through a pressure system, and the stroke was triggered with the aid of a timing circuit from the electrocardiogram of the animal. The stroke length and the delay after the R wave of the electrocardiogram were preset so that the latex tubing was inflated during diastole and remained deflated during systole.

It was possible to increase the diastolic blood flow in the arterial system and lower the end-diastolic arterial pressure. It is hoped that the use of this device in the failing heart will result in increased diastolic blood flow, improved coronary perfusion, and decreased work for the failing left ventricle. The best indication for its use would be a failing left ventricle due to an acute coronary thrombosis.

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