ABSTRACT: An intra-arterial cardiac assisting device is provided having a nonelastic polyurethane balloon which is inflated periodically for diastolic augmentation by utilization of helium. The leading end of the device, which is passed into the aorta as a catheter, has a pressure transducer therein.
CARDIAC ASSISTING PUMP

The present invention relates to a cardiac assisting pump, and, more particularly, to an autosynchronous intra-arterial balloon pumping system for temporary cardiac assistance.

Fourteen of every 100 patients with acute myocardial infarction suffer profound cardiogenic shock. Of these patients, from 9t0 13 are unresponsive to medical therapy and need some form of effective circulatory assistance. Accordingly, a vital need has existed for quickly combating profound cardiogenic shock in a relatively simple mechanical manner. While the treatment of cardiogenic shock has undergone numerous developments in recent years, primarily in the field of drug therapy, the mechanical devices which have been suggested (e.g. for elevating diastolic pressure while reducing systolic pressure) have involved extended surgical procedures. Accordingly, the need has existed for quickly combating profound cardiogenic shock, and the best mechanical approach heretofore contemplated has involved intra-arterial balloon pumping.

In 1962 Moulopoulos et al.1 used an intra-arterial latex rubber balloon as a device for diastolic augmentation. In 1962 Clauss et al.2 also experimented with intra-arterial balloon pumping. However, the devices contemplated were not generally satisfactory. Problems in prior art devices included providing a satisfactory catheter diameter, obtaining sufficiently biologically compatible materials from which the devices could be formed, providing a sufficiently great bore within the catheter to permit satisfactory inflation, the safety factor of the balloon itself, correct timing of the pumping and proper insertion of the intra-arterial pump into the aorta.

It is therefore an object of the present invention to overcome the deficiencies of the prior art, such as indicated above.

It is another object of the present invention to provide for intra-arterial cardiac assistance in a new, improved and unobvious manner and to provide a novel intra-arterial cardiac assisting pump.

It is another object of the present invention to provide an autotransplantation balloon pumping system for temporary cardiac assistance. It is another object of the present invention to provide a practical means of rapid, effective assistance to the patient in profound, refractory cardiogenic shock.

It is another object of the present invention to provide an intra-arterial cardiac assisting pump having a relatively small diameter catheter, utilizing materials which are biologically compatible and utilizing a low density driving gas, which pump is effective in its intended purpose.

It is another object of the present invention to provide an autosynchronous balloon pumping system for temporary cardiac assistance having an intra-arterial portion which senses pressures in the aorta and assists in the correct timing of the pumping.

It is another object of the present invention to provide intra-arterial cardiac assisting pump which can be simply inserted into an artery, and which subsequently takes on the shape of the aorta during use.

These and other objects of the nature and advantages of the present invention will be more apparent from the following detailed description taken in conjunction with the drawings wherein:

FIG. 1 is a partly broken away, partly schematic diagram of one embodiment of an intra-arterial cardiac assisting pump in accordance with the present invention;
FIG. 2 is a view like FIG. 1, showing another embodiment of the present invention; and
FIG. 3 is a schematic illustration of an autosynchronous intra-arterial cardiac assisting balloon pump, showing ex-

tracorporeal components.

An intra-arterial assisting device in accordance with the present invention comprises, in general, two major components, namely an extracorporeal unit 10 (FIG. 3) and an intracorporeal unit 12. A first embodiment of the extracorporeal unit 12 is shown in FIG. 1, while a second embodiment, similar in many respects to the embodiment in FIG. 1, is shown in FIG. 2.

Briefly, the extracorporeal unit 12 includes a hollow elongated arterial catheter portion 14, an inflatable, nonelastic balloon portion 16, and a perforated reenforcing portion 18. The extracorporeal unit 10 includes, very generally, a source of 50 g of gas under pressure (preferably helium), a solenoid valve unit 52 for periodically feeding the helium into the intracorporeal unit 12 and suitable electronic means for receiving a signal from the body in which the intra-arterial cardiac assisting device has been placed (such as ECG signals through leads 58 and 56) and using such signal for the opening and closing periodically of the solenoid valve 52.

The intra-arterial cardiac assisting device of the present invention works in the following manner. Normally, the heart pumps blood into the aorta, the body's main artery leaving the heart, during a period of time termed cardiac systole. The following period of time, during which the heart is not pumping, but is filling with blood, is termed cardiac diastole.

When the heart is in need of assistance, the intracorporeal unit is passed through the body's skin into a suitable artery (such as the femoral artery) and passed toward the heart so that the balloon 16 is in the thoracic aorta just below the location where the subclavian artery branches from the aorta. When the electronic means embodied in the extracorporeal components receives an appropriate signal from the balloon, the solenoid valve is actuated so as to admit helium through the catheter 14, through the perforations in the reenforcing portion 18, and finally into the balloon 16 at the beginning of cardiac diastole, thus inflating the balloon. During cardiac diastole the resistance to flow in the vessels of the heart, i.e. the coronary arteries, is at a minimum. Inflation of the balloon 16 at this time increases the flow through the coronary arteries and pumps blood along the aorta toward the neck and head and toward the kidneys, liver, stomach and other organs.

Deflation of the balloon 16 at the end of cardiac diastole aids the heart by reducing the pressure in the aorta which the heart must normally pump against during cardiac systole. This permits the heart to pump a large volume of blood with each contraction and also reduces the pressure in the aorta, carotid, or main pumping chamber of the heart, at the end of cardiac diastole. The combined effects of inflation and deflation of the balloon in this manner provide significant aid to the heart in need of assistance.

Describing the intracorporeal unit 12 of FIG. 1 in greater detail, it will be seen that the leading end 20 of the device comprises a stainless steel housing 22 in which is incorporated a pressure transducer 24 having suitable insulated electrical leads 26, which pass backwardly through the perforated reenforcing element 18 and along the catheter portion 14, as illustrated, to a junction 28 and then to an electrical lead carrying portion 30 terminating in an electrical outlet 32. While the housing 22 is preferably formed of stainless steel, it will be understood that any rigid, biologically inert material may be used for such housing. In addition, other rigid materials can be used and can be coated with a biologically compatible material such as polyurethane.

The housing 22 is connected to the end of the hollow, elongated, perforated reenforcing element 18, such as by being inserted therein. Such reenforcing element 18 preferably comprises a flexible braided tube of metal wires, such as copper braid, conventionally used as electrical shielding. Such copper braid has been found to be highly advantageous since it is flexible and conforms to the shape of the artery during operation of the intracorporeal unit, and also permits the flow therethrough of the inflating gas into the balloon 16. Where the reenforcing element 18 comprises the copper braid, the lead 26 from the pressure sensor transducer is woven into the copper braid 18.
Along a portion 34 of the device 12 of FIG. 1, the copper braid 18 and the catheter 14 are coextensive, the copper braid being soldered or otherwise adhered tight over the preferably etched end of the catheter 14. Overlying the entire copper braid 18, at least a portion of the housing 22 (preferably the entire housing 22) and the entire length of the junction portion 34 is the thin walled, flexible, generally nonelastic, inflatable balloon 16, desirably formed of polyurethane. Polyurethane is the preferred material since it is not only biologically compatible, but it has the best combination of desirable physical properties such as abrasion resistance, ease of handling, tensile strength, and resistance to elastic inflation.

The catheter portion 14 is, as described above, a hollow elongated tube adapted, along with the housing 22, the reenforcing element 18 and the balloon 16, to be inserted into the artery. It is, accordingly, essential that the outer diameter of the catheter 14 be sufficiently small to permit its insertion into the artery. While the catheter 14 may be formed of any suitable material which is sufficiently flexible to permit it to elobent, or coiled, it is necessary that its outer surface be provided with a biologically compatible material. Thus, the catheter 14 may be formed of vinyl plastic material coated with polyurethane; however, it is preferably formed of polytetrafluoroethylene which is, itself, biologically compatible and which has other desirable properties. Particular advantages of polytetrafluoroethylene include its inertness and its very smooth surface.

It is preferred in the FIG. 1 embodiment that the catheter 14 be formed of two concentric polytetrafluoroethylene tubes, the outer of which has been heat shrinked about the inner, the sensor leads 26 being retained between the two concentric tubes. This will be understood, of course, that the catheter portion 14 is sufficiently long so that the balloon 16 may be deposited in the aorta while the junction 28 remains outside the body. The catheter 14 continues beyond the junction 28, as an extracorporeal tube 36, terminating in a connector 38 for attachment to the solenoid valve unit 52.

The extracorporeal unit 12 of FIG. 2, is, in many respects, similar to that described above in relation to FIG. 1. The primary distinctions include the use of a temperature-compensated pressure sensor having two transducer elements 24 and 24', and the use of a copper braid 18 which extends not only the length of the balloon 16 and along only a small portion of the catheter 14, but which spans the catheter 14 along its entire length, the leads 26 from the pressure transducer elements 24 and 24' being woven into the copper braid 18 along its entire length. In addition, an extracorporeal housing 40 is provided of suitable semiflexible plastic, such as molded polyurethane, into which the gas connection 38 and the electrical connection 32 are embedded for improved ease of connection with the solenoid valve unit 52. Also, instead of the polytetrafluoroethylene catheter, polyurethane is extruded over the copper braid 18. Since all external surfaces of the entire assembly except for the connectors to the solenoid valve 52 and the electrical outlet are made of polyurethane, very highly reliable junctions between these surfaces can be achieved.

The extracorporeal unit 10 includes, besides the source 50 of helium under pressure and suitable passageways and pressure regulating valves and metering devices therealong passing to the solenoid valve unit 52, as part of the control means, a modified double beam oscilloscope 60 and a recorder 62. The patient's EECG is recorded through leads 58 and passed through to the oscilloscope 60 through the leads 56. Central aortic pressure is measured by the pressure transducer elements 24 and 24' and passed through the leads 26 to the oscilloscope 60 and from these through leads 66 to the recorder 62. In turn, the oscilloscope 60 passes a signal through a lead 64, based on information received through the leads 58 and 26 from the opening and closing of the solenoid valve 52. By means of the modified double beam oscilloscope 60, a preselected point either of the central aortic pressure, as obtained from the transducer 24, or of the ECG, controls the solenoid valve of the pumping unit causing the helium to flow into the balloon 16 very quickly to inflate such balloon 16 to its preselected nonelastic maximum diameter.
It will be obvious to those skilled in the art that various changes may be made without departing from the scope of the invention and that the invention is not to be considered limited to what is shown in the drawings and described in the specification.

What we claim is:

1. An intra-arterial cardiac assisting pump comprising:
a hollow elongated arterial catheter portion having an outer diameter sufficiently small to permit the insertion thereof into an artery, at least the outer surface thereof being provided with a biologically compatible material;
a hollow elongated, perforated reinforcing element having a leading end and extending along at least a portion of said catheter and extending beyond the end of said catheter portion, said perforated reinforcing element having approximately the same diameter as said catheter portion and forming an extension thereof;
a very thin-walled, generally inelastic, cylindrical polyurethane balloon portion surrounding said perforated reinforcing element and in gas sealing relationship with said catheter portion, said balloon portion having an area in cross section when inflated of approximately 20—80 times as great as that of the said reinforcing element;
means for periodically feeding low density gas to said balloon through said catheter and reinforcing element to periodically inflate said balloon to its maximum inelastic diameter; and
internal pressure measuring means including a pressure transducer located at and connected to the leading end of said reinforcing element, electrical leads passing from said transducer through said reinforcing element and catheter, and means to translate the electrical signal from said transducer.

2. A pump in accordance with claim 1 wherein said transducer is provided with a rigid housing, said housing comprising said connection to the end of said reinforcing element.

3. A pump in accordance with claim 2, wherein said catheter is formed of polytetrafluoroethylene.

4. A pump in accordance with claim 2 wherein said reinforcing element comprises a flexible braided tube.

5. A pump in accordance with claim 4 wherein said braided tube is metallic.

6. A pump in accordance with claim 5, wherein said polyurethane balloon has an inflated diameter on the order of 1—2 cm., wall thickness on the order of 0.100—0.125 mm., and a length of about 10—17 cm., and wherein said catheter and braided tube have outer diameters of about 5 and 3—5 mm., respectively.