

Original Article

An In Vitro Analysis of a One-Way Arterial Check Valve

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ABSTRACT

The utilization of a centrifugal pump during extracorporeal circulation may result in retrograde blood flow through the circuit. The non-occlusive characteristics of a centrifugal pump could create a condition where regurgitant flow is possible when the pressure in the cannulated vessel exceeded the pressure in the extracorporeal circuit. The reversal of flow, from patient to pump, could entrain air from multiple points including cannulation sites, suture holes, or open vessels or chambers. The following study was conducted to evaluate the ability of an arterial check valve (ACV) to prevent retrograde flow.

An in vitro circuit was designed to evaluate the flow dynamics of an ACV under a variety of test conditions including the following: flow rates between 0 and 7.5 L/min, and at temperatures of 37°, 25° and 15°C. The design characteristics of the ACV permitted easy priming, aided by gentle turbulence at the junction of the valve attachment to the casing. There was no difference in pressure drop across the ACV at any flow when compared to an identical circuit without the valve. The pressure drop across the ACV never exceeded 5 mmHg, at any temperature, when flow was less than 2 L/min. Retrograde leak volume was determined by creating “back” pressures on the valve, ranging from 25 to 500 mmHg. One ACV malfunctioned at a back pressure of 250 mmHg, and the data for that valve was omitted for comparative purposes. On the remaining valves, leak volume did not exceed 1.2 ml, and was a result of the compliance of the leaflet structures causing a slight volume displacement due to valve motion in a retrograde fashion. The results of this study show that the ACV permitted unimpeded, unidirectional flow at all operating conditions considered clinically relevant, and may be efficacious in alleviating the chance of retrograde circuit flow.

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INTRODUCTION

The centrifugal pump (CP) was originally designed in 1972 to be used as an implantable artificial heart (1), but gained acceptance for use during routine cardiopulmonary bypass (CPB). Utilization of the CP has been reported to reduce red blood cell hemolysis and maintain platelet counts higher than traditional positive displacement roller pumps (2,3). The physical flow conditions created by the vortexing action of a CP act as a safety feature during extracorporeal circulation. The maximum energy imparted to a fluid by the CP will not exceed the limits of properly connected tubing, and there are no reported cases of tubing rupture with increasing resistance to fluid movement. The constrained housing of a CP will deprime when large boluses of air are entrained into the system, limiting the potential for gross air embolism to the patient (4).

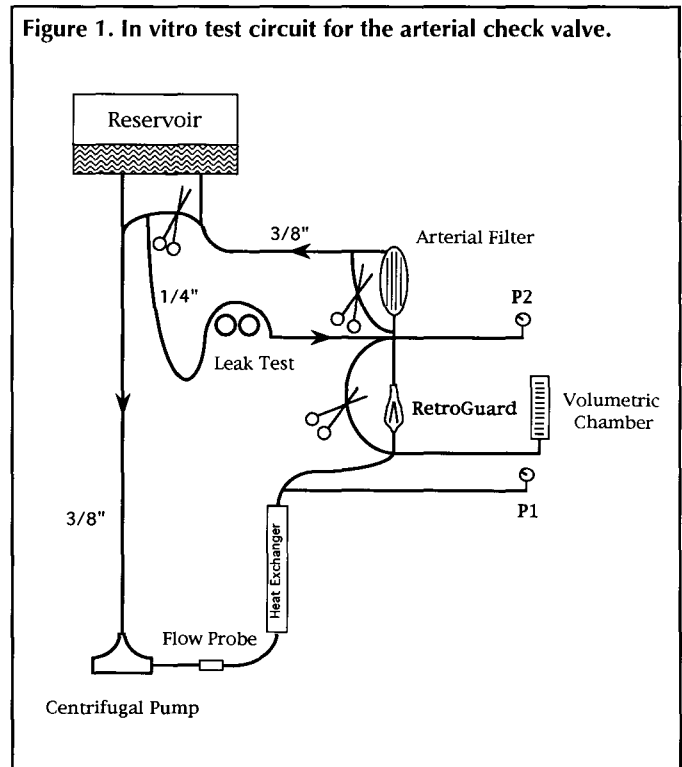
The non-occlusive nature of a CP creates the potential for retrograde blood flow when the pressure in the cannulated vessel exceeds the pressure within the circuit connected to the outflow side of the pump (2). This situation may result in patient exsanguination, which may lead to systemic hypotension. When the cannulated vessel is the ascending aorta, the potential for cerebral hypoperfusion is increased. In addition, the entrainment of air may occur from suture holes at the cannulation site (2,5-7). In the event of an air entrainment at the cannulation site, air detection systems may not be effective since they are most often located proximal to the cannula. When forward flow is re-established, the entrained air, which maintained its position because of buoyancy, can be directly infused to the patient.

This study was designed to examine the function of an arterial line check-valve (ACV), purported to be a safety device designed to reduce the chance of retrograde flow in the event of a reduction in circuit energy to less than that seen in the cannulated vessel.

MATERIALS AND METHODS

The ACV is composed of an acrylonitrile-butadiene-styrene (ABS) casing with an internal "duckbill" valve made of rubber silicone, and is designated the RetroGuard by the manufacturer^a. To determine the effectiveness of this device an *in vitro* circuit was designed and utilized in this study (Figure 1). The circuit consisted of the following components: a centrifugal pump^b, heat exchanger^c, arterial line filter^d, soft shell venous reservoir^e, twin roller head pump^f and a heater cooler^g. Six

- a RetroGuard, Quest Medical, Allen, TX 75002
 b BP 80, 540 Bio-Console, Medtronic Bio-Medicus Inc., Eden Prairie, MN 55344
 c A-19-38 Omnitherm, AVecor Cardiovascular Inc., Minneapolis, MN 55345
 d Bentley ALF10, Baxter Healthcare Corp., Irvine, CA 92714
 e BMR 1900, Baxter Healthcare Corp., Irvine, CA 92714
 f CAPS, Sorin Inc., Irvine CA 92713
 g TCM, Sarns 3M Health Care, Ann Arbor, MI 48106



devices were tested on this circuit with regard to the following protocols.

PRESSURE DROP EXPERIMENT

The circuit was primed with a physiologic saline solution and filtered expired human blood to a hematocrit of 25% (23.5%-27%). The pressure drop across the arterial check valve was measured by fluid filled transducers designated as pressures P1 and P2 on Figure 1. The control pressure drop was measured by isolating the ACV in the circuit, with flow directed through the bypass loop. Pressure drops were obtained after the circulating perfusate equilibrated at each of the following temperatures: 37°, 25°, and 15°C. At each temperature the pressure drop was recorded at flows ranging from 0.25 L/min to 7.5 L/min.

LEAK VOLUME EXPERIMENT

The leak volume of the arterial check valve was obtained through the use of an integrated circuit. A separate roller pump with 1/4 inch tubing was used to create retrograde flow conditions on the outlet port of the arterial check valve. Leak volume was collected in a 2 ml graduated pipette. By clamping distal to the heat exchanger and proximal to the arterial line filter, leak volume could be directed into the pipette. The leak volume was recorded at pressures ranging from 25 mmHg to 500 mmHg and was measured at P2, which was recorded just distal to the ACV. Pressures were obtained by slowly handcranking the roller pump to the desired pressure. The roller pump was made totally occlusive on the 1/4 inch line assuring fluid movement forward with no retrograde leakage through the raceway. The determina-

Figure 2. Comparison of pressure drop between circuit with check valve and without at 15°C.

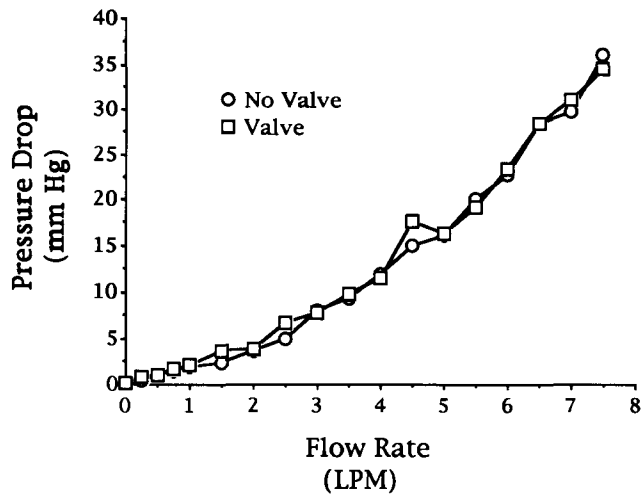


Figure 4. Comparison of pressure drop between circuit with check valve and without at 37°C.

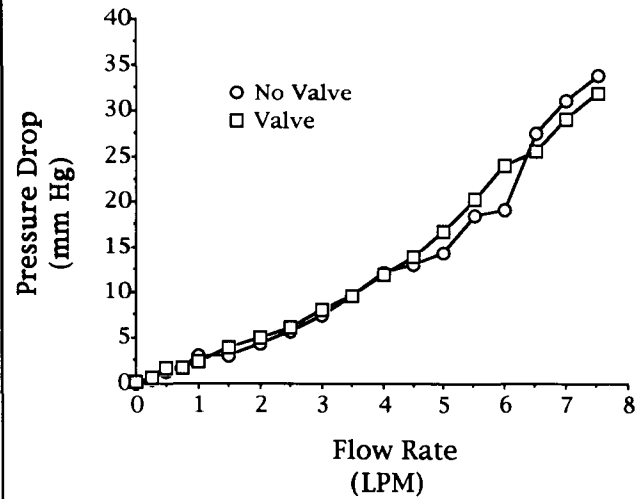


Figure 3. Comparison of pressure drop between circuit with check valve and without at 25°C.

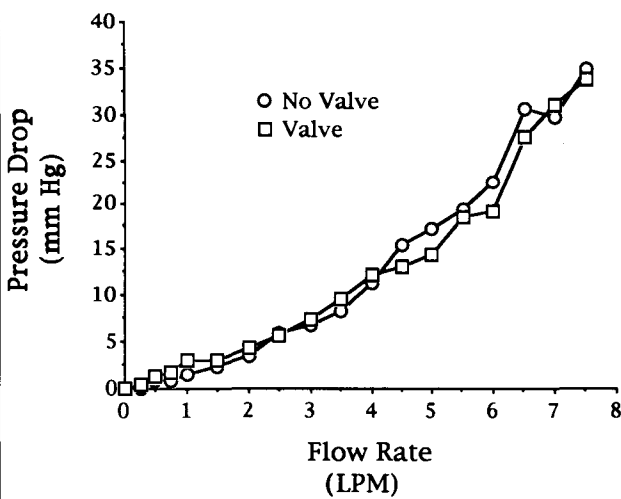
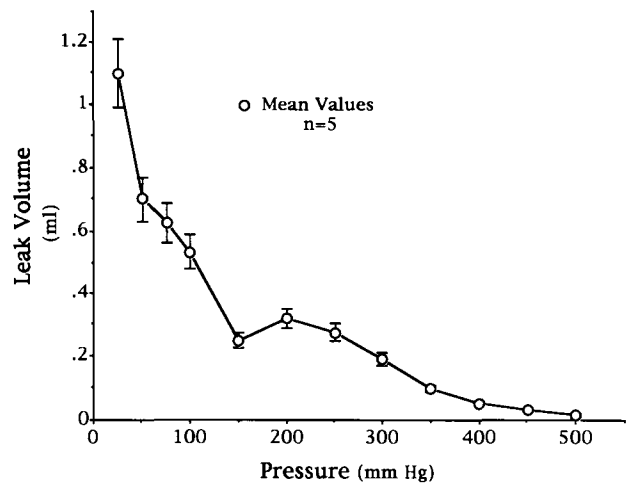


Figure 5. Leak volume of check valve at 15°C.



tion of leak volumes was completed at 37°, 25°, and 15°C.

STATISTICS

All data was loaded onto a personal computer in a spread sheet format. One-way analysis of variance was performed for intragroup comparisons, and when significant F ratios were achieved, an additional multiple comparison test (Fisher's least significant difference) was performed. Statistical significance was accepted at $p < 0.05$ level. All data are reported as mean \pm standard deviation of the mean.

RESULTS

Results of the pressure drop experiment are shown in Figures 2 through 4. There were no differences between groups

in pressure drop observed at any temperature.

The results of the leak volume experiment are shown in Figures 5 through 7. The leak volume ranged from 0.05 ml to 1.5 ml. The leak volume is indicative of the deformation of the valve at high retrograde pressure. It should be noted that the leak volume is measured at the proximal side of the valve while the pressure measured at P2 reflects the pressure of retrograde flow. Therefore, since the valve material is made of silicone, the compliant characteristics of the valve will displace volume equal to the deformation of the valve. At pressures greater than 300 mmHg minimal displacement of the valve structure was noticed.

The greatest leak volume was seen at a perfusate temperature of 15°C at 25 mmHg pressure. However, there were no statistically significant differences in leak volume between the three temperatures at any measured pressures. During one ex-

Figure 6. Leak volume of check valve at 25°C.

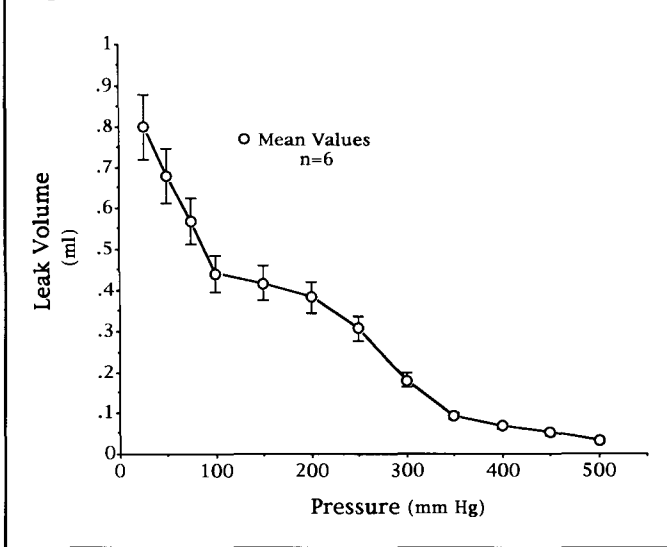
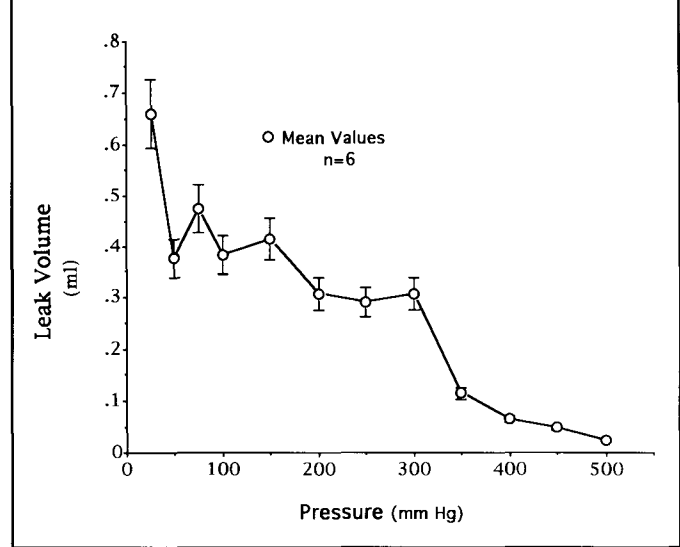


Figure 7. Leak volume of check valve at 37°C.



periment, however, one ACV became incompetent at a pressure of 250 mmHg, causing significant regurgitant flow.

DISCUSSION

Centrifugal pump design features that contribute to the safety of CPB have been researched and discussed in reviews on extracorporeal equipment (2,3). Unlike an occlusive roller pump, the non-occlusive constrained vortex created by a centrifugal pump protects the circuit from excessive outflow pressures if a line is unintentionally clamped or kinked. Another advantage of the centrifugal pump is the tendency for the pump head to deprime in the event of a large bolus of introduced air. However, there is no protection against retrograde flow when the energy imparted to the circulating fluid drops below the energy in the cannulated vessel (5). In the aortic position, back flow of blood can result via a siphon effect creating the possibility of entrainment of air emboli into the aorta from suture holes, or from the cannula connection points. In the event of electrical or pump failure, this retrograde flow may occur rapidly, which may limit the effective intervention of a perfusionist. Once forward flow is reestablished the air emboli will be infused directly into the patient (2,5-7). The consequences of this event going unnoticed are evident and the prevention of such an occurrence has been the primary focus for the development of an ACV.

When considering any device in the circuit it is important to know the flow dynamics of that component. In this study, pressures were measured pre and post valve under a wide range of flows. In turn this was repeated at different temperatures to simulate conditions of normal cardiopulmonary bypass. Pressure drops across the valve were not significant in comparison to the pressures of the circuit without the valve, indicating that the valve offers no additional resistance to the forward movement of fluid (Figures 2 through 4).

The introduction of any new arterial device distal to the

oxygenator needs careful evaluation. Analogous to all other circuit components, when priming the ACV it is important to remove all gaseous emboli from the device prior to CPB. This was easily facilitated by the observation of a gentle turbulence around the valve leaflets that aided in dislodging residual air. Another feature of having the valve in place is removing the need for immediate clamping of the arterial line following termination of CPB with non-occlusive pumps. The arterial pump can be turned off without the worry of exsanguination.

To assess the compliance of the valve we applied pressure (0 to 500 mmHg) to the outflow side of the valve measuring the leak volume past the valve at three different temperatures. It was determined that the valve closed virtually immediately after pump flow stopped disallowing any retrograde flow through the circuit. The pressures applied simulated clinical and non-clinical situations where the pressure distal to the ACV exceeded the pressure proximal to the ACV. As shown in Figures 5, 6 and 7, there was a minimal amount of volume that could be recorded retrograde past the valve. Although a volume was noted, this was not actually reflecting an incompetent valve leak but rather deformation of the pliable valve itself as pressure was exerted upon it. This was confirmed by maintaining a constant pressure on the valve and observing no increase in the volumetric pipette after initial displacement. It is unknown whether the failure of one of the six ACVs at 15°C at 250 mmHg during our study was temperature dependent, or corresponded to the physical characteristics of the silicone material, or device design. To date we have utilized the ACV in over 50 clinical perfusions and have experienced no device failure of any kind.

In conclusion, the ACV proved to safely perform over all simulated clinical conditions in this in vitro experiment. The prevention of retrograde flow from cannulated vessels during extracorporeal circulation with centrifugal pumps will improve the overall safety of cardiopulmonary bypass.

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