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Laboratory Evaluation of the Limitations of Positive Pressure Safety Valves on Hard-Shell Venous Reservoirs

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Abstract: Vacuum-assisted venous drainage (VAVD) is a technique used to increase venous return during cardiopulmonary bypass (CPB). However, VAVD has created some new safety concerns. One potential problem is the pressurization of the venous reservoir in the event of vacuum failure. To prevent this overpressurization, a positive pressure release valve (PPRV) is placed on the venous reservoir. The purpose of this study was to determine if there is a difference in the pressurization of venous reservoirs using various PPRVs. The method of this study included evaluation of four different venous reservoirs and their associated PPRVs. Each reservoir was completely sealed, and two roller pumps with ¼-in tubing were connected to the reservoir suction inlet. The roller pumps were calibrated, and a disposable pressure transducer was used to measure pressure at the venous inlet. Each reservoir was first sealed and then pressurized to test the occlusion of the roller heads. The PPRVs were tested by measuring the venous inlet pressure at a range of suction flow rates from 0–5 L/min. Linear regression analysis was performed to predict the venous inlet pressure from the rate of suction flow for each PPRV. The PPRV in the Baxter, Gish, and Gambro reservoirs maintained a low reservoir pressure (<40 mmHg) even at excessive suction flow rates (3–5 L/min). The PPRV in the Medtronic reservoir allowed excessive pressures (>40 mmHg) even at low flow rates (1–2 L/min). It is recommended that any reservoir used for VAVD be evaluated in a similar manner to determine whether it is safe under the maximal suction and vent flow conditions possible during clinical practice. **Keywords:** vacuum-assisted venous drainage, VAVD, positive pressure relief valves, safety valves, cardiopulmonary bypass. *JECT. 2002; 34:115–117*

Vacuum-assisted venous drainage (VAVD) is a technique being reintroduced to the perfusion community because of several advantages. It has been useful in reducing priming volumes in small adult and pediatric patients by allowing initiation of cardiopulmonary bypass with an unprimed and smaller diameter venous line (1–3). Without the dependency of venous return on reservoir height, the perfusionist the can decrease the length of tubing and decrease table line volume. VAVD allows the use of smaller venous cannulas, thus improving visibility in the surgical field without comprising venous return. This is especially advantageous in minimally invasive cardiac surgery, or femoral–femoral bypass used for reoperative surgery.

The use of VAVD has also brought to the forefront some new safety issues for the perfusionist to consider during cardiopulmonary bypass. A potential problem associated with VAVD is the pressurization of a hard-shell reservoir in the event of vacuum failure with high-volume return from sucker and vent lines. During this event, the reservoir can overpressurize, and large amounts of air can be forced up the venous line into the patient or forward through the arterial line if a centrifugal pump is employed. Another source of air embolism can occur in situations where the vent is underoccluded and not in use. This could lead to massive arterial air embolism if the aortic root vent is being used without a check valve to prevent reversal of vent blood flow.

Positive pressure relief valves (PPRV) to prevent overpressurization of the reservoir are either integrated or attachable to the venous reservoir. The PPRV are available in a range of diameters and are made from various materials. The purpose of this study is to evaluate the different PPRVs and their ability to limit the maximum amount of positive pressure in the venous reservoir during a sudden loss of vacuum.

MATERIALS AND METHODS

The PPRVs evaluated in this study were as follows: Baxter (Baxter Healthcare Corp., Irvine, CA) Gish (Gish Biomedical, Inc., Irvine, CA), Medtronic (Medtronic Perfusion Systems, Minneapolis, MN) and Gambro (Cobe/Gambro/Sorin, Lakewood, CO). Each group had a sample size of five ($N = 4$). Each of the above venous reservoirs came equipped with an integrated PPRV except for Baxter. Baxter offers an attachable PPRV, which comes sepa-

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rate from the venous reservoir and must be attached by the perfusionist. Each company markets their venous reservoir as VAVD ready and the ability of their PPRV to function as a safety device that will open and release air at positive pressures greater than 5 mmHg. This information can be found in the package insert provided with each reservoir.

Each reservoir was placed in its appropriate holder. The venous reservoir was completely sealed, and two ¼-in suction lines were connected to the reservoir suction inlet. A Stöckert-Shiley (Sorin Biomedical, Irvine, CA) 2-pump base was used to control suction return. Each roller pump was calibrated at 1.25 L/min for every 100 rpm, which was confirmed by volume measurement. The console was equipped with the Stöckert–Shiley computer-assisted perfusion system (CAPS) to monitor pressure. A Baxter disposable pressure transducer was zeroed and then connected to the CAPS, which was used to monitor pressure at the venous inlet. Each reservoir was then pressurized to 150 mmHg for 1 min to test the occlusion of the roller heads. After releasing the pressure in the sealed reservoir, each PPRV was tested by measuring the venous inlet pressure at a range of suction flow rates from 0–5 L/min. The speed of the rollerhead was increased by increments of 100 mL/min and the pressure at each increment recorded. Linear regression analysis was performed to predict the venous inlet pressure from the rate of suction flow for each PPRV.

RESULTS

Each PPRV was determined to be safe if a reservoir pressure of greater than 40 mmHg was not observed during the experiment. This number is a calculated value, based on a height difference of approximately 20 inches from the patient to the reservoir. Figure 1 shows the mean positive pressure observed in each reservoir at flow rates of 0–5 L/min. The Baxter PPRV allowed a positive pressure of 38 mmHg at 5 L/min. It also produces an audible sound at pressures greater than 5–7 mmHg. The Gish and Gambro PPRVs allowed maximum pressures of 10 and 22 mmHg, respectively, at flow rates 5 L/min. Neither of these valves made an audible sound that would cause the perfusionist to suspect positive pressure. The Medtronic PPRV exceeded 40 mmHg at flow rates greater than 1.2 L/min and allowed a maximum pressure of 130 mmHg at a flow rate of 5 L/min. This PPRV made no audible sound.

A linear regression analysis was performed to predict pressure at varying flow rates for each PPRV. Figures 2–5 show the results of each PPRV tested.

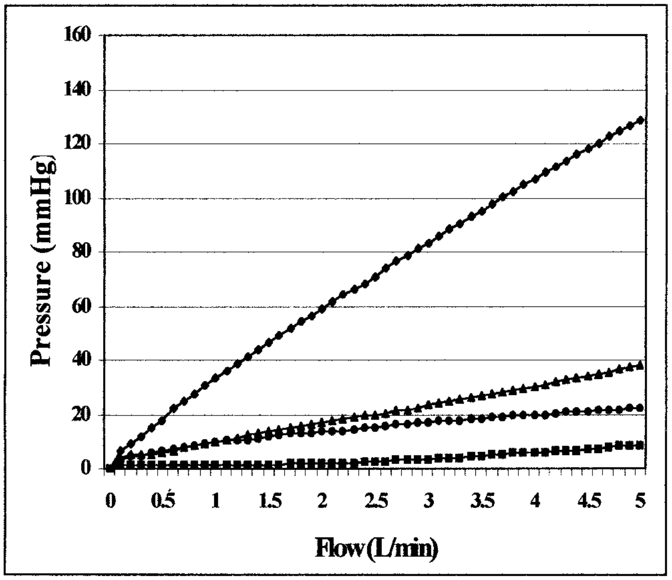

Figure 1. Positive pressure exerted at flow rates ranging from 0–5 L/min. Baxter ▲; Medtronic ♦; Gish ■; Gambro ●.

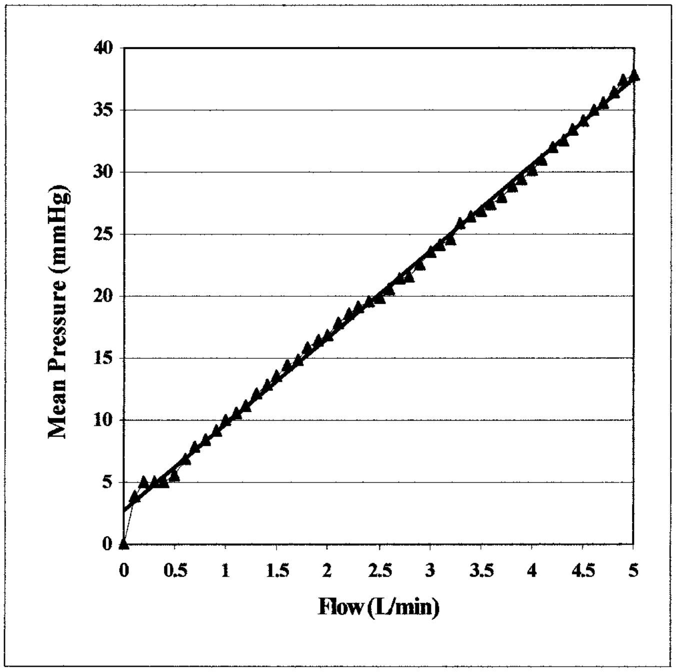

Figure 2. Linear regression analysis of the Baxter PPRV. Linear regression equation to determine pressure at varying flows: mmHg = 2.72 + [6.97 * Flow (L/min)]. R = 0.999.

DISCUSSION

The advantages of using VAVD to decrease priming volumes and permit full flow femoral venous drainage have been well documented (1–3). Safety issues associated with VAVD include increased gaseous microemboli (GME). Several studies have shown that this increase in GME occurs when air is entrained into the venous line during VAVD (4, 5). Another type of gaseous embolic event can also occur if a loss of vacuum takes place during VAVD and is the focus of this investigation. The results of this study show that three out of four of the reservoirs tested were equipped with a PPRV that can prevent posi-

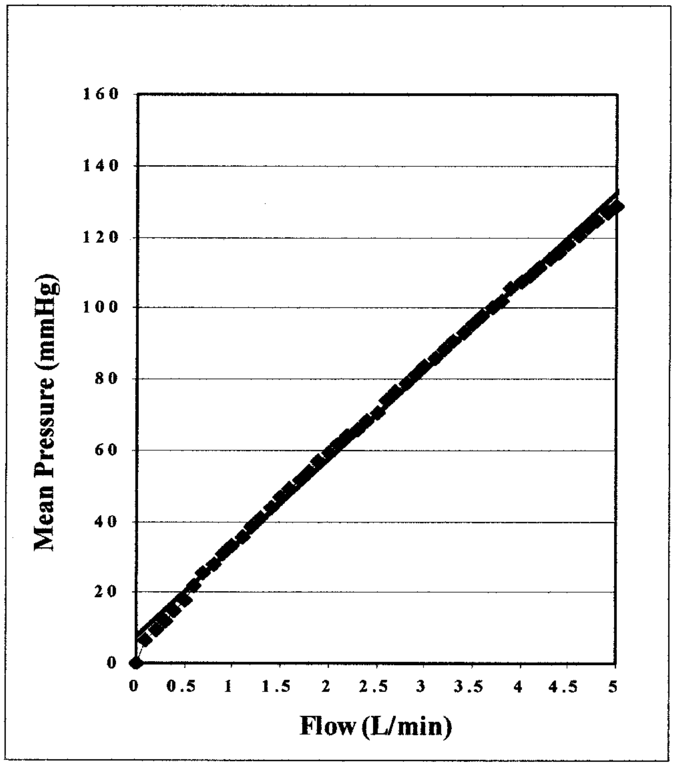

Figure 3. Linear regression analysis of the Medtronic PPRV. Linear regression equation to determine pressure at varying flows: mmHg = 7.44 + [24.92 * Flow (L/min)]. R = 0.999.

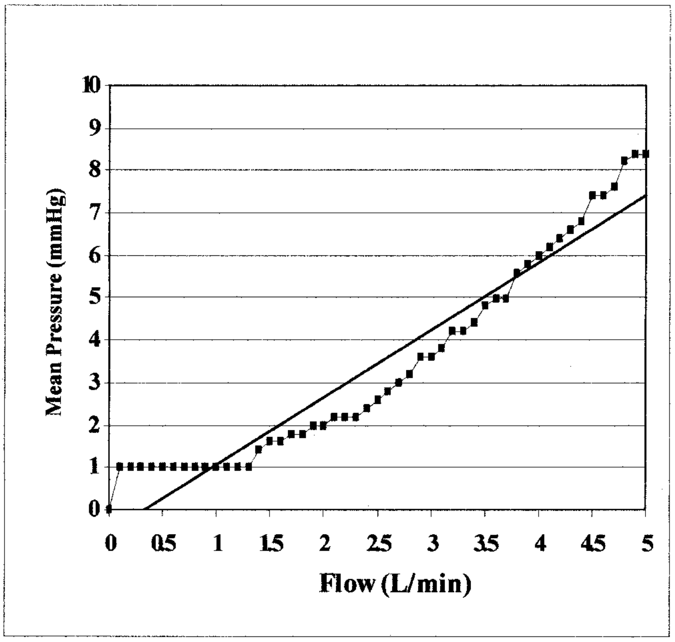

Figure 4. Linear regression analysis of the Gish PPRV. Linear regression equation to determine pressure at varying flows: mmHg = −0.544 + [1.59 * Flow (L/min)]. R = 0.965.

tive pressurization above 40 mmHg at less than 5 L/min airflow. One reservoir PPRV could not handle this airflow rate adequately.

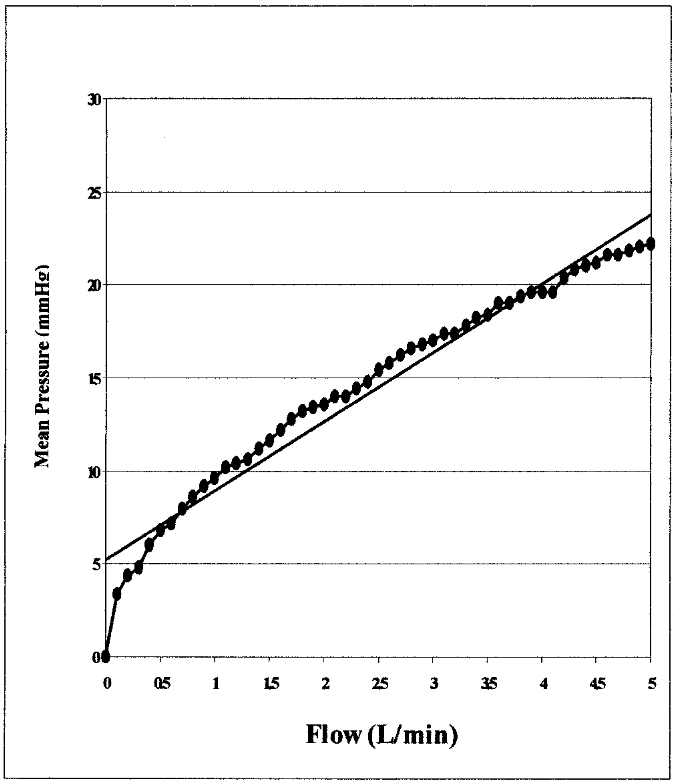

Figure 5. Linear regression analysis of the Gambro PPRV. Linear regression equation to determine pressure at varying flows: mmHg = 5.27 + [3.70 * Flow (L/min)]. R = 0.979.

It is recommended that any reservoir used for VAVD be evaluated in a similar manner to determine whether it is safe under the maximal suction and vent flow conditions possible during clinical practice. Positive pressure in the venous reservoir is a life-threatening event, which may take only seconds to harm a patient because of a massive venous or arterial air embolism. It is important that the limitations of these devices be recognized and used with extreme caution to prevent these untoward events.

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