■ LABORATORY REPORT

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Testing the Competency of the Hemostasis Valve in Introducer Catheters

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INTRODUCER catheter systems are large-bore intravenous catheters that are combined with a valve-side port apparatus, which allows for penetration by a multi-lumen or pulmonary artery catheter (PAC). The valve apparatus is designed to prevent fluid from the inside lumen of the catheter from leaking and to prevent air from entering the catheter and, thus, the vascular system. The Arrow® Corporation (Arrow International, Inc., Reading, PA) also distributes an obturator cap that is designed to cover the valve apparatus and penetrate the valve to increase the mechanical barrier function of the valve apparatus. Arrow® Corporation advises that the obturator cap should be used anytime the valve is not being penetrated by another catheter to fully protect against air embolism. Our hypothesis is that the hemostasis valve apparatus of the introducer catheters will remain competent to pressures in excess of intrathoracic pressures, which may be generated under clinical conditions, and the obturator cap is not essential to prevent air embolization.

Methods

Valve Apparatus

We obtained 29 Arrow® introducer catheters that had been used in patients within the adult intensive care unit (ICU) of Wake Forest University Baptist Medical Center, a multi-disciplinary, university-affiliated ICU. When available, the duration that the catheter had been in place was recorded, as was the duration of penetration by either multi-lumen catheter or PAC. The external surface of the catheters were wiped with saline, but no specific flush or treatment of the interior of the catheter was performed after removal from the patient. We also obtained 50 new Arrow® catheter/sheath adapter with hemostasis valve and side port, part #SV-7000, which were tested immediately after removal from the package.

Test Procedures

Each valve apparatus was connected *via* stopcocks and pressure tubing (fig. 1) such that negative pressure could be applied to the valve *via* a Harvard Apparatus 22 syringe pump (Harvard Apparatus Co., South Natick, MA) and measured by an in-line transducer calibrated to −450 mmHg and recorded on a Grass Model 7D Polygraph (Grass Instrument Co., Quincy, MA).

All pressure measurements were determined in triplicate, with measures exceeding −450 mmHg recorded as −450 mmHg. Once the apparatus was connected, the syringe pump was activated, and negative pressure was applied. Visual observation of the connection of the valve and the stopcock was used to determine when air became visible, demonstrating failure of the hemostasis valve, and noted on the polygraph tracing for calculation of the actual pressure. Pressure was then released, and all air bubbles were flushed through the system before the next pressure measurement. All experiments were carried out at room temperature with 0.9% saline solution within the system.

Results

Twenty-seven of 29 used catheters had documentation; the average duration of catheter use was 4.6 days, and the average duration of penetration of the valve by

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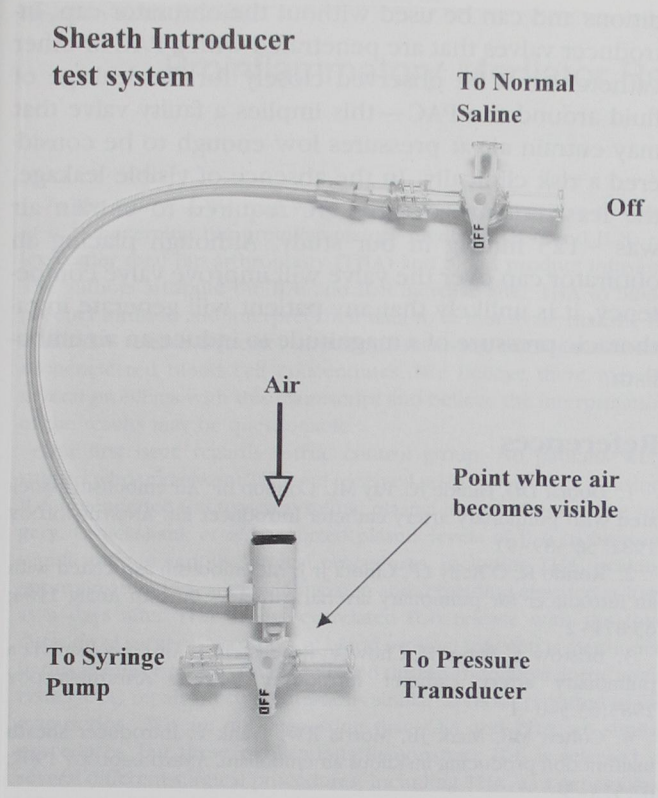

Fig. 1. Each valve apparatus was connected to a syringe pump and pressure transducer. Once filled with 0.9% saline, negative pressure was applied until air bubbles became visible at the connection between the stopcock and the valve (see arrow).

either a PAC or multi-lumen catheter was 3.5 days. Table 1 shows the number of catheters tested and the failure pressure for each of the experimental conditions: used valves, new valves, new valves with a segment of PAC inserted, PAC immediately removed, PAC left in for 8 days, PAC removed after 8 days, and for 5 used and 15 new valves with the obturator cap in place.

The least amount of pressure required to entrain air through the hemostasis valve in any of the 79 catheters before penetration by a PAC was −240 mmHg. Once the new valves had been penetrated, two catheters had visible fluid leaking around the PAC. For the two valves that allowed fluid to leak, the mean failure pressures were −443 mmHg and −378 mmHg before penetration, decreasing to −70 mmHg and −75 mmHg, respectively, with the PAC in place. When the PAC was removed, the failure pressures returned to −440 mmHg and −388 mmHg, and no fluid was observed leaking through the valve.

To measure the effect of the obturator cap, 5 used and 15 new valves were tested again before and after the cap was placed. Eighteen of the 20 had fail pressures increase to >−450 mmHg. However, the two valves that had been observed to leak were retested, and the mean fail pressures were again −430 mmHg and −378 mmHg, but decreased to −242 mmHg and −133 mmHg, respectively, when the obturator cap was applied.

Discussion

Introducer catheters provide direct access to the central venous circulation, with the tip of the catheter located within the thoracic cavity when the lines are placed *via* the subclavian or jugular venous approach. As such, the lumen of the catheter is subject to changes in intrathoracic pressures, both positive and negative. Complications resulting from the use of large-bore central catheters include air embolism and leakage of fluids or blood out of the catheter.[1-6] The primary functions

Table 1. Median, Mean, and Lowest and Highest Negative Pressures Required to Entrain Air through the Hemostasis Valves under the Conditions Stated*

Condition	n	Median	Mean	Lowest	Highest
Used valves	29	380	368	240	450
New valves	50	450	433	325	450
PAC inserted (new valves)	50	450	416	50	450
PAC immediately removed	40	440	427	330	450
PAC in place for 8 days	10	420	413	325	450
PAC out after 8 days	10	295	275	125	380
Obturator cap in place	20	450	424	130	450

Values are Negative Pressure (mmHg); n = no. of catheters tested within each condition.

* The lowest and the highest values represent the single lowest and highest pressures required in any individual measurement, *not* the average of the triplicate measurements.

of the valves associated with introducer catheters are to prevent fluids inside the catheter from leaking when there is positive intraluminal pressure and to prevent the entrainment of air from the outside when there is negative intraluminal pressure. The valve must accomplish this whether or not the valve has been penetrated with another catheter. The ability of introducer sheath self-sealing valves to maintain competence with changes in pressure has been tested by Conahan *et al.* and found to be generally satisfactory under simulated *in vivo* pressure conditions of up to −30 cm H_2O.[7] In another, small descriptive study, Arrow® introducer valve competence was maintained at *in vitro* positive pressures up to 300 mmHg.[3]

Air can enter the venous system during either insertion of the catheter or during removal, but it is perhaps most common when the catheter is accessed for medications or becomes disconnected for any reason.[8,9] Obviously, valves will not alter the occurrence of air embolism from these etiologies. The extent to which introducer valves prevent air from entering the catheter is the subject of the present investigation. The Arrow Corporation recommends that an obturator cap be used to prevent air embolism. This cap seals the external surface of the valve apparatus using an O-ring located on the external surface of the side port-valve assembly. The obturator also penetrates through the valve itself to provide the mechanical seal, thus offering theoretical structural benefits. However, there are no data in the scientific literature to suggest that this combination is necessary.

The maximum negative intrathoracic pressure that can be generated in humans remains somewhat unclear. Studies using maximal inspiratory pressures at the mouth have ranged from approximately −50 to −150 mmHg, and esophageal transducer experiments during a sniff test have shown maximal transdiaphragmatic pressures in healthy adults to range from −82 to −204 cm H_2O (−61 to −152 mmHg).[10–13] There are, however, no data concerning the maximal intrathoracic pressure in critically ill patients that require placement of an introducer catheter.

Our data demonstrate that new hemostasis valves will not entrain air at pressures encountered in clinical conditions and can be used without the obturator cap. Introducer valves that are penetrated with a PAC or other catheter must be observed closely for the leakage of fluid around the PAC—this implies a faulty valve that may entrain air at pressures low enough to be considered a risk clinically. In the absence of visible leakage, the least amount of pressure required to entrain air was −125 mmHg in our study. Although placing an obturator cap over the valve will improve valve competency, it is unlikely that any patient will generate intrathoracic pressure of a magnitude to induce an air embolism.

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