

## CORRESPONDENCE

generic terms; perhaps thinking that this report could apply to all valves in all introducers consequently may develop into a false sense of security. We recommend that an obturator be used anytime the hemostasis valve of the introducer is empty, which applies to the period of time after a catheter has been removed or if the catheter insertion is delayed.

It is important to note that the function of the hemostasis valve is to serve as a seal when a catheter is indwelling or temporarily removed from the indwelling sheath. The valve is not designed as a long-term seal against vacuum or backpressure. The one-way valve must seal well without dampening, occluding, or impeding the insertion and manipulation of the indwelling catheter. For this reason, the valve design is a compromised balance between sealing well and gently holding various catheter sizes. Even though our percutaneous sheath introducer products are manufactured to the highest of standards, no valve is infallible. This simple "better safe than sorry" position is the reason for the obturator use recommendations in our product instructions.

The soft valve in the hemostasis assembly maintains a seal by fully closing around and conforming to an inserted object like a catheter. It is possible, however unlikely, for this material to take a "set" around an inserted catheter so that when the catheter is removed, the soft valve material does not rebound fully to make a complete seal. The function of the obturator is to reduce this potential risk of embolism by ensuring the sealing of the valve after removal of a catheter. Consequently, we unequivocally recommend the use of an obturator cap under any circumstances.

As the authors stated, their hypothesis was that "hemostasis valves of

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 embolism."

The researcher tested 79 valves; 29 had been used in patients, and 50 were new. All of these valves when tested withstood extreme negative pressures. Even though these data are impressive, the researchers' sample size is small compared with the number of valved percutaneous sheath introducer products that Arrow International® has sold during the past 16 years.

We agree that the frequency of a failed valve caused by whatever set of circumstances is extremely rare, but we cannot in good conscience make the recommendation to clinicians that the researchers have made in their article. It seems that to place an obturator cap is such an easy task to potentially save a patient's life.

I hope that you and your subscribers find this information helpful. If you have any questions that I can help answer, please do not hesitate to contact me.

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*In Reply:*—We appreciate the concern of Mr. Moore and the Arrow® Corporation relative to our study of the competency of hemostasis valves associated with introducer catheters.<sup>1</sup> As a matter of fact, it was a similar letter sent to our ICU Medical Director that initiated a debate. Part of our faculty agreed with Arrow®, that a seal (obturator) over a seal (the valve) would provide additional safety by preventing fluid from leaking *out* through the valve and air entrainment *in* through the valve. Other clinicians believed that the obturator represented an additional expense to the patient and hospital with no tangible benefit to the patient. It was our decision to settle this dispute with data rather than rhetoric, and thus our study was performed.

In our study, we obtained 29 introducer catheters that had been used in ICU patients and 50 new valves from Arrow. We filled a closed system with saline solution and applied negative pressure to the valves, measuring the pressure at which the valves "failed" by entraining air into the system. We repeated the test with segments of pulmonary artery catheter (PAC), inserted short term and long term (8 days), and repeated measurements with an obturator cap in place. Our results demonstrated that the valves associated with introducer catheters remain competent to pressures far in excess of intrathoracic pressures that would be encountered clinically. Our data also demonstrated that using the obturator cap further augmented the protective effect of the valve by increasing the amount of negative pressure required to entrain air through most of the valves.

There were, however, two valves that initially demonstrated normal competency with negative pressures of  $-443$  mmHg and  $-378$  mmHg required to entrain air that dropped to  $-70$  mmHg and  $-75$  mmHg, respectively, after insertion of the PAC. Competency improved with

removal of the PAC (to  $-430$  mmHg and  $-378$  mmHg), but when the obturator cap was applied, the failure pressure decreased to  $-242$  mmHg and  $-133$  mmHg. Thus, placement of the obturator cap actually *worsened* the function of these two hemostasis valves.

No laboratory study, including ours, can recreate every situation that might be encountered clinically. In our study we used a modest number of valves and subjected them to a few clinically relevant tests to determine the validity of the claim that obturator caps are necessary to maintain competency. Our data showed that the obturator cap is not necessary to maintain the competency of the hemostasis valves associated with Arrow® introducer catheters and may actually degrade the function of the valves. If Arrow® has data to suggest otherwise, we would be anxious to see it published.

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## Reference

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