

Herbert N. Chado, M.D.
Senior Medical Consultant
Neurotron, Inc.
Evergreen Medical Consultants
Evergreen, Colorado

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In Reply:—We appreciate Dr. Chado's comments and interest in our article. We have reanalyzed the data as suggested by Dr. Chado. The ratio of pre- and posttreatment current perception threshold values were not significantly different (table 1). There was a trend for the 250- and 5-Hz lumbar groups to have a greater change posttreatment (as would be predicted), but the variability was too great to demonstrate this difference statistically. It is possible that a larger sample size or a crossover study design would have decreased the variability and demonstrated the predicted differences (we have considered both factors in subsequent studies). Another factor may be that the neurometer is not sensitive enough to measure the mild sensory changes effected by intrathecal opioids.

Finally, we agree with Dr. Chado that there is good evidence that the

neurometer selectively stimulates various nerve fibers. However, to our knowledge, definitive patch clamp experiments have yet to be performed.

Edward T. Riley, M.D.
Sheila E. Cohen, M.B. Ch.B., F.R.C.A.
Cathy L. Hamilton, M.D.
Department of Anesthesia
Stanford University School of Medicine
Stanford, California 94305
edriley@Leland.Stanford.edu

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Table 1. Ratio of Pretreatment and Posttreatment Current Perception Threshold Values

Group	Cervical			Lumbar		
	2,000 Hz	250 Hz	5 Hz	2,000 Hz	250 Hz	5 Hz
Saline	1.1 ± 0.2	1.0 ± 0.3	0.9 ± 0.5	1.0 ± 0.1	0.8 ± 0.3	0.9 ± 0.7
Sufentanil	1.1 ± 0.3	1.3 ± 0.5	1.1 ± 0.2	0.9 ± 0.2	1.3 ± 0.6	1.9 ± 1.7

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Valve System Performance

To the Editor:—I read the laboratory report, *Testing the Competency of the Hemostasis Valve in Introducer Catheters* published in *ANESTHESIOLOGY* 1998; 88(5):1404-6, with great concern and alarm.

Arrow® strives to manufacture our hemostasis valves to the highest

standards of performance. However, we think that it is important that practitioners not misread the results of this testing to infer that any manufacturers' valve system is infallible. Another concern is that many practitioners refer to an *introducer system* and a *hemostasis valve* in

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.

Matthew J. Moore
Product Specialist
Critical Care Products
Arrow International, Inc.
Reading, Pennsylvania
matt_moore@arrowintl.com

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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.¹ 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.

Drew A. MacGregor, M.D.

Assistant Professor of Anesthesiology and Medicine
dmacg@wfubmc.edu

Phillip E. Scuderi, M.D.

Associate Professor of Anesthesiology
Wake Forest University School of Medicine
Winston-Salem, North Carolina 27157-1009

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