Drs. Trerotola et al respond:

We are pleased that Drs. Falk and Vesely took such an interest in our article (1) and are delighted to have the opportunity to address their concerns. In fact, virtually all of them are addressed within the published article (as detailed later), but we welcome the opportunity to expand on those explanations. First and foremost, as acknowledged in the Limitations section, this was a retrospective study, with all the associated limitations of such a study. We sincerely hope it can form the basis for future prospective studies in this important area. Second, this was an outcomes study, not a technical note, and therefore the data analyzed and reported focus on outcomes, not on technical details. With that said, we are happy to specifically address the concerns of Drs. Falk and Vesely.

Regarding the inclusion of graft/fistula hybrids, we believe this is a matter of opinion. Because a hybrid is neither pure graft nor pure fistula, but in our experience behaves more like a fistula than a graft, we believed that including these would be of interest. We did recognize this distinction and applied statistical testing to determine whether this group behaved differently from the pure fistulas. As stated in the article (1), it did not, and because it did not, we believed it appropriate to include hybrids. Had the statistical analysis shown hybrids to have different outcomes from fistulas, we might well have considered excluding them, but this was not the case.

Regarding clot burden, although this is addressed in detail in the article, we will reiterate and expand here. The stated purpose of the article was to describe our experience with the Arrow-Trerotola percutaneous thrombectomy device (PTD) in native fistula thrombosis and to look at variables that might affect outcomes. Because we do not use the PTD when there is little or no clot in a “thrombosed” fistula, we believe it would have been highly inappropriate to include such fistulas. We believe this is a very important distinction because it is not uncommon to encounter a thrombosed fistula, particularly a forearm fistula, with very little clot. Some authors, notably Liang et al (2), have included these and reported results that, in our opinion, do not reflect the actual practice of fistula declotting. We reiterate that no PTD fistula thrombectomy procedure was excluded from this series; we simply do not use the device in the minimal thrombosis setting. It is unnecessary because balloon maceration and angioplasty alone are effective in restoring flow.

Regarding thrombolytic drug use, again, this is addressed in detail in the article, and we applied multiple statistical tests to determine whether the addition of lytic agents affected the outcome. This is a question we have frequently asked and are asked by others, and we searched for an answer. Within the limitations clearly spelled out on page 1610 of the article (1), we did not find that lytic agents changed the outcome, despite the assertion by Drs. Falk and Vesely that the drug “likely improved the ability... to clear the thrombus.” Their statement that no data are provided is simply wrong; the statistical subgroup analysis suggested by Drs. Falk and Vesely is clearly described on page 1607.

Regarding the use of the PTD as an adjuvant treatment, Drs. Falk and Vesely are correct, and as they point out themselves, this is acknowledged on page 1608 of the article (1).

Regarding the technical success issues mentioned in the letter, at the time the Society of Interventional Radiology standards (3) were prepared, the concept of use of the physical examination to determine a procedural endpoint had not yet been published. However, we have validated this approach (4) and use it as our determinant of technical success based on our published results. In retrospect, this deviation from the definitions should have been noted; however, neither we nor the reviewers and editors noted the discrepancy. We are grateful to Drs. Falk and Vesely for pointing out our error. As for other technical details, the SIR reporting standards have their critics, including Dr. Vesely (personal communication, S.O.T.), and we also believe that, at times, they are unnecessarily restrictive. Perhaps the time has come to revise these standards. Regardless of our feelings about these standards, it would not have been appropriate to describe “device success” in this article because it was not a technical evaluation but an outcomes study.

Regarding the issue of reporting of results mentioned in the letter, as clearly noted in the article (1), these variables were collected and analyzed. The analysis did not show any effect of the primary outcome variables, ie, primary and secondary patency. Drs. Falk and Vesely are correct, and as they point out, this was not a technical note, given that the technique for PTD fistula declotting has already been published (5); rather, the focus of this article was outcomes. Because these variables did not affect outcomes according to the statistical analysis, they were not separately reported.

Regarding the reporting of complications, much has been written about the subjectivity of “major” and “minor” complications. The complications experienced in this series, in sharp contrast to many earlier similar series, are reported in sufficient detail for the reader to make his or her own determination of their significance and relationship to the procedure. We believe this is a far more honest and open approach than hiding behind arbitrary definitions of “major” and “minor.” Nonetheless, Drs. Falk and Vesely have incorrectly characterized two of these complications (which were successfully treated with balloon tamponade and stent placement respectively) as resulting in loss of the fistula. In this case, we disagree with Drs. Falk and Vesely regarding the remaining venous ruptures; in point of fact, two of the three patients with unsalvageable venous rupture had existing venous access. In the third, a tunneled dialysis catheter was placed the next day. However, this does not increase the level of care compared with what would have been done if declotting had not been attempted. Therefore, as accurately stated in our article, the complications did not increase the level of care and clearly fall into the SIR definition of “minor.” With respect to the death not related to the procedure, we agree that 30-day mortality rates should be reported, and we have done so in compliance with the SIR reporting standards (3).

Again, we are pleased that Drs. Falk and Vesely took the time to carefully read our article. With their letter, they have asked that we hold ourselves to some very rigorous standards, which arguably are too rigorous for retrospective analysis. Because they are frequent contributors to the he-

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modiﬁcation access literature, we can only assume that they will hold themselves to equally rigorous standards in their future reports.

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References

Air Flow through a Valved Introducer Sheath

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Editor:  
We read with interest the article by Vesely et al (1) regarding the 16-F valved peel-away introducer sheath (FlowGuard; Enpath Medical, Minneapolis, MN). Their in vitro bench-top experiment demonstrated that virtually no air (mean of 0.004 mL/sec) passed through the valve when subjected to a pressure of −5 mm Hg.

However, a word of caution may be in order. After inserting several hundred 14.5-F HemoSplit catheters (Bard Access Systems, Salt Lake City, UT) uneventfully, we recently observed a fairly prominent air embolus while inserting the catheter through their 15-F valved peel-away introducer sheath (AirGuard; Bard Access Systems). Immediately after the venous lumen of the HemoSplit catheter passed through the valve, but just before the arterial lumen traversed the valve, the patient inspired and a dreaded “sucking sound” was heard. The catheter was immediately inserted fully. Fluoroscopy revealed a large rounded gas bubble in the distal main pulmonary artery. Oxygen was administered by mask, and the patient remained in a supine position. The patient’s oxygen saturation decreased from 99% to 90%. Over a period of 10–15 minutes, oxygen saturation gradually returned to 99% as the gas bubble slowly disappeared fluoroscopically.

Our experience led to a closer inspection of the sheath valve and what it looks like when a split catheter passes through it. The valves on FlowGuard and AirGuard sheaths were evaluated. The valves have a junction or slit down the center, and the straight sides of two D-shaped membranes abut each other in the center of the sheath’s lumen. When the tip of the venous lumen traverses the valve’s center slit, a small, but real, open space is created on either side of the catheter. This space is maximized if the tip of the venous lumen is oval and its long axis is at a right angle to the long axis of the valve’s slit. Only when the venous and the arterial lumens pass through the valve does the slit conform fairly snugly around the catheter. However, even when fully inserted, there remains a small gap in the valve on either side of the round catheter.

Vesely et al (2) observed one small air embolus while placing an Ash Split-Cath (Medcomp, Harleysville, PA) through a 14-F FlowGuard sheath. They attributed that to air passing through the catheter itself as a result of the multiple side holes, which are momentarily on both sides of the hemostatic valve during insertion.

Although we continue to use the AirGuard valved peel-away sheath, we now use the same precautions we use when inserting a catheter through a valveless sheath. Our recent experience reminded us that nothing is foolproof.

References

Percutaneous Removal of Migrated Nitinol Stents from the Right Ventricle

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Editor:  
We recently performed a percutaneous removal of a migrated nitinol stent from a right ventricular cavity. Stent removal was attempted using a 5-F Medikit catheter (Terumo, Somerset, NJ) through the right femoral vein. However, during withdrawal of the catheter, the stent fragment became dislodged into the IVC. After injecting 10 mL of contrast medium, a large amount of air was aspirated. A fluoroscopic image was acquired, which showed a large amount of air within the right ventricular cavity. The patient was immediately placed on cardiac arrest, and chest compression was initiated. Despite vigorous chest compressions, the patient died within minutes. The cause of death was likely due to air embolism into the pulmonary arteries.

References

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