Fellows Debate: Access for EVAR

Percutaneous or femoral artery cutdown? A debate from the multispecialty conference at the Texas Medical Center.

BY FIRAS F. MUSSA, MD; JAMES H. MITCHELL, MD; JOSEPH J. NAOUM, MD; ZVONIMIR KRAJCER, MD; AND ALAN B. LUMSDEN, MD

This article is a reproduction of a debate conducted on August 23, 2006, at the Endovascular Forum meeting at Texas Medical Center in Houston, Texas.

FEMORAL ARTERY CUTDOWN

Dr. Mussa: An increasing number of abdominal aortic aneurysms are being repaired using an endovascular approach. In addition to vascular surgeons, other specialties are involved with the endovascular repair of aortic aneurysms (EVAR). Before dismissing my counterpart's viewpoint as "a work in progress," I would like to highlight our common ground at the beginning of this debate: We agree that percutaneous access for EVAR and arterial closure using the Prostar XL device (Abbott Vascular Devices, Abbott Park, IL) is safe, feasible, and probably preferable for placement of contralateral endoprostheses (12 F to 14 F) in select groups of patients.

In general, endovascular complications can be classified into three broad categories: (1) access site complications, (2) complications related to passage of catheters and devices, and (3) intervention-specific complications. Today, we are comparing a well-recognized method for access to the femoral artery, with its well-published risks and benefits, to an evolving technique of percutaneous access and repair of the femoral artery, pioneered and popularized by Dr. Krajcer and his colleagues here at Texas Medical Center.

It is important to recognize that to date, there has been one published prospective randomized trial that reports on wound complications.[1] In the DREAM trial, the rate of wound complications was 3.5%, and of those, 0.6% were classified as severe. However, there was no description of the nature of these complications and the definitions of severity. In a study by Sampram et al, the Cleveland Clinic experience was reviewed, with 703 patients undergoing EVAR. Wound problems, such as hematoma, occurred in eight patients. All of these patients underwent evacuation of hematoma with (n=4) and without (n=4) femoral artery repair.[2] More recently, Bush and colleagues reported a 3.9% wound complication rate in 717 patients who underwent EVAR in 123 VA hospitals.[3] Table 1 lists the parameters used for comparing the two access approaches. I am interested in my counterpart's comments on issues not usually addressed in previous reports. These include the rate of endograft infection, the acuity of complications arising after use of closure device, and finally, the off-label use of a 10-F Prostar XL for large size arteriotomy (>12 F).

In order to make it clear to our nonsurgical colleagues, I will briefly describe our approach to the femoral artery. We use the standard oblique groin incision to gain access to the common femoral artery. The length of incision is 4 cm to 6 cm and varies depending on the patient's body habitus and the presence of previ-

TABLE 1. PARAMETERS USED FOR COMPARING THE TWO ACCESS APPROACHES

- Complication of groin access
- Pseudoaneurysm
- Infection
- Thrombosis
- Lymph leak
- Stenosis
- Duration of procedure
- Time for ambulation
- Blood loss/transfusion requirements
- Cost

ous incisions. Local wound complications are generally self-limiting or are amenable to successful operative repair. We do not routinely follow-up patients with ultrasound examinations. We are not convinced that a percutaneous approach reduces the access site complication rate, especially with large sheaths (>16 F). We can easily refute the notion that femoral artery cutdown necessitates longer hospital stay, longer operative time, or more blood transfusions. In a prospective randomized study by Torsello et al, there was no statistically significant difference in hemoglobin loss and the need for transfusion, nor site complications.[4] Morasch et al reported an average of 1.89 days for length of stay after EVAR with femoral artery cutdown.[5] My point is, do you really think that timing of ambulation matters when the length of hospital stay is the same?

Although I am not an anesthesiologist, I do know some basics of anesthesia. Your group has previously stated that percutaneous access in EVAR avoids the potential hazards of general anesthesia, as well as the invasive lines and catheters introduced by the anesthesiologists for intraoperative monitoring. We believe that hemodynamic monitoring is important because most of these patients have significant medical history of cardiac conditions. We have yet to see a relationship between anesthesia and an adverse outcome from EVAR. All of our lines and catheters are removed on postoperative day 1, and the patient is allowed to eat the evening after the operation.

I am not entirely against percutaneous access for EVAR. As I mentioned before, we agree that this approach has some applications in select groups of patients. A few questions come to mind when one contemplates doing percutaneous access outside the Texas Medical Center. First, what do you think of percutaneous access in obese patients? Second, what are your thoughts on cases with tortuous iliac arteries? Third, how about those with previous groin incision? Other questions I have for your group are, what if you are the only vascular specialist in town and ran into uncontrolled hemorrhage or the patient developed acute leg ischemia shortly after the procedure? What is the actual learning curve for gaining proficiency to this approach? I have not seen data on the time needed to acquire this skill. It is clear that your results are unmatched with others in the literature.

PERCUTANEOUS REPAIR AFTER EVAR

Dr. Mitchell: Although open surgical repair of the femoral artery after EVAR has been the standard of care, we at the Texas Heart Institute have worked over the years to develop a new and better technique to close the groin involving the use of the Prostar XL percutaneous suture-mediated vessel closure device with local anesthesia. This is a technique that avoids the risks of general anesthesia and reduces morbidity.[6]

I would like to present a brief case report to illustrate what type of patient would benefit from our approach. A 79-year-old man presented to our emergency room at 12:20 AM reporting severe abdominal and back pain. His medical history was significant for severe oxygen-dependent emphysema, coronary artery disease, chronic renal insufficiency with a baseline creatinine of 2.4 mg/dL, and cerebrovascular disease. Physical examination findings were significant for hypotension with a blood pressure of 90/40 mm Hg and tachycardia of 125 beats per minute. His abdomen was significantly distended without bowel sounds and was extremely tender to palpation. Initial laboratory values revealed a hemoglobin of 8.2 g/dL and an elevated creatinine of 2.8 mg/dL. Because of our concerns of a ruptured abdominal aortic aneurysm, an emergency CT scan of the abdomen without contrast was obtained. The CT scan confirmed the presence of rupture of a large infrarenal abdominal aortic aneurysm. Due to the patient's comorbidities, we elected to repair the abdominal aortic rupture with EVAR via a percutaneous approach and avoid the risks of conventional open surgical repair, which the patient may not have survived. Gadolinium was used as a fluoroscopic contrast agent to reduce the risk of contrast nephropathy. Single 10-F Prostar XL devices were deployed bilaterally to avoid the risk of general anesthesia required for open femoral arterial repair. A 26-mm X 14.5-mm X 16-cm Excluder endograft (Gore & Associates, Flagstaff, AZ) was placed via the right femoral approach, and a 14.5-cm X 12-cm device was placed in the contralateral femoral artery. The entire procedure took 1 hour to perform. There was no residual endoleak. Postprocedure hemoglobin after 1-unit packed red blood cell transfusion was 9.8 g/dL. The patient remained stable throughout the hospital stay and was discharged after 48 hours with a creatinine of 1.9 mg/dL. There were no complications related to percutaneous access.

EVAR has been shown to offer certain advantages over open aortic aneurysm repair. The purpose of EVAR has been to avoid the risks of open surgery and anesthesia, reduce patient discomfort, reduce length of hospital stay, and provide a quicker return to normal activities of life. In addition, multiple clinical trials have demonstrated lower mortality rates with EVAR, along with reduced morbidity. Outcome advantages of EVAR include a shorter procedural time, less blood loss, an earlier return to normal diet, and earlier ambulation and discharge.[1,7]

Approximately 80% of all EVAR procedures in the US are still performed with general or spinal anesthesia, along with open surgical femoral arterial access and repair. This technique increases the invasiveness, complications, and cost of the procedure. In various trials using

Figure 1. Prostar XL percutaneous suture-mediated vessel closure device.

the open cutdown, complication rates have ranged from 16.8% to 20%, and vascular complication rates have ranged from 5.3% to 8.9%.[8-10] The question becomes, how do we avoid the large incisions in the groin and decrease the use of general anesthesia?

Our group has answered this question. In 1996, Dr. Krajcer and his colleagues at the Texas Heart Institute demonstrated an innovative approach to closing femoral access after EVAR using the Prostar XL suture-mediated closure device (Figure 1). While initially designed for use with 8-F and 10-F over-the-wire systems, the technique was modified to "pre-close" large-bore sheaths ranging from 16 F to 24 F.

The technique has been previously described.[6] In brief, after percutaneous access with the modified Seldinger technique, a 6-F sheath is placed in the groin. A 1-cm incision is made around the sheath, with blunt dissection of the subcutaneous tissue. The sheath is removed over the wire, and a 10-F Prostar XL device is advanced into the common femoral artery. When pulsatile blood flow is seen through the marker lumen, indicating that the sutures and needles are within the vessel lumen, all four needles and sutures are deployed. The sutures are then separated from the Prostar XL and placed under towels across the groin. The device is removed over the wire, and progressive dilations are performed to allow placement of the appropriate sheath for endograft deployment. The procedure is repeated on the opposite groin for the contralateral limb.

The two Prostar XL sutures are tied using a sliding-knot technique. A wire is placed in the sheath to maintain arterial access in case of device failure. As the sheath is removed, both suture rails are pulled with tension to slide the knots downward to the femoral arterial wall. If bleeding is absent, the wire is removed, and a knot pusher (Abbott Vascular Devices) is used to advance the sliding knots to the vessel wall. Lastly, pulling on the non-rail end of the suture will lock the knot in place. Sutures are then cut, followed by closure of the incision with Steri-Strips (3M, Maplewood, MN).

Initially, at the Texas Heart Institute, we used both an 8-F and 10-F device for sheath sizes of 16 F to 24 F, deploying the two Prostar XL devices at 90° to one another to avoid suture laceration by overlapping deployment. To simplify the technique, we have since changed to a single 10-F Prostar XL deployment on each groin, regardless of sheath size, without a change in outcomes.

What data do we have supporting the use of the "pre-close" technique over open surgical repair for femoral access? Since 1995, 1,043 patients have undergone EVAR at our institution. Since May 2002, 465 patients have undergone EVAR with local anesthesia and percutaneous repair of the femoral artery. What is most important to this discussion is the success of percutaneous femoral closure with the Prostar XL. The success rates for closure at the Texas Heart Institute were 91% for 21-F sheaths, 93% for 18-F sheaths, 94% for 16-F sheaths, and 97% for 12-F sheaths. These are rather impressive results. In addition, because of the avoidance of general anesthesia, the average return to a normal diet was 1 hour. The average time to ambulation was 8±3 hours. When compared to femoral artery cutdown, patients who underwent EVAR with local anesthesia and percutaneous repair at our institution had statistically significant reduction in procedure time, decrease in hematocrit, blood transfusion requirements, and length of hospital stay (Table 2).

Arguments have been made that percutaneous repair using the "pre-close" technique can lead to long-term damage to the vessel wall and subsequent stenosis. In a comparison at our institution of ankle-brachial indices (ABIs) obtained before the procedure and 1 month after the procedure, the average ABIs were identical, at 1.06. When compared to patients undergoing percutaneous

TABLE 2. PERCUTANEOUS REPAIR VERSUS OPEN REPAIR

	Percutaneous Repair N=465	Surgical Repair N=339	*P* Value
Total procedure time (min)	136±24	237±21	<.0001
Holding area stay (min)	68±37	200±89	<.0012
Change in hematocrit	4.1±1.7	8.7±2.6	<.0004
Blood transfusion (pts)	14 (2.4%)	27 (8%)	<.0001
Length of hospital stay (days)	1.4±0.20	2±0.9	<.016

versus surgical closure, the risk of vascular complications was reduced from 15.1% to 3.7%. Groin infections, neuropathies, hematomas, and the need for embolectomy were all reduced (Table 3).

We must acknowledge that despite the superior results of our technique, some patients are not ideal candidates for the use of the Prostar XL. Those with significant obesity, small vessel diameters (<6 cm), artificial arterial conduits, or coagulopathies may not be suitable. In addition, severe femoral artery calcification, fibrosis, and access that is obtained too low (within the superficial femoral/profunda region) or too high (above the inguinal ligament) are prone to device failure. Nevertheless, a review of published articles on percutaneous closure of EVAR reveals success rates ranging from 90% to 93.8%.[4,5]

Thus, based upon the currently available data, and our experience at the Texas Heart Institute, percutaneous femoral arterial repair for EVAR is a successful and safe procedure that should be used in the majority of patients. Without a doubt, the "pre-close" technique with local anesthesia is associated with fewer complications than surgical access and general anesthesia, including shorter procedural times, less patient discomfort, less blood loss, earlier return to a normal diet, earlier ambulation, and a lower risk of infection.

TABLE 3. VASCULAR COMPLICATIONS: PERCUTANEOUS REPAIR VERSUS OPEN REPAIR

	Percutaneous Repair (N=465)	Surgical Repair (N=339)
Groin infection	2 (0.2%)	9 (2.7%)
Femoral neuropathy	0	11 (3.2%)
Hematoma	14 (2.5%)	23 (6.7%)
Femoral laceration	2 (0.4%)	1 (0.2%)
Embolectomy	0	7 (2%)
Pseudoaneurysm	4 (0.6%)	1 (0.3%)
Total	**22 (3.7%)**	**52 (15.1%)**

REBUTTALS

Dr. Naoum: A reason for the use of percutaneous closure devices is that it significantly decreases procedural blood loss. In a study by Howell et al, percutaneous femoral access closure in 30 patients was compared to 96 patients in whom open surgical repair was performed.[11] The authors concluded that percutaneous repair resulted in a significant decrease in blood loss. However, anesthesia staff using visual assessment and measurement of blood accumulation in the aspiration container calculated blood loss. Unlike open repair, with a percutaneous technique, it is difficult to evaluate "unseen" blood loss that occurs in the thigh or retroperitoneum. Furthermore, the reported decrease in hemoglobin and hematocrit was based on nonmatched controls. Therefore, the validity of the author's comparison is to be questioned.

In contrast, in a prospective randomized study by Torsello et al, no significant difference in postoperative hemoglobin and hematocrit concentrations was observed between the percutaneous and the cutdown procedures.[4] The technical success of percutaneous closure devices should be gauged against the current open surgical standard. The current percutaneous closure device failure rate is between 0% and 34%. The current conversion to open surgical repair rate is between 0% and 24%. Additionally, in their review, Starnes et al identified that significant failure rates occurred with a sheath size of 20 F or greater.[12] Börner et al studied the consequences of percutaneous closure device failure. With the percutaneous technique, success rates of 95% and 84% were achieved for the 14-F to 16-F and 18-F to 20-F sheath sizes, respectively. However, the technical failure rate for access sites associated with a 24-F sheath was 30%.[13] In addition, in those patients in whom percutaneous closure failed and intraoperative cutdown was required for repair, estimated blood loss and the operative time increased. In light of the potential complications of failed percutaneous closure, it is advocated that a vascular surgeon be present during closure time.

Groin or femoral access site complications are also a focus of safety parameters addressed when comparing percutaneous and open femoral artery access site closure. Morasch et al compared 47 bilateral percutaneous femoral artery access site closures to 35 bilateral femoral artery cutdowns and found that twice as many patients required repeat operation for complications due to percutaneous closure as compared to those undergoing cutdown followed by open repair. At 1-month follow-up, access site complications were present or persisted only in the femoral artery cutdown group.[5] However, the long-term safety and outcome of percutaneous closure still needs to be established.

Percutaneous closure of the femoral artery access during EVAR offers the potential benefit of reduced time to ambulation. However, multiple reports suggest that there is no reason or justification for patients remaining nonambulatory for a mean of 20 hours.[4,5] I am intrigued by what prevents patients from ambulating early after either percutaneous or open access repair. For instance, aside from nonmatched controls, there is not enough evidence to support that early ambulation in these patients leads to a decrease in length of hospital stay.

Open common femoral access should be the standard of care to which other maneuvers or closures are com-

pared. However, percutaneous access and closure is a viable alternative to open repair. Yet, the technology for percutaneous closure devices needs to improve. Furthermore, the device must achieve FDA approval for large-French–sized arteriotomy access sites because the current technology, with its technique modifications, has a high failure rate. Long-term data need to be obtained. Prospective randomized studies are needed in which percutaneous and open access and closure are evaluated. Adequate patient selection criteria are also required. Last, a decrease in the profile of stent graft delivery systems can simplify and improve the success of percutaneous approaches to EVAR.

Dr. Krajcer: The important advantages of our approach are avoidance of general anesthesia, placement of central venous lines, Foley catheter, nasogastric tube, and additional arterial lines that are routinely used by anesthesiologists. It is clearly evident from Dr. Mitchell's presentation that our patients with percutaneous EVAR and local anesthesia have a lower incidence of complications and faster recovery than patients who have general anesthesia and surgical repair of femoral artery access sites. This is not surprising because we all know the inherent risks of general and spinal anesthesia and surgical incisions. Dr. Mussa and Dr. Naoum failed to comment on the incidence of general and vascular complications reported in the four clinical trials conducted in the US.[8-10] These trials revealed similar incidence of vascular complications as evidenced in our patients who had general anesthesia and surgical femoral artery access and repair. In Dr. Mitchell's presentation, as well as in our previous publications, we have clearly delineated the contraindications for the use of this technique. To gain expertise in percutaneous access and repair of femoral arteries, the interventionist must be able to use this technique on a regular basis. Unfortunately, many physicians performing EVAR are unfamiliar with this technique. However, it is true that this was a nonrandomized study, and further studies are necessary to reveal all the advantages and disadvantages of each technique. I believe that a surgical backup is essential during these procedures. Presently, this technique should be only used by experienced operators who clearly understand its benefits and limitations. We also agree that there is a need for refinements in closure devices that will be dedicated to percutaneous femoral artery repair for large-bore sheaths. ■

Firas F. Mussa, MD, is a Fellow in Vascular Surgery and Endovascular Therapy at Baylor College of Medicine in Houston, Texas. He has disclosed that he holds no financial interest in any of the products or companies mentioned herein. Dr. Mussa may be reached at (713) 798-8412; mussa@bcm.edu.

James H. Mitchell, MD, is an Interventional Cardiovascular Fellow at St. Luke's Episcopal Hospital and the Texas Heart Institute in Houston, Texas. He has disclosed that he holds no financial interest in any of the products or companies mentioned herein. Dr Mitchell may be reached at (832) 355-6676; jmitchell1@sleh.com.

Joseph J. Naoum, MD, is a Fellow in Vascular Surgery and Endovascular Therapy at Baylor College of Medicine in Houston, Texas. He has disclosed that he holds no financial interest in any of the products or companies mentioned herein. Dr. Naoum may be reached at (713) 798-8412; naoum@bcm.edu.

Zvonimir Krajcer, MD, is a Clinical Professor of Medicine at Baylor College of Medicine and the University of Texas Health Science Center in Houston. He is an interventional cardiologist and Director of Peripheral Vascular Intervention at St. Luke's Episcopal Hospital and the Texas Heart Institute in Houston, Texas. He has disclosed that he holds no financial interest in any of the products or companies mentioned herein. Dr. Krajcer may be reached at (713) 790-9401; ZvonkoMD@aol.com.

Alan B. Lumsden, MD, is from the Department of Cardiovascular Surgery, Methodist DeBakey Heart Center, in Houston, Texas. He has disclosed that he holds no financial interest in any of the products or companies mentioned herein. Dr. Lumsden may be reached at (713) 441-6201; ablumsden@tmh.tmc.edu.

Acknowledgment: The authors thank Dr. Ruth L. Bush for her assistance in preparing this manuscript.

1. Prinssen M, Verhoeven EL, Buth J, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. N Engl J Med. 2004;351:1607-1618.
2. Sampram ES, Karafa MT, Mascha EJ, et al. Nature, frequency, and predictors of secondary procedures after endovascular repair of abdominal aortic aneurysm. J Vasc Surg. 2003;37:930-937.
3. Bush RL, Johnson ML, Collins TC, et al. Open versus endovascular abdominal aortic aneurysm repair in VA hospitals. J Am Coll Surg. 2006;202:577-587.
4. Torsello GB, Kasprzak B, Klenk E, et al. Endovascular suture versus cutdown for endovascular aneurysm repair: a prospective randomized pilot study. J Vasc Surg. 2003;38:78-82.
5. Morasch MD, Kibbe MR, Evans ME, et al. Percutaneous repair of abdominal aortic aneurysm. J Vasc Surg. 2004;40:12-16.
6. Haas PC, Krajcer Z, Diethrich EB. Closure of large percutaneous access sites using the Prostar XL Percutaneous Vascular Surgery device. J Endovasc Surg. 1999;6:168-170.
7. Greenhalgh RM, Brown LC, Kwong GP, et al. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. Lancet. 2004;364:843-848.
8. Zarins CK, White RA, Schwarten D, et al. AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. J Vasc Surg. 1999;29:292-305; discussion 306-308.
9. Greenberg RK, Chuter TA, Sternbergh WC III, et al. Zenith AAA endovascular graft: intermediate-term results of the US multicenter trial. J Vasc Surg. 2004;39:1209-1218.
10. Buth J. Endovascular repair of abdominal aortic aneurysms: results from the EUROSTAR registry. EUROpean collaborators on Stent-graft Techniques for abdominal aortic Aneurysm Repair. Semin Interv Cardiol. 2000;5:29-33.
11. Howell M, Doughtery K, Strickman N, et al. Percutaneous repair of abdominal aortic aneurysms using the AneuRx stent graft and the percutaneous vascular surgery device. Catheter Cardiovasc Interv. 2002;55:281-287.
12. Starnes BW, Andersen CA, Ronsivalle JA, et al. Totally percutaneous aortic aneurysm repair: experience and prudence. J Vasc Surg. 2006;43:270-276.
13. Borner G, Ivancev K, Sonesson B, et al. Percutaneous AAA repair: is it safe? J Endovasc Ther. 2004;11:621-626.