Perspective: Exploring Outpatient EVAR

Pipe dream or reality? With a new generation of low-profile devices emerging, Michael D. Dake, MD, shares his thoughts on the future of taking endovascular aneurysm repair to the outpatient setting.

What has led to interest in researching endovascular aortic repair (EVAR) as an outpatient procedure?

The main objective of outpatient procedures is to provide a better patient experience at a lower cost; we're all looking for value now in our practices. Outpatient EVAR is not for everyone, but in patients who have the appropriate anatomy, (eg, the femoral access doesn't have a circumferentially heavily calcified artery, the artery is large enough to accept a lower-profile device, etc.) the technical aspects of the procedure are coming together.

In certain patients, based on results with percutaneous EVAR (PEVAR), it has been established that there's a potential to reduce procedure times, hospitalization, and anesthesia time. PEVAR does not necessarily equal outpatient EVAR, but it is a main component when you are considering this as an outpatient procedure, along with regional, local anesthesia as opposed to general anesthesia.

What do the initial data indicate as the inclusion and exclusion criteria when it comes to patient selection?

Setting up the appropriate criteria is crucial. Obviously, patients who have unstable coronary artery disease, inappropriate anatomy, or have an aneurysm that may require a prolonged, difficult procedure may not be candidates.

Again, this is not a one-size-fits-all procedure. Patients who have good anatomy and are relatively healthy—and during the procedure there was no bleeding, hypotension, or need for prolonged intubation—could move right to a telemetry unit after the procedure without need for an intensive care unit stay. These patients could be early ambulated and have a solid food diet sooner. It is also possible that the procedure might be done without a separate arterial line in the arm, that arterial pressure could be measured through a sheath and catheters in the groin that are part and parcel to the procedure and would be removed immediately afterward. As long as the patient doesn't need a titratable intravenous drip, have any unstable respiratory or cardiac hemodynamics, does not have prolonged pain, and is not a dialysis patient, I think it's quite conceivable that these patients could move through their hospitalization very quickly.

We know from the EUROSTAR registry that anesthesia type matters in terms of mortality, morbidity, hospital stay, and intensive care unit admissions; patients have significantly lower frequencies of all of these elements with local or regional anesthesia versus general anesthesia.

What are the primary potential benefits for the hospital, patient, physician, and insurer/Centers for Medicare & Medicaid Services (CMS) of sending a patient home in the same day?

Potential benefits associated with percutaneous access are fewer groin complications from access-associated infections, nerve injuries, lymphocele, and wound dehiscence, less blood loss, and lower in-room anesthesia time. Outpatient procedures have a constellation of components; any one part does not ensure that a procedure is feasible, safe, clinically beneficial, and economically viable on an outpatient basis, but put together, there appears to be an opportunity in this case for a win-win triangle between three stakeholders (physicians, patients, and hospitals).

One of the key advantages for interventionists with the more minimally invasive approach of PEVAR plus local anesthesia is the reduction of logistical concerns—trying to set up multiple departments, anesthesia, and coordinating teams. Those problems dissolve, and physicians can act more independently.

For hospitals, anything that can reduce cost and create a more attractive margin in terms of reimbursement versus cost would clearly be a benefit. If you align the incentives between the hospital, which potentially

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might realize a less costly procedure; the physicians, who have an intervention that is logistically easier to coordinate; and the patients, with a faster recovery time, less-intense procedure, and less risk of complications, there is some momentum that could build toward making outpatient EVAR a real consideration.

Are there real cost savings?

In most settings, there are two diagnosis-related groups to bill for EVAR, of which the vast majority (88%-90%) are procedures in patients that do not have major complications or major comorbidities. The CMS payment for the majority of cases is unfortunately a break-even proposition.

With PEVAR, the addition of having to use an assisted compression device or more frequently, a suture-mediated access closure system, makes many people figure that you are essentially substituting the cost of an anesthetic (around $700) for two closure devices, which might be $500 or $600.

However, we are really looking at an overall opportunity; it is not just the closure device versus anesthesia. In the future, it's conceivable that some patients may even receive manual compression, especially for the 10-F OD range for PEVAR devices. In most cases right now, that is not advocated, but certainly, industry will start bringing out devices that are custom designed for these size-access issues. It is passing the puck to where the player is going to be; all the profiles of devices will go down, so that's where closure devices should be. The profile won't go much below 10 F, there are certain laws of physics that can't be violated. You will see new entries into the market for closure devices that address the specific challenges for 10, 12, or 14 F. With that will come competition and, in theory, the price may drop.

There is a whole consortium of potential opportunities. If you can use a closure device, then you get rid of the ICU stay, which is a huge cost. The mean time right now for EVAR hospitalization is about 2.75 to 2.8 days. With outpatient EVAR, that is reduced to 1 day or less. That doesn't seem like a big deal, but at a mean rooming cost of $400 per day of hospital stay, every little bit helps. As long as this can be done in a safe manner that doesn't jeopardize patients' outcomes and health, I think it warrants consideration.

What are the main objections to outpatient EVAR? Does this increase risk to the patient? Are physicians uncomfortable with shorter hospitalizations? Administrators?

Physicians should be uncomfortable with shorter hospitalizations until it's proven. Anything that is a change in an accepted protocol should be challenged and questioned. I'm confident, however, that over the next few years, we'll see this trend evolving into a higher frequency of consideration of PEVAR and local anesthetic, which makes for a less intense procedure that only needs a single overnight stay or even a same-day outpatient procedure.

Administrators, of course, want to make sure that any procedure is safe to patients and that patients aren't returning with complications as a result of outpatient procedures. I think administrators would trust the physicians to develop this in concert with staff at the hospital to set up the correct criteria for screening patients to be considered for outpatient EVAR and monitoring their status after the procedure to decide whether to move forward with an early discharge.

For patients, I think EVAR is being perceived as a less major procedure. Obviously, if outpatient EVAR were the same procedure as standard inpatient EVAR, with the same size devices, requiring the same sort of cutdown and general anesthesia, and we tried to usher them through in a quickstep protocol, of course patients would be a little concerned. With the downsizing of devices, however, EVAR is becoming more like a simple stent procedure, whether it's for an iliac artery or a subclavian procedure. This amalgamation of different factors is sparking ideas on how to develop a more efficient EVAR procedure and in the process, help the patients, doctors, and hospital. It's now becoming something people are willing to consider as a reality.

What will it take to make EVAR a truly same-day outpatient procedure? Will the technology have to change, or just the way it is used and reimbursed?

In theory, truly same-day EVAR is possible in certain highly select patients. Right now, for most that's pushing the envelope too far; we don't have any experience in a large volume of patients that would suggest that this is possible. I think as these devices become smaller and 10- and 12-F OD devices become mainstream, that's where it has to head.

To what degree does reimbursement affect outpatient EVAR possibilities? What is a realistic time frame for this to become more widely reimbursed?

There is a potentially powerful alignment between the patients, interventionists, clinicians, hospital systems, and payers for this. But the big question is, if we do this as an outpatient procedure, will it still be reimbursed similarly to how it is now? It is likely just a matter of education and getting proof of concept established in the literature from well-designed scientific trials. If presented to CMS and insurers as something that can be performed safely and in a way that could be beneficial for patients and hospital systems, there would have to be a consideration for adjusting reimbursement.

Is reimbursement the reason outpatient EVAR is still generally limited to VA hospitals in the US?

VA hospitals, of course, have always been operated under a unique situation, which has often allowed them to be the cradle of new ideas. They are able to be creative and do things that work for patients. However, the VA is also very sensitive to doing what's right for their patients, so the fact that they are involved with outpatient EVAR is a good sign. I think you will start to see various industry concerns and strategic EVAR suppliers start to push this way. The number of stakeholders that could potentially benefit from this procedure is an almost perfect storm to drive it forward, under the constraints that there are certain patients in whom it's not appropriate. ■

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