



EVAR in Its Native Country

BY MARIANO FERREIRA, MD

Endovascular aneurysm repair (EVAR) has changed the practice of abdominal aortic aneurysm (AAA) treatment. Since the initial report by Parodi et al,¹ stent graft repair of AAAs has emerged as a potential alternative to traditional open repair. We retrospectively examined our database to establish the effect of the introduction of EVAR into Argentina. No official data were available. This study is also based on data provided by local distributors of endografts.

THE SUCCESS OF EVAR

AAA management has substantially improved with new treatments, techniques for detection, devices for monitoring, and drugs for avoiding or postponing surgery. Seventeen years after the first successful endoluminal treatment of an AAA, we gained much experience using this novel approach.

The first system Dr. Parodi used was composed of an extra-large Palmaz stent, designed in Buenos Aires, and a knitted polyester tubular graft. The graft was manufactured according to his indications, which included the design of a tubular fabric graft with radially expandable ends. This expandability allowed the use of only one size of graft, balloon, and stent for every patient. The concept of "one size fits all" was founded.

However, early work demonstrates straight tube grafts without distal stent fixation failed uniformly. When a distal stent was applied to the straight tube graft, the results were considerably better. Unfortunately, we soon discovered that only few patients can be successfully treated using the straight tube prosthesis. The majority of aneurysms require interventional treatment involving aortic bifurcation. For this reason, most investigators and corporate sponsors concentrated on developing bifurcated devices.

After the above-mentioned dramatic failure, we decided to use the simple aorto-uni-iliac system that we still use from time to time. This system appears to be very useful in cases of ruptured aneurysms and in cases with

very tortuous iliac arteries.

With the appearance of industrial, self-expandable endografts, procedures were simplified because of a lower-profile, and an enhanced flexibility characterized the new devices. More than 700 procedures, in a sample of patients whose clinical condition was too risky to undergo standard AAA repair, confirmed promising and encouraging results, both in the short and midterm follow-up and also using third-generation devices.

Since 1990, an exponential increase in the number of EVAR procedures occurred in Argentina due to more experience, better technology, more acceptance to costs, and treating-physician's preference. Although the overall volume of AAA repair has not changed substantially in the past 5 years, EVAR is now used for nearly 20% of the AAA cases. Approximately 600 implants (20% more than the preceding year) were performed in Argentina during 2006. This increase in the number of cases is due to the inclusion of patients from the public health system.

ARGENTINE COLLEGE OF CARDIOVASCULAR SURGEONS

Argentine College of Cardiovascular Surgeons is devoted to train, examine, and authorize its members for the practice of AAA repair. Its medical advisors provide important guidelines not only for patient selection but also into the outcomes for management of AAAs, giving clear guidelines for treatment in Argentina. They recommended EVAR only for high-risk patients with aneurysms having a diameter >50 mm or expanding at a rate >1 cm per year. Therefore, according to their criteria, the first line of therapy in a low-risk patient with a AAA is the open approach.

SURGEONS, CARDIOLOGISTS, AND RADIOLOGISTS

EVAR must be performed in a center that routinely does both open surgical repair and EVAR. Although our group consists of only surgeons, vascular surgeons, cardiologists, and radiologists should collaborate. To be certi-



EVAR in Argentina

fied for the procedure, practitioners must have assisted and performed EVAR as a main operator in the presence of a certified expert. The operating room must be adequately furnished with digital equipment.

ADVANCEMENTS

In the last decade from the introduction of EVAR, the field has advanced steadily via improvements in system design. Late-generation devices benefit from features such as bifurcated configurations, modularity, full stent support, secure fixation systems, and structures capable of accommodating anatomic challenges such as fenestrations, branches, and endosutures.

EVAR 1, EVAR 2, AND DREAM

Recent randomized trials have compared conventional and EVAR treatment of asymptomatic AAAs (DREAM and EVAR I trials), and EVAR with no intervention in high-risk patients (EVAR 2 trial). The EVAR 1 and DREAM trials observed an initial mortality advantage for EVAR, but overall midterm survival was equivalent in both groups. Both trials found significantly higher complication and intervention rates and higher hospital costs with EVAR, and by 1 year, the quality-of-life benefit was not evident. On the other hand, outcomes of the EVAR 2 trial have not settled the choice between EVAR and no treatment. It may or may not offer a mortality benefit over nonoperative management in patients with large AAAs who are unfit for open repair, but the statistical significance of this comparison is inconclusive.

APPROVED DEVICES

Seven different devices were employed in Argentina last year, including five stent grafts manufactured by different American and European companies. Only two stent grafts are made in Latin America (SETA, Latecba Enterprise, Buenos Aires, Argentina; Braile Device, Braile Biomédica, San Jose de Rio Preto, Brazil). The Zenith (Cook Medical, Bloomington, IN), Talent (Medtronic, Inc., Santa Rosa, CA), and Excluder (Gore & Associates, Flagstaff, AZ) stent grafts led the market.

REIMBURSEMENT

Most AAA repairs are currently reimbursed to hospitals by public and private (prepaid and funds for salaried workers) insurance. The insurance providers impose strict regulatory requirements and clinical guidelines for the use of stent grafts. Currently, public insurance is the most important customer for this treatment. However, in private practice, endografts were inserted according to patient preference; nevertheless, they represent less than 5% of the market.

Despite a significantly shortened length of stay and reduction in hospital bed costs, EVAR was considerably more costly than open repair. The device cost accounted for more than 50% of the total expense and was clearly the single largest cost. Our background information also suggested increased costs for diagnostics and follow-up in the endovascular group, which contributed to the greater overall insurance cost.

SURVEILLANCE

Follow-up was conducted at hospital discharge, at 1, 6, and 12 months, and every 6 months thereafter. Evaluation included CT, abdominal radiography, laboratory tests, and physical examination. Current surveillance protocols after EVAR follow secondary markers of sac pressurization, namely endoleak, and sac enlargement. Plain x-ray imaging can detect stent migration and stent fractures, as well as early signs of limb dislocation. We participated in the first clinical experience with the use of a permanently implantable chronic pressure transducer to monitor the results of EVAR in humans. Aneurysm exclusion leads to gradual diminution of sac pressure over several months. However, additional clinical follow-up will be necessary to determine whether aneurysm sac pressure monitoring can replace CT in the long-term surveillance of patients after EVAR. Some patients, such as those with renal insufficiency, undoubtedly benefit with this new development.

THE FUTURE OF EVAR

The future of AAA treatment will include medical management of risk factors of atherosclerotic disease; biological and genetic engineering advances, such as suppression of inflammatory and proteolytic destruction of the aortic wall; and the use of vascular growth factor and endothelial progenitor cells. On the other hand, public policies and economic changes in patient screening, device approvals, and reimbursements will increase the number of patients treated and will decrease aneurysm-related mortality. However, the increasing use and utility of this less-invasive procedure and, in general, its effectiveness and safety is quite clear from this analysis. ■

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