Indication and Durability of EVAR: A Korean Perspective

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Endovascular aneurysm repair (EVAR) was initially introduced by Parodi et al[1] as a less-invasive alternative to conventional open repair. EVAR was subsequently adopted as a treatment option for abdominal aortic aneurysms (AAAs).

EVAR STUDIES

Previously, EVAR was accepted as a comparable method to more conventional options because of its early safety and favorable outcomes.[2-4] Early clinical studies reported significant reductions in intensive care unit time, total hospital stay, as well as in major complications, such as bleeding or 30-day mortality.

Furthermore, due to the advantages of EVAR, such as prompt recovery and early ambulation, EVAR has emerged as a replacement therapy to surgery, especially in treatments for elderly patients with multiple comorbidities. However, some conflicting results have been reported from more recent studies measuring mid- to long-term impacts of EVAR.

For instance, studies by Blum at al[5] and Cuypers et al[6] revealed inconsistencies in the early, positive outcomes of EVAR. Although one study reported 3 to 6 years of sustained benefits, another raised concerns of the accepted durability of EVAR. In addition, other studies[7-11] reported concerns of increased risk of possible graft failure and the need for reintervention or surgical conversion in a later phase.

EVAR IN KOREA

In Korea, open repair is more widely available than EVAR, although EVAR can be performed in several hospitals. The approved devices in Korea are the Zenith (Cook Medical, Bloomington, IN), the Excluder (Gore & Associates, Flagstaff, AZ), and the SNG, a domestic device. In the past 2 years, only 138 EVARs were performed in Korea. The Zenith was used for 24 procedures in 2005 and 84 procedures in 2006; the Excluder was used for 13 procedures in 2005 and eight procedures in 2006. The remaining nine procedures were done with the SNG. The AneuRx (Medtronic, Inc., Santa Rosa, CA) was recently approved for use in Korea, although we are still waiting for approval of the Talent (Medtronic).

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Due to the rapidly aging population in Korea, there has been a shift from private healthcare to government-regulated universal coverage. Korean government insurance pays for 90% of the EVAR device; the remaining 10% comes from the patient.

EVAR 1, EVAR 2, AND DREAM

EVAR 1, involving patients who could endure both open and endovascular repair, reported patients experiencing significantly lower 30-day mortality rates, yet with an increase of postoperative reintervention rates.[12] EVAR 2 researchers compared EVAR-treated patients with patients who received no intervention and found that the former group reported significantly higher rates of all-cause and aneurysm-related mortality, as well as negative results in cost-effectiveness. Therefore, researchers concluded that careful case selection and clinical follow-up

when treating AAAs with EVAR are critical.[13]

In the DREAM trial, the open repair and EVAR groups were compared based on accumulated aneurysm-related mortality rates, yet study results did not show any significant differences in their primary endpoints. Therefore, short-term advantages, such as immediate postinterventional safety and early positive outcomes should not be the primary determinants in the prognosis of EVAR, nor should they be coincided with its long-term outcomes.[14,15] However, there have not been any randomized prospective clinical trials on long-term outcomes for patients within a high–operative-risk group.

NATURAL HISTORY AND INTERVENTIONAL DECISION MAKING

The mortality rate of patients with ruptured AAAs is greater than 90%, although it could be decreased with the implantation of emergency stent grafts.[16] Therefore, it is crucial to manage AAAs before they rupture, even though the possibility and timing of rupture may vary considerably for each case. It has been generally reported that the risk of rupture increases substantially if the diameter of the AAA is between 5 cm and 6 cm. For example, the annual risk of rupturing is 5% to 11%[17] when the diameter of the AAA is greater than 5 cm.

High-risk factors for rupture include: diameter greater than 6 cm or annual progression greater than .6 cm, heavy smoking, family history of vascular disease, poorly controlled hypertension, eccentric aneurysmal shape, and female gender.[18]

In our experience, mortality rates could not be greatly reduced by urgent procedures after AAA rupture due to progressive multiorgan failure, including renal shutdown. Therefore, it is critical to detect progression of an AAA in its early stage with close clinical and radiographic follow-up.

INDICATION AND EXPERTISE

In our experience, accurate preprocedural analyses of imaging studies and proper selection of instruments have been very effective for successful cases of AAA and bi-iliac artery with vascular tortuosity. More importantly, the levels of experience and expertise of the operators were critical in successful implantations of stent grafts.

New procedures and instruments have been introduced for cases previously considered as contraindications (eg, aneurysms with an acute angle extremely extended to the renal or iliac artery): incorporation of uncovered stents for apposition support, the staged embolization of the internal iliac artery, and modification of the puncture site vertically. With these adjustments, successful EVAR cases have increased gradually compared to cases of conventional open repair.

A review of our past data shows a relatively positive indication of the need for endograft implantation to treat AAAs with a diameter ranging from 5 cm to 5.5 cm, depending on the patient's native vessel diameter or enlargement progress of the aneurysm (ie, 1 cm per year).

Despite adequate medical treatments, new onset or aggravation of pain, or other medically intractable conditions, such as rupturing in either acute or chronic presentation, are also indications for EVAR.[19,20] With considerable variations of individual aortic aneurysms, however, it is not a simple task to state the appropriateness of EVAR clearly, especially when treating patients with grave comorbidities, even with results from large, randomized clinical trials.

COMPLICATIONS AND DURABILITY

Complications such as stent graft migration, stent thrombosis or spontaneous leak, and porosity, have occurred during follow-up, with some requiring either reintervention or operative correction.[21] Type I or type III endoleak should be corrected, because the aneurysmal sac would be exposed to systemic blood pressures without any possibility of spontaneous resolution.[22,23] Therefore, without sound evidence of initial endoleak, it is critical to detect the existence of endoleak using computed tomography follow-up, and it is helpful to pursue additional interventions, such as coiling, or to redo stent graft implantation, to prevent progressions of pressure overload to the aneurysm.

Generally, cases that required additional procedures have not been considered clinically successful. As we expand the meaning of success, however, and place some value on subsequent procedures, the impact on effective prognosis of patients is substantial. In addition, managing comorbidities intensively with antihypertensive, antilipidemic, and antiplatelet agents for patient prognosis is important; it is also imperative to consider stent durability and patency against the remodeling of the aorta or thrombosis.

CONCLUSION

The research and development of EVAR have gained much attention and speed over the past decade with the effort of its pioneers. Although there are still some tough questions to answer, such as what are the ideal indications and durability of EVAR, the procedure does have some advantages. EVAR is more attractive for patients, and it has less invasive effects and comorbidities. In Korea, vascular surgeons, interventional radiologists, and interventional cardiologists alike understand

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EVAR in Korea

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the benefit of EVAR. The future prospect of EVAR in Korea is bright. ■

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