

INT SY-1 The Status of Endografting Procedures for AAA and TAA

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Over the past 2 decades, the evolution of endovascular technology has resulted not just in significant improvements in stent graft design but also in patient outcomes with endovascular aneurysm repair (EVAR), and endovascular thoracic aortic aneurysm repair (TEVAR). The culmination of data has led to the tipping point in that today EVAR and TEVAR have become the gold standard for treatment of abdominal aortic aneurysms (AAA) and thoracic aortic aneurysms (TAA). Several randomized controlled trials (EVAR1, EVAR2, and DREAM) that were initiated a decade ago and used only the 1st and 2nd generation stent grafts have indicated survival advantage in EVAR patients at various time periods following repair. Furthermore, several pivotal TEVAR trials have led to the approval and availability of various thoracic stent grafts resulting in a significant paradigm change in the treatments of TAA. The status of endovascular procedures is evolving rapidly with emphasis beyond the feasibility and efficacy in treating descending TAA and infrarenal AAA. Improvements in stent graft technology and techniques are ongoing, and the focus has shifted to treatment of complex TAA and AAA that involve the arch and visceral vessels.

The future of AAA and TAA therapies holds great promise as the pipeline of 3rd and 4th generation stent grafts is just maturing with several clinical trials underway – all focused on tackling the proximal and distal aortic and iliac attachment sites. Further innovations in stent graft design will focus on separating stent graft fixation and seal, lower delivery system profile, controlled deployment, and preserving blood flow to the arch, visceral and pelvic circulation – all properties that would enable us to treat upwards of 80-90% of all AAA and TAA patients by endovascular therapy. The technology is also evolving towards utilization of branched and fenestrated stent grafts; although these devices and procedures are complex and rapid dissemination of these devices have failed to gain traction. Rather, improvements in novel ‘chimney and snorkel’ techniques in combination with currently available EVAR and TEVAR stent grafts have evolved and are gaining traction in treatment of complex AAA and TAA without adequate landing zones. This presentation will focus on currently available abdominal and thoracic stent grafts, their practical indications for use, the associated outcomes, and the evolution of these technologies in the near future

INT SY-2 Stent Graft versus Open surgery: Trend for the US

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Thoracoabdominal aortic aneurysm (TAAA) repair remains one of the most challenging operative procedures in cardiovascular surgery. Although much advancement in this field has occurred over the past 2 decades, significant morbidity and mortality still remains. Although single center series from specialized centers report excellent results for TAAA repair, general centers have not been as successful. For this reason, endovascular repair, including hybrid-debranching approaches, have been developed with the hope of providing a less invasive approach to TAAA repair. In addition, endovascular technology also hopes to provide an equally durable repair.

Because endograft durability remains in question, availability of fenestrated or branched endografts remains limited, and such measures are likely not indicated in the patients with aortic dissection or genetically-triggered aortic pathologies, open surgery for thoracoabdominal aortic aneurysm repair remains the standard treatment. Despite these limitations, however, trends have increased regarding endovascular repair in the US. This report will summarize these trends.

INT SY-3 Endovascular Surgery for aortic aneurysm in Korea

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It was 1996 when stent graft was firstly put to treat an AAA in Korea and total 1,090 cases of EVAR had been performed between 1996 and 2008.

EVAR had been usually performed by interventionist until 2007 when a vascular surgeon began to perform EVAR for AAA in Korea.

There are four kinds of commercially available stent grafts only for infrarenal AAA in Korea at present.

Although the number of EVAR has been sharply increasing since 2006 when medical expense for EVAR has been covered by insurance, there has been no nationwide data regarding EVAR including endoleaks, complications and even indications until now.

So, I would like to present the result of EVAR for AAA in Asan Medical Center, Seoul, Korea where more than 500 cases of AAA including 160 cases of EVAR have been experienced since 2001.

At present, main obstacles limiting use of stent graft are unsuitable neck anatomy, access problem, and patient's age under 65 years old in AMC.

INT SY-4 Paradigm shift from open to endovascular surgery

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Endovascular repair of abdominal aortic aneurysms (EVAR) has enjoyed a quick widespread over the last 15 years. Although early benefits of EVAR have been confirmed in two randomized trials, the number of late complications and re-interventions remains an issue for debate. In addition, the trials failed to demonstrate late overall survival gain. Nevertheless, this important surgical innovation has continued to evolve. The treatment of ruptured aneurysms is one example; the development of fenestrated and branched grafts another one.

A meta-analysis of open repair of ruptured aortic abdominal aneurysms (RAAA) demonstrated a 30-day mortality of 48% over the last 50 years, with an estimated operative mortality rate for the year 2000 of 41%. These poor results probably triggered the development of EVAR for RAAA. Potential benefits of EVAR for RAAA were confirmed by two systemic reviews. It is however difficult to interpret current results from the literature, due to patients selection criteria, definition of anatomic suitability for EVAR, and definition of hemodynamic stability. In addition, it must be clear that logistical and organisational requirements must be met, before being able to provide an efficient and safe service around the clock. This prerogative clearly asks for regional organisation in the treatment of acute aneurysms.

Feasibility of fenestrated EVAR for short-neck/juxtarenal aneurysms has been established. Nevertheless, it is important to consider the alternative options: open repair and standard endovascular repair. Standard endovascular repair in short-neck aneurysms is and will remain a discussion point for some time. It is clear that many patients with a proximal neck outside the official instructions for use are wrongly offered standard EVAR. Open surgery in short-neck/juxtarenal aneurysms is not extensively described in the literature, but several reports do specify the greater risks of mortality and morbidity. The fenestrated technique also provided a useful platform in the development of branched grafts to treat thoraco-abdominal aortic aneurysms (TAAA). Other innovative techniques including open debranching followed by EVAR of the complete thoraco-abdominal aorta, and chimney and sandwich-chimney techniques may play a role in patients with specific anatomy or in more urgent cases.

Endovascular techniques will undoubtedly continue to evolve. In view of the major impact of open surgery in TAAA, we presume that most suitable patients will not be treated by open means anymore in the future. Only major centres will be able to offer these elaborate endovascular techniques to patients with complex abdominal and thoracoabdominal aortic aneurysms. Nevertheless, the future will probably see more of a centralization of complex open aortic surgery because of the lower number of patients requiring complex open techniques.

INT SY-5

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INT SY-6 Overall trend of surgical treatment for aortic aneurysm in different countries

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It is always difficult to understand a general trend of a whole country at a moment when the therapeutic approach to certain diseases is rapidly changing as a consequence of a new technological development.

By dividing the aorta into three simple sections: ascending arch and descending we could show how the trend going from open surgery to hybrid approach to totally endovascular might vary tremendously.

In the ascending aorta, whether or not the root is involved, the general practice is still a standard open surgical approach with the sole addition of a mini-sternotomy in selected cases just to reduce the surgical trauma. This is also the standard approach when the ascending aneurysm extends into the aortic arch.

On the other hand, the hybrid approach plays a major role in case of arch aneurysm whether isolated or extending into the descending thoracic aorta. The simplest and most frequent cases are the subclavian artery de-branching to create a satisfactory landing zone for the subsequent endoprosthesis insertion. All other types of partial de-branching sporadically utilized in the first years have been replaced by the more radical total de-branching of the epiaortic vessel for the subsequent deployment of the endoprosthesis in landing zone "0". Another option frequently utilized in this setting is the so called "frozen elephant trunk". Although the idea of treating a portion of the descending aorta at the same time of surgical treatment of the arch pathology is appealing, doubts remain on the increased risk of paraplegia.

Isolated thoracic aortic aneurysm, whether atherosclerotic or traumatic are treated almost exclusively with an endovascular approach as are treated all traumatic rupture of the aortic isthmus. Regarding the acute or chronic dissection the opinion are mixed but a surgical attitude still prevails.

The collection of more long-term data will undoubtedly contribute to a better tailoring of the therapeutic approach for each anatomic location and for each specific patient.

INT SY-7 Endovascular therapy for Arch and Thoracoabdominal aneurysm

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In 2006, the Zenith endograft (Cook) won approval for the first time in Japan which lagged USA by 7 years. This was followed by approval of the Excluder (2007, WL Gore), Powerlink (2008, Endologix) and the Talent (2011, Medtronic). Reimbursement is however limited to only those patients who are at high risk for surgery and this need to be revised. In 2006, it was estimated that 10,000 AAA surgeries were performed in Japan of which almost 99% were open repairs. In 2010, a total of 15,000 (+50%) AAA repairs were performed of which 6,000 (40%) were EVARs. The market share in 2010 for Excluder, Zenith, Powerlink were 50%, 41%, 9%, respectively. During the last 4 years, at Jikei University, we have performed 752 EVARs for AAAs (death rate 0.2%), 380 TEVARs for Descending TAAs (0.5%), 60 Fenestrated/Branched stent-graft for thoraco-abdominal aneurysms (1.7%), 56 hybrid TEVARs for Arch aneurysms (2%). Vast majority of these procedures were performed in one of the 2 hybrid ORs equipped with either the Innova (GE) or the Artis Zeego (Siemens). During the same period, 100 open AAA repairs and 90 open thoracoabdominal aneurysm repair was performed. The Branched stent-graft was procured by Cook Inc. Atrium covered stent was used for the reconstruction of the visceral branches. For Arch aneurysms, in addition to TEVAR, a number of enabling procedures were performed including carotid-carotid bypass (n=31), total deb-raching from the ascending aorta (15), the Chimney procedure (8) and the RIBS (Retrograde Insitu Branched Stentgraft, (1). The RIBS constituted of deployment of a standard stent graft across the entire arch covering the orifices of each great vessel and then the stent-graft was quickly punctured in a retrograde manner from the common carotid (surgically exposed) and then reconstructed with the Atrium covered stent.

In an attempt to abolish above mentioned device lag, we have initiated 4 USA-Japan simultaneous stent graft trials (Zenith LP, Zenith Thoracic LP, C-TAG, Cordis InCraft) along with 2 SFA international trials. Although Japan lagged in terms of the introduction of endovascular repair of aortic aneurysms, we have rapidly caught up with swift penetration of EVAR and TEVAR and we also aim to lead the World with cutting edge technology.