REVIEW

Endovascular surgery: Has it improved outcomes?

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Introduction

The field of endovascular surgery is a relatively new addition to the vascular surgery armamentarium. It has its origins in the realm of interventional radiology and interventional cardiology. However it was the pioneering work of Parodi [1] and Palmaz [2], who used these techniques to repair aortic pathology such as aortic aneurysms and arterial stenoses, which alerted vascular surgeons to take note of the tremendous potential of endovascular approach. Since then, vascular surgeons have quickly adopted this new technology, and soon endovascular surgery became integrated into surgical training programs. As a result, the modern vascular surgeon is equally adept at both endovascular and open technique. Technical basis of all endovascular procedures is obtaining wire access into the target vessel. This is done either percutaneously or via open method depending on the intended procedure. Using the wire as the platform, different type of devices can be used to treat vascular pathology. They include balloon catheters for angioplasty, stent systems to treat stenoses, plaque excision devices for atherectomy, and stent-graft systems to repair aneurysms. The advantages of percutaneous endovascular procedures include the avoidance of general anesthesia and incision-related wound complications, reduced cardiovascular stress, and earlier recovery and ambulation. When required, re-intervention can also be performed more easily.

Ostial lesions, complex stenoses, occlusions, and aneurysms can be treated using existing technology with excellent outcomes. Occlusive disease of aorto-iliac, femoral-popliteal, subclavian, carotid, renal and tibial segments can be treated with balloon angioplasty and stents. Aneurysms of the thoracic and abdominal aorta and peripheral arteries can be treated with stent grafts. Newer stent grafts are being developed to treat complex aortic pathology such as thoracoabdominal aneurysms, aortic arch lesions and aortic dissection. Some of these devices are already being used in clinical trials in the United States and Europe [3]. There is a preponderance of high quality data that show excellent outcomes of endovascular surgery in all vascular beds. However, it is useful to examine several specific areas and pathology where endovascular approach has been scientifically evaluated in large multi-center clinical trials, viz. thoracic and abdominal aortic aneurysms, carotid artery stenoses and peripheral vascular disease.

Endovascular repair of abdominal aortic aneurysms

Since the introduction of first generation endovascular stent grafts, e.g. AneuRx stent graft [4], for repair of abdominal aortic aneurysms (AAA), we have seen rapid

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advances in this field. Devices currently available for use in the United States are all second-generation devices that have seen further improvements since their first introduction (Cook Zenith®, Gore Excluder®, Medtronic Talent/Endurant®, and Endologix Powerlink®). The efficacy of endovascular (EVAR) versus open repair of AAAs was studied in two European, multi-center, randomized clinical trials (Endovascular Aneurysm Repair Trial 1(EVAR-1) and The Dutch Randomized Endovascular Aneurysm Management Trial(DREAM)) in which patients with large aneurysms (>5.5 for EVAR-1 and >5.0 cm for DREAM) were randomized to open repair or EVAR [5,6]. Primary endpoint was overall mortality. In both trials, 30-day mortality was lower with EVAR compared to open repair (1.7% versus 4.7% in EVAR-1 and 1.2% versus 4.6% in DREAM). Four (4) years after randomization, all-cause mortality was similar in the two groups (about 28%) and the survival rates were similar. However, the rate of re-interventions was higher in the EVAR group. In the United States, the OVER trial (Open versus Endovascular Repair) showed similar results [7]. Following these results, EVAR has been widely adapted as the first-line therapy for AAAs with suitable anatomy. However, we still do not have longterm data for these patients, i.e. 10 – 20 year outcomes. Therefore, for younger patients, with low cardiac and medical risk, open repair should still be offered as a first – line treatment option.

Endovascular repair of thoracic aortic aneurysms

Open repair of thoracic aortic aneurysms have traditionally been associated with high perioperative mortality and morbidity (up to 10% and 50% respectively). Introduction of endovascular stent grafts to treat descending thoracic aortic aneurysms (DTAA) once again changed the "playing field." According to the data extracted from non-randomized but prospective databases used for regulatory trials for the United States Food and Drug Administration (FDA) approval, the reduction in mortality and major perioperative co-morbidities such as respiratory failure and paraplegia has been considerable [8,9] (Table 1). A recent meta-analysis of endovascular intervention versus open surgery for thoracic aortic pathology revealed similar outcomes: mortality in the stenting group was 5.57%

Table 1. Summary of Results from Three Regulatory Trials and One Large registry from Europe for Endovascular Repair of Descending Thoracic Aortic Aneurysms (DTAA)

	FDA Regulatory Trials				
	Gore TAG Study	**STARZ**	**VALOR**	**Combined Open Repair Controls from Trials**	**Eurostar + UK Registry**
Stent Graft	TAG	TX2	Talent	-	Multiple
Patient No.	140	160	195	353	249
		30-day Outcomes:			
Mortality (%)	1.5	1.9	2.1	7.1	5.3
***SCI (%)**	2.8	5.6	8.7	13	4
Stroke (%)	3.5	2.5	3.6	6.7	2.8
****MAE (%)**	28	41.9	30	77.3	-
Vascular Complications (%)	14	22	9.2	16.3	2.4

*SCI – Spinal Cord Injury   **MAE – Major Adverse Events compared to and 16.5% in the open arm. Similarly, the incidence of major neurological complications was 5.4% in the stent patients and 14% in open patients [9]. According to follow up data, these early benefits of thoracic endovascular aneurysm repair (TEVAR) appear to persist up to 5-years. In view of these findings, it is inconceivable that we will ever have a randomized clinical trial to compare endovascular versus open treatment for DTAA. Therefore, TEVAR has become the preferred treatment modality for all patients with DTAA who have suitable anatomy. Endovascular repair has also been used to repair aortic arch aneurysms and thoracoabdominal aortic aneurysms using either hybrid technique (endograft exclusion of the aorta with open bypass of critical aortic branches) or fenestrated stent grafts. Early results, though encouraging, have not shown conclusive benefit over open repair [10,11,12,13]. It is likely that in near future we will see some form of a prospective clinical trial to evaluate the outcomes of endovascular versus open treatment of aortic arch pathology and thoracoabdominal aneurysms.

Endovascular treatment of carotid disease

Several, landmark multi-center randomized clinical trials in Europe and North America have firmly established efficacy of carotid endarterectomy (CEA) for stroke prevention [14,15,16,17]. The open surgical technique has become so refined over the years that routine carotid endarterectomy in the United States has a reported stroke and death rate of only 2 percent [18]. However in both high medical risk patients and in those undergoing re-operative carotid surgery, risk of stroke, myocardial infarction and nerve injury is higher. Carotid angioplasty and stenting (CAS) was attempted in these patients to minimize the above complications. Several large case series and clinical trials reported good outcomes but these were flawed in terms of scientific method to be considered as the highest level of evidence. Therefore, two large, simultaneous trials, Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST) and International Carotid Stenting Study (ICSS), were conducted in the United States and Europe respectively to directly compare CAS with CEA [19,20]. The North American CREST trial showed that the two techniques were equivalent when stroke, death and myocardial infarction were considered together as a composite endpoint (5.2 % versus 4.5 %). When individual endpoints were analyzed, the stroke rate was twice as high with CAS compared CEA (4.1% vs. 2.3 %). CAS patients had lower rate of myocardial infarction. Overall, the quality of life of patients was affected more by stroke (Table 2). In the European ICSS trial, which incidentally had a higher overall stroke and death rate when compared to the CREST trial,

Table 2. CREST Trial Outcome: Primary endpoint, components of primary endpoint and other events according to the treatment group

End Point	CAS (N=1252)	CEA (N=1240)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	(%)			
Death	0.7	0.3	2.25	0.18
Stroke	4.1	2.3	1/79	0.01
Myocardial Infarction (MI)	1.1	2.3	0.50	0.03
Primary end point (Stroke, MI or death)	5.2	4.5	1.18	0.38

Table 3 . ICSS Trial: Outcome measures

	Stenting group (N=853)	Endarterectomy (n=857)	Hazard ratio (95% CI)	Risk difference, % (95% CI)	P Value
	(%)				
Stroke, death or myocardial infarction	8.5	5.2	1.69	3.3%	0.006
Any stroke	7.7	4.1	1.92	3.5%	0.002
Any stroke or death	8.5	4.7	1.86	3.8%	0.001
All-cause death	2.3	0.8	2.27	1.45%	0.017

CEA was superior for all endpoints (Table 3). The verdict from these two large trials did not leave a clear victor. Instead, the current consensus is to consider both CEA and CAS as complimentary procedures for treatment of carotid disease, and the choice of procedureshould be individualized according to patient risk factors and comorbidities. One important caveat is that CEA was found to be safer in patients over age of 80 years. The presumption is that the calcified aorta and tortuous aortic arch anatomy in older patients placed them at higher risk for stroke during CAS.

Endovascular treatment of peripheral vascular disease

Peripheral arterial occlusive disease involves the aorto-iliac, femoro-popliteal and tibial arterial segments. Open bypass still remains the gold standard to which all other treatment approaches to aorto-iliac occlusive disease (AIOD) is compared. Procedures such as aorto-femoral, ilio-femoral and femoro-femoral bypass have proven long-term patency. The primary patency rates of aorto-femoral bypass and femoro-femoral bypass are approximately 90% and 70% respectively at 5 years [21,22,23,24]. Compared to these results, 5-year, secondary patency of TASC (Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease) A and B lesions following angioplasty and stenting is reported at around 80 percent [25,35]. However, endovascular intervention for TASC C and D lesions (more diffuse disease including chronic total occlusions, bilateral occlusions and disease extending to external iliac arteries) has markedly inferior patency rates of around 75% at 2 years [26,27]. Therefore, in the aorto-iliac segment, angioplasty and stenting is considered first line therapy for TASC A and B lesions whereas open surgery is indicated for most TASC C and D lesions.

In the femoro-popliteal segment, angioplasty and stenting is widely used to treat both claudicants and patients with critical limb ischemia. More recently, other techniques such as excisional atherectomy, cryoplasty and laser atherectomy have also been used. No comprehensive clinical trial has been conducted to assess the efficacy of endovascular intervention versus open bypass across all clinical groups. Instead, limited trial data is available for angioplasty in the femoro-popliteal segment for mixed group of patients with claudication and critical limb ischemia. Open bypass patients had superior patency rate but higher long-term mortality compared to the angioplasty group In the BASIL (The Bypass versus Angioplasty in Severe Ischemia of the Leg) trial [28]. Other reported literature reflects retrospective data from cases series. Overall patency rate of angioplasty and stenting ranges 63% to 66% at 2 years in these analyses [29,30]. A more recent study reported overall 36-month primary, primary-assisted, and secondary patency rates of 52%, 64%, and 59%, respectively following primary stenting of superficial femoral artery [31]. This must be compared with femoro-popliteal bypass surgery, which has a reported 4-year patency of up to 80 percent. In spite of the paucity of high quality data, endovascular interventions have been widely adapted as the first line treatment approach to treat femoro-popliteal disease. For the patients, morbidity and mortality associated with open surgery and long hospital stay are avoided. In addition, endovascular intervention has enabled us to revascularize patients who are otherwise considered too-high risk for open surgery. For management of tibial occlusive arterial disease, there are very few durable treatment options. Many different endovascular interventions including atherectomy, angioplasty and laser treatments are performed [32]. None have proven to be durable. For limb salvage, open distal bypass remains the proven treatment. However, in major centers with experienced practitioners and close surveillance programs, encouraging results have been reported with tibial angioplasty. These patients however need many secondary interventions to ensure patency and amputation –free survival.

Endovascular surgery in other vascular beds

Angioplasty and stenting of renal artery lesions is widely performed by interventionists and vascular surgeons all over the world. In general, renal artery revascularization for salvage of renal function or for treatment of hypertension remains controversial. Recently concluded Angioplasty and Stenting for Renal Artery Lesions (ASTRAL) trial showed no benefit following angioplasty and stenting for asymptomatic renal artery stenoses [33]. A multi-center, randomized trial looking at different endpoints is underway in the United States [34]. In other areas, the use of endovascular technique continues to expand: salvage of dialysis access grafts, treatment upper extremity arterial stenosis, endovenous ablation therapy for superficial venous reflux, and treatment of acute and chronic mesenteric ischemia. However, long-term data is not available to evaluate the efficacy of these approaches compared to standard open surgery.

Summary

Endovascular surgery is rapidly replacing open surgery as the primary means of providing therapy in many areas of vascular surgery. As a result, the modern vascular surgeon should be able to offer a full spectrum of treatment options ranging from percutaneous interventions to open surgery to his or her patients. At a recent meeting in the United States, a senior vascular surgeon remarked "vascular surgery is the most exciting field to be in practice today". By embracing endovascular surgery, modern vascular surgeons have expanded their scope of practice and treatment strategies by many folds. As an example, complex aortic aneurysms that could not be treated by open surgery are now being treated by combined endovascular and open surgical strategies, i.e. hybrid procedures. Typically, this involves excluding the affected aneurysmal segment with endografts while bypassing the critical aortic branches in that segment (i.e. renal, mesenteric, carotid or subclavian arteries, depending on the segment of the aorta excluded) using bypass grafts with inflow from either distal or proximal aorta. Therefore, the advent of endovascular surgery has not only improved treatment outcomes in many areas of vascular surgery, it has also vastly broadened our scope of treatment of vascular pathology. Future developments in technology, clinical practice and vascular surgical training will only serve to further enhance this very exciting facet of modern surgery.

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