

VASCULAR, SURGICAL & PERCUTANEOUS INTERVENTIONS – A BALANCING ACT

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Abstract: Peripheral vascular diseases (PVD) encompass an entire gamut of conditions related to arteries and veins of the body. This niche speciality has come a long way since its origins in the 1950's. Today, it is perhaps the only speciality where the barriers between surgery, percutaneous interventions and vascular medicine are becoming blurred and the providers of care are becoming multi-skilled to provide the patients with the most appropriate care under evidence based medicine. This article touches on the aspects of a multi-specialized approach to vascular interventions, where time tested results of standard surgical procedures are now being matched by percutaneous techniques in many areas. It also highlights the importance of good patient selection for a particular procedure rather than having a single point program of treatment for all patients suffering from a particular condition. Treatment of carotid stenotic disease is changing, surgical results have been excellent from most reputed centres. However a subset of patients may be suitable for percutaneous techniques particularly with modern imaging and hardware at our disposal. Percutaneous approach to the thoracic aorta is novel and extremely promising; it may become the approach of choice in times to come. Treatment of aneurysmal as well as stenotic disease of the abdominal aorta has changed as well. The clinical evidence in favour of percutaneous techniques, in well selected patients is mounting; surgery as well as stent-grafting will almost certainly have a role in treatment in the future. Infra-inguinal vascular disease has also become amenable to treatment by percutaneous techniques. Again patient selection seems to be the key to success. In conclusion, percutaneous techniques are here to stay and are the way forward as well, the key factor being good training and committing our practices to evidence based medicine.

INTRODUCTION

Surgical treatment in its entire range, for a particular condition in the body, undergoes change from time to time. This was proven when the laparoscopic revolution overtook open surgery in the last decade of the previous millennium.

Vascular surgery is a highly specialized field, requiring good training & experience. However, the era of endo vascular treatment is here and it is for the surgeons to understand, appreciate and actively join others to become endovascular specialists.

CAROTID INTERVENTIONS

Nowhere else has the usage of endovascular techniques caused more confusion than in the carotid circulation. The carotids remain a victim of the 'oculo-stenotic' reflexes of most interventionists. The results of surgery in indicated cases of carotid endarterectomy (both symptomatic and asymptomatic), have been established over the last fifty years or so^{1,2}. First reported cases of carotid angioplasty came way back in 1988-89, way before a safe protection device or durable stent was designed or conceived^{3,4}. However carotid angioplasty with stenting (CAS), with modern hardware is becoming more acceptable with the providers and the patients. Much of this enthusiasm for CAS has been fostered by nonsurgeons.^{7,8}

Indications for Carotid Angioplasty/ Stenting in High-Risk Patients

1. Severe chronic obstructive pulmonary disease (a) requiring home oxygen (b) FEV-1 < 20% predicted (forced expiratory volume one second)
2. Severe chronic renal insufficiency (a) Serum creatinine > 3.0 mg% (b) Currently on dialysis
3. Prior carotid endarterectomy (CEA) (restenosis); contralateral vocal cord paralysis
4. Surgically inaccessible lesions (a) at or above the 2nd cervical

vertebra (b) inferior to the clavicle

5. Radiation-induced carotid stenosis

6. Prior ipsilateral radical neck dissection

Limitations/Contraindications to Carotid Angioplasty/ Stenting

- Inability to obtain femoral artery access
- Unfavorable aortic arch anatomy
- Severe tortuosity of the common or internal carotid arteries
- Severely calcified / undilatable stenoses
- Lesions containing fresh thrombus
- Extensive stenoses (>2cm)
- Critical (99%) stenoses ("string sign")
- Lesions adjacent to carotid artery aneurysms
- Contrast-related issues
- Chronic renal insufficiency
- Previous life-threatening contrast reaction
- Preload dependent states—severe aortic valvular stenosis

In conclusion, CAS is an evolving technique that has significantly improved our ability to treat patients with carotid bifurcation disease, especially those at high risk for carotid endarterectomy. It is currently approved for use in high-risk patients, as defined by clinical trials. As with CEA, proper patient selection and attention to procedural detail are imperative to produce exemplary results.

The raging controversy in this field remains good patient selection between surgery and stenting as well as lesions that need to be treated. To answer these basic questions, it is important that the interventionist is well read and informed regarding the natural history of carotid stenotic disease as well as the evidence based information regarding need for intervention. This is of course, essentially in the interest of the patient who is our primary concern.

THORACIC ENDOGRAFTING

Since the first report of endovascular therapy for descending thoracic

aortic pathology in 1994 by Dake et al, the advent of commercially available devices has been relatively slow. This is primarily due to the relatively lower volume of thoracic aortic aneurysms as compared with infra-renal aortic aneurysms. Technical and anatomic challenges in thoracic endografting, such as proximity of the great vessels and tortuosity around the arch, also pose a challenge. In addition, a larger device profile and hostile hemodynamic forces complicate the technical aspect of the deployment procedure.^{7,8}

Surgical repair of thoracic aortic aneurysms (TAA) is demanding both for the surgeon and the patient. The experience and expertise of the surgical team including the anesthesiologist and the post operative care for patients undergoing TAA repair, is crucial in producing successful results. This fact along with the morbidities involved, including that of ischemic injury to the spinal cord has contributed to a large extent in compelling providers to look for alternative means of treating this difficult problem.

Endovascular technology is expected to result in more pronounced benefits in the treatment of aneurismal disease in the chest than in the abdomen because of the higher morbidity of thoracic aortic procedures. Peri-operative mortality and morbidity, particularly with respect to SCI and cardiopulmonary complications, have been noticeably lower than those observed in open surgical repairs. These endografts have been applied to a variety of clinical settings beyond aneurismal disease, including aortic dissections, transections, and most other pathologies of the descending thoracic aorta.⁹

No device-specific results are yet available. All devices tested to date carry a large profile, ranging from 20F to 25F, and require a large access vessel for introduction. Access to the thoracic aorta continues to be a main source of complications. Almost 15% of the patients required access proximal to the femoral artery. The increased prevalence of TAA in women compared with abdominal aneurysms clearly exacerbates this problem.¹⁰

Although the incidence of spinal ischemic injury was low and less than that reported with open repair, it does occur with thoracic endograft repair. Although previous aortic surgery and coverage of long segments of aorta have been reported to portend a higher risk of paraplegia with endovascular repair of TAA.^{10,11} To conclude, endovascular treatment may become more acceptable for higher-risk patients, with TAA and new trials are expected to expand indications of this technique. The hope is of a viable alternative to surgery with consistent results in the near future.

ENDOGRAFTING FOR ABDOMINAL AORTIC ANEURYSMS

Surgical repair of an infra-renal aortic aneurysm was first done by Matas in the early 1900s. He repaired the aneurysm from within calling the technique as endo-aneurysmorrhaphy.

In the decades that followed with the advancement of anesthetic techniques and post operative care the mortality associated with this surgery has steadily declined, to the current figure of 3% for elective repairs.¹⁶ Most if not all, the large surgical invasion that the patient's body has to undergo to have the repair done. As would be expected majority of these people are in their seventies or above.

A need for a more minimally invasive procedure, which would produce similar results, was felt since the mid eighties. Credit must be given to pioneers such as Parodi et al. who dared to attempt endovascular management of abdominal aortic aneurysms with most

primitive hardware and imaging techniques in the early nineties¹³. Endovascular repair of abdominal aortic aneurysm was introduced in the early 1990s as a minimal access alternative to conventional repair. The first stent-grafts implanted were homemade devices and served to establish the feasibility of the technique. We are today in the midst of a quiet revolution, where we find minimally invasive and minimal access techniques have gained credibility, with suitable support from the industry, and a teamwork approach from the providers.

To be effective, a stent-graft needs to maintain fixation, hemodynamic seal, mechanical integrity, and patency over many years. However, a stent-graft implanted in an aortic aneurysm is subjected to several adverse factors that tend to compromise these functions.^{14,15}

The EUROSTAR comparative analysis is indeed one of the most comprehensive multicenter registry of its kind.

EUROSTAR Project

EUROSTAR (European Collaborators on Stent-graft Techniques for Abdominal Aortic Aneurysm Repair) project was launched in 1996 in response to the introduction of the new technique of repairing aortic aneurysms. The project was designed as a voluntary pan-European multicenter registry to allow collection of as much data as possible in as short a time as possible for expeditious scientific evaluation of this technique.

Patient Sample : During the observation period, 6787 patients (6341 men; mean age 72 years, range 28–100) from 181 hospitals (Appendix) in 19 countries were included in this analysis.

Statistical Analyses: The primary aim of the analysis was to compare patients who were treated by the different stent-graft models.

Adverse events during follow-up were examined to characterize the performance of different models. In order to render this comparison quantitative, annual incidence rates (IRann: number of events/person-years at risk) for each complication were calculated for the entire cohort and for each stent-graft model.

RESULTS

Endoleaks Device-related endoleaks were observed at 1 month in 10% (n=673) of the 6787 patients. Overall, the annual incidence rate was 6.2%.

Change in Aneurysm Diameter Aneurysm diameter increased in 6%; the annual incidence was 3.3%, ranging from 2.2% to 4.3%. Shrinkage of the aneurysm diameter occurred in 5 times as many patients (30%, n=2031). The overall annual incidence rate was 22.7%.

Migration: Graft migration was observed in 5% (n=323). The annual incidence rate, which was 2.8% overall

Kinking: Stent-graft kinking occurred in 4% (n=257) of the patients. Overall, the annual incidence rate of kinking was 2.3%.

Occlusion : Stent-graft occlusion was also reported in 62% lower in patients with a Ze-5% (n=367) of the patients

Reinterventions: Conversion to open repair was performed in 3% (n=234) of all patients. Of these, 76 conversions were performed within 30 days of the initial operation. The annual incidence for conversion was 2.0% overall.

One or more secondary interventions were necessary in 11% (n=771) of the patients. Although the eurostar study, had its share of

Table: Annual Number of Registered Stent-Graft Implantations

	Total	1995	1996	1997	1998	1999	2000	2001	2002	2003
AneuRx	999 (15%)	—	4	89	265	273	205	90	49	24
EVT/Ancure	176 (3%)	11	10	41	30	34	16	6	23	5
Excluder	808 (12%)	—	—	—	29	90	108	153	190	238
Stentor	308 (5%)	165	143	—	—	—	—	—	—	—
Talent	1579 (23%)	—	9	60	101	168	223	282	306	430
Vanguard	929 (14%)	—	89	372	304	149	15	—	—	—
Zenith	1988 (29%)	—	—	—	15	159	317	483	487	527
Totals	6787	176	255	562	744	873	884	1014	1055	1224

limitations, it has provided us with objective evidence that endografting for aortic aneurysms, is safe and can be performed with acceptably low rate of complications and mortality.

With the newer generation devices on smaller sized delivery systems, the technique is set to become more attractive both to the patients and operators. On the basis of this analysis, one can safely hope to have wider usage of stent-grafting for AAAs. There will perhaps always remain a subset of patients in whom a surgical repair would be a more suitable and therefore the decision regarding patient selection must involve people who have intimate knowledge regarding advantages and limitations of both these techniques.

INFRA – INGUINAL ENDOVASCULAR INTERVENTIONS

Surgical treatment of infra-inguinal arterial disease remains the gold standard even today. However a definite shift towards minimal access and percutaneous techniques is taking place in most centers around the world. The TASC (Transatlantic Inter-Society Consensus) recommendations have been modified and as in other blood vessels, the hardware has improved by leaps & bounds to make it more acceptable, durable and user friendly. Almost all infra-inguinal lesions from high grade symptomatic stenosis to occlusive disease have become approachable by endovascular means. There are a few studies that support the usage of modern stent grafts in the short and medium term (upto four years) in the superficial femoral artery (SFA), results being comparable to those of surgical bypasses.¹⁶

Usage of stent grafts in popliteal aneurysms, particularly behind the knee, is controversial, but is gaining support as technology advances further. Popliteal artery aneurysms (PAA) account for the most frequently seen peripheral aneurysms. They are potentially dangerous, with a 5-year cumulative risk for complications of 68%. The most common complications are acute thrombosis, with occlusion of the aneurysm, and distal^{17,18} embolization.

Open surgical treatment with a venous bypass graft is still the treatment of choice for most surgeons.

Advantages of the endovascular treatment include the minimally invasive character of the procedure, with only a small incision in the

groin, minimal morbidity, and a shorter operation time and hospital stay. A particular problem associated with this technique is that the stent graft crosses the knee joint. Repetitive stress on the device in this bending zone may lead to complications, including kinking, fracture of the stent-graft material, and occlusion. The newer generation of stent grafts address the problems of the tortuous course of the SFA and the need to maintain integrity, when deployed behind a joint.¹⁹ Endovascular management of focal lesions in the aorto-iliac segment is standard procedure now, but once again, it is worth mentioning that the wire may not be the best approach in all patients with these lesions.

CONCLUSION

A few facts emerge as an overall conclusion of this article. Firstly vascular surgery has emerged as a stand alone specialty and endovascular techniques are an integral extension of our field. The future will belong to groups of providers who are capable of working together and come up with complete treatment plans for vascular patients. The vascular specialists of the future will need to have in-depth knowledge on surgical, percutaneous and evidence based techniques, if our patients are to be offered treatments that meet the international standards.

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