Is Stenting Going to Put Open Surgery Out of Business?

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Kevin Burnand, MBBS, FRCS, MS, London, UK

Endovascular procedures developed from Charles Dotter's original concept that atherosclerotic stenoses would be amenable to dilatation by a balloon inserted through a needle placed in the arterial lumen. Prior to Dotter, the semi-open/semi-endovascular procedure of balloon embolectomy using the Fogarty catheter had been successfully employed for many years.

Mobin-Udin and Greenfield had also used the hybrid concept of open surgical access, combined with endovascular passage of a catheter delivery system, to successfully deploy filters in the inferior vena cava from a remote access site to prevent the passage of pulmonary emboli.

Technological developments in catheter balloon manufacture provided physicians with low profile co-axial balloons, which were strong enough to distend tough fibrotic atherosclerotic plaques. Longitudinal plaque fissuring and over distention of the vessel wall were subsequently shown to be the main mechanisms responsible for the beneficial effects of balloon dilatation (angioplasty). Active remodeling of the vessel wall following angioplasty occasionally resulted in rapid recoil, or severe restenosis as a consequence of myointimal-hyperplasia. The recognition of the many suboptimal results achieved by simple balloon dilatation led to the idea that the outcome might be improved by inserting an internal support (stent) inside the ballooned segment to "smooth out" the luminal surface. The stent would also cover any tears or dissections and would theoretically prevent post dilatation recoil and restenosis. A series of differently configured, expandable stents were developed and were made from a variety of different materials. These stents were placed through catheter-based delivery systems into the ballooned segment, where they self-expanded (nitinol) or were distended by a balloon. The assumption that these "stents" would dramatically improve the results of angioplasty was soon dispelled when early trials demonstrated that, at least in the aorto-iliac segment, the routine placement of a stent had a marginal effect on vessel patency.

Over the subsequent years, it became apparent that balloon dilatation with or without stenting was good at treating short stenosis or occlusions in large vessels (eg, the iliacs) but far less effective at treating long occlusions in smaller vessels. This was confirmed by the results achieved in the coronary arteries where short single stenoses were found to be amenable to balloon dilatation or stenting, whereas multiple or extensive stenoses in many of the branches still required surgical correction. The development of subintimal angioplasty allowed longer occlusions to be treated in the distal vessels of the lower limbs. Not all centers have been able to achieve good results, with this technique.

Endovascular techniques have also been used to allow coil and particulate embolization of arteriovenous fistulae, bleeding small vessels, and as a means of infarcting large tumors or by cutting off their blood supply. It has become apparent that embolic destruction of tumors and arteriovenous malformations is merely palliative and has to be endlessly repeated unless combined with ablative destruction. Endovascular stents have been placed over sites of arterial trauma to control hemorrhage and have also been used to close traumatic arteriovenous fistulae. They can be an extremely effective form of treatment in these circumstances.

The availability of stents encouraged Parodi to develop the concept of an endovascular graft to line and exclude aneurysmal sacs. Early homemade devices, which required many steps with complex wires and pulleys to achieve deployment, have given way to much simpler manufactured devices, which are much easier to deploy. The availability of these stent grafts that can be delivered into the thoracic and abdominal aorta via a cut-down incision in the groin has led to an explosion in their use to treat aneurysmal disease of the aorta and iliac arteries. Two recent multicenter trials of elective abdominal aortic aneurysm repair have shown that there is a considerable early advantage with a reduced 30-day mortality when stents are compared with an open operation. This early advantage is reduced or lost after 2 to 3 years. Continuing problems of endoleaks into the excluded aneurysmal sac, migration, kinking and disruption of the modular devices remain to be overcome, and lifetime surveillance must be maintained. Forty-one percent had required an additional intervention by a mean/average follow-up of 3 years. The UK EVAR II trial has shown that the mean hospital cost per patient in the EVAR group over 4 years is £13,632 compared with £4,983 in the no intervention group, without any difference in health-related quality of life.

Many patients with complex aneurysm morphology cannot be treated by stent grafting. The open operation, which is known to be extremely durable, remains, in this author's opinion, the treatment choice for relatively young (under the age of 80 years) fit patients without serious comorbidity. The role of stent grafting for treatment of leaking aneurysms remains to be established. The development of early customized and fenestrated branch grafts for patients with suprarenal or thoracoabdominal aneurysms is still in its infancy. At present, the prohibitive cost of these devices will have to be tested in appropriately organized, randomized studies. The newer concept of combining extra-anatomical bypasses with stent graft occlusion for thoracoabdominal aneurysms (hybrid procedures) is still in its infancy.

It is in the thoracic aorta that stent grafting is having its greatest impact where a staggering improvement in mortality compared with open surgery combined with a reduction in the risk of paraplegia makes stent grafting a very attractive option. The problems of endoleak, stroke, and graft migration remain, but the reduction in both mortality and paraplegia has made this the treatment of choice for localized thoracic aneurysms. This is also true in the treatment of stable aortic transections, and stent grafting is rapidly becoming the treatment of choice for complicated or unstable patients with type B dissecting aneurysms. The value of deploying stent grafts in all type B dissecting aneurysms needs assessment, and trials are now underway.

The proof that carotid endarterectomy is beneficial in symptomatic and asymptomatic patients with severe carotid stenosis is now irrefutable. This, not surprisingly, was extended to the concept that carotid angioplasty and stenting would be equally beneficial. The original trials which set out to prove this hypothesis were seriously flawed and only reached equivalence because of appalling surgical results. It became blindingly apparently to even the most biased of interventional radiologists that angioplasty without stent graft placement and some form of cerebral protection, was not acceptable. Further trials are now underway to compare surgery with stenting and cerebral protection. Unfortunately, many patients will probably be excluded from these studies and will have preferential surgery because of anatomical considerations, which will continue to make comparisons extremely difficult. Recent reports at the Society for Vascular Surgery meeting in Chicago 2005, indicate that the risk of stroke and death following stenting remains double that of surgery.

The endovascular explosion has also reached the venous system where intraluminal devices that "cook" or "burn" the long saphenous veins can be induced via a catheter placed in the vein lumen under ultrasound guidance. These devices have been introduced with little supporting evidence of their efficacy and trials are now underway to assess these treatments against standard surgery and foam sclerotherapy. Other devices aimed at dissolving or disrupting thrombus are still in development. Venous stents have a place in palliating malignant infiltration of large veins and in treating iliac vein compression syndrome.

At the present moment, endovascular treatments are of value for the following:

1. Dilating localized arterial stenoses or short occlusions in peripheral arteries
2. Placing caval filters
3. Treating thoracic aneurysms and unstable dissections and thoracic aortic transections
4. Embolizing arteriovenous fistulae
5. Treating abdominal aortic aneurysms in unfit or very elderly patients with the caveat that EVAR II has not shown a reduction in mortality in very unfit patients treated with EVAR

At present, the place for endovascular treatment remains to be established for long peripheral arterial occlusions, aortic aneurysms in fit patients, thoracoabdominal aneurysms, and in all patients who have a carotid cause for cerebrovascular symptoms. It is also important to consider the group of patients who develop restenosis or other complications related to endovascular treatment. There are a growing number of these patients who will require challenging open surgery or endovascular solutions to salvage the situation. The vascular community must be careful to properly appraise patients of the risks and benefits of both open and endovascular treatments in order that they come to a considered view on the best method of treatment for their condition. This should not be based on pecuniary reward or technologic bias but on clear, hard, facts. At present, there is no way that stenting is going to put vascular surgery out of business.

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