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Aneurysm sealing

Leading article

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Every so often a new technology comes along that has the potential to significantly change the way patients are managed. Despite impressive early outcomes associated with endovascular aneurysm repair (EVAR), endoleaks and stent-graft related failure were soon identified as deficiencies. Endovascular aneurysm sealing (EVAS) was developed to solve these problems. In general, EVAS may be considered a more straightforward procedure than EVAR. It involves filling the aneurysm sac with a permanent material, in an attempt to improve long-term durability and reduce late stent-graft related complications. In the context of abdominal aortic aneurysm (AAA), stent grafts are deployed bilaterally, extending from the infra-renal aortic neck to the iliac arteries. Bags ('endobags') attached to the grafts are filled with liquid based polymer to obliterate residual space within the aneurysm sac surrounding the stent grafts. Typically, between 50-100ml of polymer is injected at supra-systolic blood pressure (180-220mmHg) to create a blood tight seal in the neck of the aneurysm and iliac arteries and contribute to stent graft stability. It cures to a permanent solid state within a few minutes.

The opportunity to improve stabilisation of stent-grafts using the aortic sac remains an appealing idea to overcome many of the late device related failures with endovascular technologies, although the introduction of a stabilising agent within a stent graft delivery system has proved challenging. Biocompatibility, safety in the event of bag rupture and durability of the seal are considered essential features and critics of EVAS have suggested that polymer is unnecessary since thrombus within the sac after EVAR itself provides a stabilising effect. Concerns have been raised over rupture risk, embolization by the inflation of endobags at high pressure, and risk of infection posed by introducing a large volume of foreign body in to the AAA sac. In practice, complication rates have been very low and either comparable or lower than those seen after standard infra-renal EVAR [1]. The risk of polymer leaking in to the retroperitoneum or systemic circulation appears rare although every case may not have been reported.

EVAS has the potential to prevent retrograde filling of the aneurysm sac from patent side-branches (type 2 endoleak). Efforts to prevent this type of leak during EVAR have been made by embolization of side-branches or filling the aneurysm sac with haemostatic material to induce sac thrombosis [2], but it has become apparent that these leaks are less dangerous than initially feared. Evidence from open surgical bypass and exclusion of AAA suggested that it was unusual to pose a clinical problem [3] and reports of sac rupture remain rare. Concerns about infection and neurological sequelae (embolisation through lumbar vessels)

meant that embolisation and the introduction of embolic material in to the sac has largely been abandoned.

Thrombus within the aneurysm sac is, nevertheless, biologically active. Data from the long-term follow-up of randomised trials in AAA surgery has demonstrated an excess of late deaths in patients undergoing EVAR compared with open repair. Many of these were cardiovascular, raising the possibility that retained thrombus within the AAA sac may play a role in these events. Reducing the volume of thrombus, for example by replacing it with polymer in EVAS might plausibly mitigate this risk [4]

The aneurysm sealing system is a simple endovascular technique that permits more rapid aneurysm exclusion than a bifurcated modular system, but there is a recognisable learning curve and there have been adaptations in technology and deployment techniques with time. [5]. This means that there is a relative paucity of high quality published data.

Outcomes in the industry sponsored US PIVOTAL trial and the EVAS Forward Global Registry seem encouraging[1, 6]. Technical success rates were high (99-100%) and peri-operative mortality low (0-0.7%) with complications rates comparable to standard infra-renal EVAR. In the PIVOTAL trial, freedom from major adverse events was 97.3% (95% CI 93.3-99.0) at 1 month; much lower than reported in comparative open repair cohorts. Endoleak rates have been low but their detection following EVAS can be difficult both on Duplex ultrasound and CT imaging [7]. The treatment options for endoleaks and device failures post EVAS are often more complex and the outcomes less certain [8].

The morphological criteria of AAA for EVAS are broadly similar to standard infra-renal EVAR [9]. Proximal and distal landing and sealing zones are required above and below the aneurysmal segment. Patients with large empty (thrombus free) aneurysm sacs are currently unsuitable for treatment due to the capacity of the endobags. The aneurysm sealing technique has been complemented with visceral vessel stents in patients with more complex aortic morphology such as juxta-renal AAA, but as with standard infra-renal EVAR, this approach comes at a cost of increased secondary interventions [10].

Iliac limb occlusion resulting in limb ischaemia remains a common problem after EVAR. EVAS uses a balloon expandable stent system which is somewhat less conformable to tortuous arteries compared to the self-expanding stents used in standard infra-renal EVAR. Concerns about limb occlusion in EVAS do not appear to have been borne out. Occlusion and re-intervention was identified in only 7 of 277 patients followed for 18 months); lower than

many comparable EVAR series [10]. One explanation for low rates of iliac limb occlusion may have been high rates (59% in one study) of prophylactic adjunctive re-lining of the EVAS limbs with additional self-expanding stents [5].

In the EUROSTAR Registry caudal migration occurring 1-2 years after implantation of EVAR was a major risk factor for subsequent aortic rupture [11]. Consequently many second and third generation stent grafts evolved to include more robust fixation systems including hooks and barbs placed either in the aortic neck or the relatively disease free supra-renal aorta. EVAS does not rely on these fixation systems but instead on the stents and polymer as well as the integrity of the aneurysm sac. The data on migration rates are sparse but one recent small study suggested these may be concerning (28% at 12months follow-up)[12].

The challenge now is to gain more information about EVAS so that if it is to be widely adopted, this is based on high quality evidence regarding safety, success and complication rates and economic considerations. When considered in the context of the IDEAL guidance, EVAS is now probably at IDEAL stage 2a [13] and this means reporting how patients are selected for the new treatment, what other treatments are offered to patients with similar characteristics within the same time frame and why. It requires transparent reporting of outcomes (whether positive or negative) and details about how and why the intervention is modified as experience is gained with it. IDEAL also recommends that ethical approval is obtained to ensure patients receive full informed consent about the novel intervention – with documentation of the information provided, to protect patients and surgeons from known and unknown adverse events associated with a new technique. Following this approach allows patients to make informed choices about whether to participate in early phase studies or to select standard treatments [14]. It follows that a system of compulsory registration should be in place, to ensure that wider adoption of this technology is truly evidence-based.

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