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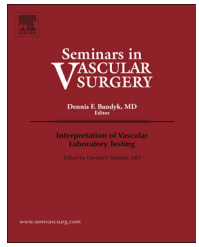

Endovascular aneurysm sealing addresses several limitations of conventional endovascular aneurysm repair

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ABSTRACT

Endovascular aneurysm repair has enabled a broad population of patients with infrarenal abdominal aortic aneurysm to be treated by a less-invasive technique. However, endovascular aneurysm repair has therapeutic limitations, including the need for lifelong surveillance and a higher rate of secondary interventions than open repair. These outcomes can promote patient dissatisfaction and result in increased health care costs and associated morbidity and mortality. The primary reason for secondary interventions is continued abdominal aortic aneurysm sac enlargement due to endoleaks. Conventional endovascular aneurysm repair procedures do not address aortic branch vessels that are ligated during open repairs. Secondary measures to occlude these branch vessels have shown efficacy in limiting sac growth, but do not predictably eliminate the need for further interventions. Endovascular aneurysm sealing is a new technique that addresses some of the limitations of conventional endovascular repair. Endovascular aneurysm sealing secures the stent graft flow lumens within a biostable polymer. This stability prevents stent migration while also sealing branch vessels that are otherwise not addressed by other endovascular devices. This new approach to endovascular repair has shown early promise in reducing the rates of endoleak and need for secondary interventions, while opening up the possibility of durable endovascular repair to a more challenging type of anatomy.

1. Introduction

Open aortic aneurysm repair has been associated with morbidity and mortality, especially with sicker and more elderly patients. The era of endovascular aneurysm repair (EVAR) has significantly reduced operative risk and made aneurysm repair available to a larger population whose comorbidities presented too great of an operative risk. EVAR is not without its drawbacks, however. Compared to open repair, EVAR has a greater rate of reintervention, which necessitates routine surveillance [1–3]. The basic concept of open aneurysm repair has been the exclusion of the aneurysmal vessel from circulation by replacing the aneurysmal segment with a more durable conduit able to withstand the radial force of systemic blood pressures. EVAR achieves exclusion of the aneurysm with proximal and distal radial fixation within a segment of normal artery. This rechannels flow through the endograft, thus excluding flow to the aneurysm sac. Nevertheless, the repair is at risk of failure from migration of the endograft, leading to loss of seal and

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expansion of the aneurysm. Retrograde perfusion of the aneurysm sac by perforating branches can also compromise the repair. Endovascular aneurysm sealing (EVAS) is a novel technique that addresses many of these technical issues.

EVAS relies upon deployment of endografts with concomitant obliteration of the excluded aneurysm sac. This method has the advantage of fixing the endografts in position, making them resistant to migration or kinking, while also filling the aneurysm sac and thereby preventing any retrograde filling via branch vessels. EVAS has demonstrated improved quality of life over open aortic aneurysm repair out to 12 months follow-up, similar to conventional EVAR. Additionally, hospital length of stay was an average of 5 days shorter than with open repair [4–6]. One commercial product, the Nellix device (Endologix, Irvine, CA) has been available in Europe with a CE mark since 2013, and is currently available in the United States for investigational use.

2. Nellix

The Nellix endovascular sealing device is designed with expanded-polytetrafluorethylene covered cobalt chromium alloy stents as flow lumens. These balloon-expandable stent grafts are surrounded by biocompatible nonporous polyurethane bags—endobags—which are subsequently filled with a biostable polyethylene glycol material to precisely fill the aneurysm sac and seal off any branch vessels. The material is instilled under pressure and cross-links in vivo within 3 to 5 minutes of deployment, solidifying to a density similar to a soft pencil eraser. Figure 1 shows a rendering of the device deployment. The polymer contains radiopaque contrast facilitating visualization during deployment. The contrast was seen to gradually migrate to the endobag edges and dissipate during surveillance exams [7]. The Instructions for Use for the device dictate a neck length $\geq$10 mm, diameter of 18 to 32 mm, aortic neck angle $<$60 degrees, aorta flow lumen of $<$60 mm, and iliac vessels of 8 to 35 mm. The device is deployed via a 17Fr sheath from each groin in a manner akin to bilateral iliac "kissing" stents. Each stent is 10-mm diameter, available in variable lengths (100 to 180 mm). Iliac extensions, with their own endobags, enable distal sealing and the treatment of isolated iliac artery aneurysms. Data accrual is ongoing, but so far EVAS has shown a high rate of technical success (99%), with lower rates of all types of endoleak (7%) and secondary intervention (9%) than conventional EVAR [8].

3. Endoleaks

3.1. *Type I*

Type I endoleaks, the loss of a proximal or distal seal, represent a major complication of EVAR. These endoleaks lead to systemic blood pressures within the aneurysm sac, putting the patient at risk for aneurysm expansion or rupture. EVAR studies (Dream [Dutch Randomized Endovascular Aneurysm Repair], EVAR-1 [Comparison of Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm], ACE [Anevrysme de l'aorte abdominale, Chirurgie versus Endoprothese]) have found that the risk of developing a Type I endoleak is 6% [2,3]. Furthermore, Type I endoleaks are the most common cause of rupture post-EVAR [9]. These devices all still depend on a certain length of healthy, normal artery to create a seal zone via radial force. Early devices were also at risk for proximal migration, with an incidence of approximately 3% [2,3]. Although active fixation and fixation at the bifurcation has improved this, endovascular sealing secures the stents within the aneurysm sac and can eliminate migration altogether, as there is no sac to migrate into. In addition, there is the possibility of reducing the need for a healthy neck both proximally and distally, as again, the sac is completely filled.

3.2. *Type II*

Type II endoleaks have been the Achilles' heel of EVAR. During open aneurysm repair, lumbar branches supplying the aneurysm sac are directly oversewn. Likewise the inferior mesenteric artery, if patent, is ligated. During EVAR, these branches remain patent. The EVAR trials demonstrated Type II endoleak rates of 10% to 16% [1–3]. At times, these endoleaks can contribute to aneurysm sac growth and expansion, ultimately leading to rupture.

Many methods have been introduced to address or eliminate Type II endoleaks. These have included preemptive embolization of branch vessels off of the aneurysm sac. In a comparison of preoperative coil embolization of aortic branch vessels, the inferior mesenteric artery, lumbar arteries, or medial sacral arteries were coil-embolized based on preoperative computed tomographic angiography. At post-procedure and at 6-month surveillance, there was no difference in the rate of persistent Type II endoleak [10,11]. Other procedures included thrombosis of the aneurysm sac with coils, cyanoacrylate glue, or Onyx ethylene vinyl alcohol copolymer at the time of device deployment. There are no standardized protocols for the amount of material needed and so far reports have not borne out great success [12,13]. In one study combining aneurysm coiling and fibrin glue embolization at the time of endograft deployment, there was no difference in the rate of Type II endoleak compared to endograft deployment without adjunctive measures, and no correlation between patency of the inferior mesenteric artery or lumbar arteries and development of Type II endoleak [14]. With EVAS, endobags form a physical filling of the sac, thus obliterating any empty space. With deployment of the biostable polymer at 180 mm Hg, it ensures a complete seal of the aneurysm lumen. This theoretically prevents any potential retrograde flow, as there is no space to flow into (Fig. 2). The largest series of EVAS patients reported Type II endoleak rates of 0% to 2% [8,15].

4. Hostile neck anatomy

One of the major limitations of EVAR has been challenging aortic necks. Necks that are too short, angulated, calcified, trapezoidal, or have mural thrombus limit aneurysm seal. Often these patients receive devices deployed outside of the Instructions for Use, with adjunctive measures, such as