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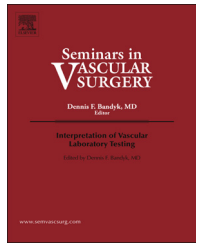

Percutaneous interventions following endovascular aneurysm sac sealing: Endoleak embolization and limb-related adverse events

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ABSTRACT

The Nellix endovascular aneurysm sealing system is a novel alternative to conventional endovascular aneurysm repair for aortic aneurysm management using paired balloon-expandable endografts supported by polymer-filled endobags to achieve sealing and anatomic fixation. Part of the promise of endovascular aneurysm sealing is increased resistance to lateral and longitudinal forces and a potential for reduced rates of device-related failures, particularly endoleaks. Initial efficacy data on this device are encouraging, but our knowledge of its associated complications and their management is limited. Reported adverse events include Type I and II endoleaks, graft stenosis, and occlusion. The aim of this article was to review the early experience of endovascular aneurysm sealing, focusing on the incidence, significance, and management of device-related complications.

1. Introduction

The Nellix device (Endologix Inc., Irvine, CA) is a novel endograft for aortic aneurysm repair based on endovascular aneurysm sealing (EVAS). Early efficacy data have been encouraging, but our knowledge of EVAS complications and long-term durability are limited. Our aim in this review is to detail the endovascular management of the Nellix device-related complications associated with EVAS and the rationale of the intervention strategies.

2. Overview of complications following EVAS

Several randomized trials and systematic reviews have shown endovascular aneurysm repair (EVAR) to be associated with reduced early mortality and morbidity rates compared to open surgery, but with a higher re-intervention rate due to graft-related complications, including endoleak and stent migration, which in turn require regular and long-term surveillance at increased cost [1–4]. Endoleaks and the ensuing risk for sac pressurization and rupture have been the main contributory factors in this regard.

The Nellix sealing system has been well described previously [5]. In brief, it comprises two balloon-expandable 10-mm chromium–cobalt stent grafts mounted on identical 17Fr-catheter–based delivery systems, one for each side, which provide a flow lumen in parallel to the non-aneurysmal aorta proximally to the iliac artery distally. Each stent is surrounded by a polymer-filled endobag that conforms to the shape of the aneurysm. The endobags fill the aortic lumen, thereby eliminating the otherwise open space of the sac. Positional stability is therefore provided by anatomic fixation, as well as a proximal and distal seal. It is hoped by the manufacturers that this would minimize any potential longitudinal and lateral movements, which can

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contribute to Type 1 endoleaks (EL1) [6]. In addition, filling of the sac by the endobags can tamponade any side branch flow that would produce any Type II endoleaks (EL2) [5]. EVAS also enables treatment of a wider range of aortic anatomies than does conventional EVAR [7].

Although this device has been used in a relatively large number of patients since its introduction in 2010, knowledge of the potential complications following Nellix is limited. The first published data on the outcome of Nellix in 2011 included a small series of 34 patients [8], which included 21 cases analyzed in an earlier publication [9]. These cohorts included two cases of endoleaks, a transient Type Ia (EL1a) and a Type Ib (EL1b) treated by placement of an extension endograft. However, in the last 2 years, there have been five publications of single or multicenter outcomes [1–14]. The main device-specific complications within these reports are EL1 and EL2, limb stenosis, and limb occlusion. These are summarized in Table 1 and will be reviewed in more detail.

2.1. *Endoleaks*

Endoleaks are categorized into five main types. Type I arises at the proximal (Ia) or distal (Ib) endograft attachment site, Type II is due to filling of the sac from retrograde flow in the side branch vessels, Type III is from fabric tear or modular disconnection, Type IV is usually transient and seen at the time of implantation in anticoagulated patients due to graft porosity, and Type V is defined as an increase in the sac size in the absence of a visible endoleak (endotension).

The unique design of the Nellix endograft relies on endobags for device stability rather than the radial force and barb engagement provided at the proximal and distal fixation sites in conventional EVAR. As described here, the only reported endoleaks with the Nellix device are Type I and II. The absence of Type III endoleak is explained by its single-unit separate right and left stent design without modular components.

2.1.1. *Type Ia endoleak*

A review of the literature shows an EL1a rate of 0% to 3% following Nellix implantation. In the largest cohort of patients to date, Böckler and colleagues [11] reported on their experience in 171 cases performed at multiple European centers. They found no intraoperative EL1a, but five EL1a on follow-up, three seen at 1 month, and two at 6 months. One of these resolved spontaneously, two were embolized, and two were observed. There was no difference in the aortic neck length in cases with or without EL1a (22 $\pm$ 12 mm *v* 28 $\pm$ 15 mm; $p = 0.39$). Four of five EL1a were seen in the 116 cases within the manufacturer's Instructions for Use (IFU) and 1 within the 55 cases outside the IFU.

Brownrigg et al [12] reported 4 EL1a among a cohort of 105 patients that were all seen in patients with adverse proximal necks and all successfully embolized with Onyx (Covidien, Irvine, CA) and coils. The 30-day outcome results of the US pivotal trial involving 150 patients reported one EL1a treated by coil embolization [10]. Reijnen et al [14], reporting on the global Nellix experience of ruptured (28 cases) and symptomatic (30 cases) aneurysms, found a case of EL1a in the ruptured group in conjunction with distal migration of the stents, and subsequent fatal second rupture. Another case of EL1a in the symptomatic group was successfully embolized.

Finally, Zerwes and colleagues [13] reported one EL1a among a cohort of 50 patients that was associated with a partial rupture of the aneurysm sac during device implantation. The endoleak was successfully eliminated by implanting two additional Nellix endografts in combination with chimney grafts into both renal arteries (Viabahn 6/50 and 8/50).

The data available currently present the early follow-up results, and the endoleaks observed may relate, in part, to technical factors during deployment, resulting in lower than intended positioning of the proximal graft and insufficient coverage of the proximal neck. For example, of the four endoleaks reported in the Brownrigg series [12], two were thought to be related to inadequate correction for parallax

Table 1 – Published outcome data on endoleaks and limb occlusions following Nellix endovascular aneurysm sealing.

Study, first author, year	Patient population, study type, and population cohort	Aortic morphology, n (%)	Endoleak			Limb stenosis/occlusion
			Type Ia	Type Ib	Type II	
Reijnen, 2016 [14]	n = 58 Multicenter retrospective Symptomatic (n =30) and ruptured (n = 28) aneurysms	30 (52), outside IFU	2	1 (bilateral)	0	0
Böckler, 2015 [11]	171 median 5 (range 0–14) mo Multicenter retrospective Elective cases	55 (32), outside IFU	5	3 (1 bilateral)	4	5 limb stenoses and 8 limb occlusion
Brownrigg, 2015 [12]	n = 105 Single-center prospective Elective cases	72 (69), with adverse proximal necks	4	0	0	3 limb stenoses
Zerwes, 2016 [13]	n = 50 Single-center prospective Elective cases	14 (28), outside IFU	1	0	1	3 graft stenoses (2 associated with distal embolism)
Carpenter, 2016 [10]	n = 150 Multicenter prospective Elective cases	All within IFU	1	0	8	0

Abbreviation: IFU, Instructions for Use.