On-label Use of Commercially-available Abdominal Endografts for Para-anastomotic Aneurysms and Pseudoaneurysms After Infrarenal Abdominal Aortic Aneurysm Open Repair

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WHAT THIS PAPER ADDS

Open repair of abdominal aortic para-anastomotic aneurysms (PAAs) and pseudoaneurysms (PSAs) after infrarenal abdominal aortic aneurysm open repair is burdened by increased challenges and complications related to the redo procedure. Complex endovascular techniques (fenestrated/branched, chimney, and periscope parallel grafts) have been developed in the last decade in order to treat these lesions; however, larger series are currently still limited, long-term follow-up is poorly known, patient customization (making the treatment unavailable in emergency) may be required, and treatment cost is often high. As a result, the standard use of commercially-available abdominal endovascular devices is nowadays one of the most appealing options, routinely performed whenever possible in most centers. However, in the analysis of previous series of PAAs and PSAs treated with standard commercially-available abdominal endovascular devices, the anatomical inclusion criteria were usually not specifically defined and the series included various off-label uses of the devices. In our study, we specifically analyzed the feasibility and outcomes only of strict on-label use of the devices (OnL-endovascular aortic repair [EVAR]) for the treatment of abdominal PAAs and PSAs. Our analysis confirmed both limited feasibility of OnL-EVAR and high rates of late complications and reinterventions.

Objectives: To analyze feasibility and outcomes of endovascular aortic repair (EVAR) with a strictly on-label use of abdominal aortic endografts (OnL-EVAR) to treat para-anastomotic aneurysms (PAAs) and pseudoaneurysms (PSAs) after infrarenal abdominal aortic aneurysm open repair (OR).

Methods: The data of all consecutive patients treated between 1999 and 2012 for non-infected abdominal PAAs and PSAs at our center were prospectively collected. All cases fit for EVAR based on the instructions for use of a series of abdominal aortic endografts commercially available during the study period were scheduled for OnL-EVAR regardless of patients' surgical risk. Any patients unfit for OnL-EVAR underwent OR or other complex endovascular techniques.

Results: One hundred and forty-three patients were collected; 78 underwent OR and 65 endovascular repair with different strategies. Coil embolization, hybrid, and chimney/periscope grafts techniques were limited to seven patients unfit both for OR and OnL-EVAR. Inclusion criteria for OnL-EVAR were reached in 58 patients for an overall OnL-EVAR feasibility of approximately 40% (21% for PAAs and 55% for PSAs). In particular, OnL-EVAR feasibility was 19% in case of involvement of proximal aortic anastomosis, 71% for distal aortic anastomosis, and 80% for iliac arteries. Overall, 25 aortouniiliac and 11 bifurcated implants were performed, single proximal aortic cuffs were used in 10 patients, and iliac extension in 12. Primary technical success was 98% without perioperative mortality. At a median follow-up of 67 months (range: 1–144 months), cumulative aneurysm-related mortality was 7%, endograft migration 7%, and reintervention was 17%. Life-table analysis showed actuarial survival and freedom from aneurysm-related death at 1, 3, and 5 years of 100%, 98%, and 95%, and of 100%, 98%, and 95%, respectively. Freedom from aortic reintervention or open conversion at 1, 3, and 5 years was 94%, 90%, and 85%.

Conclusions: Feasibility of OnL-EVAR was limited for PAAs and PSAs, with a rate that was lower than 20% in case of involvement of proximal aortic anastomosis. Aortouniiliac configuration was the most commonly feasible implant and, despite strict on-label use of abdominal devices, the rate of late complications and reinterventions was high.

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INTRODUCTION

Abdominal aortic aneurysm (AAA) open repair is generally considered as safe and durable. However, this procedure is burdened by the risk of some long term complications, such as para-anastomotic aneurysms (PAAs) and pseudoaneurysms (PSAs).[1–9]

PAAs and PSAs are defined as aneurysm formation near the anastomotic line either proximal or distal to the implantation of a graft. According to Haimovici,[7] PAAs are enclosed by uninterrupted arterial wall components, and they may represent a residual lesion or more likely the progression of aneurysmal disease, while PSAs are characterized by breaks in the arterial wall with extravasation in surrounding tissues and the formation of a fibrous capsule that gradually expands with blood pressure.

The PAAs and PSAs following AAA open repair range from 0.5% to 15.0% in different series,[8,9] and are both potentially fatal conditions as they may lead to aortic rupture, bleeding, or even infection and fistulization within the duodenum.[1,5,6,8,9]

Conventional treatment of para-anastomotic aneurysms and PSAs is open surgical repair (OR) and is burdened with perioperative mortality ranging from 4.5% to 67.0%.[10–13]

Over the last two decades endovascular aortic repair (EVAR) has emerged as a promising alternative to OR with reduced early morbidity and mortality.[14,15] However, the feasibility of standard device-based endovascular technology with the on-label use of commercially-available endografts (OnL-EVAR) is limited, especially for the proximity of renal arteries to the failed proximal aortic anastomosis. As a result, branched endovascular technology,[16,17] chimney/periscope (CHIMPS),[18,19] and "hybrid" techniques[20,21] have been developed over the last few years in order to treat abdominal aortic lesions near to renal and visceral arteries; however, indications and long-term results are debated and costs are high.

The aim of this study is to investigate the feasibility rate and outcomes of OnL-EVAR for PAAs and PSAs after prior AAA open repair in a single-center setting.

METHODS

We performed a retrospective analysis of prospectively collected data of all consecutive patients who underwent open or endovascular repair for PAAs or PSAs (aortic or iliac) following previous OR for atherosclerotic AAA. All cases with suspected graft infection and/or aorto-enteric fistula were excluded from the study. All cases available for OnL-EVAR based on the manufacturer's instructions for use (IFU) were scheduled for EVAR regardless of the surgical risk of the patient. Any patients unfit for OnL-EVAR were treated with conventional OR whenever possible; cases unfit both for OR and OnL-EVAR were treated with alternative strategies, such as coil embolization, CHIMPS, and "hybrid" techniques. No cases of custom-made fenestrated or branched endografts were used in the study period to treat PAAs or PSAs.

Data were collected from clinical and radiological records, and entered onto a computerized database. Demographics, clinical manifestations, and preoperative risk factors of patients who underwent OnL-EVAR (summarized in Table 1) were reported according to the Society for Vascular Surgery Suggested Reporting Standards[22] and to the Society for Vascular Surgery/American Association for Vascular Surgery medical comorbidity grading system.[23]

All patients underwent a preoperative contrast-enhanced computed tomography angiography (CTA). Preoperative

Table 1. Clinical manifestations and preoperative risk factors of on-label endovascular aortic repair (OnL-EVAR) study group.

		OnL-EVAR (%)
Gender	Male	39 (67)
Age (y)	<55	4 (7)
	55–69	8 (14)
	70–79	31 (53)
	>80	15 (26)
Manifestations	Asymptomatic	26 (45)
	Expansion	24 (42)
	Compression (GU tract)	2 (3)
	Compression (GI tract)	1 (2)
	Contained rupture	3 (5)
	Free rupture	2 (3)
Cardiac status[a]		
	0 Asymptomatic, with normal electrocardiogram	3 (5)
	1 Asymptomatic but with either remote myocardial infarction by history (6 months), occult myocardial infarction by electrocardiogram, or fixed defect on dipyridamole thallium or similar scan	11 (19)