Comparison of outcomes for short-neck and juxtarenal aortic aneurysms treated with the Nellix endograft versus conventional endovascular aneurysm sealing

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ABSTRACT

Objective: The objective of this study was to evaluate the results of the off-label use of the Nellix endograft (Endologix, Irvine, Calif) for the treatment of short-neck aneurysms and juxtarenal aortic aneurysms (JAAs) compared with the outcomes of patients with infrarenal abdominal aortic aneurysms treated in accordance with the manufacturer's instructions for use.

Methods: Data available from patients treated with the Nellix endograft from September 2013 to January 2016 were reviewed to create a case-control analysis (1:2). Fourteen elective patients with a short-neck aneurysm or JAA (<10 mm) and mild aortic neck angulation (<35 degrees) were included. As a control group, 28 elective patients who had been treated in accordance with instructions for use were included. Patients were matched for age, sex, aortic diameter, and aortic neck angulation. The final cohort group included 42 patients: 14 in the JAA off-label group (5 with aortic neck length ≤4 mm and 9 with necks of 5 to 10 mm) and 28 in the control group. Technical and clinical success, freedom from any secondary intervention, any type of endoleak, and aneurysm-related death were evaluated.

Results: There were no significant differences between the two groups in terms of comorbidity, intraoperative time, radiation time, contrast agent volume, and perioperative mortality and morbidity. Two patients of the JAA group subsequently underwent open repair (14%), both with aortic neck length <4 mm (2/5; 40%), for type Ia endoleak. Two of the control group also subsequently underwent open repair (7%). At a mean follow-up of 22 ± 3.9 months, freedom from any reintervention was 85% for the JAA off-label group vs 92% for the control group (log-rank test, $P = .33$).

Conclusions: The off-label use of the Nellix endograft for the treatment of JAA showed a higher rate of subsequent conversion to open repair for JAA patients (aortic neck length ≤4 mm), underlining the need for a proximal sealing zone. Longer term data are needed to verify the possible use of the Nellix endograft in selected short-neck aneurysms with aortic neck length >5 mm. (J Vasc Surg 2017;■:1-8.)

In recent years, endovascular aneurysm sealing (EVAS) using the Nellix endograft (Endologix, Irvine, Calif) has become established as a potential alternative to conventional endovascular aneurysm repair (EVAR) for the treatment of abdominal aortic aneurysms (AAAs). The relatively straightforward deployment and its success at reducing type II endoleaks make this new device an attractive alternative. Long-term data are still unavailable; however, medium-term results from the multicenter registry with 17 months of follow-up published by Böckler et al[1] report a 3% type Ia endoleak rate, a 5% rate of limb occlusion, type Ib endoleaks in 2% of patients, and type II endoleaks in 2.3% of patients. Notably, the same registry reported aneurysm-related reinterventions in 9% of patients.

Even when it is used in accordance with instructions for use (IFU), the Nellix endograft is more widely applicable than current EVAR devices,[2] and experience of its use outside of IFU, particularly in adverse anatomy, has already been reported.[3] Specifically, the treatment of short-neck aneurysm and juxtarenal aortic aneurysm (JAA) with or without specific adjuncts, such as covered parallel stents in a "chimney technique," has been reported.[4,5] The treatment of a complex pathologic process like JAA with a standard endograft is attractive and has also been reported with other available devices.[6]

This study focuses on a single institution using the Nellix endograft in short-neck aneurysm and JAA to determine feasibility, safety, and efficacy at medium-term follow-up.

METHODS

Study design. A case-control study was conducted to assess the efficacy of endovascular repair of JAA with the Nellix device outside of the manufacturer's IFU. Between September 2013 and January 2016, 33 patients presented to our institution with JAA disease (aortic neck

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Author conflict of interest: none.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

http://dx.doi.org/10.1016/j.jvs.2017.03.444

length <10 mm), of whom 14 patients were treated with the Nellix endograft without adjuncts. Three patients were treated with conventional EVAR without adjuncts (using other endografts), four patients were treated with chimney-Nellix (ch-EVAS), three patients were treated with fenestrated EVAR (FEVAR), and nine patients were treated with open surgery. The treatment algorithm for these patients was that all JAAs were evaluated for endovascular repair. If the patient was deemed anatomically suitable for EVAR (with the potential exception of aortic neck length), patients underwent endovascular repair. Patients were given the option of Nellix endograft repair without adjuncts if their aortic anatomy was evaluated as being within the device's IFU (with the potential exception of neck length) and in the case of moderate angulations of the aortic neck. If patients were deemed to have unfavorable anatomy for EVAS, other endovascular solutions were evaluated, but only for short-neck aneurysms, not for aortic neck length <4 mm. Either a chimney technique or FEVAR was planned in patients who had a mismatch of the renal arteries with an inter-renal distance >0.5 cm associated with short-neck aneurysm, aneurysmal extension above the renal arteries with posterior aortic wall involvement, or inter-renal aneurysms. Finally, if an anatomic severity grade for endovascular repair was deemed to be unacceptable and the patient was assessed to be fit for open repair, the patient was offered and treated with open surgery.

There is no generally agreed on definition of short-neck aneurysm and JAA. According to Verhoeven et al,[7] we define short-neck aneurysms as those with a proximal neck between 4 and 10 mm. We define JAAs as those without a proximal neck or with a proximal neck between 0 and 4 mm. The manufacturer's IFU for the Nellix endograft recommend a proximal aortic neck length >10 mm with <60 degrees of infrarenal angulation and a diameter between 18 and 32 mm. A dedicated database was created to collect demographic data, preoperative planning, intraoperative details, and patient outcome.

In the cases of JAA treatment, an evaluation of the potential risks and benefits of the off-label use of the device rather than an open surgical procedure, which was also proposed, was made for every patient. All patients signed the hospital's informed consent form before surgery.

The review committee of the Department of Cardiovascular Surgery of our institution approved the study.

JAA off-label group. From September 2013 to January 2016, a total of 85 Nellix endografts for the treatment of AAA have been implanted at our center. Of these 85 cases, 14 patients (16%) were treated with standard Nellix endografts for short-neck aneurysm (n = 9) or JAA (n = 5) having a proximal neck ≤10 mm and infrarenal angles ≤35 degrees. Patients with JAAs and with moderate to severe angulations were not treated with Nellix endografts at our center: first, because it has been demonstrated that significant aortic neck angulations may predispose to suboptimal outcomes after endovascular AAA repair; and second, because the use of the Nellix device can lead to slight straightening of the aortoiliac anatomy, and this behavior might create inadequate proximal sealing, which is extremely important in JAA patients.[8,9]

At our institution, the main indications for JAA treatment with the Nellix device without adjuncts were high-risk surgical patients, defined as the presence of one or more of the following classifications: age >80 years, creatinine concentration >2.0 mg/dL, compromised cardiac function (diminished ventricular function or severe coronary artery disease, or poor pulmonary function), with mild infrarenal aortic angulations (≤35 degrees); aortic neck diameter between 18 and 32 mm; maximum aortic blood flow lumen diameter <60 mm; and maximum common iliac artery diameter <35 mm. Contraindications to this treatment were a mismatch of the renal arteries with an inter-renal distance >0.5 cm associated with short-neck aneurysm; aneurysmal extension above the renal arteries, namely, with posterior aortic wall involved (such as a JAA type A according to the classification proposed by Ayari et al[10]); and inter-renal aneurysm.

JAAs (no-neck aneurysms) and short-neck aneurysms with mild angulation (<35 degrees) were planned to receive EVAS without adjuncts, with deployment of the proximal bare-metal stent of the endograft at the level of the renal arteries and with the covered portion of the stent immediately inferior to the lowest renal artery, as shown in Fig 1. Patients with JAA treated with EVAS and parallel grafts as a chimney technique (ch-EVAS) were excluded from this study.

On-label control group. The control group was selected among patients treated during the same time

ARTICLE HIGHLIGHTS

- **Type of Research:** Case-control retrospective study
- **Take Home Message:** The conversion rate for type Ia endoleak was 14.2% of 14 endovascular aneurysm repairs with the Nellix endograft for short-neck and juxtarenal aortic aneurysms vs a conversion rate of 7.1% in 28 matched endovascular aneurysm repair patients with infrarenal abdominal aortic aneurysm following the manufacturer's instructions for use.
- **Recommendation:** The off-label use of the Nellix endograft showed a higher rate of conversion to open repair for juxtarenal aortic aneurysm patients (aortic neck length ≤4 mm), underlining the need for a proximal sealing zone.