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;66:1371-8.)

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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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 sealing 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.

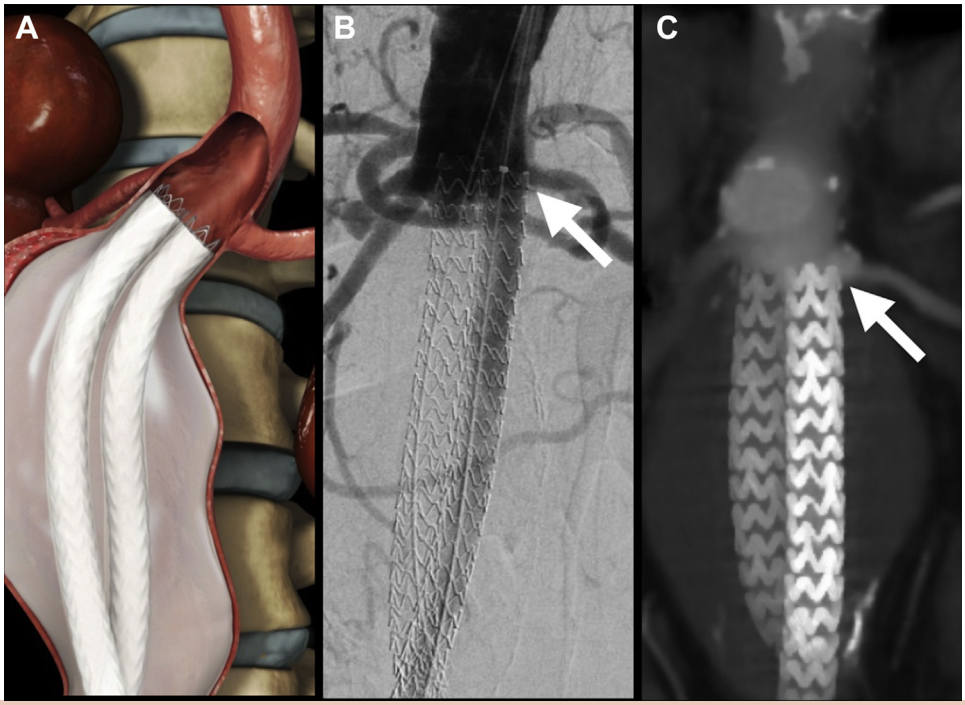

Fig 1. A, Schematic of Nellix devices after deployment. **B,** Intraoperative angiography with evidence of proximal deployment with the 4-mm bare-metal stent at the level of the renal artery (*arrow*). **C,** Three-dimensional reconstruction of computed tomography scan showing regular patency of the renal arteries through the first 4-mm bare-metal stent (*arrow*) in a juxtarenal aortic aneurysm (JAA).

with the same device for infrarenal AAA with proximal neck >10 mm and mild angulations (<35 degrees). Patients were matched (2:1) for age, AAA diameter and angulations, and gender. Twenty-eight patients were enrolled in the control group. Patients with moderate to severe neck angulations (>35 degrees) were excluded. To limit the selection bias, the first eight patients treated with Nellix endografts in our center were excluded for the following reasons: first, the learning curve associated with using the product; and second, because the manufacturer's representative initially suggested filling the endobags with polymer at 200 mm Hg pressure, whereas after the eighth case, the pressure filling was amended to 180 to 190 mm Hg for all the patients. This study included patients treated with both surgical and percutaneous access. The final cohort consisted of 42 patients, 14 in the JAA off-label group and 28 in the control group.

Planning and procedure. EVAS planning was performed using a workstation with OsiriX (Pixmeo, Bernex, Switzerland) or 3mensio (Medical Imaging BV, Bilthoven, The Netherlands). The length of the proximal neck was measured between the distal end of the ostium of the lowest renal artery and the beginning of the aneurysm, in stretched anatomy using the center lumen line.

All procedures were performed in a hybrid operating room using an Artis zeego system (Siemens AG, Forchheim, Germany) under local or epidural anesthesia. A percutaneous approach or a surgical cutdown of both femoral arteries was performed at the discretion of the first surgeon after duplex ultrasound evaluation of the common femoral artery. In cases in which percutaneous femoral access was used, two ProGlide devices (Abbott Vascular, Abbott Park, Ill) were deployed before insertion of the sheath with the sutures left extracorporeally for closure after conclusion of the procedure, in accordance with preclose technique.[11] The Nellix endograft consists of dual cobalt-chromium alloy balloon-expandable stents, each covered with expanded polytetrafluoroethylene and surrounded by an endobag, which is filled with an in situ curing polymer. Full details of the device and of the clinical standard procedure of EVAS with Nellix endograft are described in previous publications.[12-15] We emphasize that the cobalt-chromium endoframe is not covered by the endograft at the level of the proximal first bare-metal stent of 4-mm length. The Nellix design ensures that this proximal bare-metal stent remains uncovered even in the case of high-pressure filling of the endobags. This allows deployment of the first bare-metal stent at the level of the renal ostia, without occluding the renal arteries (Fig 1). For JAA repair, the procedure was carried out like a standard procedure, but particular attention was paid to the proximal edge of the stent graft with image magnification during deployment of the stent grafts. Proximal landing of the two components of the endograft was deployed in every case at the same level, avoiding mismatch between the

Table I. Demographic and baseline characteristics

Baseline characteristics	JAA group (n = 14)	Control group (n = 28)	*P* value
Age, years	77.53 (7.59)	74.80 (7.08)	.26
Male gender	14 (100)	26 (92.8)	.54
Hypertension	13 (92.9)	24 (85.7)	.65
Coronary artery disease	3 (21.4)	6 (21.4)	.99
COPD	5 (38.5)	17 (60.7)	.18
Diabetes	0 (0.0)	6 (21.4)	.08
Smoke	6 (42.8)	18 (64.3)	.19

COPD, Chronic obstructive pulmonary disease; *JAA*, juxtarenal aortic aneurysm.
Data are described using mean (standard deviation) for continuous variables and frequency (percentage) for categorical variables.

components of the endograft. Completion angiography was performed in every case.

Follow-up. Technical success was defined as endograft deployment with patency of endograft limbs without complications (such as endoleak or renal artery occlusion), with maintained internal and external iliac artery patency, and without the need for a secondary intervention within the first 24 hours. Patients were discharged, in the absence of any complications, with a body temperature of <37°C for at least 24 hours and a white blood cell count <12,000/mL. All patients underwent computed tomography scan at 1, 6, 12, and 24 months with physical examination. According to Krievins et al,[3] during follow-up, change in aneurysm diameter, change in device position relative to the superior mesenteric artery, and change in device position relative to the vertebral body were monitored.

Statistical analysis. Data were described using mean and standard deviation and median and interquartile range for continuous variables and frequency and percentage for categorical variables. The normality of the distribution of variables was tested using the Kolmogorov-Smirnov test. Differences between the two groups were tested using the *t*-test or Wilcoxon rank sum test for normally distributed and not normally distributed quantitative variables, respectively, or the χ^2 test for categorical variables. To evaluate the different incidence of reintervention, a Kaplan-Meier curve was drawn and the log-rank test was performed. All tests were two sided, and a *P* value of .05 was considered significant. All analyses were performed using Stata version 13 software (StataCorp LP, College Station, Tex).

RESULTS

Demographic data of the patients are summarized in Table I. No significant differences in comorbidities were noted between the two groups. Aortic preoperative data and operative details are summarized in Table II. Epidural anesthesia was used for the majority of cases. Intraoperative time, radiation time, and contrast agent amount were similar between the groups.

Hospital stay was uneventful for all patients. All patients were discharged after a mean hospital stay of 4 days (range, 3-7 days), with no in-hospital complications in both groups.

The mean follow-up time was 22 ± 3.9 months. In the JAA group, two patients (14.2%) underwent open conversion, both with aortic neck length <4 mm (2/5; 40%), for type Ia endoleak. The first patient had a proximal aortic neck length of 3 mm, and the second patient had a no-neck aneurysm. Both patients underwent open conversion for type Ia endoleak with lateral and longitudinal migration of the endografts (Fig 2). This kind of type I endoleak, with contrast material in the cleft between the endobags associated with sac enlargement and distraction of the endobags, is an indication for open conversion in our center. Both patients underwent Nellix removal and aortoaortic bypass grafting after 16 and 24 months of follow-up, respectively. No perioperative mortality was registered for these patients, and their recovery after the reinterventions was uneventful, without in-hospital complications. Both patients were asymptomatic, and the endoleak was found by control computed tomography or duplex ultrasound.

In the control group, two patients (7.1%) underwent open conversion; one patient underwent open conversion 7 months postoperatively for an aortoenteric fistula and died the month after (details previously published).[15] The other patient in the control group underwent open conversion for type Ia endoleak with lateral and longitudinal migration of the endografts at 20 months of follow-up. No other endoleak of any kind was found in either group. One patient in the control group died of an unknown cause 14 months after the procedure. This patient suffered from coronary artery disease and had previously undergone coronary artery bypass grafting; however, he did not undergo an autopsy.

No significant differences were found in conversion rate between the two groups: 2 of 14 (14.2%) vs 2 of 28 (7.1%) for the JAA group and control group, respectively (Fig 3; log-rank test, $P = .33$).

DISCUSSION

JAAs are complex pathologic processes that often require complex treatment. The "gold standard" treatment, if feasible, remains open surgery; this typically requires suprarenal aortic clamping and generally has good long-term results if patients are fit enough to undergo this surgery.[16] With the liberal use of EVAR during the last decade, JAAs are more and more frequently treated by endovascular means. The use of fenestrated endograft (FEVAR) for the treatment of JAAs is now widely recognized as the first-line endovascular therapy, with satisfactory early and midterm results.[17] However, the feasibility of FEVAR is limited by anatomic

Table II. Preoperative assessment and operative details

	JAA group (n = 14)	Control group (n = 28)	*P* value
Preoperative assessment			
Neck length, mm	5.0 (4.0-8.0)	27.5 (19.5-31.5)	<.0001
Aneurysm diameter, mm	57.8 (55.0-70.0)	55.0 (53.0-59.5)	.17
Neck diameter, mm	24.7 (21.3-26.1)	23.2 (20.5-24.7)	.24
Suprarenal angle (a angle[a])	9.75 (7.0-20.9)	12.0 (7.5-17.35)	.77
Infrarenal angle (b angle[b])	11.0 (5.0-30.4)	11.5 (0.0-27.7)	.71
Operative details			
Epidural anesthesia	10 (71)	20 (71)	.99
Intraoperative time, minutes	98.5 (75.0-143.0)	87.0 (73.0-99.5)	.35
Radiation time, minutes	8.8 (6.4-9.9)	7.8 (7.1-9.8)	.98
Contrast agent, mL	87.5 (50.0-126.0)	60.0 (41.0-87.5)	.12

JAA, Juxtarenal aortic aneurysm.
Data are described using mean (standard deviation) and median (first quartile-third quartile) for continuous variables and frequency (percentage) for categorical variables.
[a]The angle between the flow axis of the suprarenal aorta and the infrarenal neck.
[b]The angle between the flow axis of the infrarenal neck and the body of the aneurysm.

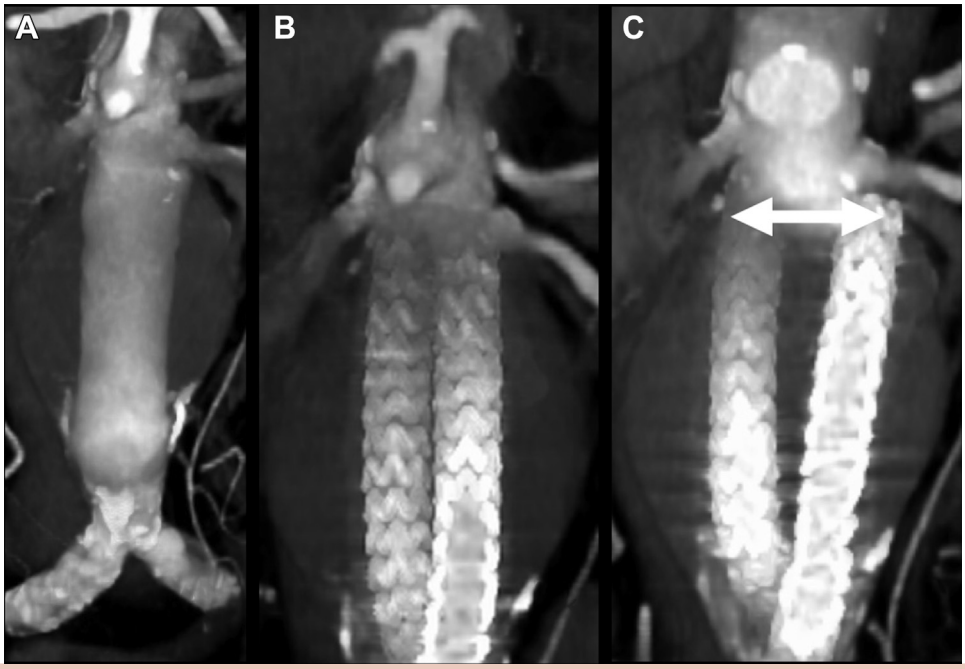

Fig 2. A case of type I endoleak after endovascular aneurysm sealing (EVAS) for juxtarenal aortic aneurysm (JAA). **A,** Three-dimensional reconstruction of the preoperative computed tomography scan, which shows JAA (no-neck aneurysm). **B,** Three-dimensional reconstruction of the 1-year computed tomography scan, which shows regular patency of the renal arteries and correct deployment of the endograft. **C,** Three-dimensional reconstruction of the 2-year computed tomography scan, which shows disconnection of the bags (*arrow*) and lateral and longitudinal migration with contrast material between the endobags.

requirements, costs, and lengthy manufacturing lead times. Snorkel or chimney EVAR has emerged as a valid off-the-shelf and immediately available alternative in the treatment of JAA.[18,19] Although endovascular treatment with a standard endograft of patients with a short aortic neck is associated with a significantly higher rate of early and late type I endoleaks, the use of EVAR out of the manufacturer's IFU with or without specific adjuncts is increasing.[4,19,20] Some endografts available on the market have been tested out of the IFU for the cure of short-neck aneurysm and JAA with acceptable short-term and midterm results.[6,19,20]

The rationale for choosing Nellix for the treatment of a JAA is that Nellix provides a rigid system, with columnar strength and a sealing zone along the length of the aneurysm. The endobags are specifically designed to

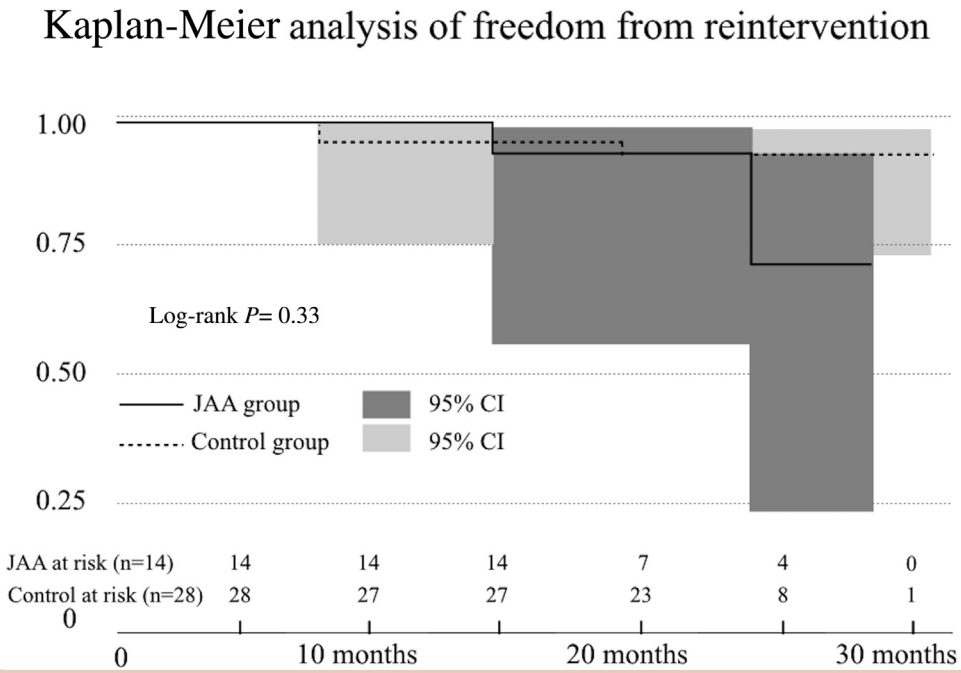

Fig 3. Kaplan-Meier analysis of freedom from early or late intervention (log-rank test, $P = .33$). Kaplan-Meier plot is shown for all follow-up lengths, although in the last follow-up period, error is >10%, and the result for this period should be carefully interpreted. One patient in the control group was lost at the 14-month follow-up interval for unknown cause. *CI,* Confidence interval; *JAA,* juxtarenal aortic aneurysm.

limit their proximal extension, leaving the proximal 4-mm bare-metal stent patent. Therefore, it is possible to deploy the endograft with the proximal bare-metal stent at the level of the renal arteries. Moreover, it has been demonstrated that EVAR using standard endografts resulted in progressive infrarenal aortic neck enlargement, whereas thus far EVAS with Nellix endograft has resulted in no neck enlargement over time.[21] This concept has led other authors to test Nellix endograft in JAA, but this kind of off-label use has never been the object of a focused study. In the study published by Krievins et al,[3] 8 of 34 patients were treated with Nellix endograft for JAA (neck length <10 mm). The study considered these eight patients together with other patients treated for adverse anatomy and showed no significant differences in outcomes for patients with favorable and adverse anatomy. Off note, the only endoleak in the adverse anatomy group was seen in a patient with an angulated aortic neck. In the multicenter registry published by Böckler et al,[1] 14 of 171 patients were treated with the Nellix endograft for JAA (neck length <10 mm). In this study, the average proximal aortic neck length did not differ in patients with or without type Ia endoleak. A different conclusion from these studies was published by Silingardi et al[14]; in this dual-center experience with Nellix endograft, patients treated outside the IFU had a significantly higher incidence of device-related complications ($P = .03$), and this result seems to better reflect our results.

In our series, patients with JAA with aortic neck length between 0 and 4 mm had a high rate of open conversion because of type I endoleak. Of note, even the 7% rate of open conversion in the control group is high. However, this is mitigated somewhat by the fact that one of the two conversions was due to an early fistula rather than failure of aneurysm treatment, and those two conversions are the only open conversions we have experienced of a total of 85 EVAS procedures at our institution, which probably also reflects the effects of a learning curve. Interestingly, the recorded open conversion occurred after the first year from the index procedure. This kind of type I endoleak, with endobag distraction, is effectively a new type of endoleak that requires open surgery. Once it is detected, its presence is an irremediable sign of a lack of proximal sealing, something that cannot currently be remedied once a Nellix has been deployed. The bags follow the progressive aortic sac enlargement. In this case, trying to fill the space between the bags would probably only accelerate this process. This kind of endoleak occurred in asymptomatic patients and was diagnosed during a control duplex ultrasound scan. Considering that less is known about the natural history of this type of endoleak, we suggest open conversion without delay. It is difficult to speculate on the possible causes that led to the type I endoleak formation in the control group patient. When detected, the endoleak was associated with distal migration of the Nellix endograft. Further analysis could address the question of whether distal migration itself could have been the *primum movens*, as per the study published by England et al.[22] We believe that a proximal sealing zone, of at least 5 mm, is mandatory to

create a reliable sealing zone to stabilize the endograft over time. If this sealing zone is not adequate, other solutions can be considered, such as the so-called chimney EVAS (ch-EVAS), to gain a proximal landing zone. Some authors have reported their experiences with ch-EVAS in JAA or as a cure for type I endoleak. This technique could have the potential to minimize the risk of gutter formation as a consequence of endobag conformability to the aortic wall and could therefore minimize the risk of type I endoleak compared with the chimney technique performed with other endografts. Results of this technique are anecdotal with variable short-term or midterm follow-up.[5,23,24] FEVAR represents today a valid endovascular treatment alternative for JAA patients, with validated long-term follow-up.[25,26]

This study is limited by the small sample size and by the duration of follow-up. Although no statistical difference was observed in terms of reintervention between the two groups, a statistical type II error could be hypothesized.

CONCLUSIONS

Our single-center experience of the off-label use of the Nellix endograft for the treatment of JAA shows a conversion rate to open of 14.2% vs 7.1% in our control on-label group; however, the cohort size of this study is small, and evaluation of larger numbers of patients is warranted for firmer conclusions to be drawn. We think that a proximal sealing zone of at least 5 mm is required. Longer term data are needed to verify these results and to evaluate the use of Nellix endografts in patients with 5- to 10-mm aortic neck lengths and with mild neck angulation. Close follow-up protocols in testing of a new device out of the IFU are necessary; however, it has to be borne in mind that for many patients undergoing EVAS outside of IFU, other endovascular options may be unsuitable and open repair may not be an option.

AUTHOR CONTRIBUTIONS

Conception and design: DP, MF, EF, FN
Analysis and interpretation: DP, MF, EF, SB, AV, AP, FR, FN
Data collection: DP, MF, AV, AP, FR
Writing the article: DP, EF, SB, AP, FN
Critical revision of the article: DP, MF, EF, SB, FN
Final approval of the article: DP, MF, EF, SB, AV, AP, FR, FN
Statistical analysis: AV, FR
Obtained funding: Not applicable
Overall responsibility: FN

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